

The American Cheese Society's

Best Practices Guide for Cheesemakers

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Best Practices Guide for Cheesemakers

Introduction

In 2016, the American Cheese Society (ACS) released its Best Practices Guide for Cheesemakers (Guide). Its completion was a key strategic goal of the Board of Directors, and the central task with which the Regulatory & Academic Committee had been charged. ACS members requested such a resource, and by way of response, this Guide was created to encompass currently accepted best practices for cheesemaking. This second edition of the Guide includes updates based on changing regulations, incorporates direct feedback and clarification from reviewers at the U.S. Food & Drug Administration, and provides more current resources and templates where available.

This Guide provides an easy reference for busy cheesemakers—especially small- to mid-size producers—one which can be readily accessed. Regulatory agencies and academics provide information in great detail, but it is often buried within volumes of text. This Guide gleans the key requirements, suggestions, and practices from that vast sea of information, and attempts to condense them into a more easily digestible format written in more accessible language. I hope you will find that the information provided in this Guide is useful and answers some of your key questions.

Please keep in mind that this is not a static document. The Guide will continually grow and change based on feedback from members, academics, regulators, and others. It takes everyone's input to keep this document up-to-date and accurate. As part of the cheese community, we rely on you to share insights, information, and suggestions that will enhance the Guide, and in turn, enhance cheese quality and safety. The ACS Regulatory & Academic Committee will review and update the Guide accordingly, publishing updates as needed to keep up with changing regulations and scientific advances. Please send me your comments anytime at nweiser@cheesesociety.org.

Sincerely,

A handwritten signature in blue ink, appearing to read "Nora Weiser".

Nora Weiser
Executive Director

Acknowledgements

There are dozens of industry experts who generously gave of their time to aid in the development of this Guide, and while we have attempted to compile a comprehensive list of those who assisted with this project, if anyone was inadvertently omitted, please let us know and we will amend the oversight right away. Sincere thanks and gratitude go out to all those who helped in the creation of this Guide.

Of particular note are the following ACS leaders. Their contribution cannot be overstated, and this Guide would not exist without their commitment of time and expertise over these past few years:

Jeff Jirik of Caves of Faribault/Swiss Valley Farms, Dick Roe of Gourmet Foods International, Peggy Smith of Cowgirl Creamery, and Greg O'Neill of Pastoral Artisan Cheese, Bread & Wine served as presidents of ACS during the time the Guide was in development.

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About the ACS Best Practices Guide for Cheesemakers

This document was compiled and prepared for the American Cheese Society (ACS) by a wide-ranging group of industry experts under the aegis of the ACS Regulatory & Academic Committee. It is an original compilation of current regulatory requirements and generally accepted best practices for small- to mid-size cheesemakers in the United States, with information gleaned from existing, trusted sources based on real-world cheesemaking practices and scientific research. As such, content has been modified and restructured as needed to ensure clarity and ease-of-use for busy cheesemakers. Each chapter includes references and resources to credit original sources, and there is no intent to imply ownership of the work of others.

Where available, regulations were cited directly, with an effort made to provide useable information in an easy to understand format. Contributions and materials came from volunteers throughout the cheese industry, and references, citations, original source documents, and credit have been given wherever provided/known. As a document created by volunteers to aid members of a non-profit organization, the document was developed in good faith and is intended to grow, change, and evolve over time. The contents of this document are not intended as legal or regulatory advice. The contents are also in no way to be construed as all-encompassing or complete; omissions are to be expected.

Good Faith Effort

The document is presented in good faith to provide information that might aid American cheesemakers in producing better, safer cheeses that meet or exceed current regulatory standards. Any errors, omissions, misstatements, inaccuracies, misattributions, subjectivity, suggested practices, and/or other erroneous items are unintentional and will be amended, corrected, removed, annotated, cited, and/or credited wherever such errors are found and duly noted to ACS.

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Changes or Additions

Suggested changes or additions should be addressed to the ACS Regulatory & Academic Committee via ACS Executive Director, Nora Weiser:
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Chapter 1 On-Farm Milk Production

The production of high quality milk is essential for producing safe, high quality cheese. The cheese may be produced from milk of a single herd, multiple herds, or blended from different species. The Pasteurized Milk Ordinance (PMO) defines milk as:

Milk is the lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy cows, goats, sheep, water buffalo, and other hooved mammals¹.

Please note that the PMO definition of milk may become state law where it is adopted as such. The *Codex Alimentarius* provides more information about milk and milk quality in the “Milk and Milk Products, CAC/RCP 57-2004.”²

The legal definition of milk as it relates to cheese manufacture is found within the Code of Federal Regulations 21 C.F.R. § 133.3(a)³:

Milk means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, reconstituted milk, and dry whole milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

Variations of this definition, such as the inclusion of additional milking species, are found within subpart B 21 C.F.R. § 133.3(a): with the individual standards of identity for each named cheese.

Milk is considered adulterated if it contains a foreign substance, foreign material, objectionable odors, or an abnormal appearance or consistency. Water, salts, and added fats and solids are considered adulterants.

Safe levels and tolerance limits including maximum residue limits exist for chemical contaminants such as antibiotics, pesticides or herbicides, and cleaning solutions. US federal regulations define tolerance levels for antibiotics. Each processor receiving raw milk into their production area is required to have that load of milk tested for antibiotics. Common approved test kits typically test at, or around, these safe or tolerance levels.

When milk leaves the healthy udder of an animal, it is relatively free from bacteria. Some contamination occurs from the udder, milking environment, and equipment. The PMO bacterial limit for grade A raw milk is 100,000 per ml (milliliter), whereas, for grade

Raw milk has 300,000 per ml. Good milking practices achieve bacterial counts in the range of 1,000-10,000 per ml. In order to achieve a good bacterial standard for milk at the farm level, one must recognize the sources of contamination and understand how they can be controlled.

1.1 Design of Farm Buildings

The dairy barn and farm buildings have a direct impact on the production of good quality milk. On-farm processing facilities must take extra precautions to prevent cross-contamination from the farm. Livestock workers as well as other farm employees should not be allowed to enter the processing plant without showering and a complete change of clothes. Only dedicated footwear or boots should be allowed within the facility. Dedicated footwear is recommended for the processing facility, but disposable coverings may be used as an alternative option. All methods of footwear control should include walking through a sanitary footbath, foam, or crystals. This strict policy is needed in order to prevent pathogenic bacteria commonly found on a farm from getting into the processing plant. These bacteria (*Listeria monocytogenes*, *Salmonella enterohemorrhagic Escherichia coli*, *Campylobacter jejuni*, and others) are serious public health threats and every effort must be taken to minimize the introduction of such pathogens into a processing plant.

Other important elements to consider in the design of farm buildings:

- Animal housing must have good ventilation, adequate lighting, be kept in good repair, be free of rodents and birds, and be easily cleanable.
- Buildings should be designed to prevent cross-contamination between animal housing areas and milk handling/processing areas.
- Designs should take into account future expansion plans, if any. Designing farm buildings with future expansion in mind makes good sense. Most farmers find that, after a while, the original structures are too small for future needs and/or the needs to grow the business. If a building is originally designed and built with future expansion in mind, the expansion plans are much easier and less costly to implement.
- Designs should consider the future possibility of expanded milking.
- Walls, ceilings, floors, and gutters must be constructed and maintained so that they may be easily cleaned. In barns where the animals are housed, the construction should consist of cement that can be swept or scraped to remove manure and organic materials, metal siding that may be washed, or a poly-based dairy board. Wood may be used in physical support areas, taking care that it will not be used in areas that get wet.
- The milk house is an enclosed facility separate from the milking barn or parlor, where the milk is cooled or stored. It must be constructed in such a manner as to protect the milk supply from contamination.
- A training program for employees on steps to take to avoid contamination should be in place to prevent contamination from occurring. Training should include

preparing animals for milking, milking procedures, barn cleaning procedures, and steps necessary to prevent chemical hazards from contaminating the milk.

- The processing area should not be located near a hay barn or animal feed storage area where mold spores and dust are present, as they can contaminate the raw material and products. These areas may also contain and transmit contaminants including *L. monocytogenes*, *Bacillus* spp., and *Clostridium* spp., among others. It should also be located away from other sources of contamination such as manure handling or animal assembly areas. Regardless of location, all processing areas should be supplied with positive pressure filtered air. Food and Drug Administration (FDA) recommends that the air in areas where refrigerated ready-to-eat (RTE) foods are processed or exposed be filtered through High Efficiency Particle Air (HEPA) filters that have an efficiency of 99.97-99.99 percent at 0.3 micron⁴. If such filters are not possible, it is recommended that the final filter have an efficiency of at least 90-95 percent at 1 micron as rated in ASHRAE standard 52.2-2007.⁵ Chapter 8 of this guide has more information on sanitary processing rooms in the section 8.6, "Sanitary Cheesemaking Facilities."
- Water supply, water pressure, back flow prevention, and water heating facilities need to comply with current codes and regulations.
- Facilities should be designed to make cleaning and maintenance as easy as possible.
- Facilities should include toilet and hand washing and sanitizing stations to accommodate personal hygiene.

1.2 Animal Health

Animals in poor health can produce milk that contains human pathogens such as *Salmonella* spp. The major causative agents of mastitis such as *Streptococcus agalactiae* are not considered human pathogens. The presence of foodborne pathogens in milk is due to direct contact with contaminated sources in the dairy farm environment and to secretion from the udder of an infected animal. Outbreaks of disease in humans have been traced to the consumption of unpasteurized milk and consumption of several types of cheeses manufactured from unpasteurized milk.

Milking animals that appear to be producing abnormal milk in one or more quarters must be milked last or with separate equipment, and their milk must be discarded. If an animal consumes or is treated with antibiotics or other chemicals should be milked last or with separate equipment, and the milk should be discarded.

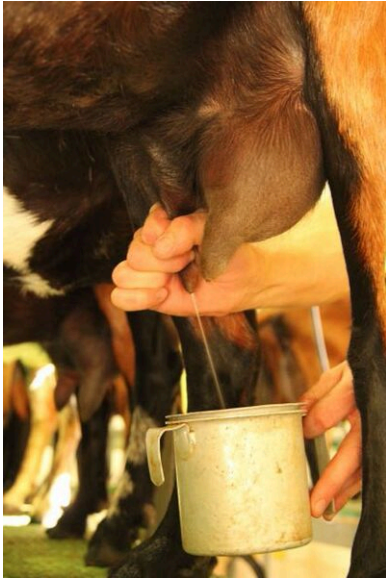


Figure 1.1: Arding, Kate. *Animal Health*. Collection of Kate Arding.

The use of a strip cup (*Figure 1.1*) will aid in the determination of abnormal milk. After squirting a stream of milk onto the fine mesh screen of the strip cup, look for flakes, lumps, strings or other signs of abnormal milk. The use of an unclean strip cup may spread bacteria leading to mastitis.

Somatic Cell Count (SCC) is one tool used to evaluate the condition of the animals' health. Increased SCC indicates increased inflammation, very likely caused by intra-mammary infection. Infection and disease are the result of failed milk production hygiene.

Figure 1.2. depicts the maximum permissible somatic cell counts by species as defined in the Pasteurized Milk Ordinance. These numbers represent herd amounts, not individual animals.⁶

Figure 1.2 Maximum Permissible Somatic Cell Counts

Species	Permitted Somatic Cells per ml
Cow	750,000
Sheep	750,000
Goat	1,500,000

The maximum acceptable SCC for cow's milk in the European Union (EU) is 400,000/ml. This standard should be kept in mind if a producer is exporting or might wish to export cheese in the future. There is no current intent to adopt lower standards than those that already exist in the United States.

As SCC increases, the bacterial count of the milk may also increase. Causative organisms of mastitis include (but are not limited to) major pathogens such as *Streptococcus agalactiae*, non-agalactiae Streptococci, *Staphylococcus aureus*, Corynebacteria, Mycoplasma and coliforms, including *Escherichia coli*, *Klebsiella spp.*, *Enterobacter spp.*, and *Citrobacter spp.* Human pathogens including *Listeria monocytogenes* may also cause mastitis as can Campylobacter species. Various studies in regards to mastitis have stated that for cows, somatic cell counts over 200,000 are an indication of chronic mastitis. Others have established a threshold of 100,000 cells/ml.

Poor barn hygiene and poor milking procedures can lead to contamination of milk by enteric pathogens such *Escherichia coli*, *Salmonella*, *Listeria*, *Yersinia*, and *Campylobacter*. *Mycobacterium tuberculosis*, the organism that causes tuberculosis

(TB) in humans, may also be present in milk unless the herd is TB-accredited. Paratuberculosis or Johne's disease is caused by *Mycobacterium avium paratuberculosis* and can be chronic, contagious, and fatal to the animal. *Brucella abortus* causes brucellosis, aka undulant fever, if consumed in raw milk.

Hazards

- Zoonosis or zoonoses is any infectious disease that can be transmitted (in some instances, by a vector) from non-human animals, both wild and domestic, to humans; or from humans to non-human animals (the latter is sometimes called reverse zoonosis).
- Change in milk composition due to increase in number of somatic cells (white blood cells present in high numbers during an udder infection) that leads to rapid proteolysis and lipolysis, along with reduced lactose concentration, and increased sodium (Na⁺) and chloride (Cl⁻) concentrations. This results in lower shelf life, more off-flavors, and lower milk yields.

Controls

- Monitor animal health and maintain a vaccination program under veterinary supervision.
- Isolate and treat sick animals with precautions in place to prevent milk contamination.
- Separate treated animals from the main milking string and milk them last. In order to prevent milk contamination, the milk from treated animals should not be commingled with milk from untreated animals.
- Design barn areas to promote animal health and discourage pests, such as rodents and wild birds. Other farm animals such as poultry and swine need to be segregated from milking animals.
- Institute a mastitis control program that includes:
 - regular monitoring of SCC
 - observation of foremilk prior to milk collection
 - segregation and disposal of milk from infected animals, and
 - treatment protocol including adequate withdrawal time for treated animals and culling of chronically affected animals.
- Keep animals comfortable, for example to reduce heat stress in warm weather consider sprinklers, ventilation fans, sidewall opening, and ridge ventilation.
- Properly store, label, and use antibiotics and antimicrobials.

Records to maintain

- Animals should be readily identifiable with corresponding health records that include documentation of illnesses, treatments, and withholding times.

1.3 Milking Animal Cleanliness

Cleanliness of the milking animal is directly related to animal health and the prevention of pathogenic organisms contaminating the milk. The animal's environment influences animal hygiene. Farm premises adjacent to the milking barn, parlor, and milk house need to be kept free of contamination and debris. Dirt or manure in loafing areas and muddy environments make it easier for bacteria to penetrate the teat canal. They can then travel into the mammary gland and establish an infection, causing an inflammatory response that can destroy milk-secreting cells release somatic cells as previously discussed. Removing udder hair can make further improvements in animal cleanliness.

Bedding sources that are clean, dry, and comfortable will minimize pathogen growth. Inorganic bedding such as sand is often the best choice for reducing pathogen numbers. Not all sand is created equal. Fine, washed sand is recommended because other varieties may be too abrasive causing foot problems. Sand must be groomed daily to remove gross soiling.

When rubber-filled mattresses are used for cushioning stalls, it is important to bed the stalls in a manner that ensures they remain dry. It is a good practice to remove udder hair at least twice yearly.⁷

Hazards

- Environmental pathogens (coliform bacteria and species of streptococci other than *Streptococcus agalactiae*) which are a major cause of mastitis in herds.
- Pathogenic bacteria from fecal and environmental contamination which enter the teat canal.
- Starter culture inhibition, poor drainage, and spoilage of cheese due to high levels of organisms in the milk.

Controls

- Manage practices to reduce teat end exposure to environmental mastitis pathogens which are often present in organic bedding sources and wet, muddy pens.
- Ensure clean lying areas, passageways, gateways, and pathways on the farm.
- Grade barnyards to permit good drainage and to keep them free from standing water. Remove enough manure to prevent excessive accumulation on the udders and flanks of milking animals.
- Removed accumulated waste feed to deter rodents and insects.
- Accommodate the animals comfortably in housing that is large enough, and buildings that are well-ventilated to reduce condensation.
- Do not site water troughs on bedded areas as they can lead to wet soiled areas due to increased traffic and leaks.
- Keep milking areas of the animals clean and dry, especially teats, udders, flanks, hindquarters, abdomens, and tails.

An excellent resource for udder preparation prior to milking may be found at:

Hurley, Walter L., Department of Animal Sciences, and University of Illinois, Urbana, IL. "Milking Process." *Lactation Biology Website*, 2009. <http://web.archive.org/web/20160121222133/http://ansci.illinois.edu/static/ansc438/Mastitis/milkprocess.html>.

1.4 Milking Procedures

Pre-milking preparation is a balance between speed and efficiency, and completion of the required steps to clean udders and stimulate milk letdown. Teat-end disinfection is important in reducing the number of bacteria. It is well established that thorough teat-end disinfection can reduce teat surface bacteria by 75%. The lowest milk bacterial counts result from methods that wet and clean teats only (not udders).

If animals are clean, teats can be disinfected by pre-dipping without additional washing. Pre-dipping is most effective in the control of environmental pathogens (*E. coli* and environmental *Streptococci*) and has been shown to have limited effectiveness against coagulase negative *Staphylococci*. A minimum contact time of 20–30 seconds is needed for effective disinfection.

When applying disinfectant solutions (*Figure 1.3*) cover only the teats and not the complete udder. Disinfectant and/or water dripping from udders will increase risk of bacteria being transferred to teats and teat ends and will increase drying time. Use of excess water when prepping the animal is also associated with elevated bacteria counts in bulk tank milk.

Washing can be used either as the sole method of teat disinfection or as a step preceding pre-dipping. If washing is utilized, the following principles should be followed: 1) only teats should be washed; 2) minimal water should be used; 3) teats should be thoroughly dried. Cloth towels have the advantage of being more absorbent than paper. When cloth towels are used, disinfect them by washing with bleach and hot water (over 130°F or 54°C) and drying at high temperature in an automatic dryer. Single service paper towels may also be used. One towel per animal per milking is used whether the towel is cloth or paper. These methods have been demonstrated to significantly reduce pathogen numbers.



Figure 1.3: Arding, Kate. *Milking Procedures*. Collection of Kate Arding.

Teats should be stripped vigorously to get a good milk flow. Additionally, milkers' use of latex or nitrile gloves can help reduce pathogen transfer. Gloves both protect milkers' skin and reduce contamination that can be caused by the skin. It is important that

everyone performing milking tasks wear disposable gloves designed for milking. This includes not only the workers stripping milk from the animal, but also those people hanging milking units and especially those people checking for and treating mastitis. It is also recommended that gloves be sanitized periodically and changed as needed. Gloves should be thrown away at least after each milking ends, with new and clean gloves worn at the beginning of the next milking. At larger dairies, depending on the number of animals and hygiene in the parlor, at a minimum, gloves should be thrown away and new ones worn as each animal group is changed. In some cases, gloves may need to be replaced more frequently depending on type of infections, number of mastitis-infected animals, or hygiene of animals in the parlor. If drop hoses or spray bottles with disinfectant are available, then gloves may be disinfected and thoroughly dried after handling mastitis animals or when gloves appear visually dirty. It is important to thoroughly clean and dry the gloved hands when disinfecting dirty gloves.

The overriding goal of all milking procedures is to attach milking units to clean, dry teats.

Hazards

- Contamination of milk by bacteria that pose a health risk or will reduce safety during cheesemaking. Common sources of contamination may include mastitic milk, dirty teats, and the milking area environment.
- Contamination of the milk by chemicals, including antibiotic residues and cleaning chemicals, that may be harmful to human health and may cause processing problems during cheesemaking.
- Contamination of milk by ill workers.

Controls

- Monitor animal cleanliness.
- Monitor milking environment cleanliness.
- Ensure gloves are being used, and that they are changed a minimum of once per milking.
- Use Pre-dip that has been registered and proven effective by the manufacturer⁸.
- Follow label directions for length of time dip is on teat prior to drying, most require 20-30 seconds.
- Strip teats vigorously for good milking hygiene and to encourage good milk flow.
- Use a strip cup to detect early cases of mastitis and decrease the chance of pathogen spread.
 - Perform the California Mastitis Test (CMT) on animals that are suspected to have an infection⁹.
- “Dip-Strip-Dry-Apply” preparation is recommended (“Dry” must be the last step before attaching the milking unit).
- Dry teats furthest away from milking first to reduce the risk of recontamination.
- Reject milk unfit for human consumption. This will include mastitic milk, milk contaminated with antibiotics, and milk showing any abnormality. Colostrum or milk containing colostrum is unfit for cheesemaking and must also be rejected.
- Ensure there is no residual chemical contamination from the milking equipment.

- Ensure that infected/treated animals are milked last or with separate equipment and lines.
- Use post milking disinfectants for teats per manufacturer’s recommendations. Keep dip cups and spray heads clean and sanitized, as organic matter in contact with the disinfectant weakens the disinfectant.
- Minimize air admission when changing clusters/transferring milk to avoid debris being sucked into the milk.
- Minimize surrounding activities that create dust, as contamination may be drawn through the milking equipment and into the milk during milking.
- During or immediately after milking, and before cooling, milk should be adequately filtered to remove extraneous matter that may have inadvertently contaminated the milk during milking. Filters should be observed for abnormalities. A fresh, clean filter should be used at every milking.

1.5 Cleanliness and Maintenance of Milking Equipment



Figure 1.4: Arding, Kate. *Cleanliness of Milking Equipment*. Collection of Kate Arding.

Meticulous cleaning and maintenance of milking equipment prevents the presence of bacterial biofilms that may contain pathogens, spoilage microorganisms, and other bacteria harmful to the safety of the cheesemaking process. All surfaces of milking equipment should be smooth, readily cleanable by manual or mechanical means, and designed to drain freely after cleaning. Sanitize all equipment prior to use. Maintain all equipment to prevent foreign material from entering the milk supply.

Milking units (*Figure 1.4*) should be aligned immediately following attachment to be approximately parallel to the teats and with the goal of minimizing liner slips. It is not unusual to hear a sucking or a “squawking” noise, but if they are too frequent, it is a sign of air entering the milking system and liner slips.

The non-sanitary parts of the milking system (pulsator airline, back flush system, etc.) may also be a source of bacterial contamination. If milk quality tests indicate equipment cleaning and sanitation problems in the milking system, and the source cannot be found in the milking units, hoses, milk line, or receiver, a visual inspection of airlines and ancillary equipment is indicated. These non-sanitary parts of the system should be cleaned periodically as part of routine maintenance of the system. The seals and gaskets and all rubber fittings should be changed at least annually. Aged rubber may crack or becomes porous and is very difficult to clean.

Producers must fully recognize the fact that certain components cannot be effectively washed without disassembly.

Hazards

- Contamination of the milk by chemicals used in the cleaning process, including disinfectants and antibiotic residues, that may be harmful to human health or may cause processing problems during cheesemaking.
- Contamination of milk by bacterial biofilms on improperly cleaned equipment that may pose a health risk or will reduce safety during cheesemaking.
- Contamination of the milk by physical hazards from damaged equipment.

Controls

- Ensure all equipment is made from food grade material and is kept clean and in good condition. Food grade means the material can come in direct contact with the food during harvesting, processing, or packaging of the food. The FDA, National Skills Academy (NSA), 3-A Sanitation Standards, Inc., and others can certify an item. Clean means that the surface/area does not have visible filth, milk residue, or milkstone build up. Cleaning procedures involve the four cornerstones of temperature, time, velocity or mechanical force, and concentration of chemical agents. Equipment and chemical manufacturer's recommendations should be followed at all times.
- Where milk is to be processed without pasteurization, fit milk lines with silicone joints that are less prone to deterioration and may be disinfected more readily than rubber items.
- Make sure O-rings and gaskets are any color other than white in order to easily notice if they disintegrate and become incorporated into product.
- Fit clusters with a system that enables a disinfectant rinse, such as chlorine or peracetic acid, between animals.
- Keep milking equipment clean during milking.
- Follow a recommended cleaning, sanitizing, and storage routine for the milking equipment.
- Use the correct temperature and measurement of cleaning and sanitizing solutions to improve the efficiency of the cleaning process. Correct flow rates of the solution as well as correct exposure time aid in thorough cleaning and sanitizing processes.
- Where a Clean-In-Place (CIP) system includes air injection to aid turbulent flow of the cleaning solution, ensure that the air supply is of high hygienic quality¹⁰.
- Wash any components that are not amenable to CIP manually. This includes but is not limited to vacuum drain mechanisms built into the milking system, bulk tank valves, butterfly valves, any nipple hoses clamped to other hoses, etc.
- Do not use cloths to dry equipment; equipment should be allowed to air dry.
- Store equipment in a clean environment to avoid contamination before the next use.
- Change rubber components such as liners, milk tubes, and vacuum seals regularly to prevent deterioration or erosion which makes them uncleanable, and thus susceptible to the development of biofilms.

- Increase protection by using a suitable combination of time and temperature can to clean gaskets, which are difficult to sanitize with chemicals.

Records to maintain

- Sanitation Standard Operating Procedures (SOPs)¹¹
- Inspection, maintenance, and replacement schedule for equipment.

¹ U.S. Department of Health and Human Services, Public Health Service, and Food and Drug Administration. Pasteurized Milk Ordinance (2011). <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM291757.pdf>.

² World Health Organization, and Food and Agriculture organization of the United Nations. *Codex Alimentarius: Milk and Milk Products*. 1st ed. Milk and Milk Products, CAC/RCP 57-2004. Rome: World Health Organization: Food and Agricultural Organization of the United Nations, 2011. ftp://ftp.fao.org/codex/Publications/Booklets/Milk/Milk_2007_EN.pdf.

³ U.S. National Archives and Records Administration. Cheeses and Related Cheese Products, 21 Electronic Code of Federal Regulations § 133. Accessed August 23, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=3251256a7255e92cf1ed3808d844c6c8&mc=true&node=pt21.2.133&rgn=div5>.

⁴ U.S. Food and Drug Administration. "Food Processing & HACCP - Guidance for Industry: Control of Listeria Monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance." *U.S. Food and Drug Administration*. Accessed December 8, 2016. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>.

⁵ American Society of Heating Refrigerating and Air-Conditioning Engineers. "Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size Standard 52.2-2007." ASHRAE, 2008. https://www.ashrae.org/File%20Library/docLib/Public/20081029_52_2_supplement_final.pdf.

⁶ U.S. Department of Health and Human Services, Public Health Service, and Food and Drug Administration. Pasteurized Milk Ordinance (2011). <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM291757.pdf>.

⁷ Endres, M. I. "Bedding Options for Dairy Cows." *WCDS Advances in Dairy Technology* 24 (2012): 361–69. <http://www.wcds.ca/proc/2012/Manuscripts/Endres.pdf>

⁸ National Mastitis Council (NMC). "Summary of Peer-Reviewed Publications on Efficacy of Premilking and Postmilking Teat Disinfectants Published since 1980." National Mastitis Council Online, 2014. <http://www.nmconline.org/docs/Teatbibl.pdf>.

⁹ Ruegg, Pamela. "California Mastitis Test Fact Sheet 1," 2005. <http://milkquality.wisc.edu/wp-content/uploads/2011/09/california-mastitis-test-fact-sheet.pdf>.

¹⁰ American National Standards Institute. "ANSI/ASABE AD5707:2007. Milking Machine Installations.," March 2016. <http://webstore.ansi.org/RecordDetail.aspx?sku=ANSI%2FASABE+AD5707%3A2007+MAR2016>.

¹¹ United States Department of Agriculture, and Food Safety and Inspection Service. "Sanitation Standard Operating Procedures," March 21, 2016. http://www.fsis.usda.gov/wps/wcm/connect/4cafe6fe-e1a3-4fcf-95ab-bd4846d0a968/13a_IM_SSOP.pdf?MOD=AJPERES.



Chapter 2

Raw Milk Chilling, Storage, Purchase, Transport, and Receipt

Milk leaves an animal at the body temperature of the animal from which it comes. For commercial milking species, a temperature range of 100-104°F (38-40°C) depending upon the species of animal, is ordinarily expected. Milk is virtually free of bacteria when secreted if the animal is healthy and in good condition. Bacteria that contaminated the milk during its collection will grow at rapid rates – even doubling their population every 15-30 minutes if conditions are favorable. Favorable conditions for bacterial growth differ by bacterial species and depend on temperature, water activity, food source, pH, and available oxygen.

Refrigeration reduces the growth rates of bacteria.

Pathogenic and spoilage organisms are commonly of the Mesophilic type, growing best at moderate temperatures. Mesophilic cultures grow at temperatures between 50-113°F (10-45°C) with optimal growth between 86-99°F (30-37°C). Cooling the milk rapidly slows growth for these microorganisms.

Organisms that grow at or below temperatures of 45°F (7°C), with a generation time of 9 hours or less, are known as psychrotrophic bacteria. However, the optimum growth temperature is 70-82°F (21-28°C), at which point the psychrotrophic bacteria will multiply at a much faster rate. If milk is not properly cooled, psychrotrophic bacteria will take over the natural flora of the milk. This will create issues in the milk supply as the psychrotrophic bacteria produce lipolytic and proteolytic enzymes that will cause deterioration of the milk. Some of these enzymes can resist pasteurization.

Psychrotrophic bacteria from numerous genera have been isolated from milk, both Gram negative (*Pseudomonas*, *Aeromonas*, *Serratia*, *Acinetobacter*, *Alcaligenes*, *Achromobacter*, *Enterobacter*, and *Flavobacterium*) and Gram positive (*Bacillus*, *Clostridium*, *Corynebacterium*, *Microbacterium*, *Micrococcus*, *Streptococcus*, *Staphylococcus*, and *Lactobacillus*). Of these, *Pseudomonas* is the most frequently reported psychrotroph in raw milk.

2.1 Chilling and Storage of Fresh and Frozen Raw Milk

Unless milk is to be used immediately after milking, it must be rapidly cooled to refrigeration temperatures in order to protect its quality. The Pasteurized Milk Ordinance (PMO) states that Grade A milk must be cooled to a temperature of 45°F (7°C) or less within two hours of milking¹.

When commingling milk with a previous milking, at no time may the temperature exceed 50°F (10°C), and it must also reach 45°F (7°C) within two hours after blending.

Grade B milk, also referred to as manufacturing grade milk, should be cooled to 50°F (10°C) or less within two hours after milking, and maintained at or below 50°F (10°C). If milk is stored or cooled in cans and/or single use bags, then milk from the morning milking may not be commingled with milk from an evening milking.

These designations of Grade A and B refer to conditions at the farm level, based on the above criteria and the overall bacteria counts. Dairy plants also have a Grade A and B designation based on the products they produce. In the United States, Grade A milk refers to milk produced under sufficiently sanitary conditions compliant with PMO requirements and that meets Grade A standards. Only Grade A milk is regulated under federal milk marketing orders. Grade B milk, also referred to as manufacturing grade milk, does not meet Grade A standards and can only be used in cheese, butter, and nonfat dry milk. More than 99 percent of all milk produced nationally is Grade A.

Can Cooling Method (*Figure 2.1*): The milk is filtered as it enters the can. The can sits in a food grade propylene glycol and water solution during milking. A digital temperature logger is inserted and the chilling temperature is recorded. The can is stirred with a can agitator during chilling (after milking). The milk reaches the goal temperature of <39°F (4°C) within 20 minutes after milking is completed.

A milk producer may not commingle milk from one species of milking animal with the milk of another species of milking animal. Once the milk has been received at the cheese plant, milk from different species may be blended for cheese production purposes.



Figure 2.1: Caldwell, Gianacis. *Can Cooling Method*. Collection of Gianacis Caldwell.

When freezing milk, the temperature should be such that the milk freezes as rapidly as possible. A suggested temperature is 0°F (-18°C) or less. Home freezers do not work well as they are unable to achieve this temperature.

Hazards

- Pathogenic bacteria may multiply in the milk during storage due to inadequate temperature control or extended storage times, resulting in increased health risks. This is especially true for the raw milk cheesemaker, but it can also contribute to pathogen growth in pasteurized products and the plant in general.
- Temperature abuse of milk may lead to increased growth rates for any microbes present.

Controls – General

- When milking, cool the milk as quickly as possible down to 45°F (7°C) or less within two hours after the end of milking.
- Pre-cool the refrigerated storage tanks to aid in a more rapid cool-down of the milk.
- During the commingling of milk from previous milkings, ensure the blended temperature does not exceed 50°F (10°C) at any point, and that it drops to 45°F (7°C) within two hours after blending.

Controls – Bulk tank

- Equip bulk tanks with a temperature device for monitoring the effectiveness of cooling. This monitoring may be done manually, if the tank was manufactured prior to January 1, 2000. Any bulk tank manufactured after January 1, 2000 is required to have a recording device installed for temperature monitoring.
- Equip bulk tanks with an agitator to ensure homogeneity of all milk contained in the bulk tank.
- Cover and cap openings at all times to prevent contamination.
- During milking, close seal or drip shield around the delivery pipe into the milk tank.
- Clean and sanitize the bulk tank each time it is emptied. The tank needs to be self-draining for complete removal of any chemical solutions or water.
- Place compressors in a shaded, well-ventilated area. Clean and service compressor units regularly, and have the refrigeration system serviced and calibrated on a regular basis per manufacturer's guidelines.

Controls – Milk cans and bags

- Immediately cool milk in cans to 45°F (7°C) or lower within two hours after milking. In some jurisdictions, it is acceptable to chill milk in Grade A-quality stainless steel milk cans. The cans are cooled using ground water, well water, or ice water. Propylene glycol and all additives used in the cooling medium must be food grade. For questions regarding cooling, producers should consult their state regulatory agency.
- Immediately cool milk in bags to 45°F (7°C) or less within two hours after the end of milking. If the bags of milk are to be cooled using some type of pre-cooled water or other fluid in a tank, this fluid needs to be chlorinated or otherwise rendered microbiologically safe. Note: The use of bags to store Grade A raw milk is not covered in the PMO.
- If milk is stored or cooled in cans or bags, do not commingle milk from a morning milking with milk from an evening milking.

Controls – Freezing and defrosting

Please note that this is not common practice, and these are recommendations only for those who may freeze and thaw milk for cheesemaking on occasion.

- Use only food-grade bags that originate from companies on the list of "Certified Manufacturers of Single-Service Containers."²
- Ensure frozen milk remains frozen at 0°F (-18°C) or less and store up to 12 months as long as it is kept in a frozen state. However, for optimum cheese quality, milk should be used within three months after freezing.
- Defrost frozen milk under refrigerated conditions, 45°F (7°C) or less.

Records to maintain

- Cleaning records for bulk tanks may be provided via the installed recorder. After January 1, 2000 per the PMO, all new bulk tank installations are required to have a recording device for temperature records. These recording devices should also document the cleaning of the bulk tank. These records must be maintained for at least two years. Manual cleaning of a tank must also be documented.
- Test records for the cooling medium of cans or bags should include microbial results, concentration levels of sanitizers used in the medium, and Material Safety Data Sheets (MSDS or SDS) for glycol usage provided by the manufacturer.
- Daily temperature records of tanks, refrigerators, and freezers must be maintained for at least two years.³
- A production log for bulk or frozen milk must be maintained.
- Sedimentation and antibiotic beta lactam test results should be available.

2.2 Purchase of Fresh and Frozen Raw Milk

The purchase of raw milk takes place on a contractual basis between the producer or milk distributor (like a cooperative) and the cheesemaker. The agreement may be as simple as a verbal commitment or as involved as a very specifically written and signed document. It is in the best interests of both parties to have a formal written and jointly signed agreement in place. If the farm producer chooses to separate the farm entity from an on-farm processing entity, there may be no contract, since both are owned by the same individual. The two basic objectives of farmer payment schemes are

- (1) to balance the supply and demand in the market; and
- (2) to use financial penalties or incentives as a means of improving milk quality.

Milk samples are analyzed for components such as fat, protein, total solids, and for adulteration by water, for sediment, prohibited chemical additions, as well as microbial loads and Somatic Cell Counts (SCC). Limits of acceptability are based on federal standards where applicable. However, the cheesemaker, farmer, and/or plant may agree to more stringent requirements. The original purchaser of the milk, whether it is fresh or frozen, is required to sample the milk for any of the aforementioned standards where applicable. The test results should be submitted to the required regulatory agency on a monthly basis. For a cheesemaker purchasing milk from a distributor, the distributor assumes the responsibility for testing. These test results should be supplied to the cheesemaker and kept on record for compliance. It would be highly beneficial for a cheesemaker to have his/her own testing completed to verify the seller's testing.

Appendix N of the 2007 PMO requires milk to be screened for antibiotic residue prior to unloading/receipt⁴. This requirement still exists for the farmstead/artisan cheesemaker. This is true even for organic producers who do not use antibiotics. According to Appendix N, records of all sample results shall be maintained for a minimum of six (6)

months by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency.

Milk received in cans or bags is also required to be sampled and tested. A composite sample of that shipment needs to be collected in a sanitary manner and analyzed for acceptability. The sampling procedure includes aseptically pulling samples from each bag or can that constitutes a load of milk from that given farm on that day. These individual bag or can samples are then combined and thoroughly blended. A composite sample is then taken for testing to comply with requirements. Testing individual bags or cans is not an acceptable practice.

Records to maintain

- Records related to milk receipt and producer payments should be maintained for three years.
- Records of all milk quality standards should be maintained for two years.
- Records of antibiotic testing should be maintained for two years.
- If buying milk directly from a farm or milk cooperative, ensure and record that the transport company is properly licensed and has the appropriate knowledge required for legal transport of raw milk.

2.3 Transport and Receipt of Fresh and Frozen Raw Milk

The PMO dictates that state and local regulatory agencies are responsible for the enforcement of sanitation requirements on dairy farms, milk hauling receiving and transfer stations, and in processing plants. When considering purchasing milk from a producer, the cheesemaker should evaluate the regulatory reports to verify that minimum sanitary standards on the farm have been met. Reviews of the inspection reports will aid the cheesemaker in the decision to accept or reject the producer as a milk supplier. No dairy plant operator may collect or receive milk from a dairy farm unless the milk producer holds a current license for that dairy farm.

No dairy plant operator may receive any milk products transported in a bulk milk tanker unless the tanker operator holds a current license.

Transfer of milk into a bulk tank should be done with lids closed to prevent dust and insects from entering the tank. Milk flowing down the inside wall of a tank will aid in reducing aeration. Foaming of the milk should be avoided as much as possible.



Figure 2.2: Arding, Kate. *Transport and Receipt of Fresh and Frozen Raw Milk (A)*. Collection of Kate Arding.

Appendix B of the PMO states that a bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station, or transfer station and has in his/her possession a permit from any state to sample such products⁵. The bulk milk hauler/sampler occupies a unique position, making this individual a critical factor in the current structure of milk marketing. As a weigher and sampler, they stand as the official – and frequently the only – judge of milk volumes bought and sold. As a milk receiver, their operating habits directly affect the quality and safety of milk committed to their care. When the obligations include the collection and delivery of samples for laboratory analysis, the bulk milk hauler/sampler becomes a vital part of the quality control and regulatory programs affecting producer dairies (*Figure 2.2*).

Section 3 of Appendix B of the PMO requires that regulatory agencies establish criteria for issuing permits to bulk milk hauler/samplers. These individuals are evaluated at least once each two-year period using Form FDA 2399a - MILK TANK TRUCK, HAULER REPORT AND SAMPLER EVALUATION FORM. This can be found in Appendix N of the PMO.⁶ These industry plant samplers are employees of the dairy plant, receiving station, or transfer station and are evaluated at least once each two-year period by a properly delegated Sampling Surveillance Official (SSO). These industry plant samplers are evaluated using Form FDA 2399 - MILK SAMPLE COLLECTOR EVALUATION FORM.⁷ This form is derived from the most current edition of *Standard Methods for the Examination of Dairy Products*.⁸

The milk tank truck hauler is any person who transports raw or pasteurized milk or milk products to or from a milk plant, receiving station, or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples (*Figure 2.3*).

A dairy plant operator must collect a sample of milk from the shipment prior to unloading. This sample must be evaluated for antibiotic residue prior to acceptance of the shipment. This also includes milk produced organically. The milk is placed on a hold until the results of this test have been received.



Figure 2.3: Arding, Kate. *Transport and Receipt of Fresh and Frozen Raw Milk (B)*. Collection of Kate Arding.

Farmstead operators must follow the above stated requirements for transport and receipt of milk as well. The method of transport, sampling, and receipt should be preapproved by the local regulatory agency. Records for transport and receipt will also need to be kept and submitted.

In the case of farmstead cheesemakers using their own milk, the cheesemaker may contract with an outside laboratory to analyze the milk for antibiotics. Any cheese made prior to obtaining results must be placed on hold for shipment until results are obtained. This process should be approved by the local/state regulatory agency in writing to ensure that the cheese is not adulterated with antibiotics. It would be beneficial to the cheesemaker to have test results prior to making cheese, as the antibiotics may inhibit the starter culture.

Hazards

- The milk may become contaminated if the transportation vessel is not cleaned or contains contaminated milk.
- Lack of temperature/time control maintenance during transport, especially with respect to raw milk products.
- The exterior of the tanker hose may be contaminated with pathogenic bacteria during use at multiple farms. If the hose is not handled in a controlled, hygienic manner, the milk can become contaminated during off-loading.

Controls

- Only purchase dairy ingredients from a milk producer who is licensed and inspected for the production of milk.
- Ensure that written supplier assurances are in place confirming the control measures required for milk production, storage, freezing (if applicable), and transport.
- Ensure your milk supplier knows the standards required, and for what purpose the milk will be used.
- Periodically visit and inspect the supplier premises. A copy of the latest inspection report should be available to review. Sanitary conditions in the milking area, milk house, as well as the housing areas for the milking herd should be evaluated.
- Only use licensed milk haulers with approved/licensed transport vessels. Obtain necessary documentation including hauler permit and identification, point of origin of shipment, tanker identification, date of transport, and cleaning/sanitation of the vessel.
- Complete antibiotic testing prior to unloading any shipment of milk.
- Obtain and monitor the quality test results of every milk shipment.
- Reject any liquid milk delivery (raw or pasteurized) which:
 - Has an abnormal smell or appearance
 - Is delivered above 45°F (7°C)
 - Is delivered in a visually soiled vessel
 - Is delivered in a vehicle that is not dedicated to milk or not '*for foodstuffs only*'
 - Has not been adequately protected

- Has an excessive storage/transport time (while this is left up to the cheesemaker, some producers prefer to use milk within 24-36 hours of collections, with temperature being the determining factor).
- Reject any frozen milk delivery which:
 - Is delivered at a temperature above 0°F (-18°C)
 - Is not marked with a traceable batch code
 - Has any damage to the packaging
- Operate strict hygienic procedures when off-loading milk from the tanker:
 - The raw milk receiving area shall be separate from the processing area. Ideally, the intake area is completely enclosed, but that is dictated by individual state laws.
 - Receiving areas should be covered to prevent contamination by birds or other airborne pollutants. This is also dictated by state regulations and does vary from state to state.
 - The area for cleaning milk transport vessels must be separated from the processing area.
 - It is recommended that the tanker hose not be taken into the dairy, but if this is unavoidable, the exterior of the hose should be cleaned and disinfected before it is brought into the receiving area.
 - Milk tankers should be locked or sealed when not being loaded or unloaded to help reduce the possibility of intentional adulteration. A sanitation tag showing cleaning and sanitizing information should also be displayed on the truck intake.

Records to maintain

- Supplier assurances of compliance with raw milk production and storage steps.
- Contract and transport agreements with milk hauler.
- Correspondence relating to hygiene standards or milk quality.
- Copies of microbiological, Somatic Cell Counts, and antibiotic residue test results.
- Records of:
 - milk deliveries including identity of milk producer, volume, date, temperature and details of tanker Clean-in-Place (CIP), tanker receipts, and logs,
 - batch codes of frozen milk,
 - visits and inspections made to milk producers,
 - deliveries rejected and reasons why, and
 - disposal for any loads failing antibiotic tests.

2.4 Cleanliness and Maintenance of Chilling, Storage, and Transport Equipment

All equipment used in the chilling, storage, and transport of milk needs to be properly cleaned and maintained. All non-PMO compliant components (such as the flexible impeller pump and hoses with stainless steel nipples seen in *Figure 2.3*) that are not amenable to CIP must be disassembled at each washing according to strict protocols, and should be recorded on a chart to document cleaning frequency. The owner of the

vessel as well as the regulatory agency should do inspection of the vessel on a routine basis. If construction or repair defects are noted, the vessel should be removed from service until repairs and sufficient cleaning are verified. Temperature controls should be checked and verified annually.

The PMO states the following requirements for inspection purposes:

1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every 12 months.
2. Inspect each bulk milk hauler/sampler's dairy plant and industry plant sampler's pickup and sampling procedures at least once every twenty-four months.
3. Inspect each milk plant and receiving station at least once every three months, except that, for those milk plants and receiving stations that have Hazard Analysis and Critical Control Points (HACCP) systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace such regulatory inspections. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K of the PMO⁹.
4. Inspect each milk tank, truck, cleaning facility, and transfer station at least once every six months, except that, for those transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace such regulatory inspections. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K of the PMO.
5. Inspect each dairy farm at least once every six months.

Hazards

- Contamination of the milk by chemicals harmful to human health and/or chemicals that can cause processing problems during cheesemaking.
- Contamination of milk by bacterial biofilms on improperly cleaned or poorly maintained equipment that pose a health risk or will reduce safety during cheesemaking.
- Contamination of milk by other biological hazards from poorly positioned and protected equipment.
- Contamination of the milk by physical hazards from poorly maintained or damaged equipment.

Controls

- The lining and milk contact surfaces of a bulk tank must be constructed of stainless steel or other materials that are equally smooth, nontoxic, stable, non-absorbent, corrosion resistant, and capable of withstanding cleaning and sanitizing treatment. Milk contact surfaces shall be readily accessible for inspection.
- Bulk tanks shall be self-draining. Opening and covers shall be constructed and installed to prevent drainage into milk or onto milk contact surfaces.
- Ensure bulk tanks have sufficient clearance on all sides so they can be accessed for cleaning (a minimum of 24 inches of clearance is recommended)

- Bulk tank openings may not be located directly under a ventilator or directly over a floor drain.
- Follow a recommended cleaning, sanitizing, and storage routine for equipment.
- Understand correct temperature and measurement of cleaning and sanitizing solutions, correct flow and solution rate, and correct exposure time.
- For transport equipment, when CIP facilities are not available, any hose or pipework owned by the dairy should be cleanable internally, e.g. by using short sections of a large diameter pipe that can be cleaned using a pipe or bottle brush.
- Milk tanks shall be emptied and cleaned at least every 72 hours.

Records to maintain

- Cleaning and sanitizing records should be kept for at least two years.
- Inspection, maintenance, and replacement schedule for equipment.

¹ U.S. Department of Health and Human Services, Public Health Service, and Food and Drug Administration. Pasteurized Milk Ordinance (2011). <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM291757.pdf>.

² U.S. Center for Food Safety and Applied Nutrition. "Federal/State Food Programs - Interstate Milk Shippers List." U.S. Food and Drug Administration. Accessed December 7, 2016. <http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2007965.htm#ss>.

³ Hugo, Cornelis. "The Importance of Records Under FSMA." *Quality Assurance & Food Safety*, December 11, 2015. <http://www.qualityassurancemag.com/article/qa1215-aib-fsma-records-importance/>.

⁴ U.S. Food and Drug Administration. "Milk - PMO 2007: Appendix N - Drug Residue Testing and Farm Surveillance," 2007. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm064367.htm>.

⁵ U.S. Food and Drug Administration. "Milk - PMO 2007: Appendix B - Milk Sampling, Hauling and Transportation." *U.S. Food and Drug Administration*, 2007. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm064241.htm>.

⁶ U.S. Food and Drug Administration. "Milk - PMO 2007: Appendix N - Drug Residue Testing and Farm Surveillance," 2007. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm064367.htm>.

⁷ U.S. Food and Drug Administration. "Milk - PMO 2007: Appendix M - Reports and Records." *U.S. Food and Drug Administration*, 2007. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm064363.htm>.

⁸ Wehr, Michael, PhD and Joseph F. Frank, and PhD. *Standard Methods for the Examination of Dairy Products*. 17th edition. Washington, DC: American Public Health Association, 2004.

⁹ U.S. Food and Drug Administration. "Milk - PMO 2007: Appendix K - HACCP Program." U.S. Food and Drug Administration. Accessed February 7, 2017. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm064412.htm>.



Chapter 3

Heat Treatments for Milk

Heat treatment of raw milk is an excellent method to eliminate and control microbial contaminants. When choosing the method of heat treatment for your cheese milk, one must remember that not only the heat treatment, but also the method of heat application, will directly affect the outcome of microbial control. If pasteurization is chosen, the process must meet the definition of pasteurization under 21 C.F.R. §131.3(b)¹. The Pasteurized Milk Ordinance (PMO) defines pasteurization as a process that heats every particle of milk or milk product in properly designed and operated equipment, at or above the specified time and temperature. Local regulatory agencies are responsible for the approval of the equipment to meet the PMO requirements. Depending on state regulations, the pasteurizer operator may be required to have certification or meet licensing requirements.

PMO approved time and temperature relationships for milk pasteurization include:

- Vat or Batch Method, Low Temperature Long Time (LTLT): 145°F (63°C) for 30 minutes
- High Temperature Short Time (HTST): 161°F (72°C) for 15 seconds (16 seconds in Canada)

Note: If the fat content of the milk product is ten percent (10%) or greater, or if total solids are 18% or greater, or if it contains added sweeteners, the specified temperature must be increased by 5°F (3°C).

3.1 Types of Heat Treatment

Thermization is a sub-pasteurization heat treatment undefined by current United States regulations. It is the process of heating milk to a temperature in the range of 135-155°F (57°C-68°C) for at least 15 seconds². It is intended to extend the storage time of raw milk by destroying the psychrotrophic spoilage organisms. While it may also achieve the destruction of Gram-negative bacteria such as *Salmonella* and *E. coli*, the destruction of all vegetative pathogens cannot be guaranteed; for example, *Listeria monocytogenes* and *Mycobacterium tuberculosis* may survive in certain circumstances.

There is a significant difference between thermization and pasteurization. Some cheesemakers consider any milk heated above the body temperature of the animal no longer raw milk. As far as the Food & Drug Administration (FDA) is concerned, it is still considered raw milk and the cheese made from thermized milk must be labeled and handled as a raw milk product. Cheesemakers have the option of choosing whether to apply heat to the milk prior to cheese manufacture. Much of the native flora and some enzymes found in raw milk will be destroyed by thermization. However, this destruction

is not complete as this is time and temperature dependent. Any heat process will directly affect the unique characteristics of milk and the cheese made from it.

