Selected Sections of a Food Safety Plan Teaching Example

Penn State Extension
Food Safety Plan
for
Raw Milk Gouda Cheese

Developed by: Ellie Cee Cee PCQI Date: 7/19/19

Approved by: Kay Smith Plant Manager Date: _____

The information in this example is for training purposes only and does not represent any specific operation. Processing steps may have been 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.

This Food Safety Plan example is modeled after forms developed for the FSPCA Preventive Controls for Human Food curriculum, and can be modified to reflect the needs of individual establishments. FSPCA has no input on Food Safety Plans for individual establishments.

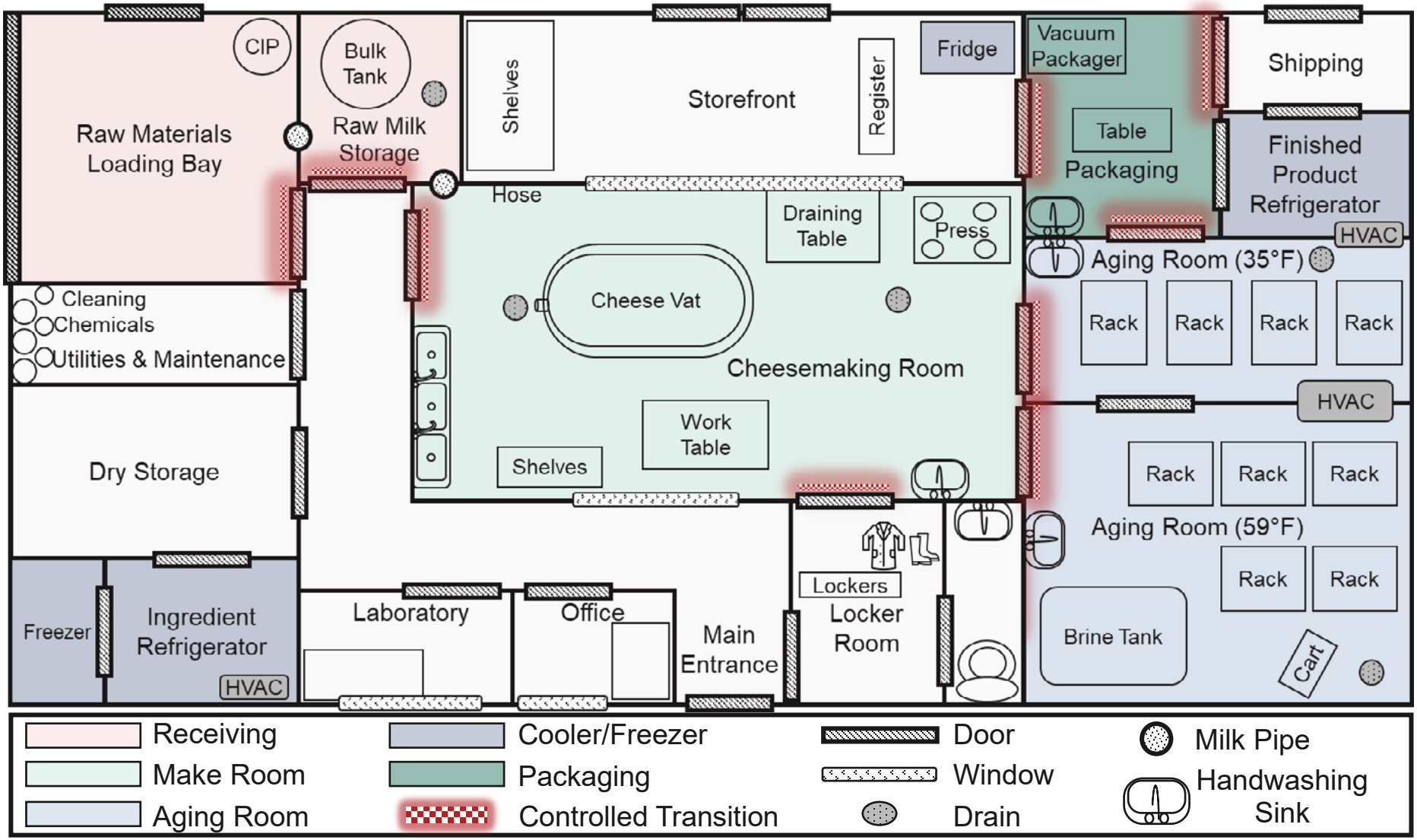
There is no standardized or mandated format for a Food Safety Plan. The information should be arranged in a progressive manner that clearly explains the thought process for the Hazard Analysis and the individual steps in the Food Safety Plan. Forms used for process Preventive Controls may be adapted 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.

The following forms are provided as examples. These worksheets can be copied for routine use, but if they are used for official use, they must include details that identify the commercial firm and related information.

Contents

Plant Layout

Plant layout is not to scale.



