



# FSMA Implementation: Import Safety

Collaborative Food Safety Forum  
Imports Session  
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# What the Statute Requires

- **Sec 301 – Foreign Supplier verification program**
  - Requires importers to verify their suppliers use risk-based preventive controls that provide same level of protection as U.S requirements.
- **Sec 302 – Voluntary qualified importer program**
  - Allows for expedited review and entry; facility certification required
- **Sec 303 – Certification for high-risk food imports**
  - FDA has discretionary authority to require assurances of compliance for high-risk foods
- **Sec 304 – Prior notice of imported food shipments**
  - Requires information on prior refusals to be added to prior notice submission
- **Sec 305 – International Capacity Building**
  - Develop a plan to expand the technical, scientific and regulatory food safety capacity of foreign governments and industry exporting to the US



# What the Statute Requires

- **Sec 306 – Inspection of foreign food facilities**
  - Can deny entry if FDA access for inspection is denied
- **Sec 202 – Lab Accreditation**
  - An importer must use an accredited lab if it has imported food tested in support of admission
- **Sec 307 – Accreditation of third-party auditors**
  - In certain situations, accredited third parties must certify that foreign food facilities meet U.S. requirements
- **Sec 308 – Foreign Offices of the Food and Drug Administration**
  - Establish offices in foreign countries to provide assistance on food safety measures for food exported to the U.S.
- **Sec 309 – Smuggled Food**
  - In coordination with DHS, better identify and prevent entry of smuggled food



# Implementation Management Structure

- Current chart found here:  
<http://www.fda.gov/Food/FoodSafety/FSMA/ucm247556.htm>
- Implementation Executive Committee with 6 teams
  - Prevention Standards,
  - Inspections & Compliance
  - **Imports**
  - Federal/State Integration
  - Fees
  - Reports & Studies



# Implementation Management Structure

- Imports Team
  - David Elder, Chair
  - 7 Work Groups
    - Importer Verification & VQIP
    - Import Certification
    - Accredited Third-Party Certification
    - Lab Accreditation and Integrated Consortium/FERN
    - International Capacity Building
    - Comparability
    - Prior Notice



**Accreditation Body**  
Accredit 3rd parties

*FDA sets standards for accreditation bodies and recognizes those that meet standards. FDA may serve as an accreditation body and perform direct accreditation*

**Third Party Entity Certification**

*FDA audits accredited 3rd parties and relies on their certifications.*

**Importer**  
Verification  
Certification  
VQIP

*FDA inspects importers, holds them accountable, requires certification as needed, and expedites entry of products for firms under VQIP.*

**Foreign Manufacturer**  
Mfr under preventive controls  
Obtain 3rd party certification  
as needed

*FDA inspects foreign manufacturers and may rely on 3rd parties to inspect, FDA also works internationally to develop foreign capacity.*



# Questions?