Selected Sections of a Food Safety Plan

Teaching Example

Food Safety Plan
for
Pepper Jack Cheese

Prepared by: ___________________________ Preventive Controls Qualified Individual

Date: ________________

Approved by: ___________________________ Owner, Operator, or Agent in Charge

Date: ________________

This model plan was developed by a group of industry and academic subject matter experts assembled by the Wisconsin Milk Marketing Board, who developed this Food Safety Plan Teaching Example from the template developed for the FSPCA Preventive Controls for Human Food curriculum.

The information in this example is for training purposes only and does not represent any specific operation. Many processing steps were omitted or combined to facilitate its use for class exercises. **It is not complete and contains both required and optional information.** Because development of a Food Safety Plan is site specific, it is highly unlikely that this plan can be used in a specific facility without significant modification. Conditions and specifications used (e.g., validation information) are for illustrative purposes only and may not represent actual process conditions.

**There is no standardized or mandated format for a Food Safety Plan,** but the information should be arranged in a progressive manner that clearly explains the thought process for the hazard analysis and the individual steps in the Food Safety Plan. Forms used for process preventive controls may be adapted for other types of preventive controls, but other formats are entirely acceptable if it works for your organization and contains all of the required information.
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Company Overview
This cheese company manufactures and converts pepper flavored Monterey Jack cheese. The cheese plant operates 5 days a week, pasteurizer operates 12 hours per day, making 14 vats of cheese with an additional 4 – 6 hours for sanitation. Company follows all current Good Manufacturing Practices [cGMPs] plus a dedicated uniform and shoe policy. Company has a robust environmental monitoring program including hygienic zoning. An integrated pest control program is also in place.

The company has been in business since 1953 and moved into its current 50,000 sq. ft. building in 1989. There are 30 full and part-time employees.

The Food Safety Team members include:
- Director, Quality Assurance [company PCQI]
- Operations Manager [PCQI back up]
- Head cheesemaker
- VP, Sales and Marketing
- Maintenance Manager

Product Description

<table>
<thead>
<tr>
<th>Product Name(s)</th>
<th>Pepper Jack Cheese</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Description, including Important Food Safety Characteristics</strong></td>
<td>Pepper Jack cheese is a pasteurized semi-soft natural cheese with added peppers. Product’s pH (5.0 – 5.4), competitive inhibition from the cheese starter culture, enzymatic activity and salt during the short aging process has the potential to reduce or eliminate pathogens over time. Diced peppers in brine drained prior to addition after pasteurization.</td>
</tr>
<tr>
<td><strong>Ingredients</strong></td>
<td>Pasteurized milk, peppers, salt, cultures, enzymes, calcium chloride.</td>
</tr>
<tr>
<td><strong>Packaging Used</strong></td>
<td>40 # block final package is high density polypropylene bag shrink-wrapped and heat sealed. 1 # retail chunk package is high density polypropylene bag vacuum packed and heat sealed with the label applied prior to case packing in corrugated box.</td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>Initially stored as 40 # blocks in film-lined corrugated boxes for short aging period in company coolers. Distributed using refrigerated trucks (35 °F – 45 °F) to conversion facilities for further processing and sale to retail stores and foodservice distributors. 1 # retail chunk is sold at cheese plant retail store as well as local retail stores.</td>
</tr>
<tr>
<td><strong>Intended Consumers</strong></td>
<td>Ready to eat product for industry and consumers.</td>
</tr>
<tr>
<td><strong>Shelf Life</strong></td>
<td>180 days at 35 °F – 45 °F.</td>
</tr>
<tr>
<td><strong>Labeling Instructions</strong></td>
<td>40 # block case: Cheese name, Plant number, Vat number, Manufacture Date and Block weight. Retail label: Cheese name, Keep refrigerated; Best used by date Retail label allergen statement: Contains: milk</td>
</tr>
<tr>
<td><strong>Storage and Distribution</strong></td>
<td>Refrigerated storage and retail and foodservice distribution.</td>
</tr>
</tbody>
</table>
Flow Diagram – Cheese Make

