

Accredited Third Party Certification

Collaborative Food Safety Forum
November 16, 2011
Washington, DC

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Third Party Accreditation – *Key Messages*

- 1) Certification by an accredited third party is an effective tool to assess food safety and is an important component of several FSMA mandates: Import Certifications, VQIP, FSVP.
- 2) For efficient use of resources, FDA should establish a system for the recognition of accreditation bodies that accredit third party auditors to certify food facilities, rather than directly accrediting third party auditors.
- 3) Certification should be performed by an independent (third party) organization that is accredited by a non-profit authoritative body (*i.e.*, accreditation body) that is a signatory to the Multilateral Recognition Arrangement overseen by the International Accreditation Forum (IAF).
- 4) Currently, this model is already in place for the most widely and internationally used food safety schemes, such as those recognized by GFSI (*e.g.*, FSSC 22000).

Background

- In developing our recommendations, we reviewed FDA's prior experience with third parties:
 - Aquacultured Shrimp Pilot: Developed in response to the President's Action Plan for Import Safety (November 2007), and the call for development of voluntary third party certification programs for foreign producers that export to the U.S.
 - Manufactured Food Regulatory Program Standards: Developed for state and local food regulatory agencies to ensure equivalency in regulatory programs.
 - FDA Guidance for Industry: Voluntary Third Party Certification Programs for Foods and Feeds: Describes the general attributes FDA believes a certification program should have to provide quality verification of product safety.

Accredited Third Party Certification – *Terms & Definitions*

International Accreditation Forum (IAF): Through the IAF Multilateral Recognition Arrangement (MLA), IAF helps ensure that all accreditation bodies are following the rules of accreditation and applying the standards to affirm consistent delivery of certification schemes. Members (national accreditation bodies) perform verification activities by peer review using ISO 17011 to ensure conformance to IAF membership rules.

Accreditation Body (AB): An authoritative body that gives formal recognition of the competence of a certification body to provide certification services against a scheme or a standard. ABs ensure that certification bodies are subject to oversight using ISO 17021 or ISO Guide 65 (to be replaced by ISO 17065 in 2012).

Certification Body (CB): An independent (third party) organization that conducts certification audits and provides written assurance of an audited food company's conformance to a certain scheme or standard. A CB is accredited (by an AB) for its ability to certify a food facility's conformance to a defined scheme or standard.

Standard: Auditable and certifiable food safety requirements.

Scheme: A standard plus a governance and management system to assure the integrity of the standard's delivery.

Recommended Required Elements for FDA's Accreditation Program

Recommended Required Elements:

- 1) Supplier's commitment to implement and sustain a food safety management system in full compliance with FDA requirements
- 2) Compliance with regulatory requirements and alignment with international food safety and hygiene management standards
- 3) A systems-based approach to accreditation, with oversight of the *Accreditation Bodies* (must be IAF members) and *Certification Bodies* through conformity assessments
- 4) Transparency and independence of the assessment process (to ensure the integrity of the assessment process and results)
- 5) Impartiality and management of conflicts of interest, such as independence of the scheme from the CBs

Unaccredited Third Party Certification/Audit – *Was common in US*

Potential Benefits to Industry:

- ✓ *Cheap*
- ✓ *Quick*
- ✓ *Flexible*

Lacks:

- ✓ *Oversight*
- ✓ *Transparency*
- ✓ *Independence*
- ✓ *Competition*
- ✓ *Credibility*
- ✓ *External Rules*

Audit Controls

What (Std), How (Process), Who (Auditor)