Penn State Extension Raw Milk Gouda Teaching Example

Company Overview

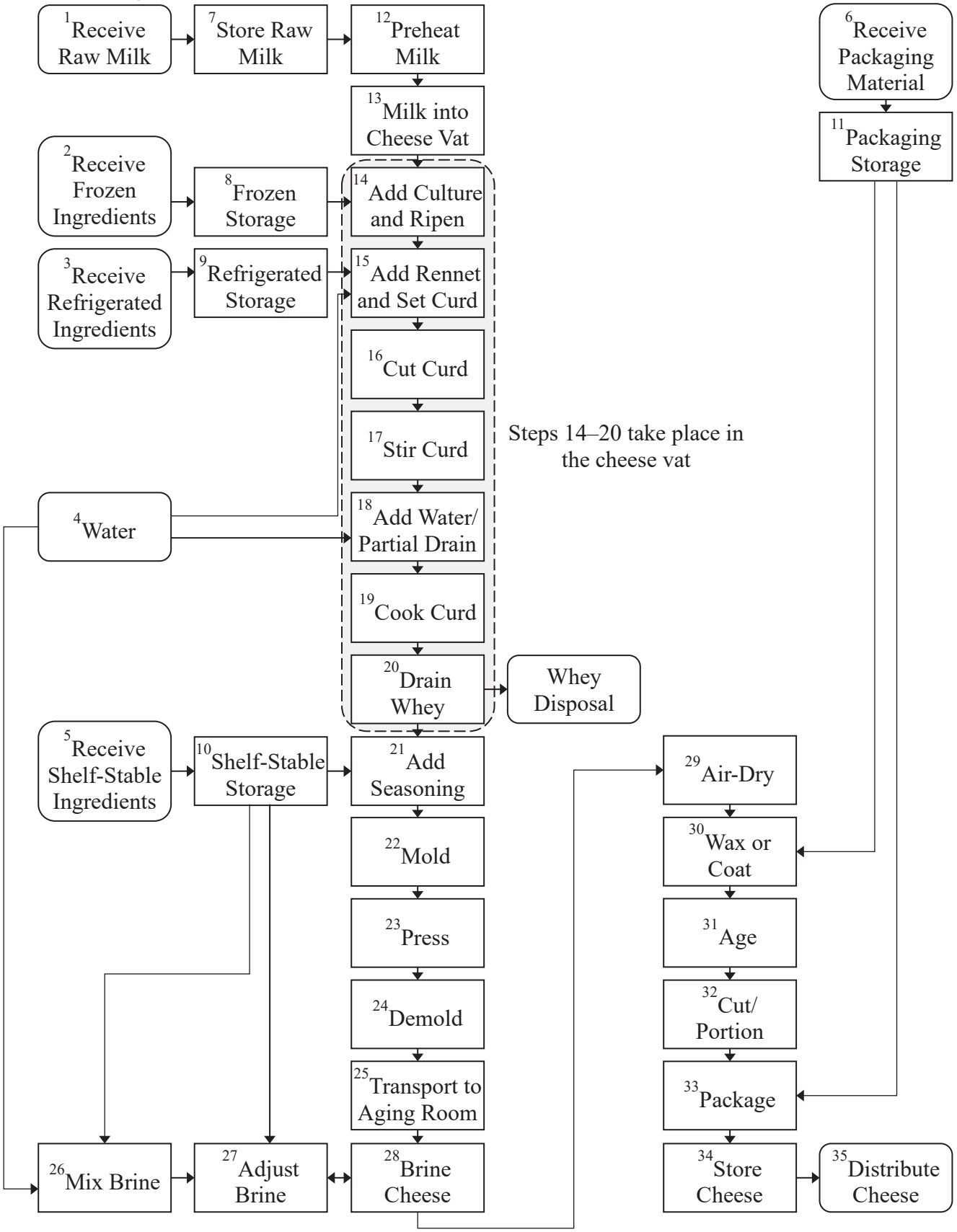
EllCeeCee Cheese is a family-owned artisan cheese processor of semi-soft and hard cheeses made with unpasteurized milk. Raw milk is sourced locally from farms within 50 miles of the facility, including EllCeeCee farm. Approximately 800 gallons of milk are processed daily, 3 to 5 days per week. Cheeses are aged from 6 months to 2 years. Cheese is distributed locally to specialty stores, farmers markets, and restaurants.

EllCeeCee Cheese follows GMPs and uses Prerequisite Programs to manage employee training, SOPs, SSOPs, pest control, brine maintenance, water quality, chemical storage, and preventive maintenance of equipment, wooden shelves, molds, knives, and other utensils.

Product Description

Product Description Distribution, Consumers, and Intended Use	
Product Name(s)	Pepper and Herb Raw Milk Gouda
Product Description, Including Important Food Safety Characteristics	Semi-soft cheese made with unpasteurized cow milk and flavored with dried herbs and spices. Cheese is aged for a minimum of 6 months, with a final pH between 5.4 and 5.3, and final salt-in-moisture between 4.5 and 5.5%.
Ingredients	Unpasteurized milk, salt, black pepper, dried herbs, cultures, enzymes, calcium chloride.
Packaging Used	Whole wheels are coated in polyvinyl acetate (PVA). Retail portions are vacuum-packaged in high-density polypropylene bags and labeled with adhesive labels.
Intended Use	Ready-to-eat product.
Intended Consumers	Healthy individuals above the age of 3 years.
Shelf Life	360 days at less than 41°F if uncut; 3-4 weeks refrigerated once cut.
Labeling Instructions	Keep refrigerated. Code date. Allergen statement: Contains: milk.
Storage and Distribution	Refrigerated storage and distribution. Retail on-farm and farmers markets in Pennsylvania. Wholesale to specialty stores and restaurants in the Northeast and Mid-Atlantic region.
Approved: Signature: Print name: Ellie CeeCee	**Date:** 7/19/19

Flow Diagram



Process Narrative

Receiving Ingredients and Packaging
Ingredients and packaging materials are purchased from approved suppliers and stored according to manufacturers' requirements.

Ingredients and packaging materials are received and stored according to EllCeeCee Cheese's current procedures described in the Prerequisite Programs for receiving and storing ingredients and materials.

1. Receive Raw Milk: Raw milk is received at a temperature of < 45°F. Milk is tested for antibiotic drug residues following PMO Appendix N procedures. Milk is filtered during transfer to a sanitized storage tank.

2. Receive Frozen Ingredients: Freeze-dried cultures are received from the supplier within 3 days at ambient temperature and put in the freezer upon arrival.

3. Receive Refrigerated Ingredients: Liquid double-strength rennet is received in 1-gallon jugs at < 41°F.

4. Water: Municipal water is managed using a Prerequisite Program.

5. Receive Shelf-Stable Ingredients: Salt is received in 25-lb bags. Liquid calcium chloride is received in 5-gallon jugs. Proprietary spice blend is received in 10-lb boxes, lined with heavy blue plastic.

6. Receive Packaging Material: Polyvinyl acetate (PVA) is received in 130-lb drums. High-density polyethylene vacuum bags are received in boxes. Preprinted adhesive labels are reviewed for correct ingredients and allergen statements.

Storing Ingredients and Packaging
Storage is managed using Prerequisite Programs and GMPs for segregation of allergens and use of products on a first-in-first-out basis.

