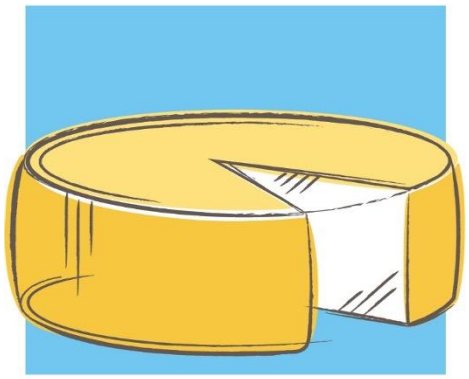

AMERICAN CHEESE SOCIETY

Best Practices Guide for Cheesemakers 2025

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History

In 2016, the American Cheese Society (ACS) released its *Best Practices Guide for Cheesemakers* (BPG). Its completion was a key strategic goal of the ACS Board of Directors, and the central task with which the Regulatory & Academic Committee (now Food Safety & Regulatory Committee) had been charged. ACS members requested such a resource, and by way of response, this BPG was created to encompass currently accepted best practices for cheesemaking. 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 now Food Safety & Regulatory Committee.

It is an original compilation of 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. This second edition of the BPG 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.

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 usable 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.

Terms of Use

This BPG 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 BPG 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. We hope you will find that the information provided in this BPG is useful and answers some of your key questions.

Please keep in mind that this is not a static document. The BPG 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 BPG, and in turn, enhance cheese quality and safety. The ACS Food Safety & Regulatory Committee will review and update the BPG accordingly, publishing updates as needed to keep up with changing regulations and scientific advances.

As a document created by volunteers to aid members of a non-profit organization, it 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. 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.

User Agreement

All users of the information contained in this document understand and agree that ACS is not responsible for the accuracy or inaccuracy of the information provided herein. This document was prepared as a tool to assist ACS members in improving their cheesemaking practices. Unless required by law, members are in no way required to implement the practices contained herein. Local, state, and federal regulators and inspectors are your best source for accurate regulatory information.

Acknowledgements

There are dozens of industry experts who generously gave of their time to aid in the development of this BPG, 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 BPG. Of particular note are the following ACS leaders whose contribution cannot be overstated. This BPG would not exist without their commitment of time and expertise.

We owe thanks to the following for the most recent edition of the BPG:

Susan Rigg of River Whey Creamery, Chad Galer of Dairy Management, Inc., Eric Holley of Sweet Grass Dairy, Stephanie Clark of American Dairy Products Institute, Dariann Gallegos of Rogue Creamery, Krista Jacobsen of Murray's Cheese, Reuben Nilsson of the University of Wisconsin-River Falls, Arnaldo Ramirez of Cabrillo Cheese, and Nikki Roof of Kentucky Department of Public Health.

In addition, we wish to recognize the contributors to the original BPG:

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. Kate Arding of Talbott & Arding Cheese and Provisions, Marianne Smukowski of University of Wisconsin's Center for Dairy Research, Bob Wills of Cedar Grove Cheese, and Dennis D'Amico of University of Connecticut

Thanks are also owed to the following ACS Board Members, Regulatory & Academic Committee Members, volunteers, and ACS staff who have assisted with the first and/or second editions:

John Antonelli, Jill Allen, Kate Arding, Jane Bauer, Steve Binns, Alyce Birchenough, Brian Bailey, Jeff Bloom, Gianaclis Caldwell, Stephanie Clark, Dennis D'Amico, Marc Druart, Rachel Dutton, Pat Ford, Jason Foscolo, Cathy Gaffney, Chad Galer, Dariann Gallegos, David Gremmels, Andy Hatch, Eric Holley, Tara Holmes, Krista Jacobsen,

Jeff Jirik, Mark Johnson, Michael Kalish, Mateo Kehler, Michelle Lee, Ranee May, Neville McNaughton, Paul McNeely, Emilio Mignucci, Greg O'Neill, Rueben Nillson, Rebecca Orozco, Brian Ralph, Aldo Ramierz, Matt Ranieri, Matt Richard, Susan Rigg, Dick Roe, Nikki Roff, Kendall Russell, Allen Sayler, Peggy Smith, Marianne Smukowski, Sarah Spira, Ron Tanner, Dan Utano, Nora Weiser, Eliza Wetherill, Bob Wills, Mark Wustenberg, Marilee Yorchak.

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First Edition, 2016; Reprinted with revisions, 2017, 2025

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Section 1: Glossary

Some key terminology used in the ACS Best Practices Guide.

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 CXS 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 (**CFR**)

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 (CFR) 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 CFR.

The purpose of the CFR 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 CFR (CFR Food and Drugs.

Codex Alimentarius

International food standards, guidelines, and codes of practice contribute to the safety, quality, and fairness of the international food trade (accessible at CODEX).

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.

Covered Facility

A covered facility is a business that is required to have and implement a written Food Safety Plan (FSP; US FDA 2025).

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 waste 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 environmental 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 (accessible at General Specs). Along with Federal guidelines, state and local authorities may impose additional regulations.

Facility

Under FSMA, a facility is a domestic or foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FDA 2018b), in accordance with the requirements of part 1, subpart H of the Code of Federal Regulations (US National Archives 2025a).

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 Registration 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 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 childcare centers. Food safety practices at these facilities play a critical role in preventing foodborne 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 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 (mitigation strategies) 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, "Guidance for Industry: Food Labeling Guide" includes 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 (see CFR).

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 to 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 the current National Advisory Committee on Microbiological Criteria for Food (NACMCF) consistent with current FDA recommendations.

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.

- **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.
- **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. To assist states and municipalities in initiating and maintaining effective programs for the prevention of milk borne disease, the USPHS, in 1924, developed a model regulation known as the Standard Milk Ordinance for voluntary adoption by state and local milk control agencies. To provide for the uniform interpretation of this Ordinance, an accompanying Code was published in 1927, which provided administrative and technical details as to satisfactory compliance. This model milk regulation, now titled the Grade "A" Pasteurized Milk Ordinance (Grade "A" PMO), most recent revision, incorporates the provisions governing 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 products.

The USPHS/FDA alone did not produce the Grade “A” PMO. As with preceding editions, it was developed with the assistance of Milk Regulatory and Rating Agencies at every level of federal, state, and local government, including both Health and Agriculture Departments; all segments of the dairy industry, including producers, milk plant operators, equipment manufacturers, and associations; many educational and research institutions; and with helpful comments from many individual sanitarians and others.

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.

Prerequisite 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 reduces 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 here (Preventive Controls).

Proteolysis

The breakdown of proteins into simpler compounds, such as peptides or amino acids.

Psychrophiles (psychrophilic microorganisms)

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 59-68F° (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 florescens* 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 thermoduric 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. Qualified Facilities, as defined by the Rule in 21 CFR 117.3, are those businesses that meet one of the following two definitions:

1. Very small business: <$1 million in annual gross sales of human food, based on an average of the three preceding years; **OR**
2. "Tester-Hagan amendment": < $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. Because the Tester-Hagan 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.

Any company that does not meet the definition of a Qualified Facility will need to meet all Preventive Controls regulations in 21 CFR 117as proscribed by FSMA.

Qualified Individuals

A "qualified individual" is 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. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties. 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. Trainings may be performed internally or through a 3rd party, online or in-person. Although the rule does not specify a specific training program, the FDA has funded the

Food Safety Preventive Controls Alliance to develop a model curriculum that can be used in-house to provide the needed training as can online CGMP or other food safety courses.

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.

Records

Records must be maintained for Qualified Facilities to support the various attestations (sales and food safety related documentation) 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 Qualified 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.

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.

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 animal rennet in cheesemaking. In addition to chymosin, animal rennet contains other important enzymes such as pepsin and lipase. Other types of rennet include microbial, recombinant, and vegetable rennet.

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 mandate the action be done. **May** gives the option of doing the action.

Small Business

FSMA defines small business in 21 CFR § 117.3 (US National Archives 2025a) as “a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.”

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.

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).

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.

Section 2: Milk Handling and Production

Chapter 1: Farmstead Milk Production

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 Pasteurized Milk Ordinance (PMO, US FDA 2023) bacterial limit for grade A raw milk (required for fluid milk and soft dairy products (e.g., sour cream)) is 100,000 CFUs per mL (milliliter), whereas, for grade B raw milk (permissible for cheese) it is 300,000 CFU/mL. Good milking practices achieve bacterial counts in the range of 1,000-10,000 per mL. 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.

Poor barn hygiene and poor milking procedures can lead to contamination of milk by enteric pathogens such *Escherichia coli*, *Salmonella, Listeria, Yersinia, Campylobacter, Staphylococcus aureus, and others. 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. Zoonoses are infectious diseases 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).

In addition to microbial hazards, 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 also 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 beta-lactam antibiotics. Common approved test kits typically test at, or around, these safe or tolerance levels.

Design of Farm Buildings

[See Section 5 Chapter 11 (Regulatory Compliance/GMPs) for more information regarding Good Manufacturing Practices.]

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 a sanitation step such as walking through a sanitary footbath, foam, or crystals. This strict policy is needed in order to prevent pathogenic bacteria commonly found on farms from getting into the processing plant. *Listeria monocytogenes, Salmonella,* shiga

toxin-producing *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.

Walls, Floors, and Ceilings

- Walls should be constructed of a smooth, non-toxic, and easily cleanable material that is impervious to water, cleaning chemicals, sanitizers, etc.
- Walls, floors, and ceilings should be free of cracks and holes which may harbor pests, reduce cleaning efficiencies, or become harborage sites for pathogens.
- Walls should be sealed at the wall & floor juncture to ensure no seepage from the production area, as well as around openings through which equipment, pipes, and other items pass.
- Ceilings should be constructed of a smooth, non-absorbent, and easily cleanable material, and all overhead lights need to have plastic coverings with no glass from lighting exposed.
- Floors should be constructed of a smooth, easily cleanable, material with no open cracks or holes, and should be regularly maintained to ensure proper drainage.
- Floors should be constructed in a way to ensure proper drainage.
- Floor drains should be in compliance with state and local regulations.

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

Animal Housing

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.

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.

Milking House

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.

Milking Parlor

Milking parlors should be constructed for adequate drainage and ease of cleaning. Milk parlor walls should be lightly colored, smooth, water-resistant, and capable of withstanding pressurized cleaning. Glazed block, tile, plastic, fiberglass sheets, sealed concrete block or poured concrete can all be used. Ceilings also need to be water resistant, smooth, and easily cleaned. Walls and ceilings should be insulated to prevent condensation build-up.

Traffic Flow

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.

Animal Health

Animals infected with pathogens can produce milk that contains human pathogens such as *Salmonella* spp. It is important to monitor animal health and maintain a vaccination program under veterinary supervision. 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 or have clinical or subclinical mastitis in one or more quarters must be milked last or with separate equipment, and their milk must be discarded. Identified animals can be treated. It is important to properly store, label, and use antibiotics and antimicrobials and ensure a Veterinary Client Patient Relationship (AVMA 2023) is in place.

If an animal consumes or is treated with antibiotics or other therapeutic drugs banned from the food supply chain, it must be milked last or with separate equipment, and the milk should be discarded. Milk from treated animals should not be commingled with milk from untreated animals. Care must be taken with the cleaning and sanitation of milking equipment (e.g. milking clusters) to avoid the transmission of causative agents.

The use of a strip cup can aid in the identification 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 collection hygiene.

Regular bulk tank testing for SCC helps create a baseline for your herd/flock and can be helpful in determining if there is a need to find animals with sub-clinical mastitis. Recently-freshened animals and animals being weaned from offspring are at a greater risk of mastitis and higher SSC.

Table 1 depicts the maximum permissible SCC by species as defined in the Pasteurized Milk Ordinance (US FDA 2023). These numbers represent herd amounts, not individual animals.

Table 1. **Maximum Permissible Somatic Cell Counts for Grade "A" Milk Per Pasteurized Milk Ordinance (US FDA 2023)**

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

Note: these numbers represent herd averages, not individual animals
Additional Note: Refer to individual state and local requirements to be in compliance.

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) *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 regarding 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. It is highly suggested to contact a veterinarian in the case of chronic mastitis.

In addition to the potential and actual impacts on human and animal health, inflammation in the mammary gland can affect the cheese made from that milk. Change in milk composition due to the infection (i.e increased white blood cell counts, increased enzymatic activity, etc.) can lead to rapid proteolysis and lipolysis, along with reduced lactose concentration, and increased sodium (Na^+) and chloride (Cl^-) concentrations. These changes can result in shorter shelf life, off-flavors, and lower milk and cheese yields.

Milking Animal Health and Cleanliness

The animal's environment influences animal hygiene. The cleanliness of the milking animal is directly related to animal health and the prevention of pathogenic organisms contaminating the milk. These include environmental mastitis pathogens (coliform bacteria and species of streptococci other than *Streptococcus agalactiae*) from feces and the environment. In addition, high counts of bacteria in milk can inhibit starter cultures and hasten spoilage of cheese. Thus, management should focus on reducing

teat end exposure to environmental pathogens as well as keeping milking areas of the animals clean and dry, especially teats, udders, flanks, hindquarters, abdomens, and tails. Manure should be managed and removed to prevent excessive accumulation on the udders and flanks of milking animals.

Farm premises adjacent to the milking barn, parlor, and milk house need to be kept free of contamination and debris. Efforts should be made to ensure clean lying areas, passageways, gateways, and pathways on the farm. Barnyards should be graded to permit good drainage and to keep them free from standing water. Removing accumulated waste feed can help deter rodents and insects. Excessive dirt or manure in loafing areas and muddy environments make it easier for bacteria to contaminate teats and subsequently contaminate milk or enter 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 and 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. Water troughs should not be located near bedded areas as they can lead to wet soiled areas due to increased traffic and leaks. 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 good practice to remove udder hair at least twice yearly.

