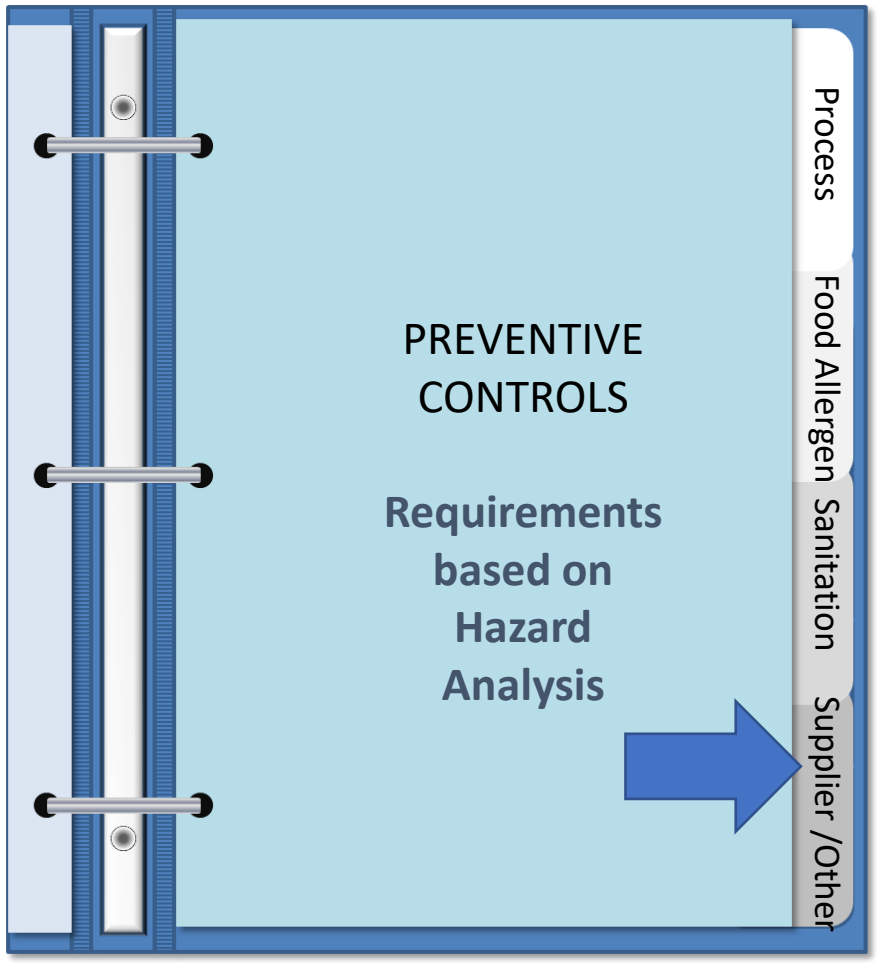
Supply Chain Preventive Controls

Supplier Preventive Controls Objective

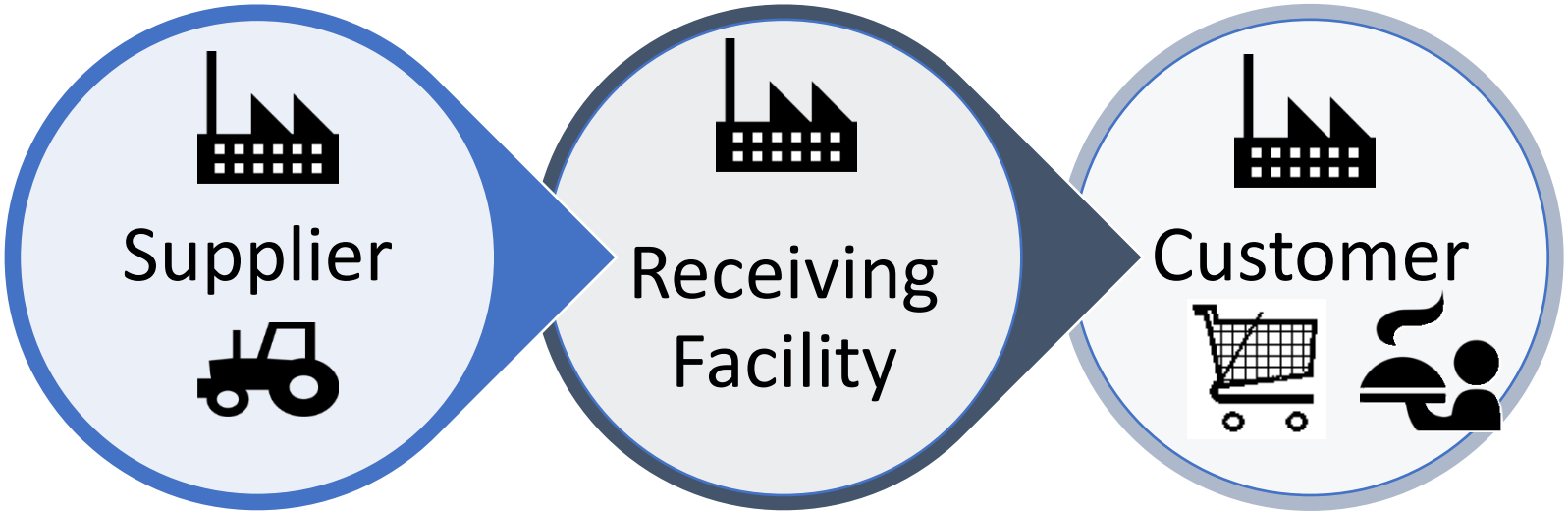
- That supply-chain preventive controls are linked to the hazard analysis
- Definitions of supplier, receiving facility and customer
- Supply-chain program contents
- Supply-chain program records



