Selected Sections of a

**Food Safety Plan**

**for**

**Pepper Jack Cheese**

**Teaching Example**

Prepared by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Preventive Controls Qualified Individual

Date:

Approved by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Owner, Operator, or Agent in Charge

Date:

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.

Table of Contents

[Company Overview 3](#_Toc465412839)

[Product Description 3](#_Toc465412840)

[Flow Diagram – Cheese Make 4](#_Toc465412841)

[Flow Diagram – Retail Packaging 5](#_Toc465412842)

[Process Narrative 6](#_Toc465412843)

[Hazard Analysis 8](#_Toc465412868)

[Process Preventive Controls 12](#_Toc465412869)

[Allergen Preventive Controls 16](#_Toc465412870)

[Sanitation Preventive Controls 17](#_Toc465412873)

[Supply-Chain Preventive Controls Program 22](#_Toc465412876)

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# Company Overview

This cheese company makes a variety of flavored Monterey Jack cheeses that are intended to be ready-to-eat products. Products include Monterey Jack cheese, Pepper Jack cheese, and other various pepper flavored Jacks. 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. Water is treated and tested per EPA requirements by the plant. An integrated pest control program is also in place. Company has a robust environmental monitoring program.

This Food Safety Plan covers production of Pepper Jack cheese, but parts of it (e.g., pasteurization, metal detection, allergen, sanitation and supply-chain controls) apply to other products made in the plant as well.

# Product Description

|  |  |
| --- | --- |
| **Product Name(s)** | **Pepper Jack Cheese** |
| **Product Description, including Important Food Safety Characteristics** | Pepper Jack cheese is a pasteurized semi-soft natural cheese with added peppers. Product supports limited growth of a number of pathogens during processing and early aging; however natural 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. |
| **Ingredients** | Pasteurized milk, peppers, salt, cultures, enzymes, calcium chloride. |
| **Packaging Used** | 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. |
| **Intended Use** | Initially stored as 40 # blocks in film-lined corrugated boxes for short aging period. Distributed using refrigerated trucks (35 °F – 45 °F) to conversion facilities for further consumer packaging and sale to retail stores and foodservice distributors. 1 # retail chunk is sold at cheese plant retail store as well as local retail stores. |
| **Intended Consumers** | Ready to eat product for industry and consumers. |
| **Shelf Life** | 180 days at 35 °F – 45 °F. |
| **Labeling Instructions** | 40 # block case: Plant number, Vat number, Manufacture Date and Block weight.  Retail label: Keep refrigerated; Best used by date  Retail label allergen statement: Contains: milk |
| **Storage and Distribution** | Refrigerated storage and retail and foodservice distribution. |

# Flow Diagram – Cheese Make



# Flow Diagram – Retail Packaging



# Process Narrative

## Receiving Ingredients and Packaging:

Ingredients and packaging materials are purchased from approved suppliers with validated and verified food safety programs and stored appropriately according to manufacturers’ requirements.

* **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 product allergen requirements and ingredients
  + 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 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 packaging area.
* **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.

## 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 cheese 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:**
  + Whey drained from curd, cooled and stored for further processing
  + Cold water added to cool the curd, then drained off
  + Peppers [drained] added and stirred/salt added and stirred
  + Curd augured to end of table and pneumatically transferred to block-forming towers
* **Block-forming towers:**
  + Curd pressed and formed into approximately 40 # blocks
* **40 lb. block packaging:**
  + 40 # blocks packaged into blue cryovac bags and sealed
* **Metal detection:**
  + Block in blue cryovac bag is passed through a metal detector [5.0mm-ferrous/nonferrous; 7.0 mm stainless steel]
  + Rejected product segregated for further inspection/disposition
* **Weigh/Scale weighed:**
  + Product passed over scale and weighed
* **Corrugated box and label:**
  + Block in cryovac bag packaged into corrugated box
  + Plant number, Vat number, Date of manufacture, and block weight coded onto box
* **Refrigerated storage:**
  + Product transferred to refrigerated storage at 35 °F – 45 °F
* **Refrigerated shipping:**
  + Product is shipped in refrigerated trucks at 35 °F – 45 °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:**
  + Product received at ≤ 45 °F from plant refrigerated storage
  + Block deboxed and unwrapped
  + Block inspected
* **Cheese cutting:**
  + Block passed through stainless steel wire into 1 # chunk
  + Trim is segregated, vacuum packaged, weighed and labeled, passed through metal detector, refrigerated and shipped for further processing.
* **Cheese packaging:**
  + 1 # chunk packaged into clear cryovac bags and sealed
* **Weigh and label**
  + Product weighed
  + Label applied to package
* **Metal detection:**
  + Chunk is passed through a metal detector [2.5mm-ferrous; 3.0mm nonferrous; 4.0mm stainless steel]
  + Rejected product segregated for further inspection/disposition
* **Case and Label**
  + Product cased 12 per box and case label applied to box
* **Refrigerated storage:**
  + Product transferred to refrigerated storage at 35 °F – 45 °F
* **Refrigerated shipping:**
  + Product is shipped in refrigerated trucks at 35 °F – 45 °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