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

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. The process is sometimes referred to as “Dip-Strip-Dry-Apply”. Pre-dipping is most effective in the control of environmental pathogens (*E. coli* and environmental S*treptococci*). There are a number of teat dips and teat dip formulations available on the market. Iodine has traditionally been the common approach, followed by chlorhexidine. Their efficacy is considered to be similar, but chlorhexidine has the advantage of being non-irritating and has a residual antimicrobial effect making it an especially good choice for post-dip. Some acidified sodium hypochlorite dips have been shown to be effective. Hydrogen peroxide containing products have become a more popular and cost-effective option (Enger et al. 2015). The bubbling action of these applications is thought to assist in physical cleansing as well making them a good choice for pre-dip. These products often contain organic acids to increase their effectiveness. Organic acids, including dodecylbenzene sulfonic acid and lactic acid have been shown to be very effective especially when used in combination with other germicides. Be sure to follow the

manufacturer's directions. For example, iodine requires a minimum contact time of 20–30 seconds for effective disinfection.

When applying disinfectant solutions cover only the teats and not the complete udder. Disinfectant and/or water dripping from udders will increase the 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 them 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. It is essential that one towel is used per animal per milking whether the towel is cloth or paper. Be sure to dry teats furthest away from milking first to reduce the risk of recontamination. These methods have been demonstrated to significantly reduce pathogen numbers.

Teats should be stripped vigorously to get a good milk flow. The use of a strip cup can help detect early cases of mastitis and decrease the chance of pathogen spread. Reject milk unfit for human consumption including mastitic milk and milk showing any abnormality. Colostrum or milk containing colostrum is unfit for cheesemaking and must also be rejected. The California Mastitis Test (CMT) can also be used on animals that are suspected to have an infection.

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. To be effective, gloves must be cleaned or changed once they become contaminated. 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 gloved hands when disinfecting dirty gloves.

The overriding goal of all milking procedures is to attach milking units to clean, dry teats. During milking, minimize surrounding activities that create dust, as contamination may be drawn through the milking equipment and into the milk during milking. Minimize air admission when changing clusters/transferring milk to avoid debris being sucked into the milk. After milking is complete, 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 can weaken the disinfectant. 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.

Cleanliness and Maintenance of Milking Equipment

Meticulous cleaning and maintenance of milking equipment helps reduce the levels of contaminating microbes including pathogens, spoilage microorganisms, and other unwanted microbes. For example, fitting clusters with a system that enables a disinfectant rinse, such as chlorine or peracetic acid, between animals can aid in reducing the transmission of mastitis pathogens.

All equipment should be made from food grade material (according to 3-A standards, 3-A 2025) and 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. All surfaces of milking equipment should be smooth, readily cleanable by manual or mechanical means, and designed to drain freely after cleaning. Certified conformance Evaluators (CCEs) through 3-A can certify an item (3-A 2025).

Clean means that the surface/area does not have visible filth, milk residue, or milkstone (minerals) 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. Sanitize all equipment prior to use. Maintain all equipment to prevent foreign material from entering the milk supply.

Milking units 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. Slipping liners can lead to teat end damage, erosion and are a site for infections to reside.

Be sure to follow a recommended cleaning, sanitizing, and storage routine for the milking equipment. This includes using the correct temperatures and measurements of cleaning and sanitizing solutions to improve the efficacy of the cleaning process. This also includes the use of correct flow rates for solutions as well as correct exposure time. Many systems can be cleaned using a clean-in-place (CIP) system. In such cases it is advised to include air injection to aid turbulent flow of the cleaning solution. It is recommended to ensure that the cleaning solutions contact the entire inner pipe surface and that the air supply is of high hygienic quality. Components that are not amenable to CIP must be washed 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. Once clean, allow equipment to air dry and do not use cloths for drying. Store clean equipment in a clean and dry environment to avoid contamination before the next use.

The non-sanitary parts of the milking system (pulsator air line, 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 air lines and

ancillary equipment is indicated. These non-sanitary parts of the system should be cleaned periodically as part of routine maintenance of the system.

Be sure to 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. Change rubber components such as liners, milk tubes, and vacuum seals regularly (and document changes) to prevent deterioration or erosion, which makes them uncleanable, and thus susceptible to the development of biofilms. Monitor the usage based on the manufacturer's recommendations. The seals and gaskets and all rubber fittings should be changed at least annually. Aged rubber may crack or become porous and is very difficult to clean. Using O-rings and gaskets that are any color other than white can aid in visualizing if they disintegrate and become incorporated into product. One can increase protection by using a suitable combination of time and temperature to clean gaskets, which are difficult to sanitize with chemicals. Cleanliness can be verified through testing. Producers must fully recognize the fact that certain components cannot be effectively washed without disassembly.

Cleanliness can be verified through ATPase testing (e.g., see Section 4 Chapter 8).

During or immediately after milking, and before cooling, milk should be adequately filtered to remove extraneous matter (physical hazards) that may have inadvertently contaminated the milk during milking. Inline (“sock”) filters are common. Filters should be observed for abnormalities after each milking. A fresh, clean filter should be used at every milking.

Refrigeration systems must be regularly inspected to ensure proper cooling and maintenance of refrigeration. For Grade “A” milk, it is required that milk temperature be dropped to or below 45°F (7°C) within 2 hours of completing milking of the last animal in the cycle. Milk must be maintained at that temperature and may not remain in a tank for longer than 72 hours for Grade “A” status (US FDA 2023).

Summary of risks to quality and safety

- Contamination of milk with chemical hazards including but not limited to antibiotics and chemicals used for cleaning and sanitation. These may be harmful to human health or may cause processing problems during cheesemaking.
- Contamination of milk with biological hazards including human and animal pathogens. Sources include sick animals, unsanitary milking practices, and improperly cleaned equipment.
- Poor quality milk and subsequent cheese resulting from high bacterial counts, mammary gland infections, and high SCC.
- Contamination of milk by physical hazards from equipment.

Summary of best practices for mitigating risks to quality and safety

Animal environment

- Design barn areas to promote animal health and discourage pests, such as rodents and wild birds.
- Other farm animals such as poultry and swine should be segregated from milking animals.
- Remove accumulated waste feed to deter rodents and insects.
- Grade barnyards to permit good drainage and to keep them free from standing water.
- Ensure clean lying areas, passageways, gateways, and pathways on the farm.
- Avoid organic bedding sources and wet, muddy pens.
- 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
- Monitor animal cleanliness. Keep milking areas of the animals clean and dry, especially teats, udders, flanks, hindquarters, abdomens, and tails. Remove enough manure to prevent excessive accumulation on the udders and flanks of milking animals.

Animal health

- Monitor animal health and maintain a vaccination program under veterinary supervision.
- 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 includes adequate withdrawal time for treated animals and culling of chronically affected animals.
- Isolate and treat sick animals with precautions in place to prevent milk contamination.
- Properly store, label, and use antibiotics and antimicrobials and ensure a Veterinary Client Patient Relationship is in place.

Milking procedures

- 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 manufacturer.
- 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 infection.
- "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.

Milking equipment

- Ensure all equipment is made from food grade material and is kept clean and in good condition.
- Equipment and chemical manufacturer's recommendations should be followed at all times.
- Make sure O-rings and gaskets are any color other than white 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.
- 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 efficacy of the cleaning process.
- Where a Clean-In-Place (CIP) system includes air injection to aid turbulent flow of the cleaning solution, ensure that it contacts the entire inner pipe surface and that the air supply is of high hygienic quality.
- Use correct flow rates of the solution as well as correct exposure time to aid in thorough cleaning and sanitizing processes.
- 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 to clean gaskets, which are difficult to sanitize with chemicals. Cleanliness should be verified through testing.

Records to maintain

- Animals should be readily identifiable with corresponding health records that include documentation of illnesses, treatments, and withholding times.
- Sanitation Standard Operating Procedures (SOPs) and Good Manufacturing Processes (GMPs)
- Inspection, maintenance, and replacement schedule for equipment.

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Section 2: Milk Handling and Production

Chapter 2: Milk Handling

The production of high-quality milk is essential for producing safe, high quality cheese. The cheese may be produced from milk from a single herd, multiple herds, or blended from different species. The Pasteurized Milk Ordinance (PMO, US FDA 2023) defines milk as:

> *"...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 mammals."*

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 "Code of Hygienic Practices for Milk and Milk Products" CAC/RCP 57-2004 (WHO FAO 2004).

The legal definition of milk as it relates to cheese manufacture is found within the Code of Federal Regulations Title 21 Chapter 1 Subchapter B Part 133.3(a) (National Archives 2024):

> *"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 CFR 133.3(a): with the individual standards of identity for each named cheese.

Microbiology of Milk

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.

Bacteria that contaminate 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 and freezing reduce the growth rates of bacteria but do not kill them.

Pathogenic and spoilage organisms common to milk (e.g., *L. monocytogenes, Salmonella* species, and shiga toxin producing *E. coli*) are generally of the mesophilic type, growing 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) are known as psychrotrophic or psychrotolerant bacteria. However, their optimum growth temperature is typically 70-82°F (21-28°C), at which point psychrotrophic bacteria will multiply at a much faster rate. Psychrotrophic organisms are the result of poor

sanitation. If sanitation is insufficient or if milk is not properly cooled, psychrotrophic bacteria will take over the natural flora of the milk. Although vegetative forms of these bacteria are killed by pasteurization, some of their enzymes, mainly proteases and lipases, resist pasteurization and cause spoilage. Furthermore, some psychrotrophic microorganisms are thermotolerant and form spores during pasteurization. When conditions are suitable (during extended refrigerated storage), spores can germinate and cause further deterioration of milk. This creates issues in the milk supply, as the lipolytic and proteolytic enzymes cause deterioration of the milk.

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.

Milk Quality

Both the biological and the physical quality of milk are important to cheesemaking. The biological quality of milk determines potential risks of which the cheesemaker must be aware. The physical quality of milk is also important to the cheesemaker both for yield and organoleptic qualities. Multiple types of testing for milk quality can include antibiotic testing, taste and smell, somatic cell count, bacteria count, protein count, fat content and freezing point.

Several factors can impact the quality and flavor of milk during handling and care should be taken to avoid these defects. The most obvious contribution to off flavors in milk and cheese is bacterial contamination, especially those that cause degradation by proteolytic enzymes (leading to bitterness) and lipolytic enzymes (leading to hydrolytic rancidity). Excessive agitation or foaming of raw milk can also yield hydrolytic rancidity, especially to sheep and goat milk. Silage, wild onions, and other by product 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. Communication with milk suppliers about feed rations and changes in feed are critical in maintaining flavor profiles.

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 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 cells per unit would be reduced to less than 10. Alternative treatments or a series of procedures may have a similar effectiveness (thermization), but are not legally considered pasteurization, thus requiring 60 days of aging prior to sale of the cheese.

Producing and 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 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.

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 somatic cells 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 quality.

Typical Tests for Milk Quality

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 PMO and 21 CFR § 240.61 and 21 CFR § 133.3d (National Archives 2024).

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, batch pasteurizer 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 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 must 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, fresh cheese (e.g., cheese curds) and soft cheeses may only be sold if 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.

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. For Grade “A” milk, the requirement is for milk to be cooled to or below 45°F (7°C) within 2 hours of milking the last animal, and when commingling milk with a previous milking, at no time may the temperature exceed 50°F (10°C) (PMO 2023). This can be done in bulk tanks, milk cans, or plastic bags. Bulk tanks should be equipped with a temperature measuring device for monitoring the rate and 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. Tanks should also be equipped with an agitator to ensure homogeneity of all milk contained in the bulk tank. All cap openings should be covered at all times to prevent contamination. Tanks should be thoroughly cleaned and sanitized each time they are emptied and the tank needs to be self-draining for complete removal of any chemical solutions or water. It is also advised that compressors are placed in a shaded, well-ventilated area and that they are cleaned and serviced regularly. This includes servicing and calibrating the refrigeration system on a regular basis per manufacturer’s guidelines.

Grade “B” milk, also referred to as manufacturing grade milk, is subject to different recommended minimum cooling requirements. Milk in cans shall be cooled to 50°F or lower immediately after milking unless it is delivered to the plant within 2 hours after milking. Milk in farm bulk tanks shall be cooled to 40°F or lower within 2 hours after milking and maintained at 50°F or lower until transferred to the transport tank. Milk in plastic bags shall be cooled to 40°F or lower within two hours of milking. Sheep milk shall be cooled to 45°F or lower within (2) hours of milking. Cooling water used in bulk tanks in which bags of sheep milk are cooled shall be chlorinated. If milk is cooled by pouring into plastic bags and then floating the bags of milk in cooling water, the process must preclude contamination of the milk by the water. All water must be safe and of sanitary quality.

Regardless of grade, pre-cooling refrigerated storage tanks can aid in a more rapid cool-down of milk.

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. Review local and state regulations to ensure compliance.

Storage of Milk for Quality

Bulk tanks shall be emptied, cleaned, and sanitized every 72 hours. More regularly is highly recommended, as bacterial enzymes, oxidative characteristics, and changes to calcium and other milk ions have been shown to negatively affect cheese when milk is stored as little as 48 hours (Guggisberg et al. 2022, Paludetti et al. 2020, Tripaldi et al. 2021).

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 1*)

The milk is filtered as it enters the canister, and the canister 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).

Figure 1. Can cooling method of cooling milk.
Kate Arding Collection

Freezing and defrosting frozen milk

This is not common practice, and these are recommendations only for those who may freeze and thaw milk for cheesemaking on occasion (e.g., sheep milk).

