FDA FSMA Implementation Strategy

PMA Produce Safety Policy Conference

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Topics

• FSMA Implementation in Phases

• Guiding Phase 2 FSMA Implementation
  – Program Alignment Initiative
  – FSMA Operational Strategy
    • Integrated Food Safety System

• Focus on Produce Safety Rule Phase 2 FSMA Implementation
  – Key Principles, Strategies and Concepts

• Implementation Challenges

• FY2016 President’s Budget Proposal for FSMA
FSMA Implementation is a Continuum

• **Phase 1**: Set Standards
  – Develop regulations, guidance, policy

• **Phase 2**: Implement Standards
  – Design strategies/frameworks to implement rules

• **Phase 3**: Implement, Monitor, Evaluate, Refresh
  – Performance Metrics
## Phase 1: Standard Setting

<table>
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<tr>
<th>Regulation</th>
<th>Proposal</th>
<th>Final (consent decree)</th>
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<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>
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<td>Intentional Adulteration</td>
<td>Dec 24, 2013</td>
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*Supplemental proposals published September 2014*
Produce Regulation Implementation Timeline

**Large Farm**
- Compliance Date: December 30, 2017
- **All Provisions**
- **Except Water**

**Small Farm**
- Compliance Date: December 30, 2018
- **All Provisions**
- **Except Water**

**Very Small Farm**
- Compliance Date: December 30, 2021
- **All Provisions**

**Full Implementation and Transition to Operational Mode**: 2023+

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**Planned Publication of Final Rule**
- October 31, 2015
- Effective December 30, 2015

**Implementation and Compliance Guidance Publication**
- February 2016

**Implementation and Compliance Guidance Publication**
- February 2016
Phase 2: Operations and Policy Working Together

- High-level FDA Oversight
  - FVM Governance Board
  - FVM Executive Council

- 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
Phase 2 Charge to Workgroups

• Develop a framework and multi-year implementation plan for ensuring compliance with regulations:
  • Education, outreach and technical assistance for industry
    – Alliances
  • Training for regulators
  • Data collection, analysis, updated IT
  • Performance goals and metrics
  • Inspections, compliance and enforcement
Guiding Phase 2 FSMA Implementation

*Program Alignment*

- Program Alignment Initiative Announced in February 2014 Memo by Commissioner
  - Vertically integrated, commodity-based programs
  - Specialization of inspection/compliance staff, regulatory labs
  - Clear, current, consistently applied policy
  - Roles, responsibilities, streamlined decision-making
  - Risk-based allocation of program resources
  - Agreed-upon performance/public health metrics

- Result: Successful FSMA Implementation
Guiding Phase 2 FSMA Implementation

**FDA’s FSMA Operational Strategy Document**

- Made Public May 2014
  - View at fda.gov/fsma

- Foundation for Developing and Implementing FSMA Standards
  - Regulations, guidance, protocols

- Captures in Broad, High-Level Terms our Current Thinking on Strategy and Guiding Principles for Implementation
General FSMA Implementation Guiding Principles

*Industry/Regulator Education, Outreach and Technical Assistance*

- Facilitate industry compliance with prevention oriented standards (rules) through: commodity/sector-specific guidance; education, outreach and technical assistance; regulatory incentives for compliance
  - *Alliances*
  - *Technical Assistance Networks*

- Invest in regulator training/continuing education, on-going calibration of regulators to promote consistent inspections and decision making
General FSMA Implementation Guiding Principles

**Conduct of Regulatory Inspections**

- **Goal:** Gain Industry Compliance
- **Not a “One Size Fits All Approach”**
  - Wider range of inspection, sampling, testing and data collection activities
  - Consider firm’s food safety culture, compliance history, work of public-private third parties to establish frequency/scope of inspections
- **Systems Based Inspections, Not “Observation Focused”**
  - Observations do not present same risk; Noncompliance viewed in context of firm’s food safety programs/systems, public health risk/impact; identification of systems/program failures important
  - Review of self identified non-conformances, firm’s response critical; Recognize firms for finding/fixing problems, continuous improvement
- **Interactive, Cooperative Inspections**
  - Open dialogue with firm employees during inspections
  - Investigators and Center subject matter experts work together to gain firm compliance/corrective actions
General FSMA Implementation Guiding Principles

