

The History and Use of Certification in International Trade

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USDA'S USE OF FOREIGN GOVERNMENT CERTIFICATION

- USDA requires foreign governments to utilize the same approach to inspection as is mandated for meat and poultry products produced in the United States
- Foreign governments identify the facilities that will be subject to the same inspection requirements and they are certified to ship products to the United States
- Only meat and poultry from identified facilities can be admitted to the United States
- USDA audits foreign programs to ensure compliance
- USDA monitors incoming products from each country to ensure that they are in compliance
- Findings from USDA audits and border inspections are fed in USDA's review of foreign governments

CODEX'S ADOPTION OF CERTIFICATION CONCEPTS

- The Codex Alimentarius has adopted a number of provisions addressing recognition of certification systems in international trade

“Certification is the procedure by which official certification bodies or officially recognized certification bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.”

“Official accreditation is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services.”

“An effective certification system depends on the existence of an effective inspection system as described . . . above.”

Source: *Codex Alimentarius Food Import and Export Inspection and Certification Systems*, Fourth edition

APPLICATION OF CERTIFICATION CONCEPTS TO FDA IN FSMA

- FDA's oversight of imports relied on the inspection of imports at the border
- Following passage of the 2002 Bioterrorism Act, over 250,000 food facilities from more than 150 countries registered with the FDA
- FDA clearly does not have the capacity to rely on on-sight inspection of this number of facilities, so a modified approach similar to that used by USDA was proposed
- Concerns that this approach might result in a disruption of trade led to the multiple components that are in the current legislation which includes both government and accredited third party certification concepts

LESSONS FROM HACCP AND ORGANIC STANDARDS

- Third party auditing/certification is being relied on heavily by retailers, especially in Europe and a growing number of U.S. multinationals.
- The companies have been working on the concepts for a number of years, including the relationship and accountability of the players
- Similar food industry-driven approaches have evolved into governmental programs, some using private certification bodies
 - HACCP
 - ORGANIC STANDARDS

CONCERNS ABOUT THIRD PARTY SCHEMES

- Assuring the stringency of food safety standards
- Are standards prescriptive or outcome focused
- Costs of certification/requirement for multiple certifications
- Impact on access to markets
- Impact on public health
- Transparency/Involvement of key stakeholders in standard setting and decision making
- Legitimacy of the private schemes and their potential to undermine public food safety programs

Source: *Private Food Safety Standards*, White Paper of the Food and Agricultural Organization of the United Nations (2009)

Thank you!

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FSMA: IMPORT PROVISIONS

- **Food importers will be required to ensure their foreign suppliers comply with U.S. food safety laws**
- **FDA can require high-risk imported food to be certified as complying with U.S. law**
- **FDA shall establish a program for accrediting private auditors to perform certifications**

LIMITATIONS

- An accredited third party auditor may not perform a regulatory audit of an eligible entity if such agent has performed a consultative audit or a regulatory audit of such eligible entity during the previous 13-month period.
- **WAIVER**— The Secretary may waive the application of clause if the Secretary determines that there is insufficient access to accredited third-party auditors in a country or region.

CONFLICTS OF INTEREST

■ THIRD-PARTY AUDITORS

- An accredited third-party auditor shall:
 - Not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by such auditor;
 - In carrying out audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of such auditor that has a financial conflict of interest regarding an eligible entity to be certified by such auditor; and
 - Annually make available to the Secretary disclosures of the extent to which such auditor and the officers and employees of such auditor have maintained compliance with clauses
 - And relating to financial conflicts of interest.

■ AUDIT AGENTS

- An audit agent shall:
 - Not own or operate an eligible entity to be audited by such agent;
 - In carrying out audits of eligible entities under this section, have procedures to ensure that such agent does not have a financial conflict of interest regarding an eligible entity to be audited by such agent; and
 - Annually make available to the Secretary disclosures of the extent to which such agent has maintained compliance with clauses and relating to financial conflicts of interest.

WITHDRAWAL OF ACCREDITATION

- **The Secretary shall withdraw accreditation from an accredited third-party auditor:**
 - If food certified under section 801(q) or from a facility certified under paragraph (2)(B) by such third-party auditor is linked to an outbreak of foodborne illness that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;
 - Following an evaluation and finding by the Secretary that the third-party auditor no longer meets the requirements for accreditation;
 - Or following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to ensure continued compliance with the requirements set forth in this section.

WITHDRAWAL OF ACCREDITATION

- **Additional Basis for Withdrawal of Accreditation:**
 - In the case that such third- party auditor is accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked, if the Secretary determines that there is good cause for the withdrawal.
- **Exception**
 - The Secretary may waive the application of subparagraph (A)(i) if the Secretary:
 - Conducts an investigation of the material facts related to the outbreak of human or animal illness;
 - And reviews the steps or actions taken by the third party auditor to justify the certification and determines that the accredited third-party auditor satisfied the requirements under section 801(q) of certifying the food, or the requirements under paragraph (2)(B) of certifying the entity.