SUPPLIER VERIFICATION
FOREIGN AND DOMESTIC

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Soterian Systems, LLC is an innovative food safety and quality management technical advising firm that provides clients with industry leading tools and training specifically designed to successfully build and maintain world class Food Safety Management Systems.

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Discuss an Effective Supplier Verification Program – Foreign and Domestic

Part 1: Interactive session around various product types and who controls the Hazard?

Part 2: Global case studies around general FSMA and GFSI Compliance; theoretical vs. actual compliance around requirements

Part 3: Solutions and examples to implementing an effective Supplier Program – Documents to request, based on RISK and GLOBAL REGION

Part 4: Managing quality standards and brand safety in the foodservice industry

Questions and Discussion
Interactive session around various product types and **who controls the Hazard?**
Part 1: Who is controlling the Hazard & Responsible for Supplier Verification?

PRODUCT: RTE - IQF STRAWBERRIES FROM CHILE

Finished Product Example: ‘RTE’ IQF Strawberries from Chile (intended for Retail)

Identified Hazard: *Listeria monocytogenes (LM)*

Who is controlling the Hazard? IQF Strawberry Processor in Chile (Processor controls pesticide/heavy metal hazards with Grower)

Applied Regulatory Rules:
1. PC for Human Food - 21 CFR Part 117 (Processor) (domestic and foods offered for USA Import)
2. FSVP – 21 CFR Part 1, 11, 111 (Importer)

Who is responsible for Approving and Monitoring Supplier?
FSVP Importer of Record (Qualified Individual)
Part 1: Who is controlling the Hazard & Responsible for Supplier Verification? (cont.)

PRODUCT: RAW BROWN RICE FLOUR FROM THAILAND

Finished Product Example: Bulk, Raw Brown Rice Flour from Thailand for USA Bakeries

Identified Hazard: Salmonella spp., Aflatoxins, Fumonisins

Who is controlling the Hazard? 1. USA Bakeries (for Salmonella) & 2. Thailand Processor (for Aflatoxins and Fumonisins)

Applied Regulatory Rules:
1. PC for Human Food - 21 CFR Part 117 (Processor) (domestic and foods offered for USA Import)
2. FSVP – 21 CFR Part 1, 11, 111 (Importer)

Who is responsible for Approving and Monitoring Supplier?
1. FSVP Importer of Record (Qualified Individual) for Chemical Hazards and...
2. USA PCQI since the Receiving Facility ‘controls the hazard’ through baking
Part 1: Who is controlling the Hazard & Responsible for Supplier Verification? (cont.)

PRODUCT: WASHED & BAGGED SPINACH FROM MEXICO

Finished Product Example: Washed & Bagged Spinach from Mexico (RTE)

Identified Hazard: Salmonella spp., EHEC, Listeria monocytogenes

Who is controlling the Hazard? Mexico Processor

Applied Regulatory Rules:
1. PC for Human Food - 21 CFR Part 117 (Processor) (domestic and foods offered for USA Import)
2. FSVP – 21 CFR Part 1, 11, 111 (Importer)

Who is responsible for Approving and Monitoring Supplier?
FSVP Importer of Record (Qualified Individual)
PART 1: WHO IS CONTROLLING THE HAZARD & RESPONSIBLE FOR SUPPLIER VERIFICATION? (CONT.)

PRODUCT: CANNED BABY CORN FROM VIETNAM

Finished Product Example: Canned Baby Corn from Vietnam

Identified Hazard: *Clostridium botulinum*, Pesticides & Heavy Metals

Who is controlling the Hazard? Vietnam Factory & Vietnam Growers

Applied Regulatory Rules:

1. PC for Human Food - 21 CFR Part 117 (Processor) (for chemical, radiological, physical & EMH only)
2. LACF – 21 CFR Part 113 for microbiological hazards only (Processor)
3. FSVP – 21 CFR Part 1, 11, 111 (Importer)

Who is responsible for Approving and Monitoring Supplier?

FSVP Importer of Record (Qualified Individual)
PART 2

Global case studies around general FSMA and GFSI Compliance; theoretical vs. actual compliance around requirements
GLOBAL CASE STUDIES

Some personal input after traveling globally for 20 years conducting 2nd party & customer audits and consulting with foreign factories...

Tips to enhance your Supplier Management Assurance...

1. Focus on obtaining Verification Documentation = Type of Hazard the Supplier is controlling (documents must match the type of hazard needing controls)

2. Do not just rely on the 3rd party audit to ‘show the supplier is controlling the hazard’

3. I do not TRUST and VERIFY….I JUST VERIFY...here is why...
The following foreign factory examples all had GFSI 3rd party Audits with very high ratings for multiple years.

They had written HACCP Plans that were mostly ‘generic’ (maybe internet downloads) and did not address specific hazards to their product type, i.e. *Listeria monocytogenes* for frozen fruit / environmental pathogen controls, etc.