Link to Hazard Analysis

- The hazard analysis identifies hazards requiring a supply-chain-applied control
- An ingredient may not have a hazard requiring a preventive control; e.g., vinegar
- A hazard requiring a preventive control that is associated with an ingredient or raw material may not require a supply-chain program; e.g.,
  - Pathogens that will receive a validated kill step in your facility

Who Controls The Hazard?



- Manufacturer, processor
- Raise the animal
- Grow the food

- Manufacturer, processor

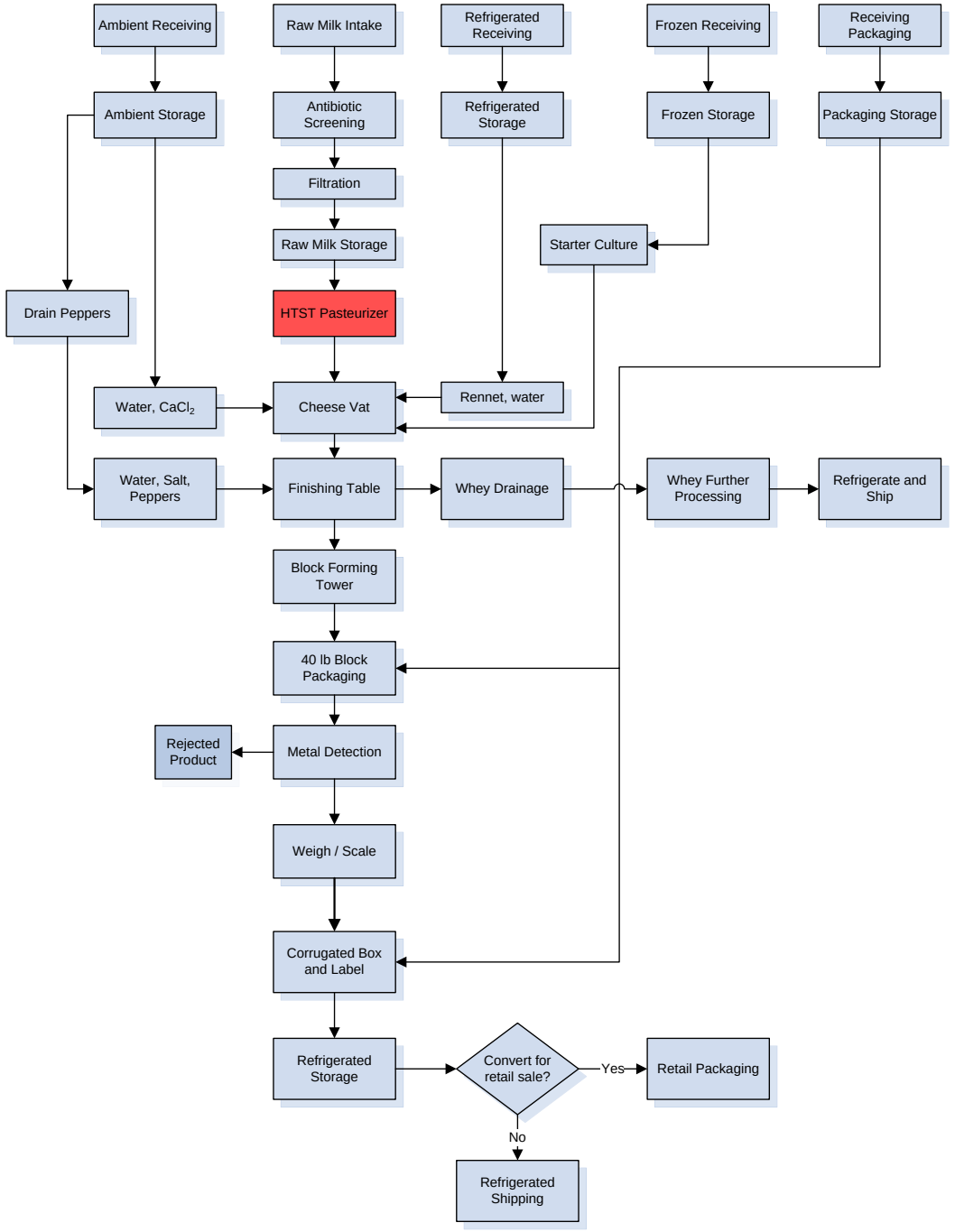
- Manufacturer, processor or preparer

Supply-chain Program **Not** Required:

1. When no hazards requiring a supply-chain-applied control exist

   OR
2. When you (the receiving facility) control the hazard OR
3. When a Customer or downstream entity provides written assurance that they control the hazard

Model Review: Pepper Jack Cheese



Using Approved Suppliers

- Applies to hazards requiring a supply-chain-applied control
- Approval required *before* receiving the ingredient
  - Temporary exception may be possible with justification
- Written procedures for receiving
- Receiving records required

Appropriate Supplier Verification Activities

Conduct one or more of the following verification activities *before* using and periodically thereafter:

- Onsite audit
- Sampling and testing
  - By the supplier or the receiving facility
- Review supplier's food safety records for the ingredient
- Other if applicable

Onsite Audit Requirements

- For serious hazards requiring a supply-chain-applied control
  - Documented onsite audit *before* using the raw material
  - *At least annually* after the initial audit
- Exception
  - You document that other verification activities or less frequent auditing provides adequate assurance

Onsite Audits – Who and What

- Must use a qualified auditor
  - Lab testing → by the supplier (COA) or by the buyer
  - Third party audit
  - Second party audit
  - Broker
- Review supplier's written HACCP or other Food Safety Plan and implementation documents for hazard identified in your hazard analysis

Other Verification Activities

- Records reviews
- Requesting certificates of conformance