| (1)  Ingredient/ Processing Step | (2)  Identify potential food safety hazards introduced, controlled or enhanced at this step | | (3)  Do any potential food safety hazards require a preventive control? | | (4)  Justify your decision for column 3 | (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* | (6)  Is the preventive control applied at this step? | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | No | Yes | No |
| Receiving packaging –  Bags, corrugated boxes, labels | B | none |  |  |  |  |  |  |
| C | Allergen - milk | X |  | Milk is considered a major food allergen | Allergen control - for pre-printed label review | X |  |
| P | None |  |  |  |  |  |  |
| Ambient receiving - salt, calcium chloride, peppers | B | Pathogens | X |  | Peppers may contain pathogens. Supplier has validated blanching/brining process to kill vegetative pathogens | Supply chain control - for pathogens in peppers in brine/receiving check for proper documentation | X |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Raw milk intake | B | Pathogens | 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 | Process control –pasteurization |  | X |
| C | Drug Residues |  |  | Mandatory testing prior to unloading any milk trucks as per Appendix N of the PMO. Presence of antibiotics in milk have never been shown to be a significant hazard. |  |  |  |
| P | Metal | X |  | Pumps and valves may shed metal into raw milk stream | Process control – metal detection |  | X |
| Refrigerated receiving –rennet | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Frozen receiving – cultures | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Packaging storage – packaging, corrugated boxes, labeling | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Ambient Storage (salt, calcium chloride, peppers) | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Refrigerated storage – rennet | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Frozen storage –cultures | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Raw milk storage | B | Growth of Pathogens | X |  | Temperature control will minimize growth of pathogens present | Process control –temperature control | X |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| HTST | B | Vegetative pathogens | X |  | Raw milk may contain a variety of pathogens. Proper pasteurization is an effective kill step | Process control - pasteurization | X |  |
| C | None |  |  |  |  |  |  |
| P | Metal | X |  | Metal could be present in finished product | Process control – metal detection |  | X |
| Cheese Vat (make procedure, ingredient addition & whey transfer) | B | Pathogens | X |  | Environmental cross-contamination | Sanitation control – hygienic zoning, environmental monitoring | X |  |
| C | None |  |  |  |  |  |  |
| P | Metal | X |  | Metal could be present in finished product | Process control – metal detection |  | X |
| Finishing Table (water, pepper addition & salting | B | Pathogens | X |  | Environmental cross-contamination | Sanitation control – hygienic zoning, environmental monitoring | X |  |
| C | None |  |  |  |  |  |  |
| P | Metal | X |  | Metal could be present in finished product | Process control – metal detection |  | X |
| Block Forming Tower | B | Pathogens | X |  | Environmental cross-contamination | Sanitation control – hygienic zoning, environmental monitoring | X |  |
| C | None |  |  |  |  |  |  |
| P | Metal | X |  | Metal could be present in finished product | Process control – metal detection |  | X |
| 40 lb block packaging | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Metal Detection | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | Metal | X |  | Metal could be present in finished product | Process control – metal detection | X |  |
| Corrugated box and label | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Weigh/Scale | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Refrigerated Storage – Finished product | B | Pathogen | X |  | Temperature control will minimize growth of pathogens present | Process control –temperature control | X |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Refrigerated Product Shipping | B | Pathogen | X |  | Temperature control will minimize growth of pathogens present | Process control –temperature control | X |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Refrigerated storage, deboxed unwrap, inspect | B | Pathogens | X |  | Environmental cross-contamination | Sanitation control – hygienic zoning, environmental monitoring | X |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Cheese cutting | B | Pathogens | X |  | Environmental cross-contamination | Sanitation control – hygienic zoning, environmental monitoring | X |  |
| C | None |  |  |  |  |  |  |
| P | Metal | X |  | Metal could be present in finished product | Process control – metal detection |  | X |
| Cheese packaging | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Weigh and label | B | None |  |  |  |  |  |  |
| C | Allergens | X |  | Milk is considered a major food allergen | Allergen control - for label review | X |  |
| P | None |  |  |  |  |  |  |
| Metal Detection | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | Metal | X |  | Metal could be present in finished product | Process control – metal detection | X |  |
| Case and label | B | None |  |  |  |  |  |  |
| C | Allergens | X |  | Milk is considered a major food allergen | Allergen control - for case label review | X |  |
| P | None |  |  |  |  |  |  |
| Refrigerated Storage – Finished product | B | Pathogen | X |  | Temperature control will minimize growth of pathogens present | Process control –temperature control | X |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Refrigerated Product Shipping | B | Pathogen | X |  | Temperature control will minimize growth of pathogens present | Process control –temperature control | X |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |

# Process Preventive Controls

| **Process Control(s)** | **Hazard(s)** | **Critical Limits** | **Monitoring** | | | | **Corrective**  **Action** | **Verification** | **Records** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **What** | **How** | **Frequency** | **Who** |
| Milk Pasteuriz-ation | Biological – pathogens | ≥ 161 °F  ≥ 15 secs | Milk temperature | Recording thermometer and chart recorder | Continuous monitoring of Mag Flow/Temperature at end of holding tube | Certified or trained pasteurizer operator | Flow divert, recirculate and Pasteurize  Broken Seal Report – phosphatase every 4 hours  Hold finished product for further disposition  Determine cause of temperature deviation and correct. Document corrective action. | State timed & sealed record;  Review of chart, Seal checks, Daily cut in/cut out, Recorder vs. indicating thermometer and signed by PCQI or designee within 7 working days; | HTST Chart and Deviation Reports  Hold records  Validation record as per 21 CFR Part 131.3(b) legal definition of pasteurization |

**Process Preventive Controls**

| **Process Control(s)** | **Hazard(s)** | **Critical Limits** | **Monitoring** | | | | **Corrective**  **Action** | **Verification** | **Records** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **What** | **How** | **Frequency** | **Who** |
| Metal detection | Physical: Metal inclusion | 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)  No metal fragments are in the product passing through the metal detector | All of the product passes through an operating metal detector | Visual examination that the metal detector is on and reject device is working | At start up, then every 2 hours and end of run  Product changes from 40 # block to 1 # chunk | Trained production employee | If metal is found in the product, segregate product, inspect back to last good check, rework or discard product depending on metal type and prevalence. Identify source of the metal found and fix damaged equipment if relevant | Pass 40 # block with 5 mm ferrous and non-ferrous and 7 mm stainless steel standard wands or 1 # chunk with 2.5 mm ferrous, 3 mm non-ferrous and 4 mm stainless steel standard wands through detector at start-up, then every 2 hours and end of run to assure equipment is functioning  Review of Metal Detector Log and Corrective Action and Verification records and signed by PCQI or designee within 7 working days  Annual service by manufacturer | Metal Detector Log  Manufacturer’s Validation Study that determined detector settings and sensitivity standards  Corrective action records  Annual calibration records |

**Process Preventive Controls**

| **Process Control(s)** | **Hazard(s)** | **Critical Limits** | **Monitoring** | | | | **Corrective**  **Action** | **Verification** | **Records** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **What** | **How** | **Frequency** | **Who** |
| Tempera-ture Control | Biological – pathogens | ≤ 45 ˚F | All milk stored in raw milk silos | Continuous chart recorder | Continuous or twice daily | Trained and designated employee per SOP | 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. | Review of charts and temperature logs and signed by PCQI or designee within 7 working days  PMO 2013 for validation of product holding temperatures  Annual calibration of thermometers | Milk silo charts  Thermometer calibration records |
| Tempera-ture Control | Biological – pathogens | ≤ 45 °F | All refrigerated storage coolers | Continuous chart recorder or calibrated thermometer | Continuous or twice daily | Trained and designated employee per SOP | Place product on hold, evaluate product based on time and temperature held above 45 ˚F.  Determine cause of temperature deviation and correct. Document corrective action. | Review of charts and temperature logs and signed by PCQI or designee within 7 working days  PMO 2013 for validation of product holding temperatures  Annual calibration of thermometers | Cooler charts  Thermometer calibration records |
| Tempera-ture Control | Biological – pathogens | ≤ 45 °F | All refrigerated shipping and receiving trucks | Continuous chart recorder or calibrated IR thermometer | Every truck | Trained and designated employee per SOP | Rejection of truck or receive and hold product for retest/release or reject | Review of charts and temperature logs and signed by PCQI or designee within 7 working days  PMO 2013 for validation of product holding temperatures  Annual calibration of thermometers | Receiving and shipping logs  Thermometer calibration records |

