Supplier Management Programs
The Risk Assessment

Presented by

Debby Newslow

D. L. Newslow & Associates, Inc.

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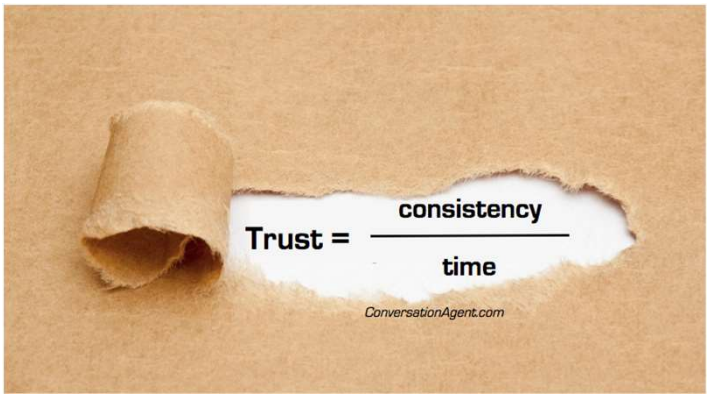
What role does your supplier play in your Food Safety Program?

I have heard (numerous times) that we can't control the supplier, so why do we need to bother with defining requirements? They have been in business a long time! They wouldn't be selling their products if they didn't know what they are doing.

We have to trust them – we just do!



Why should we be concerned?

- A hazard comes from two places
  - It is added during your process or
  - It is created and received from the supplier.
- Garbage in, garbage out!
- Let's think about a recent recall…

Critical Questions

- How are suppliers chosen and approved?
- What must be done to ensure that we are not receiving hazards from the suppliers?
- What requirements must be defined?
- Must we audit everyone?
- Do we treat all suppliers equally?
- How do we ensure that our program is effective?

Considering the Risk -- What is a "*Risk*"?

"*Risk* is a measure of the probability and consequence of uncertain future events. It is the chance of an undesirable outcome."

Considering the possibility of a hazard or an opportunity there are two components:

1. **Chance or probability**
2. **An undesirable outcome or consequence**

Risk = Probability x Consequence

Identifying the Problem

We tend to seek evidence that confirms our beliefs while devaluing what does not.

- ***We tend to see what we expect to see and do not see what we do not expect to see or want to see.***
- ***Our minds are very good at reconfiguring evidence to make it consistent with our expectations.***
- ***Risk* analysis t*akes into account the explanations that our minds may lead us to, but it also seeks a scientific explanation whether it conforms to our mind set or not.***

What is a *Risk* analysis?

- It separates what we know (scientific) from what we don't know (the uncertainty).
- Focuses on what we don't know and how that could affect the outcome.
- Uses what we do know to investigate and make a sound decision based on what we don't know.
- Focuses on properly defining the problem; If we don't accurately identify the problem then we won't be able to assess it.

Uncertainty **is the reason for doing a** ***Risk analysis.***

Severity or Impact

- The severity factor is a measure of the degree of consequences that are ***most likely*** to occur as associated with a ***risk*** issue.

- Consequences could be either
  - Negatively impact the business, its brand, and its stakeholders, or
  - Be the expected level of unrealized opportunity for gain that could be missed (opportunity cost).

What must we require from the source of our supplies?

- **A well-defined, compliant Food Safety/HACCP and quality program that provides structure and discipline in the production of a safe product that meets all quality specifications.**
- **Availability of records that demonstrate compliance to specified requirements.**
- **Evidence of positive *Management Commitment.***

How Do We Choose a Supplier?

- Ensure that supplier can meet your company needs.
- Define both product and service requirements.
- Preference is the presence of a sound and effective management systems (i.e., food safety, quality, etc.).
  - Is compliance confirmed through third party certification?
  - Review their management system structure, documents, etc. whenever possible.

What is the product or service supplied?

What is the risk?

GFSI Requirements

- Documented specifications
  - Prepared, securely stored, and readily accessible at the point of use.
  - For all items and services (including utilities, transport, and maintenance) purchased or provided that have an effect on product safety.
  - Raw Material Specifications (MSDS, Letters of Guaranty, Tech/Catalog Sheets, Product Label – e.g., EPA registration).

Have a documented supplier approval procedure and continual assessment program in place, based on risk assessment.

GFSI Requirements

- **Purchasing requirements must be defined.**
- **This must include a specification review process.**
  - ***Formally defined purchasing process that ensures that all externally-sourced items conform to requirements/specifications.***
- **Traceability**
  - ***Be prepared to trace back to the raw ingredient or material.***
  - ***Confirm effectiveness through Mock Recalls.***

Customer Required Suppliers

- **Who is ultimately responsible?**
- **Customer approved suppliers or customer pre-approved samples do not relieve the manufacturing site of the responsibility to make sure the item is in spec and free of hazards.**

An operation must ensure well-defined programs for incoming inspection and testing are in place and effective.

FDA Guidance

- **The FDA released a guidance document on the topic of supplier management for co-manufacturers, which can be downloaded from www.fda.gov.**
- **Companies have until November 6, 2019 to either get visibility to the work performed by the brand owner, or do the work themselves.**

Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry

Your Company is the Supplier

- **Ask yourselves…**

  Just because your company makes the item to be used in the finished product – does that magically make it ok?