Ambient Receiving

- Ambient Storage
  - Refrigerated Receiving
    - Frozen Receiving
      - Packaging Storage
  - Raw Milk Intake
    - Antibiotic Screening
      - Filtration
        - Raw Milk Storage
      - HTST Pasteurizer
        - Cheese Vat
          - Rennet
            - Whey Drainage
              - Whey Further Processing
                - Refrigerate and Ship
            - Finishing Table
              - Block Forming Tower
                - 40 lb Block Packaging
                  - Rejected Product
                    - Metal Detection
                      - Weigh / Scale
                        - Corrugated Box and Label
                          - Refrigerated Storage
                            - Convert for retail sale?
                              - Yes
                                - Retail Packaging
                              - No
                                - Refrigerated Shipping
          - Water
            - CaCl₂
              - Salt, Peppers
                - Drain Peppers
                  - Filtration
                    - Whey Drainage
                      - Whey Further Processing
                        - Refrigerate and Ship
                      - Finishing Table
                        - Block Forming Tower
                          - 40 lb Block Packaging
                            - Rejected Product
                              - Metal Detection
                                - Weigh / Scale
                                  - Corrugated Box and Label
                                    - Refrigerated Storage
                                      - Convert for retail sale?
                                        - Yes
                                          - Retail Packaging
                                        - No
                                          - Refrigerated Shipping
                          - Filtration
                            - Whey Drainage
                              - Whey Further Processing
                                - Refrigerate and Ship
                              - Finishing Table
                                - Block Forming Tower
                                  - 40 lb Block Packaging
                                    - Rejected Product
                                      - Metal Detection
                                        - Weigh / Scale
                                          - Corrugated Box and Label
                                            - Refrigerated Storage
                                              - Convert for retail sale?
                                                - Yes
                                                  - Retail Packaging
                                                - No
                                                  - Refrigerated Shipping
Bacterial Screening

Antibiotic Screening

Cheese Vat

40 lb Block Packaging

Rejected Product

Metal Detection

Weigh / Scale

Corrugated Box and Label

Refrigerated Storage

Convert for retail sale?

Yes

Retail Packaging

No

Refrigerated Shipping

Food Safety Plan Teaching Example
For Exercise After Chapter 6: Preliminary Steps in Developing a Food Safety Plan
Flow Diagram – Retail Packaging

1. Refrigerated Storage – 40 lb cheese blocks
2. Debox, unwrap and inspect
3. Cheese Trim
4. Cheese Cutting
5. Cheese Packaging
6. Weigh and Label
7. Metal Detection
8. Rejected Product
9. Case and Label
10. Refrigerated Storage
11. Refrigerated Shipping

Food Safety Plan Teaching Example
For Exercise After Chapter 6: Preliminary Steps in Developing a Food Safety Plan
Process Narrative

Receiving Ingredients and Packaging:
Ingredients and packaging materials are purchased from approved suppliers with validated and verified food safety programs that meet approved product specifications, received following written SOP's [including COA's where specified] and stored appropriately according to manufacturers’ requirements. All incoming ingredients and packaging include lot numbers for traceability.

- **Receiving packaging:**
  - Cryovac 40 # block bags: blue bags with specifications for product contact use
  - Cryovac 1 # chunk bags: clear with specifications for product contact use
  - Labels are reviewed for conformance with approved label specifications
  - Corrugated boxes: received in bulk and meets specification

- **Receiving ambient [shelf stable] ingredients:**
  - Salt: received in 2000 # tote
  - Calcium chloride: received in 55 gallon drums
  - Diced peppers in brine: received in 380 # drums

- **Raw milk intake:**
  - Raw milk: received following PMO procedures at temperature ≤ 45 °F, tested for antibiotics prior to unloading in the receiving bay and filtered prior to transfer to milk silo

- **Receiving refrigerated ingredients:**
  - Rennet: received at ≤ 41 °F in 5 gallon cubes

- **Receiving frozen ingredients:**
  - Dairy cultures: received at minimum – 70 °F

Storing Ingredients and Packaging:
- **Packaging storage:** labels, cryovac bags and corrugated boxes are stored in the dry storage room at ambient temperature in the dedicated packaging area of the warehouse.
- **Ambient storage:** Salt, calcium chloride and peppers are stored in the dry storage room at ambient temperature in the ingredient area, arranged by ingredient code number. All containers are sealed to avoid cross-contamination during storage. Ingredients are used on a First-In-First-Out [FIFO] basis.
- **Refrigerated raw milk storage:** Raw milk is stored in silos at ≤ 45 °F until used but no longer that 36 hours. Receiving bay and silos are segregated from rest of plant.
- **Refrigerated ingredients storage:** Rennet is stored in sealed containers to avoid cross-contamination in a cooler that is kept at ≤ 45 °F and used on a FIFO basis.
- **Frozen ingredients storage:** Frozen cultures are stored in a freezer at minimum – 70 °F and utilized on a rotational basis for bacteriophage control as well as on a FIFO basis

Cheese Make Process:
Cheese making follows standardized make process for Pepper Jack cheese that details ingredient usage rates, times and temperatures of various process steps and product pH at each step.

