FSMA: Imports and Accredited Third-Party Certification

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Topics

- FSMA Title III (Imports)
- FSMA 3d Party Requirements
- FSMA Certification Requirements
- Discussion
FSMA Title III (Imports)

- Makes importers responsible for ensuring their suppliers have preventive controls in place
- Allows FDA to deny entry of product if FDA access for inspection is denied
- Adds refusal information to prior notice
- Requires FDA to develop an international capacity-building plan
FSMA Title III (Imports)

- Foreign Supplier Verification Program
- Prior Notice
- Capacity Building (Comparability)
- Foreign Inspections
- Foreign Offices
- Smuggled Food
- Accredited Third-Party Certification
- Voluntary Qualified Importer Program
- Mandatory Certification for Imported Food
FSMA 3d Party Requirements

• Establish a program to accredit third-party auditors (a/k/a certification bodies, or CBs)

• Accredited CBs conduct food safety audits of foreign entities, issue food + facility certifications
  – May be an individual
  – May use audit agents
  – No geographic restriction
FSMA 3d Party Requirements

• Recognition
  – FDA can recognize accreditation bodies (ABs) that themselves accredit CBs

• Direct accreditation
  – After the 3d party program has been in effect for 2 years, FDA can begin to directly accredit CBs—but only if there is an unmet need
FSMA 3d Party Requirements

• Issue implementing regulations, standards:
  – Requirements that 3d parties must meet to be accredited under the FDA program
  – Audit reporting requirements
  – Conflict of interest provisions
  – Look to existing standards

• Issue user fee regulations
FSMA 3d Party Requirements

• Deadlines:
  – Issue (final) regulations and model accreditation standards: July 2012
  – Begin program operations: January 2013
FSMA Certification Requirements

• **Voluntary qualified importer program** gives participating importers expedited review and entry of food from certified facilities
  
  – Process consistent with 3rd party program
  
  – Eligibility factors: exporting nation’s capability
  
  – Review and revocation of status
FSMA Certification Requirements

• **Mandatory certification** when FDA determines that a high-risk food import needs food certification or other assurances of compliance to support admissibility

  – May be issued by an accredited third-party certification body or by an FDA-designated government of an originating country

  – Renewal and refusal of certification
FDA
Recognizes accreditation bodies (ABs)
Directly accredits auditors where unmet need § 307

Recognized AB
Accredits 3rd parties § 307

3rd Party Certification
Facilities and high-risk food imports §§ 302, 303

Voluntary Qualified Importer Program
Facility certification for expedited entry § 302

High-Risk Food Imports
Food certification or other assurances § 303
Discussion

• **Effectiveness**
  – Who? What? How?
  – Rigor; best practices

• **Efficiency**
  – Cost / benefit
  – Existing infrastructure, administrative burden

• **Transparency**
  – Consumer confidence
  – Changes in current practices