Site

Food/Feed Safety System

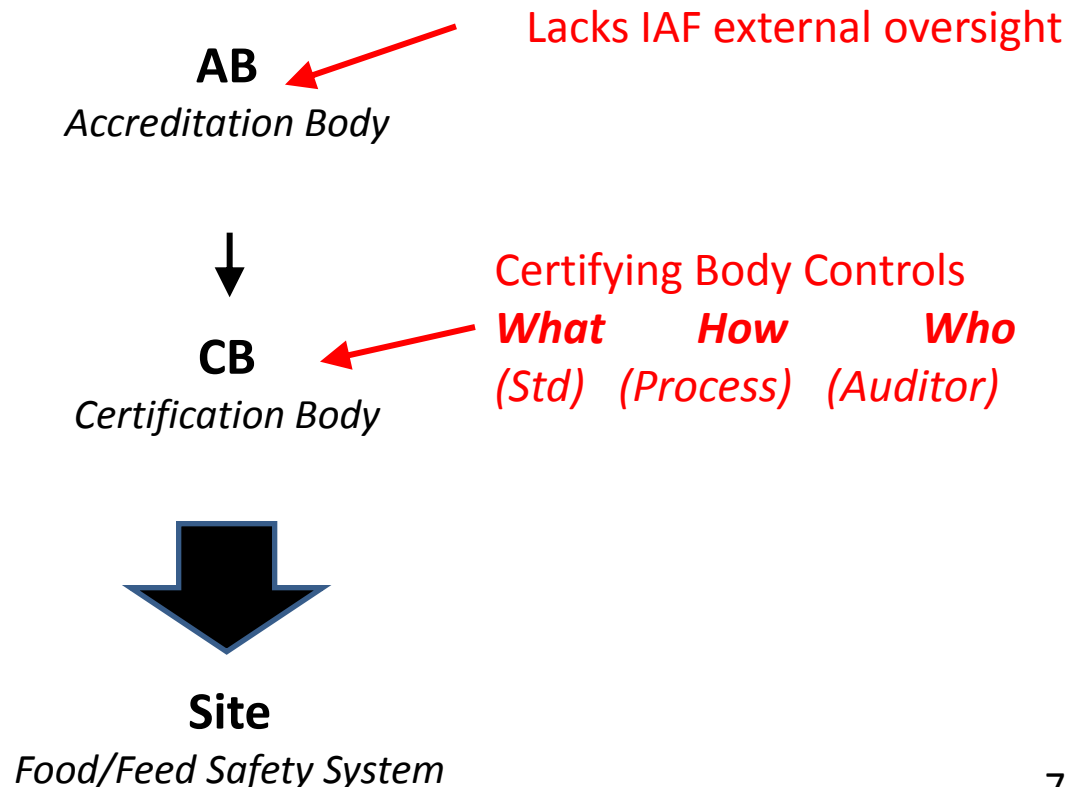
“Accredited” Third Party Certification – *But not IAF recognized*

Potential Benefits to Industry:

- ✓ *Less expensive*
- ✓ *Says “Accredited” (what does that mean?)*
- ✓ *Flexible*

Lacks:

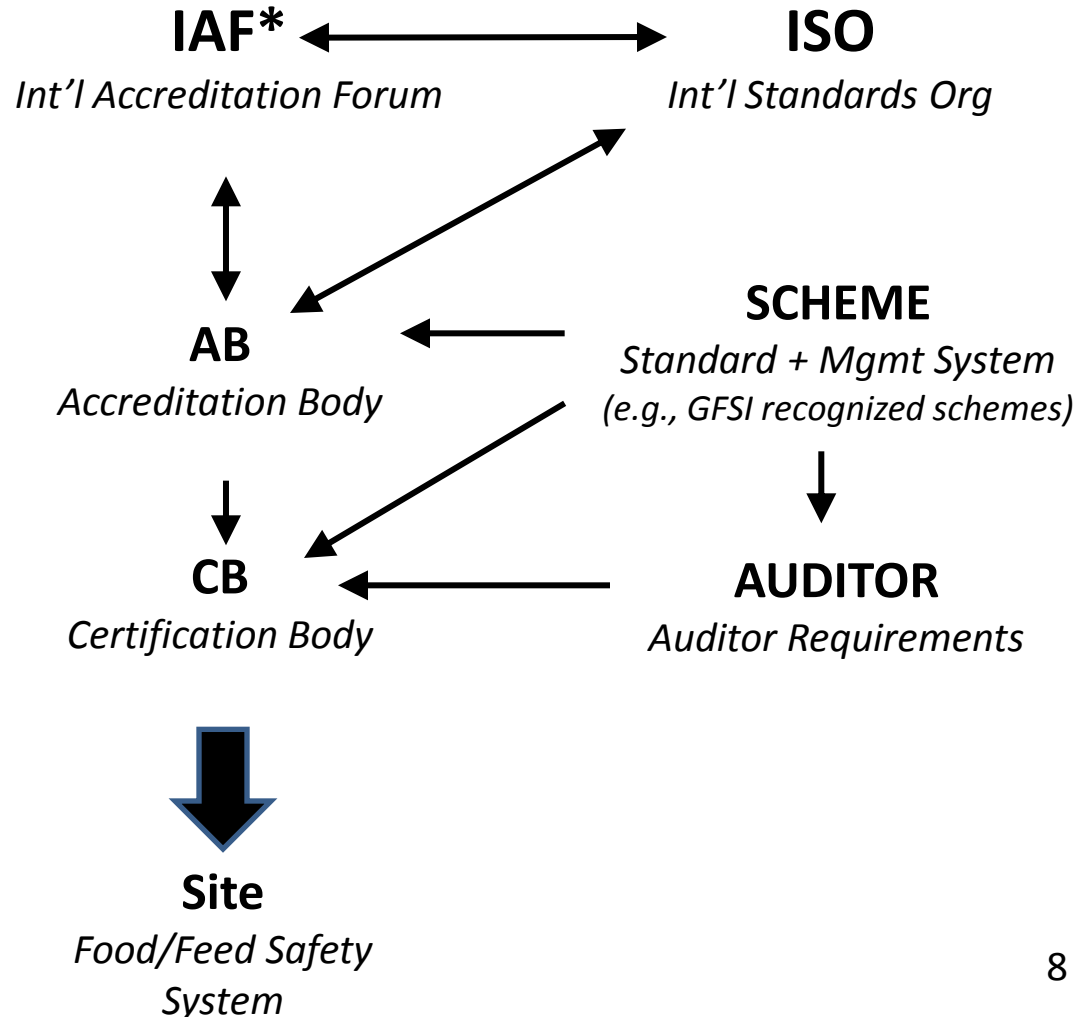
- ✓ *Oversight*
- ✓ *Transparency*
- ✓ *Independence*
- ✓ *Competition*
- ✓ *Credibility*
- ✓ *External Rules*



