Pre-Read Material: PEW Certification Meeting 16-Nov-2011

Background:
The FDA Food Safety Modernization Act discusses Accredited Certification, Third Party Certification, Audits, Accredited Auditors, and Harmonization to CODEX Alimentarius in sections: 103, 202, 302, 303, 305, 307. Purpose of this pre-read is background for understanding of rules, concepts, and terms that apply to foster a collaborative food safety effort to protect consumers using accredited third party certification.

Rules:
A key understanding is that an auditing company can operate by three major sets of rules that tend to increase independence, transparency and robustness.

1. Private audit
   a. Checklist owned by audit company, audit controlled solely by audit company, lacks independence/transparency, closed system.
   b. Common domestically (ie PCA, Wright Farms, Jensen Farms)

2. Accredited certification
   a. An authority accredits the checklist or standard and/or audit process.
   b. Concerns: is the accrediting body (AB) recognized by the International Accreditation Forum (IAF) and/or using ISO rules for assessment. If yes, this is a fair starting point, but “accreditation” does happen outside of this recognized model. Does the Certifying Body (CB) own or monopolize the standard? Is the standard benchmarked by the benchmarking organization the Global Food Safety Initiative (GFSI)?

3. Enhanced/GFSI level Accredited Certification with benchmarked schemes
   a. Accredited Certification process rules using ISO rules and only International Accreditation Forum member Accrediting Bodies (AB) plus additional GFSI rules for AB’s and CB’s are layered on top of the existing ISO/IAF accredited certification process for better oversight and transparency to ensure the independence and integrity of the accredited certification process.
   b. Scheme must have owner with system to manage delivery quality of the standard, be GFSI benchmarked, independent of Certifying Body (CB), and open for any approved CB to audit.
   c. Auditor competency rules from GFSI apply.

Concept: The audit 3 legged stool:
What standard is being used?
- Is the standard international? Transparent to CODEX? Benchmarked? Open to any qualified Certifying Body? Is there a quality management system to control delivery of the standard (a standard just a piece of paper – interpretation and consistent control of delivery is key)?
- When a standard is combined with a management system to control delivery of the standard by an owner who is responsible to meet benchmarking criteria it is called a scheme.

How does the audit process work?
- What level of independence & transparency of the 3 components are there? What type/level of accreditation? How is the quality of the delivery of the standard controlled? Independence? Transparency?

Who is competent to audit or assess effectiveness of the site designed food safety management system?
- Qualifications and experience are just the beginning, what skills are needed, how can application of these skills be measured in auditor competency?
Terms:

**Standard** is a document with a set of repeatable requirements. *Scheme* takes a standard and adds an owner responsible for the consistent delivery quality of the standard and for the scheme to meet GFSI benchmarking criteria. **Conformity Assessment** is evaluation of food safety management system (FSMS) conformity to a standard. Non-conformities are not allowed on going; corrective actions must be taken and verified as closed in a specified time. Management commitment, resources & training, hazard assessment, HACCP program, validation, verification, control of non-conformity, and continual improvement are key elements of FSMS.

Industry & government collaboration:

FDA and the food industry can proactively to build capacity and protect consumers aligned with accredited 3rd party certification with the GFSI enhancements providing independence and transparency.

- **Global-to-local food safety systems aligned with CODEX** *(Figure A)*
  1) Harmonization of food safety begins with science based CODEX standards (the only standards recognized by WTO & SPS agreements)
  2) Country laws and regulations derived from CODEX, some use ISO voluntary measures
  3) ISO voluntary measures build on CODEX, facilitates trade, and 163 countries develop transparent processes (accreditation, certification, auditing, competency)
  4) Business Initiatives like GFSI and food safety systems build on CODEX and ISO

- **An internationally recognized and widely adopted GFSI model of accredited 3rd party certification** *(Figure B)*
  - Multi-stakeholder, global, transparent
  - GFSI is fully representative of the global supply chain including a broad representation of US based food industry

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**Figure A**

**Global-to-Local Food Safety Systems Aligned with CODEX**

1. **International Governance**
   - CODEX-OIE-IPPC & WTO
2. **Country Infrastructure**
   - Laws & Regulations
     - Nat’t to Local Regulations, Imports/Exports
   - Inspection & Compliance
     - Network of Labs & Inspectors
     - Verify Compliance
3. **International Organization for Standardization**
   - Guidelines & Recommendations
4. **Business Initiatives**
   - GFSI
     - Capacity Building, Benchmarked Systems
   - Food Safety Management Systems
     - Accredited Certification, Transparency

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**Figure B**

**A Model for Accredited 3rd Party Certification**

- **GFSI** Global Food Safety Initiative
- **IAF** Int’l Accreditation Forum
- **ISO** Int’l Standards Org
- **SCHEME** Standard + Mgmt System
- **AB** Accreditation Body
- **CB** Certification Body
- **AUDITOR**
  - *IAF includes Int’l Lab Accreditation Cooperation (ILAC)

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**Site**
Food/Feed Safety System

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