7. Store Raw Milk: Raw milk is stored in a refrigerated tank at a temperature no higher than 45°F.

8. Frozen Storage: Cultures are stored in a freezer at a maximum of 32°F.

9. Refrigerated Storage: Rennet is stored in opaque, sealed jugs in a refrigerator < 41°F.

10. Shelf-Stable Storage: Salt and spices are stored at room temperature in labeled, sealed containers. Calcium chloride is stored in an opaque, sealed container at room temperature.

11. Packaging Storage: Packaging is stored at room temperature.

Curd Making
Before cheesemaking, the pH meter is calibrated. All equipment and utensils are inspected for cleanliness, recleaned if needed, and sanitized, according to the appropriate SSOP or Prerequisite Program. Cheesemaking procedures, monitoring activities, analytical measurements, and records are described in the SOP.

12. Preheat Milk: Milk is preheated to 90°F using a plate heat exchanger.

13. Milk into Cheese Vat: Milk is pumped into the sanitized vat.

14. Add Culture and Ripen: Cultures are added within 30 mins of putting milk into the vat. Calcium chloride is diluted in water and added to the vat.

15. Add Rennet and Set Curd: Rennet is diluted in cool water immediately prior to use and added to the vat. Curd is set for 20-30 mins.

16. -19. Cut, Stir, and Cook Curd: Curd is cut, healed, and stirred. Half of the whey is drained and replaced with water. Curd is cooked to 95°F.

Draining, Molding, and Pressing

All equipment and utensils are sanitized before use and maintained using Prerequisite Programs. All personnel follow GMPs and hygienic product handling practices. Procedures are described in the SOP.

20. Drain Whey: Whey is drained into whey drainage tank.

21. Add Seasoning: Curd is seasoned by hand with spice blend and mixed using shovels.

22. Mold: Curd is scooped from vat by hand into hoops to form 10-lb wheels.

23. Press: Curd is pressed according to the SOP at room temperature.

24. -25. Demold and Transport to Aging Room: Wheels are removed from hoops by hand onto trays. Trays are fully covered using sanitized plastic covers and carried to adjacent aging room. Target pH is 5.4.

Brining and Aging

26. -28. Brine: Saturated brine is mixed using water and salt. Brine mineral content and pH are adjusted using calcium chloride and lactic acid. Cheeses are brined for 2 days in a brine tank in the aging room at 59°F. The brine is managed using a brine SOP and maintenance program.

29. -30. Dry and Coat: Cheeses are removed from brine onto sanitized plastic racks to air-dry for 6-12 hours in the aging room at 59°F. Wheels are coated in warm Plasticoat® using a roller.

31. Age: Cheeses are aged at a temperature of 59°F for 4 weeks. They are then moved to a second aging room and aged for a minimum of 6 months at 35°F or higher. Cheeses are aged on wooden boards, which are cleaned, dried, and inspected prior to use, and managed using a Prerequisite Program. Wheels are flipped by hand every 2-3 days.

Packaging and Distribution

32. -33. Cut/Portion, and Package: Cheese is cut into ½-lb wedges using a sanitized knife and cutting board, and vacuum packaged in high-density polyethylene bags. Labels are reviewed for correct ingredients and allergen statements, and applied to the wedges. Lot number is added to label using permanent marker.

34. Store: Cheese is stored in a refrigerator < 41°F.

35. Distribute: Cheese is kept < 41°F during distribution. Cheeses for distribution at farmers markets are kept in a cooler with wet ice. Cheese for wholesale distribution is packed with cold packs in shipping coolers.

Hazard Analysis

This teaching example is for a raw milk cheese that does not have a validated kill step, such as pasteurization. In order to completely control biological hazards, a validation study, including critical limits to control pathogen growth, would need to be completed for each specific cheesemaker's process. In the absence of a scientifically validated study, complete risk control is not achievable. Instead, the cheesemaker must rely on the combined effect of the following hurdles:

- Raw milk that is managed using supply chain controls
- Competitive inhibition from cheese cultures
- Aging at a minimum of 35°F for at least 60 days per CFR Title 7 Part 58.439: Cheese from Unpasteurized Milk (Ref: 11)
- Cheese composition (salt, moisture content, pH)
- Manufacturing and packaging environment that is managed using sanitation controls and environmental monitoring

All equipment and utensils used in the cheese make are sanitized *before* processing begins. For processing steps relying on sanitation controls, the preventive control is applied before the step requiring it occurs (see column 6 in the hazard analysis table below). When environmental monitoring is used as a sanitation control, monitoring is ongoing, but not necessarily applied at the step requiring control.

Highlighted rows denote examples where two different approaches can be used to manage a hazard. It is up to the cheesemaker to select the method most appropriate to their facility, practices, and product.

(1) Ingredient/processing step	(2) Identify *potential* food safety hazards introduced, controlled or enhanced at this step	(3) Do any 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?	(6) Is the Preventive Control applied at this step?
1. Receive Raw Milk	***B:** Presence of vegetative pathogens	Yes	Scientific studies have shown that a wide range of pathogens can be present in unpasteurized milk. Ref: 14	**Supply-Chain Control:** Milk purchased from an independent supplier is free from pathogens *(This is a crucial control to reduce risk in a nonvalidated process.)*	Yes
	***B:** Presence of vegetative pathogens	Yes	Scientific studies have shown that a wide range of pathogens can be present in unpasteurized milk. Ref: 14	**Supply-Chain Control:** Milk sourced from the cheesemaker's own farm is collected following best practices in the PMO *(This is a crucial control to reduce risk in a nonvalidated process.)*	Yes
	B: Contamination with vegetative pathogens	Yes	Unsanitary conditions in the milk receiving area may cause contamination. Ref: 14, 21	**Sanitation Control:** Milk receiving sanitation	Yes
	C: Presence of antibiotic residues	Yes	Dairy farmers treat sick dairy cattle with various drugs and residues may be present in raw milk Ref: 14	**Process Control:** PMO Appendix N testing for drug residues	Yes
	C: Presence of mycotoxins	Yes	Aflatoxin has been shown to be present in raw milk due to mold growth in animal feed. Ref: 8, 12	**Supply-Chain Control:** Milk is free from mycotoxins	Yes
	C: Presence of mycotoxins	No	Mycotoxins are not a problem in my area.		