- **Cheese vat:**
  - Milk is pasteurized at minimum 161 °F for 15 seconds prior to addition to the vat
  - Frozen culture, calcium chloride [with water dilution] and rennet [with water dilution] added after pasteurization
  - Vat cut, cooked and curd/whey transferred to Finishing Table
• Finishing table:
  o Whey drained from curd, cooled and stored for further processing
  o Cold water added to cool the curd, then drained off
  o Peppers [drained] added and stirred/salt added and stirred
  o Curd augured to end of table and pneumatically transferred to block-forming towers
• Block-forming towers:
  o Curd pressed and formed into approximately 40 # blocks
• 40 lb. block packaging:
  o 40 # blocks packaged into blue cryovac bags and sealed
• Metal detection:
  o Block in blue cryovac bag is passed through a metal detector [5.0mm-ferrous/nonferrous; 7.0 mm stainless steel]
  o Rejected product segregated for further inspection/disposition
• Weigh/Scale weighed:
  o Product passed over scale and weighed
• Corrugated box and label:
  o Block in cryovac bag packaged into corrugated box
  o Plant number, Vat number, Date of manufacture, and block weight coded onto box
• Refrigerated storage:
  o Product transferred to refrigerated storage at 35 °F – 45 °F
• Refrigerated shipping:
  o Product is shipped in refrigerated trucks at 41 °F to customers for further processing into consumer packages and sale to retail stores/foodservice distributors

Retail Packaging Process
40 # blocks received from refrigerated storage and further processed into 1 # chunks for retail sale.
• Debox, unwrap and inspect:
  o Product received at ≤ 45 °F from plant refrigerated storage
  o Block inspected after deboxing and unwrapping
• Cheese cutting:
  o Block passed through stainless steel wire into 1 # chunk
  o Trim is segregated, vacuum packaged, weighed and labeled, passed through metal detector, refrigerated and shipped for further processing.
• Cheese packaging:
  o 1 # chunk packaged into clear cryovac bags and sealed
• Weigh and label
  o Product weighed/Label verified against “master label proof” for “Contains Milk” statement prior to being applied to package
• Metal detection:
  o Chunk is passed through a metal detector [2.5mm-ferrous; 3.0mm nonferrous; 4.0mm stainless steel]
  o Rejected product segregated for further inspection/disposition
• Case and Label
  o Product cased 12 per box and case label verified against “master label proof” for “Contains Milk” statement prior to being applied to box
• Refrigerated storage:
  o Product transferred to refrigerated storage at 35 °F – 45 °F
• Refrigerated shipping:
  o Product is shipped in refrigerated trucks at 41 °F to local retail store
## Hazard Analysis

Hazard identification (column 2) considers those hazards that are known or reasonably foreseeable to be present in the food because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

- **B** = Biological hazards including bacteria, viruses, parasites, environmental pathogens and other pathogens
- **C** = Chemical hazards including radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives
- **P** = Physical hazards including stones, glass, metal fragments, rubber and wood

