IMPLEMENTATION

Strategic Implementation of FSMA Prevention-Oriented Import Safety Programs

http://www.fda.gov/fsma

FDA FOOD SAFETY MODERNIZATION ACT

THE FUTURE IS NOW

Challenges Presented by Globalization

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- 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

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- 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 FY13
- >114,000 foreign food facilities are registered with FDA
- >200 countries/areas exporting food to the U.S.

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Traditional Import Paradigm

- Border focused
- Virtually all of the information used to assess admissibility came from the import submission
- FDA made a decision about the compliance status of the product at the time of entry with limited time, resources, and information

Paradigm Shift

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- 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

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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

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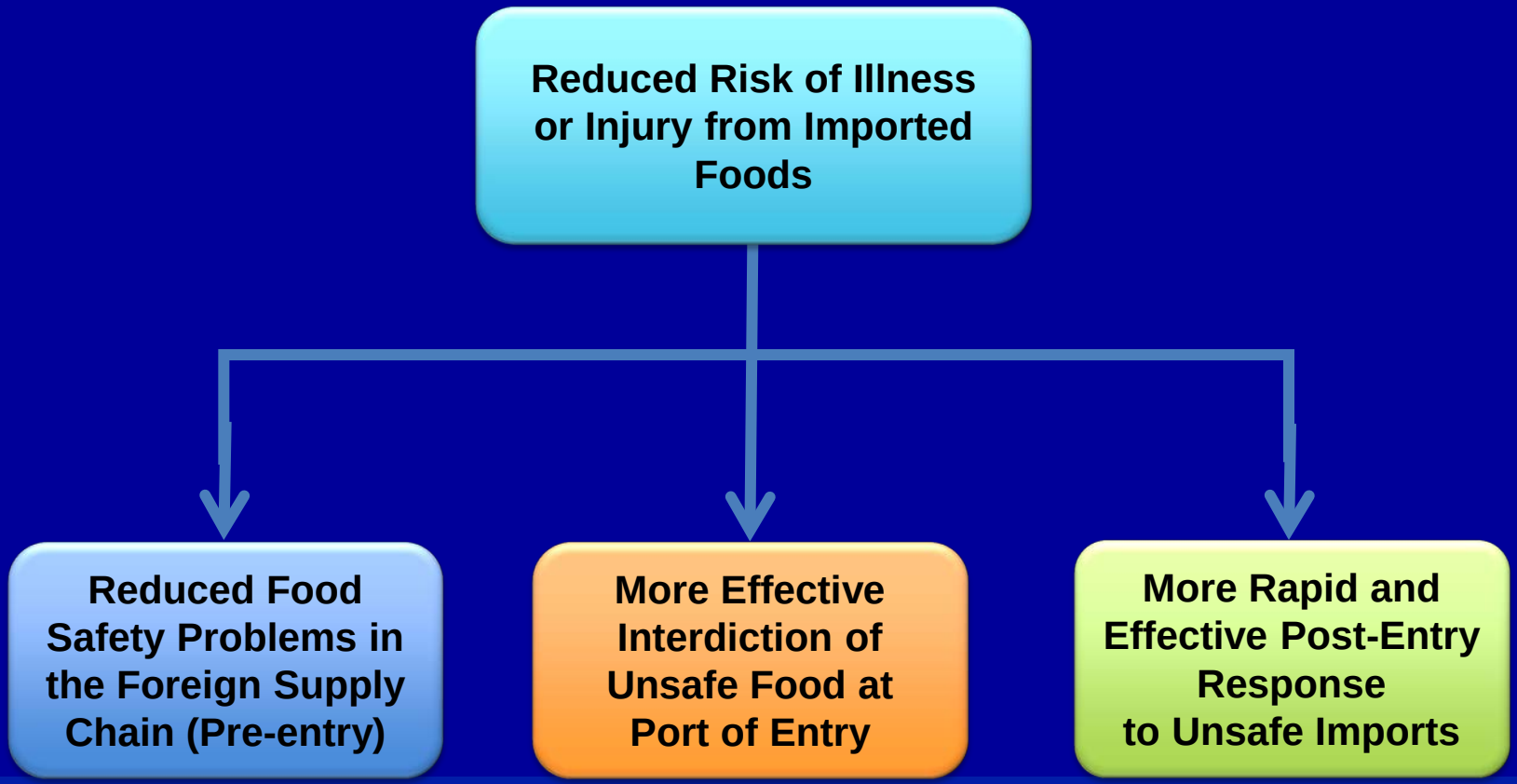
Strategic Objectives for New Import Paradigm