**Compliance/Regulatory Strategies**

• Clearly Defined Compliance Strategy Linked to Public Health Outcomes

• Encourage Industry to Comply and Make Corrections on its Own
  – Timely, adequate corrective actions to areas of noncompliance
  – Swift enforcement when corrective actions are not forthcoming

• Recognition that Not all Observations are Equal Relative to Risk and Potential for Public Health Impact
  – Deviations categorized as critical, major, minor; linked to public health outcomes
  – Varied industry corrective action timeframes/FDA verification of corrective action timeframes
FSMA Implementation

Requires Integrated Food Safety System

- International, Other Federal, State, Tribal, Territorial, and Local Regulatory and Public Health Partners
- Academia, Industry, Consumers
  - Trade/Consumer Associations, Cooperatives
- Other Private Sector Entities
  - NGOs, Third Party Accreditation/Auditors
- FSMA Implementation: Major Areas for Integration of the Food Safety System
  - Industry and Regulator Training
  - Industry and Regulatory Education
  - Outreach and Technical Assistance
  - Industry Inspections and Compliance
Produce Safety Rule

Key Implementation Principles
Approved Strategies and Concepts
Key Implementation Principles

**Produce Safety Rule**

• Invest in specialized training and implement produce safety in a way that:
  – Promotes consistency in regulatory approach/decision making
  – Allows the flexibility needed to recognize the diversity/complexity of the fresh produce farming community

• Work closely with farming community, government agencies, academia, and other partners

• Recognize the role of the marketplace in influencing and expanding industry compliance with the rule

• Develop meaningful public health metrics to measure success, such as reductions in produce-related foodborne illnesses
Key Implementation Principles

*Produce Safety Rule*

- Partnerships remain key to successful implementation
- FDA is currently partnering with multiple organizations in planning for implementation of the produce safety regulations, including:
  - Other federal, state, and foreign government agencies and organizations
  - Land grant universities and other academic institutions
  - Produce farm and food industry associations
  - Food safety professional organizations
Technical Assistance

Strategies and Concepts

Industry and Regulators
Technical Assistance

• Goal
  – Facilitate industry understanding and compliance with the produce safety rule
  – Assist regulators when they begin industry education, outreach, assessments, inspections

• Technical Assistance Initiatives
  – Guidance
  – Technical Assistance Network
  – NASDA/USDA/FDA On-Farm Assessment Program
  – FDA Specialized Produce Safety Cadre
Guidance (Tentative List)

• Produce Safety Rule Compliance and Implementation Guidance
• Updated Good Agricultural Practices Guidance (directed by FSMA)
• Produce Safety Rule Sprout Guidance
• Produce Safety Rule Variance/Alternative Guidance
• Co-Management Guidance (being considered in view of FSMA language around considering conservation practices relative to food safety)
• Guidance Specific to Commodities, Practices and/or Conditions (as needed)
Technical Assistance Network

Objectives

• Establish within FDA a Food Safety Technical Assistance Network to provide central, consistent sources of outreach and real-time technical assistance to regulators and industry

• Leverage existing internal information/call center infrastructure, processes and IT (Knowledge/Case Management System)

• Leverage external Technical Assistance Networks/resources
  – PSA and SSA; State Agencies/NASDA; Cooperative Extension; USDA AMS and NIFA National and Regional Coordinating Centers
On-Farm Assessment Program

- FDA is working with NASDA to develop a voluntary on-farm assessment program

- Objectives
  - State of knowledge/readiness of farming community to comply with the Produce Safety Rule; Promote compliance with Produce Safety Rule
  - Promote coordination, strengthen relationships between industry, FDA, states, other produce safety partners
  - Provide on-farm learning experience for FDA/State regulators
  - Identify knowledge/guidance gaps - regional, national, commodity

