



Supply Chain Verification Challenges and Realities

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Introductions

- **Lillian Hsu**, Microbiologist, FDA – CFSAN
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Supply-chain preventive controls

- Receiving facilities now have an obligation to verify that their suppliers are controlling hazards in raw materials or other ingredients prior to receipt of these foods
- Requirements found in Subpart G of the *Hazard Analysis and Risk-Based Preventive Controls for Human Food* regulation (21 CFR 117.405 – 117.475)
- FDA issued draft guidance on compliance with the Supply-Chain Program requirements in January 2018 – Chapter 15 of *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food*

Who is subject to Subpart G?

Subject:

- “Receiving Facilities” – a facility that manufactures/processes a raw material or other ingredient it receives from a “supplier”
- There is a hazard that requires a supply-chain-applied control
 - E.g. there is a hazard controlled before receipt of the raw material or other ingredient

Not subject

- Entities that do not meet the definition of a receiving facility (e.g. brokers, food distributors)

Components of the supply-chain program

- Use approved suppliers
- Determine, conduct, and document the conduct of appropriate supplier verification activities, including frequency with which to conduct them
- Maintain records demonstrating compliance

Supplier approval

Receiving facility must approve suppliers by considering:

- Hazard analysis
- Entity controlling the hazard
- Supplier performance:
 - Supplier's food safety procedures, processes, and practices
 - Applicable food safety regulations
 - Supplier's food safety history

Using approved suppliers

- Facilities must **establish and follow written procedures for receiving raw materials and other ingredients** to ensure that these are only received from approved suppliers
 - Or, when necessary, from unapproved suppliers on a temporary basis whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use

Supplier verification activities

- Onsite audit
 - Annual onsite audit is required when controlled hazard is likely to result in serious adverse health consequences or death to humans (SAHCODH hazard)
- Sampling and testing
- Review of food safety records
- Other activities as appropriate

Must document the determination of the appropriate supplier verification activities and the conduct of the verification activities

Supply-chain records

- Written supply-chain program
- For importers, compliance with FSVP requirements
- Supplier approval
- Written procedures for receiving raw materials and other ingredients from approved suppliers
- Documentation that written procedures are followed
- Determination of appropriate supplier verification activities
- Specified details of onsite audits
- Sampling and testing verification activities, including corrective actions taken when hazards are detected

Supply-chain records (cont'd)

- Review of supplier's food safety records
- Other appropriate supplier verification activities
- Documentation of any determination that verification other than onsite auditing is an adequate hazard control
- Required documents for alternative verification activities (written assurances)
- Actions taken with respect to supplier nonconformance
- Verification of a supply-chain-applied control by an entity other than the supplier, when applicable

Inspections: Two-tier approach

Tier 1 inspections:

- Assess adequacy of the written supply-chain programs and recall plans and compliance with all applicable requirements in part 117
- Will be pre-announced, focused Preventive Controls for Human Food (PCHF) inspections that are conducted preferably at a facility in close proximity to corporate headquarters
- Will be used to inform Tier 2 inspections

Tier 2 inspections:

- Will assess compliance with all applicable requirements in part 117 except for the adequacy of written supply-chain programs and recall plans that were reviewed during the Tier 1 inspection
- Will be unannounced and occur after a Tier 1 inspection

Strategies for Supplier Program

- Collaborate to create a system of protocols, systems, and tracking devices that will work for your organization
- Consider synergies across the organization – various facilities, food categories, uses
- Establish a global supply catalog
 - Include all suppliers, supplier sites, importers, importer sites
 - Make sure to identify the actual importers, not just the broker or parent company
 - Need to maintain documentation of all approved suppliers and document that ingredients received are from approved suppliers

Strategies for Supplier Program

- Document management system
 - Develop a system to organize all food safety documents and certificates you require from suppliers and importers
 - Keep documents in a central location, and add key documents you receive for each shipment:
 - Certificate of Analysis
 - Lab results
 - Safe handling documents
 - Consider utilizing specialized software to manage supplier documents and communications
 - Consider separating “inspection file” to be shared with FDA from other documents

