

Import Safety Phase 2 Workgroup

<http://www.fda.gov/fsma>

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW

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

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)

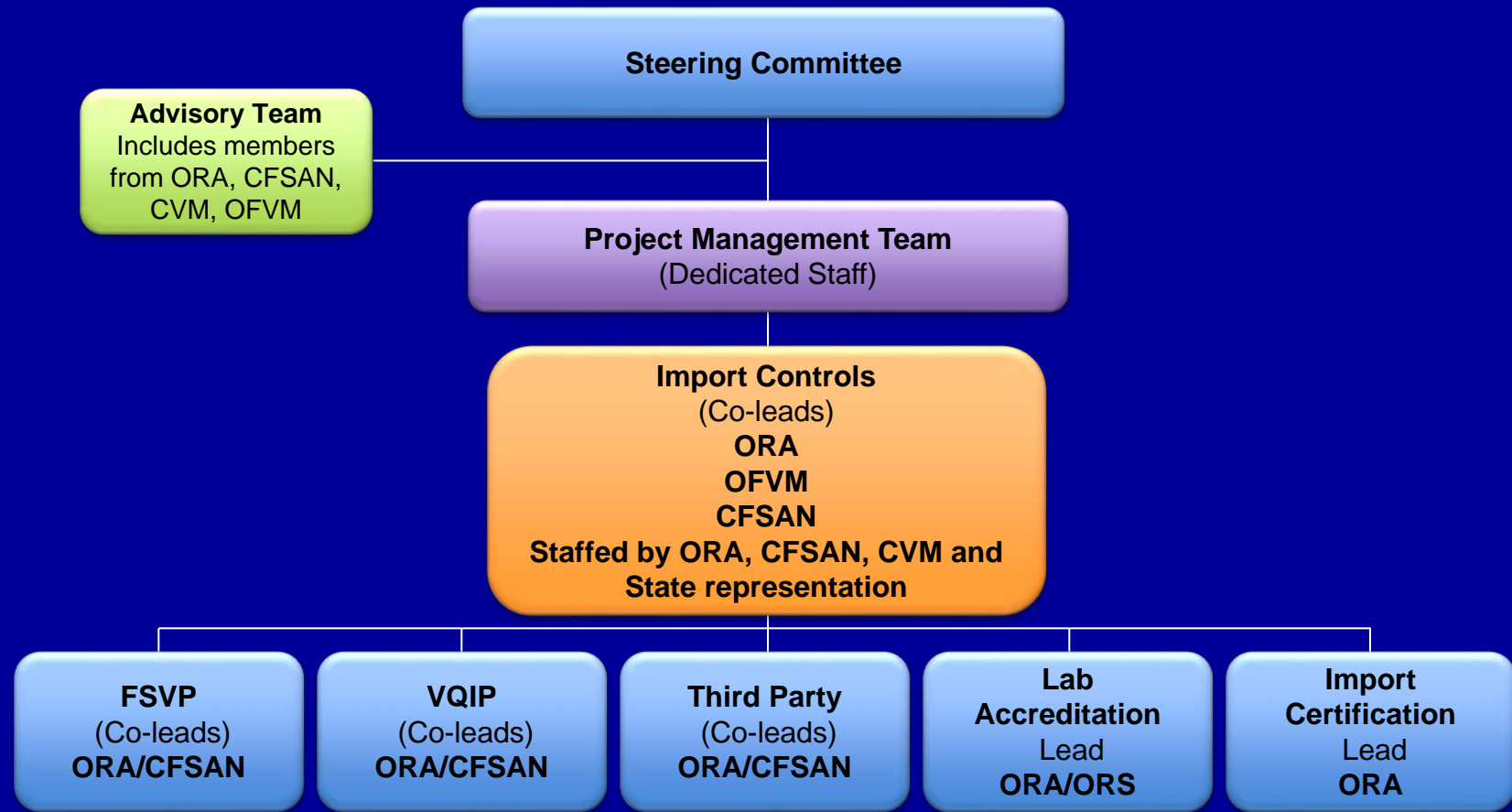
FSVP

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



Imports Safety Phase 2 Workgroup



Operational Areas in each sub-workgroup:

Inspections, Compliance and Enforcement | Regulator Training | Workforce Planning
Information Technology | External Outreach and Technical Assistance



FSVP: Outreach, Industry Education, Technical Assistance

- Web materials
- External presentations (U.S. and foreign)
- Developing FSVP course through the Food Safety Preventive Controls Alliance (FSPCA)
- Developing draft guidance
- Technical Assistance Network (TAN)

FSVP: Inspections, Compliance, Enforcement

- Developing a risk-based inspectional strategy for importers
- Considering both on-site and electronic records reviews
- Will include procedures for inspections of importers who must meet full FSVP requirements and those who must meet modified requirements

FSVP: Regulator Training

- Developed initial draft of FDA regulators training course.
- Utilization of “Train-the-Trainer” concept to effectively train the workforce
- Consistency is a priority.