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1. Receive Raw Milk	**C:** Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on equipment. Ref: 14, 22		
	C: Allergen	Yes	Milk is an allergen. Ref: 9, 24	**Allergen Control:** Finished product label review; label includes "Contains: Milk"	No
	C: Radiological	No	Plant is not sited near a radiological hazard. Ref: 15		
	P: Foreign materials	No	Prerequisite programs for equipment and utensils prevent metal fragments. Milk receiving SOP includes use of a filter. Ref: 10		
2. Receive Frozen Ingredients (cultures)	**B:** None				
	C: None				
	P: None				
3. Receive Refrigerated Ingredients (rennet)	**B:** None				
	C: None				
	P: None				
4. Receive Water	**B:** Pathogens	No	Prerequisite program for water safety. Ref: 14		
	C: Toxic chemicals	No	Prerequisite program for water safety. Ref: 14		
	C: Radiological	No	Plant is not sited near a radiological hazard. Ref: 15		

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	P: None				
5. Receive Shelf-Stable Ingredients (salt, calcium chloride, black pepper, dried herbs)	**B:** Presence of pathogens	Yes	Dry seasonings, including pepper and dried herbs, have been associated with pathogens such as *Salmonella.* Ref: 12, 16, 20 .	**Supply-Chain Control:** Seasonings are free from pathogens	Yes
	C: Toxic chemicals	Yes	Adulteration of seasonings with toxic chemicals, including heavy metals and pesticide residues, has been documented. Ref: 26	**Supply-Chain Control:** Seasonings are free from toxic chemicals	Yes
	C: Allergens	Yes	Some ingredients may contain allergens or may have been processed in facilities with allergens.	**Allergen Control:** Finished product label review	No
	C: Allergens	Yes	Some ingredients may contain allergens or may have been processed in facilities with allergens.	**Supply-Chain Control:** Review allergen statement from supplier	Yes
	P: Foreign materials	Yes	Seasonings may have foreign material. Ref: 10	**Supply-Chain Control:** Seasonings free from foreign material	Yes
6. Receive Packaging Materials and Labels	**B:** None				
	C: Allergen	Yes	Milk is a known allergen	**Allergen Control:** Review incoming labels for allergen statement	Yes
	P: Foreign materials	No	Receiving SOP include inspection for presence of foreign materials or damaged packaging materials.		

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7. Store Raw Milk	***B:** Contamination with vegetative pathogens	Yes	Milk can be contaminated by unclean storage vessels. Ref: 14	**Sanitation Control:** Sanitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by equipment.		
	B: Growth of vegetative pathogens	Yes	Without proper temperature controls, vegetative pathogens can multiply. Ref: 14	**Process Control:** Milk storage tank temperature control	Yes
	C: Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on equipment. Ref: 14, 22		
	P: None				
8. Frozen Storage (cultures)	**B:** None				
	C: None				
	P: None				
9. Refrigerated Storage (rennet)	**B:** None				
	C: None				
	P: None				

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10. Shelf-Stable Storage (salt, calcium chloride, seasonings)	**B:** None				
	C: Allergen cross-contact	Yes	Allergens that may be present in seasonings may contaminate other ingredients (if using ingredients with allergens) Ref: 9, 24	**Allergen Control:** Prevent cross-contact	Yes
	P: None				
11. Packaging Storage	**B:** None				
	C: None				
	P: None				
12. Preheat Milk	***B:** Contamination with vegetative pathogens	Yes	Milk can be contaminated by unclean equipment or utensils. Ref: 14	**Sanitation Control:** Sanitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	SOP for plate heat exchanger includes necessary sanitation steps to prevent contamination.		
	B: Growth of vegetative pathogens	Yes	Potential for pathogen growth if held for long times at warm temperatures Ref: 20, 23	**Process Control:** SOP for cheesemaking has time and temperature limits	Yes
	C: Boiler additives	No	Preventive maintenance program for plate heat exchanger prevents leaks and approved boiler additives are used. Ref: 13, 14		
	P: None				

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13. Milk into Cheese Vat	***B:** Contamination with vegetative pathogens	Yes	Milk can be contaminated by unclean equipment or utensils. Ref: 14, 22	**Sanitation Control:** Sanitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by unclean equipment.		
	B: Contamination with vegetative pathogens	Yes	Pathogens have been known to be present in cheesemaking environments. Vat is open to environment. Ref: 3	**Sanitation Controls:** Hygienic zoning, environmental monitoring	No
	B: Growth of vegetative pathogens and toxin production	Yes	Potential for pathogen growth if held for long times at warm temperatures Ref: 20, 23	**Process Control:** SOP for cheesemaking has time and temperature limits	Yes
	C: Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on equipment. Ref: 14, 22		
	P: None				

Steps 14–20 take place in the cheese vat.

14. Add Culture and Ripen	***B:** Contamination with vegetative pathogens	Yes	Milk can be contaminated by unclean equipment or utensils. Ref: 14, 22	**Sanitation Control:** Sanitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by unclean utensils.		

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14. Add Culture and Ripen	**B:** Growth of vegetative pathogens	Yes	Cheesemaking conditions are conducive to pathogen growth. Ref: 5, 20, 23	**Process Control:** SOP for cheesemaking has time and temperature limits for proper acidification *(This is a crucial control to reduce risk in a nonvalidated process.)*	Yes
	B: Toxin production by vegetative pathogens	Yes	Cheesemaking conditions are conducive to production of bacterial toxins Ref: 1, 5	**Process Control:** SOP for cheesemaking has time and temperature limits for proper acidification	Yes
	C: Cleaning and sanitizing resid	No	SSOPs ensure excess residues do not remain on utensils. Ref: 14, 22		
	P: None				
15. Add Rennet and Set Curd	***B:** Contamination with vegetative pathogens	Yes	Milk can be contaminated by unclean equipment or utensils. Ref: 14, 22	**Sanitation Control:** Sanitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by unclean utensils.		
	C: None				
	P: None				