Use only food-grade bags that originate from companies on the list of "Certified Manufacturers of Single-Service Containers" (US FDA 2025). When freezing milk, the temperature should be such that the milk freezes as rapidly as possible. The suggested temperature is 0°F (-18°C) or less. Home freezers do not work well as they are unable to achieve this temperature. 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.

Sourcing and Purchasing 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. Only purchase dairy ingredients from a milk producer who is licensed and inspected for the production of milk. 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. Ensure your milk supplier knows the standards required, and for what purpose the milk will be used. 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. Ensure that written supplier assurances are in place confirming the control measures required for milk production, storage, freezing (if applicable), and transport. 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. Periodically visit and inspect the supplier's 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.

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 (by freezing point), 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 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/receipt. 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 constitute a load of milk from that given farm on that day. These individual bags or canister 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.

Consideration for Mixed Milk Cheesemaking

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

Transport and Receipt of Fresh and Frozen Raw Milk

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 products (US FDA 2023). Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples *(Figure 2).* No dairy plant operator may receive any milk products transported in a bulk milk tanker unless the tanker operator holds a current license.

Figure 2: Arding, Kate. Transport and Receipt of Fresh and Frozen Raw Milk (A). Collection of Kate Arding.

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 (US FDA 2023). 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).*

Requirements for milk tank trucks and hauler licenses can be found in Section 3 of Appendix B of the PMO. These industry plant samplers are employees of the dairy plant, receiving station, or transfer station and are evaluated at least once every two-year period by a properly delegated Sampling Surveillance Official (SSO).

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 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 pre-approved 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.

When receiving milk, obtain necessary documentation including hauler permit and identification, point of origin of shipment, tanker identification, date of transport, and cleaning/sanitation of the vessel. 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; or has an excessive storage/transport time. This time specification is up to the cheesemaker, but some producers prefer to use milk within 24-36 hours of collections, with temperature being the determining factor. Reject any frozen milk delivery that is delivered at a temperature above 0°F (-18°C), is not marked with a traceable batch code, or 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 sanitized 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. 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 receiving tank will aid in reducing aeration. Foaming of the milk should be avoided as much as possible.

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 that are not amenable to CIP (Clean in Place) 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 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 PMO.*
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.*

Milk tanks shall be emptied and cleaned at least every 72 hours. It is required that a cleaning, sanitizing, and storage routine for equipment be followed and documentation is required to record it being completed. This includes the use of the correct temperature and concentrations of cleaning and sanitizing solutions, correct flow and solution rate, and correct exposure times. Milk contact surfaces shall be readily accessible for inspection. 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. 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 tanks shall be self-draining. Bulk tank openings may not be located directly under a ventilator or directly over a floor drain and openings and covers shall be constructed and installed to prevent drainage into milk or onto milk contact surfaces. When CIP facilities are not available for transport equipment, 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).

Summary of risks to quality and safety

- Undesirable microbes including both spoilage and pathogenic bacteria, if present, may multiply in the milk during storage and/or transportation especially with inadequate temperature control or extended storage times, resulting in increased health risks.
- Milk may become contaminated with undesirable microbes if the transportation vessel is not cleaned properly or if it contains contaminated milk.
- The exterior of tanker hoses may be contaminated with pathogenic bacteria and cross-contaminate between multiple farms if not cleaned properly.
- Contamination of milk by chemicals that are harmful to human health and/or chemicals that can cause processing problems during cheesemaking.
- Contamination of milk by physical hazards from poorly maintained or damaged equipment.

Summary of best practices for mitigating risks to quality and safety

Cooling milk

- Cool the milk as quickly as possible to at least meet recommended times and temperatures.
- Pre-cool the refrigerated storage tanks to aid in a more rapid cool-down of the milk.
- Equip bulk tanks with a temperature device for monitoring the effectiveness of cooling.
- 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.
- 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.
- Propylene glycol and all additives used in cooling media must be food grade.
- If milk is stored or cooled in cans or bags, do not co-mingle milk from a morning milking with milk from an evening milking.
- If the hose is not handled in a controlled, hygienic manner, the milk can become contaminated during off-loading.
- Regularly inspect equipment to minimize potential for physical contamination.

Sourcing and purchasing raw milk

- 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's 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.

Transporting and receiving milk

- 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 (missing or broken tamper-evident seal)
    - Has undergone 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
- The raw milk receiving area shall be separate from the processing area. Ideally, the intake area is completely enclosed.
- Receiving areas should be covered to prevent contamination by birds or other airborne pollutants.
- 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 sanitized 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.

Cleanliness and Maintenance of Chilling, Storage, and Transport Equipment

- 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. In addition, proper recording and documentation of sanitation procedures is a best practice and regulatory requirement.
- 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.
- 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.
- Regularly inspect equipment to minimize potential for physical contamination.

Records to maintain

Milk cooling and storage

- Temperature records for bulk tanks may be provided via the installed recorder. After January 1, 2000 per the PMO (US FDA 2023), 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 (Hugo 2015).
- A production log for bulk or frozen milk must be maintained.
- Sedimentation and antibiotic beta lactam test results should be available.
- Regularly inspect equipment to minimize potential for physical contamination.

Purchase and receipt of milk

- 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.
- Obtain supplier assurances of compliance with raw milk production and storage steps.
- Obtain contract and transport agreements with milk hauler.
- Request correspondence relating to hygiene standards or milk quality.
- Obtain copies of microbiological, somatic cell counts, and antibiotic residue test results.
- Request inspection, maintenance, and replacement schedule for equipment.
- Maintain 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.
- 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.
- Cleaning and sanitizing records should be kept for at least two years.

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Section 2: Milk Handling and Production
Chapter 3: Biological Hazards, 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 more commonly 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. Because of the industry's efforts to refrigerate milk quickly to minimize bacterial growth, the organisms naturally present in raw milk have changed from predominantly Gram-positive, acid-producing bacteria to largely Gram-negative, psychrotrophic microorganisms (Marth et al. 2001).

Psychrotrophic bacteria grow at or below 45°F (7°C), even if this is outside of their optimal growth temperature. Psychrotrophic bacteria 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 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 endure pasteurization, contributing to spoilage not only of raw milk, but of pasteurized milk and milk products as well (Cousin 1982). Some psychrotrophic bacteria are thermotolerant. They produce spores that endure pasteurization, then germinate during refrigerated storage, leading to spoilage of pasteurized milk.

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 enterocolitis, acute diarrhea, terminal ileitis, mesenteric lymphadenitis, pseudoappendicitis, and sepsis if it spreads systemically. *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. Microbial testing of products 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 finished samples should be sent to an accredited outside, independent laboratory to prevent the introduction of unwanted microorganisms through the laboratory and normal test procedures.

Regulatory Rationale and Limits for Pathogens and Indicator Organisms
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. 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; see Section 4 Chapter 8) and other programs.

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 death.

Organisms of Concern

The *Compliance Policy Guide* for FDA staff defines pathogens of concern as follows (US DHHS, FDA 2010):

- ***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. For more information on how Salmonella presents, see the table at the end of this chapter.
- **Enterohemorrhagic *Escherichia coli* (EHEC) O157:H7 and other** Shiga toxin-producing *E. coli (STEC)* - The infectious dose of EHEC is estimated to be between 10-100 organisms. When food contaminated with the EHEC 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 (HUS) or thrombotic thrombocytopenic purpura. HUS is characterized by low red blood cells, acute kidney failure and low platelets. The mortality rate is <5% but ~25% of patients have ongoing kidney problems throughout life. EHEC/STEC O157:H7 is the predominant EHEC/STEC strain that has caused illness worldwide. However, other STEC serotypes have also been implicated in illness and are of public health concern (US CDC 2010).
- **Non-toxigenic *Escherichia coli* –** *E. coli* has traditionally been used as a microbiological indicator of poor sanitation during processing. *Escherichia coli* is 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. Unsanitary conditions, including poor employee hygiene practices, improperly sanitized utensils and equipment, or contaminated raw materials, may also be a source of non-toxigenic *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.
- *Staph aureus* has traditionally been used as a microbiological indicator of poor sanitation during processing, as has *E coli.* Because of environmental factors, low levels of *Staph aureus* may be found in raw milk, even when produced using GMPs. However, excessive numbers of *Staph 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. Cfu/g 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. O*utbreaks 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 (US CDC 2016).

Additional information about foodborne pathogens and associated diseases can be found in the table at the end of this section, as well as in *The Bad Bug Book, Second Edition* (US FDA 2022).

Regulatory Limits for Pathogens in Cheese

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-toxigenic *Escherichia coli*." (US FDA 2022).

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 (US FDA 2022) 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 10,000 cfu/g in one or more subsamples.
- *Bacillus cereus* is found at levels greater than or equal to 10,000 cfu/g in one or more subsamples.

Milk Testing

Raw Milk Quality Indicator Organisms

Minimizing bacterial contamination and growth in raw milk is critical to the quality and shelf life of milk products. When bacteria counts become excessive, microbial enzymes cause degradation of milk components (lactose, protein and fat) 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. Bacteria counts are controlled by ensuring healthy animals, good hygiene, proper cleaning, sanitizing and temperature control as well as limited storage time of raw milk are some ways to control microbial numbers.

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. 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 (APC) 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) leads to 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 unsanitary conditions. Poor milking hygiene, poor animal housing, seasonal conditions (muddy/rainy), and improper cleaning and sanitizing of equipment, may result in elevated coliform counts. Grade “A” raw milk and pasteurized fluid must not exceed 10 CFU/mL (US FDA 2023). There is no federal standard for numbers of coliforms that may be present in raw milk used for cheese. 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. Coliforms are readily killed by pasteurization.
- Preliminary incubation counts (PIC) consist of incubating raw milk or cream for 24 to 36 hours at 45°F (7°C) followed by SPC. The PIC gives some idea as to the number of psychrotrophs present. Numbers should not exceed 10,000 CFU/mL for quality.
- The test for thermoduric bacteria is known as a laboratory pasteurization count (LPC). High thermoduric counts are consistently associated with unhygienic production practices (e.g., the buildup of biofilms or milkstone on milking lines). Thermoduric bacteria (e.g., 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 SPC method.

Be aware that such tests give an overall indication of hygienic quality; they provide no information about the presence of 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) and Preventive Controls for Human Foods Food Safety Plans.

All 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, Preventive Controls, and testing of products. Tests for raw milk cheese quality and safety should include all tests mentioned above, and in addition, *the 'Big 4' organisms that are generally of concern for cheese made from raw milk are Salmonella, Listeria, STEC, and enterotoxigenic Staphylococcus aureus (coagulase-positive staphylococci) so it is reasonable to screen the milk supply for these. Tests for coliforms or Enterobacteriaceae might also provide useful information.*

Environmental Monitoring

Environmental monitoring is a systematic process used to test the food production environment, including food contact surfaces, for potential contamination, to verify the effectiveness of your food safety program. Common targets in an EMP include pathogens, spoilage organisms, and indicator organisms. Different food types have different risks and regulatory requirements vary. Different EMP may be necessary based upon product types and processing environments. Establishing an effective environmental monitoring program (EMP) is essential to detect the presence of soil and potentially pathogenic bacteria (e.g., *Listeria* species) in the cheese processing plant before they cause quality defects or a foodborne illness outbreak. The goals of an environmental monitoring program include finding pathogens and harborage sites if present in your plant, and ensuring that corrective actions have eliminated pathogens and harborage sites when found in your plant (FDA HHS 2017). Environmental testing is an important verification step of any risk reduction plan.

To evaluate the cleanliness of food contact surfaces prior to the sanitation step adenosine triphosphate (ATP) test kits are commonly used. ATP is a component of all organic material (including living and dead 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 cleanliness of equipment surfaces. The swabbing generally takes place prior to the start of the day's production or immediately after cleaning (before sanitation). 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 re-cleaning is advised. The commercial ATP test kits include clear instructions about how to conduct the tests. It is important to swab hard-to-clean areas, since the goal should be to catch problems before they occur.

Sampling

Environmental sampling 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.

Your written environmental monitoring procedures should specify an appropriate number of selected sampling sites and frequency (FDA HHS 2017). Sites should be selected based on the potential for them to be contaminated. The number of samples generally is higher in zones 1 and 2 because of the greater risk of food contamination if the organism is present in these zones (FDA HHS 2017). Working with your state inspector and/or testing laboratory is recommended (see Section 4 Chapter 11).

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 (NFCSs) are in these areas that are directly adjacent to Zone 1. This includes NFCSs that are directly adjacent to Zone 1 sites. This zone includes draining tables, racks, and the outside area of vats. 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 presents the risk of cross-contamination within production. These areas include non-product contact surfaces within the processing area including 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 typical that non-food contact surfaces in Zones 2-4 are tested for *Listeria* species. It is not recommended to composite samples taken from food contact surfaces because it can increase the time required to identify the source of contamination, should a sample result be positive (FDA HHS 2017).

Brine tanks, drying racks, aging rooms, and air quality should be sampled on a routine basis, as these areas constitute a potential environmental concern for cheese contamination.

Frequency of Environmental Testing for Listeria

FDA's 2017 "Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-to-eat Foods; Draft Guidance" on environmental sampling (US DHHS FDA 2017) recommends the following frequency for testing of each Zone.

- *Zone 1*: Critical Food Contact Surfaces (FCSs)
- Collect samples from all or representative sets of FCSs at least once per week. If using a 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 representative sets at least once every two weeks. If using a 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*:
- Monthly testing is recommended. Some producers 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 Zone 2. In this instance sanitation and its frequency should be reassessed.

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 may already be contaminated and may lead to product recalls. Therefore, some suggest that 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 can 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.