Qualifying Suppliers

- **How should you qualify, monitor, review and potentially disqualify suppliers?**
- Overall approach
 - Establish written procedures for supplier approval
 - Develop a comprehensive schedule for on-site audits and other verification activities, and document all activities and results
 - Create a tracking system that alerts when a supplier has not timely fulfilled a requirement
 - Utilize your data to monitor supplier performance and measure effectiveness of your safety programs

Key Considerations re: Contract Manufacturers

- As needed: clearly assign responsibilities amongst contractual partners
- **Supplier Approval/Verification: FDA will not take enforcement action against a receiving facility that is a co-manufacturer, and that is not in compliance with 21 CFR 117.410(d) and 117.415(a)(3) until November 6, 2019** under the following circumstances:
 - (1) a brand owner conducts supplier approval/verification activities for the co-manufacturer,
 - (2) the co-manufacturer describes these activities in its food safety plan, and
 - (3) the co-manufacturer conducts any necessary supplier approval/verification activities not conducted by the brand owner

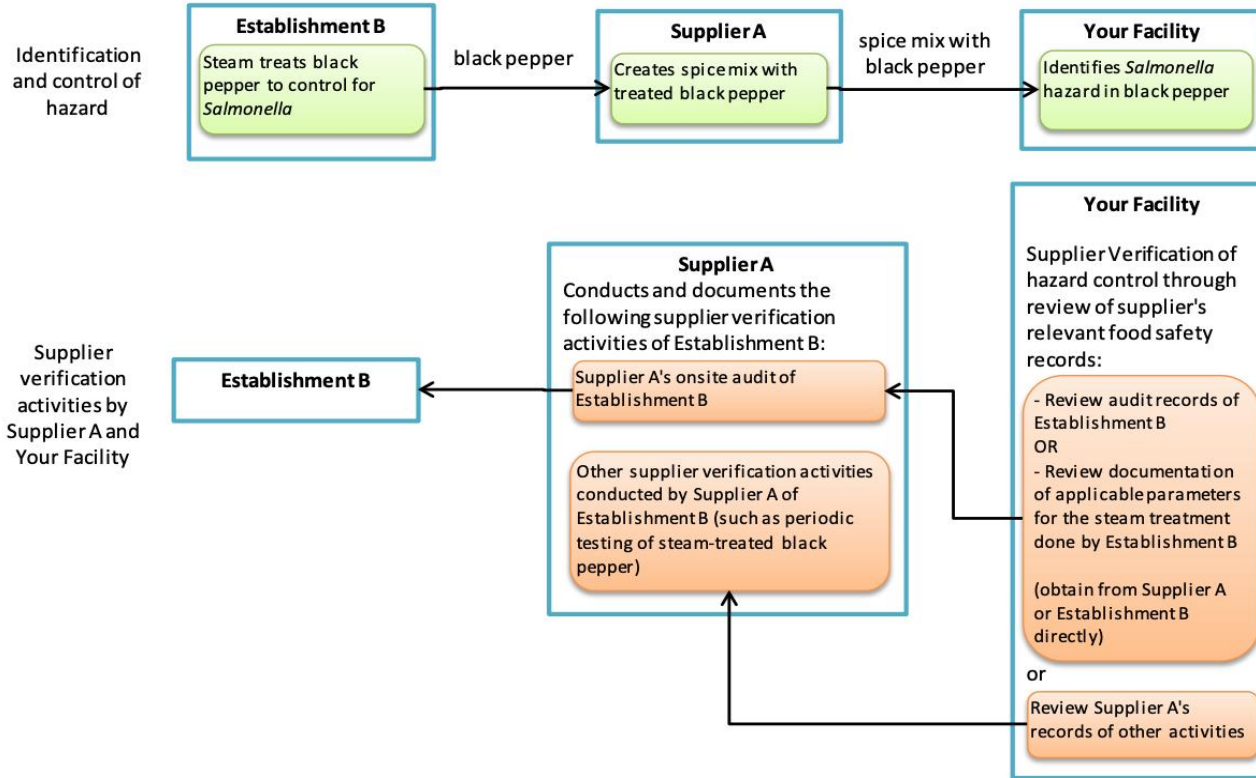
Managing Risk

- **What do you need in your supplier program and agreements to address both regulatory requirements and risk reduction and liability?**
 - Quality and product specification agreements
 - Continuing product guarantee
 - Representations and warranties of compliance with regulatory and supplier approval/qualification requirements
 - Inspection rights/ Access to records
 - Solid indemnification provisions - defense for allegations
 - Insurance coverage agreements

Why does supply-chain verification matter?

