FSMA: Where We’ve Been and Where We’re Going

Collaborative Food Safety Forum

Roberta F. Wagner, B.S., M.S.
Deputy Director for Regulatory Affairs
CFSAN/FDA

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Presentation Overview

• FSMA implementation as a continuum
• Phase 1: Set standards
  – Develop regulations, guidance, protocols for new administrative enforcement tools
• Phase 2: Implement standards
  – Establish programs and strategies to promote and oversee compliance
• Phase 3: Monitor, evaluate, refresh
• Stakeholder engagement throughout the process
Collaboration within FDA Food / Feed Program

*Spans Two Directorates and Four Offices/Centers*

**Office of the Commissioner**
Commissioner of Food and Drugs
Dr. Margaret Hamburg, M.D.

**Directorate of Foods and Veterinary Medicine**
Deputy Commissioner
Michael Taylor, J.D.

- Center for Food Safety and Applied Nutrition
  Director
  Michael Landa, J.D.

- Center for Veterinary Medicine
  Director
  Bernadette Dunham, D.V.M., Ph.D.

**Directorate of Global Regulatory Operations and Policy**
Deputy Commissioner
Howard Sklamberg, J.D.

- Office of Regulatory Affairs
  Associate Commissioner
  Melinda Plaisier

- Office of International Programs
  Associate Commissioner
  Mary Lou Valdez
FSMA Implementation

PHASE 1
Standard Setting

PHASE 2
Implement Standards

PHASE 3
Monitor, Evaluate & Refresh

FDA FOOD SAFETY MODERNIZATION ACT
Phase 1: FSMA Standard Setting
Phase 1: FSMA Standard Setting

• Six core teams were formed in January 2011 to focus on FSMA deliverables
  – Preventive Standards
  – Inspection and Compliance
  – Imports
  – Federal/State Integration
  – Fees
  – Reports and Studies

• Teams are developing regulations, guidance, and protocols for new administrative tools
## Phase I: Standard Setting

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Proposal</th>
<th>Final (consent decree)</th>
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</thead>
<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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</tbody>
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*Supplemental proposals for some sections – summer 2014*
Phase 1: Other Accomplishments

• Administrative enforcement tools
  – Administrative detention, mandatory recall, suspension of registration

• Registration – biennial registration

• Manner of inspection
  – Component inspections, intelligent questionnaires
Transition to Phase 2: Implementation

- Teams continue rulemaking, guidance and other policy work until completed
- Concurrently, workgroups:
  - Implement the final rules, programs established through guidance and other policy
  - Develop specific strategies, capacity building, training and operation plans needed to implement FSMA
- Steering Committee oversees 3 workgroups:
  - Preventive Controls in Food and Feed Facilities
  - Produce Safety Standards
  - Import Oversight
Phase 2: Implementation of Standards
Phase 2: Implement the Standards

• What is changing?
  – FDA will operate differently
  – FDA will educate before it regulates and along the way
  – Company’s food safety culture will guide FDA’s approach

FDA will continue to engage partners, encourage transparency
How FDA Will Operate Differently

• FDA will speak with one voice
• Inspection, compliance functions specialized
• Invest in regulator training to promote consistent inspections, decision making
• Investigators and subject matter experts work together to drive correction of problems
How FDA Will Operate Differently (cont.)

• Robust data integration, analysis and information sharing
• Public health metrics
• Work closely with government counterparts and other food safety system stakeholders
Education Before Regulation and Along the Way

• Facilitate industry implementation of modern, preventive practices with FDA’s new toolkit, which includes:
  – Commodity and sector-specific guidance
  – Education, outreach and technical assistance
  – Regulatory incentives for compliance
Company’s Food Safety
Culture Guides FDA Approach

- Targeted, risk-based inspection models
- Wider range of inspection, sampling, testing and data collection activities
- Improve risk-based work planning through targeted data collection and more timely data analysis and program evaluation
FSMA Operational Strategy

• Provides a foundation for implementing FSMA standards
  – Regulations, guidance, protocols
• Captures in broad, high-level terms our current thinking on strategy and guiding principles for the implementation of FSMA standards.
• View at fda.gov/fsma
Phase 2: Workgroups Charge

• Develop 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
Operations and Policy Working Together

High-level FDA Oversight

Advisory Team

Steering Committee

Import Controls
Preventive Controls
  Human Food
  Animal Food
Produce Safety

ORA, CFSAN, CVM and State representation.

Sanitary Transportation
Intentional Adulteration
How the Operational Strategy Applies to Each Rule
Produce Safety

• Educate before regulating and along the way
  – Technical assistance

• Consider work performed by public-private parties to drive food safety in determining FDA activities

• Create and deploy cadre of specialized produce safety experts for on-farm activities

• Encourage industry to comply and make corrections on its own
  – Use of enforcement tools if action is not forthcoming
Import Oversight

• Develop skills, capacity, and processes to:
  − Audit Foreign Supplier Verification Program and accredited third-party certifiers;
  − Conduct comparability assessments

• Implement Voluntary Qualified Importer Program and other measures to expedite entries for good performers

• Reconfigure current import screening and field exam activities for oversight of all import activities
Preventive Controls

• Build on FDA’s experience with seafood and juice HACCP
• Place more emphasis on data collection and analysis
  – Assess compliance of individual firms through range of inspection and sampling techniques
  – Use data to guide risk-based inspection priority, frequency, depth and approach
• Efficiently screen firms for food safety performance, evaluate food safety culture
Preventive Controls

New Compliance and Enforcement Strategy

• During inspections, seek compliance
  - Encourage firms to correct violations on their own
  - Increase the incentive for compliance

• If compliance is not achieved, use a variety of enforcement tools
  - Deficiency letters at district level
  - Administrative enforcement tools
  - Judicial enforcement tools
Stakeholder Engagement
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, including working with multiple partners, to foster industry understanding of final rules/guidance and encourage firms to comply and initiate any corrections on their own.
More Information Available

- Web site: http://www.fda.gov/fsma
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov
Questions?

Thank you for your attention!