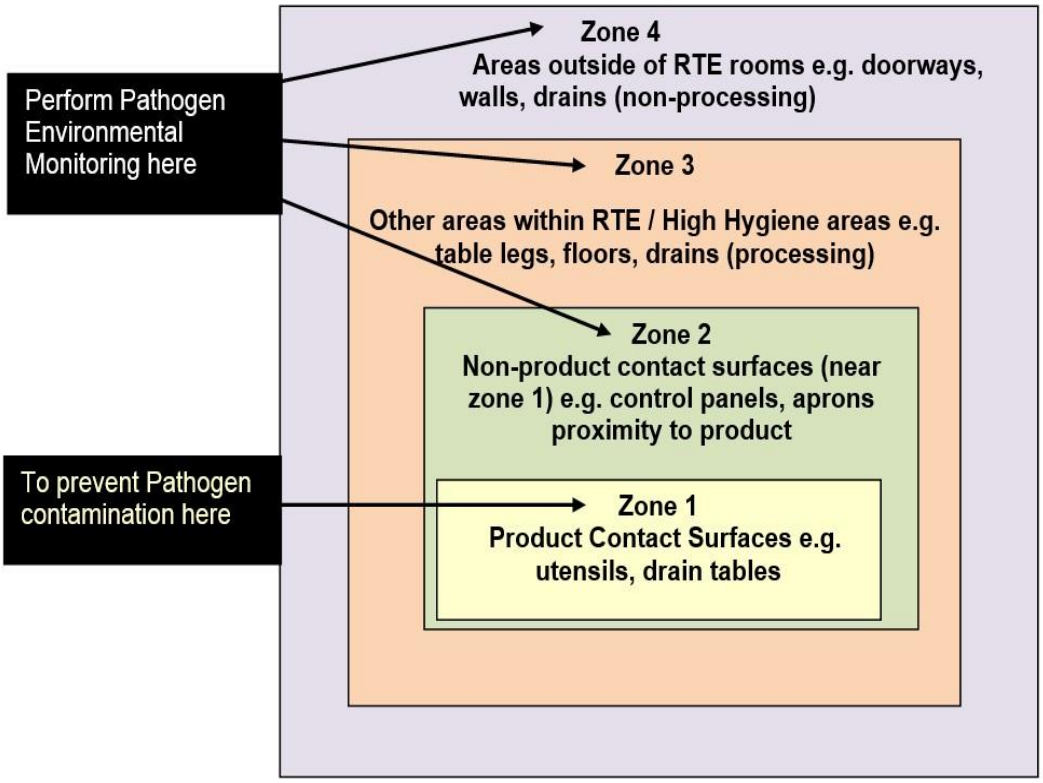

Figure 1. Food Safety Modernization Act Zone ID Chart.

Corrective actions if you detect Listeria spp. on a Non-Food Contact Surface (Zone 2-4):

If you detect Listeria spp. on a non-FCS, the FDA recommends that you follow risk-based corrective action procedures that describe the steps to be taken, and assign responsibility for taking those steps, to ensure that the cause of the contamination is identified and corrected, and to minimize the potential for FCSs, RTE food, ingredients or packaging to become contaminated.

We specifically recommend that you follow the details and guidance for appropriate corrective actions found in the FDA Draft Guidance “Control of Listeria monocytogenes in Ready-To-Eat Foods; Section XIII.E”.

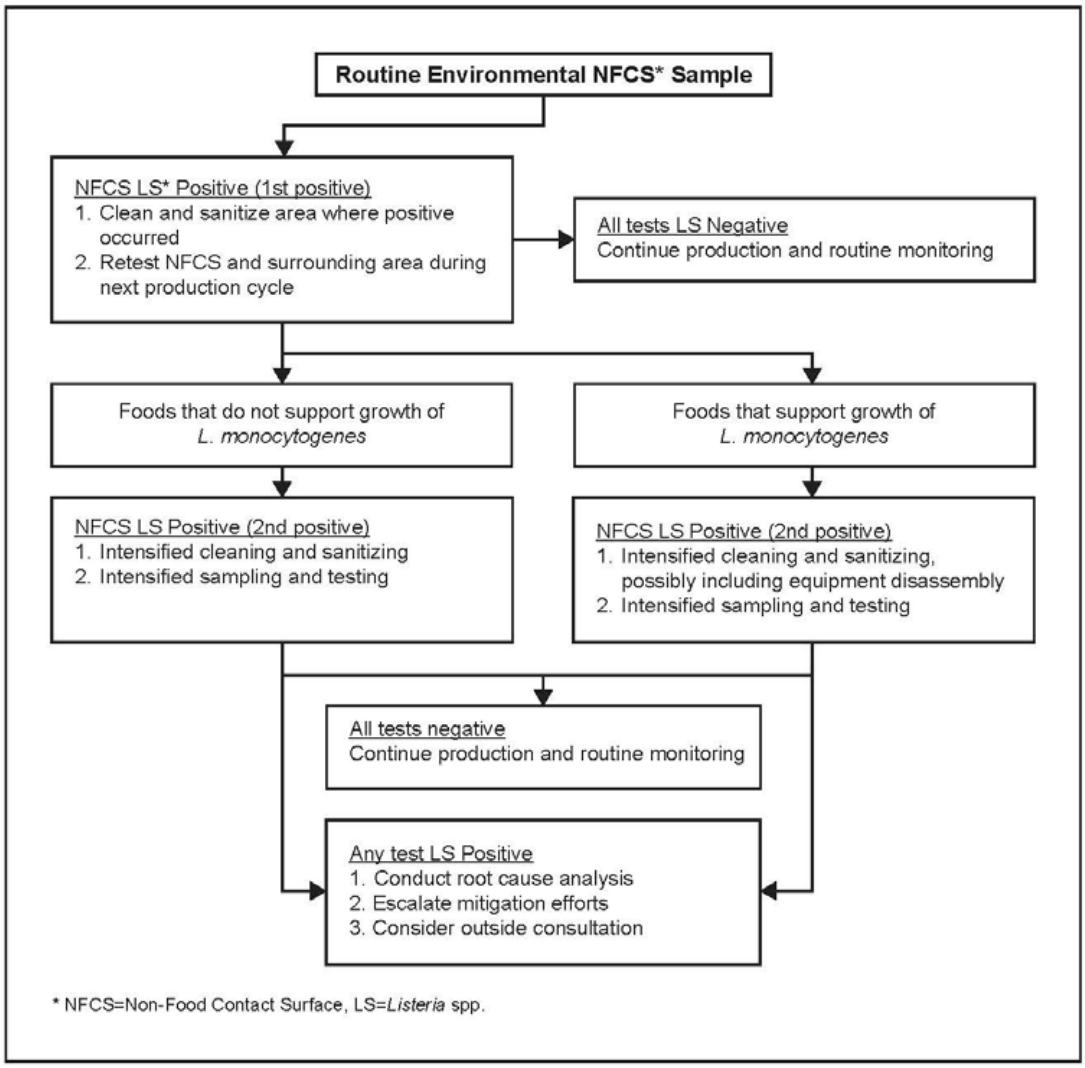

Figure 2. Routine Environmental Non-Food Contact Surface Sampling Process (US DHHS FDA 2017).

Corrective Actions if you Detect Listeria spp. on a Food-Contact Surface (Zone 1):

If you detect Listeria spp. on an FCS, the FDA recommends that you follow risk-based corrective action procedures that describe the steps to be taken, and assign responsibility for taking those steps, to ensure that the cause of the contamination is identified and corrected, and to minimize the potential for release of RTE food that is contaminated with *L. monocytogenes*. The goal is to find the source of contamination and eliminate it.

If you detect *L. monocytogenes* on an FCS, you should either reprocess with a validated control measure, divert to a use in which the food will not be consumed by humans or animals, send for use in food to be consumed by animals where appropriate, or destroy that lot of RTE food, and consider whether there is product in commerce that should be recalled (see chapter on Recalls).

We specifically recommend that you follow the details and guidance for appropriate corrective actions found in the FDA Draft Guidance “Control of Listeria monocytogenes in Ready-To-Eat Foods; Section XIII.F” (US DHHS FDA 2017).

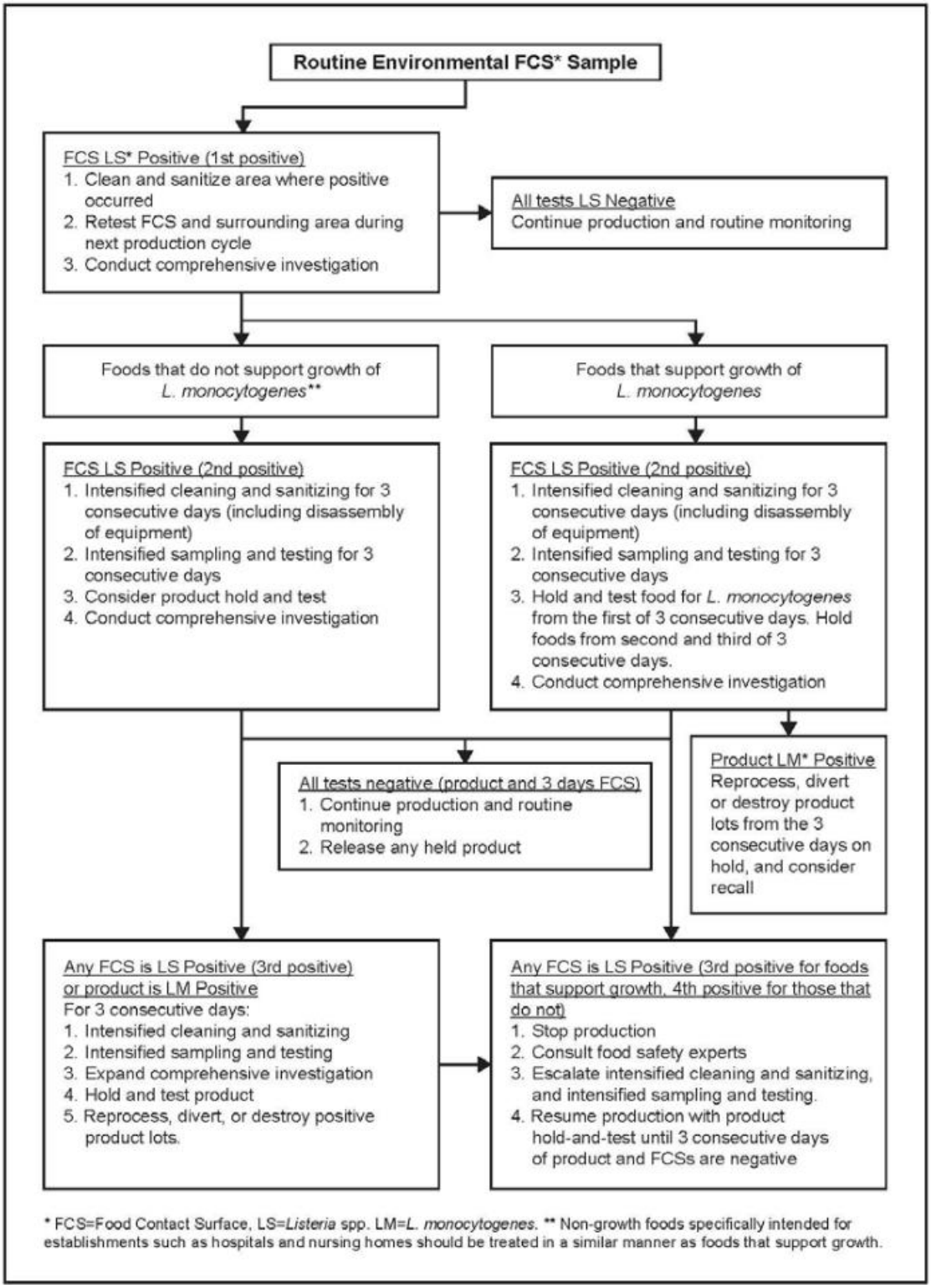

Figure 3. Routine Environmental Food Contact Surface Sampling Process (US DHHS FDA 2017).

Product Testing

If present in high enough numbers, pathogens can survive 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 if the tests are imperfect or not statistically reliable. In-process and end product testing depend on whether 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 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 regard 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 documentation and evidence that their procedures and processes are under control.

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 making 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.

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 (Food Directorate et al. 2015).

The frequency of testing can be anywhere from daily to twice-yearly 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.

Retaining Product

It is best practice to hold all product lots from release until all test results are back. It is also a best practice to hold the product and have a plan in place as to when the product will be released – based not only on testing protocols, but other steps and checklists which must be followed. Basically, if for any reason a product does not conform to standards or specifications, it should not be shipped until such issues have been addressed and/or remedied.

Prior to release from hold, the facility should ensure that:

- Products are confirmed as compliant before release to the market.
- All staff are familiar with product release procedures and that personnel authorized to release products 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 (Vat ID, Make Date, Raw Ingredients Specifications), 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 (see Section 4 Chapter 9).

Table 1: Human Pathogens Associated with Contaminated Milk and Milk Products (Hays et al. 2001; Schmidt 2009).

