Third Party Audits and FSMA

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FDA Food Safety Modernization Act

There are several areas of FSMA where third-party audits will play a role:

- FDA's Third-Party Accreditation Program
- Supplier Verification Activities in the FSVP and PC rules
- Potential for Leveraging Audits in Compliance Strategies

FDA's Third-Party Accreditation Program

Establishes a program for the accreditation of third-party auditors to
1) conduct food safety audits
2) issue certifications of foreign facilities and the foods they produce.

FDA will recognize accreditation bodies (ABs) who will then accredit certification bodies (CBs) to conduct audits.

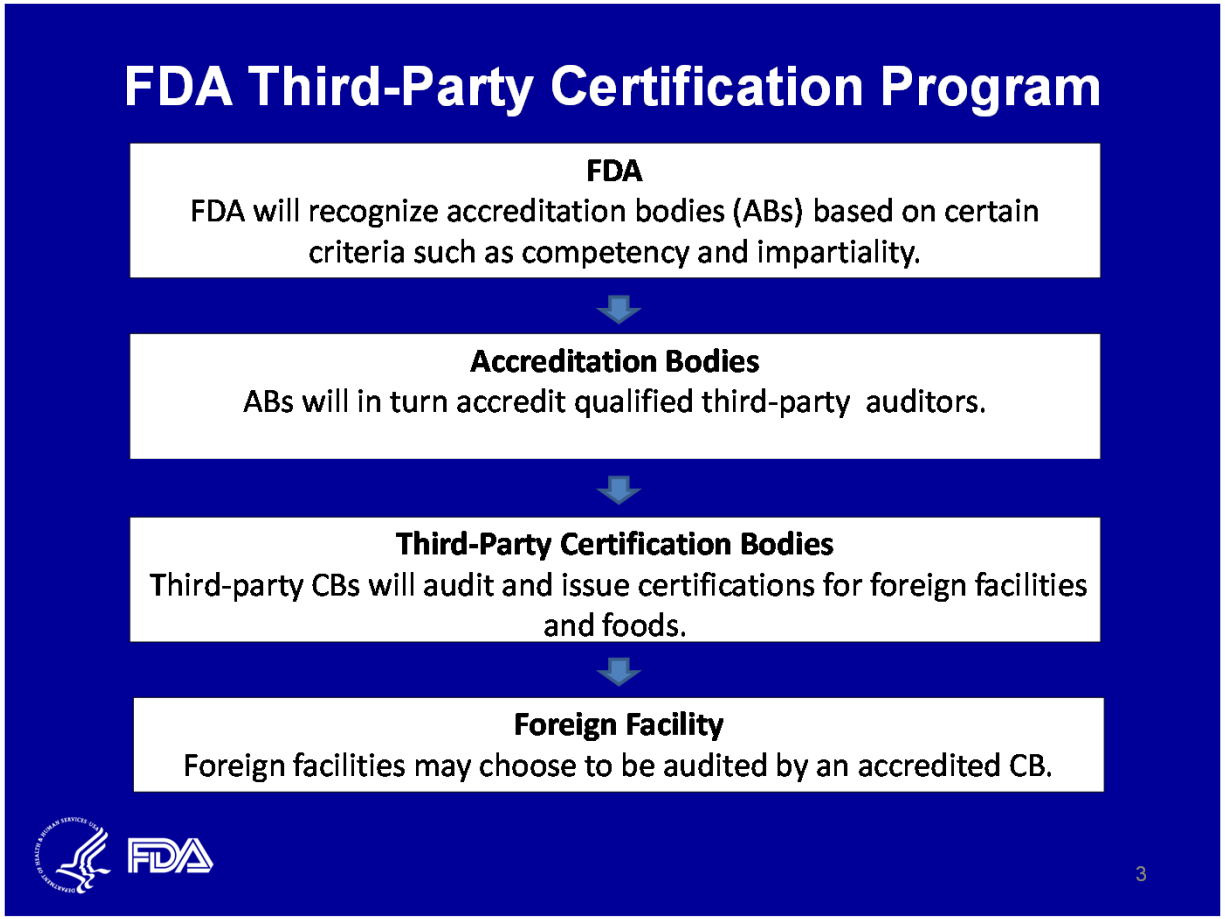
FDA's Third-Party Accreditation Program

FDA's Third-Party Program has two limited uses:

1. Importers will use facility certifications from foreign suppliers in support of their eligibility to participate in the Voluntary Qualified Importer Program (VQIP)

2. In specific circumstances where certification may be required as a condition of entry—a tool FDA does not intend to use routinely

FDA's Third-Party Accreditation Program



FDA's Third-Party Accreditation Program

What must Accreditation Bodies Do?

- Assess third-party certification bodies for accreditation.
- Monitor the performance of third-party certification bodies they accredit.
- Assess and correct problems in their own performance.
- Submit reports and other notifications to FDA.
- Maintain and provide FDA access to certain records.

FDA's Third-Party Accreditation Program

What must Certification Bodies Do?

- Ensure their audit agents are competent and objective.
- Verify the effectiveness of facilities' corrective actions to address identified deficiencies.
- Assess and correct any problems in their own performance.
- Maintain and provide FDA access to certain records.

FDA's Third-Party Accreditation Program

Audit Requirements

- When performing audits under this program, accredited third-party CBs must:
  - Perform facility audits unannounced
  - Notify FDA on discovering a condition that could cause or contribute to a serious risk to public health
  - Submit regulatory audit reports
  - Maintain consultative audit reports

FDA's Third-Party Accreditation Program

Related Documents

- Model Accreditation Standards Guidance
- Third-Party User Fee Rule

Third-Party Audits as Verification Activities

The **Foreign Supplier Verification Program rule and the Preventive Controls rules** include audits as one option for supplier verification activities.

These audits
1) must be conducted by a qualified auditor
2) must consider applicable FDA food safety regulations.

Leveraging Third-Party Audits

Produce Rule

FDA intends to explore whether reliable information from reliable entities -- be they private entities or foreign governments -- can inform our risk-based decision making, especially with respect to inspections.

We look forward to continuing the dialogue on third party programs.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