Pasteurization is designed to kill pathogenic microorganisms. There are indigenous enzymes in milk that will survive pasteurization, whether performed under low temperature long time (LTLT) or high temperature short time (HTST) conditions. A misunderstood concept is that survival of “healthy” bacteria and enzymes differs substantially between LTLT and HTST

Vat or Batch Pasteurization (LTLT) and HTST Pasteurization are regulation- defined processes that are used to destroy pathogens and reduce the number of spoilage organisms in milk. If milk is to be pasteurized before cheesemaking, this step is likely to be regarded as a Critical Control Point (CCP). In addition, avoidance of post-pasteurization contamination is important. Pasteurization is at least 99.999% effective against the most heat resistant pathogens and kills vegetative cells, including vegetative cells of spore formers. Psychrotrophic spore formers such as those of the genus *Bacillus* may be heat-shocked into germination and grow slowly post-pasteurization. Some thermoduric bacteria can also survive and may multiply in the pasteurized milk if temperature control is inadequate, so rapid cooling and correct storage after pasteurization are critical. Once the milk has been pasteurized, it is more susceptible to microbial contaminants. The competing flora has largely been destroyed so post-pasteurization contamination control is an absolute necessity.

There are two types of pasteurization commonly used for cheese milk:

- 1) Vat or Batch, Low Temperature Long Time (LTLT):
Minimum 145° F (63°C) for 30 minutes

Air space temperatures must be maintained at least 5°F (3°C) above the minimum legal pasteurization temperature during the 30-minute hold time. At no time during the 30 minutes may the lid of the vat pasteurizer be opened. If the lid is opened, the 30-minute hold time will be restarted.

- 2) High Temperature Short Time (HTST, also called continuous flow):
Minimum 161° F (72°C) for 15 seconds (16 seconds in Canada)

The HTST pasteurizer is designed as a failsafe method. The various components such as divert valves, time/temperature recording device, controllers, flow meters, and pumps are all interwired so that they will only run when the pasteurizer is in forward flow (correct pasteurization). If there is something malfunctioning, the system will remain in divert flow (incorrect pasteurization).

Divert flow prevents the milk from flowing through the entire process and it is instead returned to balance tank (holding receptacle). All flow-promoting devices are sealed by the regulatory agency to ensure safe pasteurization.

Pasteurization is only effective when the required heat treatment/hold time are attained using equipment that has been inspected and approved by the local regulatory agency.

Pasteurizers designed for this purpose will have a mandatory recording chart that will document the correct time and temperature relationship. This chart will need to be verified on a daily basis by the operator. Depending on whether this chart is for a vat pasteurizer or HTST, much of the information required for the chart remains the same. This information includes:

- Date and time of the pasteurization
- Facility at which the milk was pasteurized
- Amount of milk
- Product to be made from that milk
- Operator
- Any unusual occurrences
- Specific information in regards to the type of pasteurizer

Local regulatory officials will check these records to ensure that pasteurization is occurring as required. The chart needs to be kept for a minimum of 6 months. It is highly recommended that the chart be kept for as long as the product is in the food chain. If pasteurization is a CCP for the cheesemaker, this chart becomes the necessary documentation for verification purposes.

3.2 Phosphatase Testing

Lactoperoxidase and alkaline phosphatase are two naturally occurring heat stable enzymes in milk. The former, being more heat stable, is used as a measure of adequate flash (high heat) pasteurization and the latter for LTLT and HTST pasteurization. These tests are also used to detect raw milk that has been introduced into pasteurized milk. Phosphatase tests are used to confirm pasteurization on properly installed and operated equipment, and are not used as verification for raw milk safety. In case of a malfunction of the pasteurizer, the pasteurizer shall not be allowed to operate until the pasteurizer operation has been corrected and verified.

Raw milk from different species of animals contains different levels of alkaline phosphatase, with the following values published, expressed as µg/ml (microgram per milliliter) phenol:

- Raw cows' milk: range 1,870-4,740
- Raw sheep's milk: range 8,300-16,300
- Raw goats' milk: range 117-1,292³

The alkaline phosphatase test was designed and is used for the testing of pasteurized cows' milk. Applying the test to milks from other species such as goat and sheep may not be useful given the differing levels of alkaline phosphatase present in such milks. For example, it is plausible that correctly pasteurized sheep's milk may give a FAIL result because the initial level in the raw milk is high; conversely, goat's milk that has been incorrectly pasteurized may PASS the phosphatase test.

For verification of pasteurized milk, the sample needs to be cooled to $\leq 45^{\circ}\text{F}$ (7°C) and maintained at this temperature until the test is run. Verification of milk pasteurization in finished product may not be done on a cheese sample without alternative sample preparation. Current methodology will distinguish between cheeses made from raw milk and cheeses made from pasteurized milk provided that that cheese curd was not cooked at higher temperatures for extended periods of time.

Hazards

- Pathogenic and/or spoilage bacteria may survive heat treatment if incorrect temperatures and/or incorrect holding times are applied to the milk.
- Improper operation of the pasteurizer will result in inadequate heat treatment.
- If using direct steam injection, culinary grade steam needs to be used with approved additives and/or filters.
- Pasteurized milk may become contaminated with harmful bacteria:
 - if a plate pasteurizer is poorly maintained and allows leakage of non-pasteurized milk across the plates into the pasteurized product stream;
 - from inadequately cleaned pasteurizers and auxiliary equipment;
 - if post-pasteurization contamination occurs; or
 - if pasteurized milk is stored warm or for excessive time (in extreme cases, this may result in the production of toxins that survive cheesemaking and render the final product unsafe).
- Broken seals on the pasteurizer (both LTLT and HTST) imply that safety of the milk is in question. Seals on the pasteurizer are intended to maintain the integrity of the pasteurizer and its efficiency.

Controls – General

- Ensure that staff are trained in correct pasteurization and cleaning routines.
- Check all pasteurizer seals as part of daily start-up procedures to ensure pasteurization integrity.
- Sanitize the pasteurizer and auxiliary lines prior to operation.
- Use pasteurized milk immediately for cheesemaking or cool to $< 39^{\circ}\text{F}$ (4°C) and use within 24 hours.

Controls – Vat/Batch LTLT

- Ensure adequate mixing of the milk to obtain even heating throughout the batch.
- Ensure that the lid to the pasteurizer remains closed throughout the entire time period. All openings to the vat pasteurizer must be capped or sealed during

operation. All inlet and outlet lines must be disconnected from the vat pasteurizer during pasteurization and should be capped or sealed off.

- Ensure correct batch pasteurization temperature (minimum 145°F/63°C) and air space temperature (150°F/66°C) during the 30-minute hold time.
- Ensure chart recorder is fitted with a pen that works correctly, that the pen is working, and that the correct recording chart has been placed in the recorder.
- Reconcile the product thermometer with the recording thermometer to ensure accuracy and ability to monitor pasteurization temperatures for each batch of milk processed.
- Record air space temperature on recording chart for each batch of milk pasteurized. This should be a minimum of 5°F (3°C) over the legally required pasteurization temperature. Air space temperature should be recorded at the beginning of the hold time and at the end of the hold time.
- Ensure that the entire heating/cooling time in the vat pasteurizer is limited to 4 hours. The exception is if the vat pasteurizer is also the cheese vat.
- If culinary steam is used for air space heating, filter it prior to its entering the vat pasteurizer. If boiler compounds are used, they need to be GRAS (Generally Recognized as Safe). Check the Code of Federal Regulations for an approved list of boiler compounds⁴. Where potable water is used for steam generation, no filters are needed.
- Check thermometers monthly with a reference thermometer traceable to a national standard.
- Have a regulatory agent inspect the vat pasteurizer.

Controls – HTST

- Conduct a daily test of cut-in/cut-out temperatures. This will verify that the divert valves and thermometers are working correctly and must be done prior to the start of pasteurization.
- Ensure that all seals are in place prior to the start of pasteurization.
- Ensure the chart recorder is fitted with an event pen that works correctly, the pen contains ink, and that the correct recording chart has been placed in the recorder.
- Verify the product thermometer and recording thermometer daily.
- Ensure you have a reference thermometer traceable to a national standard for in-house calibrations.
- Have the system timed and re-sealed by a regulatory agent after changing a pump out, or changing thermometers or other pieces of equipment that may affect flow or temperature. The HTST is inter-wired and sealed by regulatory agents, so that the maximum flow rate and minimum temperature may not be changed.
- Implement preventive maintenance procedures to avoid internal leakage of unpasteurized milk to pasteurized milk. Annually, plates should be opened and evaluated for integrity of seals and cleanliness.
- Check for a positive pressure of at least 2 psi (pounds per square inch) between pasteurized and unpasteurized milk plates. Positive pressure is also required between heating and cooling medium and milk sides of the plates.

- Follow correct cleaning solution concentrations and temperatures. It is generally recommended that the cleaning solution be 5°F (3°C) higher than the processing temperature. However, extreme temperatures and caustic solutions may damage rubber gaskets. Working with a knowledgeable chemical representative will ensure the best cleaning procedure for your equipment.
- Immediately report broken seals or equipment changes to regulatory authorities. Products made while awaiting the re-inspection need to be segregated, and tested prior to release or treated as unpasteurized product.

Records to maintain

- Operating procedures for pasteurizer
- Sanitation Standard Operating Procedures (SSOP)⁵
- Staff training records
- Phosphatase test results in the event of a malfunction or loss of seal on a pasteurizer
- Chart Recording for Vat Pasteurizer LTLT to include:
 - Date, time and operator
 - Identification of plant and pasteurizer if more than one is used
 - Product identification to include type and amount
 - Filling and emptying times
 - Pasteurization temperature and holding time
 - Air space temperature at beginning and end of holding time
 - Any unusual circumstances
 - Cleaning and sanitizing times and temperatures
 - Signature of person who is verifying the chart information
- Chart Recording for Continuous Flow HTST to include:
 - Date, time and operator
 - Identification of plant and pasteurizer if more than one is used
 - Product identification to include type and amount
 - Cut-in and cut-out temperatures at time of start up
 - Event pen should be recording temperature and whether or not the pasteurizer is in forward flow or divert flow
 - Any unusual circumstances
 - Cleaning and sanitizing times and temperatures
 - Signature of person who is verifying the chart information
- All recording charts need to be kept a minimum of 6 months. It is highly recommended that the chart be kept for as long as the product is in the food chain.

3.3 Maintenance and Cleaning of Pasteurizers

Routine maintenance for pasteurizers includes checking and replacing leaky gaskets, verifying procedures for all temperature and time controls, ensuring functioning of mechanicals, and checking for all seals placed by regulatory agents. In case of a

malfunction with an HTST, only qualified personnel should perform repairs. This may mean bringing a technician in from the equipment dealer.

Vat pasteurizers may be manually cleaned and sanitized if they are less than 96 inches in height. A Clean-in-Place (CIP) system is required for those vats greater than 96 inches in height, and for any HTST system. The dairy plant operator shall clean the pasteurizing equipment after each day's use and shall sanitize prior to using the equipment.

The primary reason to maintain and clean pasteurizers is to eliminate soil. "Soil" can be defined as any material found in an incorrect location.⁶ Examples of soil are fat deposits, lubricant deposits equipment, and deposits on processing equipment such as pasteurizers. Soil provides nutrition for bacteria, and other pathogens, and varies depending on type of food manufacturing plant. Dairy products processing plants have heavy soil that includes proteins and lipids.

The primary soil in dairy plants and the best substance for cleaning consists of:

- Milk sugar or lactose: Lactose solubility is temperature and concentration dependent as well as being dependent upon the type of lactose added to solution. The alpha- and beta-forms have distinctly different degrees of solubility.
- Butterfat: butterfat is most economically removed with the aid of an emulsifying agent at temperatures above the melting point of fat 84-97°F (29-36 °C).
- Proteins: easily changed or denatured by the action of heat or acid, and then they may no longer be soluble or dispersible in water alone.
- Denatured proteins: may be dissolved in dilute alkaline solutions or in chlorinated alkaline solutions.
- Mineral salts: precipitated mineral salts can form milkstone.
- Hot milk films: incomplete cleanings or deposits are insoluble in water and straight alkalis.
- Milkstone: soluble in acid solutions with a pH of 5 or less.

Cleaning factors of equipment:

- Processing equipment should be all-welded, polished stainless steel. Sharp corners, cracks, and exposed threads should be eliminated on all inside and outside surfaces.
- There must be sufficient ventilation and adequate lighting on all surfaces to be cleaned.
- Equipment must be located far enough from the floor, walls, ceiling, and other equipment to provide ample space for the cleaning operation. A minimum of 18 inches is recommended.

Precautionary measures during production and prior to cleaning:

- Heating at the minimum temperature for the minimum time with the heating medium at the lowest practical temperature.
- Cooling heating surfaces before and during emptying of vats if possible and practical.

- Rinsing away foam and milk film from equipment surfaces immediately after processing each batch, or at least immediately after the run.
- Keeping the film on equipment surfaces moist until ready to clean by avoiding steam or hot water leaks to the vat jacket.
- Rinsing with soft, tempered water 115°F (46°C) and not with hot water.
- Using sodium (in place of calcium) hypochlorite for sanitizing, if a hypochlorite is used.

Basic CIP steps:

- Rinse with warm water to remove gross soil.
- With water recirculating, slowly add caustic cleaner to water in accordance with manufacturer's recommendations.
- Follow the cleaning procedure of the manufacturer of the pasteurizer. A majority of systems need to be cleaned for at least 30 minutes at a temperature that is 10°F (6°C) hotter than pasteurization temperature. Note that temperatures over 185°F (85°C) or concentrations over 1% can be detrimental to rubber gaskets⁷.
- Flush solution from pasteurizer.
- Rinse with potable water.
- Add the acid cleaner according to the manufacturer's recommendations to fresh clean water to attain a pH of 3.0 or less.
- Heat solutions to at least 155-160°F (68-71°C) or as recommended and circulate for 20-30 minutes.
- Flush to drain with cold water until cool.
- Sanitize prior to use at beginning of start-up.
- Pump the chemical sanitizing solution through the equipment for at least 1 minute.

Hazards

- Introduction of pathogens due to unclean, unsanitized, and/or poorly-maintained equipment.
- Failure to notify regulatory agency when malfunction or loss of seal occur. This results in product not being legally pasteurized.

Controls

- Training personnel in maintenance and sanitation protocols
- Making sure SOPs are implemented and enacted
- Pre-operational check list for daily start-up
- Equipment swabs for checking sanitation
- Notify regulatory agency when malfunction or loss of seal occur.

Records to maintain

- Records shall identify every CIP system that has been cleaned or sanitized
- Date and time when each system was cleaned and sanitized
- Temperature of cleaning and sanitizing solution
- Length of time for which CIP system was exposed to solution.

- Signature or initial by responsible person
- Records need to be kept for a minimum of 90 days

Check with your individual state regulatory branch, as each state has varying rules involving certification and licensing requirements for safe pasteurizer operations.

¹ U.S. National Archives and Records Administration. Milk and Cream, 21 Electronic Code of Federal Regulations § 131. Accessed December 7, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=fbb49391bf496929e7d1e51f80728ae4&mc=true&node=pt21.2.131&rgn=div5>.

² Early, Ralph. *Technology of Dairy Products*. Springer Science & Business Media, 1998.

³ Harding, Frank. "Alkaline phosphatase content of different milks." *Milk Quality*. Springer Science & Business Media, 1995. https://books.google.com/books/about/Milk_Quality.html?id=PWmQTKDWPz0C.

⁴ U.S. National Archives and Records Administration. Boiled Water Additives, 21 Electronic Code of Federal Regulations § 173.310. Accessed January 30, 2017. http://www.ecfr.gov/cgi-bin/text-idx?SID=57534aa27644d13e5a588040de86ae4d&mc=true&node=se21.3.173_1310&rgn=div8.

⁵ United States Department of Agriculture, and Food Safety and Inspection Service. "Sanitation Standard Operating Procedures," March 21, 2016. http://www.fsis.usda.gov/wps/wcm/connect/4cafe6fe-e1a3-4fcf-95ab-bd4846d0a968/13a_IM_SSOP.pdf?MOD=AJPERES.

⁶ Marriott, Norman. *Principles of Food Sanitation (Food Science Text Series)*, 2006. <http://www.librarything.com/work/7102482/book/136885146>.

⁷ James, Robert E., and M. Chase Scott. "On Farm Pasteurizer Management for Waste Milk Quality Control." Department of Dairy Science, Virginia Tech, 2006. <https://www.vtdairy.dasc.vt.edu/docs/replace-on-farm-mgmt-waste-milk-qc.pdf>.



Chapter 4

Microbiological Sampling and Testing

Modern milk handling and processing have dramatically changed the microbial make up of raw milk itself. Where hand milking of animals was once the norm, we now use the modern day pipeline. Milk that was once cooled in cans immersed in water is now cooled and held in modern, energy-efficient bulk tanks. Even the commercial transport of raw milk has changed—all causing the organisms naturally present in raw milk to change from predominantly Gram-positive, acid-producing bacteria to largely Gram-negative, psychrotrophic microorganisms.¹ The definition of psychrotrophic bacteria used in the dairy industry includes organisms that grow at 45°F (7°C) or less, even if this is outside of their optimal growth temperature.² These bacteria can grow under refrigerated conditions.

Psychrotrophic bacteria that are significant in the microbiology of milk include both Gram-negative and Gram-positive organisms. The Gram Stain, a staining procedure that results in the absorption or loss of crystal violet stain by the bacteria, helps to differentiate between the two types of bacteria. Gram-negative organisms lose the color of the stain, while Gram-positive organisms retain the crystal violet stain. Gram-negative bacteria include *Pseudomonas*, the most common and often the most harmful to the milk quality, as well as *Achromobacter*, *Aeromonas*, *Alcaligenes*, *Chromobacterium* and *Flavobacterium*. Some enzymes produced by Gram-negative psychrotrophs during refrigerated storage of raw milk are heat-stable. This means they can survive pasteurization, contributing to spoilage not only of raw milk, but of pasteurized milk and milk products as well³.

Psychrotrophic organisms found in raw milk can be pathogenic or non-pathogenic. For example, *Yersinia enterocolitica* is a Gram-negative pathogenic psychrotroph that can cause acute appendicitis. *Bacillus cereus* and *Listeria monocytogenes* are Gram-positive psychrotrophic pathogens that produce foodborne illness with a wide range of symptoms.

Other species found in raw milk include Gram-positive *Lactobacillus*, *Staphylococcus* and *Micrococcus*, Gram-negative *Acinetobacter* and *Flavobacterium*, as well as species that belong to the coliform group. These bacteria produce a variety of end products such as lactic acid, propionic acid, butyric acid, and proteolytic and lipolytic enzymes.

Microbiological sampling of the milk supply, the processing environment, and the cheese produced provide information demonstrates compliance with regulatory limits, verifies the cleaning and sanitation procedures, and provides a means of controlling overall quality.

4.1 Regulatory Rationale and Limits for Pathogens and Indicator Organisms

The Food & Drug Administration (FDA) documents *Guidance for FDA Staff Compliance Policy*⁴ cover the federal policies and recommendations concerning pathogens⁵. and non-toxicogenic *Escherichia coli* (*E. coli*) in dairy products⁶.

Illnesses associated with dairy products include salmonellosis, hemorrhagic colitis, listeriosis, staphylococcal food poisoning, botulism, and *Yersinia enterocolitica* infection. Illnesses may be caused by an infectious organism or a toxin produced by the organism. Symptoms of illness may range from mild discomfort to vomiting, diarrhea, and hemolytic uremic syndrome. In some cases it may lead to kidney failure and death.

Pathogens in dairy products can indicate poor sanitation, temperature abuse, inadequate pasteurization, fermentation failure, and/or obtaining milk from diseased animals. Lack of sanitary practices or inadequate processing conditions may contaminate the raw milk and dairy products made from the milk. While pasteurization of raw milk is lethal to pathogens, post-pasteurization contamination is a risk that must still be prevented through Good Manufacturing Practices (GMPs) and other programs.

4.1.1 Organisms of Concern

The *Compliance Policy Guide* for FDA staff defines pathogens of concern as follows⁷:

- **Salmonella** - *Salmonella* is a pathogen that, when consumed, can cause an infection. A dose of as little as 15-20 organisms can cause illness. The symptoms of infection include gastroenteritis. *Salmonella* is shed in the feces of infected animals and can contaminate pastureland and milking parlors.
- **EHEC/STEC (Shiga toxin-producing *Escherichia coli*) O157:H7 and other enterohemorrhagic *Escherichia coli*** - The infectious dose of EHEC/STEC O157:H7 is estimated to be between 10-100 organisms. When food contaminated with the EHEC/STEC O157:H7 is consumed, the pathogen colonizes the intestinal tract where it produces a toxin and causes hemorrhagic colitis that can progress to more serious complications such as hemolytic uremic syndrome or thrombotic thrombocytopenic purpura. EHEC/STEC O157:H7 is the predominant EHEC/STEC strain that has caused illness worldwide. However, other EHEC/STEC serotypes have also been implicated in illness and are of public health concern.⁸
- **Non-toxicogenic *Escherichia coli*** - *Escherichia coli* have traditionally been used as a microbiological indicator of poor sanitation during processing. *Escherichia coli* are not inherently present in the milk of a dairy animal. *Escherichia coli* in milk and dairy products generally originate from animal or human feces. Thus, the presence of this organism in milk or other dairy product means that the milk or dairy product was exposed either directly or indirectly to feces.

Insanitary conditions, including poor employee hygiene practices, improperly sanitized utensils and equipment, or contaminated raw materials, may also be a source of non-toxicogenic *Escherichia coli* in milk and other dairy products. GMPs are followed to reduce potential contamination of the raw milk as well as reducing risk for post-pasteurization contamination.

- ***Campylobacter jejuni*** - A dose of 400-500 organisms of *Campylobacter jejuni* can cause infection. Symptoms of infection include abdominal pain, fever, diarrhea, and vomiting. *Campylobacter jejuni* can either be shed in feces or in milk from an infected udder of a dairy animal. Most human outbreaks of infection of *Campylobacter jejuni* that are associated with dairy products have been linked to raw milk or inadequately pasteurized milk.
- ***Yersinia enterocolitica*** - *Yersinia enterocolitica* is a pathogen that causes infection. Symptoms of infection include gastroenteritis, fever, diarrhea, bloody stools, rash, joint pain, nausea, vomiting, headache, and malaise. Infection by *Yersinia enterocolitica* is also considered a cause of reactive arthritis. *Yersinia enterocolitica* has been found in many different animals and is shed in feces.
- ***Clostridium botulinum*** - *Clostridium botulinum* produces a neurotoxin, a substance that is poisonous to nerve tissue. A few nanograms (ng) of the neurotoxin can cause illness. Symptoms include lassitude, weakness, vertigo, double vision, difficulty speaking, and difficulty swallowing. Symptoms can progress to difficulty of breathing, weakness of other muscles, abdominal distention, and constipation. The incidence of this disease is low, but the mortality rate is high if not treated immediately. Although the neurotoxin is heat labile and can be destroyed when exposed to a minimum of 176°F (80°C) for 10 minutes, the neurotoxin is not destroyed at normal pasteurization temperatures.
- **Enterotoxigenic *Staphylococcus*** - Some species of *Staphylococcus* produce an enterotoxin, (a toxin specific to the intestines, that is extremely heat stable and is not inactivated at pasteurization temperatures). When ingested, the enterotoxin may rapidly produce symptoms including nausea, retching or dry heaving, vomiting, abdominal cramps, muscle cramping, headache, and transient changes in blood pressure and pulse rate. The presence of any *Staphylococcus* enterotoxin in a dairy product is of public health concern.

A dairy animal with mastitis may be the source of enterotoxigenic *Staphylococcus* in raw milk, which may subsequently be commingled with other milk. Also, at any point from the milk collection process to the packaging of the finished product, enterotoxigenic *Staphylococcus* species can be introduced by an infected human, inadequate employee hygienic practices, such as inadequate hand washing, equipment and utensils that are not cleaned and sanitized, or contaminated materials used in the production of the cheese.

Staphylococcus aureus has traditionally been used as a microbiological indicator of poor sanitation during processing, as has *Escherichia coli*. Because of environmental factors, low levels of *Staphylococcus aureus* may be found in raw milk, even when produced using GMPs. However, excessive numbers of *Staphylococcus aureus* organisms in raw milk or other dairy products (greater than or equal to 10,000 cfu/g) indicate that the product was produced under insanitary conditions. Cfug refers to colony-forming units per gram, a measurement used to estimate the number of viable bacteria cells in a sample.

- ***Bacillus cereus*** - *Bacillus cereus* can cause illness when 1 million cfu/g or more are consumed in food. There have been two enterotoxins produced by *Bacillus cereus* identified as causing foodborne illness. Illness is characterized by abdominal pain and diarrhea or nausea and vomiting. *Bacillus cereus* is commonly found in soil, on vegetables, and in many raw and processed foods, including milk and cheese.
- ***Listeria monocytogenes*** is a bacterium that is ubiquitous in soil, water, and some animals, including cattle. It can be present in raw milk and foods made from raw milk, and can also cause post-production contamination of pasteurized milk products if *Listeria* in the environment is not controlled. *Listeria* can grow even in cold environments and under refrigeration. Listeriosis is a rare and serious illness caused by eating food contaminated with *Listeria*, recent outbreaks have been linked to products as diverse as cantaloupes, soybean sprouts, caramel apples, and both pasteurized and non-pasteurized dairy products including cheese and ice cream.⁹

Additional information about foodborne pathogens and associated diseases can be found in:

U.S. Center for Food Safety and Applied Nutrition. *Bad Bug Book (Second Edition)*, 2012. <http://www.fda.gov/Food/FoodbornellnessContaminants/CausesOfIllnessBadBugBook/>.

4.1.2 Levels of Organisms

The Food and Drug Administration (FDA) maintains guidelines establishing unacceptable levels of pathogens, stating that “FDA will review the available evidence on a case-by-case basis to determine whether a dairy product is adulterated and, in doing so, will be guided but not bound by the following general statements of policy relating to the presence in those products of pathogens, and non-toxicogenic *Escherichia coli* or alkaline phosphatase.”¹⁰

For some pasteurized milk cheeses the maximum level of alkaline phosphatase is established in the Federal Standards of Identity for Cheese, as spelled out in the C.F.R.¹¹ For other cheeses and related products that are required to be made from pasteurized milk, the alkaline phosphatase level should not be greater than 3-5 micrograms/0.25 g (12-20 micrograms phenol equivalents per gram), depending on the variety of cheese.

It is important to keep in mind that regulatory limits vary around the world and affect both imported and exported cheese. Dairy products are considered adulterated and subject to regulatory action if:

- *Salmonella* species, EHEC O157:H7 or other enterohemorrhagic *Escherichia coli*, *Campylobacter jejuni*, *Yersinia enterocolitica*, vegetative cells of *Clostridium botulinum*, *Clostridium botulinum* toxin, *Staphylococcus* enterotoxin, or *Bacillus cereus* enterotoxin are present.
- *Listeria monocytogenes* is present. There is zero tolerance for *Listeria monocytogenes*.
- *Escherichia coli* (*non-toxigenic*) is found at levels greater than 10 MPN/g (most probable number per gram) in three or more of five subsamples, or greater than 100 MPN/g in one or more subsamples. As of 2/8/2016, FDA has paused such testing and any subsequent enforcement actions.
- *Staphylococcus aureus* is found at levels greater than or equal to 10^4 cfu/g in one or more subsamples.
- *Bacillus cereus* is found at levels greater than or equal to 10^4 cfu/g in one or more subsamples.¹²

4.2 Milk Testing

Microbial testing of product and ingredients as well as environmental sampling provides the necessary results and documentation to meet the goals of food safety programs and to ensure that raw milk, other ingredients, and finished products are of high quality. It is strongly recommended that testing for pathogens should not be done in the dairy plant, but rather samples should be sent to an accredited outside, independent laboratory to prevent the introduction of unwanted microorganisms through the laboratory and normal test procedures.

4.2.1 Raw Milk Considerations

The quality of finished dairy products is influenced substantially by the quality of raw ingredients. Therefore, it is critical that the processor evaluate the raw milk to ensure that only high quality milk is accepted. Bacteria counts are controlled by ensuring healthy animals, and through good hygiene, sanitation, and refrigeration throughout the raw milk handling process. Regarding the influence of raw milk microorganisms on fluid milk quality and shelf life, the most critical factors are the total numbers and the types of microorganisms at the time of processing. Keep in mind that the test results only provide a numerical value; they say nothing about what organisms are present. Further identification tests would be needed to confirm the organisms.

Tests:

- Total count or aerobic plate count is determined by the Standard Plate Count (SPC). The SPC is the standard to which other screening tests are compared.
- The legal SPC limit for producer Grade A milk is 100,000 cfu/ml (colony forming units per milliliter) and for Commingled or Grade B milk is 300,000 cfu/ml. Counts

of less than 10,000 cfu/ml at the farm and less than 50,000 cfu/ml at the time of processing are desirable for optimum shelf life of fluid milk and can be readily achievable by many producers.

- Direct Microscopic Count (DMC) are rapid results obtained in approximately 15 minutes. This test is used for liquid foods that are diluted and observed on a slide under a microscope. Only a trained laboratory technician should perform this test. Dead as well as living cells are counted, so the DMC may result in slightly higher counts.

Coliforms are a group of organisms used as indicators of sanitary conditions. Poor milking hygiene, poor animal housing, seasonal conditions (muddy/rainy), and improper cleaning and sanitizing of equipment, may result in elevated coliform counts. There is no federal standard for numbers of coliforms that may be present in raw milk used for cheese or for raw milk products. There may be legal requirements in individual states, so always check state and local requirements. A recommended value is <10 CFU/ml for raw milk, but some reference <100 CFU/ml as an initial screening tool.¹³ Coliforms in pasteurized milk should be less than 10 CFU/ml, and for pasteurized milk products, less than 10 CFU/g as these organisms are readily killed by pasteurization.

Be aware that such tests give an overall indication of hygienic quality; they provide no information about the presence of harmful bacteria, food-poisoning organisms, or pathogens. Knowledge of the pathogen content of the milk supply is essential for raw milk cheesemaking. A testing program for pathogens in raw milk will form an important element for the verification of most Hazard Analysis Critical Control Points (HACCP) plans.

4.2.2 Raw Milk Quality Indicator Organisms

Controlling bacterial contamination and growth in raw milk is critical to the quality and shelf life of pasteurized milk products. When bacteria counts become excessive, microbial enzymes cause degradation of milk components resulting in off flavors and other defects. Some microorganisms produce enzymes that are heat-stable, and which continue to be active after pasteurization even though the bacteria themselves are destroyed.

Tests:

- Standard psychrotrophic plate count (SPC) requires incubation of the plate for 10 days at 45°F (7°C). This length of time is commercially unacceptable to determine the psychrotrophic population of raw milk. Instead a modified Preliminary Incubation (PI) Count, which consists of incubating raw milk or cream for 24 to 36 hours at 45°F (7°C) followed by SPC, gives some idea as to the number of psychrotrophs present.
- The test for thermophilic bacteria is known as a laboratory pasteurization count. High thermophilic counts are consistently associated with unhygienic production practices, for example the buildup of milkstone on milking lines. Thermophilic bacteria such as some *Micrococcus* spp. are capable of surviving pasteurization.

The thermoduric count indicates thoroughness of equipment sanitation and assists in detecting sources or organisms responsible for high counts in pasteurized milk products. Milk in test tubes is heated at 145°F (63°C) for 30 minutes to simulate the Vat Pasteurization method. Survivors are counted as thermoduric organisms using the standard plate count method.

4.2.3 Raw Milk Cheese

Cheesemakers should expect to have their food safety protocols as well as overall plant conditions examined. Under the Food Safety Modernization Act (FSMA), these protocols should include written GMPs, a risk assessment plan such as HACCP or Preventive Controls, and testing of products after the 60-day aging requirement.

Tests for raw milk cheese quality and safety should include all tests mentioned in 4.2.2 above, and in addition:

- The 'Big 4' organisms that are generally of concern for cheese made from raw milk are *Salmonella*, *Listeria*, STEC *E. coli*, and enterotoxigenic *Staphylococcus aureus* (coagulase-positive staphylococci) so it is reasonable to screen the milk supply for these. However, *E. coli* O157:H7 is also relevant to raw milk supplies and requires a separate test that should be added to the list from time to time, especially if *E. coli* is detected. Tests for coliforms or *Enterobacteriaceae* might also provide useful information.

4.3 Environmental Monitoring

The purpose of an environmental monitoring program is to establish an effective system to detect the presence of *Listeria* species in all areas of the cheese processing plant. Environmental testing is an important verification step of any risk reduction plan. Brine tanks, drying racks, aging rooms, and air quality need to be sampled on a routine basis, as these areas constitute a potential environmental concern for cheese contamination.

4.3.1 Sampling

Environmental swabbing must be done in an aseptic manner. This means that contamination is prevented through the act of swabbing. Hands and equipment used for swabbing must be sanitary. Guidance on how to correctly take samples can be found in *Aseptic Tips and Techniques for Environmental Samples*.¹⁴

ATP (adenosine triphosphate) is a nucleoside triphosphate component of all organic material that includes living cells. ATP swab tests determine ATP content via the use of bioluminescence (measurement of light emission). This is a rapid test that correlates to the overall sanitary condition of equipment surfaces. The swabbing generally takes place prior to the start of the day's production. Test results reveal food residue or ATP from microorganisms, whether dead or living, and indicate the efficacy of cleaning and sanitation protocols. Values above an internal threshold indicate inadequate cleaning and sanitation.

Testing for pathogens and indicator organisms is done by swabbing the facility's "zones."

Generally, zones can be thought of as follows:

- *Zone 1:* This zone contains Food Contact Surfaces (FCSs), and includes all processing equipment and lines, such as pasteurizers, bulk tank, curd knives, pipes, cheese vats, paddles, draining mats, knives, cheese hoops and other utensils, packaging equipment, or anything that comes in direct contact with the product. If testing finds results outside of the acceptable limits established by the individual company, production must be stopped immediately, and a complete cleaning and sanitizing operation needs to take place.
- *Zone 2:* Nonfood Contact Surfaces (NFCSSs) are in these areas that are directly adjacent to Zone 1. This includes NFCSSs that are in the area around the production zone. Aprons worn by employees, hoses used for cleaning, the floor path that exposed food product travels, overhead conveyors or equipment supports, cat walks, presses, draining tables, racks, framework over vat, overhead structures (lights, pipes, etc.), floor, and control panels are all examples that should be tested. Zone 2 is not always environmentally controlled. This zone includes draining tables, racks, and the outside area of vats that can be warm or humid, especially in the summer. This area is also often the area where milk and whey may be contaminating the environment due to the nature of small production facilities. Areas that are warm and wet can promote bacterial growth.
- *Zone 3:* This is the area that directly surrounds Zone 2 and holds the risk of cross-contamination within production. These areas include non-product contact surfaces within the processing area and storage areas for packaging, ingredients, and finished product. For example, floors, hoses, ventilation, drains, carts, dollies, wheeled trash bins, employees' boots and shoe soles, cleaning tools, walls, ceilings, hand washing sinks, overhead piping, conduit and structural supports, drains, and forklifts and pallet jacks that enter processing and packaging areas (these should be numbered for identification).
- *Zone 4:* This zone includes sites that are not located where food is produced or exposed; areas that are located outside of production rooms. Warehouses, dock areas, break rooms, coolers, hallways, floors in locker rooms, bathrooms, loading docks, etc. are all areas that fall into Zone 4. This area can serve as an indicator of initial sources of contamination in Zones 1-3. Consider traffic patterns that could allow organisms to migrate to production areas and ensure that heavy traffic areas are sampled routinely.

It is important to note that Zones 2-4 can be tested for *Listeria* species.

4.3.2 Frequency of Environmental Testing

FDA's 2008 "Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-to-eat Foods; Draft Guidance" on environmental sampling recommends the following frequency for testing of each Zone¹⁵:

- **Zone 1: Critical Food Contact Surfaces (FCSs)**
Collect samples from all or representative sets of FCSs at least once per week. If using representative set, testing should be planned so that all sites are tested at least once a month. The number of samples to collect depends on the size of producer, but even the smallest producers should collect from a minimum of five sites.
- **Zone 2: Critical Nonfood Contact Surfaces**
Collect samples from all or representative sets at least once every two weeks. If using representative set, testing should be planned so that all sites are tested at least once per quarter. The number of samples to collect depends on the size of producer, but even the smallest producers should collect from five or more sites in each area where cheese is processed or exposed. Collection sites should be varied on a rotating basis, especially if results are consistently negative.
- **Zones 3 and 4:**
Testing frequency is at the discretion of the producer, but is recommended monthly. Some choose to conduct testing quarterly or even with longer intervals between testing. Increase sampling when tests show levels above baseline or when positives are found in Zones 1 and/or 2. In this instance sanitation and its frequency should be reassessed.

Figure 4.1: American Cheese Society.
Zone ID Chart.

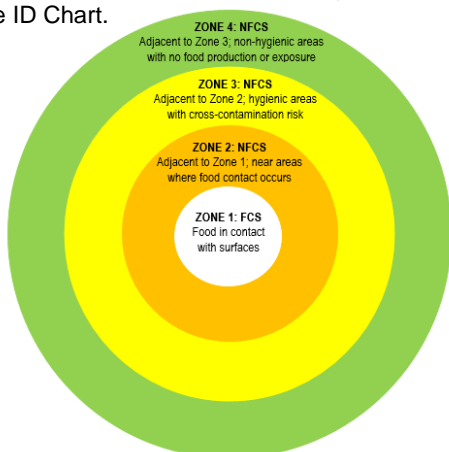


Figure 4.1 shows how zones may be defined in a cheese plant. When determining which zone to test for pathogens, one’s first instinct might be to focus testing in Zone 1. Unfortunately, finding pathogens in this zone means it is too late – the product is already contaminated and may lead to product recalls. Therefore, the least amount of testing should be done in this area. Zones 2 through 4 may be considered high-risk areas. Day-to-day operations in these zones may transport pathogens into Zone 1. Most testing efforts should be concentrated in these areas.

GMPs and sanitation procedures must be strictly followed to prevent the transport of pathogens from Zones 2, 3, and 4 into the Zone 1 production area.

4.4 Product Testing

When present in high enough numbers, pathogens can survive many process steps and controls. For this reason, product testing is important to verify the efficacy of interventions and process controls. While microbiological tests on finished cheeses have an important place in quality control, these tests cannot ensure the microbiological safety of the cheese. The tests may be imperfect or may not be statistically reliable. In-process and end product testing depend on whether or not the cheese is manufactured from raw or pasteurized milk. For raw milk cheese, testing will depend on the extent and results of raw milk testing, as well as the testing of the finished product itself. Some cheesemakers believe that if their raw milk source has a low number of organisms, the milk is safe and free from pathogens. What one needs to remember is that the results of a Standard Plate Count (SPC) in raw milk are only enumerations; they show the existence of organisms, but not the type of organisms present. It is highly possible to have pathogenic bacteria in raw milk at low numbers, and then find that the cheesemaking process contributes to their growth in number. Using pasteurized milk may give a sense of complacency in regards to pathogens. But, as with raw milk cheese, it is highly possible that milk contaminated with low levels of pathogens post-pasteurization can grow during the cheesemaking process. GMPs and process controls are of utmost importance at all times.

Finished product testing will provide some additional consumer protection. Test results give the cheesemaker the documentation and evidence that their procedures and processes are under control.

4.4.1 Sampling

The cheese itself may not always be the source of contamination. All ingredients added to the curd after production and prior to pressing, such as herbs, spices, and other flavorings, should be tested to prevent the addition of contaminants. Packaging

materials for the cheese should also be tested to prevent contamination of the finished product after the basic cheese make is completed. Obtaining letters of guarantee or certificates of analysis (COA) for added ingredients, as well as for cheese packaging, will help to avoid introducing contaminants to the product. COAs and other guarantees still require routine verification.

Samples should be taken when the pathogen population is expected to be highest; this varies according to the type of cheese and its processes. Acceptable levels are not defined, for unacceptable levels please see sections 4.1.2, and 4.2.2, above.

4.4.2 Frequency of Product Testing

Frequency of finished product testing will be very specific to the risk of the product. For example, soft, ripened cheeses pose a greater risk of pathogen growth than hard cheeses with a long maturation time.¹⁶

The frequency of testing can be anywhere from weekly to bi-annually, and should be reviewed and increased or decreased per the laboratory results obtained, and any changes within the business. Pathogen testing should only be undertaken by an accredited laboratory and not conducted in-house. A third-party testing facility reduces pathogen risk contamination of the plant and provides an unbiased test result.

In addition, testing frequency may differ based on the relationship between the milk producer and the cheesemaker, the size of the business, and any requirements imposed by customers – especially major retail chains and wholesalers.

In July 2015, a consortium of retailers made up of Whole Foods Market, Wegman's Food Markets, and Lund Food Holdings, jointly developed an "Artisan Cheese Maker Level One Food Safety Audit and Supplier Checklist" which details their baseline requirements for any producer wishing to sell product in their stores.¹⁷

¹ Marth, Elmer H., and James Steele, eds. *Applied Dairy Microbiology, Second Edition*. 2 edition. New York: CRC Press, 2001.

² Champagne, C. P., R. R. Laing, D. Roy, A. A. Mafu, and M. W. Griffiths. "Psychrotrophs in Dairy Products: Their Effects and Their Control." *Critical Reviews in Food Science and Nutrition* 34, no. 1 (1994): 1–30. doi:10.1080/10408399409527671.

³ Cousin, M A. "Presence and Activity of Psychotrophic Microorganisms in Milk and Dairy Products: A Review." *J Food Prot.* 45 (1982): 172–207

⁴ U.S. Office of Regulatory Affairs. "Manual of Compliance Policy Guides." *U.S. Food and Drug Administration*. Accessed December 8, 2016. <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/>.

⁵ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, and Office of Regulatory Affairs. "Guidance for FDA Staff: Compliance Policy Guide Sec. 527.300 Dairy Products-Microbial Contaminants and Alkaline Phosphatase Activity," December 2010. <http://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM238465.pdf>.

⁶ Office of Regulatory Affairs, Center for Food Safety and Applied Nutrition. "Compliance Policy Guides - CPG Sec. 555.320 Listeria Monocytogenes." *U.S. Food and Drug Administration*. Accessed February 8, 2017. <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm136694.htm>.

⁷ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, and Office of Regulatory Affairs. "Guidance for FDA Staff: Compliance Policy Guide Sec. 527.300 Dairy Products-Microbial Contaminants and Alkaline Phosphatase Activity," December 2010. <http://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM238465.pdf>.

⁸ U.S. Centers for Disease Control. "Multistate Outbreak of E. Coli O157:H7 Infections Associated with Cheese (FINAL UPDATE)." *U.S. Centers for Disease Control and Prevention*, November 24, 2010. <https://www.cdc.gov/ecoli/2010/bravo-farms-cheese-11-24-10.html>.

⁹ U.S. Centers for Disease Control. "Listeria (Listeriosis)." *U.S. Centers for Disease Control and Prevention*. Accessed August 12, 2016. <http://www.cdc.gov/listeria/>.

¹⁰ U.S. Office of Regulatory Affairs. "Manual of Compliance Policy Guides: 7106.08" *U.S. Food and Drug Administration*. Accessed December 8, 2016. <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/>.

¹¹ U.S. National Archives and Records Administration. Cheeses and Related Cheese Products, 21 Electronic Code of Federal Regulations § 133. Accessed August 23, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=3251256a7255e92cf1ed3808d844c6c8&mc=true&node=pt21.2.133&rgn=div5>.

¹² U.S. Office of Regulatory Affairs. "Manual of Compliance Policy Guides: 7106.08 and 527.300" *U.S. Food and Drug Administration*. Accessed December 8, 2016. <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/>.

¹³ Wehr, Michael, PhD and Joseph F. Frank, and PhD. *Standard Methods for the Examination of Dairy Products*. 17th edition. Washington, DC: American Public Health Association, 2004.

¹⁴ Food Safety Net Services. "Aseptic Tips and Techniques for Environmental Samples." Accessed December 8, 2016. http://fsns.com/docs/FSNS_Aseptic_Sampling_Training.pdf.

¹⁵ U.S. Center for Food Safety and Applied Nutrition. "Guidance for Industry: Control of Listeria Monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance." *U.S. Food and Drug Administration*, February 2008. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm#ftn5>.

¹⁶ Food Directorate / Direction des aliments, Health Canada / Santé Canada, Center for Food Safety and Applied Nutrition, Food and Drug Administration, and U.S. Department of Health and Human Services. "Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Interpretive Summary," 2012. <http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM338618.pdf>.

¹⁷ Lund Food Holdings, Inc., Wegmans Food Markets, Inc. and Whole Foods Market, Inc. "Artisan/Farmstead Cheese Maker Level 1 Audit and Supplier Compliance Checklist," 2015. <http://www.cheesesociety.org/wp-content/uploads/2017/02/Lund-Food-Holdings-Artisan-Supplier-Compliance-Checklist-Level-One.pdf>.



Chapter 5

Definitions and Classification of Cheese

Cheeses can be defined and classified in many different ways. Examples of classification include milk type, texture, fat content, ripening method, or country of origin. The *Codex Alimentarius* provides international standards for cheese classification.¹ In the United States, the Standards of Identity for cheese can be found in the Code of Federal Regulations (C.F.R.) 21 C.F.R. § 133. Regardless of classification system, many varieties of cheese cross over from one category to another. For instance, a Gouda-style cheese can be sold to customers at many different ages, and therefore textures; can have a natural or waxed rind; and can be made from different milk types.

5.1 Regulatory Definitions

The US Food and Drug Administration (FDA) maintains and enforces a number of standards of identity for 72 cheeses and cheese products. Each specific standard of identity can be found in the Code of Federal Regulations (C.F.R.) 21 C.F.R. § 133.² Any cheese labeled with one of the cheese names identified must comply with the compositional and manufacturing requirements of that cheese.

The Federal Standards of Identity moisture and fat content were established to “promote honesty and fair dealing in the interest of consumers” as per the Federal Food Drug & Cosmetics Act (FFDCA), section 401. Setting a maximum moisture content ensures that the buyer/consumer will receive a minimum amount of solids; similarly, setting a minimum FDB allows the buyer/consumer to determine if the ratio of fat to the remaining solids is acceptable. Descriptive terms for cheese are legally defined according to the federal standards in the C.F.R.³

In the federal Standards of Identity, cheese can be categorized by name (e.g. Monterey Jack, Colby) as well as additional categorical standards characterized by moisture and fat in dry matter (e.g., semi-soft). Unfortunately, the C.F.R. lacks a semi-hard category causing an overlap between hard and semi-soft cheeses. The US Department of Agriculture (USDA), which grades cheeses, and the FDA use the same standards of identity found within the C.F.R.

It should be noted that most chapters in the C.F.R. contain the following wording in regards to production methods: “*or by any other procedure which produces a finished cheese having the same physical and chemical properties.*” This is frequently referred to as the technology clause, and it exists so as not to lock the industry to any traditional, old, or outdated technology.

The moisture content of a cheese is an important characteristic that is used to help differentiate cheeses when classifying them in conjunction with the fat content. Fat content provides a measurement of fat within the cheese that is used to meet the Standard of Identity. There are two ways in which the fat content is expressed: The fat as a percentage of the solids and fat as a percentage of the cheese as a whole.

Fat as expressed by a percentage of the solids is referred to as Fat on a Dry Basis (%FDB), Fat in Dry Matter (FDM) or Fat in the Water-Free Substance (FWFS).

Fat is expressed as a percentage of the cheese as a whole is referred to as Fat on an As Is Basis, or Weight by Weight (Fat% w/w). For example, a Brie may contain 60% FDB, but if you take the cheese as a whole, i.e. including its significant water content, it might have just 31% Fat on an As Is basis. The %FDB is determined mathematically after the Fat% (Fat As Is) and the moisture are determined. To do this:

$$\text{FDB} = \text{Fat\%} \div (100 - \text{Moisture\%}) \times (100 \div 1)$$

$$\text{FDB} = 31\% \div (100 - 50\%) \times (100 \div 1)$$

$$\text{FDB} = 31\% \div (50\%) \times 100$$

$$\text{FDB} = 31 \div 50 \times 100 = 62\% \text{ (similar to the example given above, e.g. a double cream brie)}$$

In addition, the USDA Agricultural Marketing Service (AMS) has standards, specifications, and commercial item descriptions for various cheeses that are not mandatory unless there is an intention to sell a cheese to the US government. These standards are based on the C.F.R. standards.⁴

5.2 Artisan, Farmstead, and Specialty Definitions

The following terms are widely used in the cheese industry but are not defined legally. The American Cheese Society (ACS) uses the following definitions:

Artisan: The cheese is produced primarily by hand, in small batches, with particular attention paid to the tradition of the cheesemaker's art, and thus using as little mechanization as possible in the production of the cheese.

Farmstead: The cheese must be made with milk from the farmer's own herd, or flock, on the farm where the animals are raised. Milk used in the production of farmstead cheeses may not be obtained from any outside source.

Specialty: Specialty cheese is defined as a cheese of limited production, with particular attention paid to natural flavor and texture profiles.

5.3 ACS Judging & Competition Categories

The ACS Judging & Competition (J&C), the largest competition of its kind, is a premier competition for cheeses produced in the Americas. The Judging & Competition classifies cheeses and cultured dairy products in 20 different categories. These categories are then subcategorized based on milk type, age, style, fat and salt content, added ingredients, and/or moisture content.

For the most up-to-date listing of categories, please refer to the ACS Judging & Competition Category List (updated annually) which can be found on the ACS Website. 2017 Categories can be found here: http://cheesejudging.org/wp-content/uploads/2014/02/2017_Categories_FINAL_2016-12-12.pdf

5.4 Milk Source or Milk Type

Milk source plays an important role in cheese production. Cheesemakers have the opportunity to produce cheese from the milk of many types of hooved animals. This allows a cheesemaker to use blends of milk from multiple species. Each blend of milk provides its own unique characteristics to the cheese. Blended milk cheeses do not currently have a standard of identity, but must follow the same food safety requirements as any other cheese.

5.5 Milk Treatment (Raw or Pasteurized)

Current regulations in the United States allow for the sale of cheeses made from unpasteurized milk as long as the cheese is aged for a minimum of 60 days at a temperature no less than 35°F (2°C). Cheeses made using milk that has been subjected to a heat treatment below that of pasteurization cannot be labeled as pasteurized. Please see the Glossary section of this guide for definitions.

5.6 Method of Coagulation

Cheeses may be categorized by the way in which they are coagulated.

Acid coagulated or lactic cheeses: The precipitation, or separation, of curds from milk by the addition of acid has been common for many years. Vinegar, acetic acid, citric acid, lemon juice, lactic acid, and even hydrochloric acid, have been used to produce curds. In this process, the pH of the milk drops to the acidic range (pH < 4.6). This alters the interaction of the colloidal calcium phosphate molecules with the casein micelles, and they begin to dissociate. Once this happens, the micelles become destabilized and begin to interact with each other, forming a coagulum or gel.

