



Food Safety Modernization Act Operational Strategy

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ABA Section of Litigation Food & Supplements Workshop

June 5, 2014

Presentation Overview:

- **Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)**
- **FDA FSMA Implementation**
 - FSMA Implementation Teams (FIT)
 - FSMA Operations Team (FOT)
- **Stakeholder Engagement**

**Protecting Public Health by Strategic Implementation of
Prevention-Oriented Food Safety Standards**

*Operational Strategy for Implementing
The FDA Food Safety Modernization Act*

May 2, 2014



Available at

FDA's FSMA Operational Strategy Document

- Provides a foundation for creating an operational strategy that supports the reduction of preventable foodborne illness
- Outlines the drivers of change in FDA's approach to food safety oversight
- Guides the next phase of FSMA implementation which reflects the Agency's current thinking
- Dove tails with the FDA Commissioner's Program Alignment initiative

FDA's Program Alignment Initiative will support FSMA Implementation

- In February 2014, FDA's Commissioner of Food and Drugs, Margaret A. Hamburg issued a memorandum announcing a core set of operational changes recommended by the Program Alignment Group <http://www.fda.gov/AboutFDA/CentersOffices/>
- The Commissioner charged the group to develop plans to improve the efficiency, effectiveness, and timeliness of the Agency's regulatory and compliance activities including:
 - Commodity-based and Vertically-Integrated Regulatory Program
 - Specialization
 - Training
 - Agency Work Planning
 - Compliance Policy and Enforcement Strategy
 - Imports
 - Laboratory Optimization
 - Streamlining

FDA's Program Alignment

Goal: Improve communications and collaboration and to clarify roles, responsibilities and decision rights across all Agency components

Scope: Office of Regulatory Affairs and all Centers

Timing: Action plans finalized by October 1, 2014 and implemented over subsequent fiscal years

Program Alignment will support FSMA Implementation

An Operational Strategy for the Future

Advancing Public Health

Fostering consistent industry understanding & implementation of standards

Promoting widespread voluntary industry compliance

Strengthening FDA's leadership role in science & innovation

Leveraging & Collaboration

Establishing a global food safety network

Integrating data & sharing information amongst & between public & private partners

Enhancing operational partnerships with States and other government counterparts

Strategic and Risk-Based Industry Oversight

Expanding workforce skills through training & real-time technical support for frontline to promote consistent inspections & decision making

Expanding oversight tool kit to promote and verify compliance

Developing explicit enforcement strategies including use of new administrative tools

Improving risk-based work planning through enhanced, systematic data collection, sharing, and evaluation

Establishing public health metrics

Operational Strategy Document - Appendices

Preventive Controls in Food and Feed Facilities

• General

- Build on FDA’s experience in implementing seafood and juice HACCP
 - use different approaches due to larger number and diversity of covered facilities
- Change how we inspect by seeking voluntary compliance first
 - use administrative and judicial enforcement tools when necessary
- Put more emphasis on data analysis and targeted risk factors
 - use overall compliance history of the firm to determine focus

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Preventive Controls in Food and Feed Facilities

Inspection and Surveillance

- Efficiently screening firms for food safety performance
 - to guide risk-based inspection priority, frequency, depth
- Providing firms incentives for compliance
 - enhanced presence in high-risk firms and products
 - reduced scrutiny of firms with proven track record
- Assessing the compliance of individual firms
 - through range of inspection and sampling techniques

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Preventive Controls in Food and Feed Facilities

Inspection and Surveillance

- Making in-depth assessments of individual firms when needed
 - To increase the incentive for compliance
 - To determine the need for compliance or enforcement actions
- Collecting data to inform understanding and analysis
 - of sector-wide hazards, practices, & deficiencies
- Collecting data on compliance rates
 - to evaluate program performance and plan future efforts

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Preventive Controls in Food and Feed Facilities

- **Voluntary Compliance**

- Voluntary correction of problems including recalls at the facility level
- Voluntary correction achieved at the District level through deficiency letters

- **When Voluntary Compliance cannot be achieved**

- Administrative Enforcement Tools
 - Administrative detention
 - Mandatory recalls
 - Suspension of registration
- Judicial Enforcement Tools
 - Seizure actions
 - Injunction actions
 - Prosecution

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Produce Safety Standards

- Deploying a cadre of produce safety experts in headquarters and the field
- Actively supporting education and technical assistance for growers
- Supporting public and private parties involved in audits and other accountability functions

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Produce Safety Standards

- Conducting targeted on-farm surveys and inspections
 - Gaining voluntary industry compliance first
 - Using administrative compliance and enforcement actions when necessary
- Responding to produce outbreaks effectively and conducting in-depth environmental assessments to identify contributing factors

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Import Oversight

- *Developing the skills, capacity, and processes to audit foreign supplier verification programs and hold importers accountable*
- *Reconfiguring current import screening and field exam activities to complement oversight of FSMA's foreign supplier verification requirement*
- *Implementing the voluntary qualified importer program and other measures to expedite entries for good performers*

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Import Oversight

- *Developing the skills, capacity, and processes to audit accrediting bodies and accredited third-party certifiers*
- *Developing the skills, capacity, and processes to conduct comparability assessments of foreign government regulatory systems*
- *Building data integration and analysis systems and harnessing all available sources of relevant information*



FSMA Implementation

FSMA Implementation

- FDA is in the midst of the rulemaking and guidance development process
- FSMA implementation teams (FIT) have already developed many ideas for how FDA can better oversee the food industry, strengthen the global food safety system, and enhance public health



FSMA Implementation Teams (FIT)

Six core teams were formed in January 2011 to develop:

- Regulations and guidance
- Inspection and compliance strategies
- Administrative enforcement tool protocols
- Reports and studies



Prevention Standards FIT Accomplishments:

Proposed Regulations

Preventive Controls (Human Food)*

– Jan 2013

- **Preventive Controls (Animal Food)***

– Oct 2013

- **Produce Safety***

– Jan 2013

- **Intentional Adulteration**

– Dec 2013

- **Sanitary Transport of Food and Feed**

– Fe 2014

**Re-proposals of sections summer 2014*

Imports FIT Accomplishments:

Proposed Regulations

- **Supplier Verification Programs for Importers***
 - July 2013
- **Accredited 3rd Party Certification**
 - July 2013
- **Lab Accreditation**
 - In-progress

**Re-proposals of sections summer 2014*

Imports FIT Accomplishments:

Guidances (in-progress)

- **Voluntary Qualified Importer Verification (VQIP)**
- **Import Certification of Imported Foods**

Other

- **International Capacity Building**
 - Published report
- **Systems Recognition**
 - Completed pilot in New Zealand
 - Initiated pilot in Canada



Stakeholder Engagement

Stakeholder Engagement

- **Inclusive/Coalition Approach**
 - Engage internal and external stakeholders to help determine reasonable and practical ways to implement provisions and concepts
 - Engage with external public sector stakeholders that will be assisting with industry oversight, e.g. public meetings
- **Transparency is a Priority**

Stakeholder Engagement

- Develop and implement mechanisms to elicit input from stakeholders to inform the development of post final rule and final guidance, and FOT implementation strategies
- Establish mechanisms that include working with multiple partners to foster industry understanding of final rules/guidance, and to facilitate/ensure high rates of voluntary industry compliance