- Conduct prior to compliance dates for covered farms
- Pilot if Funds Available, Spring 2016
- Assessment Tool made Available Online
Education and Training

Strategies and Concepts

Industry and Regulators
Training: Rule Requirements

*Industry/Grower Training*

- FDA is working with two organizations to develop training on the regulatory requirements of the Produce Safety Rule
  - Produce Safety Alliance (PSA), Cornell University, curriculum to assist the farming community understand the requirements in the rule and how to comply with these requirements
  - Sprout Safety Alliance (SSA), Illinois Institute of Technology, is developing a curriculum to assist sprout growers
Produce Safety Alliance (PSA)

*Industry/Grower Training*

**Goals**

- Develop standardized educational curriculum to increase understanding of produce safety
- Education/outreach, enhance understanding/implementation of GAPs, co-management strategies
- Education/outreach, regulatory requirements, Produce Safety Rule
  - Proposed 21 CFR 112.22(c): At least one supervisor from farm must complete food safety training equivalent to standardized curriculum recognized by the FDA
- Build upon existing information/training materials on produce safety
- Establish national education, training, technical assistance networks
  - Train-the-trainer to build cadre of qualified instructors; Collaborate on international training; Conduct grower trainings
PSA Curriculum

*Industry/Grower Training*

- Best Practices and Regulations Related to:
  - Worker health, hygiene and training
  - Water
  - Soil Amendments
  - Wildlife and Domestic Animals
  - Facilities, Equipment, and Tools
  - How to Develop a Farm Food Safety Plan

- USDA and FDA Overviews
FDA’s FSMA Training Workgroup

Regulator Training
FSMA Workgroups Established by FVM Executive Council

FVM Governance Board

FSMA Steering Committee

FSMA Decision Tracker

FVM Executive Council

Phase 2 FSMA Workgroups

Import Controls

Produce Safety

Intentional Adulteration

Preventive Controls

Human Food
Animal Food

Training Strategies and Frameworks

Future Hand Offs

Hand Off

FSMA Training Workgroup
ORA, CFSAN, CVM

Observation Corrective Action Report (OCAR) Workgroup
ORA, CFSAN, CVM

State Strategy Workgroup
ORA, CFSAN, CVM

Sampling Strategy Workgroup
ORA, CFSAN, CVM
Regulator Training

- FDA/State regulators will attend PSA and SSA Alliance training on requirements of the rules
- Regulators will also attend regulator-specific training
- Regulator training will incorporate new tools and introduce techniques needed to perform farm inspections and achieve consistency
  - Farm regulatory inspection approach protocols
  - FDA produce farm inspection reporting tools
  - On-farm bio-security and behavior protocols
PC Training Plan: FY15 PC Rule Readiness Plan & FY 15-18 PC Regulator Plan

Develop PC Regulator Training

Develop & Deliver PC Rule Readiness Training

Deliver PC Regulator Training
FY2016-2018

Technical Knowledge

Behavior & Systems Thinking

Inspectional Skills & knowledge

FS Culture 101 – March 19
Systems Thinking - May 28

Environmental Monitoring – June 25

FS Culture 201 – July 23

Supplier Management Program - August 27

FS Culture 301 – September 24

Minimizing Allergens Risk – October 22

Jan. 2016 thru Sept 2018

Behavior & Systems Thinking

Technical Knowledge

FSPCA Training

Inspection Skills & Knowledge

Spring 2015

Summer 2015

Fall 2015
2015 Sessions

- Food Safety Culture 101 – March 19
- Systems Thinking – May 28
- Environmental Monitoring - June 25
- Food Safety Culture 201 - July 23
- Supplier Management Program- Aug 27
- Food Safety Culture 301 - Sept 24
- Minimizing Allergens Risk - Oct 22

Events for sharing industry best practices & FDA perspectives

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Development and Delivery Model