<table>
<thead>
<tr>
<th>(1) Ingredient/Processing Step</th>
<th>(2) Identify potential food safety hazards introduced, controlled or enhanced at this step</th>
<th>(3) Do any potential food safety hazards require a preventive control?</th>
<th>(4) Justify your decision for column 3</th>
<th>(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?</th>
<th>(6) Is the preventive control applied at this step?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving packaging – Bags, corrugated boxes, labels</td>
<td>B none C Allergen - milk</td>
<td>X Milk is considered a major food allergen</td>
<td>Allergen control - for pre-printed label review [40 # blocks and 1 # chunks]</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Ambient receiving - salt, calcium chloride, peppers</td>
<td>B Pathogens</td>
<td>X Peppers may contain pathogens. Supplier has validated blanching/brining process to kill pathogenic sporeformers and vegetative pathogens</td>
<td>Supply chain control - for pathogens in peppers in brine/receiving check for proper documentation</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Raw milk intake</td>
<td>B Pathogens such as <em>Listeria monocytogenes</em>, <em>E. coli</em> 0157:H7 or <em>Salmonella</em></td>
<td>X Raw milk received below 45 °F as per PMO. Raw milk may contain a variety of pathogens that must be subjected to a kill step</td>
<td>Process control – pasteurization</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Refrigerated receiving – rennet</td>
<td>B None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frozen receiving – cultures</td>
<td>B None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) Ingredient/Processing Step</td>
<td>(2) Identify potential food safety hazards introduced, controlled or enhanced at this step</td>
<td>(3) Do any potential food safety hazards require a preventive control?</td>
<td>(4) Justify your decision for column 3</td>
<td>(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</td>
<td>(6) Is the preventive control applied at this step?</td>
</tr>
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</tr>
<tr>
<td>Packaging storage – packaging, corrugated boxes, labeling</td>
<td>B None</td>
<td>Yes</td>
<td>Temperature control will minimize growth of pathogens present</td>
<td>Process control – temperature control</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>C None</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>P None</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Ambient Storage (salt, calcium chloride, peppers)</td>
<td>B None</td>
<td>Yes</td>
<td>Raw milk may contain a variety of pathogens. Proper pasteurization is an effective kill step</td>
<td>Process control - pasteurization</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>C None</td>
<td>No</td>
<td></td>
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<td></td>
<td>P None</td>
<td></td>
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</tr>
<tr>
<td>Refrigerated storage – rennet</td>
<td>B None</td>
<td>Yes</td>
<td>Environmental cross-contamination</td>
<td>Sanitation control – hygienic zoning, cleaning and sanitation</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>C None</td>
<td>No</td>
<td></td>
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<tr>
<td></td>
<td>P None</td>
<td></td>
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<tr>
<td>Frozen storage – cultures</td>
<td>B None</td>
<td>Yes</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>C None</td>
<td>No</td>
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<tr>
<td></td>
<td>P None</td>
<td></td>
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</tr>
<tr>
<td>Raw milk storage</td>
<td>B Growth of Pathogens</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C None</td>
<td>No</td>
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<tr>
<td></td>
<td>P None</td>
<td></td>
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<tr>
<td>HTST</td>
<td>B Vegetative pathogens</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>C None</td>
<td>No</td>
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<tr>
<td></td>
<td>P None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheese Vat (make procedure, ingredient addition &amp; whey transfer)</td>
<td>B Pathogens such as <em>Listeria monocytogenes</em></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>C None</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P Foreign Material [Metal]</td>
<td>X</td>
<td>Metal could be present in finished product due to metal on metal processing [cheese vat knives]</td>
<td>Process control – metal detection</td>
<td>X</td>
</tr>
<tr>
<td>Finishing Table (water, pepper addition &amp; salting)</td>
<td>B Pathogens</td>
<td>X</td>
<td>Environmental cross-contamination</td>
<td>Sanitation control – hygienic zoning, cleaning and sanitation</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>C None</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P Foreign Material [Metal]</td>
<td>X</td>
<td>Metal could be present in finished product due to metal on metal processing [drain table stirring forks]</td>
<td>Process control – metal detection</td>
<td>X</td>
</tr>
</tbody>
</table>
### Block Forming Tower
- **Block Forming Tower**
  - **Product:** Pepper Jack Cheese – Ready-to-Eat
  - **Issue Date:** 3/19/2018
  - **Address:** 123 Main Street, Monterey, WI

<table>
<thead>
<tr>
<th>Block Forming Tower</th>
<th>B Pathogens</th>
<th>X Environmental cross-contamination</th>
<th>Sanitation control – hygienic zoning, cleaning and sanitation</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>C None</td>
<td></td>
<td></td>
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<td>P None</td>
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<table>
<thead>
<tr>
<th>40 lb block packaging</th>
<th>B None</th>
<th>C None</th>
<th>P None</th>
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</thead>
<tbody>
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<td></td>
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<table>
<thead>
<tr>
<th>Metal Detection</th>
<th>B None</th>
<th>C None</th>
<th>P None</th>
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<td></td>
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<table>
<thead>
<tr>
<th><strong>Type</strong></th>
<th>Block Forming Tower</th>
<th>40 lb block packaging</th>
<th>Metal Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hazard</strong></td>
<td><strong>Control</strong></td>
<td><strong>Hazard</strong></td>
<td><strong>Control</strong></td>
</tr>
<tr>
<td>Pathogens</td>
<td>Environmental cross-contamination</td>
<td>Sanitation control – hygienic zoning, cleaning and sanitation</td>
<td>X</td>
</tr>
<tr>
<td>C None</td>
<td>C None</td>
<td>C None</td>
<td>P None</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Weigh/Scale</th>
<th>B None</th>
<th>C None</th>
<th>P None</th>
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<tbody>
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<td></td>
<td></td>
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<table>
<thead>
<tr>
<th>Corrugated box and label</th>
<th>B None</th>
<th>C None</th>
<th>P None</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<table>
<thead>
<tr>
<th>Refrigerated Storage – Finished product</th>
<th>B None</th>
<th>C None</th>
<th>P None</th>
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<tbody>
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<td></td>
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<table>
<thead>
<tr>
<th>Refrigerated Product Shipping</th>
<th>B None</th>
<th>C None</th>
<th>P None</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Refrigerated storage, deboxed, unwrap, inspect</th>
<th>B Pathogens</th>
<th>X Environmental cross-contamination</th>
<th>Sanitation control – hygienic zoning, cleaning and sanitation</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>C None</td>
<td></td>
<td></td>
<td></td>
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<td>P None</td>
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<table>
<thead>
<tr>
<th>Cheese cutting</th>
<th>B Pathogens</th>
<th>X Environmental cross-contamination</th>
<th>Sanitation control – hygienic zoning, cleaning and sanitation</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>C None</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>P Foreign Material [Metal]</td>
<td>X Metal from broken cutting wires could contaminate product</td>
<td>Process control – metal detection</td>
<td>X</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Cheese packaging</th>
<th>B None</th>
<th>C None</th>
<th>P None</th>
</tr>
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<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Weigh and label</th>
<th>B None</th>
<th>C Allergens</th>
<th>X Milk is considered a major food allergen</th>
<th>Allergen control - for 1 # chunk label review</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C None</td>
<td>P None</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Metal Detection</th>
<th>B None</th>
<th>C None</th>
<th>P Foreign Material [Metal]</th>
<th>X Metal that may have been introduced in earlier processing steps controlled at this step</th>
<th>Process control – metal detection</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case and label</td>
<td>B</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------</td>
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<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>Allergens</td>
<td>X</td>
<td>Milk is considered a major food allergen</td>
<td>Allergen control - for case label review</td>
<td>X</td>
</tr>
<tr>
<td>Refrigerated Storage – Finished product</td>
<td>B</td>
<td>Non</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerated Product Shipping</td>
<td>B</td>
<td>Non</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Process Preventive Controls