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16. Cut Curd	***B:** Contamination with vegetative pathogens	Yes	Curd can be contaminated by unclean equipment or utensils. Ref: 14, 23	**Sanitation Control:** Sanitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by unclean utensils.		
	C: Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on utensils. Ref: 14, 22		
	***P:** Metal pieces	Yes	Wire pieces from cheese knives have been known to break off into vat during cutting. Ref: 10	**Process Control:** Visual inspection of cheese knives/harps before and after cutting	Yes
	***P:** Metal pieces	No	Prerequisite programs for equipment and utensils ensure cheese knife/ harp integrity. Ref: 10		
17. Stir Curd	***B:** Contamination with vegetative pathogens	Yes	Curd can be contaminated by unclean equipment or utensils. Ref: 14, 22	**Sanitation Control:** Sanitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by unclean utensils.		
	B: Growth of vegetative pathogens	Yes	Cheesemaking conditions are conducive to pathogen growth. Ref: 5, 20, 23	**Process Control:** SOP for cheesemaking has time and temperature limits for proper acidification	Yes

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17. Stir Curd	**C:** Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on utensils. Ref: 14, 23		
	P: None				
18. Add Water/Partial Drain	**B:** Contamination with vegetative pathogens	No	Prerequisite program for water safety.		
	C: Toxic chemicals	No	Prerequisite program for water safety.		
	P: None				
19. Cook Curd	**B:** Growth of vegetative pathogens	Yes	Cheesemaking conditions are conducive to pathogen growth. Ref: 5, 20, 23	**Process Control:** SOP for cheesemaking has time and temperature limits for proper acidification	Yes
	C: None				
	P: None				
20. Drain Whey	**B:** None				
	C: None				
	P: None				
21. Add Seasoning	***B:** Contamination with vegetative pathogens	Yes	Curd can be contaminated by unclean equipment or utensils. Ref: 14, 22	**Sanitation Control: S**anitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by unclean utensils.		

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21. Add Seasoning	**C:** Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on utensils. Ref: 14, 23		
	P: None				
22. Mold/Hoop	***B:** Contamination with vegetative pathogens	Yes	Cheese can be contaminated by unclean equipment or utensils. Ref: 14, 23	**Sanitation Control:** Sanitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by unclean utensils.		
	C: Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on utensils. Ref: 14, 23		
	P: Foreign materials	No	Prerequisite programs for equipment and utensils and routine inspection of molds prevent shards.		
23. Press	***B:** Contamination with vegetative pathogens	Yes	Cheese can be contaminated by unclean equipment or utensils. Ref: 14, 23	**Sanitation Control: S**anitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by unclean equipment.		
	B: Growth of vegetative pathogens	Yes	Cheesemaking conditions are conducive to pathogen growth. Ref: 5, 20, 23	**Process Control:** SOP for cheesemaking has time and temperature limits for proper acidification	Yes

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23. Press	**C:** Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on equipment. Ref: 14, 23		
	P: Foreign materials	No	Prerequisite programs for equipment and utensils and routine inspection of press prevent fragments.		
24. Demold	**B:** Contamination with vegetative pathogens	No	GMPs prevent contamination by personnel.		
	C: Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on equipment or utensils. Ref: 14, 20		
	P: None				
25. Transport to Aging Room	***B:** Contamination with vegetative pathogens	Yes	Cheese can be contaminated by personnel, transport containers, or carts. Ref: 14, 23	**Sanitation Control:** Sanitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by unclean equipment.		
	B: Contamination with vegetative pathogens	Yes	Cross-contamination from environmental pathogen. Ref: 3, 20	**Sanitation Control:** Environmental monitoring	No
	C: None				
	P: None				

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26. Mix Brine	**B:** Contamination with vegetative pathogens	No	Prerequisite programs for equipment and utensil sanitation and brine SOP prevent contamination by unclean utensils.		
	B: Contamination with vegetative pathogens	Yes	Cross-contamination from environmental pathogen. Ref: 3, 20	**Sanitation Control:** Environmental monitoring	No
	C: None				
	P: None				
27. Adjust Brine	**B:** None				
	***C:** Brine adjustment chemicals	Yes	Chemicals are used for brine acidification, neutralization, or mineral adjustment.	**Process Control:** Follow brine SOP for proper chemical use concentrations	Yes
	***C:** Brine adjustment chemicals	No	Prerequisite program for brine maintenance includes proper chemical use concentrations.		
	P: None				
28. Brine Cheese	**B:** Contamination with vegetative pathogens from brine	No	*Listeria monocytogenes* has been shown to be capable of growing in saturated brine solutions. Ref: 18, 19, 20, 27. Contamination from brine is controlled by Prerequisite Program for brine maintenance.		

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28. Brine Cheese	**B:** Contamination with vegetative pathogens from environment	Yes	Cross-contamination from environmental pathogen. Ref: 3, 20	**Sanitation Control:** Environmental monitoring, hygienic zoning	No
	B: Survival of vegetative pathogens in the cheese	Yes	Adding salt to cheese is one hurdle needed to limit the growth of vegetative pathogens.	**Process Control:** Cheese is brined for the proper time in brine at the proper salt concentration following the cheese SOP *(This is a crucial control to reduce risk in a nonvalidated process.)*	Yes
	C: None				
	P: None				
29. Air-Dry	**B:** Contamination with vegetative pathogens	Yes	Cross-contamination from environmental pathogen Ref: 3, 20	**Sanitation Control:** Environmental monitoring	No
	C: None				
	P: None				
30. Wax or Coat	**B:** Contamination with vegetative pathogens	No	SOP for coating cheese includes raising Plasticoat® temperature to above 225°F. Ref: 20, 27		
	C: None				
	P: None				

(1) Ingredient/processing step	(2) Identify *potential* food safety hazards introduced, controlled or enhanced at this step	(3) Do any 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?	(6) Is the Preventive Control applied at this step?
31. Age	***B:** Contamination with vegetative pathogens	Yes	Cross-contamination of pathogens from aging shelves. Ref: 20	**Sanitation Control:** Sanitation of aging room shelves	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for wooden aging board maintenance prevents contamination by unclean shelves.		
	B: Contamination with vegetative pathogens	Yes	Cross-contamination from environmental pathogen. Ref: 3, 20	**Sanitation Control:** Environmental monitoring	No
	B: Contamination with vegetative pathogens	No	GMPs prevent contamination from personnel handling cheese.		