- Requesting continuing guarantees

Actions Taken for Non-conformance

- Non-conformance actions focus on:
  - Identification of the issue
  - Steps taken to mitigate the effects of the issue
  - Steps taken to correct the issue
  - Identification of the root cause of the issue
  - Steps taken to modify the system to prevent reoccurrence
- Document all root cause and corrective actions
  - Ensure that corrective actions are implemented
- Records of actions taken for non-conformance are **required**

Supply-chain Program Documentation

- Written supply-chain program
- For import facilities, FSVP compliance documents
- Documentation of supplier approval
- Receiving procedures
- Receiving records
- Determination of appropriate supplier verification activities

Onsite Audit Documentation

- Must include
  - Supplier name and location
  - Audit procedures
  - Audit dates
  - Audit conclusions
  - Corrective actions taken in response to significant deficiencies identified
  - Documentation that the audit was conducted by a qualified auditor

Sampling and Testing Documentation

- Must include:
  - Identification of the raw material or other ingredient, including lot number, as appropriate, and number of samples tested
  - Test(s) conducted, including analytical method used
  - Date the test was conducted and date of the report
  - Results of the test
  - Corrective actions taken in response to detection of hazards
  - Identifying the laboratory conducting the test

Written Supply Chain Program

Supply Chain Program	
Ingredient requiring supplier-applied control	
Hazard	
Name of supplier Supplier approval?	
Receiving procedures	
Receiving records	
Supplier verification activities	
Verification records	
Non-conformance actions	

Supply-chain-applied Preventive Controls Program

The following suppliers provide ingredients or raw materials requiring a supply-chain-applied control because we do not have an effective control in our facility. Each of these approved suppliers is evaluated through an on-site third party audit conducted by a qualified auditor. Additional verification activities are also conducted as noted below. The supplier approval process is documented in SOP 16-321.