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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

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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**

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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*"

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- **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

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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

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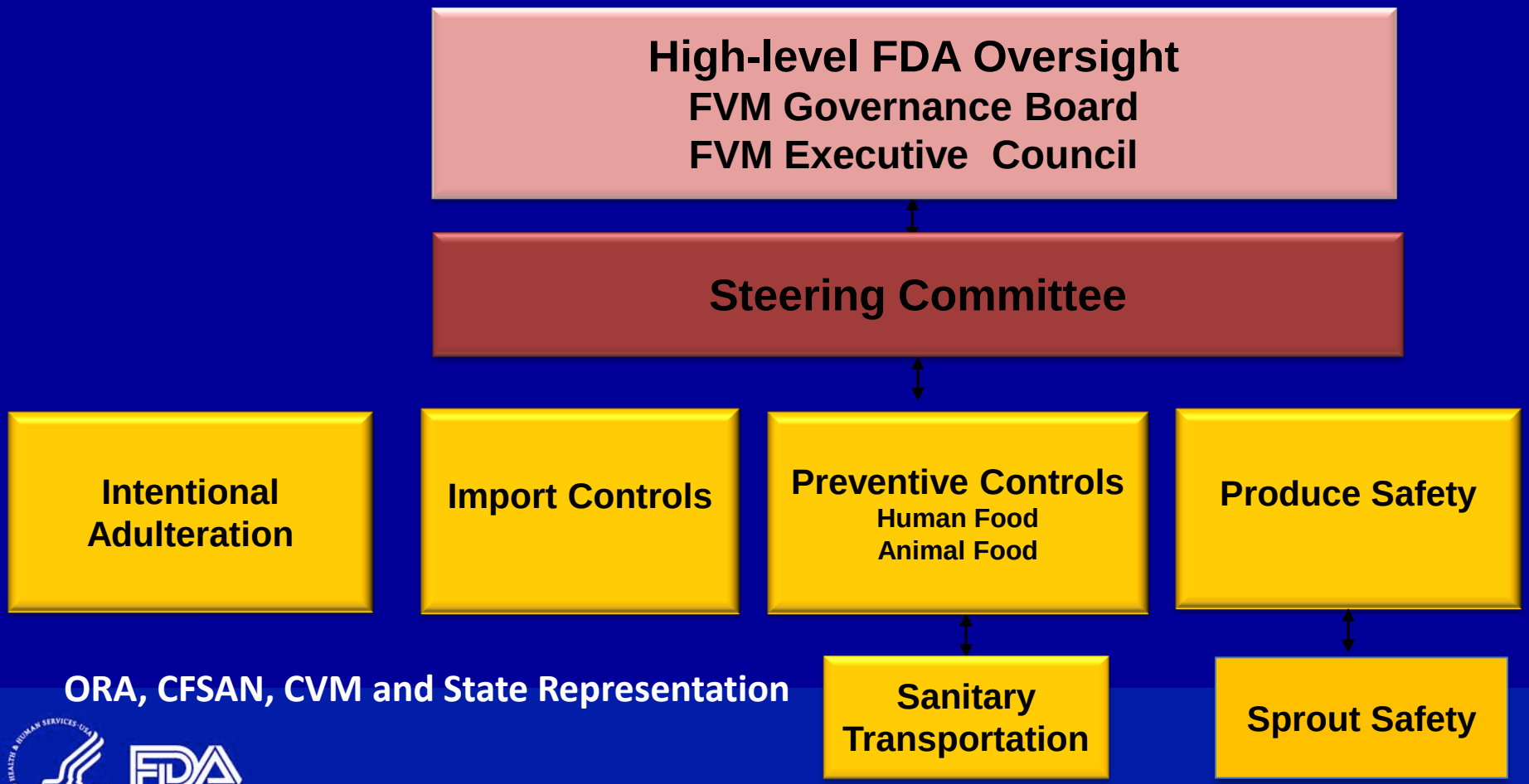