FSVP: Information Technology

- Automating our inspectional approach
- Developing the “FDA Data Dashboard” to assist importers
- Developing modifications to current entry data
- Integration of old and new IT systems

FSVP: Performance Goals and Metrics

- Development of a comprehensive plan identifying short- and long-term performance goals and metrics to evaluate the program's effectiveness

FSVP: Workforce Planning

- Development of long-term staffing requirements for FDA
- Congress approved funding for FSVP hiring.

VQIP: Outreach, Industry Education, and Technical Assistance

- Engaged with industry to create a program in which industry wants to participate
- Technical assistance through the Technical Assistance Network (TAN)
- Developing VQIP Importers Help Desk

VQIP: Inspections, Compliance, and Enforcement

- Progress on development of procedures
 - Drafting internal operational procedures for application review, field investigations, prioritization of sample analysis, & Help Desk
 - Procedures will detail revocation process, reinstatement, and collaboration with other Federal agencies.

VQIP: Regulator Training

- Developing training material content for FDA staff working with VQIP
- Developing training material content for the VQIP applicant inspections
- Finalizing a guide to be used during the inspection
- Will develop education for our Customs and Border Patrol counterparts.

VQIP: Information Technology

- Significant progress in building an integrated IT system to receive and review VQIP Applications
- Developing IT tools for use by FDA staff during VQIP Inspections
- Developed screening criteria for PREDICT to expedite release of VQIP food

VQIP: Performance Goals and Metrics

- Development of a comprehensive plan identifying short- and long-term performance goals and metrics to evaluate the program's effectiveness
- Will be conducting evaluation of the benefits given to participants
 - Release times, Help Desk assistance, sample processing, participant feedback

VQIP: Workforce Planning

- Development of long-term staffing requirements for FDA
- Dependent on participation rates

VQIP: User Fees

- Reviewing comments
- Exploring user fee structure options
 - Will consider any burden on small business

Third Party: Outreach, Industry Education & Technical Assistance

- Engaged with Industry in development of program
- Web materials
- External presentations (U.S. and foreign)
- Developing Model Accreditation Standards

Third Party: Oversight, Compliance and Enforcement

- Developing internal operational procedures for application review and oversight activities
- Working with other FSMA programs and existing FDA programs to establish procedures where programs intersect

Third Party: Regulator Training

- Developing training program that has components from both external and internal materials and courses
- Developing guides to be used for internal reviews and audits

Third Party: Information Technology

- Significant progress in building a new and integrated IT system for the program
- Automating all processes
- Integration of old and new systems

Third Party: Performance Goals and Metrics

- Development of a comprehensive plan identifying short and long term performance goals and metrics to evaluate the program's effectiveness

Third Party: Workforce Planning

- Development of long-term staffing requirements for FDA

Third Party: User Fees

- Reviewing comments on July 2015 proposed rule
- Program will launch after the final user fee rule takes effect.

Sanitary Transportation

Shippers, carriers by motor vehicle and rail vehicle, loaders and receivers engaged in the transportation of covered food, including food for animals, must use sanitary transportation practices to ensure the safety of the food they transport.

- Principal types of foods covered:
 - Foods transported in bulk, e.g., animal feed
 - Packaged foods not fully enclosed by a container, e.g., fresh produce
 - Foods that require temperature control for safety
- Compliance dates:
 - April 2018 for small businesses, April 2017 for all other businesses

Intentional Adulteration

- Update and add to existing intentional adulteration guidance and technical assistance documents already available
- Recognize the need to establish training programs for both regulators and industry
- Inspection must be tailored to the unique challenges of food defense
- Establish an efficient and effective system, potentially leveraging resources being used to conduct food safety inspections

Public Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us