Objective: To develop and deliver PC Regulator & Train-the-Trainers (TTT) curricula
Curricula Developers, TTT, and Instructor Cadre will include experts from ORA/CFSAN/CVM/States
FSMA Training Workgroup established Selection Criteria for Curricula Developers, TTTs and Instructors

Curricula Development

- **Curricula Developers** (≈24)
  - Design & Develop PC Regulator curriculum
  - Design & Develop TTT curriculum

Train-the-Trainers (TTT) (≈10)
- Receive:
  - Instructor Skills Course
  - FSPCA TTT Course (knowledge)
- Deliver PC Regulator & TTT curricula to Instructor Cadre
- Provide support & mentoring to Instructor Cadre
- Provide technical assistance to Industry, Instructor Cadre, and Food & Feed Safety Staff

Instructor Cadre (≈30)
- Receive:
  - Instructor Skills Course
  - FSPCA TTT Course (knowledge)
  - FDA PC Regulator & TTT Courses
- Deliver PC Regulator curriculum to Food & Feed Safety Staff (phased approach FY16-18)
- Provide support & mentoring to Food & Feed Safety Staff
- Provide technical assistance to Food & Feed Safety Staff on PC inspections

Food and Feed Safety Staff*
- Receive:
  - FSPCA course (prerequisite)
  - PC Regulator Training
- Conduct PC Inspections Phased in over 3 years:
  - Large Firms FY 2017
  - Small Firms FY 2018
  - Very Small Firms FY 2019

* Includes FDA investigators, supervisors/managers, compliance officers, Subject Matter Experts, Technical Experts, and state inspectors
FDA Specialize Produce Safety Cadre

A workforce with a specialized skill set focused on produce safety
FDA Specialized Produce Safety Cadre

- A regionally-based network of FDA CFSAN and ORA Staff with local knowledge and expertise in produce
- Collaborate with State agencies, PSA/SSA, USDA, cooperative extension, NIFA Centers and other produce safety partners in their region
- Joint effort to execute aspects of the produce safety regulatory program to promote industry compliance with the Produce Safety rule
FDA Specialized Produce Safety Cadre

- Roles and Responsibilities (Current Thinking)
  - Technical assistance
  - Outreach and training
  - Work planning
  - Outbreak investigations
  - Inspections (particularly foreign)
  - Enforcement
Produce Safety Rule

*Inspection Program*
Inspection Program

• Collaborating with NASDA to develop an inspectional approach that can be implemented by State regulators and FDA
  – Anticipate most routine on-farm inspections will be conducted by State regulators
  – FDA may do inspections in States that choose not to conduct produce inspections; FDA Produce Safety Network staff would conduct the inspections
  – FDA Specialized Produce Safety Cadre will conduct foreign inspections
Inspection Program

• **Objectives**
  
  – Facilitate compliance through standardized, education-focused regulatory inspections using farm inspection reports that include guidance and educational references
  
  – Collect and evaluate inspection data to identify regional trends for targeted outreach, education, research, and work plan prioritization
  
  – Develop relationships between produce farmers and local FDA Produce Safety Network staff & regulatory partners
  
  – Initiate legal action as needed to protect public health
Implementation Challenges

- **Resources** to do the Work
- Creating the Internal/External *Infrastructure* to do the Work
- No *Inventory* of Growers
- Industry and Regulator *Education, Outreach, Training* and On-going *Technical Support*
- *Consistency* in Industry Oversight
- Driving the Internal *Culture Change*
President’s FY2016 Budget Proposal

• An increase of **109.5 million** requested in the President’s budget for FSMA implementation

• FDA plans to continue to make improvements in the following areas:
  
  – Inspection Modernization and Training **25 million**
  – National Integrated Food Safety System **32 million**
  – Industry Education and Technical Assistance **11.5 million**
  – Technical Staffing and Guidance Development at FDA **4 million**
  – Modernized Import Safety Programs/System **25.5 million**
  – Risk Analytics and Evaluation **4.5 million**

*And **7 million for necessary infrastructure costs*
Thank You For Your Attention!

Questions???

Feel free to contact me at:
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