*Highlighted rows denote examples where two different approaches can be used to manage a hazard. It is up to the cheesemaker to select the method most appropriate to their facility, practices, and product.

(1) Ingredient/processing step	(2) Identify *potential* food safety hazards introduced, controlled or enhanced at this step	(3) Do any 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?	(6) Is the Preventive Control applied at this step?
31. Age	**B:** Survival of vegetative pathogens	Yes	Pathogens are known to survive in aged raw milk cheese. Ref: 2, 4, 7, 11, 25, 27. Aging gouda has been shown to decrease viable counts of some pathogens. Ref: 6. The aging time and temperature process controls meet or exceed those required by the CFR for cheese made using unpasteurized milk. Additional hurdles to pathogen survival include the salt content, moisture content, low pH, competitive inhibition from cheese cultures, and reduced likelihood of contamination due to sanitation and supply chain controls.	**Process Control** (nonvalidated): Cheese is aged at a minimum of 35°F for at least 6 months *(This is a crucial control to reduce risk in a nonvalidated process.)*	Yes
	C: Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on utensils. Ref: 14, 20		
	***P:** Splinters	Yes	Poorly maintained wood boards may have splinters.	**Process Control:** Visual inspection of shelves	Yes
	***P:** Splinters	No	Prerequisite program for wooden aging board maintenance prevents use of damaged boards.		

*Highlighted rows denote examples where two different approaches can be used to manage a hazard. It is up to the cheesemaker to select the method most appropriate to their facility, practices, and product.

(1) Ingredient/processing step	(2) Identify *potential* food safety hazards introduced, controlled or enhanced at this step	(3) Do any 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?	(6) Is the Preventive Control applied at this step?
32. Cut/Portion	***B:** Contamination with vegetative pathogens	Yes	Cheese can be contaminated by unclean equipment or utensils. Ref: 14, 23	**Sanitation Control:** Sanitation of equipment and utensils	No
	***B:** Contamination with vegetative pathogens	No	Prerequisite program for equipment and utensil sanitation prevents contamination by unclean utensils.		
	B: Contamination with vegetative pathogens	Yes	Cross-contamination from environmental pathogen. Ref: 3, 17, 20	**Sanitation Control:** Environmental monitoring	No
	C: Cleaning and sanitizing residues	No	SSOPs ensure excess residues do not remain on utensils. Ref: 14, 20		
	***P:** Metal pieces	Yes	Pieces from knives have been known to break off during cutting.	**Process Control:** Visual inspection of knives before and after cutting	Yes
	***P:** Metal pieces	No	Prerequisite programs for equipment and utensils prevent risk of broken knife pieces.		
33. Package	**B:** Contamination with pathogens	Yes	Pathogens in the environment may contaminate cheese surface. Ref: 3, 20	**Sanitation Control:** Environmental monitoring	No
	C: Allergen	Yes	Milk is a known allergen. Ref: 9, 24	**Allergen Control:** Finished product label review; label includes “Contains: Milk”	Yes
	P: None				

*Highlighted rows denote examples where two different approaches can be used to manage a hazard. It is up to the cheesemaker to select the method most appropriate to their facility, practices, and product.

(1) Ingredient/processing step	(2) Identify *potential* food safety hazards introduced, controlled or enhanced at this step	(3) Do any 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?	(6) Is the Preventive Control applied at this step?
34. Store Cheese	**B:** None				
	C: None				
	P: None				
35. Distribute Cheese	**B:** Contamination with vegetative pathogens	No	Prerequisite program for self-distribution temperature control and sanitation; use approved distributors; packaging is inspected for damage. Ref: 14, 20		
	C: None				
	P: None				

Process Preventive Controls

Process Control Steps	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
PMO Appendix N testing for drug residues	**C:** Presence of therapeutic drugs (antibiotic residues)	Not found (NF)	Raw milk	Sample using approved techniques Test using validated methods and kit	Every delivery	Certified lab analyst	Reject lot Notify regulatory authority Follow PMO Appendix N Document corrective action	Calibration of drug residue testing equipment with +/- controls (daily, on days testing)	Test result records Calibration records Validated test methods (provided by test kit supplier)
Milk storage tank temperature control	**B:** Growth of vegetative pathogens	≤ 45°F	All milk stored in bulk milk tank	Continuous chart recorder	Continuous	Trained employee	Place product on hold Based on time milk was outside of critical limit, evaluate suitability for cheesemaking Determine root cause of temperature deviation and correct	Review temperature charts weekly Calibrate thermometers quarterly	Tank temperature charts Thermometer calibration records

Process Control Steps	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
							Document corrective action		
SOP for cheesemaking has time and temperature limits for proper acidification	**B:** Growth of vegetative pathogens	Time, temperature, and pH limits specified in cheesemaking SOP	Time Temperature pH	Clock Calibrated thermometer Calibrated pH meter	Measure during each step specified in cheese make SOP and on make sheet	Trained employee	Place product on hold Assess product safety through pathogen testing and determine disposition Determine root cause and correct Document corrective action	Review make sheets weekly Calibrate thermometers quarterly Calibrate pH meter daily	Cheese make sheet Thermometer calibration records Cheese make sheet includes checkbox for pH meter calibration
SOP for cheesemaking has time and temperature limits for proper acidification	**B:** Bacterial toxin production	Time, temperature, and pH limits specified in cheesemaking SOP	Time Temperature pH	Clock Calibrated thermometer Calibrated pH meter	Measure during each step specified in cheese make SOP and on make sheet	Trained employee	Place product on hold Assess product safety through toxin testing and determine disposition	Review make sheets weekly Calibrate thermometers quarterly Calibrate pH meter daily	Cheese make sheet Thermometer calibration records Cheese make sheet includes checkbox for pH meter calibration

Process Control Steps	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
							Determine root cause and correct Document corrective action		
Visual inspection of cheese knives/harps before and after cutting	**P:** Metal pieces	Cheese knives/harps are whole and intact No sharp edges or missing pieces are observed	Cheese knives/harps	Visual inspection of knives/harps for damage, missing pieces, or broken parts	Before and after use	Trained employee	If knife/harp fails visual inspection before use, replace or repair knife/harp If knife/harp fails visual inspection after use, place product on hold until damage is assessed and replace or repair knife/harp Document corrective action	Follow preventive maintenance program for equipment and utensils Review make sheets weekly	Initial box on cheese make sheet that knives/harps were inspected before and after use