Organism	Disease
Gram-negative bacteria	
Escherichia coli	
non-EHEC pathotypes	Gastroenteritis, invasive infections
EHEC	Toxicoinfection, hemolytic uremic syndrome in children; thrombocytopenic purpurea in adults
Salmonella spp.	Gastroenteritis, invasive infections, typhoid fever (*Salmonella* Typhimurium)
Yersinia enterocolitica	Gastroenteritis, invasive infections
Aeromonas hydrophila	Gastroenteritis
Brucella spp.	Brucellosis, undulant fever
Campylobacter jejuni	Gastroenteritis, invasive infection, Guillain–Barré syndrome, colitis, septicemia

Pseudomonas aeruginosa	Gastroenteritis, invasive infections
Gram-positive bacteria	
Bacillus cereus	Gastroenteritis, invasive infection, emetic intoxication
Clostridium perfringens	Gastroenteritis, invasive infections
Clostridium botulinum	Botulism
Staphylococcus aureus	Emetic intoxication
Streptococcus agalactiae	Sore throat
Streptococcus pyogenes	Scarlet fever/sore throat
Streptococcus zooepidemicus	Pharyngitis, nephritic sequelae
Corynebacterium spp.	Diphtheria
Listeria monocytogenes	Listeriosis
Mycobacterium bovis and *M. tuberculosis*	Tuberculosis
Rickettsia	
Coxiella burnetii	Q fever
Viruses	
Enterovirus, including polioviruses, rotaviruses, Coxsackie viruses	Enteric infection
Hepatitis virus	Infectious hepatitis
Fungi	
Molds	Mycotoxicoses
Protozoa	
Entamoeba histolytica	Amebiasis
Giardia lamblia	Giardiasis
Toxoplasma gondii	Toxoplasmosis
Cryptosporidium parvum	Invasive infection, gastroenteritis

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Section 2: Milk Handling and Production

Chapter 4: Heat Treatments

Heat treatment of raw milk is an excellent method to eliminate and control microbial contaminants. When choosing the method of heat treatment for 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 as well as cheese quality. If pasteurization is chosen, the process must meet the definition of pasteurization under 21 C.F.R. §131.3(b) (US FDA 2024). The Pasteurized Milk Ordinance (PMO; US FDA 2023) 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 approval of equipment to meet PMO requirements. Depending on state regulations, the pasteurizer operator may be required to have certification or meet licensing requirements.

The most common PMO approved time and temperature combinations for milk pasteurization (and the only ones appropriate for cheesemaking) include:

- **Vat, Batch, or 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)

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).

Alternative combinations are described in the PMO (US FDA 2023).

Types of Heat Treatment

Cheesemakers have the option of choosing whether to apply heat to milk prior to aged cheese manufacture. Cheeses made from raw milk must be aged at least 60 days at no lower than 35°F (2°C).

Thermization is a sub-pasteurization heat treatment undefined by current U.S. 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 seconds (Early, 1998). It is intended to extend the storage time of raw milk by reducing the number of psychotropic spoilage organisms. While it may also reduce pathogenic bacteria numbers, the destruction of all vegetative pathogens cannot be guaranteed. For example, *Listeria monocytogenes* and *Mycobacterium tuberculosis* may survive thermization treatments in certain circumstances.

There is a big difference between thermization and pasteurization. The US FDA only considers milk to be pasteurized or unpasteurized, which is often referred to as raw. Some cheesemakers define raw milk as milk that has not been heated above the body temperature of the animal and milk that is heated beyond these temperatures is considered unpasteurized (not raw). As far as the FDA is concerned, thermized milk is still considered raw milk and the cheese made from thermized milk must be labeled and handled as a raw milk product. Any heat process will directly affect the unique characteristics of milk and the cheese made from it. Much of the native

flora and some enzymes found in raw milk will be destroyed by thermization. However, this destruction is not complete, however, because thermization is time and temperature dependent.

Pasteurization is designed to kill pathogenic microorganisms and is required for “fresh” cheeses (those not aged 60 days). 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. Treatments beyond LTLT and HTST are not recommended for cheesemaking (because of the impact on whey proteins) so will not be discussed further here. 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 regarded as a Critical Control Point (CCP) in HACCP-based food safety systems or a process control under Preventive Controls for Human Foods. In addition, avoidance of post-pasteurization contamination is important.

There are two types of pasteurization commonly used for cheese milk (see below). In all cases, pasteurized milk should be used immediately for cheesemaking or cooled to <39°F (4°C) and used within 24 hours.

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

Every particle of milk must be heated to 145°F (63°C) for 30 minutes and the air space temperatures must be maintained at least 5°F (3°C) above the minimum legal pasteurization temperature during the 30-minute hold time. If culinary steam is used for air space heating, it should be filtered prior to 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 compounds (National Archives 2024). No filters are needed when potable water is used for steam generation. Ensure that the lid to the pasteurizer remains closed throughout the entire time period. If the lid is opened, the 30-minute hold time must be restarted. 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. Adequate mixing of the milk must also be ensured to obtain even heating throughout the batch.

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, wherein every particle of milk is held at a minimum of 161°F (72°C) for at least 15 seconds. 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. Check all pasteurizer seals as part of daily start-up procedures to ensure pasteurization integrity. 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.

Pasteurization is at least 99.999% effective against the most heat resistant pathogens and kills vegetative cells, including vegetative cells of spore-forming bacteria. 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.

It is important to note that toxins produced by pathogens such as *Staphylococcus aureus* are heat stable and will not be inactivated by pasteurization.

Pasteurization is only effective when the required temperature and time are attained using equipment that has been inspected and approved by the local regulatory agency. Have the system timed (HTST) 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.

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. Regardless of 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
- Product identification to include type and amount
- Product to be made from that milk
- Filling and emptying times
- Pasteurization temperature and holding time
- Cut-in and cut-out temperatures at time of start up (HTST)
- Air space temperature at beginning and end of holding time (LTLT)
- Indicating Thermometer temperature and operator initials
- Cleaning and sanitizing times and temperatures
- Signature of person who is verifying the chart information
- Operator
- Any unusual occurrences

Ensure that the 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. For vat pasteurizers, 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.

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. Some certification bodies may have their own requirements. If pasteurization is a CCP or process control for the cheesemaker, this chart becomes the necessary documentation for verification purposes.

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 products.

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 contaminated pasteurized milk. Phosphatase tests are used to confirm pasteurization on properly installed and operated equipment. In case of a pasteurizer malfunction, it 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 ranges values published (Harding 1995), expressed as µg/mL (microgram per milliliter) phenol:

- Raw cows' milk: 1,870-4,740
- Raw sheep's milk: 8,300-16,300
- Raw goats' milk: 117-1,292

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 ≤45°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.

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 CFR (US FDA 2024). 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 micro-grams/0.25 g (12-20 micrograms phenol equivalents per gram), depending on the variety of cheese.

Maintenance and Cleaning of Pasteurizers

Processing equipment should be welded, polished stainless steel with no sharp corners, cracks, or exposed threads on all inside and outside surfaces. Equipment should 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). There should be also sufficient ventilation and lighting on all surfaces to be cleaned. The pasteurizer and milk outlet should not be located directly over or near a floor drain. 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. 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. 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.

Preventive maintenance procedures for HTST pasteurizers should be implemented to avoid internal leakage of unpasteurized milk to pasteurized milk. Plates should be opened and evaluated annually for integrity of seals and cleanliness. They should also be checked to ensure 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.

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 the soil. “Soil” can be defined as any material found in an incorrect location (Marriott 2006). 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 the type of food manufacturing plant. The primary soils in dairy plants include sugars, butterfat, proteins, and minerals. Milk sugar (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 is most readily removed with the aid of an emulsifying agent at temperatures above the typical melting point [84-97ºF (29-36 ºC)]. Proteins can be denatured by heat or acid, which can alter their solubility in water. Denatured proteins may be dissolved in dilute alkaline solutions or in chlorinated alkaline solutions. Acid cleaning or rinsing solutions (pH of 5 or less) can be used to remove precipitated mineral salts that form milkstone as well as hot milk films from incomplete cleanings or deposits.

Precautionary measures can be taken during processing that will make cleaning and sanitation easier. Care should be taken to heat to the minimum temperature for the

minimum time with the heating medium at the lowest practical temperature. Heating surfaces should be cooled before and during emptying if possible and practical. Rinse foam and milk film from equipment surfaces with warm water immediately after processing each batch, or at least immediately after the run. Keep the film on equipment surfaces moist until ready to clean by avoiding steam or hot water leaks to the vat jacket.

Basic CIP steps:

1. Rinse with soft, tempered [~115ºF (46°C)] water and not with hot water to remove gross soil, then drain and refill the tank.
2. With water recirculating, slowly add caustic cleaner to water in accordance with manufacturer's recommendations.
3. 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 gaskets (James 2006).
4. Flush solution from pasteurizer.
5. Rinse with potable water.
6. Add the acid cleaner according to the manufacturer's recommendations to fresh clean water to attain a pH of 3.0 or less.
7. Heat solutions to at least 155-160°F (68-71°C) or as recommended by the manufacturer's instructions and circulate for 20-30 minutes.
8. Flush to drain with cold water until cool.
9. Sanitize prior to use at beginning of start-up.
10. Pump the chemical sanitizing solution through the equipment for at least 1 minute.

Sanitation records should identify the following and be kept for a minimum of 90 days.

- The equipment that has been cleaned or sanitized
- Date and time when each system was cleaned and sanitized
- Temperature of cleaning and sanitizing solutions
- Length of time for which system was exposed to solution (CIP).
- Signature or initial by responsible person

Summary of risks to quality and safety

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

Summary of best practices for mitigating risks to quality and safety

- If using direct steam injection to heat milk or the headspace, culinary grade steam needs to be used with approved additives and/or filters.
- 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° F (4°C) and use within 24 hours.

Vat/Batch LTLT

- Ensure adequate mixing of the milk to obtain even heating throughout the batch.
- Ensure that the lid to the pasteurizer and all other openings remain closed, capped, or sealed throughout the entire time period. 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 the 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 it entering the vat pasteurizer. If boiler compounds are used, they need to be GRAS (Generally Recognized as Safe). Check the CFR for an approved list of boiler compounds (National Archives 2024). 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.

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 the 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.
- 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.
- Immediately report broken seals or equipment changes to regulatory authorities. Products made while awaiting re-inspection need to be segregated and tested prior to release or treated as unpasteurized products.

Maintenance and Cleaning of Pasteurizers

- 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 (James 2006). Working with a knowledgeable chemical representative will ensure the best cleaning procedure for your equipment.
- Train personnel in maintenance and sanitation protocols.
- Make sure SSOPs are implemented and followed including pre-operational check lists for daily start up.

Records to maintain:

It is highly recommended that records such as chart recordings be kept for as long as the product is in the food chain. All recording charts need to be kept for a minimum of 6 months by the PMO. Record retention policies vary, and certain certifying bodies and customers require longer retention than the 6 months identified in the PMO.

Operating procedures for pasteurizer.
Sanitation Standard Operating Procedures (SSOP-see Section 4 Chapter 8) (USDA FSIS 2016).
Staff training record.
Phosphatase test results in the event of a malfunction or loss of seal on a pasteurizer.
Daily Seal Check Confirmation.
Chart Recording.
Cleaning and sanitation records.

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

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Section 3: Cheesemaking & Aging

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 (FAO 2025). Additionally, the "Milk and Milk Products" Codex (FAO WHO 2011) 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).*

The Milk and Milk Products Codex (FAO WHO 2011) also defines acceptable ingredients and definitions for some standard varieties, including cheeses in brines. The *Codex* has a separate definition for whey cheese (FAO WHO 2022).

In the United States, the Standards of Identity for cheeses can be found in the Code of Federal Regulations (CFR) 21 CFR § 133 (National Archives 2024). 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 CFR § 133, Cheeses and related cheese products (National Archives 2024).

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 and coagulated plant-based proteins from nuts or legumes.

Regulatory Definitions

The US Food and Drug Administration (FDA) maintains and enforces standards of identity for over 70 cheeses and cheese products. Each specific standard of identity can be found in the 21 CFR § 133 (National Archives 2024). Any cheese labeled with one of the cheese names identified must comply with the compositional and manufacturing requirements of that cheese.

Dairy Ingredient Profiles is the term used for what the U.S. calls standards of identity (Government of Canada 2025). In Mexico, standards of identity, or "normatives" are also accessible online (Secretaria de Gobernación 2019).

The U.S. Federal Standards of Identity for 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 (US FDA 2024). 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 CFR (National Archives 2024).

In the Federal Standards of Identity, cheese can be categorized by name (e.g. Monterey Jack, Colby, Romano) as well as additional categorical standards characterized by moisture and fat in dry matter (e.g., semisoft, soft ripened, spiced). The CFR lacks a semi-hard category, causing an overlap between hard and semi-soft cheeses. 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 (USDA AMS 2025). These standards are based on the CFR standards (National Archives 2024).

It should be noted that most chapters in the CFR contain the following wording in regard 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 expressed as a percentage of the cheese on the 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:

FDB = Fat% ÷ (100 – Moisture%) x (100 ÷ 1)

For the Brie example:

FDB = 31% ÷ (100 – 50%) x (100 ÷ 1)

FDB = 31% ÷ (50%) x 100

FDB = 31 ÷ 50 x 100 = 62% (similar to double cream brie example)

Cheeses have also been classified by basic compositional properties that are specifically related to food safety, including pH and water activity (Trmčić 2017).

Milk Source and 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 separated standard of identity (beyond the specified cheese type) but must follow the same food safety requirements as any other cheese (e.g., CFR § 133.184 groups Roquefort cheese, sheep's milk blue-mold, and blue-mold cheese from sheep's milk).

The following terms are widely used to describe the way a cheese is produced:

- **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 primarily made by hand 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. The cheese must be ripened naturally, with emphasis on development of characteristic flavor and texture and without the use of shortcuts and techniques to increase yield and shelf life at the expense of quality. Respect for the traditions and history of cheesemaking are expected regardless of the size of the production.

- **Specialty**

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

- **Non-Dairy Cheeses**

  Non-dairy cheese is made from coagulated protein products made from nuts, legumes, or other plant-based proteins.

Milk Treatment

Sometimes cheeses are defined by if they have been made from unpasteurized, thermized, or pasteurized milk. Section 2, Chapter 4 details this information.

Milk that has been heated but not to the level or time required for pasteurization must still be called unpasteurized. The current regulations in the United States allow for the sale of cheeses made from unpasteurized milk if the cheese is aged for typically 60 days or more at a temperature greater than 35°F (2°C).