- Supply chain verification failures are **just as serious as processing failures** (which is why some of us elevate them to PCs). They too can lead to foodborne illness, death, and expensive litigation.
- The **goal** of supply chain verification is to ensure:
 - Every product is traceable back to its source
 - Ingredients, WIP, and finished products are safe as intended if no accidental or intentional adulteration
 - Food contact packaging is designed for its intended use
 - Ingredient or product handling, transportation, and processing maintain product quality and safety

In an ideal world...



But in reality, there is a lot to consider

- **Geographic location** (e.g., at higher risk of act of God; Yuma, AZ)
- **Sourcing practices** (e.g., abide by code of conduct, internal accountability built in to day to day SC mgmt, robust training for SC employees)
- **Inherent risk of raw material:** potential for (1) contamination with/survival of pathogenic microorganisms, and (2) subsequent growth and/or toxin production (moisture content, aW, pH, acidity, nutrient content, biological structure, redox potential, antimicrobials, competitive microflora)
- **Vulnerabilities/Mitigation strategies** (e.g. atmosphere, time/temperature, storage/holding conditions, processing steps, intended end-use, product history)
- **Compliance risk** (e.g., history of import alerts, bulletins, 483s, WLs)
- **Facility audit results** (e.g., internal/3P/regulatory body and history of critical findings and CAPAs)
- **Level of oversight** (e.g., conflict of interest in FSQA reporting structure, oversight by QI)
- **Exposure** (e.g., overall volume, type of consumer)
- **Interaction of *all* factors**

So how much is enough?

- When it comes to performance of supplier verification activities, you may want to weigh your ability to mitigate risk against the cost (people, time, money) associated with your verification activities.
- What are some things to consider when determining whether you've appropriately mitigated your risks?
 - Number of raw materials in your portfolio
 - Number of suppliers in your supply base
 - Length of the supply chain from you to your starting sources
 - Total volume of production
 - Primary v. secondary v. tertiary supply sources

Broad Challenges to Consider

- For each verification activity, **do what you say** and **say what you do!**
- The **resources required and costs** associated with supplier verification activities **increase** with each additional activity – process development time, system costs (hardware, software, printers), and training costs.
- Increased activity also often lends itself to increased risk of **human error**, which can create a multitude of challenges during an inspection or investigation.
- You must have an **effective way to communicate** with each supplier to gather and review required information and consider the need to **update all relevant information regularly**.

Specific Challenges:

Onsite Audits

- Conducting supplier audits can be a fulltime job, depending upon the size of your supply base.
- Requiring your supply base to undergo unannounced audits by reputable audit firms, using recognized food safety standards (e.g., GFSI, SQF) can be extremely costly for your suppliers.
- If relying on review of a 3P audit, your supplier may not provide the complete audit and recommended corrective actions.
 - Does that raise a red flag?
 - Do you need to verify the accuracy of the audit results or just the audit completion and score?

Specific Challenges: Raw Material Testing

- Often times, suppliers will validate their manufacturing process and move to skip lot testing of raw materials – what to do when this happens?
- What if your supplier does not conduct raw material testing at all?
- How do you determine what frequency of testing is appropriate and who absorbs any additional cost?
- Should you validate the appropriateness of the raw material testing conducted by the supplier, or will you rely on them as the subject matter expert?

Specific Challenges: Review of Food Safety Records

- Food Safety Plans are exhaustive and often proprietary so you may want to consider which aspects of the Plan are “must haves” and which aspects of the Plan are “like to haves”.
- A strong relationship with your suppliers can go a long way in helping you develop effective communication of pertinent information.
- While most suppliers prefer not to send electronic copies of their Food Safety Plan, many are amenable to sharing the Plan for review during an onsite audit.

Conclusion

- **Key Takeaways:**
 - Document, document, document!
 - The regulations require proactive management of safety risks, and contracts must provide the rights and tools for purchasers to manage those risks
 - Think BIG, utilize cross-functional team, and then develop a comprehensive plan.
 - Incorporate requirements into your contracts
 - Continue to evaluate and re-evaluate
- **Questions?**

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