Examples of acid-produced cheeses include fromage blanc and fresh chevre. These cheeses have a high moisture content of over 50% and shelf life of only a few weeks, which can be extended to a few months if frozen.⁵

Coagulation by acid and heat: Coagulation by acid and heat occurs when milk, milk-whey blends, or just whey is heated to at least 176°F (80°C) for at least five minutes. This denatures (unfolds) the whey proteins and encourages association of whey proteins with casein micelles. Once the milk is at the desired high temperature, acidification is slow with gentle agitation (reducing pH to about 5). The caseins and whey proteins will coagulate together and form curds. The curds produced are small and fragile, resulting in a short shelf life and greater than 50% moisture content cheeses. Heat coagulated ricotta, paneer, and queso blanco are examples of this type of cheese.⁶

Rennet coagulated: Rennet was originally produced by harvesting the digestive enzymes of a suckling calf or kid. The process of drying the animal stomach and then grinding it up to add to the cheese milk has evolved into actually producing these same enzymes through microbes such as *Mucor miehei*. These enzymes are proteolytic so that when they are added to the milk, they cleave a specific section of a particular casein species, causing a chain reaction that results in the formation of a coagulum.

After the cleavage of the peptide bond on k-casein, a new protein (para kappa casein) is formed and it is insoluble in the presence of calcium ions. Thus, coagulation begins as the casein begins to form a gel matrix. As this matrix forms, the water and fat are trapped. The time to cut is when the desired gel matrix strength has been formed. After the cut, the whey exuded from the curd should be translucent demonstrating limited losses of fat and protein to the whey.

Examples of rennet-produced cheeses include Brie, Cheddar, Gouda, and Brick. Curd is often cooked after cutting to reduce moisture content in order to produce the desired body texture.

5.7 Method of Ripening

Cheese ripening or curing may also be known as cheese maturation or *affinage*. The process involves microbiological activity from still viable starter culture organisms, biochemical reactions occurring from active enzymes that are present, and physical changes from the milk components undergoing breakdown.

Fresh or Unripened Cheeses are unaged cheeses. They have a relatively short shelf life, which may be extended by submerging the cheese in oil or freezing it. These cheeses have a moisture range of 40-80%, and per federal law must be made from pasteurized milk/cream as they are aged less than 60 days.

Surface Mold-Ripened Cheeses mature from the outside in. While their manufacture begins just as with fresh, unripened cheeses, these mold-ripened cheeses differ in that molds, yeasts, or surface-ripening bacteria are added to the milk. The paste of these cheeses softens based on which of these are added and encouraged by the cheesemaker, with pH rising from the outside of the cheese to its center. The surface ripening results in an increase in pH and moisture levels, and puts these cheese types at greater risk for growing pathogenic bacteria. The moisture contents of these cheeses ranges from 36-58%. Examples include Brie and Camembert.

Internal Mold-Ripened cheeses have the addition of mold spores from the *Penicillium* family to create rich blue veining throughout the cheese. As the mold spores grow, not only do they produce the desired color effect, they create chemical changes within the cheese. *P. roqueforti* contains lipolytic enzymes that release free fatty acids for the distinct flavor characteristics associated with veined cheeses. The texture of these cheeses will vary from soft to firm depending on fat and moisture content. Moisture content does not exceed 46%. *Penicillium glaucum* is also used. Examples of internal mold-ripened cheeses include blue, Roquefort, Gorgonzola, and Stilton.

Surface Bacteria-Ripened Cheeses, also referred to as washed or smear rind cheeses. Typically have rinds that are various shades of red-orange. The cheeses are washed during the maturation process, and the bacterium that give the cheese its color thrive with this treatment. Soft surface-ripened cheeses are often characterized by a rich aromatic, piquant flavor. Semi-hard smear cheeses are milder, with a pleasant, sweetish flavor.⁷ Tilsiter, Gruyère, Beaufort, Trappist, Munster, Brick, and Limburger are all examples of surface bacteria ripened cheese.

Internal Bacteria-Ripened Cheeses can range from semi-soft to hard grating cheese in texture, thus giving a wide array of fat and moisture content. Eyed cheese is ripened internally as well. Generally these cheeses remain stable in pH during aging as well as being lower in moisture. Cheddar, Provolone, and Swiss are a few examples of internal bacterial-ripened cheeses.

5.8 Cheese Safety Wedge

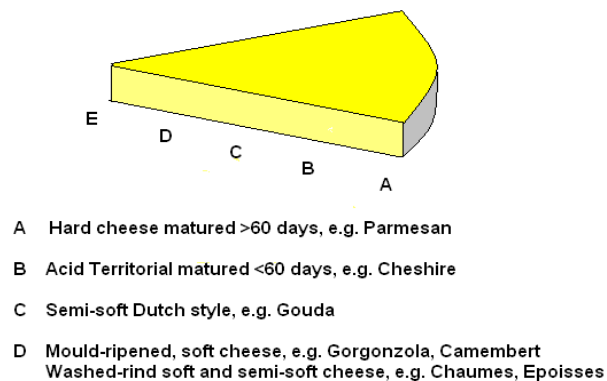


Figure 5.1: Specialist Cheesemakers Association. *The Cheese Safety Wedge*. 2015. Specialist Cheesemakers Assured Code of Practice.

The Specialist Cheesemakers Association combines several of the above characteristics and categories and then groups the cheeses by risk to create its “Safety Wedge” (*Figure 5.1*).⁸ At the ‘thick end of the wedge’ are hard cheeses that are ripened for many months (category A), which potentially pose the least risk of microbiological hazards, whereas the mold-ripened and washed-rind (category D) styles potentially pose the greatest risk and are therefore positioned at ‘the thin end of the wedge.’ Category E products

(cheeses that probably should not be made) are deliberately located off the end of the wedge, not because their physico-chemical composition is inherently dangerous, but because there are unacceptable risks in their production. An example would be a mold-ripened, soft cheese made from raw milk bought from an unlicensed or unregulated market where the cheesemaker has no knowledge of the milk production hygiene standards and the milk producer has no interest in the destiny of its commodity. In this scenario, the potential for contamination of the raw milk supply with pathogenic bacteria must be considered high, and therefore unacceptable.

¹World Health Organization, and Food and Agriculture organization of the United Nations. Codex Alimentarius: Milk and Milk Products. 1st ed. Milk and Milk Products, CAC/RCP 57-2004. Rome: World Health Organization: Food and Agricultural Organization of the United Nations, 2011.
ftp://ftp.fao.org/codex/Publications/Booklets/Milk/Milk_2007_EN.pdf.

² U.S. National Archives and Records Administration. Cheeses and Related Cheese Products, 21 Electronic Code of Federal Regulations § 133. Accessed August 23, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=3251256a7255e92cf1ed3808d844c6c8&mc=true&node=pt21.2.133&rgn=div5>.

³ U.S. National Archives and Records Administration. Cheeses and Related Cheese Products, 21 Electronic Code of Federal Regulations § 133. Accessed August 23, 2016. <http://www.ecfr.gov/cgi-bin/text->

⁴ USDA Agricultural Marketing Service. “Dairy Products.” Agricultural Marketing Service. Accessed December 22, 2016. <https://www.ams.usda.gov/grades-standards/dairy-products>.

⁵ Wilbey, R. Andrew, Scott, J.E., Robinson, Richard K. *Cheesemaking Practice*. 3rd ed. Springer US, 1998.
<http://www.springer.com/us/book/9780751404173>.

⁶ Hill, Art. *Cheese Making Technology eBook | Food Science*. Dairy Science and Technology Education Series. University of Guelph, Canada. Accessed August 8, 2016. <https://www.uoguelph.ca/foodscience/book-page/cheese-making-technology-ebook>.

⁷ Fox, P., P. McSweeney, T.M. Cogan, and T.P. Guinee. *Cheese: Chemistry, Physics & Microbiology, Two-Volume Set*. Elsevier Science & Technology, 2004. <http://books.google.com/books?id=2q4HmwEACAAJ>.

⁸ Specialist Cheesemakers Association. *The Specialist Cheesemakers Assured Code of Practice*, 2015.
<http://www.specialistcheesemakers.co.uk/assured-guide.aspx>.



Chapter 6 Cheesemaking

The *Best Practices* manual is not a recipe book or instruction manual on how to make different styles of cheese. Many sources exist for learning techniques for various styles. And, cheesemakers will want to develop their own preferred methods and signature products. What all commercial cheesemakers have in common is the desire to achieve consistency and produce their cheese safely. This chapter focuses on the decision points involved in making different styles of cheese and the implications of cheesemakers' choices on the goals of consistency and safety.

Safe cheese production combines practices that exclude hazardous ingredients, prevent contamination of product during cheese making, and eliminate hazards during cheese making and aging. Tradeoffs can exist between practices that exclude risks and those that eliminate the food safety hazards if they compromise the cheese.

Cheesemakers need to establish that the series of procedures that they choose will consistently and invariably result in food that is safe for their customers. Then they need records that verify that those procedures are followed all the time. Establishing the chain of procedures that produces safe and consistently high quality cheese will provide peace of mind for the cheesemaker. The evidence that the procedures are effective and are followed will also be the basis for satisfying inspectors.

Although the line between cheese and other dairy products may sometimes get fuzzy, cheesemakers should know what defines cheese for regulatory purposes. Among other reasons, the classified pricing system for milk in market orders may result in different milk pricing depending on whether the product is classified as cheese.

International agreement on the definition of cheese is published by the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization in the *Codex Alimentarius*. The "Milk and Milk Products Codex" defines cheese as:

Cheese is the ripened or unripened soft, semi-hard, hard, or extra-hard product, which may be coated, and in which the whey protein/casein ratio does not exceed that of milk, obtained by:

(a) coagulating wholly or partly the protein of milk, skimmed milk, partly skimmed milk, cream, whey cream or buttermilk, or any combination of these materials, through the action of rennet or other suitable coagulating agents, and by partially draining the whey resulting from the coagulation, while respecting the principle that cheese-making results in a concentration of milk protein (in particular, the casein portion), and that consequently, the protein content of the cheese will be distinctly higher than the protein level of the blend of the above milk materials

from which the cheese was made; and/or (b) processing techniques involving coagulation of the protein of milk and/or products obtained from milk which give an end-product with similar physical, chemical and organoleptic characteristics as the product defined under (a)¹.

The Codex has a separate definition for whey cheese. It also defines acceptable ingredients and definitions for some standard varieties.

In the United States, cheese is the fresh or matured product that is obtained by draining coagulated milk, cream, skimmed, or partly-skimmed milk – or a combination of some or all of these products – and includes any product that conforms to the requirements of 21 C.F.R. § 133, Cheeses and related cheese products.²

6.1 Milk

The first decision for a cheesemaker is what milk to use. Milk freshness and quality will have a major influence on the quality of cheese. A common quote from experienced cheesemakers is “you can’t make good cheese from bad milk”. Milk is also a potential source of many biological hazards that must be eliminated in the cheesemaking process if they are introduced through the milk. Safe cheesemaking is much easier if the milk is largely free of pathogenic bacteria or other hazards.

Milk quality impacts cheese consistency and the economics of cheese making. Levels and ratios of milk solids, particularly protein (casein), fat, and minerals, will determine the cheese yield (amount of cheese of a given moisture per unit of milk). These levels vary by individual animal genetics and health, breed, feed, nutritional condition, species and stages of lactation. Cheesemakers can get more consistency when they either control the farming practices, work closely with regular milk suppliers or create incentives for the milk properties they want. For instance, cheesemakers frequently pay premiums for higher levels of butterfat and protein and for lower levels of mastitis and bacteria counts. Blending milk from different farms and from animals in different stages of lactation can also provide more consistent milk characteristics. However, when milk is blended from several sources (be they animals, breeds or farms), it will probably not be in the highest possible condition from each source at the same time. Thus, a cheesemaker may need to trade consistency for superior milk quality. Cheesemakers also develop techniques for adjusting their procedures over seasons, feed regimes, and stages of lactation to improve the consistency of the cheese despite varying milk qualities.

6.1.1 Milk Source

Cheesemakers need to test the incoming milk regularly to ensure its safety and quality. Testing must verify that milk meets regulatory standards. Milk must be free of antibiotics and must meet regulatory limits on somatic cell counts and bacteria. Cheesemakers will often have higher standards, especially if the processes and variety of cheese they make are highly sensitive to use of substandard milk.

If the cheesemaker is not also the person milking the animals, then good relations and communication with the milk producer are important. Cheesemakers may want to specify some of the good procedures identified in earlier chapters and verify with the farmer that these practices are being followed. Cheesemakers can face challenges related to feeding decisions on farms. For example, silage, wild onions, and other byproduct feedstuffs can also lead to off flavors in milk, especially if the animals have consumed such items close to milking. These off flavors can be amplified in finished cheese. Some cheese makers use vacuum chambers while heating milk to remove some odors and off-flavors in their cheese. Thermophilic (*Lactobacillus* and *Streptococcus*) and spore forming bacteria (*Bacillus* and *Clostridium* species) can be at high levels in milk from animals fed fermented silage. These may survive pasteurization and often will cause late blowing or unwanted gas production in cheese. Communicating with milk suppliers about feed rations and changes in feed is critical in maintaining flavor profiles.

Cheesemakers or their field representatives should visit farms regularly to check conditions and procedures. Frequent and timely sharing of test results with farmers enables them to identify and correct problems quickly. When the cheesemaker is not transporting the milk, protocols are needed to make sure that milk arrives cold and that trucks have been properly cleaned and sanitized.

Hazards

- Changes in supplier or hauler protocols.
- Poor communication or uncooperative relationship with a hauler or milk supplier.
- Changes in farm environments such as unclean animal housing, wet or muddy conditions.
- Failure to prevent milking of animals treated with antibiotics.
- Breakdown anywhere along sanitary chain

Controls

- Keep supplier and hauler protocols up to date. Visit farms frequently to verify procedures.
- Maintain a good relationship and regular communication with haulers and milk suppliers.
- Provide incentives for quality.
- Monitor environmental conditions on farms through frequent visits and checks.
- Test milk for antibiotics and quality and reject unacceptable loads.
- Maintain documentation of milk testing, temperature of milk at farms and at receiving, and truck cleaning.

6.1.2 Milk Quality in Food Safety Programs

Milk can support pathogens and spoilage organisms that are the most likely source of food safety problems in cheese, as discussed in Chapter 4. Preventive controls to produce safe cheese must include strategies for dealing with those microbiological hazards. Cheesemakers can control these risks with legal pasteurization of reasonably

high-quality milk. Pasteurization has been shown to produce at least a five-log reduction in microbial populations for all major pathogens of concern for cheesemaking. That is, one million listeria cells per unit would be reduced to less than 10. Alternative treatments or a series of procedures may have a similar effectiveness, but it would be the responsibility of the cheesemaker to demonstrate the equivalence.

A more thorough consideration of legal pasteurization provides insight into the standards that need to be met for cheesemakers to be confident and to satisfy regulators. Requirements for legal pasteurization can be found in the Code of Federal Regulations in sections 21 C.F.R. § 240.61 and 21 C.F.R. § 133.3d.³

Pasteurization requirements for fluid milk are also contained in the Pasteurized Milk Ordinance (PMO) that has become a standard for some state regulatory officials. The principle of pasteurization is that each particle of milk must be heated to a specified temperature for a specified period of time.

For instance, for high temperature-short time pasteurization (HTST) the minimum is 161°F for 15 seconds. To guarantee that this standard is met, equipment is designed so that any milk which does not have the required holding time will flow back to a holding tank rather than going to a vat. To prevent potential leaking, higher pressure is maintained on the pasteurized side of plates than on the raw side both during forward flow and when the milk is diverting. To prevent tampering, inspectors regularly verify the settings and seal equipment so that it is not possible to reduce the holding time or temperature. Cheesemakers are required to verify that seals are intact every day. Recording charts provide evidence that the equipment was working properly and cheesemakers sign charts daily verifying that the recording charts match observed temperatures and that the forward flow (cut in) and diversion (cut out) conditions are functioning properly. This continuous monitoring and recording, along with the equipment design and calibration, assures that each particle of milk has been treated.

Similarly, with batch pasteurizers recording devices indicate that time and temperature conditions are met. Temperature controls include the air above the milk so that no drop of milk on the surface can be below the required temperature during the holding period.

A wide variety of other treatments are being used to reduce microbiological risks in milk. Some of these involve heat treatment of milk that does not meet the standards of pasteurization but may significantly reduce populations of pathogens. Bactofuges are milk separators specially designed to remove bacteria and spores from milk. These are often installed in line with a pasteurizer. Developing technologies use light, sound, pressure, competing or protective bacteria, filtration, ozone, or irradiation to kill pathogens. To date, none of these have the accepted effectiveness and procedural controls equivalent to heat pasteurization. However, cheesemakers may be able to demonstrate that a combination of procedures incorporating some of these technologies will consistently reduce pathogen populations in cheese to levels equivalent to those found in cheese made from pasteurized milk.

Legal pasteurization breaks down phosphatase in milk. If a legal seal on a pasteurizer is broken, cheesemakers may be required to test milk for phosphatase until an inspector can reseal the equipment. This test should confirm that the pasteurizer was working effectively. Milk tested for phosphatase should be kept cold and tested quickly as phosphatase can redevelop in milk even if it has been pasteurized. Some cheese producers may heat their milk in vessels that are not legally approved for pasteurization. They may choose to use phosphatase tests as verification that the heat treatment was effective. However, this procedure would not be considered legal pasteurization under federal regulations and a 60-day aging period on the cheese would be required.

Because 60-day aging is not a fool-proof procedure for eliminating pathogens, testing cheese made from unpasteurized milk is advisable, though not required. In addition, soft and semi-soft cheeses may only be made from pasteurized milk. The regulations specify some specific varieties, including Monterey Jack, Muenster and Mozzarella, that must be made from pasteurized milk. New interpretations of food safety requirements under the Food Safety Modernization Act, discussed in the following chapters, may relax these requirements if an alternative system of preventive controls is demonstrated to be effective.

We noted in the previous section that receiving clean milk is important for food safety. Cheesemakers who choose not to pasteurize will benefit greatly from milk with low pathogen counts. Clean farm conditions, healthy animals and choices of feed enable farmers to provide milk with relatively low levels of microbiological risk. Sourcing of clean raw milk is an essential part of the food safety program for cheesemakers.

Cheesemakers face the challenge of knowing and documenting that every batch of milk meets strict quality standards. This may require expensive testing for several common pathogens. Since testing of raw milk will likely not eliminate pathogens to a level equivalent to pasteurization, this will only be one step in a series of choices to reduce risk. Collectively, this series of choices is referred to as the “hurdles” used to reduce risk.

Hazards

- Pathogens in raw milk.
- Ineffective pasteurization.
- Silage feeds may be a source of spoilage microorganisms including *Clostridium tyrobutyricum* bacteria that produce hydrogen and carbon dioxide while fermenting butyric acid leading to late gas defect or “blown cheese”.
- Off flavors or pathogen growth in milk due to feed/diet of animals, unclean equipment or milk spoilage.

Controls

- Test milk for pathogens.
- Verify effective pasteurization.
- Develop a protocol for safe food production in lieu of pasteurization.

- Establish good procedures and communication with milk suppliers including animal diets.
- Establish and maintain a milk handling protocol including holding temperatures, holding time, and cleaning of tanks, pumps and pipelines.
- Maintain records of pathogen testing, equipment cleaning, holding temperatures, and pasteurization or other milk treatment.

6.2 Getting Started

One protection for cheese is to have a level of acidity that is not conducive to growth of pathogens. Most cheese goes through at least some phase where pH is reduced at least below 5.3. A few varieties of cheese are made without significant acidification. Others are treated in a way that allows the pH to increase significantly as the cheese ripens. Higher pH cheeses are more susceptible to growth of pathogenic bacteria and other microorganisms. For those varieties, cheesemakers must take other precautions or processing steps to ensure safety.

6.2.1 Starter Cultures

Most common cheese varieties are acidified using lactic acid bacteria. These starter cultures metabolize lactose releasing lactic acid. Enhanced acidity may create less hospitable conditions for growth of some pathogenic bacteria. In addition, starter bacteria may produce bacteriocins and metabolites that kill pathogenic bacteria. These include nisin, propionics, bulgaricin, thermophalin, hydrogen cyanide and other antibiotics. Furthermore, non-pathogenic bacteria may be able to colonize and capture food sources and outcompete undesirable organisms.

Starter cultures for cheese have other critical purposes, especially impacting flavor development through the release of enzymes that break down proteins and fats during aging. Starter cultures impact the elasticity of the cheese body, and may produce gas to produce flavor and open texture in cheese. The initial acidification step is a preparation for coagulation of milk for curd formation.

Purchased starter cultures must be of high quality, from a reputable source, and be properly stored, either frozen or in dry storage, to ensure their acid-producing characteristics. Cheesemaker's can purchase frozen or freeze-dried, direct-set cultures or they can grow their own bulk starter cultures.

Different varieties of cultures thrive in different temperature ranges. These differences are useful for enabling cheese makers to make different styles of cheese and control their manufacturing process. Dairy microbiologists classify **Mesophilic bacteria** as strains of bacteria that grow at temperatures between 50-113°F (10-45°C) with optimal growth between 86-104°F (30-40°C). **Thermophilic bacteria** grow at temperatures in the range of 68-122°F (20-50°C) with optimal growth between 98 and 113°F (37 and 45 ° C) and can survive at temperatures up to 131°F (55°C). Many starter cultures are a

combination of these classes of bacteria. Inclusion of thermophilic cultures may speed early acid production and protect against slow acid production in case of accidental overheating of the vat. Thermophilic cultures tend to be salt sensitive and have less impact on the cheese during the aging period.

Non-starter lactic acid bacteria (NSLAB) are also common in cheese. These bacteria may be naturally occurring in the milk or the cheesemaking environment. NSLAB are responsible for some characteristic variations in cheese between manufacturers. They also result in some acid production and spoilage in cheese made without the addition of starter cultures.

Storage: Upon receipt and recording into the ingredients log, cultures should be stored per the manufacturer's instructions. Direct Vat Set (freeze dried) cultures are typically stored in a standard freezer. Do not use "frost free" freezers, as this type of freezer goes through temperature fluctuations due to the defrosting cycle, and causes dehydration of the cultures. The frozen pellets or canned cultures must be stored at -40°F (-40°C) or colder.

Some direct set cultures are not available in small sizes appropriate for artisan cheese production. When using less than full containers of direct set cultures, cheese makers should dissolve the full container in milk and then use the necessary portion rather than taking some frozen or freeze dried pellets from the container. Individual portions may not be representative mixes of the strains because most of these purchased starter cultures are cocktails or blends of several strains of bacteria.

Use of bulk starters may be less expensive than direct set cultures and give higher cheese yield, but these present their own challenges. When growing bulk cultures, cheesemakers should test to verify that the cultures are pathogen-free. Growing and maintaining cultures requires specialized areas designated specifically for culture growth. Typically, cheesemakers who use a pH meter or Titratable Acidity (TA) can develop an ideal acid profile and rate of development over time. Many bulk starter media include buffering agents to help maintain the appropriate acidity.

An advantage of bulk starters over direct sets may be that maximum production of protective bacteriocins may require 6 to 15 hours. Bulk cultures containing thermophilic and mesophilic cultures may provide more protection against pathogens than do direct set cultures. Nonetheless, bulk starters must be used within several days and performance in the cheese vat may vary depending on bulk starter age and health. Direct set cultures may produce more consistent cheese.

The possibility of bacteriophage, a virus that attacks specific strains of bacteria, is greater in bulk starter cultures than in direct sets. To prevent bacteriophage, cheesemakers should work with culture suppliers to find and rotate combinations of strains with similar characteristics for cheese production. Since bacteriophage is specific to a strain of bacterium, removing a specific strain of bacteria from the plant for

even a couple of days reduces the ability of its bacteriophage to survive. In addition, removing whey from the cheesemaking premises, and properly cleaning and sanitizing during and after cheesemaking, help prevent growth of bacteriophage. Poorly-designed air systems in a facility can also be responsible for bacteriophage outbreaks. A bacteriophage attack is often characterized by initial acid production, which slows or halts during the cheesemaking process. In contrast, residual antibiotics in milk may kill starter cultures and prevent or delay acid production.

Hazards

- Introduction of contaminants through dirty packaging or improperly stored ingredients.
- Poor acid production due to improper storage of cultures, dosage, bacteriophage, antibiotics, or starter activity.⁴
- Pelletized starters that are a combination of different strains may not be well-blended by the manufacturer. This lack of homogeneity is greater with frozen pellets than freeze-dried cultures. Manufacturers tend to assume that entire packages will be used. Using small portions from a package may result in unbalanced and inconsistent mixes of strains.

Controls

- Clean and sanitize all equipment, utensils, measuring devices, and work surfaces.
- Receive and document all ingredients.
- Check ingredients and supplies upon arrival:
 - Containers should have dry ice present for fresh or frozen cultures.
 - Culture pellets must be frozen and they should be free-flowing (not clumped together, which indicates temperature abuse.)
- Store all materials at temperatures recommended by manufacturer.
- Store ingredients separately from any potential contaminants.
- Aseptically open, weigh dosage, and pour culture directly into milk.
- Do not thaw pellets before use or inoculation, unless using the frozen canned variety.
- Document acid development targets.
- Rotate starter to eliminate strain-specific bacteriophage.
- Thoroughly mix cultures before use, particularly if only a portion of a package is used.
- Store unused portions to prevent spoilage or contamination.

Records to maintain

Pre-Production:

- Milk receipt logs
- Milk test results for coliforms, antibiotics, standard plate count (SPC), and somatic cell count (SCC).
- Receipt logs and COAs for ingredients and packaging

Production:

- Complete pasteurization records per PMO
- Production records including lot numbers for all ingredients and packaging, temperatures used for processing, pH/TA calibration log, and amount of ingredients used.

6.2.2 Direct Acidification

In lieu of lactic acid bacteria, cheesemakers lower the pH for some cheese varieties by direct addition of acid to milk. The higher acidity may not be supportive of pathogen growth, but also won't have the antibiotic properties of some bacterial acidifiers. Weak food grade acids (such as acetic, tartaric, citric, or lactic) and strong acids (such as phosphoric or hydrochloric acids) may be added to milk, whey, or a combination thereof to create high moisture, fresh cheeses such as ricotta, mozzarella, and paneer. The choice of acid will impact the flavor of the cheese. High moisture content in most fresh cheese will support growth of pathogens; use of pasteurized milk is generally necessary.

Acids are substances that release hydrogen. Hydrogen is then picked up by water molecules converting H₂O to H₃O⁺. This water ion is measured by pH meters. Weak acids release hydrogen slowly, and more slowly the lower the pH. Temperature also effects the pH which is normalized to (77°F) 25°C. At higher temperatures, pH will be lower.

As acid is added, pH will initially drop, but will rise again as phosphorus is absorbed as phosphate or calcium phosphate. The cheesemaker may need to add more acid after several minutes to achieve the desired level. Milk that is high in minerals will have a greater buffering effect; this is true of milk from sheep or water buffalo and varies across stages of lactation.

Following cheese production and refrigeration, buffering will tend to raise pH. In cheese with active lactic acid producing bacteria, this buffering will be offset at least in part. In cheese where acid has been added, the increase in pH will likely be greater. Furthermore, pH will rise as protein is metabolized. Cheese with yeasts and molds may see significant increases in pH over time. While pH below 5.4 will deter growth of some pathogenic bacteria, if those are present, they will have opportunities to grow when the pH gets higher.

Addition of acid to the isoelectric point of casein causes the casein to precipitate. As the pH is reduced from about 6.6 to 4.6 the calcium and inorganic phosphate are removed from the casein micelles. This causes the net charge on the micelles to decrease and they become less stable until they finally coalesce. The whey proteins remain in solution at 4.6. Precipitation of casein may also be accomplished at higher pH with the addition of coagulants, as we discuss further below.

6.2.3 Other Additions to Milk

Adjunct Cultures: In addition to lactic acid producing cheese cultures, cheesemakers use adjunct cultures. These cultures generally impact flavor development and cheese texture. Other adjunct cultures produce gas (carbon dioxide) that can produce open texture or eyes in cheese. Protective cultures may be designed to include bacteriocins or bacteriophage that destroy specific types of pathogenic bacteria. Examples of protective cultures include Listex and Holdbac. Creation and commercialization of these protective cultures is a rapidly developing industry. They may become an important part of a food safety program.

Cheese color: Cheese color is added primarily for appearances. The most commonly used cheese colors, annatto and carotene, are odorless and flavorless. Annatto is available in oil or water soluble varieties; cheesemakers want water-soluble. Annatto is relatively inexpensive. One drawback of annatto is its tendency to turn pink when cheese is exposed to light or high temperatures. That can hurt sales. Color should be diluted prior to addition to the milk, being careful to avoid residual chlorine in the container. Leave time for color to mix completely before adding coagulant.

Calcium Chloride: The most common added ingredient is calcium chloride (CaCl_2). CaCl_2 preparations are available in liquid or powder form, and help develop curd firmness. Addition of CaCl_2 reduces the pH of the milk, which accelerates the hydrolytic reaction. It also increases soluble calcium ion and increases the amount of colloidal calcium phosphate. These contributions increase curd firmness and curd-firming rates.

Calcium Chloride should be diluted in clean water immediately before adding to the milk and should be distributed evenly in the milk. If calcium chloride is not mixed thoroughly before addition of coagulants, then it will not produce homogeneous curd.

Hazards

- Impurities in the acids and/or packaging materials could affect cheese quality and safety.
- Cheese lacks competing bacteria or conditions produced by starters that inhibit pathogen growth.
- Buffering may result in high pH that is conducive to pathogen growth in both milk and cheese.

Controls

- Clean and sanitize all equipment and utensils.
- Pasteurize milk per federal regulations.⁵
- Receive and document all ingredients; Certificate of Analysis (COA) must be on file for all products; all acids should be designated food grade.
- Verify supplier standards for all ingredients.
- Cover and store ingredients in a cool environment to avoid contamination by pests, condensation, and/or airborne contaminants.

Records to maintain

Pre-Production:

- Receipt logs and COAs for ingredients and packaging

Production:

- Complete pasteurization records per 21 C.F.R. § 133.3d. ⁶
- Production records including lot numbers for all ingredients, temperatures used for processing, pH/TA calibration log, and quantities of ingredients used.

6.3 Curd Formation

Cheesemakers separate the whey from the curd, or rather the curd from the whey. Casein proteins in fresh milk are evenly distributed because of a free electron that causes them to repel like north poles on two magnets. Cheese making consists of enabling the casein to form into a matrix that captures most other milk solids and then expelling the liquid from this curd. Neutralizing the casein can be accomplished through addition of enzymes, acidification or heating. The technique chosen will directly influence the texture of the cheese. Cheesemakers make choices during coagulation that impact cheese moisture and thus, its ability to support pathogens.

6.3.1 Enzyme addition

Addition of enzymes neutralizes the protein by either stripping a charged particle or attaching to that free electron. The protein micelles are then able to form together into a matrix.

The majority of cheeses, especially hard, aged cheeses, are made using rennet (animal) or other coagulants. Rennet is historically referred to as an enzyme complex harvested from the abomasum, or true stomach, of young ruminants, such as calves, kids, lambs, or camel calves. As the animal ages, the chymosin (milk coagulating enzyme) in the stomach of the young is slowly replaced by pepsin. Both chymosin and pepsin are proteolytic enzymes that act on the casein and create a coagulum. Today, rennet is often used as a generic term to refer to the coagulant, regardless of the original source.

Types of Rennet:

- (1) Animal source (calf, kid, camel, or lamb) also called “traditional rennet”.
- (2) Fermentation produced chymosin (from engineered/genetically-modified microorganisms).
- (3) Microbial rennet (sometimes organic) produced from mold or yeast, frequently referred to as vegetable, however a more accurate term would be vegetarian-acceptable.
- (4) True vegetable rennet from plants such as thistle.

These sources will cause milk to coagulate. However, the enzymes supplied by these coagulants will have varying effects. The degree and form of proteolysis caused by the enzyme affects the cheese’s aging properties and flavor development. Proteolysis is the

breakdown of proteins into peptides or amino acids by the action of enzymes. Each step that follows is influenced by this first reaction/chemical change and contributes to the outcome.

Ripening: Ripening is the stage between culture addition and coagulant addition. The ripening stage may vary from 30 minutes to 90 minutes, depending on the cheese. During this time, bacteria acclimate to their new environment (milk) since they have either been dried or frozen for some time. During the ripening period, the milk acidity falls as the bacteria grow and create lactic acid. Initially the change in pH will be very small as the bacteria acclimate to the milk. Later, given proper nutrients, temperature and acidity, the cultures will enter a logarithmic growth phase. Enzymes are added just after the change in pH begins. Monitoring the change in pH during ripening will tell a cheese maker how rapidly the pH will change (how fast the cultures will be) later in the make. The milk will coagulate faster if the acidity is higher or rising quickly when the enzyme is added.

Set temperature is typically maintained at the optimal temperature for mesophilic starter culture bacteria, 86-95°F (30-35°C), but can vary based on the cheese being produced. Different bacteria have different generation times (time it takes to double population), and generation time is influenced by the environment. For instance, a strain may double every 20 minutes within 5 °s of its optimum temperature, while generation time may increase to 60 minutes or even longer, as the temperature deviates from optimum.

- **Rates:** Dosage rates are recommended by the manufacturer and differ by country of origin. Typically, US manufactured single-strength rennet is used at the rate of 1 part rennet to 15,000 parts milk (70-100 mL (milliliters)/1000 pounds of milk). Single-strength is the usual form for traditional rennet. For double-strength rennet, the usual rate is half that of single-strength or 35-50mL/1000 pounds of milk.
- **Dilution:** Coagulants should be diluted with water immediately before adding to cheese milk to reduce shock on starter cultures and aid in even distribution within the vat. Cold water, 40-50°F (4-10°C), dilution is recommended. Coagulants are temperature sensitive and anything over 100°F (38°C) will start to inactivate them. Dilution for single-strength rennet is 1:20 and double-strength 1:40. The water must be potable. Chlorine-treated water will have adverse effects on the coagulant and should be avoided. Milk should be stirred or agitated when adding the coagulant. As soon as the enzyme is well mixed, and prior to the start of coagulation, milk movement must stop.
- **Alkaline pH:** Coagulants are very pH-sensitive. Check the pH of the water used for dilution. Make sure that the dilution container is cleaned and free of sanitizer. Milk from animals with mastitis leads to high pH. While high pH usually results in

quick coagulation, enzymes from milk with high somatic cells may break down casein and slow coagulation.

- **Storage:** Coagulants should be stored at refrigeration temperature and kept away from direct light. Follow storage shelf life recommendations. Typical shelf life is approximately one year. Expect some loss of activity over time. Animal rennet will lose approximately 1% activity per month; the loss rate is less for other coagulants.
- **Checking for Flocculation:** The first phase of coagulation is flocculation, where the insoluble particles suspended in the solution form flakes (or flocs). Although the rate and firmness of coagulation may vary due to many factors including milk quality and temperature, using the time of flocculation enables the cheese maker to achieve a consistent set. For instance, a cheesemaker may observe flocculation through identification of flakes on a knife or by observing a drop of milk in a container of water. That point may be 7 or 10 minutes after the enzyme is added. The cheesemaker may know that the particular variety of cheese meets standards when allowed to coagulate for three times that period prior to cutting (or an additional 21 or 30 minutes). Using such a rule of thumb, the cheesemaker achieves reproducible drainage characteristics, moisture and texture from the curd.

Many cheesemakers bypass this step and use a standard setting time, such as a half hour after rennet addition. When milk quality and production conditions are consistent fixed set time can result in reasonably similar cheese among batches. If more than one cheesemaker is making the cheese, this simple rule can eliminate variations caused by the different cheesemakers' perceptions of what constitutes flocculation. Flocculation can, however, greatly impact consistency and quality.

6.3.2 Acid Addition

Coagulation of milk can also be achieved by adding enough acid. Addition of acid to the isoelectric point of casein causes the casein to precipitate. As the pH is reduced from about 6.6 to 4.6 the calcium and inorganic phosphate are removed from the casein micelles. This causes the net charge on the micelles to decrease and they become less stable until they finally coalesce. The whey proteins remain in solution at pH 4.6.

In some cheese, a combination of acid addition and enzyme addition are used to produce curd. This enables cheesemakers to create curd without lowering the acidity all the way to the isoelectric point.

6.3.3 Heating to Form Curd

The third way to make milk coagulate is by raising the temperature sufficiently for the milk to become unstable. Ricotta is typically produced in this way. Milk or whey is gradually heated until the milk solids precipitate and rise to the top of the vessel. They can then be scooped off and further drained to produce cheese. This method of coagulation enables cheese to be made with a relatively sweet taste and high pH.

Heating the milk to a temperature over 160° F (71°C) provides a great deal of confidence that the curd at that point will not contain pathogenic organisms.

Often some acid production is used prior to heating the milk. With lower pH, curd will precipitate more quickly with less heat addition. Excessive heating can give cheese a burnt flavor.

Hazards

- Contamination of milk through the addition of rennet. This may occur through auxiliary equipment or supplies such as the dilution vessel and water.

Controls

- Clean all equipment and utensils and allow to dry naturally or shake dry (do not rinse).
- Use potable water for dilution to prevent contamination of milk while adding enzyme.
- Verify documentation of ingredients.
- Avoid contaminating milk with coagulant packaging or equipment for adding rennet (including measuring and not holding packaging over the milk).

6.4 Process Steps

Following coagulation of the milk, different styles of cheese use different methods for separating curd from the whey and achieving the desired texture, moisture and acidity in the final cheese. This document cannot provide full details about all the techniques, but we provide an overview of the steps. Once milk has coagulated, separation of curd and whey happens through a couple techniques. With enzyme set cheese, the coagulum is cut into small piece, heated and eventually curd is pressed into cheese pieces to remove additional whey. With heat set cheese curd can just be scooped off the vat and put into cheese forms. Acid set cheese may be put into bags and drained to remove whey before packaging. The following description gives more details about techniques used for cheese made with enzyme coagulants. Techniques that lower moisture and raise acidity of the final product will create environments that are less supportive of pathogen growth. As in all steps following pasteurization, cheese makers need to be cautious to avoid contaminating product.

- **Cutting:** After the coagulum reaches the desired consistency, as described above based on flocculation, the cheese maker will cut the gel into smaller pieces to promote expulsion of whey (syneresis). If coagulum is too weak at cutting, the curd will shatter, resulting in loss of fat and casein in the whey, lower moisture content, and decreased yields. If the coagulum is too firm, it will not contract properly to expel the whey, resulting in higher moisture content cheese and potential over-acidification. Checking the coagulum strength prior to cutting will aid in consistent syneresis. Many cheesemakers use a clean and sanitized finger or knife to gently lift the curd, looking for a clean break (*Figure 6.1*).



Figure 6.1: Kate Arding. *Breaking Curd*. Collection of Kate Arding.

Cheesemakers typically use a cheese knife or harp consisting of parallel wires strung on a frame at fixed intervals. One harp will have horizontal wires and another will have vertical wires. Cutting the vat the long way with each knife and cross cutting with the horizontal blade will reduce the gel to small cubes. Cutting the coagulum with a minimum of disturbance to create uniform cubes is an art.

Larger cubes are produced if the wires are spaced farther apart and will result in higher moisture cheese. In smaller vats or enclosed vats, a series of perpendicular cuts, sometimes with a blade strung like a tennis racket or just a regular knife, will break up the curd into less consistently-sized pieces. For some very dry cheese, cube size may be as small as rice. These techniques may result in some loss of yield.

- **Healing** is a term used to describe allowing the curds to remain still for up to 10 minutes after they have been cut, and prior to stirring and cooking. Immediately after cutting, the cubes have open edges at the cuts, are fragile and may disintegrate if stirred. Allowing the curds to heal helps the outer shell of the cut particle develop to prevent loss of solids at the beginning of syneresis.

The role of healing is different when making cheese in automated or round vats where the cutting phase may take upwards of 10 minutes. Adding an additional heal step is of little value in such situations and may in fact cause problems such as curds beginning to mat.

- **Cooking and stirring** the curds expel moisture. Cooking typically involves gradually raising of the temperature of the milk by adding steam or hot water to the liner of the jacketed vat. If cooked too rapidly, the outer shell hardens and curd cannot expel the desired amount of moisture. A recommended cooking rate is an increase of curd temperature a total of 10 or 12 degrees in 30 minutes with the speed of heating slower in the beginning that at the end. The temperature increase should be tracked and recorded. In some situations, where the

cheesemaker does not have a jacketed vat, cheese can be cooked by direct heating or a double boiler.

Achieving 40% of the intended temperature increase in the first half of cooking time, and the final 60% in the second half of cooking time is a common rule of thumb. As the curd firms, more heat addition may be needed to force whey from the curd. Jacketed vats may continue to be warmer than the contents after the steam or hot water is turned off. To avoid overcooking, cheesemakers can turn off the heat prior to the intended cook temperature so the curd will “coast” to the desired level.

Some styles of cheeses are cooked by removing and replacing a portion of the whey with hot potable water between 100°F(38°C) and 140°F(60°C) added directly into the cheese vat. Repeating this process as necessary achieves the desired curd firmness and moisture control. Cheese makers must be careful not to kill starter cultures with water that is too hot. This method also washes some minerals from the curd and temporarily increases the pH of the curd and whey.

- **Washing Curds with Water:** Some varieties of cheese have water added at some point in their production. As noted, sometimes hot water is added to help cook the curds by replacing whey. In other cheese styles, cold water may be added after the curds are cooked and some or all of the whey has been removed.
 - **Continental Styles – all variations of Gouda, Havarti, etc.:** Cooking/washing curds with water removes lactose and some surface minerals, lowering the acidity of the curds and whey. Lactose is water-soluble and readily disperses in the wash water, drawing lactose from the curd particle. The contact time between curds and whey is important as lactose will tend to continue to leave the curd rather than just surface lactose being removed if the curd continues to float in water. The timing of draining the whey off the curd thus becomes an important determinant of the residual lactose in the curds which will be the source of acid production.
 - **Washed-Curd American Styles – including Monterey Jack, Colby:** For these styles of cheese most whey is typically removed from the vat following cooking. Cool water is mixed into the remaining curd and whey to lower the temperature. Washing curds with cold water causes the warm curds to absorb water, thus increasing the moisture content in the cheese. The cold water will also reduce the activity of lactic acid bacteria slowing the development of acid and resulting in a somewhat sweeter cheese. Cheesemakers generally want to make sure they have sufficient acid production in the vat prior to the wash step.

- **Draining:** Cheesemakers remove excess whey to enable curd particles to form together seamlessly into the cheese body. A screen placed over the exit valve of the cheese vat allows the draining process to separate curds and whey. The curds may remain in the vat, allowing matting and further draining of whey, and, in the case of a dry salted cheese like Cheddar, for acid development. An alternate practice is to ladle or pump the curds directly into forms. Curds are drained in the hoops or molds rather than in the vat.



Figure 6.2: Arding, Kate. *Draining Curd 1.*
Collection of Kate Arding.

Figures 6.2 and 6.3: Draining of the curds may be accomplished through a variety of methods, from pumping directly into cheese molds (Figure 6.3), ladling (Figure 6.2), or opening the drain valve of the cheese vat.



Figure 6.3: Arding, Kate. *Draining Curd 2.*
Collection of Kate Arding.

- **Knitting** of the curds is done to expel more whey from the cheese, which fuses the curds together. It is the result of rapid chemical change due to the effect of lactic acid. During this process, the acid continues to develop. Knitting of the curd for rennet-coagulated cheeses is done in three different ways:
 1. in the cheese vat (cheddar),
 2. in the cheese press (gouda),
 3. or in the draining hoop (blue).
- **Cheddaring** is the traditional process used by cheesemakers to make cheddar cheese. Small curds are pushed to the sides of the vat, enabling whey to continue to drain. As acid develops and calcium and phosphate are lost, the curds knit together. Cheesemakers cut slabs from the mass of curd which they turn and stack repeatedly. This process helps keep curd warm and creates a homogeneous mass with few oxygen pockets or trapped whey. The resultant texture is smooth and fibrous with a moisture level in the cheese below 39%. The process was developed for cheese that could be aged.
- **Milling** is the final step in traditional cheddar production. The slabs of cheese will have stretched into thin (one or two-inch-thick) slabs. Using a mechanical cheese mill (or for small quantities a knife) the cheesemaker cuts the slabs into small (thumb-size) pieces of cheddar curd. Two distinct types of milling are generally practiced: peg milling (tears the curd apart) and cutting mills (cut the curds with knives or blades). The type of mill used impacts fat and moisture retention. Reducing the slabs to smaller curd enables cheesemakers to apply salt more evenly.

Hazards

- Poorly designed and maintained curd knives that are hard to clean may result in the loss of consistent and efficient cheese production as well as introducing the risk of contamination due to difficulty cleaning.
- Paddles, mills or other equipment that are in poor condition may be hard to clean and may introduce metal to the cheese.
- Improper cooking/stirring of curd will result in poor moisture control.
- Wash water and steam used directly on the curds must be free of contaminants. Culinary grade steam requires use of food grade boiler compounds.
- Rate of acid production affects the microbial control for cheese during manufacturing and storage as well as impacting knitting properties of the cheese curd.

Controls

- Inspect all pieces of equipment used in cheesemaking and make necessary repairs/replacement. Implement a preventive maintenance program.
- Use only food grade plastic for food contact. Document that equipment is intact before and after production.
- Color code, clean and sanitize, and maintain all cleaning utensils, brushes, pails etc. to prevent contamination.
- Maintain proper working condition of pH meters or titratable acidity testing equipment.
- Test water regularly to make sure it is free of coliform and nitrates.
- Sanitize and inspect reusable cheese cloths for cleanliness, look for holes or tears, and remove loose threads that may get stuck in the cheese. The use of single-use, disposable cloths is another possible control, though not ideal for producers seeking sustainable practices as there are no recycling options for such disposable cloths at this time.
- Use immersion clean out of place (COP) tanks to provide thorough cleaning for all equipment that is not clean in place (CIP) capable.

Records to maintain

- Make sheets for cheese production, completed with accurate information including times, temperatures, acid development, and lot numbers for ingredients and supplies.
- Maintenance logs for equipment.
- Cleaning logs.
- Logs of calibration and maintenance for pH meters and thermometers.

6.5 Salting

Salt has many functions in cheesemaking: lowering moisture, slowing acid development, enhancing flavor, and killing or slowing the growth and activity of potential

pathogenic microorganisms. Concentration of salt-in-moisture (S/M) is a strong determinant of many of the microbiological and biochemical changes that occur during cheese maturation. **Sodium chloride** (NaCl) is the basic salt used for cheesemaking. Cheese salt, available at many cheese supply shops, is refined, non-iodized rock salt, ultra-finely ground. Kosher salt is another good choice for cheesemaking. Kosher salt is a refined and additive-free salt, with flake texture that adheres well to cheese.

Other salts are generally not as successful for a variety of reasons noted below.

Unrefined sea salt contains trace minerals that add flavor and nutrients to cheese. These minerals will also add a slight bit of grey/brown color to the cheese. It must also be noted that trace minerals such as copper may catalyze fat oxidation, leading to undesirable (cardboard or copper penny-like) flavor.

Iodized salt contains iodine, a necessary human nutrient added to salt to reduce the instance of thyroid deficiencies. Iodine is also an antibacterial agent and inhibits the action of the starter culture.

Coarse-grained salt does not stick easily to the surface of cheese, but some cheesemakers prefer this type of salt because of the slow dissolving rate. The use of fine-grained or flaked salt is preferred by others, as the grains will adhere better to the cheese.

Solar salt (salt naturally dried by the sun and wind) is best avoided as it has the potential to be contaminated with a wide range of undesirable and pathogenic bacteria. Cheesemakers have attempted to use **potassium chloride** (KCl) to replace sodium chloride (NaCl) for low sodium cheeses with mixed results.

Cheesemakers apply salt in one or more of three methods.

- **Dry salting curd before pressing:** When salt is applied to cheese curds, it immediately begins to dissolve into the water phase at the surface of the curd. The salt should be applied in increments with a thorough mixing between applications (approximately 5 minutes). Water is drawn osmotically and expelled from the surface of the curd as the salt diffuses inwardly. During the pressing step, whey is further removed. As whey is lost from the cheese during salting, lactose is also removed, reducing the possibility of extremely low pH and poor fermentation during ripening.

Because salt is washed out of the cheese when whey is removed from the curd, the dryness of the curd before salting will affect the salt retention. For example, it may take salt addition of 2.5 percent to achieve a salt percentage in the cheese of 1.6 to 1.8 percent. Different types of salt have different retention rates. Fine flake salt is efficient because it dissolves within a minute and is partly absorbed in part before syneresis washes it from the curd surface. Coarse salt also seems to be relatively efficient because it is heavier and does not wash off the surface

as easily when whey is expelled although it may take over three and a half minutes to dissolve. Special and plain flake salt have lower retention. Salt crystal shape also impacts retention. Cheesemakers are advised to discuss the available options and application to their type of cheese with salt vendors.⁷

- **Dry salting after pressing surface rubbed cheese:** Dry salt is rubbed onto the surface of cheese to create a rind. The rind develops as the outer layer of cheese becomes dehydrated by the salt. The thickness of the rind is controlled by the humidity and temperature in the aging chamber. Dry-rubbing the surface results in a rind with low moisture and high salt content, both of which create a selective environment that strongly influences the microbial growth on the rind and creates a thicker, stronger barrier. Over time, salt levels will tend to equalize between the rind and the interior, but initially the interior of the cheese will develop with relatively less salt.
- **Brining:** The cheese is immersed in a brine solution containing 23 grams of salt (NaCl) per 100 grams of solution. When the cheese is immersed in a concentrated or saturated solution (23%) of NaCl, the difference in osmotic pressure between the brine and the water in the cheese causes diffusion of salt into the cheese. Therefore, water diffuses out of the cheese matrix to restore osmotic equilibrium.⁸

The quantity of water lost by the cheese is about twice the quantity of salt gained. The Center for Dairy Research (CDR), UW-Madison recommends that the brine solution should be acidified to the same pH as the cheese. This aids in preserving the outer rind and keeps protein from being sloughed off. CDR also states that calcium chloride (CaCl₂) added to the brine solution helps prevent surface and rind defects by reducing calcium migration out of the cheese surface. To control this migration, make sure the calcium level in the brine matches the calcium level in the cheese. Thus, a typical calcium level for Swiss cheese brine is 0.1%, while mozzarella brine would be 0.07% calcium.⁹

- **Combinations:** Some cheesemakers use a combination of methods for salting. For example, a small amount of salt can be added to the curd in the vat followed by brining or dry salting. Similarly, additional dry salt can be added to the surface after brining.

One major difference between hard and soft cheeses is the rate of acidification and the point at which salt is added. Hard cheese typically reaches a desired pH and is salted in one day. Conversely, soft cheeses often ferment overnight to the desired acid level and are salted the next day. Delayed salting allows more opportunity for any pathogens to grow. Since most pathogenic bacteria have limited salt tolerance, high levels of salt are often found in cheese varieties where there is little or no acid development.

