



# **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 3d 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

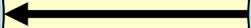
**FDA**  
Recognizes accreditation bodies (ABs)  
Directly accredits auditors where unmet need § 307

**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