# Allergen Preventive Controls

| **Allergen Controls** | **Hazard(s)** | **Criterion** | **Monitoring** | | | | **Corrective Action** | **Verification** | **Records** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **What** | **How** | **Frequency** | **Who** |
| Receiving – labels | Chemical – Milk Allergen | “Contains: Milk” statement below ingredient statement | Incoming new labels | Evaluation Checklist for all newly received labels | Receipt of every new shipment of labels | QA trained staff | Reject label shipment | Records reviewed and signed by PCQI or designee within 7 working days. | Label Evaluation Checklist – Receiving |
| Cheese (1 # chunk) weighed and labeled | Placing of Labels on product package | Check labels versus product | At start of shift and change of lot numbers | Packaging operator | Place product on hold, re-label product with correct label  Determine cause of wrong label and correct. Document corrective action. | Packaging operator daily log |

|  |  |
| --- | --- |
| **Products** | **Allergen Statement** |
| Pepper Jack Cheese | Contains: Milk |

## Production Line Allergen Assessment

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product Name** | **Production Line** | **Intentional Allergens** | | | | | | | |
| **Egg** | **Milk** | **Soy** | **Wheat** | **Tree Nut**  (market name) | **Peanut** | **Fish**  (market name) | **Shellfish**  (market name) |
| Pepper Jack | 1 |  | X |  |  |  |  |  |  |

**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

*NOTE: See Food Safety Plan in curriculum for an example of potential wording for cleaning and sanitation procedures to prevent allergen cross-contact from seafood containing product. Parameters can vary depending on the product, equipment, etc.*

## Hygienic Zoning/ Environmental Monitoring

**Purpose**: Hygienic zoning in the production facility is important to minimize potential of environmental pathogen cross-contamination. See diagram below.

Cheese Plant Diagram



CIP

Raw Milk Silos

COP

Dry Storage

Utilities

Raw Break area + Restroom

Pasteurizer and Separator

RTE Area

High Hygiene area

Transition area / Foot foamers + Hand sinks

Basic GMP area

Raw product area – traffic restricted

Frozen Storage

Lab

Refrigerated Storage

Shipping and Receiving

Office

CIP / COP Room

Make Room

Whey Processing Room

Retail Package Room

Conference Room

Office

Retail Store

Raw Milk Receiving

Towers

Finishing Tables

Women’s Lockers

Men’s Lockers

Break Room

Foot Traffic

Fork lift Traffic

To trash compactor

**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   
   1. 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.
   2. Upon entering the area, employee changes into uniform and steel toe, slip resistant boots.
   3. Employee dons hairnet and beard net (where applicable) and red bump cap. Employee then washes hands and continues into the work area.
   4. 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.
   5. 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.
   6. Tools in this area are dedicated and must remain in the area.
2. RTE areas   
   1. Employees working in RTE or High Hygiene (HH) areas change into a clean white uniforms each day and clean, dedicated slip resistant, steel toed footwear. Temporary employees use blue shoe covers.
   2. Employee dons hairnet and beard net (where applicable) prior to entering basic GMP, RTE or HH areas.
   3. Employees designated to work in the make room don green bump caps.
   4. Employees must wash hands in the gang sink located in the same hallway prior to entry into the plant.
3. High Hygiene area  
   1. 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.
   2. 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.
   3. 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.
   4. Tools in this area are dedicated and must remain in the area. Tools must be cleaned and sanitized after use.