Hazards

- Impurities of salt, creating flavor and moisture control issues or introducing contaminants.
- Uneven distribution of salt due to clumping or poor application, allowing harmful organisms to grow or flavor defects in low salt areas.
- Excess moisture may cause fine salt to be flushed out of cheese during whey loss, reducing the final salt content.
- Improper maintenance of brine concentration, which reduces salt uptake by the cheese or enables brine to be contaminated and contaminate cheese.
- Improper temperature when salting can result in cheese defects or loss of salt in whey/brine.
- Improper humidity and temperature control in the aging cooler resulting in poor rind development and loss of surface salt.
- Pathogenic bacteria such as *Listeria monocytogenes*, *Staphylococcus aureus*, enterohaemorrhagic *E. coli*, *Yersinia enterocolitica*, and several *Salmonella* species may survive in brine solutions less than 10g salt/100-gram water (10%). Yeasts and coliforms are also known to survive in brine tanks.
- Water impurities in the brine makeup.

Controls

- Add and mix salt into curds to achieve the correct Salt/Moisture (S/M) content of the cheese.
- Manage moisture content of cheese when salt is added.
- Monitor and maintain temperature of:
 - cheese curds during addition of dry salt,
 - curds or cheese block during brine process,
 - aging and storage of cheese before/after salting (as well as humidity).
- Maintain salt concentrations, temperature, and pH of the brine solution.
- Use good manufacturing practices (GMPs) focusing on cleaning and sanitation of brine tanks and surfaces.
- Test brine for microbial contamination.

Records to maintain

- Receipt and inspection of salt including lot numbers.
- COA from salt supplier.
- Cheese production records including salt application rate, acid development and temperatures.
- Monitor salt brine concentrations, and corrective actions if not to specification.
- All test results for water, such as brine concentration and microbial contamination.
- Cleaning and sanitation records.
- Salt/Moisture Phase (S/M) testing results for cheese.
- Temperature and humidity records in regards to storage and brine tanks.

6.6 Aging and Ripening

Many cheese varieties require aging, or affinage. During this process, bacteria, mold or yeast may be added to or allowed to grow on the cheese surface or interior. Combinations of bacteria, molds, or yeasts will change the appearance and color of the cheese's outer surface and change the physical-chemical properties of the cheese.

Curing, ripening, and maturing are other terms used to describe the various treatments used during cheese aging. These treatments may include, but are not limited to rubbing, brushing, spraying, wrapping in cloth or leaves or bark, and regular turning. The development of a cheese rind is influenced by temperature, humidity, and airflow in the aging or maturing room, along with the cheese composition itself. As cheese matures, conditions may become favorable for growth of pathogenic micro-organisms. Cheesemakers must take care to prevent introducing pathogens during this process. Intrinsic characteristics of the cheese, such as pH, salt, moisture and microbial diversity will impact the ability of pathogens to grow.

Cheesemakers may also modify the microbial ecology on the rind to make it less susceptible to contamination. Cheesemakers can introduce competitive flora as well as control temperature, pH, humidity, airflow in the aging chamber, and cheese composition. The control of these factors will directly influence the safety of the cheese. The environment for soft- and mold-ripened cheeses (both blue and white), increases opportunities for pathogen contamination and growth. As the surface molds grow, they increase the pH of the cheese towards a neutral value. This higher pH value will allow any pathogens that may be present to grow more readily. Sources of pathogens include, but aren't limited to, human hair, dust, soil, human or animal feces, clothing, air handling systems, water, and equipment such as brushes and shelves. Excluding pathogens from the environment is the most effective way to prevent contamination.

Temperature influences the mold growth on the surface of cheese as well as the enzymatic reactions occurring in the interior of the cheese. Temperatures between 46 and 64°F (8-18°C) should be maintained for hard cheese maturation, depending upon the cheese variety. Innocuous molds, those that typically do not produce mycotoxins, will grow in this range. Some toxin-producing molds, such as *Aspergillus ssp flavus*, may grow in this temperature range, but are less likely to outcompete the desirable varieties at the lower temperatures.

Washing cheese with brine solutions factors growth of some bacteria, such as *Brevibacterium linens*, that are desirable for producing some cheese varieties. Bacterial surface-ripened cheeses should be held at 53-57°F (12-14°C) for proper maturation. These temperatures are only general recommendations, as each type of cheese has its own specific temperature parameters. The brines and bacterial preparation need to be handled carefully to prevent contaminating the solution and promote the growth of desired yeast and bacteria used for surface-ripening of washed-rind cheeses. The

organisms modify the pH on the rind and release enzymes. These enzymes work inwardly, breaking down proteins, fats, and carbohydrates to produce desirable aroma and flavor compounds.

6.6.1 Cheese Aging Characteristics

The characteristics of cheese develop through the aging process. To get the desired characteristics of a cheese, the aging environment must be conducive to that particular cheese. The following are suggestions for aging cheese. Ultimately, the aging environment is left to the discretion of the cheesemaker. Producing safe, consistent, reproducible results is dependent on maintaining the cheese's environment consistently. The second part of this section discusses methods to gain desired characteristics of a cheese. Cheesemakers should be aware of the hazards that may be introduced when deviating from proven conditions.

Environmental Considerations:

- **Soft cheeses** such as the bloomy-rind and smear-ripened varieties are high in moisture (around 50%), have short ripening times, and attain high pH values during ripening (around 7.0). They are especially vulnerable to pathogens because of their low acidity (high pH). Brie and Camembert-type cheeses are aged in this way – they both start out at low pH, high acidity and quickly increase to high pH and low acidity due to the action of the yeast and mold. The most commonly used molds to produce bloomy, white rind cheeses are *Penicillium candidum*, *Penicillium camembertii*, and/or yeast-mold hybrid *Geotrichum candidum*. *Penicillium glaucum* is commonly used for blue veined cheeses.

Smear-ripened cheeses start out at a pH around 4.75-4.9 and increase to higher pH values at the surface due to the action of naturally- present or inoculated yeasts, molds, and bacteria.

- **Extra Hard cheeses** such as Parmigiano-Reggiano contain low moisture (around 30-35%), high salt (around 2.5-4%), moderate pH (around 5.0-5.2), and require long aging periods (one to two years). They carry a much lower risk of contamination due to the high cooking temperature, which eliminates most pathogenic bacteria, low moisture and an aging environment that has low relative humidity, resulting in a dry rind. Water activity in this cheese is about .62, which is very low and not supportive of growth or activity of principle pathogens.
- **Bacterial surface growth:** Alpine-style cheeses contain low salt (generally <1%), as well as acid levels above pH 5.1, which supports growth of *Brevibacterium linens* and other desired coryneform bacteria, a reddish growth on the surface of cheese. These are aerobic bacteria found on cheeses such as Gruyère, requiring high humidity (90-95% relative humidity).

Eye Development: Alpine style cheeses typically have a managed, slow, or delayed acid development, resulting in a sweet cheese. This type of cheese supports growth of *Propionibacterium freudenreichii* ssp. *shermanii*, which results in flavor compounds and eye (characteristic Swiss cheese hole) development. Temperature of aging will influence the size of the eyes. For example, cooler temperatures produce smaller eyes, such as in a Beaufort, whereas warmer temperatures produce larger eyes, such as in Swiss/Emmental. The warm room for eye development has a temperature range of 57-75°F (13-24°C) with 80-85% humidity. The conditions will also dictate the rind. Swiss/Emmental has a clean, smooth rind and is aged at a lower humidity than Gruyère, which requires more abrasive surface scraping and cleaning on the part of the cheesemaker. Propionic acid produced by the bacteria may provide some protection against pathogenic organisms.

6.6.2 Aging on Wooden Boards

The Food and Drug Administration's (FDA) current regulations state that utensils and other surfaces that contact food must be "adequately cleanable" and "properly maintained." While high density polyethylene (HDPE) or stainless steel (SS) racks are often used, many artisan cheesemakers feel that wooden shelves favor cheese rind development and improve the organoleptic qualities of aged cheeses, thanks to the formation of a protective biofilm on the wood surface and the ability of the wood to aid with moisture control in the cheese. At this time, FDA has agreed to continue to study the safety of wooden boards. Cheesemakers are required to use materials that are well maintained and kept clean and can use wood that is suitable for its intended purpose.

Traditional methods of cleaning wooden cheese-ripening boards by washing and soaking them in tap-temperature water and vigorously brushing them has been found to minimize the risk of contamination by pathogenic microorganisms while allowing useful microflora to be preserved. An example of how to clean wood boards is summarized below:

- The boards are pressure washed and scrubbed with 140°F (60°C) chlorinated, alkaline solution in potable water.
- The boards are rinsed with 140°F (60°C) potable water.
- The boards are then sanitized with either a chlorine (200 ppm) or hydrogen peroxide (10%) solution, which stays on the boards.
- The boards are thoroughly dried in an area with ample space between boards to ensure air flow.
- The boards are stored in a clean room until their next use.
- Kiln drying of the boards can aid in controlling organism growth.

Hazards

- Contamination from air circulation fans.
- Humidity and temperature fluctuations.
- Poor acid and moisture control of cheese, resulting in unwanted microflora growth.
- Insufficient turning of cheese during aging

- Improper cleaning of boards, shelves and utensils.
- Cheese mites causing contamination and cheese damage.
- Contamination of cheese by wooden boards or utensils used on surfaces.
- Cracked or damaged boards

Controls

- Purchase kiln-dried hardwood boards for aging
- Meet target pH, salt, and moisture values.
- Track board lots to identify shelving that has come into contact with contaminated cheese or cheese that has contacted contaminated shelving.
- Properly clean and sanitize aging facilities and shelving.
- Conduct environmental testing. (See also: Section 4.3 Environmental Monitoring)
- Test boards to be sure they are free of pathogens. Discard contaminated boards.
- Remove cracked or damaged boards that cannot be cleaned immediately.

Records to maintain

- Testing results for cheese in regards to pH, salt, and moisture.
- Environmental and board testing results.
- Inventory control for incoming and outbound product for traceability.
- Temperature and humidity control records for aging facility.

6.7 Mites

Cheese mites are small insects that are just visible to the naked eye (<0.5 mm). Despite their size, their affinity for cheese and ability to bore holes on the surface of a rind can be a costly expense for cheese plants that are infested with this pest.¹⁰ Mites have been a concern for many years. In a “Notice to the Dairy and Cheese Industry” issued April 16, 1936, FDA Chief W.G. Campbell wrote: “All cheese factories and curing rooms should be protected against the entry of flies, mites, and other insects that infest the cracks of curing cheeses and leave debris that is difficult to remove.”¹¹

When they attack cheese, cheese mites will first be detected as a brown powder on the surface of the cheese or in small cracks or breaks in the paraffin. In time, cheese mites will burrow into the cheese, leaving behind the characteristic accumulation of brown powder, which consists of dead mites, living mites, cheese debris, and excreta. This brown powder has a characteristic sharp, pungent odor¹².

There are no legal requirements set forth for cheese mites, however, FDA suggests having more than 6 mites per square inch of cheese surface is a basis for regulatory action¹³. The typical half pound wedge has three or four square inches that were part of the wheel rind. However, as soon as the wedge is cut, there are as many as 19 square inches for the mites to infest.



Figure 6.4: Arding, Kate. *Cheese mites*.
Collection of Kate Arding.

Safety and health problems may arise due to the growth of cheese mites. Mites may transfer pathogens and yeasts/molds from other surfaces to the surface, or even interior, of cheese. While cheese mites and their debris are considered allergens, only large quantities provoke allergies. According to Coudé and Wendorff, cheese mites may result in allergic responses such as atopic dermatitis, allergic rhinitis, and asthma that cause individuals physical, social, and/or mental health problems. Mites have been reported to have caused severe dermatitis in cheese handlers, as well as gastrointestinal disorders in consumers.¹⁴

6.7.1 Sources of Mites

Mites are common in factories making clothbound Cheddar or natural rind cheese that is more than 4 or 5 months old. Cheese mites find their way into the cheese room by attaching to peoples' clothing, floating on an air current, or through outside materials. Undoubtedly, many cheese rooms have small numbers of mites, even though they are not numerous enough to cause any visible damage to the cheese. Cheese mites may crawl from one cheese to another, but because of their size, they do not move very far by this method. Workers in cheese curing rooms are probably the chief means of transportation for these tiny insects. Curing room workers should be supplied with clean uniforms.

6.7.2 Growth Conditions for Cheese Mites

Several factors favor the development of cheese mites in a curing room. One generation of mites requires 10 days to reach adulthood and begin reproducing, with adult mites living 2-5 months. Temperatures of 42-86°F (6-30°C) favor their growth. Mites seem to attack old cheese in preference to young cheese. The presence of very old cheese in a curing room will usually be the first point of infection of cheese mites. Hard, aged cheese is more apt to attract their activities than softer cheese. Cheese that has been coated with paraffin (waxed) is not easily attacked by cheese mites if the coating is sound. If the coating of paraffin has been damaged by handling, cracks and nicks in the coating will offer an opening for mite infestation. Unclean conditions in the curing room such as greasy shelves, old and dirty cheese boxes, dirty walls, ceilings, or floors encourage the development of mites.¹⁵

6.7.3 Preventing Infection of Mites

The cheese curing room or cheese storage area should be kept clean. Cheese shelves should be washed thoroughly and this washing should include the shelf supports. Scrub the cheese curing room with caustic cleaner, including the ceiling, walls, and the floor at least two or three times a year. Old cheese should be removed from the cheese curing room or storage area unless it has an impervious coating. Scraps of substances, such as cheese, greasy bandages, grain, and dried fruits, which might serve as food for cheese mites, should not be allowed to remain or collect in the cheese curing room. Cheese boxes that are suspected of infection should be thoroughly scrubbed, scalded,

and dried before they are used for cheese in an unaffected room. Low temperature is effective in preventing the growth of cheese mites, keeping temperatures within a few degrees of 35°F (2°C) and not higher than 41°F (5°C). When temperatures go above 41°F (5°C), mite activity is correspondingly increased.¹⁶ In this temperature range it is difficult to maintain the high relative humidity which cheesemakers need to produce natural rind cheeses, and will slow ripening.

Alternative common means of controlling mites in cave-aged or natural rind cheese is the use of food grade diatomaceous earth. Diatomaceous earth looks and feels somewhat like baking flour and is a natural deterrent against cheese mites. Commonly, the material is spread on the top and bottom of the cheese and then rubbed into the remainder of the cheese using a brush. This method is typically used several times throughout the aging life of the cheese, and generally again before the cheese is shipped. It is most effective against adult mites. Those handling the diatomaceous earth should wear personal protective equipment (PPE) to avoid exposure. The reproductive cycle of a cheese mite is approximately nine days, so be sure that the shipping process does not leave time for the mites to develop.

6.7.4 Controlling Mites

When a cheese curing room is infected with mites, all infected cheese, boxes, and accumulations of scrap material should be moved out of the aging room. The operator should thoroughly clean the cheese curing room, scrubbing the ceilings, walls, floors, uprights, shelf supports, and shelves.

Other successful methods of controlling mites include vacuuming the cheese and environment, washing with hydrogen peroxide, regular washing and scrubbing of cheese, and surrounding the legs of shelving with diatomaceous earth.

Any worker who may have handled infested cheese should not be permitted to carry any other cheese into the aging room until s/he has changed clothes and washed thoroughly.¹⁷

Hazards

- Mites can leave behind filth on/in the cheese.
- Mites and their debris may cause dermatitis, mild eye irritations, or allergic reaction to some cheese handlers or consumers.
- Mites may potentially spread pathogens from one area to another.

Control

- Control temperature (the optimal temperature for deterring mites is around 35°F (2°C) and not higher than 41°F (5°C))
- Remove old cheese that is no longer saleable.
- Control moisture in the aging room as well as in the cheese itself.
- Clean and sanitize the aging room, including shelving and supports.
- Monitor clothing to prevent transporting mites.
- Wear PPE when working around mites or handling diatomaceous earth.

- Filter and circulate air.
- Brush, wash, or vacuum cheese to remove mites.
- Ensure proper placement and distribution of diatomaceous earth to help control mites.

Records to maintain

- Make sheet from cheese production.
- Inventory controls for cheese moving in and out of aging cooler/cave.
- Cleaning and sanitation records for aging facility.
- Temperature and humidity control records.
- Cleaning and sanitation records.

6.8 Wrapping and Rind Development

The outer wrapping of the cheese can be an aid for aging of the cheese. It may also be used as the packaging of the cheese, depending on the materials used. Whether the wrapping is made of natural materials, cloth, or even a vacuum bag, all of these wrappings will directly affect the maturation of the cheese.

6.8.1 Rind Development

Rind development requires that the cheese sit in an open environment. As moisture evaporates from the cheese, the outer surface becomes dry and forms a rind. Controlling the brining process, oil and/or salt rubs on the surface, as well as temperature and humidity of the aging chamber will determine how thick and tough the rind becomes. Using dry salt rubs on the surface of the cheese dehydrates the surface, creating a barrier that will influence the microflora activity in the aging cheese, as the barrier or rind is low in moisture content and high in salt.

Smear-ripened cheese will age differently according to the humidity and temperature of the aging facility. Conditions of the aging room as well as the moisture content and the pH of the cheese will directly affect the aging process and time required to achieve the desired results. In *“American Farmstead Cheese: The Complete Guide to Making and Selling Artisan Cheese”*, Kindstedt writes that temperatures below 52°F (11°C) will slow down the aging process. Kindstedt goes on to state that pH is key for washed rind cheeses, as well. The pH will directly affect the brining process (brine pH must match cheese pH) by either dissolving the protein surface of the cheese to create a soft rind (when brine pH is greater than cheese pH) or remaining intact to create a rind capable of hosting the *Brevibacterium linens* typically used as a smear.¹⁸

Rind development issues may include the following:

- Undesirable flora due to contamination, the substrate (pH, moisture in the nonfat solids), the environment (temperature, humidity, composition of the air, air flow, and renewal rate of the air).

- Mechanical splits in the rind.
- Excess humidity resulting in defects that may spoil cheese.
- Migration of minerals (calcium phosphate) from the cheese to the surface, creating a cardboard texture and off flavors. This is a result of poor room temperature control cycling from high to low temperatures. Aging rooms should have a near constant state of temperature and humidity or humidity that decreases gradually as the cheese rind develops.

Another natural wrapper is the use of various plant materials. The material or leaves must be pathogen-free. Some commercial fresh produce sanitizers are available and work well to sanitize the leaves. The addition of alcoholic liquids such as wines, sherries, brandies, and others may also be used. Sources of leaves may be fruits such as grapes, hard woods such as maple or walnut, nettles, pines, figs, and any other safe plant source the cheesemaker may want to try. Always be aware of potential allergens when introducing any natural wrapper to the cheese.

6.8.2 Bandaging

Bandaging is most often used with Cheddar because it results in a drier, flakier cheese body. A more robust flavor is developed due to concentration via dehydration and activating alternate bacterial enzymes that require a drier cheese body. The flavor is also strongly enhanced by the bandage wrap, because the molds (and in some instances mites) on the outside of the cheese metabolize the fat on the bandage rather than the cheese itself. The entire wheel of cheese is covered with a muslin material. It is then smeared with a fat of choice, most commonly bacon fat or lard. Bandage wrapping will discourage rind cracking in the lower moisture cheese compared to allowing the cheese surface direct contact with air.

At about one month, mold growth begins on the outside of the bandage wrap. The cheese should be gently brushed to distribute the mold. A soft-bristled synthetic brush which can be sterilized is recommended. Brushing will not eliminate the mold growth, but it slows it down and spreads it evenly. It will also aid in the control of cheese mites. When brushing the bandage, brush away from the cheese. Do not brush in a circular motion to avoid digging channels into the cheese. It is at the cheesemaker's discretion to determine how frequently to brush cheeses. A recommendation is to brush wheels at least once every other week.

Brushes may be a source of contamination and should be thoroughly cleaned with chlorinated alkaline cleanser, and sanitized with chlorine, peroxyacetic acid (also known as peracetic acid, PAA) or iodine-based sanitizer, before and immediately after use. They should then be allowed to air dry (never rinse after sanitizing). A commercial product, Deptil Acid San, is a phosphoric acid with a lot of surfactant and 24-hour residue, which is ideal for soaking brushes. Boiling brushes is an alternative option. A dishwasher with a sanitizing cycle may also be used to more thoroughly clean the brushes. Brushes should be tested for the presence of pathogens. Do not use cheese brushes for any other purpose. Color-coding brushes is recommended to avoid

unintentional use for other purposes.

6.8.3 Cheese Waxing

Cheese is waxed to create a mold barrier, to reduce the rate of moisture loss, and to make the cheese more attractive and easier to handle. Paraffin wax was originally used as a coating on young cheese. The paraffin provides a good carbon dioxide (CO₂) permeability. A flexible wax coating overlay on paraffin wax is used for young and long-hold cheese. This type of wax gives the lowest water transmission. Flexible, low-temperature wax is used as a temporary protective layer for ripening Blue or Brick cheese. Today, many cheese wax products are available in a variety of colors. Both smooth rind and rindless cheese may be waxed.

For the initial coat, cheese should be dipped in wax between 225-240°F (107-116°C) to flash off moisture and destroy surface molds and bacteria. Cheesemakers should apply successive coats between 160-180°F (71-82°C). Polyvinyl Acetate (PVA) is a common choice for coating cheeses with clean rinds such as Gouda. Natamycin, a naturally-derived anti-mycotic, or mold inhibitor, is commonly added to PVA. This anti-mycotic will permit a low-maintenance cheese aging process, which slows the rate of moisture loss and allows the release of Carbon dioxide (CO₂). PVA without color added dries to a clear film.

6.8.4 Vacuum Packaging

Cheese vacuum packaged in barrier films will not develop surface characteristics. Its surface will remain the same as when it was packaged. If the film is not tight to the cheese surface, mold may grow on the surface of the cheese inside the package due to remaining oxygen from the poor vacuum or broken seal. Since most films do not allow for vapor transmission, vacuum-packaged cheese must start drier. To be precise, the cheese must have a finished, fully legal composition when it enters the vacuum barrier film. Excess whey/moisture left in the cheese at the time of packaging might be exuded from the cheese, developing pools in the package. If packaging is loose or if moisture collects in wrinkles of the packaging, calcium lactate crystals may form in those locations¹⁹. Some consumers mistake the white crystals for mold. Non-barrier films are common for Swiss cheese and cheeses that develop carbon dioxide (CO₂) during aging; these films allow oxygen to return into the package and so are not suitable for cheese that does not produce carbon dioxide.

Cheesemakers should not use inexpensive polyethylene bags used for packaging meat. These have high oxygen transmission rates and cheese will mold quickly. They will also develop severe surface oxidation defects.

In general, whole pieces of cheese age better than cuts. The natural inclination is to cut the cheese into retail size pieces for aging as it will save time later on. While that is true, the desired aging effects will take longer or may not be achievable in this fashion. A large block of cheese has better internal water migration properties than small blocks of cheese. Remember that cheese has active cultures and enzymes in it when it begins the aging process. The cultures are dependent on the moisture content and migration of

free water within the cheese. It is possible that a small block of cheese may have a “hot spot” of high culture, moisture, or salt content. These hot spots will cause differences in aging properties between smaller pieces of cheese and can result in inconsistency within the same batch of cheese when cut to retail sizes. Brine-salted cheeses must be given a fair opportunity to reach their desired salt and moisture balance before cutting and packing.

Vacuum packaging creates an anaerobic environment, providing an environment for anaerobic pathogens such as *Clostridium botulinum*. *C. botulinum* is an environmental pathogen generally associated with plant materials. Any herbs and spices that are used, if not properly treated, may carry this organism. Clostridium contamination is an infrequent problem in cheesemaking, however in brine-salted cheeses, *Clostridium tyrobutyricum* may be present from silage and fermented feeds. Nisin-producing cultures are available. Nisin, a polycyclic antibacterial peptide produced by the bacterium *Lactococcus lactis* and used as a food preservative, is a well-recognized tool against Clostridia species, including botulinum.

- **Ash ripening:** Vegetable ash is a traditional product used for ripening of cheeses. Cheesemakers should remember that ash must be used and appropriately labeled as an aging/processing agent and not as a food additive. Ash decreases the acidity of the surface of the cheese and allows desired white molds to develop earlier in the aging process (Figure 6.5).

According to the FDA under 21 C.F.R. § 101.100, processing aids are “[s]ubstances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.” Under the current labeling rules, processing aids do not need to be included in the list of ingredients.



Figure 6.5: Arding, Kate. *Ash Ripening*.
Collection of Kate Arding.

In some cases, FDA will approve products as GRAS (Generally Regarded as Safe). Products are regularly under review and approval. As of this writing, FDA has not made such a determination as to ash. Manufacturers are able to make self-determination of GRAS status under some circumstances. Cheesemakers are advised to work with suppliers to determine appropriate sourcing and application.

Ash coated and mold ripened cheese will typically be packaged in cheese paper or freezer wrap to allow the mold to continue to thrive and the cheese to mature at retail. Wax or plastic packaging that cuts off oxygen will create excess moisture for the ash surface and will kill molds, resulting in undesirable flavor changes in these types of cheese.

Hazards

- Mold may grow under packaging material that is not tight or that is damaged.
- Impurities in the film or in the wax if applied at the wrong temperature.
- Creation of an anaerobic condition which enables growth of *Clostridium botulinum*.
- Improperly cleaned brushes can harbor yeasts, molds, and bacteria.

Controls

- Inspect all packaging materials upon arrival, recording lot numbers.
- Dry surface of cheese prior to waxing to prevent bubbling of wax and mold growth underneath.
- Use only recommended heating temperatures to apply wax.
- Obtain letters of guarantee and certificates of analysis from the packaging supplier.
- Clean and sanitize brushes.
- Protect unused packaging from contamination.
- Maintain storage temperature of packaged cheese.
- Use nisin-producing cultures if Clostridia development is suspected in the cheese, and/or when milk comes from silage-fed animals.

Records to maintain

- Receiving and inventory records for first in, first out of packaging materials and lot numbers.
- Inventory records for cheese.
- Document temperatures for cold storage of cheese.
- Maintain cleaning and sanitation records.
- Maintain letters of guarantee from suppliers of packaging materials.

6.9 Summary

As we have seen in this chapter, cheesemakers make a series of decisions that determine the variety, quality and safety of their products. Over time, cheesemakers experiment to determine their preferred path. And they refine skills that enable them to consistently produce the type of cheese that they want.

At each step in the process, the cheesemaker has opportunities to increase the safety of the cheese that will be sold and eaten by his or her customers. Those safety-related choices involve tradeoffs in terms of cheese styles, conformity with traditional methods, cost, and consistency. In the end, the cheesemaker is responsible for following a path that will always result in safe products.

Under the Food Safety Modernization Act, the cheesemaker must not only know the sources of health risks, but also be able to demonstrate to inspectors that there is valid evidence that the chosen series of steps is a process that will result in safe cheese. The

validity of established processes like legal pasteurization are easy to establish. An alternative path may rely on a series of hurdles such as milk supply controls, protective cultures, low available water, high acidity, salt, or other characteristics that challenge pathogens. The challenge to a cheesemaker is to collect or create the evidence that this series of steps is always effective. For many years, the process of aging hard cheese for over 60 days at temperatures above 35 °F was thought to be a valid alternative to pasteurization. More recent evidence has shown that 60-day aging may not always be effective. Perhaps evidence will be developed to show when that procedure is or is not effective and some valid process can be based on that evidence.

Evidence that a series of hurdles is a validated protection against pathogens could be established through experimentation. For example, using microbial species with similar characteristics to pathogens of concern, cheesemakers could dose incoming milk with levels somewhat greater than would be expected from their suppliers and then test the end-product for surviving microbes. As a community, cheesemakers may begin to share this evidence to establish generalized criteria for safe cheese practices.

Once valid procedures have been established, as we have seen, cheesemakers are responsible for verifying that those procedures have been followed. Documentation of critical procedures will be needed. It is useful to recall and review the requirements of legal pasteurization to appreciate the detail of designs, systems, checks and documentation that should apply to any cheese manufacturing procedure.

¹ World Health Organization, and Food and Agriculture organization of the United Nations. *Codex Alimentarius: Milk and Milk Products*. 1st ed. Milk and Milk Products, CAC/RCP 57-2004. Rome: World Health Organization: Food and Agricultural Organization of the United Nations, 2007. ftp://ftp.fao.org/codex/Publications/Booklets/Milk/Milk_2007_EN.pdf.

² U.S. National Archives and Records Administration. Cheeses and Related Cheese Products, 21 Electronic Code of Federal Regulations § 133. Accessed August 23, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=3251256a7255e92cf1ed3808d844c6c8&mc=true&node=pt21.2.133&rgn=div5>.

³ U.S. National Archives and Records Administration. Cheeses and Related Cheese Products, 21 Electronic Code of Federal Regulations § 133

⁴See chapters 1, 2, and 4 of this guide for more information about milk quality.

⁵ U.S. National Archives and Records Administration. Cheeses and Related Cheese Products, 21 Electronic Code of Federal Regulations § 133.

⁶ U.S. National Archives and Records Administration. Cheeses and Related Cheese Products, 21 Electronic Code of Federal Regulations § 133.

⁷ Rao, R.D. and W.L. Wendorff. "Salt Crystal Size and Salt Retention in Cheddar Cheese." Wisconsin Center for Dairy Research, *Dairy Pipeline*, Dec. 2002.

⁸ Guinee, T. P. "Salting and the Role of Salt in Cheese." *ResearchGate* 57, no. 2-3 (April 26, 2004): 99–109. doi:10.1111/j.1471-0307.2004.00145.x.

⁹ Johnson, Mark, and Karen Paulus. "Salting Your Cheese- How to Get It Right." *Dairy Pipeline*. Accessed December 8, 2016. https://www.cdr.wisc.edu/sites/default/files/pipelines/2005/pipeline_2005_vol17_01.pdf.

¹⁰ Coudé, B., and B. Wendorff. "Control of Cheese Mites During the Aging Process." *Dairy Pipeline*, 2013. https://www.cdr.wisc.edu/sites/default/files/pipelines/2013/pipeline_2013_vol25_02.pdf.

¹¹ Campbell, W.G. "Notice to the Dairy and Cheese Industry" April 16, 1936

¹² Price, Walter V. *Cheese Mites*. Department of Dairy Industry, College of Agriculture, University of Wisconsin, 1938. https://web.archive.org/web/20160304093631/http://drinc.ucdavis.edu/research/cheese_mites.pdf.

¹³ Barry, Fiona. "Mimolette 'mite' Be Blocked If Levels Are Too High, Says FDA." *FoodQualityNews.com*. Accessed December 20, 2016. <http://www.foodqualitynews.com/Industry-news/Mimolette-mite-be-blocked-if-levels-are-too-high-says-FDA>.

¹⁴ Coudé, B., and B. Wendorff. "Control of Cheese Mites During the Aging Process." *Dairy Pipeline*, 2013. https://www.cdr.wisc.edu/sites/default/files/pipelines/2013/pipeline_2013_vol25_02.pdf.

¹⁵ Coudé, B., and B. Wendorff, 2013.

¹⁶ Coudé, B., and B. Wendorff, 2013.

¹⁷ Coudé, B., and B. Wendorff, 2013.

¹⁸ Kindstedt, Paul, and Vermont Cheese Council. *American Farmstead Cheese: The Complete Guide to Making and Selling Artisan Cheeses*. White River Junction, Vt.: Chelsea Green Pub., 2005. <http://www.worldcat.org/oclc/57514711>.

¹⁹ Agarwal, S., M. Costello, and S. Clark. "Gas-Flushed Packaging Contributes to Calcium Lactate Crystals in Cheddar Cheese." *Journal of Dairy Science* 88, no. 11 (November 2005): 3773–83. doi:10.3168/jds.S0022-0302(05)73063-0.



Chapter 7

Bringing Cheese to the Marketplace

This chapter covers the final stages before cheese leaves the facility. Considerable effort, resources, and skill have brought the cheese to the point where it's ready to be packaged, sold, and shipped out, and while the cheesemaking process may be complete, correct implementation of these last steps make sure the cheese will reach its final destination in the best possible condition.

Before selecting cheese to send out, a cheesemaker should understand the needs and expectations of the customer. This will ensure the selection of cheese matches the age and flavor profile the customer's wants - and potentially help the producer avoid considerable hassle later. The cheesemaker should carefully select the sales channel(s) best-suited to the cheese and to the scale and style of the cheesemaker's business.

In addition, a cheesemaker should carefully consider the various transportation options so that the cheese reaches customers in peak condition. Having a shipment of cheese spoiled by poor transportation is demoralizing, and a waste of the producer's time and money.

In 2016 the FSMA Rule on Sanitary Transport of Human and Animal Food was finalized. This portion of the FSMA legislation works to protect food from contamination during transport. This rule is 1 of 7 proposed since 2013 to create a risk-based framework for food safety. The legislation applies to shippers, loaders, and receivers of food by motor vehicle or rail. It does not apply to food that is transported by ship or by air. The rule establishes requirements for vehicle and transportation equipment, transportation operations, records, and training.

A waiver to this rule will be published for shippers, carriers, and receivers that are inspected under the NCIMS Grade A Milk Safety Program. The waiver applies only to when those products produced under sanitary conditions are being transported.

Food establishments that hold valid permits issued by a relevant regulatory authority will also be issued a waiver. This includes restaurants, supermarkets, and home grocery delivery services.

It is best practice to ensure that the company you might use for transport of your product is in compliance with this portion of FSMA. For more information about the requirements of the rule, waivers to the rule and compliance dates, please see the FDA FSMA Webpage which has links to the law, guidance documents, and fact sheets, and key requirements of the legislation.¹

7.1 Sales Channels

Whether a cheesemaker is selling everything through a local farmers' market, working exclusively with distributors, selling direct to retailers, or using a variety of sales channels, it is essential to understand that customers have individual requirements and needs.

A successful sales program involves spending time communicating with customers and building effective relationships. This will promote greater understanding of what the customer is looking for, and how to provide the best possible service to them. It can be beneficial to identify someone within the company who is comfortable working directly with customers, keeping in mind that he or she may not be the cheesemaker.

A great start to building any customer relationship is to arrange a visit to the customer's warehouse, store, or restaurant, or to have the customer visit the creamery or facility. Such exchanges allow the cheesemaker to meet the people who will be physically handling and selling their cheese, provide an opportunity to educate customers about both the cheese and the business, and allow the producer and customer to taste products together. Just as importantly, these visits offer a chance for the customer to tour a facility and see first-hand if effective SOPs, recall procedures, and a HARPC plan are in place.

Key Considerations:

Before engaging with or pitching products to any potential customer, a cheesemaker should have all the following information available (and in a presentable format) so the customer can clearly understand it:

- the price of the product*
- how the product will get to the customer
- cost of getting the product to the customer
- handling and storage tips
- shelf-life
- milk source/farm location
- details of the cheesemaking operation
- details of the maturing operation

** All price calculations should include costs of materials and labor, as well as costs of maturation, utility costs, and overheads such as insurance, etc. Many customers, and especially those with tight margins such as distributors and wholesalers, will negotiate hard for a more advantageous price. It is imperative that a cheesemaker can set boundaries with confidence, and clearly understands what price is needed to make a sale worthwhile.*

7.1.1 Distributors and Wholesalers

The economics of most distribution and wholesale companies are such that they are working with slim margins. Therefore, to keep overheads to a minimum and to maximize profit, they usually rely on selling a high volume of product as efficiently as possible.

This often means the infrastructure is not in place to spend a lot of time tending to overly fragile or high-maintenance cheese while it's in their system.

However, there are an increasing number of distributors/wholesalers focused on higher-end specialty foods. Such distributors/wholesalers may have the specialized knowledge and bandwidth to work with cheeses requiring more care. These operations can be independent companies that specialize in working with artisan producers, or they are sometimes divisions operating within a larger company.

Either way, the nature of distribution and wholesale is that the cheese will need to successfully withstand the rigors of transportation from the creamery to the facility, warehousing, and onward delivery to the customer. If that customer happens to be a retail store, they will expect the product to arrive in good condition and to have a reasonable shelf life upon arrival.

For this reason, if selling to a distributor or wholesaler, it's important to ship cheese in stable condition. After it reaches the retailer in good condition, the responsibility of getting the cheese to the end consumer in good condition shifts, and is largely in the hands of the retailer from this point forward.

It is in everyone's best interest to provide as much support as possible to customers, in the form of advice on product care and handling. Their success with a product becomes the cheesemaker's success. An increasing number of individuals working for retailers and distributors are becoming ACS Certified Cheese Professionals™ (ACS CCPs). If a business has an ACS CCP(s) on staff, it can be taken as a positive indicator, as these professionals will greatly appreciate and understand the unique qualities and handling requirements of specific cheese(s).

Key Considerations:

- Cheesemakers should be aware that a wholesaler or distributor may ask that cheese be prepared in a particular way. For instance, a bandage-wrapped cheddar may need to have the bandages removed prior to shipping. Any additional costs incurred should be incorporated into the pricing of the cheese and communicated clearly to the customer.
- A wholesaler or distributor is likely to expect a free sampling allowance. Cheesemakers should prepare for this and build a sampling allowance into the budget.
- If a cheese is seasonal or available only during certain times of the year, the cheesemaker should make sure the distributor/wholesaler is aware of this well in advance.

7.1.2 Affineurs

Typically, cheesemakers producing cheese requiring maturation will have their own maturing caves where they control and monitor the maturation of their cheeses, making the decision as to when to release each cheese for sale. This system ties up a considerable amount of capital, especially if the cheese is long-aged, and requires

additional labor.

However, in recent years, another option has become available, and it is growing in popularity in the United States. An increasing number of specialized cheese businesses are being created that focus exclusively on the maturation of cheese. A specialist cheese maturer often works closely with several different cheesemakers, bringing cheeses into their own facility at a young age and maturing them until they are ready for sale.

There are advantages and disadvantages of this type of arrangement, and while it works very well for some businesses, it doesn't suit every situation.

Advantages:

- It frees cheesemakers from the labor and expense of maturing, selling, and shipping their own cheeses.
- It is likely to improve cash flow for the cheesemaker, as capital is no longer tied up during maturation.
- It allows the cheesemaker to focus entirely on producing good cheese.

Disadvantages:

- Cheesemakers effectively relinquish control of the maturing process for their cheeses.
- The affineur may not wish to credit the cheesemaker with the production of the cheese, effectively consigning the cheesemaker to becoming an "invisible supplier."
- The presence of an independent affineur introduces an additional step in the chain between producer and end customer, which potentially can increase the chances of product contamination either by microbial pathogens or cheese mites. Real product loss (yield loss) could become an issue and appropriate preventative steps must be taken to ensure risks are minimized and product loss prevented. Potential contaminants include, but are not restricted to: [mites, cross contact, temperature and/or humidity fluctuations exceeding limits, excess moisture.

Key Considerations

If working with an affineur is the most suitable option for a cheesemaker, it is imperative that the two parties draw up a detailed contract, under the guidance of legal counsel, that spells out how all aspects of the relationship will be handled. This should also cover liability regarding potential contamination issues. At a minimum, the contract should cover:

- The exact nature of the relationship, i.e. is the affineur buying the product from the cheesemaker, or maturing the cheese on behalf of the cheesemaker with the expectation of returning it to them when it's mature?
- The exact point at which the cheese becomes the responsibility of the affineur, i.e. is it at the point of sale or at another stage?
- Which entity is responsible/liable if something goes wrong with the cheese?

- Is this covered by insurance?
- How will the cheese be marketed and sold? Will both the cheesemaker's name and the affineur's name be referenced in marketing materials? It is recommended, for full transparency, that the name of the cheesemaker should be available to retailers even if it is not necessarily in the marketing.
 - When the cheese is sold, how will proceeds be distributed?
 - Both cheesemaker and affineur may want to document and agree upon key steps of the recipe in both cheese making and affinage.

7.1.3 Retailers and Restaurants

Working directly with a retailer or restaurant, rather than using a distributor or wholesaler, gives cheesemakers an opportunity to communicate closely with the buyer and to obtain valuable feedback about the cheese.

As with any customer, the retailer or restaurant should be asked what their needs and expectations are. For example, they may be seeking a particular flavor profile or age of cheese.

Some customers are looking for a cheese made exclusively for them in a different format or size than the normal production. If this is the case, there should be written confirmation from the retailer or restaurant detailing the nature of the contract and specifying minimum quantities of the exclusive cheese and how long this commitment will remain in place.

It is worthwhile for a cheesemaker to actively seek feedback about the products being sold from the retailer or restaurant. This allows for unbiased feedback and market research at no charge to the cheesemaker, and it may supply information that can assist in refining and improving the cheese recipe or maturation process.

Key Considerations

- Individual retailers and restaurants are likely to want to buy cheese in smaller quantities than wholesalers or distributors. A cheesemaker should be prepared to split cases if necessary and/or sell pre-cut pieces of large format cheese.
- A retailer, especially one with multiple outlets such as a grocery store chain, may request a free sampling allowance. A cheesemaker should prepare for this and know in advance which cheeses are to be sampled and promoted.
- If a cheese is seasonal or available only during certain times of year, a cheesemaker should make sure the retailer or restaurant is aware of this.

7.1.4 Farmers Markets and Self-Operated Retail Outlets

Selling at farmers' markets and through self-operated retail outlets provides many advantages to cheesemakers, especially for smaller scale producers. This includes the opportunity to make direct contact with the end consumer, which provides an ideal environment to foster education about the cheese and obtain customer feedback. In addition, participating in farmers' markets or self-operated retail outlets allows the cheesemaker to charge retail prices and generate more revenue from the cheese.

Key Considerations:

- The cold chain must be effectively maintained—especially in hot weather.
- Any unsold product that is returned to the facility after a farmers' market must be properly processed (i.e. disposed of or returned to inventory if appropriate)
- All equipment returning from a farmer's market must be correctly cleaned and sanitized before being brought into any sanitized area of the creamery, and prior to use at the next market.

Cheesemakers who sell both to retailers and farmer's markets should be aware of the regional retail pricing structures. It is preferable to price cheese in line with the local retailers to avoid conflict.

7.1.5 Approved Supplier Programs

Some customers may require that cheesemakers be an approved supplier and that they comply with certain criteria such as third party audits, allergen programs, or recall programs. The Retail Consortium, comprised of Wegman's Food Market's, Inc., Lund Food Holdings, and Whole Foods Market Services, Inc., has been working in conjunction with cheesemakers to establish base level food safety standards. For a description of the Level 1 Audit Program, see the appendix. For more on approved suppliers, please see:

Cornell University Dairy Foods Extension. "Cornell Dairy Extension- Approved Supplier Program." Accessed January 18, 2017. <https://dairyextension.foodscience.cornell.edu/sites/dairyextension.foodscience.cornell.edu/files/shared/Approved%20Supplier%20Program.pdf>.

7.1.6 Retaining Product

As part of a cheese facility's overall testing program, it is a best practice to retain a small number of cheeses from each batch produced. This allows the cheesemaker to conduct end-product testing and to assess each batch for overall quality of flavor, texture and suitability for release.

It is also a best practice to hold product and have a plan in place as to when product will be released – based not only on testing protocols, but other steps and checklists which must be followed. Basically, if for any reason product does not conform to standards or specifications, it should not be shipped until such issues have been addressed and/or remedied. Cornell University Dairy Extension offers this guideline for product hold/release programs:

Cornell University Dairy Foods Extension. "Cornell Dairy Extension: Product Release." Accessed January 18, 2017. <https://dairyextension.foodscience.cornell.edu/sites/dairyextension.foodscience.cornell.edu/files/shared/Product%20Release.pdf>.

The facility should ensure that:

- Products are confirmed as compliant before release to the market.
- All staff is familiar with product release procedures and that personnel authorized to release product are aware of their responsibilities.
- Products placed under quarantine or authorized personnel only release hold status, are released for distribution only after the product has successfully passed inspection.
- Products released for distribution should have records maintained, even after they have left the facility. These records should record the product name and identification, confirmation of product checks, and the product disposition (e.g., release, quarantine, hold). Products released from hold should also be recorded.
- Records should include the amount of product that was held and the reason for the hold. Records should be reviewed routinely to ensure that holds are closed out. Any product that is still on hold should be physically or visually verifiable.

7.2 Cheese Packing Room

7.2.1 Placement of Packing Room within the Facility

In terms of optimal layout for a creamery, the flow of products should always be “forward”. As products progress and evolve from raw materials, through production, aging, and into packaging and shipping, it is highly recommended that they never backtrack or go through the same area twice. Finished or packaged goods should not be moved through the aging or cheesemaking rooms.

If, “forward” flow is not possible due to a pre-existing layout, then additional measures must be taken to prevent cross-contamination. Measures include cleaning and sanitizing the packaging area before the cheese is brought into it, as well as after the cheese is removed. In addition, there should be self-closing doors separating the packing room from other rooms, particularly from the outside. All packing equipment should be checked to verify that no metal or plastic parts have broken off into the product as part of a control during processing. Please see Chapter 6 of this guide for more information.

7.2.2 Layout and Design of Packing Room

The purpose of a packing room is to create a specifically designed space suitable for wrapping, packing and shipping finished products once they have left the cheesemaking room or cheese aging room.

Equipment in the packing room must be constructed from materials suitable for food production areas. Tables and work surfaces should be made from stainless steel or laminate, wall and ceiling surfaces should be covered in fiberglass reinforced panels (FRP), tile or gloss paint. Floors should be made from resilient material (preferably non-slip) that can be cleaned effectively such as epoxy, tile or concrete. Floors should be constructed with a slope towards the floor drain(s) to aid effective surface drainage.

When designing a packing room, a sanitation plan specific to the space needs to be created. In addition, the following should be taken into consideration to ensure a sanitary environment in the room:

- Surfaces and all drains must be able to be effectively cleaned and sanitized, including floors, ceilings, and walls.
- Equipment and shelving must be raised at least 6" off the floor.
- A dedicated handwashing sink and foot baths (foaming or liquid) for workers.
- A three-part sink or similar system that allows equipment to be effectively washed, rinsed, and sanitized.
- Lighting in the room should incorporate safety glass.
- Positive air pressure and a dedicated table with a hood extractor fan above it are ideal to exhaust mold spores and prevent insects from entering the packing room.

When designing the packing room, it's important to ensure there is adequate space for the temporary storage of packing materials: boxes, labels, filler materials, ice packs, tape guns, etc. Packing materials should not be permanently stored in the packing room, as they pose a potential hazard by bringing in contaminants from outside, including attracting pests. Packing materials should be stored in a separate, designated area at the facility and only brought into the packing room in sufficient quantities to complete the packing tasks taking place that day. After packing is complete, the materials should be returned to their designated storage area each day.

The packing room must also include adequate space for product to be held prior to being packed, and adequate space for the packed boxes or pallets to be temporarily stored. If using pallets, there will also need to be sufficient space to use a pallet jack or another means of moving the pallets in and out of the room.

Ideally, a packing room will include an area where packed boxes can be stored at a temperature between 36-41° F (2-5° C) – preferably a walk-in cooler – to maintain the cold chain when the boxes are loaded onto a vehicle for transport.

7.2.3 Operation of the Packing Room

When working in the packing room, it is important to minimize the handling of different products at the same time – particularly when it comes to raw and pasteurized products. Workers should use special precautions when handling products where microbial growth is present, such as on the rinds of wheels of cheese. They should pay special attention to temperature-sensitive products, such as fresh cheeses, as these products need to remain at safe temperatures (<41°F/5°C) during storage and handling.

Workers must pay close attention to sanitation and personal hygiene in the packing room, as this is the last step in which product is handled before it goes to the customer. Hair should be restrained in a hair net or hat, and clean protective clothing should be worn at all times. It is recommended that equipment be color-coded or otherwise identified in such a way that makes it clear it is specific to the packing room.

Cheesemakers should pay special attention to items stored above packing tables. These should not create potential dust/condensation/sanitation hazards, which could result in product contamination. In addition, any packaging materials in the room should be protected from contamination/pathogens when packing is underway.

7.2.4 Equipment in the Packing Room

The scale and type of operation will determine the number and variety of items and equipment needed in the packing room. A good place to start is to identify the number of packing station(s) that will be required within the room. Before finalizing plans, create a mock-up to figure out how each station should be laid out, itemizing exactly what equipment will be needed at each station and where it will be placed and stored.

Workers must receive thorough and continuing training in how to use the equipment in the packing room. This severely reduces the chances of accident-related personnel/equipment issues and also adds an essential level of safety/quality control to a sanitation program. Proper training will also help prolong the life of packing equipment.

Another essential aspect of safety training should focus on the importance of regularly cleaning and sanitizing equipment. It is imperative for workers to do this in between handling different batches or styles of cheese, as well as when switching between raw and pasteurized versions of cheese.

Above all, it is paramount to ensure that all safety training is documented, and that workers who receive training sign off on it. In the event of an accident or injury, it will be required to prove that the staff member has undergone appropriate training.

7.2.4.1 Knives, Manual Cutters, Wires, and Boards

To safely and efficiently cut and pack cheese, it is necessary to have a selection of cheese knives, a countertop cheese cutter, cheese wires, and cutting boards. To avoid potential cross contamination, these items should be specific to the packing room and identified as such. The key objective when selecting tools is to ensure they can be effectively cleaned and sanitized.

Knives

Knives should have strong handles securely affixed to the blade. Stainless steel blades are preferable to carbon steel as they don't rust. Plastic handles are generally more resilient than wood against the rigors of cleaning agents and high temperature sanitation procedures. Knife blades should have a smooth surface, free from nicks,

cracks, and rust. Knives should be sharpened regularly and staff should receive training in how to do this safely.

The type and style of cheese(s) being cut will dictate what type of cutting equipment is needed to complete the task safely and efficiently. Soft, small-format cheeses will likely require small or medium size knives to cut them. A countertop cutter with a wire can also work well since the cutting action of a wire results in minimal drag through the paste of the cheese.

For aged, hard cheeses, it is useful to have a large double-handled knife available. This can either be of the straight blade variety or a traditional Dutch-style Gouda knife with a slightly curved blade, specifically designed to cut the wheel using a see-saw or rocking motion

Drawing a knife through cheese for cutting can also spread spores along the cut line and into the interior of the cheese. Every cut may introduce a contaminant. Cutting cheese with a moldy surface draws the mold across the paste of the cheese. If conditions are favorable, that mold can grow on the previously clean surface. The same is true for any pathogens that may be on the outer surface of a cheese. It is imperative to clean and sanitize knives between cutting different batches to reduce the risk of spreading unwanted microbes. Cut cheese in an environment dedicated to this work to avoid spreading contamination to other pieces. Also, minimize the number of pieces of cheese exposed to the environment where cheese is being cut.

Wires and Countertop Cutters

Double-handled cheese wires measure 36 inches across, and are very effective for cutting large wheels of cheese. Cutting aged or hard wheels is much easier if cheese is at room temperature first. It should be noted that while the main advantage of a wire is to reduce drag through the paste of the cheese, the actual wire does not have a sharp edge, like a blade. For this reason, workers should first score around the circumference of the cheese (where the wire will be placed) with a knife. This will make the task of cutting with a wire infinitely easier.

Countertop cheese cutters typically have a 24-inch wire that is threaded around a wheel tensioned with springs. This means that after each cut, the wire returns to its original position. Both plastic and metal versions are available and are the most popular kinds to use. Metal versions are typically more expensive, and they are sometimes reported to be more difficult to clean, but the cheesemaker should weigh both options and determine which cutter to use based on the facility's unique needs.

After repeated use, wires will often become curly or break, at which point the wire should be replaced.