#### Milk Pasteurization

The pasteurizer must be tested and sealed by authorized personnel from the Wisconsin Department of Agriculture, Trade and Consumer Protection [DATCP] - Dairy & Regulatory Compliance Section [regulatory agency] at least once every 12 months and any time after a seal is broken. When the regulatory agency’s test confirms that a pasteurization system is operating correctly (see definition of pasteurization 21 CFR Part 131.3 (b), the regulatory agency shall apply seals that prevent any alteration of the system that would allow any unpasteurized milk or dairy product to flow through the system. Seals may be on actual equipment (a pump, for example) or on controls (a variable frequency drive control, for example) and must remain intact for legal operation. All seal locations are identified on the Pasteurizer seal report for the Wisconsin Cheese Company. If a seal must be broken for immediate repair of equipment or is inadvertently broken, the regulatory agency must be notified within 2 hours - Regulatory agency contact information is on the Pasteurizer seal report. If a seal has been broken, samples of pasteurized product must be collected at intervals not to exceed 4 hours and tested for alkaline phosphatase at a laboratory certified to perform such testing. Alkaline phosphatase testing is an indicator that product has been effectively pasteurized. Sample collection and testing must be implemented as soon as the seal is broken and must be conducted until the seal has been replaced by the regulatory agency. Each sample tested must contain less than 350 milli-units of detectable alkaline phosphatase per liter.

<table>
<thead>
<tr>
<th>Process Control(s)</th>
<th>Hazard(s)</th>
<th>Critical Limits</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk Pasteurization*</td>
<td>Biological pathogens</td>
<td>≥ 161 °F ≥ 15 secs (or equivalent) @ &gt; 1 psi (as sealed by State)</td>
<td>Milk temperature /Forward flow Pasteurizer chart recorder Continuous monitoring Certified or trained pasturizer operator</td>
<td>Automatic divert for low temperature or high flow rate</td>
<td>Review of chart: Date Time Operator Plant ID Daily cut in/cut out product temperatures Recorder vs. indicating thermometer Divert for all events Signed by PCQI or designee within one business day</td>
<td>State timed &amp; sealed record HTST Chart and Deviation Reports Pasteurizer operator certifications [licenses]</td>
</tr>
</tbody>
</table>

---

Food Safety Plan Teaching Example
For Exercise After Chapter 9: Process Preventive Controls
<table>
<thead>
<tr>
<th>Process Control(s)</th>
<th>Hazard(s)</th>
<th>Critical Limits</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk Pasteurization*</td>
<td></td>
<td></td>
<td>Notify state of broken seal</td>
<td>Within 2 hours of breaking seal</td>
<td>Plant Manager or Designee</td>
<td>Record issue that necessitated broken seal and corrective action on CA Form.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Collect Milk samples</td>
<td>Upon seal break or at start-up and every four hours thereafter until seal is replaced</td>
<td>Cheesemaker</td>
<td>State time and seal test records</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Send samples to certified laboratory for phosphatase testing</td>
<td>Each day samples are collected</td>
<td>QA</td>
<td>CA Forms</td>
</tr>
</tbody>
</table>