Process Control Steps	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Follow brine SOP for proper chemical use concentrations	**C:** Brine adjustment chemicals	pH matches brine SOP limits Brine salt concentration matches brine SOP limits If using saturated brine, salt crystals are visible	All brines	Calibrated pH meter Salometer or visual check for salt crystals	Every time fresh brine is made and as specified in Prerequisite Program for brine maintenance schedule	Trained employee	Review concentration calculation and dilute or add chemicals to get to proper pH and concentration	Calibrate pH meter daily Review brine logs monthly	Brine log
Cheese is brined for the proper time in brine at the proper salt concentration following the cheese SOP	**B:** Survival of vegetative pathogens in the cheese	Time in brine matches cheese SOP limits Brine salt concentration matches cheese SOP limits	Time in brine Brine salt concentration	Clock Salometer or visual check for salt crystals	Every time cheese is added to and removed from brine	Trained employee	Place product on hold Assess product by testing cheese salt concentration and assess safety through pathogen testing Determine root cause and correct	Review make sheets weekly Review brine logs monthly	Cheese make sheet Brine log

Process Control Steps	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
							Document corrective action		
Cheese is aged at a minimum of 35°F for at least 6 months	**B:** Survival of vegetative pathogens	Aging cooler ≥35°F Cheese aged at least 180 days	Aging cooler	Calibrated thermometer	Daily	Trained employee	Place product on hold Assess product safety through pathogen testing and based on time and temperature below 35°F Determine root cause and correct Document corrective action	Review aging records weekly Calibrate thermometers quarterly	Cheese aging records Thermometer calibration records

Process Control Steps	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Visual inspection of knives before and after cutting	**P:** Metal pieces	Knives are whole and intact No sharp edges or missing pieces are observed	Knives	Visual inspection of knives for damage, missing pieces, or broken parts	Before and after use	Trained employee	If knife fails visual inspection before use, replace or repair knife If knife fails visual inspection after use, place product on hold until damage is assessed and replace or repair knife Document corrective action	Follow preventive maintenance program for equipment and utensils Review make sheets weekly	Initial box on cheese make sheet that knives were inspected before and after use
Visual inspection of wood shelves	**P:** Splinters	Wood shelf is whole and intact No splinters, sharp edges, or missing pieces are observed	Cheese Wood aging shelves	Visual inspection of wood shelves and cheese for splinters, sharp edges, or missing pieces	Each time a board is cleaned and before cheese is placed on it	Trained employee	Place product on hold until damage is assessed Replace shelves Document corrective action	Follow Prerequisite Program for wooden aging board maintenance Review aging records weekly	Cheese aging records

Food Allergen Preventive Controls

Allergen Verification Listing

Product	Allergen Statement
Raw Milk Gouda	"Contains: Milk"
Pepper and Herb Raw Milk Gouda	"Contains: Milk"

Allergen Scheduling and Cleaning Implications

Production Line Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shellfish
Raw Milk Gouda	1		✓						
Pepper and Herb Raw Milk Gouda	1		✓						

Scheduling Implications

All products contain milk; no special production schedule required.

Allergen Cleaning Implications

All products contain milk; no special sanitation controls required.

Allergen Controls

Allergen Control Step	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Finished product label review	**C:** Allergen: milk	All products are labeled with "Contains: Milk" below ingredient statement	Packaged product	Review labels on packages as product is packaged	At beginning of packaging for every lot	Trained employee	Place product on hold Relabel product with correct label Determine cause of wrong label and correct Document corrective action	Packaging records reviewed weekly	Packaging records
Review incoming labels for allergen statement	**C:** Allergen: milk	All labels include "Contains: Milk" below ingredient statement	Incoming labels	Review labels during receiving	Every time labels are received	Trained employee	Determine cause of wrong label and correct Document corrective action	Receiving records reviewed weekly	Receiving records
Prevent cross-contact	**C:** Allergen cross-contact	All ingredients containing allergens are stored in such a way as to prevent cross-contact	Dry ingredient storage	Visual inspection of dry storage—ingredients containing allergens are segregated and below other ingredients	Every time newly received ingredients are put in dry storage	Trained employee	Move misplaced ingredients Determine cause of misplacement and correct Document corrective action	Receiving records reviewed weekly	Receiving records