Occasionally, a wire will break while a cheese is in the process of being cut. This typically will not cause a problem with soft cheeses, however, if the wire snaps while cutting an aged cheese, the wire may become lodged partway through the cheese,

leaving the operator with no means of leverage to remove it. For this reason, it's very useful to keep a pair of sanitized needle-nose pliers, dedicated to the packing/cutting room, on hand. A snapped wire can be retrieved by pinching the broken end of the wire with the pliers and carefully rotating the end of the wire for several turns. This should provide interim leverage to pull the wire the rest of the way through the cheese.

Cutting Boards

Cutting boards are an essential part of any cutting station. Boards should be cleaned and sanitized regularly. It is recommended that boards are cleaned and sanitized when switching between cheeses, as well as different batches of a cheese. Boards should always be in good condition. If a board is showing excessive signs of wear and tear, such as rough surfaces or deep score marks that are hard to clean, it must be replaced.

To stop a cutting board from sliding around on a stainless steel or smooth surface, a damp paper towel can be placed between the board and the countertop.

7.2.4.2 Equipment for Shredding and Grating

Specialized shredding equipment such as that manufactured by Urschel, can be used to produce cheese shreds. Typically, there are heads inside the shredders that spin, and these heads determine what type of shreds are produced. The blades on the heads can be adjusted to get the desired shred width and thickness. Shaved and grated cheeses are produced the same way, simply by using a different head. Different types of films are used to package shreds for retail and food service. For food service, a nylon film with no barrier should be used. This film results in a structure with greater puncture and abuse resistance. For retail, shreds should be packed in a poly blend film with a barrier layer. This retail film is made of a stiffer, temperature-resistant material that does not absorb moisture. Non-barrier films should be used for Swiss-style cheese or other cheeses that produce carbon dioxide (CO₂) during aging.

Shreds should be packaged in modified atmosphere package. Typical gas readings should be less than 2.0% for oxygen and greater than 20% residual for carbon dioxide. These levels of gas are used to help prevent mold growth in the shreds. Anticaking agents, such as powdered cellulose or rice flour, can be added to prevent shreds or grated cheeses from sticking together. It may be beneficial to source a natural anti-caking agent but testing should be completed to see how the product reacts to the additional ingredient.

Anti-cake agents with anti-mycotic properties can help prevent mold growth and extend the shelf life of the product. The standard industry recommendation is 2-4% of total product weight. That amount might be adjusted lower based on specific customer requests. Check current with the manufacturer of the anti-cake agent selected for advice on quantity to add.

Packaged shreds should be placed into cardboard boxes with a minimum of a 32 ECT or "Edge Crush Test," which measures the "strength of the box". The higher the ECT

number, the stronger the cardboard strength; therefore, the box is less likely to get crushed.

7.2.4.3 Vacuum Packing Machines

Selecting the right vacuum packing machine is essential. Be sure to consider how much product needs to be packed, and how often. The business' projected growth, in terms of future vacuum sealed needs, should also be taken into consideration. There are many options available to fit a wide range of budgets, including some good values found via online retail and auction sites. Please note that small table-top units are designed for very small capacity packing. Budget permitting, it is best to start with a machine that has a chamber large enough for two seal bars, so that four bags can be sealed at the same time.

Hazards

- Pathogens, foreign objects, chemicals, and allergens are hazards to product safety.
- Mold spores, mites, and spoilage bacteria are hazards to product quality.
- Inhalation of released mold spores is a hazard to workers.
- Anaerobic pathogens can grow in vacuum packaging.

Controls

- Handle cheese with visible mold in an isolated area.
- Dispose of contaminated materials.
- Clean and sanitize all equipment.
- Provide protection for personnel handling cheese.
- Avoid introduction of anaerobic pathogens in vacuum packaging materials. For more on vacuum packing, please see Chapter 6.8.4: Vacuum Packaging.
- Store all packaging materials in clean conditions.

Records to maintain

- Cleaning logs indicating cleaning and sanitizing dates, times, and personnel.
- Cutting logs identifying dates, times, batch numbers, product temperature, personnel, and any non-conformities.
- Receipts and storage logs for packaging materials.
- Letters of guarantee from packaging suppliers.
- Scale weight calibration records.
- Personnel equipment training records.

7.3 Wrapping and Packing Cheese

Cheese cutting, packaging, and storage impacts product quality and shelf life – the period of time that a piece of cheese remains usable, fit for consumption, or saleable.

When cutting and wrapping cheese, it is important to remember some styles will continue to require air once wrapped. Cheeses that require air include soft ripened, blue mold, and washed rind styles. Cheeses that don't require air and can be vacuum packed include fresh unripened styles, aged hard styles (including bandaged-wrapped cheeses), and brined styles.

7.3.1 Wrapping Basics

Prior to shipping, cheese should be wrapped to protect it from potential contaminants. It is important that the rind is completely covered when wrapped. This is true even if the cheese is to be vacuum sealed, as the wrap (paper, wax, bandage, etc.) will provide an additional layer of protection.

There are different types of wrapping designed to protect different styles and types of cheese, including wax (breathable paraffin and impermeable wax), plastics (breathable plastics, impermeable plastics, plastics treated with anti-mycotic), papers, plastic wrap/cling wraps, and foils. A cheesemaker should speak with a specialty cheese equipment supplier or a food specialist from a University Dairy Extension program to identify the best wrapping options for each cheese. The type of wrapping selected will depend on the style of cheese and the length of time anticipated before it reaches consumers.

Ensure that all packaging materials are stored in a clean, sanitary area that is free of contamination. It is best practice to maintain records of batch/lot numbers of packaging materials, noting when they are used and with which batches of cheese.

7.3.2 Wrapping Materials

7.3.2.1 Cheese Paper

Cheese papers are designed to allow cheese to breathe while it's wrapped. The wrong paper can have a negative impact by making the cheese look less appealing to consumers and/or by shortening the cheese's shelf life.

The most widely used and available types of paper are:

- Breathable cheese paper. This is especially good for soft, fresh, mold-ripened, and soft, washed-rind, or other high moisture cheeses, such as blues.
- Lined freezer paper. This paper is usually quite robust and stiff, making it particularly suitable for aged, firm cheeses.
- Parchment paper. This works well for aged, firm, or semi-firm washed rind cheeses.

7.3.2.2 Vacuum Packaging

Not all cheese is suitable for vacuum packaging, due to the tightly compressed package. In some cases, modified atmosphere packaging may be used to limit compression while providing an atmosphere containing reduced oxygen or

anaerobic conditions. This process entails packaging the cheese under an inert gas, such as nitrogen, carbon dioxide, or varying combinations of the two. This creates an anaerobic condition for the cheese, but does not cause the cheese to become damaged in any way—such as crushed or smashed down. A common example of use would be the packaging of cheese shreds, cheese curds, or Swiss-style cheese with eyes.

To achieve a very slight vacuum and a visually appealing tight wrap, straight carbon dioxide (CO₂) gas can be used. However, to have a truly loose package without a crush effect, the CO₂ gas should be blended with nitrogen. CO₂ creates a tight package because the gas is soluble in the water phase of the cheese, and nitrogen is not.

Form-Fill-and-Seal Machines are automated machines that form plastic bags out of a flat roll of plastic film while simultaneously filling the bags with product and sealing the filled bags. Form-Fill-and-Seal Machines do not require the vacuum step, but the package should be flushed with the blended gas as this displaces the normal air so that oxygen levels are below the threshold to support mold growth.

Vacuum packaging cheese with a hard rind can be challenging, as it can be difficult to maintain a good seal with commonly available bags. Bags can develop leaks which result in mold or other contaminants getting onto the cheese. A cheesemaker should always discuss which options are available with a vacuum equipment supplier before making any final decisions.

When cheese is vacuum sealed, it is placed in a non-aerobic environment. For this reason, it is important to maintain the cheese in a refrigerated environment 36-41° F (2-5° C) after vacuum sealing it. If cheese is stored at a higher temperature, such as that typically found in an aging cellar, even low-moisture cheese will deteriorate rapidly. Higher moisture cheese will deteriorate even more, as the moisture trapped inside the plastic creates a high-risk, pathogen friendly environment.

If a cheese is not well-suited to being packed in a plastic bag, by design or error moisture can build up in the bag. If moisture is found in the bag, it is important to revisit the cheesemaking process, or put the product into breathable packaging. For more information, see Chapter 6.8.4: Vacuum Packing.

7.3.3 Storing Wrapped Cheese

All cut and wrapped cheese that is stored by the producer must be stored at a consistent temperature below 41° F (5° C).

7.4 Labeling, Recording, and Tracking Cheese

Any food safety program must have comprehensive documentation to be successful.

This includes documentation that will allow a producer to track or trace not only the product itself, but also the ingredients that have been used, and both the inner and outer packaging of the product.

7.4.1 Labeling Cheese for Shipment

Cheese must be clearly labeled with (at minimum):

- Item Number and/or name of cheese
- Item description and/or batch information
- Net weight in pounds
- "Use By", "Best Before" or "Produced On" date
- Storage instructions such as "keep refrigerated"
- Pieces per case

Many large distributors are moving to special inventory labels make sure labels remain adhered to the boxes in colder temperatures. With specialized labeling computer programs, these can easily be printed by anyone.

In addition to properly labeling the cheese, a packing list and invoice should be included with the shipment. These documents should contain the corresponding batch information and weight(s) to enable the customer to quickly confirm the weight(s) shipped, price the cheese accurately, and get it out for sale quickly.

7.4.2 Recording Cheese Information

To maintain an effective Traceability and HACCP plan:

- Establish an effective plan and write it down. In the eyes of regulators, if it's not written down, it doesn't exist.
- Information must be recorded regularly. Consistent recording is of paramount importance.
- Documentation should provide the ability to track or trace not only the product, but also the ingredients that have been used, and the inner and outer packaging of the product.

7.4.3 Traceability Exercises and Recall Planning

At least once each year, cheesemakers must run a traceability exercise. This exercise should demonstrate and record the path from raw material through the process to the consumer, and confirm that ingredients, packaging materials, and finished products fall within certain parameters and timeframes. Cornell University offers procedures for a twelve-step mock recall exercise.

Mock Recall Procedure

Cornell University Dairy Extension²

1. Start the clock based on scenario. Under two-hour goal within a four-hour maximum.
2. Coordinate your recall team.
3. Identify a record keeper.
4. Locate trace procedure/forms.
5. Identify production date.
6. Collect production documents for each ingredient, which could include Certificate of Authenticity (COA) and Batch Sheets.
7. Identify how much product was manufactured from the start of the run to the end of the run.
 - How much product was lost to waste?
 - Were product samples retained?
 - Check Critical Control Point (CCP) verification logs.
8. Identify where all product was shipped, taking any sales samples into account.
9. Goal is 100% recovery of the product
10. Discuss overall effectiveness of drill and frequency rate
11. Document all steps in Mock Recall Log and maintain records.
12. Non-conformances identified during the exercise must be investigated by the facility and required corrective action completed, with a follow up test completed to ensure that corrective actions are effective.

In addition, please see:

Food and Drug Administration. "Recall Procedures." In *Regulatory Procedures Manual*, 2013. <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074312.pdf>.

7.5 Packing Cheese for Transport

7.5.1 Packing Materials

A bewildering array of packing materials is available within the marketplace. To narrow down the choices, a good place to start is for the cheesemaker to decide between an eco-friendly range of packing materials or conventional products. Eco-friendly materials will likely be more expensive. However, both types can often be re-used. Some cheesemakers operate a system whereby customers can return boxes and packing materials to them at minimal cost, thus making considerable savings on buying new materials.

Whichever choice is made, the primary objective of packing materials is to protect the cheese during transportation. Once the cheese is wrapped, it is usually placed in a

cardboard box. Cardboard is a particularly suitable material as it allows a limited amount of breathability. For sealing boxes, it is worthwhile to invest in good quality packing tape and a heavy-duty tape dispensing gun.

7.5.2 How to Pack Boxes

Cheese should be packed in a sturdy box that is the appropriate size for the product being shipped. Boxes should not be overfilled with material or overloaded with weight. Weight should be evenly distributed in boxes and there should be an indication on the boxes as to which way is “up.”

It is preferable, no matter how near or far the product is being shipped, for the cheese to be placed within its own box which is then put inside an outer case. In this instance, the inner box should be sturdy, but need not be as thick as the outer case which should be able to withstand heavy force and the natural wear and tear of travelling.

Soft, fragile and small format cheeses do well if packed within a flat inner box such as a pizza box as these can be stacked within the larger outside case, without danger of crushing the cheese. The cheeses should be snugly packed in the flat boxes, but not so tight they are squashed. If there is too much space between them, then place a strip of rolled up paper between them to act as separators. Do not use Styrofoam or rice paper “peanuts” directly against a soft cheese as they are likely to leave indentation marks in the cheese.

Large format cheeses also benefit from being in their own individual boxes with scrunched up paper separators to protect them from moving around inside the box. Again, paper is preferable over Styrofoam/biodegradable peanuts to help avoid damaging the cheese.

Once the inner boxes are packed, they should be placed in their outer cases. Avoid packing cheeses or inner boxes on their sides, as they generally do not do well when transported this way. Even very aged, hard cheeses withstand impact better if they are lying flat.

If a cheesemaker is shipping both hard and soft cheese in the same box, the soft cheese should be wrapped and placed in its own separate box, on top of the hard cheese, so as not to be crushed.

Pack/fill any remaining spaces in the outer case with scrunched up paper, air pillows, or Styrofoam/biodegradable peanuts.

If packing boxes onto a pallet, ensure there is some air space between boxes, especially those in the middle of the pallet to allow cold air to circulate.

Once the pallet is packed, the entire pallet and boxes should be encased with stretch wrap to stop the boxes from moving around and to protect them from moisture. Plastic wrap is available from packaging suppliers in 12” or 18” rolls. There are also spindles or

dispensers available especially designed to fit these rolls, making the packing job infinitely easier and faster.

If shipping in a non-refrigerated truck, boxes should be insulated. Insulation material such as an inner insert of plastic air-wrap, or Styrofoam sheets cut to the size of the box, significantly help to maintain the cold chain and the correct temperature of cheese. Insulation also adds a hefty layer of protection against bumps or mishandling in transit.

The ACS Judging & Competition Committee provides tips for shipping competition cheeses, which can also inform how best to package cheese for unrefrigerated shipping more generally. Below is a brief excerpt:

1. Cheese should be placed in a foam or foil-lined shipping box, and cushioned with bubble-wrap if needed (avoid using peanuts).
2. 2-3 pounds of ice packs should be added, per 5 pounds of hard cheese. Ice packs should be protected so they don't get the cheese damp by osmosis. The average summer temperature in many parts of the country is quite high, and product must be kept cool for 48-72 hours out of refrigeration.
3. All shipment tracking information should be kept on hand, so the progress of the package(s) can be monitored through the shipping process.

Complete competition shipping tips and videos can be found at: American Cheese Society. "Shipping Tips & Videos | American Cheese Society Judging & Competition," 2012. <http://cheesejudging.org/prepareandship/shippingtips/>.

7.5.3 Ice Packs

The best way to ship cheese is to use an inflatable insert and ice packs. Ice packs are used to maintain a temperature of 32-41°F (0-5°C) during shipping, keeping the cheese at a safe temperature while traveling. When shipping, it is recommended that frozen ice packs are first wrapped with paper and placed into a re-sealable plastic bag. This prevents excess moisture from damaging the cheese as the ice packs melt during transit. One must also use caution when using biodegradable packing peanuts, as they will effectively disintegrate when wet from melting ice packs, leaving voids in the box that can de-stabilize the cheese. It is recommended that ice packs are placed on all sides, but at the very least, on top of the cheese. Ice packs should not directly touch the cheese. If reusing ice packs for multiple shipments, they should be dried and placed with adequate spacing on a flat surface in a freezer for several hours or overnight.

7.6 Transporting Cheese

Transporting cheese may be as simple as the cheesemaker moving product in a personal vehicle, or as involved as shipping via large, commercial trucks. For the safety and quality of the cheese, it is essential that the cold chain be maintained while the

cheese is in transit at a temperature not exceeding 41°F (5°C). While this is easy to achieve if the cheese is being transported in a refrigerated truck, it can pose a serious challenge if cheese is shipped via unrefrigerated transport.

With any mode of transportation, the primary concerns for the cheesemaker are proper maintenance of the temperature of the cheese, cleanliness of the transport vehicle, and the length of time the cheese will be in transit. It is recommended that all transportation vehicles are inspected for structural integrity and cleanliness prior to loading finished products. It is also recommended that transportation vehicles be adequately equipped to control and monitor the temperature of incoming ingredients and outgoing finished food products on a continuous basis.

7.6.1 Refrigerated Transport

If shipping to a distributor, it is likely that the cheese will be transported via refrigerated truck, and that the distributor will have a HACCP and/or quality control system that the cheesemaker and/or shipper must comply with.

Haulers should be asked which other products are likely to be on the truck at the same time as the cheese. It is important to avoid using a truck that may also be used to ship meat, fish, or produce. The condition of the truck should be verified by doing a physical check, and by asking to see records of the hauler's cleaning/sanitation procedures for the trailer. Additionally, cheesemakers should inquire about the haulage company's policy on temperature control, starting up the cooling unit, opening doors, etc.

Refrigerated trucks should have some type of temperature monitoring system. This may be located in the cab or on the box/trailer itself. Drivers should be asked how the pallet or products will be kept in place in the trailer, and prevented from moving around and becoming damaged. It should be verified that there are tamper-proof procedures in place to protect the cheese en-route.

The product needs to arrive at its destination at or below 41°F (5°C) and above 32°F (0°C) with proof that temperatures did not exceed the safe temperature zone during transport. Several methods can be used to monitor the temperature during transport, but the most common are data loggers.

Data loggers are small devices used to record temperature data over time or in relation to specific locations. Various types of data loggers are available ranging from those that are chemical based to complex electronic devices capable of recording and sending data wirelessly to a base location. The simplest and generally least expensive devices are loggers that contain a chemical compound. The compound is temperature sensitive and will change color if a certain temperature range is exceeded. While this informs the recipient that the cold chain has been compromised at some point during transportation or storage, it does not specify by what temperature or for how long.

Electronic data loggers can provide much more detailed information and come in a variety of types. Many commercial trucks or vans have a data logger that is hard wired

and connected to a dial or read-out device mounted in the cab or elsewhere on the vehicle. These will display the air temperature within the truck over a given period and record it either on paper or electronically

Other electronic data loggers are designed to be placed inside the boxes containing the cheese. By necessity, these are smaller devices and while the principle is the same in that they record temperature and time, the methods for extracting or reading the information can be different. Some devices are computer program specific. In other words, they require the user to download software to be able to read the recorded data.

Other devices operate on a simpler system, often with a USB port, that can be plugged into any computer and read out. Lastly, some devices operate wirelessly, allowing the user to remotely access the temperature readings via computer network.

It is important to understand what the hauler's policy is when liability issues arise. Common issues include events such as truck breakdown, temperatures falling outside the agreed-to range, or contamination of product while it is in the care of the haulage company. The data logger can be useful when needing to prove or determine issues with the truck or shipment.

It is recommended that cheesemakers speak with an insurance agent to ensure that their products are covered while in transit. A written contract should be drawn up with the haulage company that clearly states their obligations and identifies who is liable to cover damages or claims, and under which circumstances. It is a good idea to have a lawyer check this documentation over before signing off on it.

7.6.2 Palletized Shipments

Most palletized shipments are transported via refrigerated truck. That said, a cheesemaker should not rely on the truck's refrigeration system to cool down cheese that is at ambient temperature. It is always best to prepare a palletized order a day ahead, and to place the finished pallet in the walk-in cooler to thoroughly chill down so it will be completely cold (36-38°F) by the time it is loaded onto the truck.

When preparing the pallet, the cheese must be thoroughly chilled before it is placed in boxes. Warm product should never be placed in boxes, as the cumulative effect of boxes stacked together with warm (or even ambient) cheese in them can create a "compost heap" effect, and the cheeses will heat up faster than the truck's refrigeration system can cool them down.

When stacking the pallet, workers should allow for air circulation in and around the boxes, as well as around the pallet itself.

If products are transported by a small truck making frequent stops, the product has a greater chance of warming up. Depending on the circumstances, special precautions such as enveloping the pallet with an insulated blanket or adding ice packs might need to be taken to prevent adverse temperature issues from occurring.

7.6.3 Non-Refrigerated Transport

When shipping via a non-refrigerated truck, it is important to know exactly how temperature-sensitive the product is, and how long the product can remain in transit without compromising its safety or quality. Cheesemakers should first establish the insulating qualities of the Styrofoam or insulation used in the boxes by verifying any temperature guarantees from the shipping material manufacturer. For instance, different thicknesses of Styrofoam will insulate differently. Similarly, manufacturers can recommend what quantity of ice packs should be used to achieve certain temperatures, depending on external air temperature. This will determine how long a box can remain in transit. Another consideration is the weather. If it's too hot or too cold, it is likely the cheese will be exposed to temperatures outside the recommended range and thus deteriorate rapidly. In this case, a shipping method and speed should be selected that will get the product to its destination with the least risk of compromising safety or quality.

7.6.3.1 Working with Non-Refrigerated Shipping Services

Many non-refrigerated shipping services can be found online. Setting up an account with a transport service is an easy and essential step that can often give cheesemakers access to discounted rates and deals.

Specialist shipping companies can be used to ship cheese, and typically work best with hard and/or semi soft cheeses being shipped next day-day or 1-day. This is often the most cost-effective method for shipping within a cheesemaker's region.

It is important to ship cheese at the beginning of the week (Monday or Tuesday) depending on the final destination. With regional shipments, many ground shipping services will take one day. However, it is not worth risking the cheese getting stuck over the weekend, as it will sit in a warehouse or on the truck without temperature controls, and it will most likely be damaged.

Shipping costs can easily be determined by going online to the shipping provider's website, entering the destination address, the weight of the package (using a scale that is large enough to weigh a typical shipping box, with the capacity to weigh up to 30 lbs. or more), and the dimensions of the box. During warm months, additional ice packs will need to be added to the shipment. This is important to note so that the cost of shipping can be passed on to the customer. In addition, the cost of any other shipping material such as Styrofoam or air pillows should be accounted for. To save on materials and reuse packaging, cheesemakers can include a return label so that the customer can ship the empty box back with packing materials and ice packs.

Shipping rates can be drastically affected simply by using a different size box. Shipping service sales representatives can help determine which size box is the most cost-effective, based on the type of cheese that is being shipped. Costs will be based on weight and the box dimensions.

Hazards

- Cheese may become contaminated or tainted during transport from personnel, other goods, or a contaminated vehicle.
- Undesirable bacteria may grow if cheese is not maintained at a chilled temperature during transport, or if the transit time is longer than expected.

Controls

- Reputable haulers should be used to transport cheese.
- Hauler and transport vehicle should be inspected for adequate maintenance and cleanliness.
- Verify that tamper-resistant procedures are in place, such as lock tags.
- Ensure that haulers maintain temperature control, monitoring, and corrective action logs in the event of failure.
- Hauler should have a plan in place, in case the vehicle breaks down.
- Cheese should be adequately wrapped and protected for transport.

Records to maintain

- Bill of lading.
- Contracts with haulers.
- Sanitation records including transport vehicle inspections.
- All temperature controls and verification procedures, and data collected.

7.6.4 Cheesemaker Transportation (Farmers Markets, Restaurants)

Cheesemakers who deliver product to customers in their own vehicles, whether transporting to farmers' markets or delivering to retailer/restaurants, must ensure that the vehicles used for such transport adhere to the same standards of cleanliness, sanitation, and temperature control as any commercial vehicle.

For the safety and quality of the cheese, it is essential that the cold chain be maintained while the cheese is in transit at a temperature not exceeding 41°F (5°C). While this is easy to achieve if the cheese is being transported in a refrigerated truck, it can pose a serious challenge if shipped via unrefrigerated transport such as a personal vehicle.

With any mode of transportation, the primary concerns are proper maintenance of the temperature of the cheese, cleanliness of the transport vehicle, and the amount of time the cheese will be in transit. It is recommended that the vehicle be inspected for structural integrity and cleanliness prior to loading finished products.

Please refer to the ACS Judging & Competition Committee's tips for shipping for proper directions on packing and transporting cheese in a non-refrigerated vehicle:

American Cheese Society. "Shipping Tips & Videos | American Cheese Society Judging & Competition," 2012. <http://cheesejudging.org/prepareandship/shippingtips/>.

Hazards

- Cheese may become contaminated or tainted during transport from personnel, other goods, or a contaminated vehicle.
- Insufficient ice packs may be used relative to the quantity of cheese or time of delivery, resulting in un-useable product.
- Product, particularly soft cheese, may not maintain controlled time and temperature during transit.

Controls

- Cheese should be adequately wrapped, protected, and insulated with ice packs.
- Vehicle should be checked for adequate maintenance and cleanliness.
- Tamper-resistant procedures should be in place, such as locking the vehicle if/when exiting.
- Temperature control, monitoring, and corrective action log should be maintained in case of failure.
- An action plan should be developed in case of a vehicle break-down.

Records to maintain

- Contracts with customers, if applicable.
- Sanitation/cleaning records for vehicle.
- Tracking of time of departure/arrival for deliveries.
- Track driver of vehicle and ensure necessary registration and insurance documents are on hand at all times.
- Mileage record if needed for business purposes.

¹ U.S. Food and Drug Administration. "Food Safety Modernization Act (FSMA) - Fact Sheets & Presentations." *U.S. Food and Drug Administration*. Accessed February 9, 2017.
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm>.

² Cornell University Dairy Foods Extension. "Cornell Dairy Extension-Mock Recall SOP." Accessed December 20, 2016.
<https://dairyextension.foodscience.cornell.edu/sites/dairyextension.foodscience.cornell.edu/files/shared/Cornell%20Dairy%20Extension-Mock%20Recall%20SOP.pdf>.



Chapter 8

Current Good Manufacturing Practices and Hazard Analysis Risk-Based Preventive Controls

September 2015 ushered in a new era in food safety regulation when the US Food and Drug Administration (FDA), under the authority of the Food Safety Modernization Act (FSMA), finalized the Preventive Controls for Human Food production. These Preventive Controls cover five key areas:

1. Process controls
2. Food Allergen controls
3. Sanitation controls
4. Supply-Chain Controls
5. Recall plan

The Preventive Controls are part of a mandatory Hazard Analysis and Risk-Based Preventive Controls (HARPC) program. The HARPC program starts with a hazard evaluation for each potential food safety hazard in a facility or process. Risk is a function of the probability that the hazard creates an adverse health effect and the severity of that effect. For example, although listeriosis may be relatively rare, the severity of the illness and high mortality rate ranks *Listeria monocytogenes* as a high-risk pathogen.

Compliance dates for the Preventive Controls Rule vary by size of business as defined by the ruling.

- **Small Businesses:** a business (including subsidiaries and affiliates) with fewer than 500 full-time equivalent employees, must comply by September 18, 2017.
- **Very Small Businesses:** which (including subsidiaries and affiliates) average less than \$1 million per year in both annual sales or product held without sale for preceding 3-year period, are subject to modified requirements and must comply by September 17, 2018 (although the records to support this status must be collected starting January 1, 2016).
- **Other businesses** must comply by September 19, 2016.

For those cheesemakers who have previously implemented Hazard Analysis Critical Control Point (HACCP) programs, the HARPC approach combines critical control points and pre-requisite programs under the single moniker of Preventive Controls. This creates a broader approach to controlling potential hazards at all points in the manufacturing process. The Preventive Controls roughly correspond to the Prerequisite Programs that were a necessary precursor to a HACCP plan. Likewise, process preventive controls correspond to critical control points. The biggest impact of the ramped-up regulation is that cheesemakers will be expected to have a wider range of

written procedures and documentation. The current Good Manufacturing Practices (GMPs) now only include requirements instead of both requirements and recommendations as in the previous version. Of note is the requirement that each individual receive training in food hygiene and food safety as appropriate to the food, the facility, and the individual's assigned duties.

Expanding emphasis beyond just critical control points increases recognition that many food production steps work to reduce risk and enhance food safety. This new approach potentially gives cheesemakers more flexibility in developing food safety measures so long as they can demonstrate that their system of controls is effective. Hazard Analysis Critical Control Point can continue to be a part of a food safety plan, but the HACCP plan must be supplemented with other preventive controls not applied at CCPs.

Like Prerequisite Programs, Preventive Controls should be documented and regularly audited. An audit review consists of verifying that the company implements, monitors and controls each part of its food safety plan.

Throughout this chapter, we refer to 21 C.F.R. § 117, which covers Current Food Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.¹

More information can also be found on the FDA website, which offers guidance documents for the regulations, as well as fact sheets that identify key requirements, and information about waivers and compliance dates.²

8.1 Qualified Facilities

Qualified Facilities, as defined by the Rule in 21 C.F.R. § 117.3, are those businesses that meet one of the following two definitions:

- *Very small business: A business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food, plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee); **OR***
- *A facility with < \$500,000 in annual gross sales of human food, based on an average of the three preceding years AND > 50% of sales go to “qualified end-users” including consumers anywhere, or restaurants or retail food establishments in the same state or not more than 275 miles away.*

A qualified facility includes the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate.

Because the sales threshold is < \$500,000 in sales, all Tester-Hagan facilities automatically satisfy FDA's definition of very small business. It will likely be easier for all

to use the definition of a very small business because supporting records will be easier to maintain and review.

A Qualified Facility must submit two attestations³.

- An attestation that they satisfy the definition of “Qualified Facility” (above). They do not have to submit the sales records to support the attestation, but they are required to retain such financial records and make them available to FDA upon inspection. A Qualified Facility must submit form 3942a (Quality Facility Attestation) to FDA.
- The second relates to food safety practices at the facility with two options for satisfying this requirement.
 - The facility may choose to attest that it has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective, **OR**
 - The facility may choose to attest that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law. Supporting documentation to submit may include: licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.
 - If second option is followed, then consumers must be provided with the name and complete business address of the facility where the food was manufactured or processed via a label, sign at point of sale, documents arriving along with the food in the normal course of business (i.e. an invoice), or electronically for internet sales.

The PC rule states the following:

Submitted to FDA initially:

- By December 17, 2018, for a facility that begins manufacturing, processing, packing, or holding food before September 17, 2018;
- Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding food after September 17, 2018; or
- By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified facility” to “qualified facility” based on the annual determination required by paragraph (c)(1) of this section; and
- Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

A Qualified Facility must maintain records that support the documentation required. These records must be accurate and legible. Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the

status of a facility as a qualified facility during the applicable calendar year. See 21 C.F.R. § 117.315 (a) (2).

Qualified Facilities that are eligible for modified requirements are nonetheless bound to facility registration, good manufacturing practices, recordkeeping, and training requirements. Modified requirements are detailed in 21 C.F.R. § 117, Subpart D.

Any company that does not meet the definition of a Qualified Facility or is not subject to another exemption will need to meet applicable requirements of the PC rule as proscribed by FSMA. The exact application of Preventive Controls will vary across cheesemakers since each application will be product- and process-specific. Each plant must develop, evaluate, review, and update its own food safety program.

8.2 Qualified Individuals

One aspect of the Preventive Controls program is that the plant owner, operator or agent in charge must sign and accept responsibility for implementation of the food safety plan. All facilities must have a “qualified individual,” defined as someone who has the education, training, experience, or combination thereof, necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

The Preventive Controls rule requires each plant have a “preventive controls qualified individual,” which is an individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Supervisory personnel are responsible for ensuring compliance by individuals with these requirements. Facilities must retain records documenting the training provided to employees as required by the rule.

8.3 Records

Records that must be maintained to support the various attestations (sales and food safety related documentation) and the required training for food hygiene and food safety are subject to review upon inspection. Records must be kept as either original records, true copies (i.e. photocopies, pictures, scanned copies, or other accurate reproductions), or as electronic records.

Financial records (preceding three years' worth of sales) must be retained at the facility as long as necessary to support the facility's status during the applicable calendar year. All other records must be retained at least two years after the date they were prepared.

8.4 Good Manufacturing Practices

Some of the procedures below are suggestions, and some of these procedures are required by law. Included below are recommendations from Current Good Manufacturing Practices as written by law in the 21 C.F.R. § 117.10.

8.4.1 Employee, Visitor, and Contractor Hygiene and Training

Employees play a big role in producing safe dairy products. Meticulous employee hygiene and consistent, habitual practices can prevent the contamination of milk, milk products, containers, equipment, and facilities – contamination that could make consumers sick. For this reason, it is very important to train plant employees on hygiene procedures and monitor employees to make sure they consistently follow these procedures.

All dairy plants should have a written employee hygiene and training program. An outline of the expected standards of hygiene, behavior, and habits for plant employees is recommended. Employees involved in any stage of product processing, packaging, or distribution should be trained to make sure they produce food that meets federal and local regulatory standards for safety and quality.

Visitors and contractors must also know and follow the plant's hygiene standards.

An employee hygiene program should include:

- procedures
- training
- records
- monitoring and follow-up

8.4.2 Hygiene Procedures

Employees need to meet the following standards for clothing, grooming, and health at all times:

8.4.2.1 Clothing

- Put on clean uniforms immediately before starting work.
- Make sure enough clean uniforms are available for each employee so that if a uniform becomes dirty, the employee can change into a clean one.
- Select uniforms that do not have pockets above the waist or fasteners (such as buttons) that can come loose in order to prevent items such as buttons and pens from contaminating the product.
- Minimize cross-contamination between raw and pasteurized processing areas, by ensuring that the same uniform is not worn in both areas. Change into a clean uniform or put on a clean outer covering (such as a lab coat) before moving from a raw product handling area into a

pasteurized product handling area. Using different color uniforms for each area can help make sure that employees wear the right uniform in the right area.

- Change into clean footwear or clean and sanitize footwear (using footbaths or floor foam sprayers) before moving from raw product areas into pasteurized product areas of the plant.
- Cover exposed hair with appropriate hair restraints. These include hairnets, beard nets, and arm guards. Ball caps are not an acceptable hair restraint.
- Wash and sanitize hands before applying a clean pair of sanitary disposable gloves or handling products or surfaces that contact the product. If gloves become dirty or break, remove the gloves, wash and re-sanitize hands, and put on a new pair of gloves.
- Keep footwear worn in the food production area clean and in good condition. Do not wear plant footwear outside the plant.
- Store street clothes and street footwear separately from clean plant uniforms and plant footwear.

8.4.2.2 Employee Practices

- Keep hands and fingernails clean. Do not wear fingernail polish, false eyelashes, false fingernails, perfume, etc.
- No jewelry, badges, pins or watches should be worn. Fasten medical alerts by a chain worn around the neck and covered by the uniform or taped inside of a shirt.
- If a wedding band cannot be removed, it needs to be covered (with a sanitary disposable glove, for example) to prevent it from trapping dirt or food particles that could then contaminate the product.

8.4.2.3 Health Conditions

- Cover open cuts or wounds (for example, by wearing a waterproof bandage covered with a sanitary disposable glove).
- Do not allow employees with skin infections, sores, diarrhea, etc. to have any contact with food. An employee with a cold or illness should be sent home or reassigned to areas where there is no exposed product or packaging materials.
- Monitor for health problems indicative of pathogens that could be transmitted through food. These include:
 - jaundice
 - diarrhea
 - vomiting
 - fever
 - sore throat with fever
 - visible skin infections or sores (for example, boils or cuts)
 - discharge from the ears, eyes, or nose

8.4.3 Behavior

Employees should wash hands thoroughly or change gloves:

- when starting work and returning to work, like after lunch or a break
- after using toilet facilities
- before putting on gloves
- after handling food allergens
- after touching their hair, ears, nose, mouth, etc.
- after sneezing or coughing into their hands
- after handling garbage or waste bins
- any time after their hands or gloves become contaminated

Proper hand washing technique should be to:

- rinse hands with warm water
- apply soap from the dispenser
- rub hands, fingers, nails and wrists to form a lather for at least 20 seconds
- rinse off the soap with warm water
- dry hands hygienically with paper towel or a hot-air dryer
- use the paper towel to turn off the tap (if the tap does not shut off automatically) and open the door
- sanitize hands after cleaning

Post instructions by hand-washing stations.

Do not eat, drink, smoke, chew gum or tobacco, sneeze, cough, or spit in any areas used for food handling, processing, storage, or packaging. Lunches need to be stored and eaten in a separate lunchroom. Do not store lunches in lockers with plant clothing or footwear.

Keep personal items out of the food production or food storage areas. These items include gum, candy, medicine, tobacco, keys, and phones.

8.4.4 Training

The plant owner or manager is responsible for making sure that employees are trained and understand the importance of good hygiene and the impact of their behavior and habits on food safety.

Training is needed:

- when they are hired
- before starting new job duties
- when policies or procedures change
- to reinforce current policies and procedures

Provide refresher training at least once a year.

A written training program helps to ensure that requirements are communicated in a consistent fashion to all employees. The plant's training program should include the list of employees and positions that require hygiene training and dates when training occurs, including:

- the employee's name
- the date of training
- a description of the training provided (for example, subject, training materials used, and format of training)
- the name of the trainer or training provider
- training material, including written procedures and resources
- the frequency of training (including refresher training). Use a variety of training formats, including:
 - one-on-one or group instruction
 - job shadowing
 - coaching or mentoring
 - videos
 - presentations
 - on-line courses
 - review of company policies, standard operating procedures (SOPs) and sanitation standard operating procedures (SSOPs).

Since people have different learning styles, a variety of training techniques and formats is desirable. Use some test or post-training evaluation to verify that training is effective.

8.4.5 Monitoring and Follow-up

Regularly monitor and document employee hygiene practices. Monitor new workers closely to make sure they are performing tasks correctly. Encourage them to ask about anything that is not clear. When unacceptable practices are noticed, record exactly what the employee was doing wrong and correct the behavior. Record the follow-up actions taken to correct deviations, and include the date the action was taken. These records can also include actions that are planned to take in the future to ensure good employee hygiene practices.

8.4.6 Visitors and Contractors

The company should provide safety guidelines for all visitors to the facility. Visitors may require lab coats, jumpsuits, protective footwear, safety equipment, etc. A sign-in sheet includes: date, arrival and departure time, who was visited and for what purpose, and acknowledgement of receipt of guidelines. Any visitors or contractors entering the processing area must abide by the same GMP rules as regular employees.

8.5 Process Controls

Process Controls, as defined in 21 C.F.R. § 117.135, include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerated foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

- Parameters associated with the control of the hazard; and
- The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

8.5.1 Food allergen controls

Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

- Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
- Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

8.5.2 Sanitation controls

Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:

- Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;
- Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

8.5.3 Supply-chain controls Supply-chain controls include the supply-chain program as required by subpart G of this part.

Recall plan. Recall plan as required by 21 C.F.R. § 117.139.

Other controls. Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section.

Examples of other controls include hygiene training and other current good manufacturing practices.

Additional information regarding processes and controls, can be found in 21 C.F.R. § 117.80, which include the following:

- General:
 - All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.
 - Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.
 - Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.
 - Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.
 - Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.
 - All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

- Other recommendations include:
 - Keep the premises clean, orderly, and free from strong or foul odors, smoke, or excessive air pollution. Use cement, asphalt, or similar paving material to minimize dust and mud.
 - The immediate surroundings must be free from refuge, rubbish, overgrown vegetation, and waste materials to prevent harboring rodents, insects and other vermin.
 - Maintain a minimum of 18 inches around the perimeter of the building free of plants, equipment, or waste containers to discourage pests.
 - Provide a drainage system to rapidly drain water from plant surroundings and driveways.
 - Keep buildings in good repair to exclude rodents, birds, insects, vermin, dogs, and cats.
 - Seal pipe openings through outside walls including tight metal collars.
 - Design building roofs to prevent accumulation of water or contamination of air intake vents. Flat roofs are permissible as long as they drain properly.

8.6 Sanitary Cheesemaking Facilities

Interior plant cGMPs cover storage temperatures and humidity, lighting, control of air

handling/HVAC systems, isolation of non-food areas for chemical storage and maintenance activity, and water and waste water systems. This Prerequisite Program covers all floors, walls, ceilings, stairs and elevators, utility lines, and electrical boxes in the establishment. Also covered are all windows, doors and openings (plastic curtains, hose ports, can inlet and outlet), loading facilities, lighting, and ventilation.

- Plants should be designed and maintained to make cleaning easy and effective.
- Design, construct, finish, and maintain structures to avoid accumulations of dirt, dust or condensation that may contaminate products. Food-contact surfaces, as defined in 21 C.F.R. § 117.3, are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. Food-contact surfaces includes utensils and food-contact surfaces of equipment.

8.6.1 Walls, Floors, and Ceilings in Processing Rooms

- The walls, ceilings, partitions, and posts of rooms in which milk or dairy products are processed, manufactured, handled, packaged, or stored (except dry storage of packaged finished products and supplies), or in which utensils are washed and stored, should be smooth, light-colored, impervious to moisture and kept clean. Construct floors in those rooms of concrete, epoxy, or tile properly laid with impervious joint material, or other equally impervious material. Sound, smooth, cleanable wood floors are acceptable in some storage rooms.
- Ceilings with exposed steel joints and H-beams are not satisfactory in areas where the product is exposed to the atmosphere, unless a regular inspection and cleaning program assures they do not permit accumulation of dust, rust or condensation.
- For easier cleaning, have rounded cove molding at the juncture of the wall and floor in all receiving, pasteurizing, manufacturing, packaging, and storage rooms.
- The floors should be smooth, kept in good repair and sloped so that water or milk products do not pool.
- Equip drains with traps properly constructed and kept in good repair. Avoid bell and standpipe-type traps. Floor drains should be of size, number, and location to allow rapid elimination of water or milk. Clean floor drains frequently using dedicated brushes and periodically flush with a sanitizing solution.
- Clean and sanitize floor drain covers and baskets after each production run. Do not, under any circumstances, use high-pressure hoses to clean drains.
- Establishments should be designed and constructed so there is no cross-connection between the sewage system and any other waste effluent system in the establishment. Plumbing should prevent the back-up of sewage into the drain lines and to the floor of the plant. Effluent or sewage lines should not pass directly over or through production areas unless they do not pose a contamination risk (e.g. properly protected).
- Because of the potential to harbor microorganisms, locate floor drains so that they are readily accessible for cleaning, sanitizing, and inspection. Floor drains

should not be located under or near production, filling, and packaging equipment. Cold-storage rooms and starter rooms need not be provided with floor drains if the floor drains to an exit.

8.6.2 Doors and Windows in Processing Rooms

- Protect and screen all openings to the exterior including doors, windows, skylights, conveyor openings and transoms to exclude flies and other insects, rodents, birds, dust, and dirt. Flaps, fans or air curtains can provide protection at some openings.
- All hinged, outside screen doors should open outward.
- Cover outside openings for sanitary pipelines when not in use. On new construction, window sills should be slanted downward at approximately a 45-degree angle.

8.6.3 Lighting and Ventilation in Processing Rooms

- Provide at least 30 foot-candles or light on all working surfaces in rooms in which dairy products are manufactured or packaged.
- Rooms where dairy products are graded or examined for condition and quality need at least 50 foot-candles of light intensity on the working surface.
- Restrooms and locker rooms need at least 30 foot-candles of light intensity.
- All other rooms require at least 5 foot-candles of light intensity when measured at a distance of 30 inches from the floor.
- Where contamination of product by broken glass is possible, usage of shatterproof bulbs or filaments and fixtures should be used to protect against breakage.
- Ventilate all rooms to maintain sanitary and safe conditions. Provide exhaust or inlet fans, vents, hoods, or temperature and humidity control equipment as needed to eliminate objectionable odors and eliminate condensation.
- Use air filtration to eliminate dirt and dust from the incoming air.
- Ventilation systems should be cleaned and maintained in good repair.
- Exhaust outlets should be screened or provided with self-closing louvers to prevent pests.

8.6.4 Storage and Supplies

- Store cheese at least 18 inches from walls and off floor on pallets or dunnage.
- Control humidity and temperature to prevent conditions detrimental to the product and container.
- Cleaning and sanitizing Prerequisite Programs require proper storage of all chemicals, solvents, caustics, sanitizers etc., whether the materials are supplied in small spray cans or large drums.
- Material Safety Data Sheets (MSDS) are required under the U.S. OSHA Hazard Communication Standard as part of plant safety programs, along with employee training for all of those participating in cleaning and sanitation activities.

- Maintain areas used for storing packaging materials, containers, and miscellaneous ingredients clean, dry, orderly, and free from vermin.
- Label insecticides, rodenticides, cleaning compounds, and other nonfood products and store them in a separate room or cabinet away from milk, dairy products, ingredients, or packaging supplies.

8.6.5 Coolers, Aging Rooms, and Caves

- Always maintain air circulation in coolers and freezers.
- Keep storage areas free from rodents, insects, and pests.
- Keep shelves clean and dry.
- Refrigeration units should drain or evaporate condensate.
- Construct storage areas so that floors, walls, and ceilings can be kept neat, clean and in good repair.
- Properly clean and maintain shelving, including wooden boards used in the aging rooms.

8.6.6 Starter Rooms and Laboratory

- Facilities for bulk starter cultures should not be located near areas where contamination is likely and should be maintained under positive air pressure.
- Use footbaths or boot foamers outside the starter room and the laboratory.
- Locate hand washing facilities, and general sanitation supplies in close proximity to the starter room and laboratory.
- Staff any laboratory with qualified and trained personnel for antibiotic, quality control and analytical testing.
- Vent laboratory facilities to the outside, and not into the processing areas.

8.7 Equipment Standards and Maintenance

In section 21 C.F.R. § 110.40 it states that all plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

If wood boards are utilized to age cheese, there should be a cleaning and sanitation protocol for these wood boards. Non-metallic parts other than glass having product contact surfaces must comply with 3-A Sanitary Standards for Plastic or Rubber and Rubberlike Materials. Keep space around equipment to allow proper cleaning and

maintain good housekeeping. All parts or interior surfaces of equipment, pipes (except certain piping cleaned-in-place) or fittings, including valves and connections, must be accessible for inspection. Milk and dairy product pumps must be of approved sanitary design for clean in place or easily dismantled for manual cleaning.⁴

8.7.1 Cheese Vats and Drain Tables

According to the American Iron and Steel Institute (AISI), 304 stainless steel plates are used for refrigerated storage tanks, pasteurizers, maturation tanks, cheese racks and other equipment. The 316 stainless steel plates are used for pasteurizers, plate and tubular heat exchangers, packaging machinery, ultra-filtration equipment, maturation tanks and other equipment. According to Chemical Processing,⁵ the main difference between 304 and 316 stainless steel is that 316 contains 2%-3% molybdenum and 304 has no molybdenum. The “moly” is added to improve the corrosion resistance to chlorides (like sea water).

- Cheese vats, tanks, and drain tables must be made of corrosion-free metal and, where relevant, providing uniform heating.

The liner must be smooth, free from excessive dents or creases, and must extend over the edge of the outer jacket. The junction of the liner and outer jackets must prevent milk or cheese from entering the inner jacket.

- The vat, tank, and/or drain table must have a sanitary outlet valve.
- The carriages must be enclosed, and all product contact surfaces, shields, shafts, and hubs of agitators must be constructed of stainless steel or other equally corrosion-resistant metal.
- Metal blades, forks, or stirrers must be constructed of stainless steel or of material approved in the 3-A Sanitary Standards for Plastic, and Rubber and Rubberlike Materials and must be free from rough or sharp edges that might scratch the equipment or create metal particles.

8.7.2 Cheese Shovels, Rakes, and other Utensils

- Curd mill, knives, hand rakes, shovels, paddles, strainers, and miscellaneous equipment must be constructed of stainless steel or of material approved in the 3-A Sanitary Standards for Plastic and Rubberlike Material. Inspect utensils daily and repair or replace them to avoid introducing metal or plastic particles in cheese.
- The product contact surfaces of the curd mill must be stainless steel.
- The wires in the curd knives must be stainless steel, kept tight and replaced when necessary. Welds must be smooth and easy to clean to prevent growth and spreading of pathogens.

8.7.3 Cheese Molds and Presses

- Hoops, forms, followers and presses must be constructed of stainless steel or of material approved in the 3-A Sanitary Standards for Plastic and Rubberlike Material. Keep them clean and free from corrosion, scratches or cracking to prevent growth and spread of pathogens or spoilage organisms.
- Plastic materials must comply with the applicable Food and Drug Administration regulations⁶, and with the "3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment."⁷
- Use mechanical cleaning for cheese molds and followers when component perforations are 1/32 inch (0.8 mm) or less in diameter, or when component parts such as a bonded plastic cheese cloth are cleaned as assembled units.
- All welded joints and all surfaces, seams, and openings must be readily cleanable.
- Discard worn press cloths and keep them clean. Use single-service press cloths only once.

8.7.4 Brine Tanks

- All welds on stainless steel tanks should be continuous and free from pits and rough edges to prevent snags. Consider other materials to avoid issues with pitting.
- Concrete or ceramic tile covered tanks must have a smooth, cleanable interior surface. Exposed aggregate, pockets, bubbles, form impressions, missing grouting, or flaking of the surface is unacceptable. If a coating or sealer is used, comply with applicable FDA requirements for indirect and repeated food contact.
- Pit tanks must have perimeter curb extending at least 1 foot (305mm) above the floor.
- When fiberglass tanks are stacked or "piggy-backed" the exterior of all but the lowest tank must meet the same fabrication criteria as the interior surfaces of the tank which contact the brine and product.

8.8 Cleaning, Sanitizing, and Storing Processing Equipment

Create a Prerequisite Program for cleaning and sanitizing product contact surfaces of equipment used in the transportation, processing, handling, and storage of milk or milk products.

- Compile a master sanitation schedule dictating daily, weekly, and monthly cleaning and sanitizing requirements. The records should include who is responsible for each task.
- Create Standard Operating Procedures for CIP and Clean out of Place (COP) systems, hand-cleaning methods, mold washing and storage, dry clean procedures. Work instructions should be clearly documented and readily accessible to workers.

- Implement corrective actions if a pre-operational visual inspection or a reject reading on Adenosine triphosphate (ATP) bioluminescence meter indicates a dirty surface. Document the corrective action after re-cleaning and re-sanitizing.
- Store equipment in a way that facilitates drying and prevents contamination due to dirt, dust and pests.
- Thoroughly clean and sanitize all utensils and other items that come in contact with product containing an allergen and consider using that equipment exclusively for the allergen-containing product. This would be part of your allergen preventive control program.
- Avoid hard bristle brushes, stainless steel and abrasive scrub pads to prevent scratching stainless steel surfaces. Undesirable microorganisms may become embedded in the scratched areas or develop a film that adheres to a surface.
- Color code brushes and pails to facilitate their exclusive use for intended purposes.

8.9 Sanitation Controls

Proper cleaning and maintenance of facilities will help eliminate environmental pathogens for a Ready-To-Eat food exposed to the environment.