Depending on country…most DID NOT USE SOAP/DETERGENT to CLEAN (remove soils) before sanitizing, some had multiple allergens using shared equipment…only chlorine was used in most factories.

Audit scores and corrective actions did not address any of the egregious violations of major audit points…*why and how did they not get violations on their GFSI Audits?*
GLOBAL CASE STUDIES
Products: High Risk RTE Frozen Fruit

Poor personnel practices and unapproved utensils, no sleeve guards on RTE food

Washing food contact crates outside in filth with NO detergent, and comingling clean and dirty movable equipment; cannot determine clean vs. dirty

Common Background Between Facilities & Countries:
1. Already exporting to USA and other countries
2. Finished Product in pics are High Risk and no true lethality steps to control vegetative/environmental pathogens
3. GFSI Certified facilities for 4+ years in a row
4. Factories look perfect on paper, but completely fail when onsite audit conducted by 2nd party
5. Currently operates under Codex HACCP

No Master Sanitation Schedule and cleaning/sanitizing of non-food contact surfaces (no evidence, ever)
Global Case Studies
More evidence of violations in foreign factories

RTE High Risk processing using no ‘soap’ on equipment...massive build up of soils, allergens & pathogen biofilms

Active conveyor belt with IQF berries running on the line...slime and other build up of unknown substances, biofilms, etc.
Global Case Studies
More evidence of violations in foreign factories

Lack of Zone #2 cleaning/sanitizing creating biofilms which could cross-contaminate environmental pathogens on to food contact surfaces
Did the suppliers control foreseeable hazards using basic Pre-requisite Programs?

- Their Food Safety/HACCP Plans and audits were perfect on paper
  1. Environmental Pathogens
  2. Allergen Controls
  3. Pathogens potentially from personnel and handling RTE high risk products
  4. Building and Sanitary Design

NO! Supplier is NOT controlling the Hazards
WHY ARE WE SEEING WIDE-SPREAD VIOLATIONS WITH GOOD INITIAL DOCUMENTATION?

Not sure exactly... could be a number of factors that create the larger problem

• In-country auditors being bribed and it’s accepted culturally
• Attitude from top management may create fear for the auditors
• Auditors are avoiding conflict and fail to formally document major violations (cultural hierarchy may create the issue of not speaking up)
• Suppliers are brushing off the serious issues and persuading the auditor that it will be fixed right away (with no real corrective actions, just fluff)
• Flat-out disconnection between adequate food safety & sanitation principles combined with very limited resources and training in-country
Solutions and examples to implementing an effective Supplier Program – Documents to request, based on RISK and GLOBAL REGION
What Documents Should I Ask For?

In addition to the 3rd party audits, etc., ask for additional verification documentation to control specific hazards:

1. Master Sanitation Schedules & SSOPs
2. Environmental Monitoring Program and Results
3. Pre-ops and Protein/ATP Swabbing
4. Employee Training
5. Preventative Maintenance Program
6. Validated ‘Kill Step’ Studies
7. Pesticide Records
8. Allergen Swabs and Trends
In addition to 3rd Party Audit and HACCP/Food Safety Plan...

Could be more, these are just some suggestions

<table>
<thead>
<tr>
<th>IQF STRAWBERRIES FINISHED PRODUCT</th>
<th>RAW FLOUR FOR USA BAKERIES (wheat, rice/soy)</th>
<th>RTE BAGGED LETTUCE FOREIGN FACTORY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hazard</strong></td>
<td><strong>Documentation</strong></td>
<td><strong>Hazard</strong></td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>1. Master Sanitation Schedule and Pre-op Inspection Results</td>
<td><em>Salmonella spp.</em></td>
</tr>
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<td></td>
<td>4. Swabbing Protocols and Trends</td>
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# Ongoing Verification Plan (Example)...

<table>
<thead>
<tr>
<th>Hazard or Program to Control Hazards</th>
<th>Verification Documentation</th>
<th>Frequency Required (during probationary period; 2 years)</th>
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</table>
| **Vegetative Pathogens** (no true kill step) | 1. Employee Training Documentation for Handling RTE Foods  
2. Produce Wash Concentration Summaries and Trends | 1. Every 6 Months  
2. Every Quarter |
| **Environmental Pathogens** (RTE Product) | 1. Master Sanitation Schedule including all zones  
2. Pre-operational inspections with Zone # 1 Swabbing Trending  
3. SSOP’s including all zones and areas in the facility (not just FCS)  
4. Environmental Monitoring Program SOP and Trending Reports | 1. Every 6 Months  
2. Every 6 Months  
3. Every 6 Months  
4. Every Quarter |
| **Allergen Controls** (unique allergens in facility) | 1. Master Sanitation Schedule addressing allergen changeovers  
2. SSOP’s addressing allergen removal  
3. Changeover Records and Trends; including Swab results  
4. Label Review Records Summary | 1. Every 6 Months  
2. Every 6 Months  
3. Every Quarter  
4. Every 6 Months |
| **Sanitary Design and PM Programs** | 1. Onsite Audit every 2 years  
2. PM Program SOP with areas and frequency assigned  
3. PM Program Records | 1. Every 2 years  
2. Every 6 Months  
3. Every 6 Months |
PART 4