- **Purchasing from another location does not absolve the manufacturer of the finished product of the responsibility to perform supplier evaluation, approval and verification activities.**

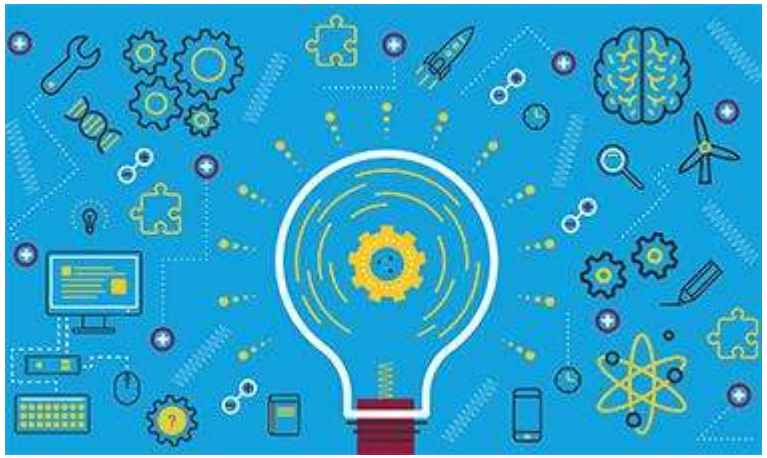
Trust but Verify

- How do we ensure that our suppliers are not sending us food safety hazards?
- Can due diligence be proven?
- Who do we blame (and does blame even matter)?
- We must be proactive!
- No longer is the answer “this is how we have always done it.”

Dr. Deming said that doing the best we can may not be good enough.

Engineering out the Hazard

- Control the hazard before it gets to the plant when possible.
- Buy raw and process in-house.
- Take responsibility for controlling the hazard yourself whenever possible.



Are All Suppliers Equal?

- Does every supplier have to be audited?
- To some extent, this is an internal question based on the product being supplied, but the FDA now has clearly defined expectations as well.
- It is recommended that the Food Safety/HACCP Team evaluate the risk of products being supplied and use this risk assessment to decide what is needed.
- For a SAHCODHA hazard, just getting a GFSI certificate is not enough to satisfy the FDA.

Supplier Evaluation and Approval

- **Choose suppliers that can meet your company needs for product and service requirements.**
- **Know your ingredient requirements, including any known food safety hazards and how these are normally controlled.**
- **Type and extent of control applied to a supplier is dependent on the effect of the purchased product on product safety, product parameters, and customer specifications.**

Know the risk of the product sourced!

SAHCODHA

- **Serious Adverse Health Consequences or Death to Humans or Animals**
- **How does this affect the requirements for supplier verification?**
- **The default verification activity will be Annual On-site Audit.**

Ingredient Requirements

- Specify sources of ingredients to be purchased.
- Are there known or reasonably foreseeable food safety hazards with the item, and if so how are these normally controlled?
- Country of origin
- Awareness of governmental agricultural residue regulations (MRLs)
- How does your supplier ensure that nonconforming material will not accidentally be shipped?

Supplier's Certificate of Analysis Data

- How is it confirmed that the information on the COA actually meets the specification?
- Who is responsible for confirming this?
- What records are maintained?
- Ensure validated methods are used and reported on the COA.

FSMA Definitions

- A “supplier” manufactures the food, grows the food or raises the animal
- A “receiving facility” is a manufacturer/processor
- A “customer” may or may not be subject to preventive controls regulation

FSMA Supplier Verification

Perform one or more of the following *before* using and then at a defined intervals thereafter:

- **On-site audit (default for SAHCODHA hazard)**
- **Sampling and testing**
  - **By the supplier or the receiving facility**
- **Review of supplier's food safety records for the ingredient**

Rating the Supplier

Recommend creating a program to rate a supplier's performance.

- **Provides a basis for comparison with other suppliers.**
- **May be used to identify potential issues with a supplier prior to a negative situation surfacing.**
- **May be used to gauge the amount of attention required for a specific supplier and also the degree required for a site inspection.**

The Risk Assessment vs. The Supplier's product

- Know your product and its ingredients
- Reference the FDA Guidance document Appendix 1 for identified hazards
- Research history & industry issues
- Discuss with supplier
- Know your source…
- Require records and confirmation
- Base decisions on FACT

Engineer out the Hazard

Common Findings

- As long as a credit was received, then the reason for the nonconformance or corrective action is not considered to be important.
- Defined frequency for evaluating suppliers not supported by records.
- Suppliers used in distant past (i.e., once three years ago and not since) are automatically approved without any recent update or evaluation.

Common Findings

- List of approval included only the company name and not the items the supplier was approved for.
- Statement that supplier provided product per the current specification but the current specification was not available.
- Suppliers are approved based on financial status with no quality evaluation.

Common Findings

- Supplies noted in the storage areas were not sourced from a listed approved supplier with no record or explanation available to explain.
- Organization's traceability program does not include traceability (i.e., lot numbers) back to the supplier.
- No evidence that an effective risk analysis either by the organization or the supplier had been performed.
- No program for management of services.

Thank you for your attention!

- **Questions?**
- **Comments?**
- **Concerns?**

Contact us at 407-290-2754

contact@newslow.com

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