- Equipment such as fork lifts, pallet jacks, carts and floor cleaners that travel throughout the plant must be well maintained and clean to control potential cross-contamination. They should also be stored in a designated area.
- Create a master sanitation log. The record sheet should include:
 - The equipment or structure (walls, ceilings, light fixtures) cleaned and sanitized.
 - The Standard Operating Procedure corresponding to cleaning that item.
 - The date of the activity.
 - Initials of the employee doing the cleaning and sanitizing.
 - Record of observations if equipment was found to need special attention such as maintenance.
 - Verification that additional procedures were done.
- Monitor the effectiveness of cleaning and sanitizing using visual inspection, with environmental swabbing procedures or with ATP bioluminescence swabs. Quality Assurance/Quality Control (QA/QC), sanitation managers or designated personnel should monitor on a routine basis (usually weekly or monthly) or as needed based on visual and test results. The monitoring should include:
 - Equipment or structure that was cleaned and sanitized.
 - Test limits and results.
 - Auditor initials and audit date.
- Test rinse water and document that cleaning chemicals and sanitizers have been thoroughly flushed from product contact surfaces.
- Locate footbaths, foot foamers or tak mats at every door entrance leading into production areas according to state law.
- If footbaths are used, check the concentration of sanitizer to assure appropriate concentrations remain throughout the day. Quaternary ammonium based

sanitizers are used at 400-800 ppm. Chlorine sanitizers in footbaths need to be maintained at 200 ppm. Use sanitizer concentration test strips specific to the sanitizer and measure the parts per million (ppm) of sanitizer immediately after filling the footbath.

- Maintain a record when footbaths have been monitored indicating the date, time, location of the footbath and person checking.
- Hand wash and hand dip or sanitizer should be placed at each door entrance leading into the production area and anywhere open product is being handled.
- Use only hand-washing facilities that don't need to be operated by hand, e.g. foot, knee activated or timed.
- The location, number and the condition of the hand washing and sanitizing facilities are extremely important to maintaining good hygienic practices.
- Provide soap dispensers, paper towels in enclosed dispensers, and properly constructed and easily maintained trash receptacles.
- Hand dip sanitizing stations are not a substitute for hand-washing stations

8.10 Pest and Waste Management

All pest management programs must comply with GMPs. Train visiting technicians in requirements of GMPs and plant implementation. Maintain written verification of training in the plant and in the company office.

Dispose of dairy waste from the plant and premises consistent with requirements of the Environmental Protection Act. The sewer system must have sufficient slope and capacity to readily remove all waste from the various processing operations. Prevent waste from contaminating milk, equipment and premises or creating a nuisance or public health hazard. Use containers constructed of metal, plastic, or other equally impervious material and keep them covered with tight fitting lids. Throw out solid waste at least daily and clean containers as needed before reuse.

- Pest management operations may typically be managed by outside contractors due to the certifications/licenses required for storage and handling of pesticides.
- The pest control program must be effective to comply with GMPs.
- Documented pest control with records of site visits and verification audits.
- Maintain an 18-inch perimeter throughout the facility for access to clean and inspect equipment and operations areas.
- Exterior requirements for effective pest management include bait stations and trap spacing and locations around exterior of facility; bird control such as netting and sound devices if necessary, and properly contained trash receptacles.
- GMP controls need to account for any risks associated with pallets, unclean trailers, railcars, construction materials, or any issues from neighboring buildings.
- If storing pallets outside of the factory, inspect and clean them as needed to protect the process areas.

- Interior requirements for effective pest management include the use of control devices compatible with food processing. Glue boards, tin cats, etc. are also recommended for rodent control.
- Map and monitor effectiveness of trap spacing and locations in the interior and exterior of the facility. Indicate corrective action.
- UV Fluorescent Tube Bug Zapper and pheromone traps are permissible in areas location outside of food processing areas or areas where food is exposed to prevent and monitor insect presence.
- Non-fragmenting glue board type insect traps are appropriate for food processing and exposure areas.
- Floor drains provide wet environments for insect breeding. These must be regularly monitored and cleaned/treated as necessary.
- If there is a garbage storage room in the plant it must be emptied daily. If odors are a problem, then a ventilation system must be installed. The surface of the walls and floors must be cleanable. To facilitate cleaning, the room should be located near a spray hose and also have a nearby drain.
- Waste disposal facilities that are located outside of the plant must not attract pests. They must have covers and be kept closed and in good condition. If compactors and bulk garbage units are used, locate them on a concrete, curbed and drained ramp to facilitate cleaning spills. Washing facilities must be nearby.
- Do not burn combustible wastes near the plant to avoid airborne contamination by ash and odors.

8.11 Environmental Monitoring and Testing

The purpose of an Environmental Monitoring Program is as follows:

- Verify how effective the sanitation program
- Verify the hygienic zoning is working to prevent product from cross contamination and prevent microbial harborage

Many production facilities have an internal laboratory for tests such as total plate counts, yeast and mold and coliform counts for microbiology assays; and moisture, fat, protein, pH and salt analysis for chemistry tests. Employ good laboratory practices from standardized testing protocols to produce accurate and dependable results. A proficiency program is highly recommended. The following practices should be developed and strictly followed:

- Develop SOPs for each analytical procedure and for using/maintaining equipment within the laboratory.
- Standard Methods for the Examination of Dairy Products covers the laboratory quality assurance and safety parameters⁸.
- Determine actual sampling location for each zone area and what action will be taken of a positive finding

- Conduct environmental monitoring to verify that cleaning and sanitation procedures in the plant eliminate disease causing microbes and allergen risks. Do not use in-plant laboratories to assay environmental samples for pathogens. This is best done and safely done by off-site plant laboratories or third party laboratories.

Types of environmental samples:

- Use swabs in areas that are small or difficult to reach. Swabs can be purchased from many dairy supply providers. Swabs should be hydrated with a neutralizing solution such as Lethen Broth, Neutralizing Broth, or Dey-Engley Broth. Follow the manufacturer's instructions to ensure correct swabbing procedure is followed.
- Use sponges to sampling large areas. Sponges must be free of any inhibitory chemicals. Natural sponges are not suitable. Sterile sponges can be purchased from many dairy supply providers.

8.12 Foreign Material Control

Develop, implement, document and maintain programs to ensure foreign materials are kept out of food products. Protect the manufacturing process from the entry of, or contamination from, foreign matter. Foreign matter is defined as anything that does not belong in the product including wood, metal, plastic, glass and other extraneous matter. Foreign matter may also consist of unwanted chemicals in the cheese. Include the following procedures:

- Monitor and document all intrusive maintenance of product contact areas of equipment and ensure that product safety is not compromised during these operations.
- Clean and maintain all in-line product filters, including milk filters, strainers, sifters and magnets.
- Operate and check in-line metal detectors. Report and follow-up when metal is detected or the metal detector breaks down.
- Regularly check all equipment in critical hygiene areas for potential sources of foreign matter, to report and rectify any problems.

8.12.1 Glass Breakage Policy

This policy is needed if an establishment handles glass containers or has glass or glass substitutes (e.g. plexi-glass) present in manufacturing areas, e.g. glass windows, UV lights, glass doors, in-line pH meters etc. Where possible, avoid use of glass and plastic in processing areas. Where glass does exist, it should be shatterproof.

Create a glass breakage policy including:

- The line or processing area must immediately shut down.

- Broken glass containers and/or loose glass fragments must be contained, removed from the area and fully accounted for.
- The line (hooping, filling, and packaging) and/or area must be inspected to ensure that clean-up was adequate.
- Record the breakage and the cause (thermal shock, impact etc.), date, location, and risk of product contamination.
- Follow up and investigate ways to and prevent reoccurrence.
- Segregate and dispose of product as needed.

8.12.2 Food Allergen Control

New Preventive Controls include food allergens. For some people, dairy is a food allergen. The “top eight” food allergens are listed in order of the number of people affected: Peanuts, Tree Nuts (e.g. almonds, pecans, walnuts), Crustaceans/Shellfish (e.g. crab, lobster, shrimp), Eggs, Milk and Dairy Products, Fish, Soybeans, and Wheat.

Processing errors or oversights that result in allergen-containing product contamination are as follows:

- poor cleaning of shared equipment (non-allergen containing products run after allergen containing products resulting in cross-contact)
- use of rework; switching of ingredients (and not following up with an allergen assessment of the new ingredients)
- labeling terms (using uncommon or incorrect terminology for the top 8 allergens.⁹)

The PC rule specifies two areas for food allergen controls:

- Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
- Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

The Allergen Control Plan (ACP) should address the following areas:

- Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
- Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.
- Obtain copies of product or ingredient formulations, specification sheets or certificates of analysis (COAs) from suppliers of raw ingredients.
- Review product flow through the production cycle. For example, look for overhead conveyors that cross one another or that cross over exposed products.
- Store all allergenic foods or ingredients derived from these foods in an area that is secluded or removed from non-allergenic materials.

- Color-code utensils used with allergens; Dedicated scoops, utensils and bins for specific ingredients assist in keeping allergens segregated.
- Schedule allergen-containing product last.
- Implement a wet cleaning procedure following the run of an allergen-containing product.
- When using reworked product, procedures should ensure the use of rework containing unique allergenic foods and/or ingredients only in the same formulation (a “like into like” or “exact into exact” practice, for example). Reworked products should always be labeled with tags that indicate which products contain allergens.
- Changes in raw materials, suppliers, formulas and customer demands result in the need for continuous reevaluation of the effectiveness of the ACP.
- Review allergen plans during an annual HACCP validation and when changing formulas or suppliers. Line items on internal audits should include specific allergen policies (scheduling, utensil usage, cleaning, raw ingredient segregation, ensuring correct label gets on product and color coding).
- Document allergen use and cleaning procedures.
- Make allergen education the first part of employee training and part of annual training updates. As always, after education sessions, document the employee by signature, date, trainer and materials covered.
- Develop a system for maintaining labels for foods containing allergens in easy-to-identify areas. Discard all old labels. Conduct a thorough review of the current recipes and match them with the labels used.
- Verify that product labels match the product and that the lot code of the finished product matches the batch record, which includes the raw materials used.

FSMA addresses allergen controls in:

U.S. National Archives and Records Administration. Food Allergen Controls, C.F.R. § 117.135(c)(2).

Accessed December 21, 2016. http://www.ecfr.gov/cgi-bin/text-idx?SID=45cf4558c52107814259117e5065b157&mc=true&node=pt21.2.117&rqn=div5#se21.2.117_1135.

8.13 Water Quality and Steam Supply

8.13.1 Water Quality

Water and steam for use in various processing application must be safe and sanitary. Verify that they are free of microbiological, chemical (e.g. agricultural, heavy metals), physical and radiological contaminants.

- Maintain a complete written and documented program to ensure use of safe/potable water in the preparation and processing of food. Monitor for microbiological, chemical (e.g. agricultural) and physical (e.g. heavy metals)

contaminants. This program covers the water source, in-plant water, reuse water, and steam.

- If the source of the water is a private well, then the manufacturer is responsible to have the water analyzed. Analyze city water supply to confirm its microbiological quality at least once a year. Keep the record of the analyses on file at the establishment.
- Test for the presence of indicator bacteria, such as coliform bacteria. Water must meet local and state requirements.
- Test product contact water once per month to determine whether the plant's water lines and filters are sanitary and effective. Product contact water is defined as ingredient water, water used for flushing product, and water used for washing and sanitizing purposes. A record of the analyses must be maintained by the plant. Suitable sites for sampling include a drinking water tap and a point of use, such as a hose. Sampling sites should be representative of different areas throughout the plant, although not necessarily the same points at each occasion. Over time, the sample sites should cover all applicable areas of the plant.
- Chemical analysis of the source water must be provided by the operator. The range of chemical analysis will depend on local conditions, such as geological formation, seepage from soil treated with fertilizers, pesticides or local exposure to industrial pollution. Consult local authorities to establish the range and frequency of tests.
- If the source of the water is a private well the analysis must be undertaken by the manufacturer. Repeat chemical testing if there is a change to the well or piping system of a private well. If the source of the water is the municipality and the chemical analysis is carried out by the municipality, the manufacturer can obtain a copy of the analysis from the municipal agency. Keep records of analyses on file at the establishment.
- Filter water used as a food ingredient or for flushing product to remove hazardous extraneous material to a particle size of 2mm. Water used for CIP purposes must be free of rust, excessive scale and other foreign material.
- Design: Water that is used solely for fire protection, boilers or auxiliary services (e.g. cooling of compressor heads) does not have to meet the same criteria as for manufacturing a food product. Eliminate cross connections between the potable and non-potable systems. Any temporary or permanent connecting arrangement through which backflow can occur is considered a cross-connection.
- Make sure water used for cooling in the heat exchanger is potable.

8.13.2 Steam Supply

Steam is typically used for cleaning and as part of the manufacturing process. If steam directly contacts product and product contact surfaces it must be culinary and have a filter as this helps protect the process equipment and process filters from damage.

- The water from which the steam is generated may be a food ingredient and must meet all the regulatory requirements for potable water. Of particular risk are boiler water conditioning compounds and corrosion inhibitors.
- Boiler feed water treatment, must be under the supervision of trained personnel or a firm specializing in industrial water conditioning. Have boiler feed water tested regularly and the chemical treatment controlled to prevent contamination.
- If the steam/hot water is in direct contact with product and/or the steam/hot water is used to sanitize product contact surfaces and is not followed by a potable water rinse then boiler treatment chemicals used must be listed in 21 C.F.R. § 173.310.¹⁰
- Periodically analyze steam condensate samples. Carryover of boiler water additives can result in the production of off flavors. Samples should be secured from the line between the final steam-separating equipment and introduction of steam into the product.

8.13.3 Water and Steam Hose Equipment

Poorly maintained hoses may contribute to the contamination of the water supply. Inspect the condition of the hose equipment (nozzles, ends and exterior) to assure it is sanitary and in good repair. Store hoses off the floor.

8.13.4 Records

Maintain records of water potability testing including water source, sample sites (including date and time sample taken), analytical results, analyst, and date. Keep water treatment records including the method of treatment, sample site (including date and time sample taken), analytical results, analyst, and date. If using recycled or reclaimed water, keep water reuse records. The records specify the person who is responsible, analyses and results, parameters of acceptability/unacceptability (tolerances), frequency and results of monitoring and verification, satisfactory follow-up for out of specification findings and are updated as required.

8.13.5 HVAC (Heating, Ventilation, Air Conditioning) System

Establish positive air pressure zones. The air pressure zone with the highest positive pressure should be the area where the product is exposed to open air.

- Make sure this air supply is not a source of contamination. Pathogenic organisms can enter the product via a contaminated air source.
- HVAC units are usually located on the roof or in a special room. Temperature is controlled by placing heating and/or cooling elements within the ducts. Filters are used to remove extraneous matter.
- HVAC systems must be cleanable and maintained clean. Special attention should be given to condensate drip pans and drain line to minimize potential growth of pathogens. Air intakes should not be located near unfavorable activities (e.g. feed mills, livestock operations).
- The method for supplying air under pressure, which comes in contact with milk or dairy products or any product contact surface, must comply with the 3-A Accepted Practices for Supplying Air under Pressure.

8.14 Loading, Transport, and Unloading Practices

In 2016 the final rule for Sanitary Transportation of Human and Animal Food was formed and required the following:

- **Vehicles and transportation equipment:** The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports to become unsafe. For example, they must be suitable and adequately cleanable for their intended use and capable of maintaining temperatures necessary for the safe transport of food.
- **Transportation operations:** The measures taken during transportation to ensure food safety, such as adequate temperature controls, preventing contamination of ready to eat food from touching raw food, protection of food from contamination by non-food items in the same load or previous load, and protection of food from cross-contact, i.e., the unintentional incorporation of a food allergen.
- **Training:** Training of carrier personnel in sanitary transportation practices and documentation of the training. This training is required when the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport.
- **Records:** Maintenance of records of written procedures, agreements and training (required of carriers). The required retention time for these records depends upon the type of record and when the covered activity occurred, but does not exceed 12 months.

Exempt from the Rule

- Shippers, receivers, or carriers engaged in food transportation operations that have less than \$500,000 in average annual revenue
- Transportation activities performed by a farm
- Transportation of food that is transshipped through the United States to another country
- Transportation of food that is imported for future export and that is neither consumed or distributed in the United States
- Transportation of compressed food gases (e.g. carbon dioxide, nitrogen or oxygen authorized for use in food and beverage products), and food contact substances
- Transportation of human food byproducts transported for use as animal food without further processing
- Transportation of food that is completely enclosed by a container except a food that requires temperature control for safety
- Transportation of live food animals, except molluscan shellfish

Food may be at risk for physical, chemical, or biological contamination during food transport due to:

- Improper refrigeration or temperature control of food products (temperature abuse).
- Improper management of transportation units (or storage facilities used during transport) to preclude cross-contamination, including improper sanitation, backhauling hazardous materials, not maintaining tanker wash records, improper disposal of wastewater, and aluminum phosphide fumigation methods in railcar transit.
- Improper packing of transportation units (or storage facilities used during transport), including incorrect use of packing materials and poor pallet quality.
- Improper loading practices, conditions, or equipment, including improper sanitation of loading equipment, not using dedicated units where appropriate, inappropriate loading patterns, and transporting mixed loads that increase the risk for cross-contamination.
- Improper unloading practices, conditions, or equipment, including improper sanitation of equipment and leaving raw materials on loading docks after hours.
- Poor pest control in transportation units (or storage facilities used during transport).
- Lack of driver/employee training and/or supervisor/manager/owner knowledge of food safety and/or security.
- Poor transportation unit design and construction.
- Lack of preventive maintenance for transportation units (or storage facilities used during transport), resulting in roof leaks, gaps in doors, and dripping condensation or ice accumulations.
- Poor employee hygiene.
- Poor policies for the safe and/or secure transport (or storage during transport) of foods, e.g., lack of or improper use of security seals.
- Improper handling and tracking of rejected loads and salvaged, reworked, and returned products or products destined for disposal.
- Improper holding practices for food products awaiting shipment or inspection, including unattended product, delayed holding of product, shipping of product while in quarantine, and poor rotation and throughput.
- Transport vehicles should have lock tags to prevent intentional adulteration and should be verified upon receipt of a delivery.

Cheese manufacturers should develop preventive controls for transportation and storage.

- Assure appropriate temperature is maintained during transport.
- Inspect vehicles and storage facilities for damage, cleanliness and sanitation and pest control.
- Use locks and seals to prevent product tampering. Verify that vehicles have required lock tags.
- Monitor loading and unloading to assure sanitary procedures are followed. Inspect pallets and packaging materials for damage and cleanliness.
- Train employees to be aware of potential for contamination.
- Maintain records of inspections, seals, and product and package integrity.

8.15 Chemical Storage, Labeling, and Use

Cleaning chemicals and sanitizers are used widely in dairy plants. A prerequisite program is needed to prevent potential for chemical contamination or injury. Numerous US government regulatory programs address use of cleaning chemicals and/or sanitizer. Use cleaning and sanitizing chemicals in accordance with the manufacturer's instructions and recommendations. Only use chemicals at proper concentrations for effectiveness and in the case of acid sanitizers for their no-rinse properties. Take caution to fully drain processing equipment of cleaners and sanitizers prior to use. During processing, pipelines and equipment used to contain or conduct milk products must be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions. Proper guidelines for proper chemical and product separation can be found in the Pasteurized Milk Ordinance (PMO) section 15p (B).

- Make sure compounds, such as cleaning and sanitizing chemical and pesticides, are properly labeled, used, and stored in a way that protects food, food contact surfaces, and packaging materials from contamination. Maintain a secured chemical storage area with limited access and removed from food storage, processing, and packaging areas.
- The original container label must remain intact, visible, and include:
 - Name of compound or solution in container
 - Name and address of manufacturer
 - Instructions for proper use
 - Potential hazards and cautions.
- Working container label must include:
 - Name of compound or solution in container
 - Instructions for proper use
 - Potential hazards and cautions.
- Separate food grade compounds from non-food grade.
- Working containers should be kept in a secure location that prevents misuse, spills, or product contamination.
- Keep Material Safety Data Sheets (MSDS) readily accessible for proper handling.
- Dispose of unused compounds in an approved manner.

8.16 Calibration of Measuring, Testing, and Inspection Equipment

Product measurements are only as good as the device used to measure that parameter. Calibration and maintenance of those devices is critical to maintain processing parameters.

Calibrate instruments before use in the laboratory to provide accurate test results. Balances should be serviced and calibrated at least on an annual basis by an outside contractor.

- The balances should be verified daily using certified weights available at laboratory/dairy supplier and covering the range of weights of the material being analyzed. Verification should be recorded including the date, person and procedure. All laboratory test weights have specific care instructions.
- Make sure scales are clean and in good repair.
- Follow the instruction manual for calibration and maintenance procedures for pH meters. For finished product cheese, the gold electrode is the preferred method as stated in Standard Methods for the Examination of Dairy Products¹¹. There are some smaller operations that do utilize the glass probe spear tip pH meters- this can be a useful and less expensive option for small operators. For testing pH during cheesemaking, a sample is taken and run in a different part of the room, using a bench top pH meter. There are also portable pH meters available. Always calibrate meters with calibration buffers 4.0 and 7.0 (and possibly 10.0 if linearity is needed to that point) at the start of each laboratory shift. Maintain documentation of the procedures. Store the pH probe in distilled water when not in use. If a quick result is desired, a pH-fix test strips may be used.
- Thermometers should be calibrated on a semi-annual basis using a certified National Institute of Standards and Technology (N.I.S.T.) thermometer.
- Indicating thermometers for use in pasteurizers are inspected minimally once a year by the regulatory inspection process.
- Verify that the thermometer is clean and in good condition (fittings and probe), is fit for purpose, and is accurate and reliable and easy to read and that there are records on file to support that the establishment's calibration program (as per the manufacturer specifications that details the calibration procedures and provides a schedule of frequencies) is effective.
- A recording thermometer automatically records the temperature of the product on a chart. Verify chart accuracy and write or stamp identifying information on charts.
- Metal detectors are designed, constructed, installed, calibrated and maintained in accordance with the equipment manufacturer's manual, to sense the presence of metals and eliminate them from products. The effective operation of metal detectors may require selecting proper equipment and adjustment for product, selection of target metal and size, timing of the reject mechanism and environmental conditions.
- Magnets may be installed in a manner to effectively remove ferrous metal prior to, or after, certain operations. They must be appropriately calibrated for the potential risk.
- Monitor magnets to ensure effective operation and surface exposure (e.g. adequately cleaned, metal particles removed).

8.17 Traceability of Ingredients, Packaging, and Finished Product

The PC rule and its supply-chain program in subpart G do not address finished product tracing. Recommendations related to finished product tracing are therefore provided as guidance for best practice. The supply-chain program includes requirements for raw material supplier approval, but only with respect to raw materials and other ingredients

when the supplier has applied the preventive control for a hazard. In that case, the rule requires not only supplier approval, but also has a requirement to document that these raw materials and other ingredients are only received from approved suppliers.

A good traceability program should create codes and document product movement from suppliers, through production and to customers.

For all companies, traceability begins at the receiving dock. All suppliers should be required to go through a qualification process that includes a quality systems audit. Part of that audit should document that the materials supplied by the vendor are traceable to their source as well as through their unit operations. All material should be coded with appropriate lot numbers that appear on the product containers delivered to a company. At the time of delivery, receiving personnel should check that the lot numbers correspond to the product received.

At the plant level, QC is responsible for the following:

- Ingredients significant to the safety of the process are identified with their specifications.
- Formulation factors that are key to the safety and integrity of the product are identified. This includes preparation/process steps and microbiological, chemical (e.g. allergens) or physical (e.g. hazardous extraneous material) concerns. Their specifications and limits are identified (e.g. water activity, as well as freedom from *Salmonella* spp.).
- When shipping finished products to distribution, the warehouse should document on all bills of lading the production codes and quantities shipped. Keep records of all shipments on file in order to reconcile and recover product in the event of a recall.
- Keep a list of key contacts on file for quick access.
- Production personnel are primarily responsible for building traceability into its finished food products. At the time of batching, production personnel must ensure that the proper materials have been withdrawn from the warehouse. They must check to see that all materials have appropriate lot numbers and reject any that do not. Cheese makers must document the lot numbers of the raw materials and the amount of each material used.
- Verify that product labels match the product and that the lot code of the finished product matches the batch record, which includes the raw materials used. This is part of your allergen preventive control program. This finished product code should then be placed both on the product on the master shipping cases.
- Trace and verify the tracking system by auditing the processes and conducting mock recalls at least yearly. Persons assigned to Quality Control (QC), with the guidance of upper management, should develop a recall manual that details each individual's responsibilities for conducting a recall. Keep the manual up to date to ensure rapid product recovery.
- Record lot numbers and amounts of ingredients received from outside suppliers. This includes but is not limited to enzymes, cultures, milk and milk products, annatto, vegetables, salt and spices.

- Record lot numbers and quantities of ingredients used in each batch for each product produced. Use a detailed make sheet and include:
 - Make date and batch number, or code date of product being made.
 - Ingredients added.
 - Lot codes of ingredients.
 - Amount of each ingredient added.
 - Vat number.
- Record lot codes of packaging materials.
- Record ingredients that are not incorporated in product, i.e. are disposed of in another manner, so that all ingredients can be accounted for in the event of a recall.

QC, as part of the raw material qualification process, should verify the supplier has:

- Supplied current technical data sheet for each raw material.
- Supplied a formula containing identification of all ingredients (e.g. brand/supplier, concentration, type, common name, specific name of food colors) and components (ingredients of ingredients, amounts of all ingredients, including food additives).
- Supplied a statement assuring products comply with food standards.
- Verified products are formulated to ensure accurate nutrition declarations
- Identified of allergens.
- Rework has a considerable risk regarding undeclared allergens in a product, or other potential hazardous material or microorganisms because the manufacturer has given up control. Communication with customers and retesting may be needed to understand what is going into the finished food. Batch documentation, including lot numbers and ingredients of any rework, must be attached to the batch record of the finished good. Think of the rework as another raw material check to make sure that the ingredients in the rework, including allergens, are included in the ingredient declaration on the finished product package.

In addition, the final rule for a supply chain program states:

- The rule mandates that a manufacturing/processing facility have a risk-based supply chain program for those raw material and other ingredients for which it has identified a hazard requiring a supply-chain applied control. Manufacturing/processing facilities that control a hazard using preventive controls, or who follow requirements applicable when relying on a customer to controls hazards, do not need to have a supply-chain program for that hazard.
- Covered food facilities are responsible for ensuring that these foods are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose materials are subject to verification activities before being accepted for use. (Approved suppliers are those approved by the facility after a consideration of factors that include a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance.)
- A facility will not be required to implement a preventive control when an identified hazard will be controlled by a subsequent entity such as a customer or other processor. The facility will have to disclose that the food is “not processed to

control (identified hazard)” and obtain written assurance from its customer regarding certain actions the customer agrees to take.

- Another entity in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility must review and assess that entity’s documentation of the verification of control of the hazard.

8.18 Recall/Withdrawal Programs

A recall is defined as a firm’s voluntary removal of distributed food products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of applicable state and federal laws. “Recall” does not include a market withdrawal or a stock recovery. A market withdrawal is a firm’s removal or correction by its own volition of a distributed product that involves a minor infraction that would not warrant legal action by regulatory agencies, or involves no violation of the state or federal laws, or health hazard. See 21 C.F.R. § 117.139 for recall plan¹².

For food with a hazard requiring a preventive control:

- *You must establish a written recall plan for the food.*
- *The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:*
- *Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;*
- *Notify the public about any hazard presented by the food when appropriate to protect public health;*
- *Conduct effectiveness checks to verify that the recall is carried out; and*
- *Appropriately dispose of recalled food--e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.*

Public notification is important, particularly in situations where the recalled product may pose a significant health hazard and may be in the hands of consumers.

- Determine product, code date, ingredient, and cause of recall.
- Designate only one company spokesperson.
- Have a statement prepared with a list of necessary information to provide to reporters.
- Collect and update contact information for customer management, including:
 - Name and position.
 - Telephone number, cell phone number, etc.
 - Secondary person to notify if main person cannot be reached.
- Compile contact information for news media and television stations to broadcast recall information.
- Compile names and telephone numbers of FDA and officials that are to be contacted. (Once FDA has been notified, within 24 hours this information will be placed on their website).

- Pre-arrange legal representation and other consultation pre-arranged.

8.18.1 Product Traceability and Recall Procedures

- If a product is recalled, determine the reason for the recall, and verify when and where the product was shipped.
- Notify all distributors/customers by phone and in writing with the following information (Follow with another phone call with contact person to ensure they have received proper notification):
 - Product being recalled
 - Reason for recall
 - Code date or other product information
 - Contact person and contact numbers who can answer questions regarding the recall.
 - How and where to return the product.

8.18.2 Product Retrieval for Recall

- Determine where product should be shipped.
- Determine method of shipment.
- Determine where this product will be kept once received. Place “Hold” tags on product once received.
- Document quantity of product received.
- Depending on type of recall, determine what will be done with the product.
- Communicate this information to the proper state and FDA contacts. (The goal of a finished product recall is to trace forward and notify all customers of the potential hazard within 2 to 4 hours of determining that a hazard exists. Practice to become efficient at this.) A trace back occurs when you need to trace where something came from such as an ingredient.
- Perform mock trace for finished product, contact packaging and ingredients a minimum of once a year. A mock trace allows the facility to be prepared and efficient in the event of an actual recall. Document when the mock trace is conducted. The following should be recorded.
 - Date of traceability exercise.
 - Product packaging materials and ingredients that were part of the mock trace.
 - Problems encountered and corrective actions taken.
 - Time required completing recall.
 - Amount of product recovered and quantity by code.

If deficiencies are identified, corrective action must be taken and documented and a follow-up mock recall must be done to validate corrective measures.

8.19 Supply-Chain Program

The FSMA rule on Foreign Supplier Verification Programs requires importers to conduct risk based activities to ensure that food items have been produced in a manner that is in accordance with U.S. food safety standards. An importer is defined in this ruling as the United States owner or consignee of a food offered for import into the United States. If you are directly purchasing and importing any ingredients for use in cheesemaking, it is important to be aware of this ruling.

Certain importers that are also manufacturers/processors are considered to be in compliance with most FSVP requirements if you are in compliance with the supply-chain program requirements under the preventive controls rules; implement preventive controls for the hazards in the food in accordance with the requirements in the preventive controls rules; or they are not required to implement preventive controls under those rules in certain specified circumstances.

The FSMA rule on Preventive Controls for Human Food requires the processing facilities to have a risk based supply chain program in place for ingredients and materials that have been identified as a hazard. Facilities covered by this rule are responsible for ensuring that these foods are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose materials are subject to verification activities before being accepted for use.

For more information regarding exemptions and compliance dates for the Foreign Supplier Verification Programs and the Preventive Controls for Human Food Supply Chain Program requirements, please see The FDA website which provides guidance documents and factsheets that list and explain key requirements.¹³

8.19.1 Approved Vendor Lists

Any outside vendor should be assessed for its ability to supply high quality products and services. Document approved vendors and back-up suppliers. Approval may be based on:

- Product quality
- Microbiological criteria
- Past history
- Product and service availability
- Product price
- Liability insurance sufficient to cover the business transaction

8.19.2 Supplier Audits

Supplier audits can either be done by plant personnel or by third party auditors. When auditing suppliers including outside laboratories, it is important to assess the following: (Note: this list is far from inclusive. An inclusive list should be developed based on specific plant needs or can be modeled from the internal audit form).

- Exterior of facility: It is clean?
- Are visitors allowed and properly identified?
- Are good manufacturing practices being followed by plant employees?
- Are hairnets worn appropriately?
- Are hands washed and sanitized before returning to work stations?
- Are uniforms clean daily?
- Are locker rooms, lunch rooms and bathrooms clean?
- Are foods, beverages or tobacco products used in production areas?
- Are employees trained in good manufacturing practices as evidenced by documentation?
- Is there a HACCP plan?
- How is rework handled?
- Is there a documented pest control program?
- Is there a sanitation plan complete with master sanitation schedule, SSOP's and chemical training for employees?
- Is there an environmental monitoring program?
- Has outside laboratory been audited for accuracy in completing procedures?
- Are there monthly internal audits conducted?
- Is a pre-operational inspection done?
- Interior of facility: Are there cracks in floor and walls or loose tiles?
- Is there a master maintenance schedule and maintenance SOP's?
- Is there rust evident?
- Is the equipment properly maintained?
- How is product stored and transported?
- Is there a recall program and what was the date of the last mock recall?
- Are ingredients and finished product mock recalls done?
- What percent of product can be tracked and how long would it take?
 - For example: Can 100% of product be tracked in 2-4 hours?
- Are code dates/lot numbers or other systems in place for tracking products?
- How are ingredients tracked through production?

In addition, an onsite audit for suppliers must meet the requirements of 21 C.F.R. § 117.435 which states:

- *An onsite audit of a supplier must be performed by a qualified auditor.*
- *If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).*

8.19.3 Ingredient Specifications

Ingredients used in the process should be from approved vendors and purchased against established specifications. An approved supplier must ensure they have controlled the hazards for the ingredient they have supplied. Copies of current specifications for ingredients must be available. Incoming ingredients must be inspected for acceptability based on ingredient specifications. Inspect for evidence of damage or contamination. Implement a sampling plan identifying which ingredients are subject to in-plant testing and which are accepted based on Certificates of Analysis (COA), specifications for ingredients and accept/reject limits, and microbiological evaluation, if required. Maintain documentation of all incoming ingredient receipts and results of inspections.

8.19.4 Supplier Performance Control

Certification that incoming ingredients and packaging materials meet specified performance criteria is an important component of a food safety program. The plant should have specifications and performance standards in place for each ingredient, packaging material and non-food chemical including:

- Certification of food-grade status for ingredients or product contact packaging material.
- Certificates of Analysis (COA) that material meets specifications.
- Letters of guarantee.
- Random checks on incoming material.
- Other supplier verification documentation.

8.19.5 Corrective Action Plan

All incoming ingredients must be inspected and approved, based on product specifications, before processing. If the product is damaged, contaminated or does not comply with specifications, the following corrective action steps must be taken:

- Hold product in a separate area away from all processing areas.
- Mark product for “hold”.
- File a corrective action report with the following information:
 - Date of rejection
 - Suppliers name, address and telephone number
 - Transporter of the ingredient
 - The ingredient and code date information
 - Complaint
- Contact the supplier of rejected material to determine if product should either be destroyed or returned to the supplier with documentation as to the reason for rejection.
- Product should be properly packaged and labeled for return to supplier.
- Corrective Action report should identify the corrective action taken with the rejected material.
- All incoming materials should be received in a separate area away from processing areas. The plant should have a documented SOP for receiving,

storing and approving all ingredients and packaging materials before use in any product. This hold and release program may include:

- Placing all newly arrived material on hold
- Evaluating against supplier performance standards
- Approving if material meets all specifications
- Storing and handling to maintain sanitary conditions
- Properly handling and storing non-conforming non-food chemicals
- Document when supplies are shipped in or arrive in unacceptable condition and who the supplier and carrier are. Documentation should include:
 - Date
 - Items shipped
 - Supplier name and lot #
 - Product(s) of concern and reason for concern
 - Corrective action taken by supplier
 - Supplier guarantee on file
 - Microbial specifications and results if required
 - Allergens present
- Build a documented history of each supplier. Review this documentation of rejected or sub-par material with the supplier and documentation responses.
- Include reviewer signature on these documentation sheets.
- As each sheet is completed, a quality assurance representative or supervisor reviews contents and then signs and dates which indicates that the sheet was reviewed.

8.20 Complaint Management

Record any complaint information and complete an investigation at the facility and/or retail outlets. Determine whether other customers may have similar problems.

A complaint file contains:

- Recording of the initial complaint information
- Investigating at the facility or retail outlet
- Action taken for the specific product

8.20.1 Recording of the Initial Complaint Information

The complaint should be recorded by a designated individual(s). It is important to include enough information so that an investigation of the problem can start immediately. This may include but is not limited to:

Complainant details:

- Name, address, telephone number(s) of the complainant
- Illness or injury involved
- What is the problem with the product, e.g. chemical taste, allergic reaction, illness, object in the food

Product details:

- Package type and size
- Product name
- Identifying codes
- Date of purchase
- Does the complainant have a sample of the product?
- Has the complaint been referred to anyone else? (e.g. manufacturer, importer, distributor, the Food Inspection Agency or Public Health)

Documenting customer complaints creates a history of problems a product may have. Response to consumer complaints should be rapid to promote good relations.

Two customer complaints logged on a product with the same code date should trigger an internal investigation.

A customer complaint form should include:

- Date of complaint
- Claimants' name, address, telephone number
- The product in question and code date information
- Complaint
- Corrective action

8.20.2 Investigation at the Retail Outlet

Investigate the complaint fully considering the possibility that problems arose after the product left the manufacturing plant.

Record in the complaint file:

- The name of the person at the facility who investigated the complaint
- Date and time of the investigation
- Investigation findings
- Other products which may be affected by the problem

8.20.3 Action Taken

When an unsafe or violative product is discovered, remove the product from sale immediately and contact the FDA and local regulatory authorities.

If notified of a recall or product action by a manufacturer, importer or distributor, immediately record:

- What the action is, i.e., recall, no recall
- The manufacturer's, importer's or distributor's instructions of what to do with any of the product that may be on site

8.21 Crisis Management

Develop a crisis management plan to handle unexpected events. Unexpected events may be either human or natural catastrophes such as tornadoes, fire or flood, or even the outbreak of employee illness. Food Defense Programs are designed to reduce the risk of tampering or other malicious, criminal, or terrorist actions on the food.

The event may result in a loss of public trust and confidence.

The crisis plan should include:

- A coordinated response plan for food defense emergencies.
- Roles of staff involved in the plan.
- Who, within the company and/or facility, is the key authority according to the plan?
- How have these individuals been trained?
- Has an alternate chain of command been established?
- Have safety/defense partnerships been established with local, state and federal law enforcement agencies, other public safety and health agencies and surrounding community leaders.
- If so, who maintains contact and contact information for these individuals?
- When this information was last updated.
- Are these individuals identified in the defense plan?
- If needed, is there a plan for emergency shut down.
- Who has the authority to initiate an emergency shut down?
- Has the individual(s) responsible for notifying authorities and the public been identified, if needed?
- Are the criteria for initiating a shutdown specified?
- Are procedures in place for securing the facility following shut-down.
- Is there a plan for emergency evacuation in place?
- Who has the authority to initiate an emergency evacuation?
- Does the plan specify how employees are accounted for in the event of an evacuation?
- Is there a specified offsite meeting place?
- Is there an established emergency contact for employees?
- Are mechanisms in place for employees to identify and refer suspicious incidents or site security breaches?
- Does the plan direct how to handle these situations?
- Have point person(s) been identified for incident identification and reporting?
- Have they been trained?
- Is all staff made aware of reporting procedures, including who to contact?

¹ U.S. National Archives and Records Administration. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 Electronic Code of Federal Regulations § 117. Accessed December 21, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=0fc50b12db22a33f6b3e5ea67a25ab2f&mc=true&node=pt21.2.117&rgn=div5>.

² U.S. Center for Food Safety and Applied Nutrition. "FDA Food Safety Modernization Act (FSMA)." U.S. Food and Drug Administration. Accessed December 22, 2016. <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>.

³ Qualified Facility Attestation." U.S. Food and Drug Administration. Accessed January 6, 2017. <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm>

⁴ 3-A Sanitary Standards, Inc. "A Primer for 3-A Standards & Practices." *3-A Sanitary Standards, Inc.* Accessed December 22, 2016. <http://www.3-a.org/Knowledge-Center/Resource-Papers/A-Primer-for-3-A-Standards-Practices>.

⁵ "Chemical Processing." *Chemical Processing*. Accessed February 9, 2017. <http://www.chemicalprocessing.com/home/>.

⁶U.S. National Archives and Records Administration. Food for Human Consumption, 21 Electronic Code of Federal Regulations § Subchapter B. Accessed January 30, 2017. http://www.ecfr.gov/cgi-bin/text-idx?SID=57534aa27644d13e5a588040de86ae4d&mc=true&tpl=/ecfrbrowse/Title21/21cfrv3_02.tpl#0.

⁷3-A Sanitary Standards, Inc. "A Primer for 3-A Standards & Practices." *3-A Sanitary Standards, Inc.* Accessed December 22, 2016. <http://www.3-a.org/Knowledge-Center/Resource-Papers/A-Primer-for-3-A-Standards-Practices>.

⁸Wehr, H. Michael, and Joseph F. Frank, eds. *Standard methods for the examination of dairy products*. Washington, DC: American Public Health Association, 2004

⁹University of Nebraska- Lincoln. "Food Allergy Research and Resource Program." University of Nebraska- Lincoln. Accessed December 21, 2016. <http://farrp.unl.edu/>.

¹⁰U.S. National Archives and Records Administration. Boiled Water Additives, 21 Electronic Code of Federal Regulations § 173.310. Accessed January 30, 2017. http://www.ecfr.gov/cgi-bin/text-idx?SID=57534aa27644d13e5a588040de86ae4d&mc=true&node=se21.3.173_1310&rgn=div8.

¹¹Wehr, Michael, PhD and Joseph F. Frank, and PhD. *Standard Methods for the Examination of Dairy Products*. 17th edition. Washington, DC: American Public Health Association, 2004

¹²U.S. National Archives and Records Administration. Recall Plan, 21 Electronic Code of Federal Regulations § 117.310. Accessed January 30, 2017. http://www.ecfr.gov/cgi-bin/text-idx?SID=57534aa27644d13e5a588040de86ae4d&mc=true&node=se21.2.117_1139&rgn=div8.

¹³ U.S. Center for Food Safety and Applied Nutrition. "FDA Food Safety Modernization Act (FSMA)." U.S. Food and Drug Administration. Accessed December 22, 2016. <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>.



Chapter 9 Food Safety Plans

In response to foodborne illnesses and hazardous events in the food industry over the past 20 years, The United States Congress has passed historic legislation in the form of the Food Safety Modernization Act (FSMA). This was the first major reform of the US Food and Drug Administration (FDA) food safety authority in over 70 years. FSMA was signed into law by President Obama in 2011. The law is intended to shift FDA focus to better protect public health by proactively preventing food safety issues, rather than reacting to outbreaks after the fact. FSMA is an enormous and complex piece of legislation intended to build a new proactive federal food safety system.

9.1 New Regulatory Changes

FDA has regulatory authority to ensure the safety of about 80% of all domestic and imported foods, excluding most meats, poultry, and processed egg products which are regulated by the US Department of Agriculture (USDA). Specifically, FSMA enhances regulation of produce from farm to sale, and all other FDA-regulated foods from processing to sale. FSMA alters FDA's role in food safety through five key changes:

1. FSMA shifts the FDA role from reactive to preventive by requiring the FDA to mandate comprehensive, prevention-based controls across the food supply and by providing new authority to prevent intentional contamination.
2. FSMA grants the FDA more authority to inspect and ensure compliance through mandated inspections with frequencies based on risk.
3. FSMA grants the FDA mandatory recall authority, enabling prompt response to problems when they occur.
4. FSMA enables the FDA to better address major weaknesses in import safety and to ensure that US food safety standards are being met.
5. FDA will strengthen partnerships with other food agencies and private entities to enhance the rule-making process. To facilitate implementation of FSMA, Congress established specific compliance deadlines for the FDA within the legislation. These deadlines were recently further modified in an agreement by FDA in federal court. At present, seven final rules have been published.

9.1.1 General Requirements for all Food Producers and Processors

All food producers (i.e., food manufacturers, processors, packers, and distributors), except USDA-regulated meat, poultry, and processed egg producers, are required to comply with general FSMA requirements unless otherwise exempted. These requirements are to:

- Register with the FDA biannually

- Create a Food Safety Plan with science-based preventive controls based on a hazard analysis prepared by a Preventive Controls Qualified Individual
- Create a Food Defense Plan with science-based mitigation strategies based on a vulnerability assessment
- Promptly report any foods that may cause adverse health effects to the Reportable Food Registry
- For dairy farms, except those properly exempted as ‘very small’ dairy farms, compliance is required with some portions of the Intentional Adulteration Rule

9.1.2 Inclusions and Exclusions Per FSMA

Dairy farms have been specifically included in FSMA’s Intentional Adulteration Rule; no other types of farms are included. Other industries, such as seafood, juice, and canned goods, have been exempted from parts of FSMA as a result of mandated FDA-regulated Hazard Analysis and Critical Control Point (HACCP) programs.

Currently, the dairy industry participates in this program voluntarily, and is instead FDA-regulated against accidental contamination through the Pasteurized Milk Ordinance (PMO). Dairy farms have been identified as vulnerable, and risk assessments have determined that intentional terrorist contaminations at dairy farms have the potential to cause significant illness or death.

The role of FDA is to regulate food safety; the responsibility of each company is to ensure the safety of their food products. FSMA is in the midst of a lengthy rule-making and guidance process, which means that FDA is turning the bill passed by Congress into actual rules and regulations, and related guidance documents.

Guidance documents, while not regulations, can be as important to industry as formal regulations. *Failing to follow issued guidance could significantly increase liability risk in the event of a food safety incident.* Most proposed regulations are released and then opened for public comment. In hopes of making the final regulations beneficial, it is important that stakeholders included in this legislation are active and vocal about their needs.

Under FSMA, food facilities must maintain Hazard Analysis and Risk-Based Preventive Controls (HARPC). The HARPC requirements are similar to the Hazard Analysis and Critical Control Point (HACCP) requirements which apply to processors of seafood and juice. HARPC applies to nearly all food facilities. Preventive controls and monitoring are part of the food safety plan. See 21 C.F.R. § 117.126,¹ excerpted in part below:

The written food safety plan must include:

- *The written hazard analysis as required by 21 C.F.R. § 117.130(a)(2);*
- *The written preventive controls as required by 21 C.F.R. § 117.135(b);*
- *The written supply-chain program as required by subpart G of this part;*
- *The written recall plan as required by 21 C.F.R. § 117.139(a); and*

- *The written procedures for monitoring the implementation of the preventive controls as required by C.F.R. § 117.145(a)(1);*
- *The written corrective action procedures as required by 21 C.F.R. §117.150(a)(1); and*
- *(7) The written verification procedures as required by 21 C.F.R. § 117.165(b).*

The ACS Best Practices Guide for Cheesemakers has included in the Appendix section a model food safety plan for Pepper Jack cheese entitled “Selected Sections of a Food Safety Plan for Pepper Jack Cheese: Teaching Example.” Please refer to this model when reading through the next section.

FSMA defines small business in 21 C.F.R. § 117.3 as “*a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.*”

Very small businesses are defined as “*a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).*”²

Such entities are exempt from certain HARPC requirements. Small businesses may pertain to certain low-risk activity/food combinations as specified in 21 C.F.R. § 117.5 and that are conducted on farms.

Qualified facilities are not required to comply with the full HARPC provisions but must still comply with cGMPs in addition to modified requirements. For more information, please see “The Food Safety Modernization Act- Preventive Controls for Human Food Rule”³ and “Food Safety Modernization Act (FSMA): The Law, Rules & Guidance.”⁴

9.2 Product Description

Cheese is the “value added” end product of milk, and ultimately the product that reaches consumers. Accurately describing the product is important both in analyzing hazards and in identifying the raw materials and the intended use in a HARPC evaluation. The first step in identifying known hazards focuses on inputs to the production system under evaluation, and the second focuses on its destination so that any known implicit aspects that affect hazard analysis can be brought forward for further consideration. The description of the product must be accurate and complete. This forms the basis for identifying and assessing potential hazards associated with the product. The specific areas of the product description are noted in the following sections 9.2.1-9.2.12.

9.2.1 Product Name

This needs to be concise but accurate. Merely 'cheese' does not contain enough information to make a reliable assessment of hazards possible. A producer may be touting a farm-produced cheese or, if the cheese has added value, it could be various cheese flavors, such as garlic or chives added from his/her own organic garden. Although these descriptors may help in the marketing of the cheese, they are not specific to the product name. The name should be specific, for example, Cheddar with chives, as it may have a standard of identity.

9.2.2 Ingredients on Package Labels

A complete listing is required of all ingredients. The ingredients are required to be listed from largest to smallest quantity in 21 C.F.R. § 101.4. To follow the example being used of Cheddar with chives, the ingredients list might include raw milk, cultures, enzymes, salt, and chives⁵.

9.2.3 Food Safety Characteristics

The information here should include any particulars directly related to safety. Each ingredient should be analyzed for its individual characteristics. Examples of characteristics include pH, water activity (Aw), or any hazardous substances.

You may also include features used to distinguish a particular product from other similar products. As an example, if the Cheddar is produced from raw milk, the characteristics statement should include raw milk cheese aged for a minimum of 60 days at a temperature greater than 35°F (2°C).

9.2.4 Packaging Used

The packaging should be fully described. For example, state whether the cheese aged is a natural rind, bandaged, waxed, or vacuum-packaged product. Then, specify the package composition, such as 3 milliliter plastic vacuum bags. This also applies to packaging of cheese that is cut and packaged.

9.2.5 Labeling

Labeling includes stating specific information about the product, as well as specific instructions for use. Continuing with the example of Cheddar with chives, the labeling information would state that the raw milk cheese had been aged for 60 days. It should also state that the cheese is to be kept under refrigeration.

9.2.6 Storage, Distribution, and Handling

During storage, distribution, and handling, store refrigerated at 41°F (5°C) or less, but not below 32°F (0°C). Distribution should also be at 41°F (5°C) or less, but not below 32°F (0°C).

9.2.7 Distribution Area and Outlets

Identify where the cheese was manufactured, where it is distributed, and how it is transported. The example here is that the cheese is shipped from plant (name it) to warehouse to retail, or directly to retail outlets in the United States via commercial transport companies (name them).

9.2.8 Intended Consumer

For the cheese referenced above (raw milk Cheddar with chives), identify how the product is stored, distributed, and intended for use by healthy adults and children, excluding those in potentially high risk groups (e.g. infants and immune compromised).

9.2.9 Intended Use

Since cheese is a ready to eat (RTE) product, it should be stated that it is a RTE product and that it may be combined with other foods or used as an ingredient.

9.2.10 Shelf Life

Shelf life refers to the number of days and temperature a product can be held before being considered “unfit for sale” based on a printed sell-by date. This may or may not correspond to its being “unsafe to consume.”

9.2.11 Company Details

On the product description page, the company’s address and contact information, such as phone, fax, or email, should be included.

9.2.12 Other Information

Other information on the description page should identify how current this page is. This should include the version/date of the document, the title, who approved the page, along with their title, signature, and date.

A template for product description may be found at <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm121105.htm>.

9.3 Product Flow Diagrams

A Flow Diagram can help you identify all of the process steps in your business, from receipt of the raw milk, through the production process, and finally the distribution steps. By creating a Flow Diagram of your operation, you will be able to break your processes down into component parts – called process steps.

A flow diagram and forms are recommended in documenting the hazard analysis and final food safety plan:

- The accuracy of the flow diagram is critical in conducting a hazard analysis.
- The hazard analysis should contain information to justify the identification of the proper preventive controls.

- Information in the food safety plan must explain the details for each HARPC step.

The preventive controls for the process should be identified on the Flow Diagram. For example, pasteurization would be a process control for controlling unwanted microorganisms. In raw milk cheese, the manufacture and aging processes and conditions are part of a series of preventive controls. Some of the hazards that you may identify are actually controlled by preventive controls previously referred to as prerequisite programs in your food safety plan. For instance, the presence of antibiotics in milk may be controlled in the prerequisite program, stating that all milk received by the plant must be tested prior to unloading of the milk.

