



Advancing American
Competitiveness through
Conformity Assessment:
LEGAL ISSUES AND
BEST PRACTICES



Assuring Food Safety

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Advancing American Competitiveness through Conformity Assessment:
Legal Issues and Best Practices | September 21, 2010

Food Marketing Institute

- **Non-profit trade association conducting programs in research, education, food safety, industry relations and public affairs**
- **Primary lobbying organization for food retailers and wholesalers in the US**
- **1,500 Member Companies**
 - **Food Retailers (26,000 supermarkets, grocery stores)**
 - **Wholesalers and Distributors**
 - **3/4 of all food retail store sales in the US (\$680 billion annual)**
 - **Large multi-store chains, regional firms and independent supermarkets**
 - **International: 200 companies in 60 countries**
- **Associate members (suppliers, service providers)**
- **FMI owns and manages the SQF Program**



FMI Mission Statement

Representing food retailers and wholesalers, FMI develops and promotes policies, programs and forums supporting its members, and their customers, in the areas of:

- **Government Relations**
- **Food Safety and Defense**
- **Public and Consumer Information**
- **Research and Education**
- **Industry Cooperation**





U.S. Government Recognition of Third Party Certifications
for Food Safety

- **Safe Quality Food (SQF)**
- **Food Safety Legislation**
- **Food Safety Regulation**
- **Benefits of A3PC and CA**

President Obama's Food Safety Working Group



3 core principles:

1. **Prioritize Prevention**
2. **Strength surveillance & enforcement**
3. **Improve response and recovery**

www.foodsafetyworkinggroup.gov



What is SQF?



- SQF = A globally recognized conformity assessment program for food safety, quality and ethical sourcing.
- SQF Program contains two parts:
 - A food safety standard
 - A system for auditing and certification
- The **standard** includes all the regulations and best practices for how to safely grow, process, manufacture and prepare food from farm to table.
- The **system** ensures that a qualified, trained independent auditor evaluates how well a supplier meets the standard and to certify that the standard is being met.

FDA Food Safety Modernization Act Food Safety Enhancement Act



Congress proposed new food safety legislation

- S.510
- HR 2749

Retail food industry supports the new legislation

- **Food safety plans (HACCP)**
- **Regulatory Standards for Fruits and Vegetables**
- **Risk-based inspection**
- **Traceability**
- **Recall authority**
- **Foreign Supplier Verification Program**
- **Accredited third-party certification**

Foreign Supplier Verification Program



VERIFICATION REQUIREMENTS:

- **FDA will have one year to develop regulations**
- **Program will be implemented in 2 years**

- **Require risk-based activities for the purpose of verifying that the imported food**
 - **is produced in compliance with US requirements**
 - **is not adulterated**
 - **Is not misbranded**

Foreign Supplier Verification Program



Verification procedures may include:

- monitoring records for each shipment
- lot-by-lot certification of compliance
- annual on-site inspections
- checking the HACCP and risk-based preventive control plan
- periodically testing and sampling shipments

Foreign Supplier Verification Program



- As a condition of granting admission to an article of food imported or offered for import into the US, FDA may require:
 - A certification of compliance
 - Shipment-specific certificate
 - Inclusion on a list of certified facilities

Voluntary Qualified Importer



“...to provide for the expedited review and importation by importers who voluntarily agree to participate...”

- FDA will establish a process for the issuance of a facility certification to accompany food offered for importation providing assurance that the food meets FDA requirements
- Application process and guidance document

Certification



So how do you get one of these certificates?

- An agency or a representative of the government of the country from which the article of food originated
- Such other persons or entities accredited to provide such certification according to this Act
- Goal: Make SQF a recognized entity

Third Party Auditing



- The term ‘third party auditor’ means a foreign government, agency of a foreign government, foreign cooperative, or any other third party, eligible for accreditation (CAB)
- ‘Regulatory audit’ means an audit to determine whether such entity is in compliance and therefore the an article of food is eligible to receive a food certification or the facility is eligible to receive a facility certification

Accreditation



- In 2 years, FDA should establish a system for recognition of accreditation bodies
- FDA shall develop model requirements for third-party auditors and audit reports
- Look to standards already in place for guidance to avoid unnecessary duplication of efforts and costs
- FDA may also “accredit” third party auditors (?)

Types of “Auditing” Bodies



- FDA may determine that a foreign government or agency of the foreign government can provide certification of compliance
- To be an accredited “third-party auditor” the accreditation body shall perform reviews and audits of the training and qualifications of the auditors who conduct such reviews
- FDA may conduct on-site visits to assess the third party auditor (CAB)

Requirements of Third Parties



- **If, at any time during an audit, an auditor discovers a condition that could cause or contribute to a serious public health risk, the auditor shall immediately notify FDA**
- Strict conflict of interest rules
- Annual re-certification of entities
- Publicly available registry
- Must issue a written and/or electronic food certification or facility certification

FDA Comment on Use of A3PC



*Guidance for Industry Voluntary Third-Party
Certification Programs for Foods and Feeds
(January 2009)*

“...voluntary certification is one way to ensure products meet US safety and security standards and allow Federal agencies to target their resources more effectively.”

Benefits of Certification



- FDA may use certification status as one way to determine inspection priorities
- Certification may reduce the “risk” status of a facility
- Imported foods qualify for expedited entry into the US
- Qualify for “Voluntary Qualified Importer Program”
- Faster outbreak follow-up investigation and “release”
- Remove company from “Alert” list for import detention
- Reduce costs
- Level the playing field

Outstanding Issues



- Accreditation of entities that are not Certification Bodies or Conformity Assessment Bodies
- Unannounced audits
- FDA access to audits and certification reports
- Immediate notification of FDA if “reasonable probability” that food will cause a serious health consequence or death
- Immediate notification of FDA if certification is withdrawn
- CAB has access to laboratory services for sample analysis

New Regulations and Legislation



- Encourage **collaboration**
- Build more public-private **partnerships**
- Focus more on **prevention** so we need less reaction
- Restore consumer **confidence**
- Enhance government **credibility**



What About the Eggs?

