Strategic Implementation of FSMA Prevention-Oriented Import Safety Programs

http://www.fda.gov/fsma
Challenges Presented by Globalization

- Increasing volume of imported products
- Greater complexity in imported products
- More foreign facilities supplying the U.S.
- Greater complexity in supply chains
- Imports coming from countries with less sophisticated regulatory systems
- Greater opportunities for economic fraud
- Food security concerns
Statistics

- 15 percent of U.S. food supply is imported
  - 75 percent of seafood
  - 20 percent of vegetables
  - 50 percent of fruit
- About 12 million line entries of food in FY15
- >114,000 foreign food facilities are registered with FDA
- >200 countries/areas exporting food to the U.S.
Paradigm Shift

• The border can no longer be our primary line of defense. It should only serve as a final checkpoint on other controls.

• FDA Food Safety Modernization Act (FSMA) creates a multilayered safety net
  – Role of Manufacturer
  – Role of Importers
  – Role of Third Parties
  – Role of Foreign Regulatory Bodies
  – Role of FDA
FSMA Imports-Related Sections

- Sec. 201. Inspection frequency
- Sec. 301. Foreign supplier verification program
- Sec. 302. Voluntary qualified importer program
- Sec. 303. Certification for food imports
- Sec. 304. Prior notice of imported food shipments
- Sec. 305. Capacity building
- Sec. 306. Inspection of foreign food facilities
- Sec. 307. Accreditation of third-party auditors
- Sec. 308. Foreign offices of the FDA
- Sec. 309. Smuggled food
- Sec. 404. Compliance with international agreements
Strategic Objectives for New Import Paradigm

- Reduced Risk of Illness or Injury from Imported Foods
  - Reduced Food Safety Problems in the Foreign Supply Chain (Pre-entry)
  - More Effective Interdiction of Unsafe Food at Port of Entry
  - More Rapid and Effective Post-Entry Response to Unsafe Imports
Tools to Reduce Food Safety Problems in the Foreign Supply Chain

- FSVP
- VQIP
- FDA Third Party Audits
- Technical Assistance to Foreign Suppliers
- Foreign Inspections
- Capacity Building
- International Agreements/Mutual Reliance
- Systems Recognition
Tools for More Effective Interdiction of Unsafe Food at Port of Entry

- Import Operations – Border (e.g., PREDICT, collaboration with other U.S. Border Agencies)
- Testing (e.g., methodologies)
- Import Alerts
- Import Certification
- Lab Accreditation
Tools for More Rapid and Effective Post-Entry Response to Unsafe Imports

- **Enforcement Tools** (in domestic commerce), e.g., Administrative Detention, Seizure, Mandatory Recall
- Voluntary Recalls
- Reportable Food Registry (RFR)
- Outreach Notification
- Domestic Inspections
- State Actions
FSMA Implementation

“A Continuum”

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

• Phase 2: Design Strategies to Promote and Oversee Industry Compliance
  – Identify performance metrics to measure success

• Phase 3: Implement, Monitor, Evaluate, Refresh
  – Transition strategies and performance metrics from design to operational, evaluate success
Phase 1 Progress

- **FSVP:** Final rule (November 2015)
  - Developing draft guidance
- **Third Party:** Final rule (November 2015)
  - Draft Model Accreditation Standards (July 2015)
  - Proposed User Fee rule (July 2015)
- **VQIP:** Draft guidance (June 2015)
Phase 2: Operations and Policy Working Together

- High-level FDA Oversight
  - FVM Governance Board
  - FVM Executive Council
- Steering Committee
- Intentional Adulteration
- Import Controls
- Preventive Controls
  - Human Food
  - Animal Food
- Produce Safety
- Sanitary Transportation
- Sprout Safety

ORA, CFSAN, CVM and State Representation
Programs Under Import Safety Phase 2 Workgroup

**VQIP**
Sec. 302: Allows for expedited review and entry; facility certification required (Sec. 806 of FD&C Act)

**Accredited Third Party**
Sec. 307: Accreditation of Third-Party Auditors / Certification Bodies to conduct food safety audits and to issue certifications (Sec. 808 of FD&C Act)

**Import Certification**
Sec. 303: Certification for high-risk food imports (Sec. 801(q) of FD&C Act)

**Import Controls**

**Lab Accreditation**
Sec. 202: Provides for recognition of laboratory accreditation bodies (Sec. 422 of FD&C Act)

**FSVP**
Sec. 301: Requires importers to develop, maintain and follow an FSVP for each food imported, unless an exemption applies (Sec. 805 of FD&C Act)

*Systems Recognition*
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/technical assistance for regulators
– Data collection, analysis, updated IT
– Performance goals and metrics
– Inspections, compliance and enforcement
Phase 3 Outcome Measures Integration Work Group Scope

- Transition FSMA strategic program planning frameworks and performance monitoring plans (PMP) from Phase 2 FSMA Work Groups to the Centers, ORA, other business owners.
- Leverage existing quarterly performance review workgroup.
- Refine measures with business owners.
- Integrate FSMA performance measures into existing performance management systems, e.g., FDA-TRACK.

Phase 3 Outcome Measures Integration Work group will ensure that measures move from design to operations and that FDA can report FSMA results and public health outcomes.