9.4 Hazard Analysis and Risk-Based Preventive Controls (HARPC)

The “HA” in HARPC stands for “Hazard Analysis” and addresses the core intent of the FSMA law: to identify hazards that might arise due to the specific foods or ingredients in the food, or due to the various processing, manufacturing, packing, and holding steps applied to the food. Once identified, the company must develop a plan to minimize or prevent the hazards from arising. See 21 C.F.R. § 117.130.⁶ In the first step, food companies must evaluate the product and its processing for hazards:

Hazard Identification

The hazard identification must consider:

- *Known or reasonably foreseeable hazards that include:*
 - *Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;*
 - *Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and*
 - *Physical hazards (such as stones, glass, and metal fragments); and*
- *Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:*
 - *The hazard occurs naturally;*
 - *The hazard may be unintentionally introduced; or*
 - *The hazard may be intentionally introduced for purposes of economic gain.*

The “RPC” in HARPC stands for “Risk-based Preventive Controls.” This is the portion of HARPC that requires companies to develop and implement a series of risk-based

controls of the manufacturing process where the identified hazards must be prevented or minimized to ensure safety of the food. These risk-based controls may include Critical Control Points (CCPs). The facility must designate control measures at each critical control point, to ensure the greatest level of risk prevention or mitigation is achieved by normal operation of that manufacturing, processing, packing, or storage step. Per the statutory language, these control measures must significantly minimize or prevent the identified hazards.

The preventive controls rule defines “Critical Control Point” as “a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.”

Some examples of preventive controls are listed below:

- Sanitation procedures at food surface contact points
- Sanitation of utensils and equipment
- Staff hygiene training
- Environmental monitoring program (for pathogen controls)
- Food allergen control program
- Recall plan
- Current Good Manufacturing Practices (cGMPs)
- Supplier verification activities

9.4.1 Monitoring of Effectiveness

The Preventive Controls rule requires the food facility to implement a monitoring program, which ensures the firm is conducting regular evaluations of the facility’s control measures to determine whether the preventive controls are working.

9.4.2 Corrective Actions

As the risk-based preventive controls and control measures in a properly designed HARPC system are monitored, any instances of deviation from the control measures must be identified, evaluated with respect to cause, and corrected. The Corrective Action steps of the Preventive Controls rule can be found in 21 C.F.R. § 117.150.⁷ The Corrective Action procedures must describe the steps to be taken to ensure that:

- *Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;*
- *Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;*
- *All affected food is evaluated for safety; and*
- *All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.*

The Preventive Controls rule requires facility owners and operators to identify and fix uncontrolled processing steps and to evaluate processed foods for safety and adulteration risks.

9.4.3 Verification

The Preventive Controls rule requires that food facilities verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards.

Verification activities. *Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:*

- *Validation in accordance with 21 C.F.R. § 117.160.*
- *Verification that monitoring is being conducted as required by 21 C.F.R. § 117.140 (and in accordance with 21 C.F.R. §117.145).*
- *Verification that appropriate decisions about corrective actions are being made as required by 21 C.F.R. § 117.140 (and in accordance with C.F.R. §117.150).*
- *Verification of implementation and effectiveness in accordance with 21 C.F.R. §117.165; and*
- *Reanalysis in accordance with 21 C.F.R. § 117.170.*

9.4.4 Record Keeping and Documentation

One key development under HARPC is its new requirements related to records and methods of documentation that have become mandatory for food manufacturing, processing, packing, and storage facilities. Previously, under the Bioterrorism Act, FDA could only require a food company to maintain records that enabled food to be traced through the supply chain (one up/one back identification records). Records required under 21 C.F.R. § 117.190 include:⁸

You must establish and maintain the following records documenting implementation of the food safety plan:

- *Documentation, as required by 21 §117.136(b), of the basis for not establishing a preventive control in accordance with 21 §117.136(a);*
- *Records that document the monitoring of preventive controls;*
- *Records that document corrective actions;*
- *Records that document verification, including, as applicable, those related to:*
 - *Validation;*
 - *Verification of monitoring;*
 - *Verification of corrective actions;*

- *Calibration of process monitoring and verification instruments;*
- *Product testing;*
- *Environmental monitoring;*
- *Records review; and*
- *Reanalysis;*
- *Records that document the supply-chain program; and*
- *Records that document applicable training for the preventive controls qualified individual and the qualified auditor.*

In other words, FDA requires that a written record be kept of the entire plan including the *process*, the *proof*, and the *problems*. A facility must make these records and documentation available to FDA upon oral or written request. The records can be in electronic format. The recordkeeping requirements, therefore, must tell the proper story to demonstrate HARPC compliance. For more on recordkeeping, please see “The Importance of Records Under FSMA.”⁹

9.4.5 Requirement to Re-analyze

After developing and implementing a food safety plan, the food facility must periodically evaluate its food safety HARPC system. See 21 C.F.R. § 117.170.¹⁰

You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years;

You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:

- *Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;*
- *Whenever you become aware of new information about potential hazards associated with the food;*
- *Whenever appropriate after an unanticipated food safety problem in accordance with 21 C.F.R § 117.150(b); and*
- *Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.*

You must complete the reanalysis and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified:

- *Before any change in activities (including any change in preventive control) at the facility is operative; or*

- *When necessary to demonstrate the control measures can be implemented as designed:*
 - *Within 90 calendar days after production of the applicable food first begins; or*
 - *Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90-calendar days after production of the applicable food first begins.*

You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or document the basis for the conclusion that no revisions are needed.

A preventive controls qualified individual must perform (or oversee) the reanalysis.

You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

Additionally, HARPC requires the facility to perform a new hazard analysis and implement any new, necessary preventive controls *before* operational changes occur. Any changes must be documented in the firm's HARPC records. If no changes are necessary after a reanalysis of a HARPC system, the firm must document the basis for that decision. Facility owners, operators, and agents may also have to reanalyze their food safety plans at any time due to new biological, chemical, or terrorist threats identified by the Department of Homeland Security.

9.5 Hazard Analysis

In order to complete the Food Safety Plan, processors will need to perform a hazard analysis. Processors conduct, or have conducted for them, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur in their product and the preventive measures that a processor can apply to control those hazards. FDA expects that a written hazard analysis will be useful when you perform mandatory Food Safety Plan reassessments and when you are asked by regulators to justify why certain hazards were or were not included in your HARPC plan.

The steps in creating an analysis include: identifying a preventive controls qualified individual and assembling a food safety team, developing the product description and Flow Diagram, then following the list of steps to complete the Hazard Analysis Worksheet.

9.5.1 Steps to Conduct a Hazard Analysis

The food safety team should list all of the hazards that may be reasonably expected to occur from each ingredient or at each step from primary production, processing, manufacture, and distribution until the point of consumption. Hazard Analysis is based on two parts: identification and evaluation. See 21 C.F.R. § 117.130.¹¹

Hazard identification. *The hazard identification must consider:*

- *Known or reasonably foreseeable hazards that include:*
 - *Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;*
 - *Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and*
 - *Physical hazards (such as stones, glass, and metal fragments); and*
- *Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:*
 - *The hazard occurs naturally;*
 - *The hazard may be unintentionally introduced; or*
 - *The hazard may be intentionally introduced for purposes of economic gain.*
- *Hazard evaluation.*
 - *The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.*
 - *The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.*

Record each of the processing steps (from the Flow Diagram) in the Hazard Analysis Worksheet. Identify potential process-related hazards – i.e., can this hazard continue through the system, or is there a stop point by implementing a control measure?

9.5.2 Steps to Conduct Control Measures

Hazards identified in the Hazard Analysis require a preventive control. The food safety team must consider what control measures, if any, exist which can be applied for each

hazard. More than one control measure may be required to control specific hazard(s), and more than one hazard may be controlled by a specified control measure.

Development of the food safety system can be facilitated by the application of a “decision tree” that indicates a logical reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, processing, storage, distribution, or other. It should be used for guidance when determining control points.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

Critical limits must be specified and validated if possible for each critical control point. In some cases, more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, A_w , available chlorine, and sensory parameters such as visual appearance and texture.

9.5.3 Steps to Monitor Procedures

Monitoring according to the Preventive Control rule means conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended. Monitoring procedures must be able to detect loss of control at the control point. Furthermore, monitoring should ideally provide this information in time to make adjustments to ensure control of the process, and to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results to indicate a trend towards loss of control at a control point. The adjustments should be taken before a deviation occurs. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the control point is in control. Most monitoring procedures for control points will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring control points must be signed by the person(s) doing the monitoring and by responsible reviewing official(s) of the company.

9.5.4 Establish Corrective Action Procedures

Specific corrective actions must be developed for each control point in order to deal with deviations when they occur. See section 9.4.2 of this chapter.

9.5.5 Establish Verification Procedures

Verification and auditing methods, procedures, and tests, including random sampling and analysis, can be used to determine if the HARPC system is working correctly. The frequency of verification should be sufficient to confirm that the HARPC system is working effectively. See 21 C.F.R. § 117.165 (b).¹²

Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the

following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:

- *Calibration of process monitoring instruments and verification instruments (or checking them for accuracy);*
- *Product testing, for a pathogen (or appropriate indicator organism) or other hazard;*
- *Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and*
- *Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:*
 - *Records of monitoring and corrective action records within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days; and*
 - *Records of calibration, testing (e.g., product testing, environmental monitoring), supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and*
- *Other activities appropriate for verification of implementation and effectiveness.*

Where possible, validation activities should include actions to confirm the efficacy of all elements of the food safety plan.

9.5.6 Establish a Record Keeping System

Meticulous record keeping is essential to the application of a HARPC system. HARPC procedures should be documented, and all documentation and record keeping should correlate to the nature and size of the operation.

Documentation examples are:

- Hazard analysis
- Determination of preventive controls
- Determination of parameters and minimum/maximum values

Record examples are:

- Monitoring control point activities
- Deviations and associated corrective actions
- Verification activities
- Modifications to the food safety system

9.6 Food Safety Plan Summary Table

Food safety plan summary tables should identify the plant and product, and should include the date that the plan was created. Its primary purpose is to summarize the control points in your plan, what hazards they control, the parameters and values that are set, the type of monitoring that takes place, corrective actions, the verification of the control point(s), and any records that may need to be maintained.

¹U.S. National Archives and Records Administration. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 Electronic Code of Federal Regulations § 117. Accessed December 21, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=0fc50b12db22a33f6b3e5ea67a25ab2f&mc=true&node=pt21.2.117&rgn=div5>.

² U.S. National Archives and Records Administration. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food:Definitions, 21 Electronic Code of Federal Regulations § 117.3. Accessed December 21, 2016. http://www.ecfr.gov/cgi-bin/text-idx?SID=e9ca025764f8adff02bc93a2655d8450&mc=true&node=pt21.2.117&rgn=div5#se21.2.117_13.

³ Buckley, Jenifer A. "The Food Safety Modernization Act- Preventive Controls for Human Food Rule," June 23, 2016. <http://jeniferbuckley.com/wp-content/uploads/FSMA-PC-Rule-Intro-160623.pdf>.

⁴ U.S. Food and Drug Administration. "Food Safety Modernization Act (FSMA): The Law, Rules & Guidance." *U.S. Food and Drug Administration*. Accessed January 30, 2017. <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359436.htm>.

⁵ U.S. National Archives and Records Administration. Food Labeling: Designation of Ingredients, 21 Electronic Code of Federal Regulations § 101.4. Accessed February 2, 2017. http://www.ecfr.gov/cgi-bin/text-idx?SID=514fefb3cfa2fdcfccd9082bbe593d2f&mc=true&node=pt21.2.101&rgn=div5#se21.2.101_14.

⁶ U.S. National Archives and Records Administration. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 Electronic Code of Federal Regulations § 117. Accessed December 21, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=0fc50b12db22a33f6b3e5ea67a25ab2f&mc=true&node=pt21.2.117&rgn=div5>.

⁷ U.S. National Archives and Records Administration. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 Electronic Code of Federal Regulations § 117. Accessed December 21, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=0fc50b12db22a33f6b3e5ea67a25ab2f&mc=true&node=pt21.2.117&rgn=div5>.

⁸ U.S. National Archives and Records Administration. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 Electronic Code of Federal Regulations § 117. Accessed December 21, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=0fc50b12db22a33f6b3e5ea67a25ab2f&mc=true&node=pt21.2.117&rgn=div5>.

⁹ Hugo, Cornelis. "The Importance of Records Under FSMA." *Quality Assurance & Food Safety*, December 11, 2015. <http://www.qualityassurancemag.com/article/qa1215-aib-fsma-records-importance/>.

¹⁰ U.S. National Archives and Records Administration. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 Electronic Code of Federal Regulations § 117. Accessed

December 21, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=0fc50b12db22a33f6b3e5ea67a25ab2f&mc=true&node=pt21.2.117&rgn=div5>.

¹¹ U.S. National Archives and Records Administration. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 Electronic Code of Federal Regulations § 117. Accessed December 21, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=0fc50b12db22a33f6b3e5ea67a25ab2f&mc=true&node=pt21.2.117&rgn=div5>.

¹² U.S. National Archives and Records Administration. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 Electronic Code of Federal Regulations § 117. Accessed December 21, 2016. <http://www.ecfr.gov/cgi-bin/text-idx?SID=0fc50b12db22a33f6b3e5ea67a25ab2f&mc=true&node=pt21.2.117&rgn=div5>.



Chapter 10 Inspections

The purpose of a food inspection is to determine whether a facility is in compliance with applicable food safety regulations. These requirements are designed to help ensure that food reaching commerce is safe and suitable for human consumption.

State and Federal inspections are typically based on the current Good Manufacturing Practices (cGMPs), which require that facilities (manufacturing, processing, packing and holding food) are: clean, cleanable, sanitary, and functional.

Additional regulations may apply, based on a facility's size and type of operations. For example, if a food facility is manufacturing cheese that meets the definition of a low acid, canned food, the facility is subject to an additional set of Good Manufacturing Practices.¹ Facilities selling human food by-product or feed to animals are subject to the Preventive Controls for Animal Food rule².

With the Food Safety Modernization Act (FSMA), U.S. Food and Drug Administration (FDA) has adopted a new approach to inspection that blends visual inspection and sampling with an auditing component:

"We are implementing a new inspection paradigm focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection and compliance"³

To prepare for an inspection, it is advisable for a business to review the applicable regulations to identify (and correct) potential gaps in their facility and food safety and quality systems.

The FDA has created a web page called "Inspection References" that houses the Compliance Guides, Compliance Policy Manual, and the Investigations Operations Manual. All forms used during inspections are publicly available on this site.⁴

10.1 Artisan Cheese Producer Inspections, Sample Collections, Analyses, Post-Sampling

FDA reviewed and provided comments on sections 10.1.1-10.1.6, detailing what artisan cheese producers can generally expect during an inspection.

10.1.1 Background

FDA regulates food products produced and shipped in interstate commerce, including artisanal cheese. FDA's focus during inspections and sample collections is on the safety

of food products, and with cheese, specific emphasis is placed on the facility's food safety program to prevent pathogenic microbial contamination.

10.1.2 Inspections

When FDA conducts an inspection of a cheese producer, they will identify themselves by displaying their federally-issued credentials and issue a Notice of Inspection (FDA Form 482) to the individual with the highest level of responsibility on-site at the time of the inspection. The investigator will begin by explaining the purpose of their visit and asking general questions about your establishment, including what types of products you produce, how you produce them, from where your raw ingredients are procured, how you store your raw materials, how you store and package your finished products, and where you distribute your products.

The inspection may proceed with the investigator conducting a physical inspection of your establishment. Generally, they will want to view all areas of your facility used to produce, pack, store, and ship FDA-regulated products. They may start in your receiving area and progress through the food processing and storage operations, observing testing, preparation, packaging, storing, and distribution areas. Observations and questions asked may be focused on learning the processes you use to produce artisanal cheeses, the environment in which products are produced and stored, practices and procedures used for effective cleaning and sanitizing of equipment and your facility, and the controls you have in place to ensure the safety of the product you produce and distribute.

If the investigator performing the inspection is a Public Health Service (PHS) Commissioned Officer, the investigator will be wearing his/her uniform. The officer wears the uniform as a Commissioned Officer in the Public Health Service. The officer may engage in a discussion with you regarding his/her uniform, discuss what he/she is wearing (e.g., blues, khakis) and explain why the officer wears the uniform as a Commissioned Officer in the Public Health Service.

10.1.3 Sample Collection

FDA collects food samples for various reasons. For instance, samples may be collected for general surveillance programs, collected "for cause" based upon observations made by an investigator while conducting an inspection, as a follow-up to a complaint, or a report of foodborne illness. With a few exceptions, you can expect the sample size to be as below.

If your product is:

- Less than one pound retail units: 10 subsamples with each subsample consisting of enough units to make up a one pound subsample.
- One pound to five-pound retail units: 10 subsamples consisting of one intact unit each.
- Wheels, loaves and bricks weighing greater than five pounds: 2 subsamples consisting of one intact unit each.

FDA may also collect environmental samples within your facility during an inspection, particularly in follow-up investigation to product contamination events or foodborne illness reports. In some cases, environmental swabs are collected as part of a surveillance assignment. Those samples will generally consist of 100 – 300 swabs collected in your production and storage environment. The purpose of these environmental samples is to assess the environment for pathogenic microorganism(s) of public health significance that may have established niche residency.

10.1.4 Sample Payment

When an investigator collects samples from you, you may provide those samples at no cost to the government or you may request payment. The investigator will provide you with a Receipt for Samples (FDA 484), whether or not payment is desired. When payment is requested, there are two business processes to accomplish payment. Payment may be made by the investigator at the time of collection using a cash advance of government funds that the investigator acquires prior to collecting samples. Another process is that you may submit a request for payment to FDA for the samples collected.

FDA pays the fair, wholesale cost for products sampled when reimbursement is sought. The investigator will provide you with the address of their district office where billing for the samples will be processed. You will need to submit your invoice and a copy of the receipt the investigator provided to you, in order to seek reimbursement for samples collected. You may also wish to prepare an invoice for the products sampled by the investigator and provide it to the investigator at the time s/he provides you with a receipt for samples. The investigator should be communicating with you as to whether you wish to provide the samples to the government at no charge or will seek payment, and the amount the samples will cost.

10.1.5 Sample Analysis

Samples collected may be analyzed for a variety of reasons including, testing for microbial contamination, filth contamination and/or phosphatase. Microbial analysis may examine for *Listeria monocytogenes*, *Salmonella* spp., *Escherichia coli* (*E. coli*) and Enterotoxigenic *E. Coli* (ETEC), Enterohemorrhagic *E. coli* (O157:H7), and *Staphylococcus aureus* (if indicated). Samples will be analyzed in accordance with the Bacteriological Analytical Manual (BAM).⁵ Results of analysis: preliminary Cannot Rule Out (CRO) results may be available in as little as three days and full analytical results are usually completed within 14 days.

10.1.6 Communications of Post-Sampling and Analysis

If your cheese was sampled during an inspection of your facility (a Notice of Inspection was issued to the individual with the highest level of responsibility on-site during the inspection), section 704(d) of the Federal Food, Drug and Cosmetic Act (FD & C Act) requires FDA to provide you with results of analysis for samples collected for filth and microbiological analyses. A report of the analytical results will be sent to the person with the highest level of responsibility at your establishment. If the samples were not collected during an inspection, you may request results of analysis through the Freedom of Information Act.⁶

If you are voluntarily holding your product pending analysis or the investigator collected environmental samples, FDA will provide the results of analysis when they are available. You should tell the investigator that you intend to voluntarily hold the product pending hearing the results.

If analytical results are negative for contaminants, you may resume shipping your products if you were holding them. If analytical results are positive for contaminants, the local FDA district office Compliance or Investigations Branch management will be contacting you to discuss the results and what steps are appropriate due to these results. Follow-up activities may include an inspection of your facility, discussion of corrective actions that may be taken, and recall of products remaining in the market place. FDA also works closely with its state partners and will share results of analysis with Integrated Food Safety System partners, and the state regulatory authority may participate in follow-up activities.⁷

10.2 The Conduct of an Investigator

The investigator will usually review his or her inspection plans with the owner or operator. This includes the reason for the inspection and the approximate length of time that the inspection will take. Depending on the nature of the inspection, the investigator may also describe the path of travel through the facility, and what and where samples and measurements will be taken. This will ensure access where necessary, safety of the investigator, and attention by the operator. It is important that the investigator comment on the inspection during its progress. This permits for timely questions and answers and provides a valuable teaching point, but moreover, it helps to clarify any misunderstandings or disagreements. At the exit meeting, the investigator should ask if the findings are fully understood and if there are any questions. The investigator will thoroughly explain all findings and answer any questions that may arise.

Every regulatory official should present themselves in a professional manner, both in dress and in action. They should wash their hands in accordance with the facility's instructions or, at a minimum, at the beginning, during, and at the end of the inspection, demonstrating a full 20-second wash each time.

10.3 Client Contact

The following are common sense client contact rules for investigators. These guidelines have served well for practicing sanitarians and hopefully they serve as a guide to investigators and auditors, as well as those being inspected.

- Do not disclose proprietary information to others.
- Be honest and impartial by avoiding conflicts of interest.
- If an unethical activity is observed, verify it, record it, and report it.
- Protect any property entrusted to you.
- Ensure sufficient resources are available for the inspection.

- Communicate expectations and methodology.
- Verify conformance to requirements.
- Stay within scope unless the degree of risk necessitates other actions.
- Justify sampling scheme; ensure samples are representative.
- Comply with establishment rules.
- Communicate progress of inspection.
- Report results truthfully and in a clear, concise, and complete manner.
- Communicate the importance of findings.
- Ensure results are traceable to requirements.

10.4 New Inspection and Compliance Mandates under FSMA

About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to 2011 estimates from the Centers for Disease Control and Prevention.⁸ This is a significant public health burden that is largely preventable.

The Food Safety Modernization Act enables FDA to better protect public health by strengthening the food safety system. It recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for FDA to provide oversight, ensure compliance with requirements, and respond effectively when problems emerge.

Building a new food safety system based on prevention will take time, and FDA is creating a process for getting this work done. Congress has established specific implementation dates in the legislation. The funding the Agency gets each year, which affects staffing and vital operations, will affect how quickly FDA can put this legislation into effect.

FSMA provides FDA with important new tools for inspection and compliance. Specific implementation dates specified in the law are noted in parentheses:

- *Mandated inspection frequency:* FSMA establishes a mandated inspection frequency, based on risk, for food facilities, and requires the frequency of inspection to increase immediately. All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter. Within one year of enactment, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next five years.
- *Records access:* FDA will have access to records, including industry food safety plans, and the records firms will be required to keep documenting implementation of their plans.
- *Testing by accredited laboratories:* FSMA requires certain food testing to be carried out by accredited laboratories and directs FDA to establish a program for laboratory accreditation to ensure that US food testing laboratories meet high-

quality standards.

10.5 Enforcement Actions

FDA has a wide variety of enforcement tools available to protect the public from dangerous and illegal products, to punish persons and companies who violate the law, and to achieve industry compliance. These tools include advisory actions, administrative actions, and judicial actions. Administrative actions are decided upon and taken by the agency in the first instance, although they can be appealed to federal courts. Judicial actions are decided upon and taken by federal courts, at the request of the Department of Justice and FDA.

- Import actions include product refusals, detention without physical examination, and debarment of individuals or companies who have been convicted of felonies related to food importation.
- Administrative actions include mandatory product recalls, suspension of food facility registration, administrative detention of food, and emergency permit control.
- Advisory actions include untitled letters and warning letters intended to achieve voluntary compliance and establish formal notice of violations. FDA may also issue press releases in certain situations to protect the public.
- Judicial actions include seizures of violative products, injunctions, and criminal prosecutions.
- Other tools like regulatory meetings may be used to communicate violations of regulatory significance in an effort to obtain commitment by responsible individuals to correct the conditions or practices that are in violation of the law; and accelerated follow up inspections or sampling activities depending on the nature of the violations and risk to public health.

10.5.1 Import Actions

The following are import actions the FDA may consider:

- Import refusals are actions taken to deny admission into the United States for imported foods when it appears from examination of samples, or otherwise, that an imported shipment is violative.
- Import Alerts instruct FDA district offices to Detain Without Physical Examination (DWPE) a food when there is information that would cause future shipments of a product or products offered for entry to appear violative. Such information includes a violative history of a product, manufacturer, shipper, grower, importer, geographic area, or country.

- Debarment is an action taken to prevent a person from participating in FDA-regulated activities. FDA has authority to debar individuals from importing an article of food or offering such an article for import into the United States if that person has been convicted of a felony for conduct relating to the importation into the United States of any food. The law also provides that the FDA may debar a person if that person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

10.5.2 Administrative Actions

The following are administrative actions that FDA may consider for enforcement:

- Suspension of Food Facility Registration allows FDA to suspend the registration of a food facility if the food manufactured, processed, packed, received, or held has reasonable probability of causing serious adverse health consequences or death to humans or animals. A suspended facility cannot import or export food into the United States, offer to import or export food into the United States, or ship food into interstate or intrastate commerce.
- Administrative Detention allows FDA to gain immediate control over food when there is reason to believe the food is adulterated or misbranded.⁹
- Mandatory Recall allows FDA to order a recall if a facility does not voluntarily cease distribution and recall violative food when there is reasonable probability that the food is adulterated or misbranded and that use of or exposure to it would cause serious adverse health consequences or death to humans or animals.
- Emergency Permit control prevents interstate shipment of acidified or low-acid canned food that is manufactured, processed, or packed without a permit.

10.5.3 Advisory Actions

The following are advisory actions the FDA may consider:

- Warning Letters informing recipients of significant regulatory violations documented during inspections or investigations that may lead to an enforcement action if the violation is not promptly corrected.
- Untitled Letters citing violations that do not necessarily meet the criteria for a Warning Letter.

10.5.4 Judicial Actions

FDA may consider the following judicial actions which involve a court of law:

- Seizures
- Injunctions
- Inspection Warrants

- Search Warrants
- Criminal Prosecutions

10.5.5 Media and Issuance of Public Notification

The FDA publishes enforcement statistics¹⁰ and issues public notices through social media and on their website, as well as through press releases. Archived recall notifications can be found on the FDA website.¹¹

10.6 What is Inspected?

The following is intended to be a walk-through of a cheese processing plant in regards to the items that are inspected. This walk-through is not all-inclusive, but it highlights some of the major areas of an inspection.

10.6.1 Raw Milk Receiving

A dedicated area for raw milk receiving is required. State laws vary in regards to having a covered or uncovered receiving bay. Segregation of this area from the actual processing area may also be required. The primary purpose is to protect the raw milk from outside contamination. The construction and design of this area is inspected to ensure compliance to regulatory laws. Receiving areas, equipment for receipt, hoses, and transport pumps should be clean, protected, and cleaned daily after the last truck of incoming raw milk or cream has been received. All components must be identified, and each part must follow the correct cleaning methods for that specific part.

Trucks used to transport raw milk should be constructed and operated to protect their contents from contamination and temperature extremes. Tank trucks should be washed and sanitized after each use. Where Clean-In-Place (CIP) is the method of cleaning, all non CIP'able components must be identified and manually cleaned and recorded on a log sheet. Items covered under this circumstance are: plug valves, butterfly valves, Lumaco valves, hoses with stainless steel nipples and hose clamp retainers, Jabsco pumps, and manhole gaskets. Cleaning and sanitation tags are required to be filled out daily and placed on the truck. Lock tags should also be in place to prevent intentional contamination or adulteration.

Single service articles are those having a milk contact surface, used in the processing of milk, and intended for one use only. Examples are certain pipeline gaskets and woven milk filter materials. Single service items are replaced daily.

An inspection will verify that each of these activities is completed. A log should cover all items that require manual cleaning in a CIP system. Documentation will be reviewed for cleaning and sanitation. This may include wash tags for transport trucks and CIP or manual cleaning records.

10.6.2 Raw Milk Storage

Indicating thermometers used on the raw milk storage tanks should comply with the requirements of the Pasteurized Milk Ordinance PMO. Raw tanks are to be cleaned and

sanitized when empty, and emptied at least every 72 hours. Bulk tank drain valves must be disassembled and cleaned manually, sanitized, and placed back on the tank prior to the CIP cycle where CIP is used. When tanks are cleaned manually, the same procedure applies. Tanks should be properly vented. Product must be maintained at 45°F (7°C) or below prior to and after pasteurization if it is not going directly to the cheese vat. Milk in storage must be protected from external contamination.

All milk must meet quality standards of Somatic Cell Count and Standard Plate Count. For more information see Chapter 1 of this guide. Sedimentation, and antibiotic beta lactam test results should be available. The documentation for these test results will be reviewed.

10.6.3 Processing

No cross-connections are allowed between raw and pasteurized product, or between cleaning chemicals and the product.

Pasteurizing, processing, cooling, and packaging of products should take place in a room separate from cleaning and sanitizing facilities for milk tank trucks and other areas in which raw milk and raw milk utensils are handled.

The pasteurization process should be reviewed in detail. If a continuous process is used, a flow diagram showing each piece of equipment (i.e. pumps, valves, thermometers, etc.) and temperatures at each point of the process should be evaluated. All pasteurization equipment is at a minimum inspected, timed, and sealed semi-annually. All recording chart documentation will be reviewed for correct information. Verification of all ingredients to be pasteurized, as well as the verification of culture media pasteurization prior to addition to the cheese vat.

Pasteurized process cheeses are required to be heated during preparation to a temperature not less than 150°F (66°C) for not less than 30 seconds. Verification of this time and temperature of the process is necessary.

10.6.4 Additional Processing Requirements

Handling practices during the addition of ingredients to milk are evaluated. If steam is used directly in products or on product-contact surfaces, the boiler water treatment compounds will be examined along with the steam filtering system. When air under pressure is used with the product or is directed at the product-contact surface, the filtering system will be evaluated.

The product and ingredients are to be protected from environmental contamination at all times. No ingredient packaging should make it directly into the production space without ensuring it is clean and sanitized before proceeding to the sanitary area. The inspection will check for excessive condensation from ceilings and from overhead pipes and equipment. Covers on tanks and vats will be checked. Caps on lines when not in use will also be noted.

The inspector will determine air flow throughout the plant. S/he will also determine if the source of the air is filtered. Maintenance documentation for these systems will be

reviewed. No cheesemaking operations should be carried out beneath a register or evaporator, and no production should take place in the primary discharge zone of an air system that is not specifically designed for food applications due to the risk of pathogen and non-pathogenic contamination.

Inspections should also take into account uncontrolled spaces above ceilings and any adjacent rooms for their potential impact on sanitation.

10.6.5 Cleaning and Sanitizing

The evaluation of the CIP system will be done to ensure proper construction. No submerged water inlets are allowed. A recorder probe should be located in the proper position. No cross-connection is allowed between CIP and product. Air valves, including those on the High Temperature Short Time (HTST) pasteurizer, are pulsated/cycled during the CIP cycle.

Recording charts should be maintained throughout the day, with correct times recorded. All circuits should be washed daily or as required by use. The cycles must be complete, i.e. no short cycles. The charts must be labeled with the date and plant identification.

Manually cleaned items should all be disassembled, cleaned, and sanitized on the day of use.

The inspection should be scheduled to determine if equipment is clean. This is typically done after clean-up and prior to start-up. Disassembly of the following equipment is necessary to verify thoroughness of cleaning:

- Plug valves
- Butterfly valves
- Lumaco valves
- Ball valves
- Air valves
- Fillers
- Vacuum breakers
- Metering valves
- Pumps
- Check valves
- Air filters
- Gasketed vines
- Plate heat exchangers
- Flow diversion device

The only valves that are approved for CIP are fully automated valves which are plumbed and cycled during the various cycles.

Plant personnel should be available to assist with the disassembly of equipment.

All available storage and processing vessels will be inspected for cleanliness, including:

- Silo tanks
- Pasteurized storage tanks
- Vat pasteurizers
- Processing vats
- Balance tanks
- Transport tankers

A black light may be used to check for milkstone on or cracks in the equipment. Presence of milkstones is an indication of insufficient or poor cleaning.

10.6.6 Packaging

Since post-pasteurization contamination is a common cause of contaminated products, the packaging process will be thoroughly reviewed while in operation to ensure no:

- Excess grease and excess lubricant
- Presence of overhead shielding above open containers prior to or after filling
- Presence of condensate which may have contact with open containers prior to or after filling
- Containers and caps that originate from an unapproved source
- Product temperatures in excess of 45°F (7°C) prior to packaging
- CIP solution remains undrained prior to the start of packaging
- Cross-connections between raw piping and storage vessels and packaging equipment
- Problems with vacuum packaging equipment, i.e. it should be in good condition with bags sealed

This list may be altered to fit the specific product type. If one is producing a processed cheese food or spread, the filling of containers is also applicable. If one is packaging cheese, the product must be protected from environmental sources of contamination. In addition, air quality should be monitored.

10.6.7 Quality Control

The dairy plant should have quality control procedures for inspection of equipment that is cleaned in place as well as for equipment that is hand cleaned.

Verification will take place that all farm bulk tanker trucks or loads of cans/bags of raw milk received at the plant are screened for beta lactam drug residues prior to processing the raw milk.

Quality control test results for raw and finished product standards include:

- Standard Plate Count
- Coliform
- Drug residues
- Phosphatase for pasteurization verification
- Temperature

- pH and/or Titratable Acidity (TA)
- Pathogen testing of finished product
- Environmental testing of processing environment

Corrective action steps need to be documented and reviewed during the inspection process.

Cheese make records will be reviewed to determine if all critical times, temperatures, and pH readings were recorded. Samples of cheese and whey may be collected for evaluation. Evaluation of tolerance levels for each value, approval of proposed actions when inside the tolerances, and what action will be taken when outside the tolerances, will also be included in the inspection process.

If raw milk cheeses are being produced, the following practices will be evaluated:

- The date stamping procedure, and the accuracy of date stamped on each individual cheese
- Aging/curing area temperatures must be verified with documentation (maintained above 35°F (2°C) with inventory being held for a minimum of 60 days)
- Labeling practices that clearly indicate what further curing or processing is necessary for cheese made from raw or unpasteurized milk
- If the warehouse is not operated by the cheese manufacturer, the existence of an agreement with the storage warehouse for storing and handling of uncured or unaged cheeses

10.6.8 Water Supply

Water purity is extremely important, as water may be a source of contamination. The water supply will be evaluated for:

- Proper construction of wells (if applicable)
- Proper analysis conducted semi-annually (if applicable)
- Submerged inlets
- Cross contamination between potable water and: product, CIP system(s), boiler water feed tank, i.e. non-potable water or cooling media, i.e. sweetwater, glycol, and tower water
- Determination if sweetwater and glycol systems are properly constructed, protected, and tested
- Determination if condensing water and water reclaimed from milk and milk products is used in accordance with Appendix D of the PMO.¹²

10.6.9 Personnel

Employee practices and dress, particularly the use of special clothing while handling or contacting in-process materials and equipment surfaces that contact the product, will be evaluated. Areas that are considered include:

- Whether employees change into clean (sanitized, sterilized, etc.) clothing prior to entering the plant for production, cleaning, or other purposes

- Hair protection
- “No smoking, eating, or drinking” practices in the storage, processing, and packaging areas
- Accessibility of hand washing facilities to processing and packaging areas
- Plant policy on visitors/personnel traffic through processing and storage areas
- Dedicated footwear
- Whether employees receive training or have experience to perform assigned duties

Each company should have in place a set of Good Manufacturing Practices (GMPs) which are read and signed by each employee outlining their responsibilities.

10.6.10 Sample Collection

Samples of product will be collected at various times and should be held and shipped under refrigerated conditions. The cheese samples should have labeling to show the code or lot numbers, the date of manufacture, and any other identification deemed appropriate by the regulatory agent.

In-plant samples of sediment pads, or other evidence necessary to document insanitary practices and the receipt and use of unclean milk, will take place. Pictures may be taken as well for documentation purposes.

Water sample records will be reviewed for potability standards. Official samples may be collected.

10.6.11 Waste and Pest Management

Suitable waste containers with lids need to be dispersed throughout the plant for employee use. Wastes that are collected should be removed from the plant to an outdoor area.

Grounds surrounding the dairy plant will be inspected to evaluate waste management and pest control practices. Garbage containers should be located away from the building and closed with lids to prevent pest harborage.

A pest control plan including diagrams for traps should be reviewed.

¹ U.S. National Archives and Records Administration. Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, 21 Electronic Code of Federal Regulations § 113. Accessed February 9, 2017. <http://www.ecfr.gov/cgi-bin/text-idx?SID=2015f830f9146797f05eb92aa6a0baaa&mc=true&node=pt21.2.113&rgn=div5>.

² U.S. Food and Drug Administration, Center for Veterinary Medicine. “Final Rule for Preventive Controls for Animal Food.” *U.S. Food and Drug Administration*. Accessed February 9, 2017. <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm>.

³ U.S. National Archives and Records Administration. “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.” *Federal Register*, September 17, 2015. <https://www.federalregister.gov/documents/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human>.

⁴ U.S. Food and Drug Administration. "Inspection References." *U.S. Food and Drug Administration*. Accessed February 9, 2017. <http://www.fda.gov/ICECI/Inspections/default.htm>.

⁵ Nutrition, Center for Food Safety and Applied. "Laboratory Methods - Bacteriological Analytical Manual (BAM)." *U.S. Food and Drug Administration*. Accessed February 9, 2017. <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm>.

⁶ U.S. Food and Drug Administration. "Freedom of Information." *U.S. Food and Drug Administration*. Accessed February 9, 2017. <http://www.fda.gov/regulatoryinformation/foi/default.htm>.

⁷ Affairs, Office of Regulatory. "National Integrated Food Safety System (IFSS) Programs and Initiatives." *U.S. Food and Drug Administration*. Accessed February 9, 2017. <http://www.fda.gov/ForFederalStateandLocalOfficials/ProgramsInitiatives/default.htm>.

⁸ U.S. Centers for Disease Control. "Burden of Foodborne Illness: Overview." *U.S. Centers for Disease Control and Prevention*. Accessed February 9, 2017. <https://www.cdc.gov/foodborneburden/estimates-overview.html>

⁹ U.S. National Archives and Records Administration. Administrative detention, 21 Electronic Code of Federal Regulations § 800.55. Accessed February 9, 2017. <http://www.ecfr.gov/cgi-bin/text-idx?SID=db8d565162e65e7376c08eec0b45ef69&mc=true&node=sp21.8.800.c&rgn=div6>.

¹⁰ U.S. Food and Drug Administration. "Compliance Actions and Activities - Enforcement Activity." U.S. Food and Drug Administration. Accessed February 9, 2017. <http://www.fda.gov/ICECI/EnforcementActions/ucm247813.htm>.

¹¹ Affairs, Office of Regulatory. "Archive for Recalls, Market Withdrawals & Safety Alerts." U.S. Food and Drug Administration. Accessed February 9, 2017. <http://www.fda.gov/Safety/Recalls/ArchiveRecalls/default.htm>.

¹² U.S. Food and Drug Administration. "Milk - PMO 2007: Appendix D - Standards For Water Sources." 2007. <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/milk/ucm064290.htm>.



Glossary

3-A Sanitary Standards

A third-party verification inspection program which assures processors that equipment meets sanitary standards. The voluntary use of this symbol on dairy and food equipment also provides accepted criteria to equipment manufacturers for sanitary design, and establishes guidelines for uniform evaluation and compliance by sanitarians.

Adenosine Tri-Phosphate (ATP)

ATP is the primary molecule for energy transfer in living cells. ATP is used in food safety to determine bacterial cleanliness by serving as an indicator of viable (living) cell numbers. It is a rapid testing method to verify equipment sanitation and several kits are commercially available.

Artisan Cheese

Cheese that is produced primarily by hand, in small batches, with attention paid to the tradition of the cheesemaker's art, and thus using as little mechanization as possible in the production of the cheese. Artisan, or artisanal, cheeses may be made from all types of milk and may include various flavorings.

Certificate of Analysis (COA)

A document issued by the supplier at the request of the receiving site (purchaser) which contains analytical test results for critical raw material/packaging material specification parameters.

Cheese

The *Codex Alimentarius* "General Standard for Cheese (CODEX STAN 283-1978)" defines cheese as:

The ripened or unripened soft, semi-hard, hard, or extra-hard product, which may be coated, and in which the whey protein/casein ratio does not exceed that of milk, obtained by:

(a) coagulating wholly or partly the protein of milk, skimmed milk, partly skimmed milk, cream, whey cream or buttermilk, or any combination of these materials, through the action of rennet or other suitable coagulating agents, and by partially draining the whey resulting from the coagulation, while respecting the principle that cheese-making results in a concentration of milk protein (in particular, the casein portion), and that consequently, the protein content of the cheese will be distinctly higher than the protein level of the blend of the above milk materials from which the cheese was made; and/or
(b) processing techniques involving coagulation of the protein of milk and/or products obtained from milk which give an end-product with similar physical, chemical and organoleptic characteristics as the product defined under (a).

Clean in Place (CIP)

Used throughout the food industry for closed systems like storage tanks/silos and the flow line circuits that deliver and remove food products which cannot be removed for cleaning. The systems typically run a wash, rinse, and sanitation cycle to thoroughly clean and sanitize the product contact surfaces of the tanks and lines.

Clean Out of Place (COP)

A cleaning and sanitation operation using wash tanks and manual cleaning for systems that are not CIP.

Code of Federal Regulations (C.F.R.)

The codification of the general and permanent rules and regulations (sometimes called administrative law) published in the Federal Register by the executive departments and agencies of the federal government of the United States.

The Code of Federal Regulations (C.F.R.) is divided into 50 titles representing broad areas subject to federal regulation. Each title is divided into chapters that are assigned to agencies issuing regulations pertaining to that broad subject area. Each chapter is divided into parts, and each part is then divided into sections -- the basic unit of the C.F.R.

The purpose of the C.F.R. is to present the official and complete text of agency regulations in one organized publication, and to provide a comprehensive and convenient reference for all those who may need to know the text of general and permanent federal regulations. Regulations established by the FDA are published in Title 21 of the C.F.R.

Codex Alimentarius

International food standards, guidelines, and codes of practice that contribute to the safety, quality, and fairness of the international food trade.

Compliance Policy Guide (CPG)

The Compliance Policy Guides together form a manual created by the FDA to provide a convenient and organized system for statements of FDA compliance policy, including those statements which contain regulatory action guidance information. The statements made in the CPG are not intended to create or confer any rights, privileges, or benefits on or for any private person, but are intended for internal guidance.

Corrective Actions

An action prescribed with a commitment to follow through in a defined time period to resolve an observed quality problem.

Critical Control Points (CCPs)

Steps at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Culinary Steam

Steam that is used in food processing. This type of steam is required to meet 3-A Sanitary Standards. Culinary steam can, and often does, come into direct contact with the final product.

Cultures, Adjunct

Also known as secondary cultures. Microorganisms added to milk to enhance flavor development, provide protection against pathogens or produce carbon dioxide for eye formation in cheese. See Cultures, Starter.

Cultures, Starter

In cheesemaking, Starter cultures are used in cheesemaking to facilitate fermentation of lactose. Starters are comprised of lactic acid bacteria that rely on sugar fermentation for energy. Starter cultures will ferment lactose, which produces lactic acid and lowers the pH of milk. Starter cultures can be used as Primary Starters, or as adjunct cultures. The following terms are used to indicate the optimum temperature for these families of bacterial cultures:

Mesophilic Cultures can ferment lactose at temperatures as low as 50-113°F (10-45°C) with optimal growth between 86-103°F (30-40°C).

Thermophilic Cultures grow at temperatures in the range of 68-120°F (20-50°C) with optimal growth between 98-113°F (37 - 45°C) and can survive at temperatures up to 131°F (55°C).

Deamination

The removal of an amine group from a molecule, resulting in the production of ammonia. This influences the ripening, and therefore texture and flavor development in bloomy rind, blue mold, and washed rind cheeses.

Environmental Regulations

The Environmental Protection Agency (EPA) has a responsibility to ensure that the environment and the health of the community are protected – both now and for future generations. The proper management of dairy wastes is essential to achieve that objective. As the dairy industry has become more environmentally aware and committed to producing good environmental outcomes, alternative mechanisms have been developed in line with the government's desire to promote **Best Practices Environmental Management (BPEM)**.

Environmentally-aware dairy companies seeking a better environment and competitive advantage should find merit in this approach. BPEM of dairy emissions will also achieve benefits for the community in terms of sustainable improvements in environment quality. The BPEM approach seeks to promote innovative uses of waste products by focusing on desired objectives and outcomes, rather than regulatory control. In this way, innovation is not stifled and flexibility is provided – but those seeking greater direction or certainty can simply apply the suggested measures. These guidelines will be reviewed regularly and updated as necessary, based on operating experience and the

development of national standards. Users of the guidelines are encouraged to provide comments to EPA to assist this process.

Many of these regulations may be found in General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service. Along with Federal guidelines, state and local authorities may impose additional regulations.

Facility Registration

Facilities that process, store, or ship food for human or animal consumption are required to register with the FDA. This was first introduced as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). This act directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take additional steps to protect the public from a threatened or actual terrorist attack on the US food supply and other food-related emergencies. To carry out certain provisions of the Bioterrorism Act, FDA has established The Preventive Controls rule under the Food Safety Modernization Act (FSMA) applies to food processing facilities that are registered with the FDA.

Visit <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm> to create a free account. Once an account is established, one can register his/her farm or company, register on behalf of others, and edit the registration information.

Farmstead Cheese

Cheese must be made with milk from the farmer's own herd, or flock, on the farm where the animals are raised. Milk used in the production of farmstead cheese may not be obtained from any outside source.

Food Code

The Food Code establishes practical, science-based guidance for mitigating risk factors that are known to cause or contribute to food borne illness outbreaks associated with retail and foodservice establishments, and it is an important part of strengthening our nation's food protection system. The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) of the US Department of Health and Human Services (HHS), and the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA) jointly designed and authored the 2013 Food Code. This is a model code and reference document for state, city, county, and tribal agencies that regulate operations such as restaurants, retail food stores, food vendors, and foodservice operations in institutions such as schools, hospitals, assisted living, nursing homes, and child care centers. Food safety practices at these facilities play a critical role in preventing food borne illness.

Food Hygiene

All conditions and measures necessary to ensure the safety and suitability of food at all stages of the product life cycle.

Food and Drug Administration (FDA)

The federal agency that is responsible for overseeing most of the US food supply, a primary task of FDA's Center for Food Safety and Applied Nutrition (CFSAN).

Food Safety Modernization Act (FSMA)

An act passed in 2011 which aims to ensure the US food supply is safe by shifting the focus from responding to contamination to preventing it. FDA is responsible for its implementation and enforcement.

Food Safety Inspection Service (FSIS)

The public health agency in the US Department of Agriculture (USDA) responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.

Good Agriculture Practices (GAPs)

Specific methods which, when applied to agriculture, create food for consumers or further processing that is safe and wholesome. While there are numerous competing definitions of what methods constitute good agricultural practices, there are several broadly accepted schemes to which producers can adhere.

Good Manufacturing Practices (GMPs)

Good Manufacturing Practices (GMPs) has two meanings when used in the context of a food processing facility. First, it refers to actual federal code sections that provide the regulation for both federal and state food processing regulations that serve as cover facility construction, equipment and utensil selection, sanitization, personnel hygiene, food handling, and production and processing controls.

The second definition refers to a set of operating procedures and practices that are required to confirm the guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products, and active pharmaceutical products. These are the minimum requirements that a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public.

Hazard

A biological, chemical, physical, or radiological agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard Analysis Critical Control Points (HACCP)

A system which identifies, evaluates, and controls hazards which are significant for food safety. HACCP identifies Critical Control Points but doesn't recognize Preventive Controls. HACCP is the internationally accepted, science-based system for ensuring food safety controls, harmonized with the current recommendations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

Hazard Analysis and Risk-Based Preventive Controls (HARPC)

Requirements are similar to the Hazard Analysis and Critical Control Point (HACCP) requirements which identify hazards that might arise due to the specific foods or food ingredients in the food or due to the various processing, manufacturing, packing, and holding steps applied to the foods. HARPC doesn't distinguish CCPs from other types of Preventive Controls.

Intentional Adulteration Rule

The intentional adulteration rule is aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply. Such acts, while not likely to occur, could cause illness, death, economic disruption of the food supply absent mitigation strategies. Rather than targeting specific foods or hazards, this rule requires mitigation (risk-reducing) strategies for processes in certain registered food facilities.

Labeling Requirements

FDA's publication, "A Food Labeling Guide," has 94 pages that include information on basic food labeling as well as information on nutrition facts, trans fat, and allergen labeling. Labeling not only is a marketing tool, but it informs the consumer of what they are purchasing. Ingredients of the food, composition (including trans fats, caloric values and other nutritional information), allergens, panel requirements and placement, company information, and much more are addressed by the Code of Federal Regulations. The full labeling requirements may be found at

U.S. National Archives and Records Administration. Food Labeling: Designation of Ingredients, 21 Electronic Code of Federal Regulations § 101.4. Accessed February 2, 2017. http://www.ecfr.gov/cgi-bin/text-idx?SID=514fefb3cfa2fdcfcdd9082bbe593d2f&mc=true&node=pt21.2.101&rqn=div5#se21.2.101_14.

Lipolysis

Lipolysis is the biochemical pathway responsible for the catabolism of triacylglycerol, yielding glycerol and free fatty acids.

Market Withdrawal

A firm's removal or correction by its own volition of a distributed product that involves a minor infraction that would not warrant legal action by regulatory authorities, or involves no violation of the state or federal laws, or health hazard.

May

Terminology in regulations which provides the option for the action be done. As opposed to **Shall**, which mandates that the action be done.

Mesophilic Cultures

Can ferment lactose at temperatures as low as 50-113°F (10-45°C) with optimal growth between 86-103°F (30-40°C). For more see **Cultures, Starter**.

Microbial Load

The total number of bacteria and fungi in a given quantity of water or food.

Milk

The lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy cows, goats, sheep, water buffalo, and other hoofed mammals.

Milkstone

A hard deposit of milk residues that accumulates on imperfectly cleansed dairy utensils and serves as a substrate for bacteria and contributes off-flavors to milk.

Modified Atmosphere Packaging

This may be used to limit compression while providing an atmosphere containing reduced oxygen or anaerobic conditions. This process entails packaging the cheese under an inert gas, such as nitrogen, carbon dioxide, or varying combinations of the two. This creates an anaerobic condition for the cheese, but does not cause the cheese to become damaged in any way—such as crushed or smashed down. A common example of use would be the packaging of cheese shreds, cheese curds, or Swiss-style cheese with eyes.

National Conference on Interstate Milk Shipments (NCIMS) HACCP

The NCIMS is a non-profit organization made up of persons from various aspects of the dairy industry. The NCIMS HACCP is a voluntary Dairy HACCP program for dairy plants to test the concept that a HACCP program could function as an equal alternative to the numerical ratings that have been used for years to measure a plant's compliance. The program utilizes current National Advisory Committee on Microbiological Criteria for Food (NACMCF) consistent with current FDA recommendations. For more information, see

<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2007982.htm>

Pasteurization

A process named after French scientist Louis Pasteur that applies heat to destroy pathogens in foods. For the dairy industry, the terms "pasteurization," "pasteurized" and similar terms mean the process of heating every particle of milk or milk product, in properly designed and operated equipment, to one of the approved temperatures outlined in the Grade A Pasteurized Milk Ordinance (PMO) and held continuously at or above that temperature for at least the corresponding specified time.