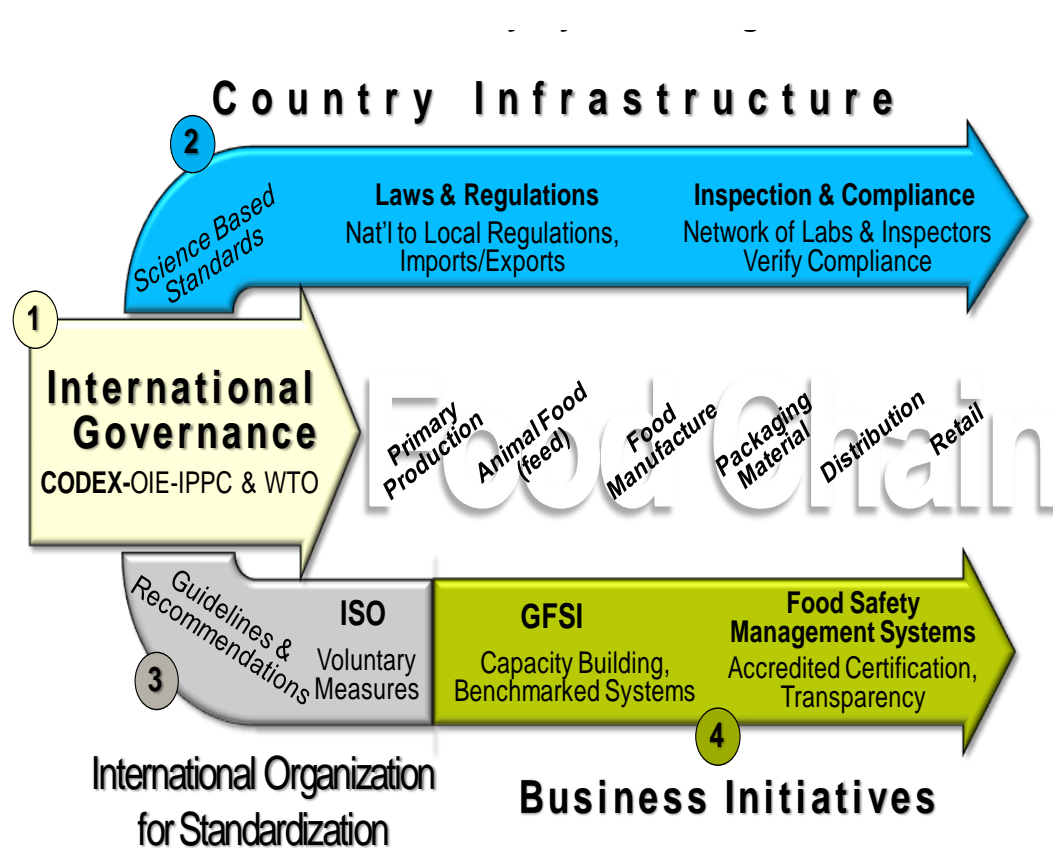
Accredited Third Party Certification – *With IAF oversight*

Benefits:

- ✓ **Process & Rules**
- ✓ **Transparency**
- ✓ **International (global) mutually recognized system**
- ✓ **Oversight**
- ✓ **Independence**
- ✓ **Harmonized requirements for AB and CB (ISO standards)**



Accredited Third Party Certification – *International Harmonization*



- Harmonization of food safety begins with science based CODEX standards (the only standards recognized by WTO & SPS agreements)
- Country laws and regulations are derived from CODEX; some use ISO voluntary measures
- ISO voluntary measures build on CODEX to facilitate trade. 163 countries develop transparent processes (accreditation, certification, auditing, competency)
- GFSI benchmarked schemes build on CODEX and ISO