Food Safety Plan Teaching Example
For Exercise After Chapter 9: Process Preventive Controls
# Process Preventive Controls

<table>
<thead>
<tr>
<th>Process Control(s)</th>
<th>Hazard(s)</th>
<th>Critical Limits</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metal detection</td>
<td>Physical: Metal inclusion</td>
<td>Metal detector present and operating Two sizes [specify] for 40 # block (5 mm ferrous and non-ferrous and 7 mm stainless steel) and 1 # chunk (2.5 mm ferrous, 3 mm non-ferrous and 4 mm stainless steel)</td>
<td>All of the product passes through an operating metal detector Visual examination that the metal detector is on and reject device is working</td>
<td>At start up, then every 2 hours and end of run as well as when production changes from the 40 # block to the 1 # chunk</td>
<td>Trained or designated production employee If metal detector not working properly or metal is found in the product, segregate product, inspect back to last good check, may need to rework or discard product depending if metal is found. Identify source of the metal found and fix damaged equipment if relevant</td>
<td>Metal Detector Log Manufacturer's Validation Study that determined detector settings and sensitivity standards Corrective action records Annual calibration records</td>
</tr>
</tbody>
</table>

---

Food Safety Plan Teaching Example
For Exercise After Chapter 9: Process Preventive Controls
### Process Preventive Controls

<table>
<thead>
<tr>
<th>Process Control(s)</th>
<th>Hazard(s)</th>
<th>Critical Limits</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature Control</td>
<td>Biological – pathogens</td>
<td>≤ 45 °F</td>
<td>Continuous calibrated chart recorder</td>
<td>Evaluate raw milk suitability for cheese making based on time and temperature held above 45 °F. Determine cause of temperature deviation and correct. Document corrective action.</td>
<td>Review of charts and temperature logs and signed by PCQI or designee within 7 working days</td>
<td>Milk silo charts</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Continuous via chart recorder</td>
<td></td>
<td>PMO 2017 for validation of product holding temperatures</td>
<td>Chart recorder calibration records</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trained and designated employee per SOP</td>
<td></td>
<td>Annual calibration of all thermometers</td>
<td>Thermometer calibration records</td>
</tr>
</tbody>
</table>
## Allergen Preventive Controls

<table>
<thead>
<tr>
<th>Allergen Controls</th>
<th>Hazard(s)</th>
<th>Criterion</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving – labels</td>
<td>Chemical – Milk Allergen</td>
<td>&quot;Contains: Milk&quot; statement below ingredient statement</td>
<td>Incoming new labels, Evaluation Checklist for all newly received labels</td>
<td>Receipt of every new shipment of labels, QA trained staff</td>
<td>Reject label shipment/contact label vendor to their Corrective Action [including Root Cause Analysis] to prevent reoccurrence</td>
<td>Labels verified against &quot;master label proof&quot; for &quot;Contains Milk&quot; statement</td>
</tr>
<tr>
<td>Cheese (1 # chunk) weighed and labeled (and) Case and label</td>
<td></td>
<td>Placing of Labels on product package (and) case box, Check labels versus product and case &quot;master label proof&quot; at time of application</td>
<td>At start of shift, change of lot numbers or when new labels are brought to the line, Trained packaging operator</td>
<td>Place product on hold, re-label product with correct label, Determine cause of wrong label and correct. Document corrective action.</td>
<td>Records reviewed and signed by PCQI or designee within 7 working days.</td>
<td>Packaging operator daily log</td>
</tr>
</tbody>
</table>

### Products

<table>
<thead>
<tr>
<th>Allergen Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pepper Jack Cheese</td>
</tr>
</tbody>
</table>

**Scheduling Implications:** Special production scheduling not necessary as all finished products contain the milk allergen

**Allergen Cleaning Implications:** No Special sanitation controls required specific to the milk allergens as all finished product contains the milk allergen
Sanitation Preventive Controls

All food contact surfaces of equipment and utensils are cleaned and sanitized according to documented procedure and in a manner to mitigate the accumulation / growth of bacteria. Surfaces are inspected after cleaning to assure that they are visibly clean. Sanitizer of appropriate concentration is applied to visibly clean surfaces prior to starting production. Microbiological swabbing is conducted as a verification activity.

Hygienic Zoning protocols are applied to minimize the potential of re-contamination of food contact surfaces. Pathogen environmental monitoring is conducted as a verification activity.