Method of Coagulation

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

- **Direct-acidified, acid coagulated, cultured, or lactic cheeses**

The precipitation, or separation, of curds from milk by the addition of or production of acid (by lactic acid bacterial cultures) has been common for many years. Vinegar, acetic acid, citric acid, lemon juice, lactic acid, and even hydrochloric acid, have been used to produce direct-acidified curds.

For milk coagulation to occur (without the aid of enzymes), the pH of the milk must drop to what is called the isoelectric point of caseins (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-coagulated cheeses include cottage cheese, 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 (Wilbey et al. 1998).

- **Chymosin, enzyme, or rennet coagulated**

“Rennet” was originally (and is still in some locations) produced by harvesting the digestive enzyme (chymosin) of a suckling calf, lamb, 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 microorganisms 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 protein (kappa-casein), causing a chain reaction that results in the formation of a coagulum.

After the cleavage of the peptide bond on kappa-casein, a smaller 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 (curd has “set”). 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.

- **Coagulation by acid and heat**

Coagulation by acid and heat occurs when milk, a milk-whey blend, 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, acid is added slowly with gentle agitation (reducing pH to about 5). The caseins and whey proteins aggregate together and form curds. The curds produced are small and fragile, resulting in a short shelf life and greater than 50% moisture content cheeses. Ricotta, paneer, and queso blanco are examples of this type of cheese (Hill 2016).

Method of Ripening

Cheese ripening or curing may also be known as cheese maturation or *affinage*. The process involves microbiological activity from microorganisms, biochemical reactions occurring from active enzymes that are present, and physical changes from the milk components undergoing breakdown. More details are included in Section 3, Chapter 7.

- **Fresh or Unripened Cheeses**

Fresh cheeses are unaged cheeses. They have a relatively short shelf life, which may be extended by submerging the cheese in oil or freezing. 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**

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**

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* and *Penicillium expansum* (formerly *P. glaucum)* contain 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%. 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, surface-ripened cheeses typically have rinds that are various shades of red-orange. The cheeses are washed during the maturation process, and the bacteria 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 (Fox et al. 2004). Tilsiter, Gruyère, Beaufort, Trappist, Munster, Brick, and Limburger are all examples of surface bacteria ripened cheese.

- **Internal Bacteria-Ripened Cheeses**

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

cheeses are 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.

ACS Judging & Competition Categories

The ACS Judging & Competition (J&C) is a premier competition for cheeses produced in the Americas. The Judging & Competition classifies cheeses and cultured dairy products into over 25 categories. These categories are then subcategorized based on milk type, age, style, fat and salt content, added ingredients, and/or moisture content (into over 100 sub-categories).

For the most up-to-date listing of categories, please refer to the ACS Judging & Competition Category List on the ACS website (https://www.cheesesociety.org/competition).

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Section 3: Cheesemaking & Aging

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 some 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. Safe cheese production combines practices that exclude hazardous ingredients, prevents contamination of products during cheesemaking, and eliminates hazards during cheesemaking and aging.

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 produce safe and consistently high-quality cheese will provide peace of mind for the cheesemaker and business owner. The evidence that the procedures are effective and are followed will also be the basis for satisfying inspectors.

Under the Food Safety Modernization Act (FSMA 2024), the cheesemaker must not only know the sources of health hazards but also be able to demonstrate to inspectors that there is valid evidence that the chosen series of steps in a process will result in safe cheese. The validity of established processes like legal pasteurization time and temperature are easy to determine. 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 evidence that the series of steps is always effective. For many years, the process of aging 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.

The reader is urged to read chapters in Section 4, Regulatory Compliance, for details about GMPs (8), Food Safety Plans and Traceability (9), Food Defense (10), and Inspections (11).

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 more likely if the milk is largely free of pathogenic bacteria or other hazards.

Milk Source

Clean farm conditions, healthy animals and choices of feed enable farmers to provide milk with relatively low levels of microbiological risk. Sourcing 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 and safety 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 (see Section 2 Chapter 2).

Milk Quality in Food Safety Programs

Milk can support pathogens and spoilage organisms that are the most likely source of food safety and quality problems in cheese. Preventive controls to produce safe cheese must include strategies for dealing with microbiological hazards. Cheesemakers can exert some level of control over these risks with heat treatments, including pasteurization, of reasonably high-quality milk (see Section 2 Chapter 3).

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. Bactofugation is another option. 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.

Cheesemaking Process

Cheese may be made with the assistance of starter cultures, direct acidification, enzyme coagulation (with or without culture or acid) or heat coagulation (often with acidification).

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. Higher pH (over 5.4) provides a more hospitable environment for pathogen growth.

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 (e.g., surface-ripened cheeses). 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.

Starter Cultures

Most common cheese varieties are acidified by the action of 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 antimicrobial metabolites including organic acids. Furthermore, these microbes may outcompete undesirable organisms. Poor acid production due to improper storage of cultures, dosage, bacteriophage, antibiotics, or starter activity can increase the risk of food safety and quality issues. High moisture cheeses produced by only adding acid may support pathogen growth due to the lack of such competing flora from cultures.

Cheesemakers can purchase frozen or freeze-dried, direct-set cultures or they can grow their own bulk starter cultures. 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. Cheesemakers should be aware that using small portions from a package may result in unbalanced and inconsistent mixes of strains.

Purchased starter cultures must be of high quality, from a reputable source, and be properly stored, either frozen, refrigerated, or in dry storage, to ensure their viability and acid-producing characteristics. 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 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. 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.

Non-starter lactic acid bacteria (NSLAB) are also common in cheese. These bacteria may be naturally occurring in the milk or the cheesemaking environment. They can also be added as "adjunct culture" (e.g., *Lactobacillus helveticus*). 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.

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 delay or prevent acid production entirely.

Direct Acidification

In lieu of lactic acid bacteria, cheesemakers may lower the pH for some cheese varieties by direct addition of acid to milk. 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. Additionally, some cheesemakers may pre-acidify milk to standardize milk pH prior to adding cultures. 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.

Weak acids release hydrogen gradually and slowly lower the pH. Temperature also affects 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. Adjustments should be made to ensure a consistent pH target is met.

Addition of acid to attain 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.

Enzyme addition

Acidification by cultures takes time. Addition of coagulant enzyme removes the negatively charged “tails” from the kappa-casein, enabling coagulation. The technique chosen will directly influence the texture of the cheese.

The majority of cheeses, especially hard, aged cheeses, are made using chymosin (the active chemical name) or other coagulants. “Rennet” is historically referred to as an enzyme complex harvested from the abomasa, 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. Non-animal (fermentation-produced or microbial) sources are available today as well as plant-based enzymes.

Ripening

Ripening is the stage between culture addition and coagulant (enzyme) addition. The ripening stage may vary from 30 to 90 minutes, depending on the cheese. During this time, bacteria acclimate to their new environment (milk) and the milk acidity increases (pH drops) as the bacteria grow and create lactic acid. 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. Tracking this time enables you to adjust the amount of enzyme added, as necessary.

Types of rennet

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

Rates

Dosage rates are recommended by the manufacturer. Coagulant strengths also differ. Typically, 1 unit US manufactured single-strength rennet will coagulate 15,000 units milk (1g (gram)/15,000 grams of milk). Around 70-100 mL (milliliters) of rennet will coagulate 1000 lbs of milk. Single-strength is the usual form for traditional rennet. Double-strength rennet is just that where 35-50mL will coagulate 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. A drop or two of cheese milk may be added to the water to bind chlorine (prevent degradation of the enzyme). Milk should be stirred or agitated when adding the coagulant. As soon as the enzyme is well mixed (minimum amount of time to evenly distribute), and prior to the start of coagulation, milk movement must stop.

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.

Hard water will also reduce enzyme activity. Adjust enzyme levels or use filtered water for enzyme dilution.

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.

Milk heat treatment

Ultrapasteurized milk (or milk that has undergone excessive recirculation (e.g., divert flow) in an HTST pasteurizer) may not coagulate because of beta-lactoglobulin (whey protein) denaturation. When beta-lactoglobulin is denatured by heat, it covers the exact location where chymosin (rennet) is meant to cleave the kappa-casein tails.

Heating to Form Curd

The third way to make milk coagulate is by raising the temperature sufficiently for the whey protein 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 is added after heating the milk. With lower pH, curd will precipitate more quickly with less heat addition. Excessive heating can give cheese a burnt flavor.

Other Additions to Milk

Adjunct Cultures

In addition to lactic acid producing cheese cultures, cheesemakers sometimes 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 selected for their ability to control specific spoilage or pathogenic bacteria are also available commercially. Creation and commercialization of these protective cultures is a rapidly developing industry. They may become an important part of a food safety program if their efficacy against the target organism in a specific cheese can be documented.

Cheese Color

Cheese color is added primarily for appearance. 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 in water 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 speed coagulation and develop curd firmness. Addition of $CaCl_2$ accelerates coagulation. It also increases soluble calcium ions 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.

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.

Process Steps to Reduce Moisture in Curds

Cheesemakers separate the curd from the whey. Casein proteins in fresh milk are evenly distributed because kappa-casein net negative charges cause 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 direct acidification or by formation of acid by lactic acid bacteria cultures. Cheesemakers make choices during coagulation that impact cheese moisture and thus, its ability to support pathogens.

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 in terms of best practice for consistency and quality.

Once milk has coagulated, separation of curd and whey happens through a few techniques, which vary with cheese type. The final structure of the cheese is partially dicated by whether the curd is acid-, heat-, or enzyme-set. Enzyme-set curds will continue to tighten through subsequent steps in cheesemaking, ultimately leading to a more rigid structure than can be obtained from an acid-set curd.

The following descriptions give more details about techniques used by cheesemakers to control the moisture and acidity of the final cheese. Techniques that lower moisture and increase acidity of the final product will create environments that are less supportive of pathogen growth. As in all steps following pasteurization, cheese makers must be cautious to avoid contaminating product. Paddles, mills or other equipment that are in poor condition may be hard to clean and may also introduce metal to the cheese. Inspect all pieces of equipment used in cheesemaking and make necessary repairs/replacement (see Section 4 Chapter 9).

Cutting

After the coagulum reaches the desired consistency, the cheese maker will cut the gel into smaller pieces to promote expulsion of whey (syneresis). If the 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 1). An effective way to test curd set is to use a straight cake spatula: to plunge the spatula in about 2 inches into the middle of the cheese vat, lift the spatula out without twisting, turn it 90 degrees and position it at the close end of the straight line to make an upside-down T. Push the butt end of the spatula down as the metal end is lifted up (Figure 2). The curd is ready to cut if the firmness resembles that of firm Greek yogurt or custard and, when removed, the upside-down T fills with clear yellow whey.

Figure 1. Breaking curd. Collection Kate Arding

Figure 2. Testing set. Collection of Stephanie of Clark

Manual cutting typically involves the use of wire (or harp) knives that fit the vat appropriately. One set of wires (on one knife) is horizontal (Figure 3) and one set of wires (on the other knife) are vertical (Figure 4). It is typical to cut the entire length of the vat with horizontal knives first, ensuring that the entire vat has layers or planes of curd. The vertical knives follow the same pattern, thus ensuring that the vat contains long strips of curds. The final cuts, cross-wise along the full length of the vat, ensuring a vat full of cubes of curd.

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.

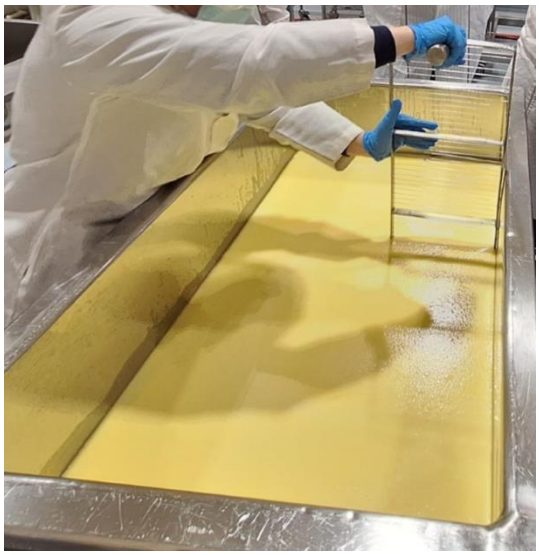

Figure 3. Cutting curds horizontally. Collection of Stephanie Clark

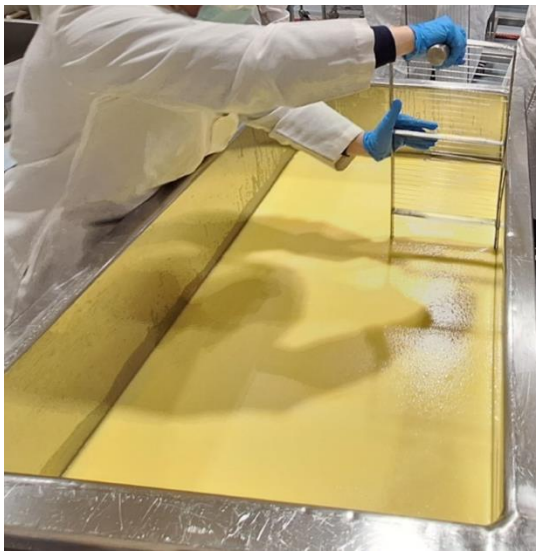

Figure 4. Cutting curds vertically. Collection of Stephanie Clark

Healing

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 break 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 and reduce fines (tiny particles of cheese that may be lost with whey).

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. Matted curds do not allow for proper cooking and moisture control.