ORA, CFSAN, CVM and State Representation

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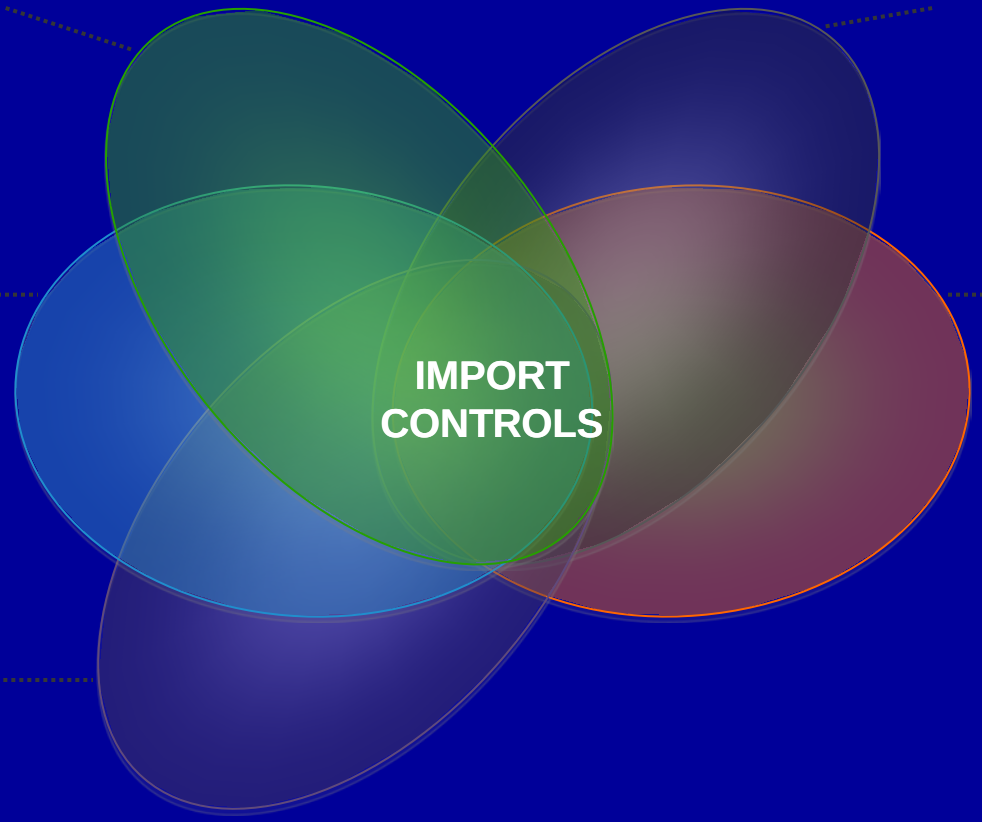
Programs Under Import Safety Phase 2 Workgroup

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)



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

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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

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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.

Phase 1
Rulemaking
Standards Setting
Guidance
Development

Phase 2
Strategic Program Planning (SPP) Frameworks
Draft Performance Measures & Monitoring Plans

Phase 3
Transition SPP frameworks, measures, and PMPs to program owners

Phase 3
Programs and FVM leadership measure operational and strategic outcomes; refresh program activities as needed