
Ingredient Supplier Qualification Workshop

Small Supplier Perspective

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Overview

- Issues with supplier certification
- Existing landscape
- Supplier observations
- Ideas for supplier certification program

Heightened Awareness

- Safe consumer products start with trustworthy suppliers
- Consumer confidence eroded by food scares
 - Public reducing use of certain foods
 - 41-48% Supplement users and 35% of General population¹
 - Consumer confidence in foods at supermarkets dropped from 82% (2006) to 66% (2007)²
 - Lowest since 1989²

¹Natural Marketing Institute, September 2009, Health and Wellness Trends Database

²Testimony of Jill Hollingsworth, Food Marketing Institute, to US House of Representatives, Subcommittee on Health, Energy, and Commerce Committee, September 26, 2007, citing U.S. Grocery Shopper Trends

Supply Chain Issues

- ❑ Part 111 ≠ Part 110
- ❑ No primary industry or government standard to qualify suppliers
- ❑ No means for communicating best practices
- ❑ Disparate certification standards and application
- ❑ SIDI not adopted universally
- ❑ Foreign suppliers not held to US standards
- ❑ Ignorance (negligent or willful)

Qualification Topics for Suppliers

- ❑ How do manufacturers *effectively* and *efficiently* qualify suppliers under Part 111 requirements?
- ❑ What does the current paradigm mean to a small supplier?
- ❑ How would a standardized supplier certification system help?
- ❑ What will happen if there is no standardized scheme?

Goal

- Industry should develop a program for supplier qualification
 - Apply current tools and best practices such as SIDI
 - Create supplier certification program
- No system will guarantee safety of food, but one could provide a reliable structure that allows for understanding risk

Past and Current Supplier Qualification

- Qualification not required by law or regulation until Part 111 took effect
- Three types of supplier qualification:
 - Negligible
 - Moderate
 - Effective

5 Easy Steps For Qualification Now

- Part 111.75 addresses supplier qualification covered by regulations describing optional use of supplier's CofA:
 - (A) You first qualify the supplier by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examinations;
 - (B) The certificate of analysis includes a description of the test or examination method(s) used, limits of the test or examinations, and actual results of the tests or examinations;
 - (C) You maintain documentation of how you qualified the supplier;
 - (D) You periodically re-confirm the supplier's certificate of analysis; and
 - (E) Your quality control personnel review and approve the documentation setting forth the basis for qualification (and re-qualification) of any supplier.



Interim Final Rule

- Interim Final Rule (IFR) for Exemption from identity testing
- Petition to FDA would include
 - Statistical verification testing plan proving standard of “no material diminution of assurance”;
 - Test results of some period of 100 percent testing (FDA assumed 1 year)
 - Ingredient/Supplier risk evaluation (can be done by 3rd party)
 - Suppliers need to show “quality management system (QMS) in place and that it has been independently audited (certified) by a third party.”
 - Supplier QMS “would, at a minimum, contain the following procedures:
 1. Monitoring of manufacturing processes to ensure they are producing quality product;
 2. Keeping proper records;
 3. Checking outgoing product for defects, with appropriate corrective action where necessary; and,
 4. Regularly reviewing individual processes and the quality system itself for effectiveness.”

Supplier Qualification Observations

- Assumption that suppliers know manufacturers' qualification processes
- Concerns with trade secret disclosure
- Demands for extra items on CofA
- Demands for certification by multiple certification programs
- On-site audits
- Use of contract labs

Supplier Qualification Observations

- Small suppliers develop systems to meet large manufacturer demands
 - Medium/Small manufacturers benefit from earlier implementation by large manufacturers
 - But, small suppliers less likely to adopt later demands from small/medium manufacturers
- E.g., Large manufacturer requiring certification by X, makes it less likely small manufacturer will later adopt Y certification
 - Supplier may be burdened with undesirable program

Actions for Current Situation

- SIDI
- 3rd party certifications
 - Educational
 - Enhances supplier credibility
 - Selection
 - Learn preference of current/desired customers
 - Understand differences/conflicts in current 3rd party certifications
 - Acknowledge some certifications are meaningless to certain manufacturers
 - Recognize expense, contradictions and redundancies of multiple certifications

Actions for Current Situation

- Supply/Quality Agreements
 - Tool spelling out parties' expectations
 - Encourages proactive understanding before issues arise
 - Avoid one-sided agreements
 - Negotiation helps manufacturer understand supplier's costs related with compliance
 - Recognize contractual liabilities

Actions for Current Situation

- Understand effect of FSEA and other pending food safety legislation
- Be active in expected revision of Food GMPs
 - Ensure Part 110/Part 111 will mesh
 - Remain active in trade associations

Actions for Current Situation

- Assist development of a supplier certification program
 - GFSI model
 - GFSI sets benchmarks and recognizes certification programs aligned with its guidelines
 - Certification programs create programs incorporating GFSI benchmarks (e.g., Safe Quality Food)
 - Tailored programs (ag products, processed foods, etc.)
 - Certification bodies carry out program by assessing auditor findings (e.g., NSF)
 - Accreditation of Certification bodies

Accredited Certification Program Benefits

- Avoids conflicts of interest
- Accreditation
 - Accountability
 - Auditor competency and consistency
 - Confidentiality requirements
- Certification body responsible for certification/decertification
- International application
- Can be coordinated with FDA

Supplier Qualification Vision

- **Supplier Certification Program**
 - Accepted by US manufacturers
 - Available to domestic and foreign suppliers
 - FDA Recognition
 - Accredited
- **SIDI**
- **CofA Verification**

Goal

- Industry should develop a program for supplier qualification to:
 - Help ensure safe products
 - Ensure consumer confidence
 - Comply with laws and regulations
 - Increase efficiency
 - Enhance relationships between manufacturers and suppliers
 - Assist small and large companies

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