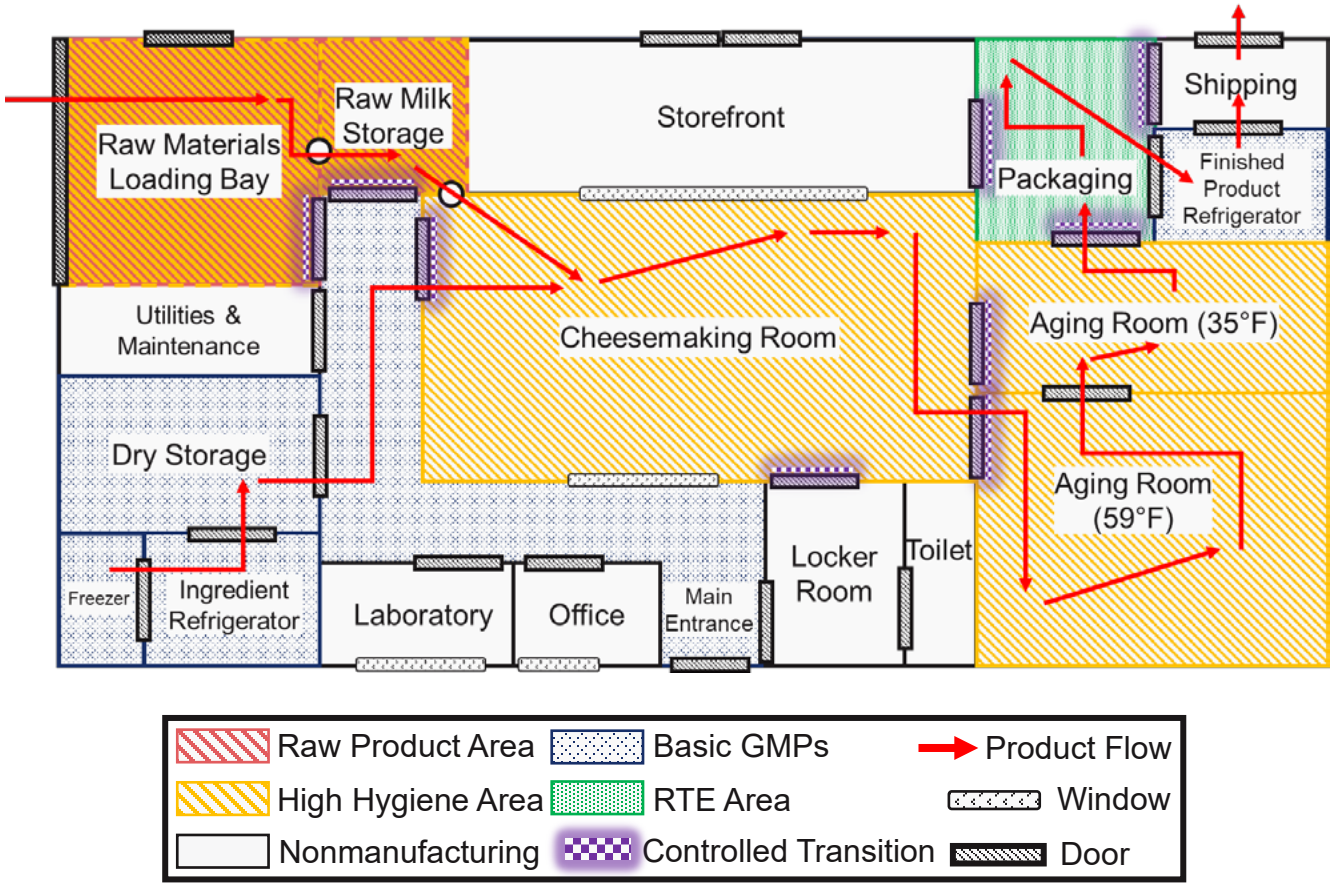
Sanitation Preventive Controls

Cleaning and Sanitizing Procedure

Location	Cheesemaking room
Purpose	Sanitize all cheesemaking equipment and utensils prior to cheesemaking
Frequency	Daily, on cheesemaking days
Who	Cheesemaker or trained employee
Procedure	Follow all relevant SSOPs
Monitoring	Visually inspect surfaces for cleanliness; test sanitizer strength before use
Corrections	Reclean surfaces that are not visually clean; remix sanitizer if strength is not at levels listed in SSOP
Records	Initial box on cheese make sheet that equipment and utensils were sanitized prior to use
Verification Activities	Review make sheets weekly

Hygienic Zoning

Hygienic Zone Map



Who

Trained employee

Procedures

Basic GMP Areas:
Dry Storage, Freezer, Refrigerated Storage, Hallways

Purpose: To prevent contamination of storage and transition areas

Procedure: Wear hairnets and beard nets (where applicable), and wash hands with soap and water

Frequency: Hands are washed every time area is entered or exited, after coughing or sneezing, between activities, and any time they become soiled

Raw Product and High Hygiene Areas:
Raw Materials Loading Bay, Raw Milk Storage, Cheesemaking Room, and Aging Room

Purpose: To keep raw milk free from contaminants as it will be used to make cheese without undergoing pasteurization; to prevent contamination of cheese as it is being made and aged

Procedure: Prior to entering, put on a clean lab coat, clean boots that are only worn in the cheese plant, hairnets and beard nets (where applicable), and wash hands with soap and water; pass through foot bath every time entering or exiting area

Frequency: Lab coats are changed daily; hands are washed every time area is entered or exited, after coughing or sneezing, between activities, and any time they become soiled

RTE Areas:
Packaging

Purpose: To protect finished product from contamination

Procedure: In addition to following all procedures for high hygiene areas, put on a clean, single-use plastic apron, only used in RTE areas

Frequency: Single-use plastic aprons are replaced every time RTE area is entered or when they become soiled

Nonmanufacturing Areas:
Utilities and Maintenance, Laboratory, Toilet, Locker Room, Office, Shipping, Storefront

Purpose: To prevent contamination from nonmanufacturing areas

Procedure: Wear clean clothes and practice basic hygiene

Frequency: Hands are washed after eating or using the toilet

Monitoring

Head cheesemaker or supervisor visually observes employees and visitors at beginning of shift and throughout the day, as appropriate.

Corrections

Instruct employees and visitors to comply with procedures for the hygienic zoning area. This may include instructing personnel to change into proper clothing and shoes, don hairnets, and wash their hands. Retrain personnel if needed.

Records

Personnel training log.

Verification Activities

Train all new employees on hygienic zoning procedures. Retrain all employees annually.

Environmental Monitoring for Sanitation Control Verification

Purpose	
Sample Identification	
Sampling Procedure	
Laboratory	
Test Conducted	
Interpretation of Results	
Action of a Negative Result	
Corrective Action for a Positive Result	

Supply-Chain-Applied Preventive Controls

Verification Procedures for Supply-Chain-Applied Control Ingredients

Raw Milk

Hazards Requiring a Supply-Chain-Applied Control	**B:** Presence of vegetative pathogens
Preventive Controls Applied by the Supplier	**Process Controls:** animal health and mastitis monitored **Sanitation Controls:** milking SOP is followed and includes teat dip; cows are visually inspected for cleanliness prior to milking
Verification Activities and Procedures	Review of monthly milk testing records for pathogens; environmental monitoring of milking parlor; on-farm audits
Records	Milking sanitation records, animal health records and corrective actions, milk test records, milking parlor environmental monitoring records, on-farm audit records

Seasonings (Pepper, Herbs)

Hazards Requiring a Supply-Chain-Applied Control	**B:** Presence of vegetative pathogens **C:** Toxic chemicals **C:** Allergens **P:** Foreign materials
Preventive Controls Applied by the Supplier	**Process Control:** Black pepper and herbs are irradiated
Verification Activities and Procedures	Receipt and review of COA with each shipment
Records	COA

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