Cooking and stirring

The purpose of cooking and stirring is to facilitate curd moisture expulsion. Improper cooking/stirring of curd will result in poor moisture control and quality defects in cheese. Cooking typically involves gradually raising the temperature of the whey/curd. If cooked too rapidly, the outer shell hardens and curd cannot expel the desired amount of moisture. The temperature increase should be tracked and recorded.

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 added directly into the cheese vat (called “washing”-next section).

Washing Curds with Water (Optional)

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. 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.

Water can be a source of unwanted microbial contaminants. Wash water and steam used directly on the curds must be free of contaminants. Test water regularly to make sure it is free of coliform and other contaminants. Culinary grade steam requires use of food grade boiler compounds.

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 (Figure 5) or pump (Figure 6) the curds directly into forms. Curds are drained in the hoops or molds rather than in the vat. Acid set cheese may be put into bags and drained to remove whey before packaging. 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.

Figure 5. Draining curd 1. Collection of Kate Arding.

Figure 6. Draining curd 2. Collection of Kate Arding.

Knitting

Curds are allowed to mat at the bottom of the vat (e.g., Cheddar) in the press (e.g., gouda), or in the draining hoop or form (e.g., blue). This allows more whey to be expelled 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, which tightens junctions between caseins.

Salting

Salt has many functions in cheesemaking: lower moisture, slow acid development, enhance flavor, and kill or slow the growth and activity of contaminants including 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. Uneven distribution of salt due to clumping or poor application can allow harmful organisms to grow or flavor defects to develop in low salt areas. Improper temperature when salting can result in cheese defects or loss of salt in whey/brine. Therefore, it is important to manage moisture content of cheese when salt is added. It is also important to monitor and maintain the temperature of cheese curds during addition of dry salt, curds or cheese block during the brine process, and aging and storage of cheese before/after salting.

- **Sodium chloride** (NaCl): Sodium chloride 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. Impurities in salt can create flavor and moisture control issues or introduce contaminants.
- **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 inward. 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 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 (Rao and Wendorff 2002).

Dry salting after pressing

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 concentrated or saturated brine solution (e.g., containing 23 grams of salt (NaCl) per 100 grams of solution (~76.5 g water and 0.5~g $CaCl_2$)). When the cheese is immersed in a concentrated or saturated solution 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 (Guinee 2004). Addition of $CaCl_2$ to brine prevents slimy curd surfaces (a result of calcium leaving the curd osmotically).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 (Johnson and Paulus 2005).

Be sure to maintain salt and $CaCl_2$ concentrations, temperature, and pH of the brine solution. Improper maintenance of brine concentration can reduce salt uptake by the cheese or enable the brine to be contaminated and contaminate cheese. Brine concentrations are critical since 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. Brines should also be tested routinely for microbial contamination.

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.

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.

Adding Flavorings

Fresh herbs and spices may be added directly to the cheese curds prior to molding or used as a wrap on the exterior surfaces of the cheese. Adding an herb or spice may introduce contaminants including unwanted microbes, chemicals, allergens, and physical hazards like soil or stones. Other flavorings may degrade after shelf life has lapsed; beers and wines may have active yeasts present, etc. If these materials are self-produced by the cheesemaker, a complete sanitation program is necessary to ensure the safety of these materials.

Source ingredients from reputable sources, including tracking of lot numbers. Receive and store ingredients in a manner that limits the possibility of cross contamination. Obtain Certificates of Analysis (COAs) or letters of guarantee from suppliers. Maintain refrigeration and humidity control during aging and storage. These materials require sampling and testing or a documented sanitizing program for the materials prior to addition to cheese. Add ingredients following manufacturer's recommendations. Label product to include potential allergens. If you are smoking cheeses, ensure that wood used for smoking is natural hard wood that has not been chemically treated.

Summary of risks to quality and safety

- Introducing vegetative pathogenic bacteria (*Listeria monocytogenes, Salmonella*, pathogenic *E. coli, Staphylococcus aureus*) through ingredients, poor handling practices.

Production

- Impurities in the acids, salt, herbs, spices and/or packaging materials could affect cheese quality and safety.
- Direct acidified 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.
- Poor acid production due to improper storage of cultures, dosage, bacteriophage, antibiotics, or starter activity.
- 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.
- Rate of acid production affects microbial control for cheese during manufacturing and storage as well as impacting knitting properties of the cheese curd.

Salt

- Impurities in 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/100g solution (10%). Yeasts and coliforms are also known to survive in brine tanks.
- Water impurities in the brine makeup.

Flavorings

- Introduction of an allergen.
- Contamination from:
  - microbial contaminants
  - ingredients and packaging
  - pesticides or herbicides used on plants from which herbs/spices come
- Foreign materials such as soil or stones from herbs and spices.
- Toxic compounds emitted if using real smoke from chemically-preserved wood.

Summary of best practices for mitigating risks to quality and safety

Pre-Production

- Clean and sanitize all equipment, utensils, measuring devices, and work surfaces.
- Wash water and steam used directly on the curds must be free of contaminants.
- Test water regularly to make sure it is free of Coliforms and other contaminants.
- Certificate of Analysis (COA) must be on file for all products.
- Verify supplier standards for all ingredients.
- Cover and store ingredients in a cool environment to avoid contamination by pests, condensation, and/or airborne contaminants.
- 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.
- Culinary grade steam requires use of food grade boiler compounds.
- Supplier contact list.
- Label information from all items used in production.

Production

- Ensure employee hygiene and use of PPE.
- Use potable water for dilution of enzymes to prevent contamination of milk.
- Aseptically open, weigh dosage, and pour culture directly into milk.
- Do not thaw pellets before use or inoculation, unless using the frozen canned variety.
- Thoroughly mix cultures before use, particularly if only a portion of a package is used. Store unused portions to prevent spoilage or contamination.
- Document acid development targets.

- All acids should be designated food grade.
- Rotate starter to eliminate strain-specific bacteriophage.
- Pasteurize milk per federal regulations (US FDA 2023).
- 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.
- Maintain proper working condition of pH meters or titratable acidity testing equipment.
- 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.

Salt

- 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.

Flavorings

- Manage materials, which may contain pathogenic spores by requiring sampling, testing, and a documented sanitizing program for the materials prior to addition to cheese.
- Source ingredients from reputable sources, including tracking of lot numbers.
- Obtain COAs or letters of guarantee from suppliers.
- Maintain refrigeration and humidity control during aging and storage.
- Label product to include potential allergens.
- Receive and store ingredients in a manner that limits the possibility of cross contamination.
- Add ingredients following manufacturer's recommendations.
- Ensure that wood used for smoking is natural hard wood that has not been chemically treated.
- Sanitize all ingredients that are self-produced, for example bark or leaves used for wrapping cheese may be blanched by boiling for 5-20 minutes, briefly soaked in 50-200 PPM (parts per million) chlorinated solution, or soaked in an alcohol solution that is at least 70% ethanol.

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.
- Cold storage temperature logs.
- Test results if producing own herbs and spices.

Production:

- Complete pasteurization records per Pasteurized Milk Ordinance (US FDA 2023).
- 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.
- 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 of storage and brine tanks.
- Documentation log for proper sanitizing of herbs and spices if self-produced.

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Section 3: Cheesemaking & Aging

Chapter 7: Aging and Ripening

Many cheese varieties require aging, or affinage. In the U.S., all cheeses made from raw milk require aging of at least 60 days at greater than 35°C. During processing, 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 microorganisms. Cheesemakers must take care to prevent introducing pathogens during this process. Intrinsic characteristics of the cheese, such as pH, salt, moisture and microbial diversity may 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. The second-most important step is prevention of pathogen proliferation. Pathogens are naturally attracted to the conditions of the aging environment, so the goal is to prevent them from being able to propagate, using sanitation protocols.

Temperature influences 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 favors 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.

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. 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 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 roqueforti or glaucum* are 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 below 0.89, which is not supportive of growth or activity of most principle pathogens (Lee 2021).
- **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:** Swiss-style cheeses typically have a managed, slow, or delayed acid development, resulting in a sweet cheese. This type of cheese supports growth of added *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 (134-24°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 mold, yeast, and pathogenic organisms but cannot be relied upon for safety.

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. Temperatures below 52°F (11°C) will slow down the aging process (Kindstedt 2005). 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 (Kindstedt 2005).

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.

Wrapping Cheese

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.

Various plant materials can serve as natural wrappers. 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.

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). Products with phosphoric acid and surfactant are ideal for soaking brushes. Boiling brushes is an alternative option. A dishwasher with a sanitizing cycle may also be used to more thoroughly clean 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.

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 good carbon dioxide (CO_2) permeability. A flexible wax coating overlay on paraffin wax can be 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.

Allow cheeses to naturally air-dry prior to waxing to prevent bubbling of wax and mold growth underneath. For the initial coat, cheese should be dipped in wax between 225-240°F (107-116°C) to flash off any remaining 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 (CO_2). PVA without color added dries to a clear film.

Vacuum Sealing for Aging

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, particularly with temperature fluctuations. Subsequently, calcium lactate crystals can form a white haze in the folds of the plastic material and on the surface of the cheese, which consumers often mistake for white mold (Agarwal et al. 2005).

Be familiar with local variances which may require approval of vacuum packaging or any kind of modified atmosphere packaging (e.g., New York).

Non-barrier films are common for Swiss cheese and cheeses that develop carbon dioxide (CO_2) 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. 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 a competitive advantage 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 contaminated 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 Clostridium species.

Vegetable Ash

Vegetable ash (also called vegetable carbon or vegetable black) is a form of finely divided carbonized material of vegetable origin, and not of petrochemical or hydrocarbon sources (EFSA 2012).

Function and Application of Vegetable Ash

There is a long history by the cheese industry of using vegetable ash in cheesemaking for technical effects in cheese. For example, vegetable ash is used as a pH buffer to decrease the acidity of the surface of cheese to allow desired fungi to develop earlier in the aging process.

According to the FDA, vegetable ash is not an approved colorant for foods in the U.S. (FDA 2023, Miranda-Bermudez 2012). Therefore, vegetable ash can only be used for a purpose or purposes other than coloring and the vegetable ash must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned (National Archives 2025a and b).

FDA currently does not have a food additive regulation permitting the addition of vegetable ash to cheese for the technical effect of acidity regulation or determined vegetable ash to be Generally Regarded as Safe (GRAS) (US FDA 2025). The FDA has not been notified of a GRAS conclusion for vegetable ash for this purpose or received any submissions through their voluntary GRAS Notification Program (US FDA 2016). Companies can make a self-determined GRAS conclusion for the use of vegetable ash as a “pH buffer”. Substances concluded to be GRAS for an intended use do not require pre-market approval nor notification to FDA. It is unlikely FDA would challenge a self-determined GRAS conclusion based on a long history of safe use of vegetable ash for acidity regulation and other uses in cheesemaking. Though, it should be noted that it is possible that FDA could undertake an effort to evaluate the science and possible negative health impacts of vegetable ash.

Sourcing Vegetable Ash

Companies using vegetable ash for technical effects in cheese products other than coloring should source the ingredient from a vendor who has made a GRAS determination and by using vegetable ash in the manner and quantity specified by that supplier. Vegetable ash sold for the purpose of coloring cheese should not be purchased and vegetable ash should not be self-produced.

Labeling Ash

If vegetable ash is being added to cheese then it needs to be included on the ingredient label. The purpose or purposes of vegetable ash as an ingredient should be noted, keeping in mind that vegetable ash cannot be used as a colorant. For example: vegetable ash (acidity regulation).

How to Pack Ash-Coated Cheese

Vegetable 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.

Aging Surfaces/ Aging on Wooden Boards

The Code of Federal Regulations' current regulations state that utensils and other surfaces that contact food must be "adequately cleanable" and "properly maintained (National Archives 2025c)." 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.

If aging on wooden boards is intended, it is recommended that producers use kiln-dried hardwood boards. European cheesemakers use spruce boards almost exclusively for aging which is a fast-growing porous wood and comparable to domestic white pine, which absorbs moisture readily. Remove cracked or damaged boards that cannot be cleaned.

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.

Swabbing of clean food-contact surfaces should be part of your environmental monitoring program (see Section 4 Chapter 9). To ensure that cheeses are not contaminated with pathogenic organisms, discard contaminated and splintered (physical hazard) boards. Cheese and board lots should be tracked to identify shelving that has

come into contact with contaminated cheese or cheese that has contacted contaminated shelving.

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. 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. This brown powder has a characteristic sharp, pungent odor (Price 1938). 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 action (Barry 2017).

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. People who handle mite-infested products can become sensitized to mites on subsequent contact, leading to contact dermatitis, allergic rhinitis, and asthma (Mulle and OConnor 2019, Coudé and Wendorff 2013)

Sources and Growth Conditions for Cheese 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.

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. Mites will likely be present if the aging room promotes the growth of *Scopulariopsis* ("Scop"), a common brown mold that attaches to clothbound cheddar and many natural rinded cheeses, including alpine styles such as Gruyere or Comte (Wolfe 2014). Scop is the cheese mites' preferred food, and what attracts them to that space (Wolfe 2015). Control and mitigation, rather than elimination, are reasonable strategies.

Cheese that has been coated with paraffin (waxed) is not easily attacked by cheese mites if the coating is sound. If the paraffin coating 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 (Coudé and Wendorff 2013).

Preventing and Controlling Infection by Mites

The cheese curing room or cheese storage area must be kept clean, including areas that house filtration, ventilation, or fans. Cheese shelves must 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-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 must 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 (Coudé and Wendorff 2013). 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.

Routinely vacuuming cheeses and their environment (including boards) starting at 3 months of age (when Scop begins to colonize the surface) is a mitigation strategy. A second larding can also help. Washing with hydrogen peroxide, regular washing and scrubbing of cheese, and surrounding the legs of shelving with diatomaceous earth can help. Grasso et al. (2023) demonstrated the effectiveness of gaseous ozone treatment on mite pest control.