Pasteurization, High Temperature Short Time (HTST) – a legal pasteurization step which ensures that milk has been heated to a minimum of 161°F (71.6°C) for at least 15 seconds also known as continuous flow pasteurization.

Pasteurization, Low Temperature Long Time (LTLT) – a legal pasteurization step which ensures milk has been heated to 145°F (62.7°C) for a minimum of 30 minutes. Also known as Vat Pasteurization.

Pasteurized Milk Ordinance (PMO), Grade A

A model milk regulation used by states to govern the processing, packaging, and sale of Grade "A" milk and milk products, including buttermilk and buttermilk products, whey and whey products, and condensed and dry milk. The PMO only covers Grade A fluid milk.

Pasteurized Milk, Grade B

Also known as manufacturing milk, it can only be used in the production of dairy products such as cheese, butter, and non-fat dry milk, and is not regulated by the PMO.

Pest Management Product

Any lure, bait, monitoring product, pesticide, or any other formulated material used to perform pest management activities.

Plant

A food manufacturing facility, including associated warehousing. Does not include restaurants or other food service facilities.

Potable

Water that is fit and safe to be consumed or used by humans with low risk of immediate or long term harm.

Pre-Requisite Programs (PRPs)

The World Health Organization defines pre-requisite programs as “practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety.” Pre-requisite programs provide a foundation for an effective HACCP system. They are often facility-wide programs rather than process or product specific, which reduce the likelihood of certain hazards.

Preventive Controls

Reasonable and appropriate procedures, practices, and processes that a person knowledgeable about the safety of food would employ to significantly minimize or prevent hazards.

Preventive Controls for Human Food Rule

The specific component of the Food Safety Modernization Act (FSMA) that affects small food processors. The Rule was finalized in September 2015. The pertinent fact sheet can be accessed in the Code of Federal Regulations (CFR), Title 21, Part 117 (21 CFR 117).

Proteolysis

The breakdown of proteins into simpler compounds, such as peptides or amino acids.

Psychrophiles

Cold tolerant bacteria. These are not used as starters in cheesemaking. These bacteria are capable of growth at temperatures as low as 44.5°F (7°C), with an optimal range of 59-68°F (15-20°C). *Pseudomonas* is an example of a psychrophilic bacterium that is of concern to the dairy industry. *Pseudomonas* can form biofilms (difficult to remove bacterial growths) in dairy processing equipment. *Pseudomonas* can cause spoilage in milk even after pasteurization, and could indicate mastitis. *Pseudomonas ssp fluorescens* is especially problematic in cheesemaking due to the production of off flavors in cheese. Clostridia is another example of a psychrophile. Psychrophiles can be present in milk as post-pasteurization contaminants due to less than adequate sanitation practice. It is possible that milk residue may contain enough nutrients to sustain bacterial growth at ambient temperature. Most are killed by pasteurization; some are thermotolerant and can survive pasteurization.

Qualified Facilities

No food facility is exempt from the responsibility to produce safe food, but those that have both gross annual sales less than \$500,000 annually and sell the majority of their food directly to consumers or to grocery stores, institutions, or restaurants in-state or within a 275-mile radius, may be deemed “qualified” for less-burdensome requirements. The Food Safety Modernization Act (FSMA) provides guidelines for the definition in 21 CFR 117.

Regulators

Along with federal regulations, the state, county, and city have the authority to add to requirements. Please check with your local governing body for local regulations. The following segments identify where pertinent regulations for the dairy industry may be found.

Research and Development (R&D)

The product development process responsible for the creation of new food products, processes, and packages, and for modifications to existing formulae, manufacturing processes, and packages.

Recall

Removal of distributed food products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of applicable state and federal laws. “Recall” does not include a market withdrawal or a stock recovery. Recalls are almost always voluntary based on a company’s discovering a problem and recalling a product on its own, or, voluntarily recalling a product after FDA raises concerns. Only in rare cases will FDA request a recall.

Rennet

A generic term used to reference enzymes (proteinases) capable of altering casein proteins in a specific way to initiate coagulation. Chymosin is the key enzyme found in animal rennet. Rennets can also be used to separate milk into solid curds used for cheesemaking and liquid whey. Calf rennet is the most widely used in animal rennet in cheesemaking. In addition to chymosin, animal rennet contains other important enzymes such as pepsin and lipase. Other types of rennets include microbial, recombinant, and vegetable rennets.

Rodent Bait Station

Any station used for placement of solid rodenticide bait.

Root Cause Analysis

Drill down capability for troubleshooting the source of a quality problem, with the intent of implementing a sustainable resolution.

Sanitation Standard Operating Procedures (SSOPs)

Written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product.

Shall

Terminology in regulations which mandates the action be done. **May** gives the option of doing the action.

Somatic Cells

The majority of somatic cells are *leukocytes* (white blood cells), which become present in increasing numbers in milk usually as an immune response to a mastitis-causing pathogen. Epithelial cells, which are milk-producing cells shed from inside of the udder when an infection occurs, are also considered somatic cells. Somatic cell count is used as an indicator of infection status as well as milk quality.

Specifications

Any criteria with which product, process, services, or other activity must conform.

Specialty Cheese

A cheese of limited production made with particular attention paid to natural flavor and texture profiles.

Supplier Assurance

A program used to approve material suppliers, and to assure their continuing ability to deliver products that meet company specifications.

Tuberculosis (TB) Accredited Herd

When herds have passed at least two consecutive annual tuberculin tests, have no other evidence of bovine TB, and meet the standards of the USDA Uniform Methods and Rules (*UMR*) for *Bovine TB Eradication*, they are eligible to be accredited bovine TB-free, by the USDA.

Tempered Water

Mixing cold water with hot water to keep the water temperature fixed at a more moderate temperature.

Thermalization

Also known as Thermization or Subpasteurization. Involves heating milk to 140-150°F (60-65°C) for 15 to 30 seconds (or any other combination of time and temperature less than the legal pasteurization requirements), before the start of cheesemaking. This process reduces the number of micro-organisms in the milk. The US FDA considers this still to be raw milk cheese production.

Thermophilic Cultures

Grow at temperatures in the range of 68-120°F (20-50°C) with optimal growth between 98-113°F (37 - 45°C) and can survive at temperatures up to 131°F (55°C). For more see **Cultures, Starter**.

Thermoduric

Bacteria that can survive the pasteurization process to varying extents.

United States Department of Agriculture (USDA)

The USDA ensures the safety of meat, poultry, and processed egg products both domestically and from countries approved to export product to the United States.

USDA's Agricultural Marketing Service (AMS)

The Agricultural Marketing Act (AMA) of 1946 (7 U.S.C. 1621 et seq.) directs USDA to develop programs which will provide for and facilitate the marketing of agricultural products. One part of the USDA's AMS is known as Dairy Programs. The mission of AMS Dairy Programs is to facilitate the efficient marketing of milk and dairy products, and it is intended to help the US dairy industry efficiently market high-quality milk and dairy products.

Zoonosis

Any infectious disease that can be transmitted from non-human animals, both wild and domestic, to humans, or from humans to non-human animals. The latter is sometimes called reverse zoonosis.



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Code of Federal Regulations

The C.F.R. can be found online, where it is known as the eCFR. This is the most up-to-date form of the CFR: <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>

You can use the advanced search feature on the site, or browse by title. The titles referenced in the ACS Best Practices Guide for Cheesemakers are Title 21: Food and Drugs, and Title 7: Agriculture.

The statutes that are most frequently discussed in this guide are the

- 21 Code of Federal Regulations § 133: Cheeses and Related Cheese Products,
- 21 Code of Federal Regulations § 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.

Dairy Practices Council Guidelines

The Dairy Practices Council is a non-profit organization comprised of persons from the dairy industry, regulatory, and education sectors that publishes guidelines for industry on sanitation, milk quality, and regulations. Many of these are referenced in the Resources section of this guide. The complete listing can be found on their website.

“Guidelines - Dairy Practices Council.” *All Guidelines: A Numerical Listing of All DPC Guidelines*. Accessed February 15, 2017. <http://www.dairypc.org/catalog/guidelines>.

FDA Factsheets and Guidance Documents

The FDA publishes resources on its site that provide at a glance information on the regulations it enforces. The links below will direct visitors to the Home Page for “Food Guidance and Regulations,” as well as subpages that house the PMO, NCIMS HAACP documents, factsheets for FSMA, and guidance for starting a new food business.

“Food Guidance & Regulations.” U.S. Food and Drug Administration. Accessed February 14, 2017. <http://www.fda.gov/Food/GuidanceRegulation/default.htm>

“FDA Food Safety Modernization Act (FSMA).” *U.S. Food and Drug Administration*. Accessed December 22, 2016. <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>.

“Food Industry - How to Start a Food Business.” *U.S. Food and Drug Administration*. Accessed February 9, 2017. <http://www.fda.gov/Food/ResourcesForYou/Industry/ucm322302.htm>.

“Milk Guidance Documents & Regulatory Information.” Accessed February 7, 2017. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/default.htm>.

Inspections

The FDA, along with the U.S. Center for Food Safety and Applied Nutrition and U.S. Office of Regulatory Affairs, put together a document for ACS that outlines what to expect when you are inspected. The link to that document can be found below, along with a link to the FDA and FSIS sites that provide guidance and training documents for inspectors.

“General Information Document: FDA Artisanal Cheese Producer Inspections, Sample Collections, Analyses, Post Sampling Communications,” February 2015.

<http://www.cheesesociety.org/wp-content/uploads/2015/02/Artisinal-Cheese-General-Inspection-Sample-Information-for-Industry-stakeholders.pdf>.

“Inspection References.” Accessed February 15, 2017.

<http://www.fda.gov/ICECI/Inspections/default.htm>

“Inspection Methods Training.” *Food Safety and Inspection Service*. Accessed August 24, 2016. <http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/inspection-methods/inspection-methods>.

Templates for Food Safety and Crisis Response Programs

The links below provide essential information about, and templates for, creating and implementing food safety and crisis response programs. The Food Safety and Preventive Controls Alliance training curriculum has templates in its Appendix.

Cornell University Dairy Foods Extension. “Food Safety Programs.” Cornell University Dairy Foods Extension. Accessed January 11, 2017.

<https://dairyextension.foodscience.cornell.edu/resources/food-safety-programs>.

Dairy Management Inc., and International Dairy Foods Association. “Crisis Preparedness Toolkit for Dairy Processing Companies,” January 2014.

<http://www.cheesesociety.org/wp-content/uploads/2017/02/DMI-IDFA-Crisis-Preparedness-Toolkit-2014.pdf>

“FSPCA Preventive Controls for Human Food Participant Manual v1.2p,” February 2016. <https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>

Home Page: Food Safety Preventive Controls Alliance. Accessed February 15, 2017.

<https://www.ifsh.iit.edu/fspca>

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Approved Supplier Program

An approved supplier program is a set of procedures implemented by the facility to assure the safety and quality of incoming goods and services. It may be based on the safety risk presented by the raw material, or based on historical performance or prior history of the supplier.

The facility should be able to provide documented evidence that incoming materials have either been inspected or that they come from an approved supplier.

The methods for selecting, evaluating, approving and monitoring an approved supplier must be documented. This will be risk-based and may be as simple as a good supply history, sourcing from certified suppliers (e.g. 3rd party audit), or personally auditing/inspecting the material supplier's operations, depending on risk, supplier knowledge and past history.

The facility should require their suppliers verify they are complying with specifications for the products supplied. The methods of analyses must conform to recognized industry standards.

The facility should maintain a list of approved suppliers, including contract service providers. All providers of goods and services must be included on the register.

The approved supplier program should be reviewed at least annually or more frequently, based on supplier performance.

In an emergency situation, a facility receives raw materials from a non-approved supplier. The ingredients should be inspected before use. Records of the use of a non-approved supplier and their inspection should be maintained.



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Product Release

A product release program ensures that only compliant products are released to the market. The facility should prepare a procedure outlining the responsibility and protocols for the release of products and effectively implement that procedure.

Product release also applies to the procedures for releasing quarantined or held product. A facility may do this by outlining in-line process measures that demonstrate that products are compliant with specified requirements. In this procedure, the supplier will identify those personnel responsible for collecting samples and carrying out inspections, or ensuring that inspections are carried out, and the methods for doing so.

The product release procedure not only applies to positive release of compliant products, the supplier should also outline the procedure for releasing products from quarantine or hold status.

In all cases, the facility should identify those staff positions with responsibility for releasing products and indicate the action they will take when results are outside specification, including reference to other procedures for holding, reworking or disposing of product.

The facility should ensure that:

- All products are confirmed as compliant before release to the market.
- All staff is familiar with product release procedures and that personnel authorized to release product are aware of their responsibilities.
- All products under quarantine or authorized personnel only release hold status after the product has successfully passed inspection. All products released for distribution should have records maintained. These records should record the product name and identification, confirmation of product checks, and the product disposition (e.g., release, quarantine, hold). Products released from hold should also be recorded.
- Records should include the amount of product that was held and the reason for the hold. Records should be reviewed routinely to ensure that holds are closed out. Any product that is still on-hold should be physically or visually verifiable.



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Non-Conforming Product Program (and/or) Hold/Release Program

Non-conforming product is product at any stage in the process that does not meet agreed food safety and quality criteria. This can apply to raw materials, ingredients, packaging materials, work-in-progress or finished product. It can also apply to any other material used in the facility that can impact product safety or quality, e.g. cleaning chemicals, processing aids, equipment.

The facility should document the procedure that outlines how to label and identify products that are rejected or quarantined as a result of inspection, audit or process deviation. The facility should describe how non-conforming product is isolated in order to avoid its re-use or shipment.

The program should also identify who can release the product from hold and determine its disposition.

Employees should be trained in the Hold procedure and what their responsibility is if a product is put on hold.

In circumstances where product is adulterated or condemned, the supplier should detail how the condemned product is identified and disposed of.

The facility should also document a procedure for equipment that has been found to be non-conforming. This procedure may be combined with, or separate from, that for non-conforming product. The equipment should be identified and placed out of production until it is repaired or otherwise disposed of.

The means of identification of non-conforming product and equipment should be communicated to relevant staff. This can be a system of tags, signs, designated storage locations and/or system holds.

A record of the disposition of non-conforming product and equipment including product that is reworked, repackaged, condemned and/or disposed of should be maintained.



Recall Program

A product recall applies when a product is found to be unsafe or otherwise in breach of regulatory requirements and is withdrawn from public sale and the consumer market is advised not to use or consume that product. Recalls may be mandatory (i.e., initiated by a regulator), retailer driven, or voluntary (i.e., initiated by the supplier).

A product withdrawal applies when a dispatched product is found not to meet safety or quality requirements, is deemed not suitable for sale and is withdrawn from the distribution chain before it has reached the consumer.

The plan should include details of how all raw materials, packaging materials and processing aids are linked through to the finished product; and should outline how the supplier accounts for the reuse of reworked product. The product trace procedure should outline how the supplier traces product to a customer and who is responsible for implementing and maintaining the product trace system.

A product recall and withdrawal procedure should be prepared, implemented and regularly reviewed to ensure everyone involved in the recall process understands their role and their responsibility in the event of a recall or withdrawal.

A Recall Team should be in place to coordinate and manage recalls. The facility should prepare a withdrawal and recall procedure describing the methods, responsibilities and procedures they implement in the event of a product withdrawal or recall.

The plan should include an up-to-date list of customers, regulators and other essential contacts that need to be notified in the event of a withdrawal or recall. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident.

It should also include an outline of the methods the supplier will implement to investigate the cause of a withdrawal or recall.

Records of any/all recalls and withdrawals should be maintained. These records may include production records, raw materials receiving records, rework records, product holds, and product storage and distribution records. The supplier should test product that has already been released so that full distribution traceability can be verified.




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The supplier should also be aware of the recall targets set by retail customers. Some may require 100% identification and quarantine of affected product within hours or recall notification. Regulatory recall requirements must also be considered.

The product withdrawal and recall system should be reviewed, tested and verified as effective at least bi-annually.

The Recall Team should be cross functional including: management, production, shipping, receiving, sales, marketing, maintenance, legal advise and (if needed) outside consultants or experts.

 <p>Cornell University Dairy Foods Extension Stocking Hall, Ithaca NY</p>	Department:	DOC#: REV:
Effective Date:	Supersedes:	Subject: Mock Recall
Issued by:	Approved by:	
Plant Number:		

1.0 PURPOSE

To have a process in place to trace product to the customer (one up) and back to the material supplier (one back). The product trace system accounts for raw materials, packaging materials and processing aids used that may impact on food safety and quality.

2.0 SCOPE

This SOP applies to all ingredients, packaging and finished products utilized and/or produced at
 ___company name___.

3.0 SAFETY & ENVIRONMENTAL CONSIDERATIONS

- This SOP complies with the Code of Federal Regulations, Title 21, section 7.40, the “Recall Policy”.
- Care has been taken to indicate to all participants that this is a **MOCK** recall.

4.0 FREQUENCY

Bi-annually.

5.0 RESPONSIBILITY

- **TASK**

Recall Team- may include all listed below:

- QA Manager/HACCP Team Leader: All steps within the procedure.
- Company Owner: 6.1, 6.2, 6.3, 6.13, 6.14, 6.15, 6.16
- Sales Department/ Consumer Affairs
- Production Manager: 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 6.13, 6.14, 6.15, 6.16
- Shipping Supervisor: 6.10, 6.11, 6.12, 6.13, 6.14, 6.15, 6.16
- Outside Consultants
- Legal

- **VERIFICATION**

All steps are documented in **Mock** Recall Log.

- **PAPERWORK REVIEW**

6.0 PROCEDURE

- 6.1 Start the clock based on scenario. Two-hour goal within a four hour maximum.
- 6.2 Coordinate your recall team.
- 6.3 Identify a record keeper.
- 6.4 Locate trace procedure/forms.
- 6.5 Identify production date.
- 6.6 Collect production documents for each ingredient, which could include COAs and Batch Sheets.
- 6.7 Identify how much product was manufactured from the start of the run to the end of the run.
 - 6.7.1 How much product was lost to waste?
 - 6.7.2 Were product samples retained?
 - 6.7.3 Check CCP verification logs.
- 6.8 Identify where all product was shipped, taking any sales samples into account.
- 6.9 Goal is 100% recovery of the product
- 6.10 Discuss overall effectiveness of drill and frequency rate
- 6.11 Document all steps in **Mock** Recall Log and maintain records.
- 6.12 Non-conformances identified during the exercise must be investigated by the facility and required corrective action completed, with a follow up test completed to ensure that corrective actions are effective.

Note: A recall and withdrawal exercise should be able to demonstrate linkage of raw materials through the process to the facilities first customer.

7.0 ATTACHMENT/DOCUMENTATION

8.0 SIGNATURES AND APPROVALS

Role	Name and Title	Signature	Date

Artisan Cheese Maker Level I Audit

Purpose:

To develop and agree upon a Level I (Basic) food safety standard for cheesemakers, primarily artisan/farmstead to be used by retailers.

Background:

Retailers are working in collaboration with local artisan cheese makers to develop minimum food safety standards. The minimum Level I (Basic) standard includes regulatory requirements and adds additional food safety criteria. The Level I criteria can be used as a first step towards a GFSI benchmarked standard (similar categories). HACCP was included in the Level I (Basic) for cheese makers.

Audit:

The initial audit *will not* be scored and the emphasis for the initial audit will be placed on the corrective actions required to correct the deficiencies. Subsequent audits (6-12 months) will be scored and a score of at least 75 is required to receive an 'acceptable' score (the acceptable score may increase over time). The audit criteria that are designated as 'critical' for food safety and a deficiency in any of these criteria will automatically score the audit as 'unacceptable.' Cheesemakers participating in a Level I audit should receive no critical deficiencies (*this includes the initial unscored audit*). **All deficiencies** require corrective actions to be submitted within 30 days of completion of the audit that address the root cause and include a timeline on implementation of the corrective actions. Critical deficiencies must be corrected before accepting product from a supplier.

The audit will be freely available for designated auditing companies to use and will be 'owned and maintained' by the Retail Consortium. The audit results should be adequate for all retailers and allow a cheese maker to be audited once (in a given time period) and use the results for multiple retailers (once certified, accepted everywhere). An audit to a GFSI benchmarked scheme can take the place of the Level I audit.

The Retail Consortium has and will continue to partner with the Innovation Center for US Dairy® on our artisan/farmstead supplier food safety training and education programs.

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**Artisan/Farmstead Cheese Supplier
Compliance Checklist
Level 1**

This documentation is used by _____ to review a new or existing local supplier. Please provide a copy of ALL documentation including any plans to address any deficiencies.

Date: _____
 Supplier Name: _____
 Address: _____
 Phone Number: _____
 Owner/Manager Name: _____
 Hours of Operation: _____
 Buyer: _____
 Region/Store: _____

Products Made and being considered for review:

Section 1 – FOOD SAFETY MANAGEMENT:					
		yes	no	n/a	value
1.01	Are all ingredients and sub-ingredients in the products to be sold at _____ compliant with the _____ Quality Standards?				0
1.02	Is the milk supply used to make _____ product rBST free? Please provide documentation and any additional steps taken to support an rBST free claim.				0
1.03	Does the milk used for cheese production meet all regulatory requirements for antibiotic testing? What test are being conducted to verify the milk does not contain antibiotic residue?				CRITICAL
1.04	Does the facility use its own dairy producing animals to provide milk used in products? Please tell us how many dairy animals are in the operation. If the milk used for making cheese is NOT produced on-site, please answer next question				0
1.05	Please provide source for the milk used to make cheese products. If milk is supplied from on-site animals, please describe the milking procedures used and how contamination is controlled or minimized. What type of systems are in place to verify the milk meets the Food Safety and regulatory standards?				4
1.06	How many stores will you be supplying product to? Provide a list of stores you are or will be providing.				0
1.07	Provide a list of products produced and production capabilities Provide a list and the possible amount of product that you may produce safely without exceeding your production capacity				0
1.08	Is an owner operated facility used to produce the product? If this is an owner operated facility, the owner/operator must complete this questionnaire and attach or provide all supporting documents				0
1.09	Does the owner use an off-site facility, shared kitchen or Co-Packer to produce, store or hold product? If yes, provide more information The supplier must provide information on any facility being used to process, package, or store the product for _____ The supplier and/or facility must assume responsibility for compliance with all requirements set forth including liability and insurance indemnification.				0
1.10	Does the facility have the required insurance for your products? We request all _____ supplier partners to carry insurance. The type of coverage and amount depends on a products risk level. Please check with your _____ contact to get specific insurance requirements. _____ and its subsidiaries must be named as an additional insured by endorsement to your insurance policy. We will request a copy of the endorsement with your certificate of insurance on an annual basis.				0
1.11	Does the facility participate in third party auditing? A supplier that participates in a third party audit system is a lower risk than one that doesn't. All suppliers participating in third party audits should make the reports available for review by authorized _____ Team Members.				0
1.12	Is the facility compliant with the Reportable Food Registry requirements? http://www.fda.gov/food/foodsafety/FoodSafetyPrograms/RFR/default.htm				0
1.13	What is the water source used in the facility? Provide documentation of testing.				4
1.14	Do you have means of disposing of waste? Waste disposal must meet all regulatory requirements and be conducted at a frequency to mitigate pest activity.				4
1.15	Do you have a record retention policy in place? A record retention policy must meet a minimum standard of 2 years and/or shelf life if longer than 2 years, with records available upon request.				4
1.16	Does the facility have finished product testing done? (Independent lab or state obtained samples) Finish product testing is highly recommended for all high-risk items. These should be done on a monthly basis look for pathogenic strains of microorganisms. Ideally the facility would test and hold each batch of product, but the shelf life of the product may not allow for this in some cases. Some state agencies may pick up samples for regular testing such as in fluid milk and dairy products.				0
				Subtotal	20

**Artisan/Farmstead Cheese Supplier
Compliance Checklist
Level 1**

Section 2 – PREREQUISITE PROGRAMS and GMPs:

		yes	no	n/a	value
2.01	Is this a raw milk cheese product?				
	If milk is supplied from a vendor/coop, please describe how its evaluated for safety before its use. Provide and verify SOPs and other documentation to ensure a minimum of 60 day aging of the product before sale. Are records maintained?				CRITICAL
2.02	Is this a pasteurized cheese product?				
	Please describe the pasteurization system used and any relevant time/ temperature requirements that must be met. The facility must have a SOP on their system. Are all charts and records maintained?				CRITICAL
2.03	Does the facility have current Good Manufacturing Practices (cGMPs) implemented?				
	A supplier should take every precaution along the way to ensure they have a safe product in the end. Good Manufacturing Practices and Good Agricultural Practices are an industry standard to follow. If this is a Farmstead Cheese operation, steps must be taken to prevent people/children, clothing, shoes, tools, and such from entering the cheese making room without adequate sanitation steps taken.				4
2.04	Does the facility provide food safety training for all food employees?				
	It is the responsibility of the supplier to ensure that all food employees are properly trained in the safe handling of food, Good Manufacturing Practices and HACCP where appropriate. Is it documented? Annual training is required. Training includes internal training specific to the job being performed and external training such as Extension Service courses.				4
2.05	Does the facility have a written employee illness policy?				
	It is the responsibility of the supplier to have a written employee illness policy. Employee illness is the number one cause of foodborne illness.				3
2.06	Does the facility participate in an environmental monitoring program that screens the facility for pathogenic microorganisms such as E. Coli, Listeria Sp., etc				
	The facility should be conducting environmental sampling/testing verification on a monthly basis. Sampling areas should include a minmum of food contact equipment, aging rooms walls, condensate drains, floor drains, wheels on equipment etc. FDA or the State conducts sampling and screening for pathogens on a routine basis. It is best for the facility operator to have a good method of surveillance to detect and mitigate any organisms of concern.				4
2.07	Does the facility have a pest management program implemented to control pests in the facility?				
	If done by a service company, please ask for reports, insurance certification, and license. If done by owner/operator, please review records and logs for license(if using pesticides), pest monitoring and measures taken to control pest.				3
2.08	If providing perishable Cheese (fresh, soft ripened, etc) that requires temperature control, does the facility have the necessary equipment to produce and hold				
	You must have the cooking, pasteurization, cooling and cold holding capacity for the product that is being made. If volume exceeds capacity, adjustments must be made and possibly more equipment added.				4
2.09	How will the products be delivered to the stores: direct to the stores, through the _____ distribution system or other?				
	Please explain how the product will be delivered to the store. If delivering cold product, it must be delivered under temperature control through refrigeration or other effective method. Please explain how traceability and cold chain integrity will be maintained.				4
2.10	Are labels in compliance with ingredient and nutrition requirements?				
	If nutritional information is being disclosed, the facility must have an accredited lab or use other industry standards to generate the information. If any health claims ("low fat", "fat free" etc.) are made, they must be in compliance with the NLEA standards.				0
2.11	Are all allergens disclosed on the labels in accordance with Law? FALCPA (Food Allergen Labeling and Consumer Protection Act)?				
	The Food Allergen Labeling and Consumer Protection Act require that ALL major food allergens (the Big 8) be clearly identified on the label.				4
2.12	Are all ingredients and sub-ingredients clearly identified in English on the label?				
	All product sold in the United States must have all information at minimum in the English language. This also includes Name and Address of Distributor or Manufacturer.				3
2.13	Are any naturally occurring or potential physical hazards present that should be disclosed to the consumer? (pits, husk, stones...)				
	Disclosing hazards such as pits, seeds, or other common items found in the product may reduce liability and insurance claims. (Note: SOME VENDORS ADD FRUIT, NUTS, OLIVES, Etc to cheese)				0
2.14	Are any organic label claims made or icons used? Products which only identify organic ingredients in the "ingredients: _____" listing, but do not use the word "organic" elsewhere on the label, are not subject to this requirement.				
					0
2.15	If providing perishable Cheese (fresh, soft ripened, etc) that requires temperature control, does the label state "Keep Refrigerated" or "Keep Frozen"?				
	It is important to have clear instructions for the retailer and consumer.				3
SUBTOTAL					36

**Artisan/Farmstead Cheese Supplier
Compliance Checklist
Level 1**

Section 3 - Control of Food Hazards and Food Safety Plans (HACCP)				yes	no	n/a	value
3.01	FSMA requires a validated FSP plan be implemented for all Milk and Dairy related items including Cheeses.						
	Ensure that the facility has a strong FSP plan and verification documents for cooking temperatures, Pasteurization temperatures, cooling temperatures, holding temperatures and transportation. Ask for copies of calibration logs as well as all other CCPs. The plan must be reviewed annually. What was the last review date?						7
	Facility should have a FSP team in place with a FSP Coordinator identified. The Coordinator should have gone through training and have a certificate.						2
	The FSP should reference regulatory pasteurization requirements if applicable.						3
	Food Safety Plan should reference Prerequisite programs such as GMP's, Cleaning and Sanitizing schedules & procedures, and other quality procedures being used.						3
	The Critical Control Points (CCPs) should be validated, verified and documented.						3
3.02	Do the cheeses produced meet all of the 21 CFR 133 "Standards of Identity"?						
	If so, which standards do they fall under?						0
3.03	Is there an allergen control program (gluten, dairy, soy, egg, etc.)?						
	The facility must have an allergen control plan in place as part of their HACCP plan.						
	The facility should conduct initial allergen screening on all products and random allergen testing after that to ensure adherence to tolerance levels.						
	The facility should also validate its cleaning program via testing.						
	The employees must have been well trained on allergen control in their facility.						3
3.04	Does the facility use a reduced oxygen or vacuum type package for its product? Is the procedure approved by a recognized process authority?						
	Reduced Oxygen packaging has been implicated in many foodborne illness outbreaks including some caused by <i>Clostridium botulinum</i> and <i>Listeria monocytogenes</i> .						
	Facility must have a HACCP plan to control the hazards associated with this type of packaging.						4
3.05	Are any of the Cheese products being provided sold or re-packed in _____ brand containers or out of an in-store bulk display?						
	Ensure that there is a good lot traceability program established from facility through retail sale.						4
3.06	Have the facilities products ever been implicated in a foodborne illness outbreak?						
	A history of foodborne illness outbreak could be caused by a poor food safety management structure. Ensure that all corrective actions have been made and no pending investigations are in operation.						
	Have facility share results of any product testing done after incident.						0
3.07	Have the facilities products ever been the subjects of a Class 1 Recall?						
	Facility must show three consecutive negative test results for pathogens of concern for each batch of products being sold to _____						
	3rd Party audit is required prior to selling products to _____						
	A history of recall should be studied and corrective actions verified for compliance prior to allowing product into the _____ product mix.						0
3.08	Does the facility have a recall system/procedure in place including mock recalls? Please provide the date of last mock recall						
	Any supplier producing items for sale at _____ must be able to recall any item that may have been adulterated, mislabeled, misbranded or otherwise negatively affected.						
	Have the supplier or operator demonstrate or share their history of mock recall test.						
	Have the supplier or operator demonstrate compliance with traceability requirements. All product (100%) from a lot or production date must be accounted for in a two hour period to be considered a successful Mock Recall.						4
3.09	Does the facility have all required regulatory permits? (State/Local Health/Ag permit, Milk and Dairy, tax id, etc)						
	Regulatory permits may be administered by the State and/or Local Health departments (Manufactured Food, Retail Foods, Meat safety, Dept of Ag) or FDA and/or USDA (if the facility operates under Interstate Commerce).						
	All permits must be current and in good standing or the product will become misbranded and detainable. If a supplier goes out of business, the product also become misbranded and cannot be offered for sale						4
3.10	Are all official audits/inspections available for review?						
	It is important to be able to verify that the products being produced in the facility are safe and the facility or operation is in good standing with Regulatory agencies.						3
3.11	If providing Organic product, does the facility have the necessary certification?						
							0
3.12	Does the product label have a clear code "Best By" date and any other recall information applied? Provide an example						
	All items must have easily identifiable information on each individual retail package or bulk container to ensure that if a recall is initiated, the product can be identified and pulled.						
	The identification system used on the package must be permanent in nature and have the required information to trace back the item to a production lot or batch.						4
							Subtotal
							44
							Total
							100



PRODUCT(S): Pepper Jack Cheese – Ready-to-Eat	PAGE 1 of 23	
PLANT NAME: Wisconsin Cheese Company	ISSUE DATE	1/27/2017
ADDRESS: 123 Main Street, Monterey, USA	SUPERSEDES	11/11/2016

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.



PRODUCT(S): Pepper Jack Cheese – Ready-to-Eat	PAGE 2 of 23	
PLANT NAME: Wisconsin Cheese Company	ISSUE DATE	1/27/2017
ADDRESS: 123 Main Street, Monterey, USA	SUPERSEDES	11/11/2016

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PRODUCT(S): Pepper Jack Cheese – Ready-to-Eat	PAGE 3 of 23	
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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.

The Food Safety Team members include:

- **Director, Quality Assurance [company trained PCQI]**
- **Operations Manager [PCQI back up]**
- **Head cheesemaker**
- **VP, Sales and Marketing**
- **Maintenance Manager**

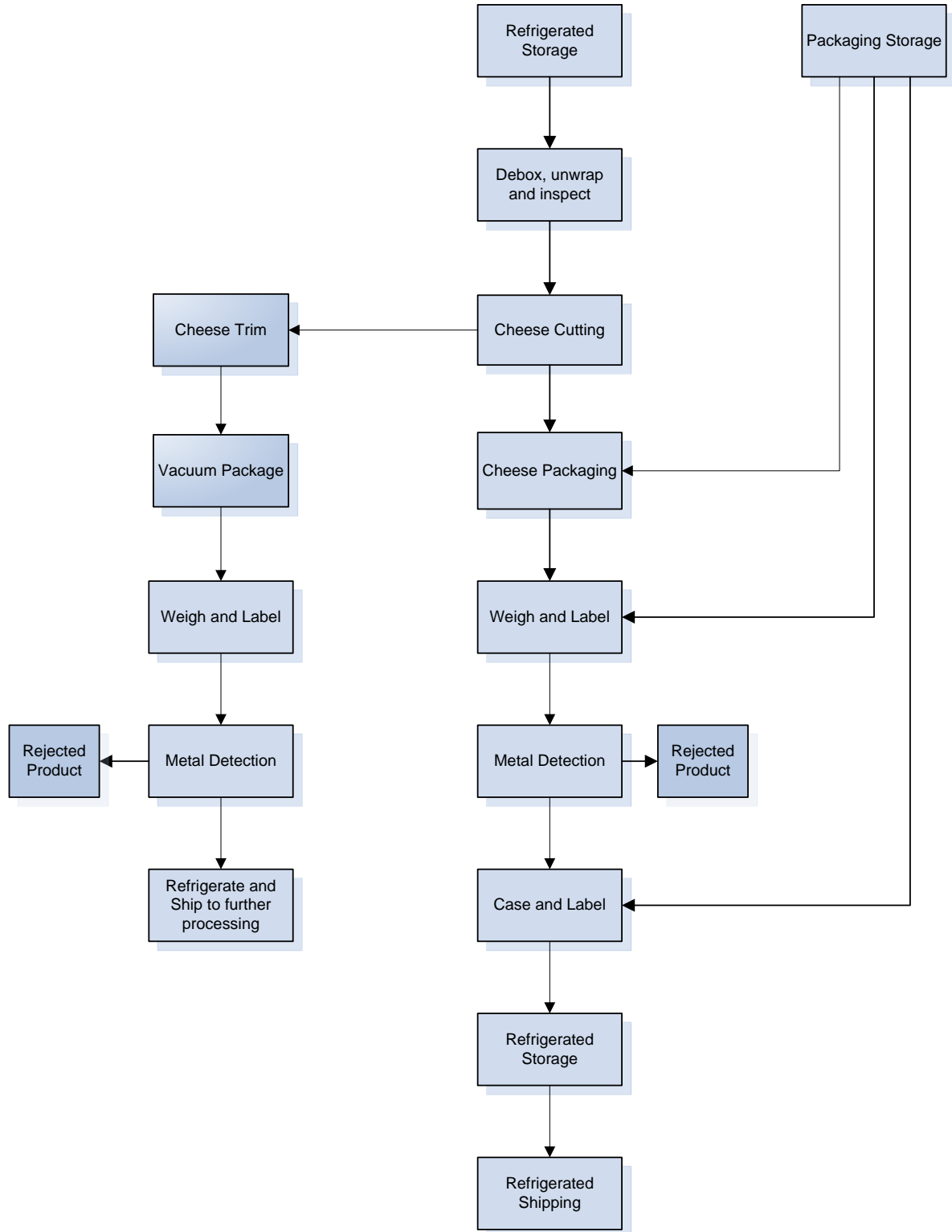
Product Description

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.



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Flow Diagram – Retail Packaging





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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 than 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



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- **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



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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 <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> 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? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(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						



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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> 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? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
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						



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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> 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? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
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	



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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> 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? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
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						



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Process Preventive Controls

Process Control(s)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Milk Pasteurization	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



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Process Preventive Controls

Process Control(s)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal detection	Physical: Metal inclusion	<p>Metal detector present and operating</p> <p>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)</p> <p>No metal fragments are in the product passing through the metal detector</p>	All of the product passes through an operating metal detector	Visual examination that the metal detector is on and reject device is working	<p>At start up, then every 2 hours and end of run</p> <p>Product changes from 40 # block to 1 # chunk</p>	Trained production employee	<p>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</p>	<p>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</p> <p>Review of Metal Detector Log and Corrective Action and Verification records and signed by PCQI or designee within 7 working days</p> <p>Annual service by manufacturer</p>	<p>Metal Detector Log</p> <p>Manufacturer's Validation Study that determined detector settings and sensitivity standards</p> <p>Corrective action records</p> <p>Annual calibration records</p>



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Process Preventive Controls

Process Control(s)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Temperature 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
Temperature 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



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Process Control(s)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Temperature 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



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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	Trained 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 Cheese	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



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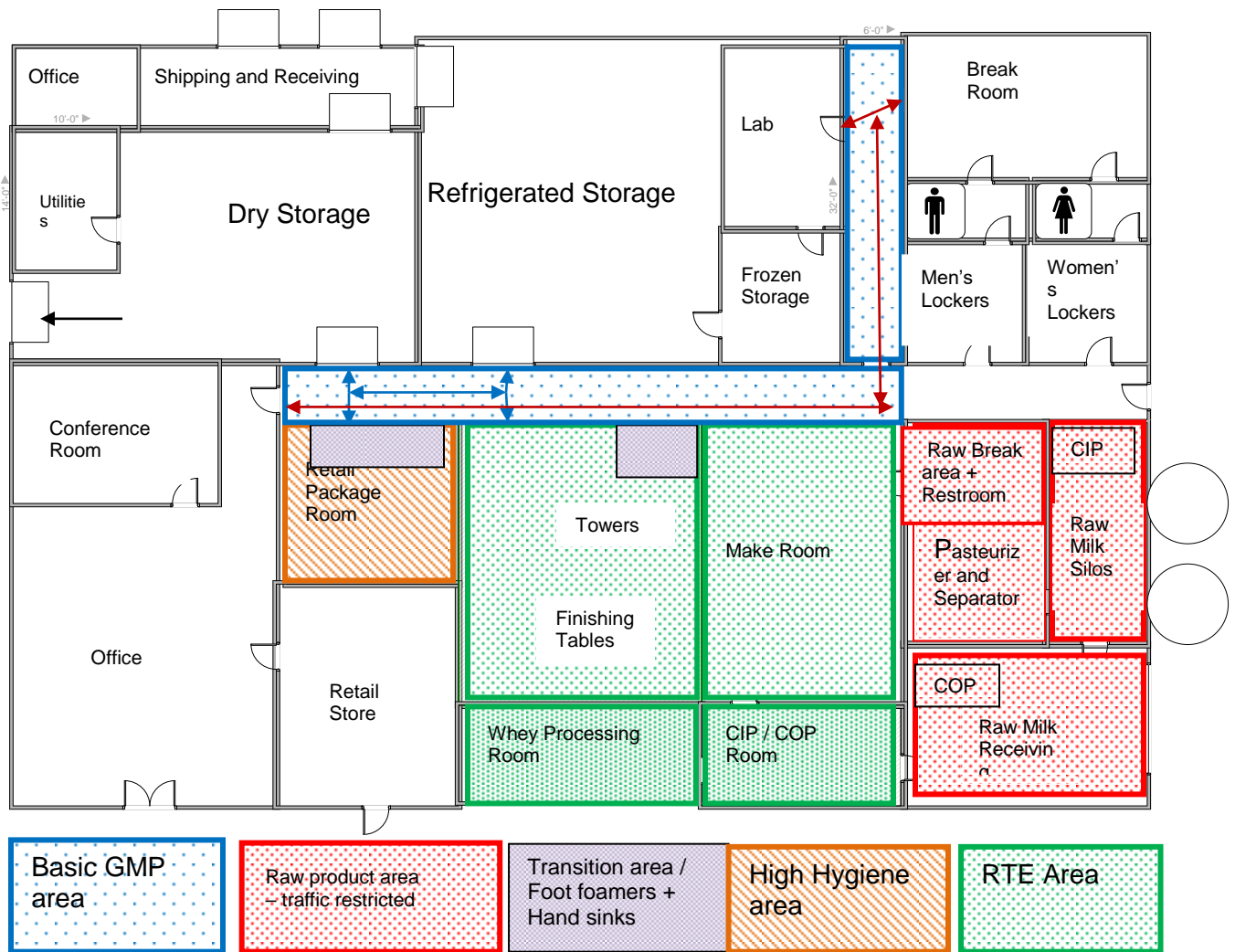
Sanitation Preventive Controls

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



- Foot Traffic
- Fork lift Traffic
- To trash compactor



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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. Upon 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. 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 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.
 - 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.

3. High Hygiene area
 - a. 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.
 - b. 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.
 - c. 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.
 - d. Tools in this area are dedicated and must remain in the area. Tools must be cleaned and sanitized after use.



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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.



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Retail Packaging Room Environmental Sanitation

Purpose: Cleaning and sanitizing of the floor and the table support (legs) in the Retail Packaging area is important to prevent establishment of environmental pathogens.

Frequency: Daily, after production

Who: Sanitation team member

Procedure:

Cleaning and sanitizing the table support structure

Cleaning is done in conjunction with cleaning of the table, following the same procedure, including table legs, and edges at the end of the day.

Cleaning floors

NOTE: Separate tools are used for floors because of the potential for higher levels of contamination.

1. Remove gross soil with a squeegee.
2. Mop floor using a washable mop head, using a clean mop each day
3. Rinse floor with clean water. Detergent remaining on the floor can inactivate the sanitizer.

Sanitizing

1. Spray floors with a 400-600 ppm quat sanitizer. Spray may also contact non-food contact table legs.
2. Allow floor to air dry overnight.

Monitoring (at each cleaning time):

1. Inspect floor and surrounding area for residual soil and cleanliness.
Record on Daily Sanitation sheet.
2. Use test strip to measure the quat concentration BEFORE application.
Record on Daily Sanitation sheet

Corrections:

1. If residual soil is observed, reclean and sanitize.
2. If quat is not at the proper concentration, make a new solution.

Records: Daily Sanitation Sheet, Daily Hygienic Zoning Record, Environmental Monitoring Sampling record and lab results

Verification: Environmental monitoring (frequency per procedure) and supervisor records review within 7 working days



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Environmental Monitoring for Sanitation Preventive Control Verification

Pathogen Environmental Monitoring Program

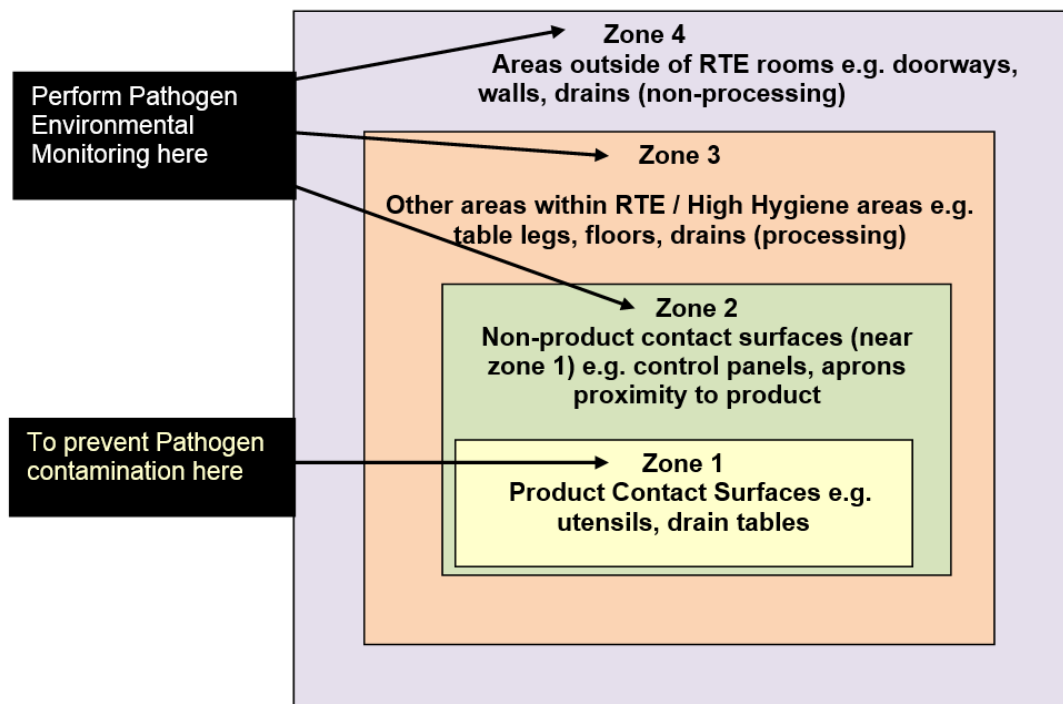
Purpose: Pathogen Environmental monitoring is conducted to verify the effectiveness of sanitation and hygienic zoning procedures in the primary pathogen control zones to control environmental pathogens such as *L. monocytogenes* and *Salmonella*.

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





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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:

Act on 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.



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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	Best Peppers Company	Biological - Vegetative pathogens [Listeria and E. coli]	3/15/16	Annual 3 rd party of supplier's facility Receipt of COA with each shipment matched with lot number received	Copy of 3 rd party audit. Supplier validation studies for blanching/brini ng 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

Appendix 2. Food Safety Plan Worksheets

Worksheets are recommended to document the product description, hazard analysis and preventive controls. The hazard analysis form should contain information to justify the identification of the hazards requiring preventive controls and the types of preventive controls applied. Information in the Food Safety Plan must explain the details for each preventive control.

There is no standardized or mandated format for these worksheets, 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 allergen preventive controls, but other formats are entirely acceptable if it works for your organization and contains all of the required information.

The following worksheets are provided as examples. The information is arranged in a similar manner, but the layouts are in either a landscape or a portrait form to suit individual preferences. Other forms can be adapted from those in the Food Safety Plan example.

Special Note: 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. The additional information must include:

- Firm name and location
- Dates and, when appropriate, the time of the activity
- Product identification
- Usually, record review signature (or initial) and date

All forms can be adapted or modified as needed. There is NO required form.

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE
Product Description Distribution, Consumers and Intended Use		
Product Name(s)		
Product Description, including Important Food Safety Characteristics		
Ingredients		
Packaging Used		
Intended Use		
Intended Consumers		
Shelf Life		
Labeling Instructions related to Safety		
Storage and Distribution		
Approved: Signature: Print name:	Date:	

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Hazard identification (column 2) considers those that may 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, and environmental pathogens

C = Chemical (including radiological) hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives

P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects

Hazard Analysis								
(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> 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? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							

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Process Preventive Controls – Landscape Layout		Records			
		Verification			
		Corrective Action			
		Monitoring			
		What	How	Frequency	Who
		Parameters, values or critical limits			
		Hazard(s)			
		Process Controls			

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Process Preventive Controls – Portrait Format

[This is an alternate layout for process preventive control.]

Process Control Step				
Hazard(s)				
Parameters, values or critical limits				
Monitoring	What			
	How			
	Frequency			
	Who			
Corrective Action				
Verification				
Records				

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Form Name: Food Allergen Preventive Controls	Records			
	Verification			
	Corrective Action			
	Monitoring	Who		
		Frequency		
		How		
		What		
	Criterion			
	Hazard(s)			
	Allergen Control			

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Form Name: Food Allergen Ingredient Analysis

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation								Allergens in Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut <small>(see label notes)</small>	Peanut	Fish <small>(see label notes)</small>	Shellfish <small>(see label notes)</small>	

NOTE:
 The above format is an alternative for an allergen specific hazard analysis. If you choose to use a form like this, then there is no need to duplicate allergen considerations in your hazard analysis chart. Duplication of information in multiple forms can create extra work and may lead to inconsistencies.

Some organizations may even choose to do an ingredient hazard analysis that considers not only allergens, but also other hazards. This may be a useful option for you.

How to Use the Chart
 List all ingredients received in the facility. Identify allergens contained in each ingredient by reviewing ingredient labels or contacting the manufacturer. Any allergens listed in “May contain” or other precautionary labeling on ingredients should be listed in the last column and reviewed to determine if allergen labeling is needed on the finished product.

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Form Name: Food Allergen Label Verification Listing

Product	Allergen Statement

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Form Name: Production Line Food Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)

Scheduling Implications:

Allergen Cleaning Implications: (Required)

How to Use This Form
 Complete for each production line. Identify each allergen contained in each product produced on the line. Identify any allergens unique to a specific product, then indicate scheduling information (i.e., run unique allergens last) and allergen cleaning information (i.e., full allergen clean before running cheese or plain omelets after a biscuit run).

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Form Name: Sanitation Preventive Controls

Location		
Purpose		
Frequency		
Who		
Procedure		
Monitoring		
Corrections		
Records		
Verification		Date

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Corrective Action Form	
Date of Record:	Code or Lot Number:
Date and Time of Deviation:	
Description of Deviation:	
Actions Taken to Restore Order to the Process:	
Person (name and signature) of Person Taking Action:	
Amount of Product Involved in Deviation:	
Evaluation of Product Involved with Deviation:	
Final Disposition of Product:	
Reviewed by (Name and Signature):	Date of Review:

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Food Safety Plan Reanalysis Checklist				
Reason for reanalysis:				
Task	Date Reviewed and Initials	Is Update Needed? (yes/no)	Date Task Completed	Signature or Initials of Person Completing the Task
List of Food Safety Team with individual responsibilities				
Product flow diagrams				
Hazard analysis				
Process Preventive Controls				
Food Allergen Preventive Controls				
Sanitation Preventive Controls				
Supply-chain Program				
Recall Plan				
Updated Food Safety Plan implemented				
Updated Food Safety Plan signed by owner or agent in charge				
Reviewer Signature:			Date Review:	
Date issued: dd/mm/yy		Supersedes: dd/mm/yy		