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

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

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

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