**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.

**Records:** Daily GMP Check. Monthly GMP audits.

**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**

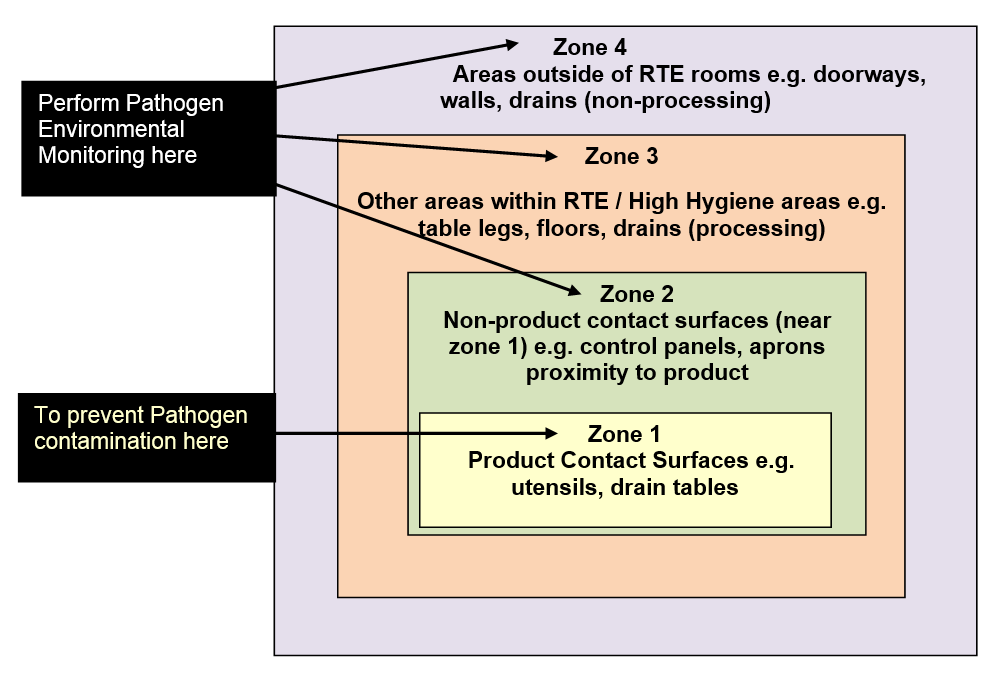
**Purpose**: Pathogen Environmental monitoring is conducted to verify the effectiveness of sanitation and hygienic zoning procedures in the primary pathogen control zones to control environmental pathogens such as *L. monocytogenes* and *Salmonella.*

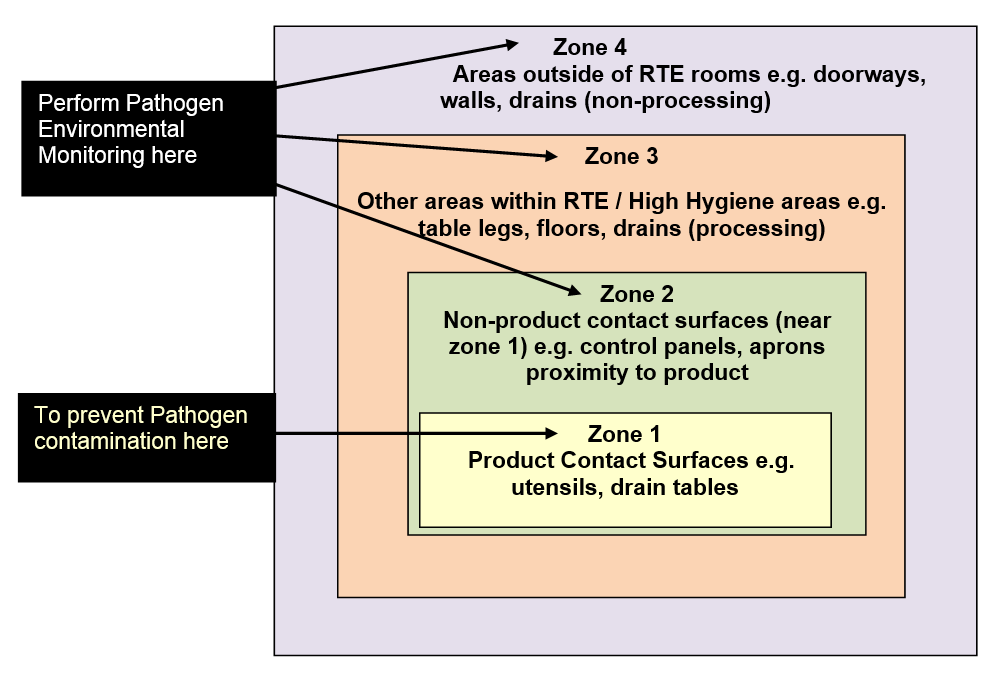
**Sample identification:** Based on observation when sampling, “worst case” areas are sampled; e.g., standing water or product residue, around table legs, crevasses, and major traffic areas. Samples identification should include the specific location sampled and the date and time the sample is taken.

**Sampling procedure:** The primary pathogen control area is 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 the 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. Total number of samples collected each week:

* Zone 2 – Minimum 6 samples
* Zone 3 – Minimum 6 samples
* Zone 4 – Minimum 2 samples
* Minimum 8 other samples (Zone 2 or 3) based on observed conditions





**Test conducted:** For routine samples, the contract lab composites sponges from the same area to run as one test for *Listeria* species. *Investigation samples must be run individually.*

Five separate swabs are taken once per month in the High Hygiene area and are tested for *Salmonella*.

**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 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.

# 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