<table>
<tr><td>Raw Material or Ingredient</td><td colspan="2">Almonds</td><td>Crisped Rice</td></tr>
<tr><td>Approved Supplier and location</td><td colspan="2">B.I.G. Almond Company, Nuttown, USA</td><td>A. Cereal Company, Grainbelt, USA</td></tr>
<tr><td>Approval Date</td><td colspan="2">10/08/2010</td><td>9/9/2009</td></tr>
<tr><td>Hazard requiring a Supply-chain-applied Control</td><td>Salmonella</td><td>Aflatoxin</td><td>Salmonella</td></tr>
<tr><td>Preventive Controls Applied by the Supplier</td><td>Propylene oxide treatment required for California almonds in North America achieves a minimum 4-log reduction of Salmonella</td><td>Sorting to remove moldy nuts that may contain aflatoxin</td><td>The crisping process provides sufficient heat to kill Salmonella. Zoning and dry cleaning used to prevent recontamination.</td></tr>
<tr><td>Type(s) of Supplier Verification</td><td colspan="2">3rd party audit of approved supplier and quarterly certificates of analysis (COA)</td><td>3rd party audit of approved supplier</td></tr>
<tr><td rowspan="4">Verification Procedure(s)</td><td colspan="3">A copy of a 3rd party audit is requested from the supplier annually. The audit date, auditor qualifications, audit procedures and audit results are reviewed by our Quality Assurance Manager. Follow up with the supplier takes place, as necessary, to verify that any corrective actions mentioned in the report have been completed, with records maintained for this activity.</td></tr>
<tr><td colspan="3">For each shipment received, the incoming goods technician verifies that the material is from the approved supplier location using the Bill of Lading, documents the check in the incoming goods log and files the Bill of Lading.</td></tr>
<tr><td colspan="2">Certificates of Analysis
The incoming goods technician:
• visually checks the COA for compliance with specification (see below),
• documents the check in the incoming goods log and
• files the COA with supplier records.
If the COA is not provided in the required timeframe, the lot is put on hold and a COA is requested.
The lot is rejected if no COA is provided for the lot.</td><td rowspan="2">NA</td></tr>
<tr><td>Salmonella not detected in 5 × 25g samples per lot</td><td>Aflatoxin < 10 ppm for lots received</td></tr>
<tr><td>Records
– ingredient or hazard specific</td><td>Quarterly COAs
Salmonella</td><td>Quarterly COAs for aflatoxin</td><td>See list below</td></tr>
<tr><td>– required for all</td><td colspan="3">• A copy of the audit report and verification of corrective actions taken by the supplier maintained on file by the Quality Assurance Manager
• Incoming Goods Log
• Bill of Lading verifying each shipment came from an approved supplier
• Corrective action records</td></tr>
</table>

Supply-Chain Preventive Controls Program – Diced Peppers

Determination of Verification Procedures

Hazards requiring a supply-chain-applied control: Hazard analysis determined that potential for pathogens to be present in diced peppers in brine requires a supply-chain preventive control for peppers. Our process does not provide a kill step for any pathogens that may be present on the peppers.

Preventive controls applied by the supplier: The approved supplier utilizes a validated blanching/brining process that kills vegetative pathogens [Listeria and E. coli].

Verification activities:

- A 3rd party audit is conducted annually including traceability study
- Quarterly testing of product received
- COA for each lot received and reviewed

Verification procedures:

- Review the 3rd party audit results
- Review the quarterly test results

Records:

- Specifications Sheet
- Supplier Letter of Guarantee
- Copy of 3rd party audit
- Quarterly testing results
- Validation study for blanching/brining process

Approved Suppliers for Ingredients Requiring a Supply-chain-applied Control

Ingredient (requiring supply-chain-applied control)	**Approved Supplier**	**Hazard(s) requiring supply-chain-applied control**	**Date of Approval**	**Verification method**	**Verification records**
Peppers	One	Biological - Vegetative pathogens [Listeria and E. coli]	3/15/16	Annual 3rd party of supplier's facility Receipt of COA with each shipment matched with lot number received	Copy of 3rd party audit. Supplier validation studies for blanching/brining to control Listeria and E. coli COA

Receiving Procedure for Ingredients Requiring a Supply-chain-applied Control

For each shipment received, the receiving department:

- verifies that the product is from the approved supplier
- matches COA and lot number for the incoming goods log

Build: Supply Chain Preventive Controls