<table>
<thead>
<tr>
<th>Sanitation Control</th>
<th>Hazard</th>
<th>Parameter</th>
<th>Monitoring</th>
<th>Correction</th>
<th>Verification</th>
<th>Corrective Action</th>
<th>Record /Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanitation Monitoring</td>
<td>Unsanitary conditions may lead to adulteration</td>
<td>Visibly Clean</td>
<td>Cleanliness Product contact surfaces</td>
<td>Reclean, Reinspect. Repeat until visibly clean</td>
<td>Quality swabs Product contact surfaces weekly and tests for Aerobic Plate Count (APC) and Coliform Records reviewed by PCQI or designee prior to release of product</td>
<td>If APC &gt; 100 or Coliform &gt;10, deep clean surface and re-swab. For repeat high count conduct Root Cause Analysis / Corrective Action.</td>
<td>Pre-Op Sanitation Inspection Forms Sanitation Swab Log Corrective Action Forms Location: QA Lab</td>
</tr>
<tr>
<td>Sanitation Monitoring</td>
<td></td>
<td>Sanitation Strength</td>
<td>Concentration of sanitizer</td>
<td>Adjust concentration by adding chemical if concentration is below desired range or water if concentration is above desired range</td>
<td>Records reviewed by PCQI or designee prior to release of product</td>
<td></td>
<td>Sanitizer Concentration Log Location: QA Lab</td>
</tr>
</tbody>
</table>
**Hygienic Zoning/ Environmental Monitoring**

**Purpose:** Hygienic zoning in the production facility is important to minimize potential of environmental pathogen cross-contamination. Because pathogens can be readily transferred, the movement of people and materials must be controlled by developing traffic patterns with strict controls. See diagram below.

**Cheese Plant Diagram** -

![Cheese Plant Diagram](https://www.usdairy.com/science-and-research/food-safety)

Source Fig. 3. An example dairy plant floor plan with traffic patterns mapped and operations segregated by hygiene requirements

**CONTROL OF LISTERIA MONOCYTOGENES - GUIDANCE FOR THE U.S. DAIRY INDUSTRY**


Food Safety Plan Teaching Example
For Exercise After Chapter 11: Sanitation Preventive Controls
Who: All employees are required to follow Hygienic Zoning protocols.

Procedure: Employees entering the described areas must follow the protocol for the area.

1. **Raw product areas**
   a. Traffic in these areas is limited to dedicated personnel. Dedicated personnel must wear a clean, gray uniform stored in lockers in Raw Area. Only employees working in this area wear gray uniforms. Employees in gray colored uniforms may not enter the common areas of the plant.
   b. Prior to entering the area, employee changes into uniform and steel toe, slip resistant boots.
   c. Employee dons hairnet and beard net (where applicable) and red bump cap. Employee then washes hands and continues into the work area.
   d. Occasional employees may enter this area only if authorized. They must don Tyvek (disposable) suits and rubberized yellow shoe covers upon entrance to the area.
   e. Upon exiting the area, employee removes bump cap, discards hair covering and changes into street clothes and shoes OR removes Tyvek suit and shoe covers (if applicable) before leaving the raw area.
   f. Tools in this area are dedicated and must remain in the area.

2. **RTE areas**
   a. Employees working in RTE areas change into a clean white uniforms each day and clean, dedicated slip resistant, steel toed footwear. Temporary employees use blue shoe covers.
   b. Employee dons hairnet and beard net (where applicable) prior to entering basic GMP, RTE or HH areas.
   c. Employees designated to work in the make room don green bump caps.
   d. Employees must wash hands in the gang sink located in the same hallway prior to entry into the plant.
   e. Employees must utilize foot foamer upon entering the room.
   f. Color coded tools in this area are dedicated and must remain in the area. Tools must be cleaned and sanitized after use.

3. **High Hygiene area**
   a. Employees working in High Hygiene (HH) areas change into a clean white uniforms each day and clean, dedicated slip resistant, steel toed footwear
   b. Employees entering the HH area must don a clean apron and arm guards upon entry to the HH area. They must wash their hands and wear gloves to handle product.
   c. Aprons and arm guards must be left in the HH area when employees go on break. At the end of the shift aprons must be placed in the soiled apron bins. Arm guards must be discarded.
   d. Gloves should be discarded as employee exits room, when non-food contact surface has been touched or if glove is torn and replaced with new prior to resuming packaging activities.
   e. Employees must utilize foot foamer upon entering the room.
   f. Color coded tools in this area are dedicated and must remain in the area. Tools must be cleaned and sanitized after use.
Food Safety Plan Teaching Example
For Exercise After Chapter 11: Sanitation Preventive Controls

Monitoring: Supervisors visually observe the presence of properly garbed employees after start-up and after lunch break and at shift change as part of daily GMP Check. QA conducts monthly GMP audits as further verification.