Managing Suppliers Verification, Standards and Brand Safety in the Foodservice Industry
Foodservice Industry

- $799 Billion Annual Sales
- More than 1 Million Locations
- $48% of the Food Dollar
- $300 Billion + In Purchases
- 1 eating establishment for every 325 people
- 14.7 million employees
Food Quality and Brand Safety Issues on the Industry

Changes in our food production and Supply
Including More Imported Foods

New and Emerging Bacteria, Toxins
and Antibiotic Resistance

Changes In The Environment
Leading To Food Contamination

More Local Foods

Changes In Consumer Preferences And Habits

Social Media
Objective

Source raw materials from suppliers that provide a consistent quality product that is safe.
Integrating Supplier Quality and Food Safety into the Supply Chain System

- Organization, People & Skillsets
- Strategic Sourcing
- Technology - SCM Management System
- System Margin & Risk Management
- Strategic Distribution System
- Transportation Management
- Brand Quality & Safety
- Forecast & Promotional Management
Foodservice Supply Chain System

Every Link In The Supply Chain Is Considered A Supply Point

Effective supplier verification programs for international and domestic suppliers are imperative to ensure safe food sourcing and brand protection throughout the system.
Total Food Safety and Food Quality System (End to End)

P = Product and Protection
I = Identify and Isolate
R = Resolve and Restore
C = Communicate and Conclude
Total Quality and Food Safety System

P = Product and Protection

Supply Optimization

- Supplier, plant and reputation
- Supplier agreements & documentation
- Specifications/clearly defined /signed
- Product verification and origin source
- Food supplier verification program (FSVP)
- Raw material/ingredient inspection
- Good manufacturing practices
- Risk based prevention-HAACP/Six Sigma
- 3rd party verification
- Technology – portal for data capture
- Traceability
- Temperature monitoring
- Supplier monitoring & reporting
- Corrective action for continuous system improvement
- Visibility to supplier data verifying product meets specifications prior to shipment
- Rapid crisis response system

Logistics/Inventory Optimization

- Traceability
- Recall capability
- 3rd Party inspection and verification
- Supplier/distributor reporting/portal
- Temperature monitoring
- Good handling practices
- Corrective action for continuous system improvement
- Rapid crisis response system

Restaurant Supply Optimization

- Incident reporting management
- Risk based preventive controls
- Training
- Audits aligned to FDA Food Code
- Critical control points
- Capture Health Dept. results
- Traceability
- 3rd party verification
- Rapid crisis response system
Total Quality and Food Safety System

P = Product and Protection

- Continuous Evaluation and Monitoring
- Corrective action for continuous improvement
Total Quality and Food Safety System

I = Identify and Isolate

Any Breakdown In Any Part Of The Supply Chain System Can Be A Potential Quality or Brand Safety Issue
Technology Is An Enabler For Quality and Brand Safety Integration Into The Supply Chain
Total Quality and Food Safety System

R = Resolve and Restore
Total Quality and Food Safety System

C = Communicate and Conclude

Restore Confidence Back in the System
Total Food Safety And Food Quality System (PIRC)

(P) Product & Protection
(only 90% assurance)
(Specifications, dirt to door, HACCP, Six Sigma)

Raw Materials → Manufacturing Plant → Production Forward Warehouse → Distribution Center → Restaurant

Data integration of QA, purchasing, vendors, employees, guests, health depts., etc., measurements

Continuous system improvement
System assessment and correction

(I) Identification & Isolation
Quick identification of problem type, size, people impacted, health risk & implications, location (X), ...

Accurate and rapid problem identification
(Benchmarks for problem identification)

(R) Resolution & Restore
Recall, quarantine, destroy store/plant, area closure, ...

Quick and appropriate reaction
System assessment and correction

(C) Communication & Conclude
Communicate to customers, employees, franchisees, analysts, media, suppliers, health departments, ...

Maintain Brand credibility/system confidence
Ten Rules to Insure Food Quality and Food Safety

1. Know your high risk products and risk based critical control points
2. Insure your specifications are comprehensive and current
3. Never assume where your ingredients are coming from and that they are properly inspected and meet your specifications
4. Whoever receives it is responsible for it
5. Make sure your third party inspection services are trained to evaluate what you want
6. Get your people on the ground (inspect the plants and inspectors)
7. Have your suppliers send you timely reports on production and tests (continuous checks/improvement)
8. Pull random product samples and provide feedback to the supplier
9. Technology is the enabler for managing all of this data and information (manage exceptions)
10. Develop a quality/food safety crisis plan and practice it with your system and the supply chain
Trust But Verify