Corrections: Employees are instructed to gown properly. Repeat offenders are subject to disciplinary action.


Verification: Daily GMP record review within 7 working days. Monthly GMP Audits and Environmental monitoring.
Environmental Monitoring for Sanitation Preventive Control Verification

Pathogen Environmental Monitoring Program

**Purpose:** Pathogen Environmental monitoring is conducted to verify the effectiveness of sanitation and hygienic zoning procedures in the primary pathogen control zones to control environmental pathogens such as *L. monocytogenes* and *Salmonella*.

**Sample identification:** Samples identification should include the specific location sampled, the date and time the sample is taken and the initials of the person taking samples.

**Sampling procedure:** The high hygiene areas are tested weekly for the presence of *Listeria* species. Sponge swabs are collected during production at least 3 hours after production starts. Sampling time is not uniform to avoid bias of results. Samples are shipped to a third party certified laboratory using the sampling kit provided by the laboratory. Samples are refrigerated and shipped in an insulated cooler with a gel pack with next day delivery. Samples are NOT frozen.

Samples are collected by trained personnel in zoned areas (see diagram). Most samples are taken in zones 2 and 3 and include pre-identified sites as well as random sites based on observed conditions. All pre-identified sites should be sampled to include some sampling each week but completion of all samples each month. The shift on which samples are taken should be varied so that some sampling occurs on each shift each month. Based on observation when sampling, random sites should be sampled that may give cause for concern: e.g., standing water, product residue, around table legs, crevasses, and major traffic areas. 10 scheduled samples sites and all drains in high hygiene areas must be tested each week.

Zone 1 samples may be taken only under direction of the QA supervisor and are generally taken to investigate a Zone 2 positive result in a high hygiene area. Follow product hold and release procedures for product when any Zone 1 samples are taken.
Test conducted: For routine samples, the contract lab enriches individual sponges and pools (up to five) aliquots of enrichment for a single test for *Listeria* species. This test protocol has been validated. Any investigative samples and all Zone 1 samples must be tested individually.

Five separate swabs are taken once per month in the High Hygiene area and are tested for *Salmonella*. No composite testing is conducted.

Laboratory: Superior Laboratory (987 Dairy Drive, Hometown, USA) conducts the analysis using approved procedures. Analysis is started within 48 hours of sampling. The test result report identifies the specific method number used.

Interpretation of results:

Acton for a negative result – continue routine operations.

Corrective action for a positive Listeria result:

1. If a composite is positive, the areas implicated by the composite are re-sampled within a day of notification and prior to implementing intensive sanitation procedures. Additional samples (number depends on size of area) are taken in adjacent problem areas (vector sampling) in an attempt to identify a source of contamination. All samples are run individually, without compositing.
2. Intensive sanitation procedures are implemented after sampling is complete.
3. Production can continue after sanitation is complete and product can be shipped.
4. Suspect area should be sampled and test negative 3 consecutive times before resuming the normal sampling frequency.
5. If one or more re-samples are positive, perform corrective action investigation to resolve the issue. Implement a hold and finished product testing procedure per the Product Testing for Verification corrective action protocol.

Corrective action for a positive Salmonella result.


Note: Pathogen Environmental Monitoring program courtesy of the Innovation Center for U.S. Dairy/Food Safety

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] and pH control for sporeforming pathogens [C. botulinum].

Verification activities:
- A 3rd party audit is conducted annually utilizing a qualified auditor
- Quarterly testing of product received
- COA for each lot received
- Regulatory inspection reports – potential 483 issuance

Verification procedures:
- Review the 3rd party audit results on file with Corrective Actions
- Review the quarterly test results
- COA’s reviewed against specifications
- Review any regulatory inspections 483 form

Records:
- Copy of 3rd party audit
- Quarterly testing results
- COA’s received

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

<table>
<thead>
<tr>
<th>Ingredient (requiring supply-chain-applied control)</th>
<th>Approved Supplier</th>
<th>Hazard(s) requiring supply-chain-applied control</th>
<th>Date of Approval</th>
<th>Verification method</th>
<th>Verification records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peppers</td>
<td>Best Peppers Company</td>
<td>Biological - Vegetative pathogens [Listeria and E. coli] Pathogenic sporeformers [C. botulinum]</td>
<td>3/15/16</td>
<td>Annual 3rd party of supplier’s facility Quarterly testing results Receipt of COA with each shipment matched with lot number received Review any 483’s</td>
<td>Copy of 3rd party audit. Quarterly testing results COA/Receiving records</td>
</tr>
</tbody>
</table>

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