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.

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 (Coudé and Wendorff 2013).

Summary of risks to quality and safety

- Syneresis (calcium lactate crystals) and/or 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*.
- Improper cleaning of boards, shelves and utensils can lead to harborage of unwanted yeasts, molds, and bacteria.
- Vegetative pathogenic bacteria (*Listeria monocytogenes*, *Salmonella* spp., pathogenic *E. coli*, *Staphylococcus aureus*) introduced by poor handling practices and non-hygienic equipment, failures in sanitation and other environmental causes.
- Cheese mite activity can compromise quality, and their residue may cause allergic reactions.
- 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
- Physical contamination of cheese by splinters from wooden boards or broken utensils used on surfaces.

Summary of best practices for mitigating risks to quality and safety

- Inspect all packaging materials upon arrival, recording lot numbers.
- Ensure surfaces of cheese are dry 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.
- Use kiln-dried hardwood boards for aging.
- 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.
- Test boards to be sure they are free of pathogens. Discard contaminated boards.
- Remove cracked or damaged boards that cannot be cleaned immediately.

Mite prevention and 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.
- Circulate filtered air (Section 4 Chapter 8).
- Brush, wash, or vacuum cheese to remove mites.
- Ensure proper placement and distribution of diatomaceous earth to help control mites.

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.
- Cleaning and sanitation records.
- Letters of guarantee from suppliers of packaging materials.
- Testing results, including pH, salt, moisture, etc.
- Environmental and board testing results.
- Inventory control for incoming and outbound products for traceability.
- Temperature and humidity control records for aging facility.
- Batch sheets.

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Section 4: Regulatory Compliance

Chapter 8: Good Manufacturing Practices (GMPs)

Good Manufacturing Practices (GMPs) are activities designed to ensure the safe production, handling, and storage of food. Anyone producing food for human consumption in the US today, regardless of size, is expected to follow Current Good Manufacturing Practices (CGMPs) as outlined in the Code of Federal Regulations part 117 Subpart B (CFR; US National Archives 2025), which are enforced by the Food and Drug Administration (FDA) (US FDA 2025).

This chapter covers the core elements of CGMPs for cheesemaking facilities, including:

1. Personnel (§117.10)
2. Plant and Grounds (§117.20)
3. Sanitary Operations (§117.35)
4. Sanitary Facilities and Controls (§117.37)
5. Equipment and Utensils (§117.40)
6. Processes and Controls (§117.80)
7. Warehousing and Distribution (§117.93)

1. Personnel (§ 117.10)

Employees play a key 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 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
- monitoring and follow-up
- records

Hygiene Procedures

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

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 communicable 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, including:
    - 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

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 to prevent items such as buttons, pens, or any loose items 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 colored uniforms for each area can help make sure that employees wear the right uniform in the right area. The same cont6rols should be taken to avoid cross-contamination between raw milk and thermized cheeses.
- Store street clothes and street footwear separately from clean plant uniforms and plant footwear.
- Keep footwear worn in the food production area clean and in good condition. Do not wear plant footwear outside the plant.
- 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. Specifying use of beard nets based on facial hair length is appropriate.
- 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.
- Gloves should be colored so that if they tear pieces will be easily found in product.

Employee Practices

- Trim fingernails regularly. 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. Wedding bands should not contain stones, as they can puncture gloves and are a potential foreign material risk.

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 (e.g., when handling raw vs. pasteurized or different allergens)
    - after handling non-food contact surface/equipment, chemicals, or dirty equipment
- Post hand-washing instructions by hand-washing stations.
- Proper hand washing is to:
    - rinse hands with warm water
    - apply soap from the dispenser
    - rub hands, fingers, nails, wrists, and up to elbows to form a lather for at least 20 seconds
    - rinse off the soap with warm water
    - dry hands and arms 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 gloves (and sleeve covers if used)
- 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, food storage areas, or in coolers that store cheese ingredients or finished product. These items include gum, candy, medicine, tobacco, keys, and phones.

Training

The plant owner or manager is responsible for making sure that employees are trained and understand the importance of good hygiene and duties, 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.

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.

Visitors and Contractors

The company should provide safety guidelines for all visitors to the facility. Visitors may be required to wear lab coats, jumpsuits, protective footwear, safety equipment, etc. A sign-in sheet should include: 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. Visitors should be accompanied by a trained employee at all times to ensure compliance.

2. Plant and Grounds (§117.20)

The plant itself, as well as the grounds around a cheese facility are under the control of the operator and must be kept in a condition that will protect against contamination of food. Adequate maintenance includes:

- Structures should be designed, constructed, finished, and maintained to avoid accumulations of dirt, dust or condensation that may contaminate products**.**
- Regardless of location, all processing areas should be supplied with positive pressure filtered air.
- Plants should be designed and maintained to make cleaning easy and effective. The Pasteurized Milk Ordinance provides some guidance in these matters (US FDA 2023).

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.
- Ceilings with exposed steel joints and H-beams are not satisfactory in areas where product is exposed to the atmosphere, unless a regular inspection and cleaning program assures they do not permit accumulation of dust, rust or condensation.
- Floors should be 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.
- 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.
- 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.

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 doors should open outward. Follow state and local fire codes.
- 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.

Lighting and Ventilation in Processing Rooms

- Provide at least 30 foot-candles of light intensity 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 with positive pressure to vent contaminants out of the processing room 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 microorganisms, 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.

Storage and Supplies

- Store all supplies, including cheese, at least 18 inches from walls and off floor on clean pallets or dunnage.
- Control humidity and temperature to prevent conditions detrimental to the product and container.
- 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.
- Cleaning and sanitizing Prerequisite Programs require proper storage (as above) of all chemicals, solvents, caustics, sanitizers etc., whether the materials are supplied in small spray cans or large drums.
- Safety Data Sheets (SDS) 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.

Coolers, Aging Rooms, and Caves

- Construct storage areas so that floors, walls, and ceilings can be kept neat, clean and in good repair.
- 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.
- Properly clean and maintain shelving, including boards (including wooden) used in the aging rooms.

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 foot 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 antibiotics, quality control and analytical testing.
- Vent laboratory facilities to the outside, and not into the processing areas.

Foreign Material Control

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.

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.

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.
- Calibrate, and check in-line metal detectors to ensure proper operation. 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.
- Processing aids (e.g. poly-webbing), packaging materials, gloves, and other non-metal materials that have direct contact with cheese should be a distinct non-food color (e.g. blue) so as to be easily identifiable as a foreign material.

Glass Breakage Policy

Where possible, avoid use of glass and plastic in processing areas. Where glass does exist, it should be shatterproof.

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.

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.
- Employees involved in breakage or cleaning activities must change uniforms and inspect boots for embedded glass.
- Record the breakage and the cause (thermal shock, impact, etc.), date, location, and risk of product contamination.
- Follow up and investigate ways to prevent reoccurrence.
- Segregate and dispose of product as needed.

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.

3. Sanitary Operations (§ 117.35)

Buildings, fixtures and other physical facilities of the plant must be maintained in clean, sanitary condition and in good repair to prevent food from becoming adulterated.

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. 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) (US FDA 2023).

- 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 (e.g., reservoirs, transfer containers, dosing equipment) labels 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 Safety Data Sheets (SDS) readily accessible for proper handling.
- Dispose of unused compounds in an approved manner.
- Fully train employees in chemical and personal protective equipment usage.

Cleaning

Proper cleaning, sanitizing, and maintenance of facilities will help eliminate environmental pathogens for a ready-to-eat (RTE) food exposed to the environment.

- 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.
- Create Standard Operating Procedures for clean-in-place (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. Validate SSOPs to ensure method is capable removing soils, biofilms and any microbial materials.
- 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.
- Avoid leaving cleaning equipment resting on floors (even if equipment is used to clean the floor) as this prevents drying and creates a potential for harborage.
- 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.
- 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.
- Equipment such as forklifts, 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.
- 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 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 or foot foamers 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 of when footbaths have been monitored indicating the date, time, concentration, 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, must be fully functional, and must be designated for hand-washing.
- Use hand-washing facilities that don't need to be operated by hand, e.g. foot, knee activated or timed.
- Provide functional soap dispensers, paper towels in enclosed dispensers, and properly constructed and easily maintained trash receptacles at each hand-washing station.
- Hand dip sanitizing stations are not a substitute for hand-washing stations. Ensure concentrations of chemicals on a regular basis (record concentration and date).
- 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

Pest and Waste Management

- 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.
- Dispose of dairy waste from the plant and premises consistent with requirements of the Environmental Protection Act.
- 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. Exclude fly-killing extermination devices that pose a risk of insects being expelled and contaminating product.
- 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 waste near the plant to avoid airborne contamination by ash and odors.

4. Sanitary Facilities and Controls (§ 117.37)

Each facility must be equipped with adequate sanitary facilities and accommodations, including water supply, plumbing, sewage disposal, toilet facilities, hand-washing facilities, and rubbish and offal disposal.

Hand-washing facilities

Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature. Multiple hand-washing stations are common in dairy facilities (e.g., at each entrance and near processing lines).

Water

Water and steam for use in various processing applications must be safe and sanitary. Product contact water is defined as ingredient water, water used for flushing product, and water used for washing and sanitizing purposes. 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.

- Test product contact water at regular intervals (e.g., quarterly) to determine whether the plant's water lines and filters are sanitary and effective. 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.
- Maintain a complete written and documented program to ensure use of safe/potable water in the preparation and processing of food. Monitor for microbiological (e.g., coliforms), chemical (e.g., agricultural), radiological, and physical (e.g., rust) contaminants. The testing program should cover the water source, in-plant water, reuse water, and steam.
- If the source of the water is a private well the analysis must be undertaken by the cheesemaker. 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.
- 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.

Steam

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 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 CFR § 173.310 (US National Archives 2025).
- 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.

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.

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 they are sanitary and in good repair. Store hoses off the floor.

5. Equipment and Utensils (§ 117.40)

Food-contact surfaces are those 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 include utensils and food-contact surfaces of equipment.

All plant equipment and utensils shall be designed and of such material and workmanship as to be adequately cleaned 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 contamination 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 (3-A 2025).

Keep space around equipment to allow proper cleaning and maintain good housekeeping. All parts or surfaces of equipment, pipes (except certain piping cleaned-in-place) or fittings, including valves and connections, must be accessible for inspection.

Cheese Vats and Drain Tables

In the dairy industry, 304 stainless steel is used for refrigerated storage tanks, pasteurizers, maturation tanks, cheese racks and other equipment. The 316 stainless steel is used for pasteurizers, plate and tubular heat exchangers, packaging machinery, ultra-filtration equipment, maturation tanks and other equipment. Cheese vats, tanks, and drain tables must be made of corrosion-free metal and, where relevant, provide uniform heating. The liner must be smooth, free from excessive dents or creases, and 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 (3-A 2025) and must be free from rough or sharp edges that might scratch the equipment or create metal particles.

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 (3-A 2025).
- Plastics and rubber-like materials should be of a contrasting, non-food color (such as blue) to easily identify any material in the 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.

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 (3-A 2025). 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 FDA regulations (US National Archives 2025), and with 3-A Sanitary Standards (3-A 2025).
- Hand-clean 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.

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.

6. Processes and Controls (§ 117.80) (also see Chapter Section 5 Chapter 13)

All operations in the manufacturing, processing, packaging, packing, and holding of food must be conducted in accordance with adequate sanitation principles. Raw materials and other ingredients and manufacturing operations are key areas of control under this CGMP.

- 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.
- Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration.
- All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

Product Testing

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.

- Determine a schedule for testing and random sampling of products.
- Strictly follow standard methods for the examination of dairy products (Wehr and Frank 2004).
- Determine what action will be taken of a positive (pathogen) finding.
- Keep meticulous records.

Environmental Testing

The purpose of an Environmental Monitoring Program is as follows:

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

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.
- 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.

This can be done on-site or by off-site plant laboratories or third-party laboratories.
- Use swabs in areas that are small and/or difficult to reach.

Types of environmental samples:

- Swabs can be purchased from many dairy supply providers. Follow the manufacturer's instructions to ensure correct swabs and swabbing procedures are followed for your facility.
- Use sterile sponges to sample 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.

Special consideration should be maintained when working with high risk and/or high moisture cheeses that can easily be contaminated.

7. Warehousing and Distribution (§ 117.93) (also see Section 5 Chapter 14)

Storage and transportation of products must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination as well as against deterioration of the food and the container (e.g., temperature control).

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 contamination.
- Maintain records of inspections, seals, and product and package integrity.

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.

Transportation activities performed by a farm are exempt from the rule.

Calibration of Measuring, Testing, and Inspection of 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 Products (Wehr and Frank 2004). 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 and occasionally throughout the shift to account for drift. Maintain documentation of the procedures. Store the pH probe in distilled water or pH storage solution 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 (NIST) thermometer.
- Indicating thermometers for use in pasteurizers are inspected at a minimum 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 (e.g., pasteurizer, silo, washing equipment). Verify chart accuracy and write or stamp identifying information on charts (US FDA 2023).
- 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).

References

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Section 4: Regulatory Compliance

Chapter 9: The Food Safety Modernization Act (FSMA) and Food Safety Plans (FSP)

In response to foodborne illnesses and hazardous events in the food industry in the early 21st Century, the U.S. Congress passed historic legislation in the form of the Food Safety Modernization Act (FSMA) in 2011 (US FDA 2017). 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. The role of FDA is to regulate food safety. The responsibility of each company is to ensure the safety of their food products.

The 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 *(e.g., dairy)* from processing to sale. FSMA alters FDA's role in food safety through four 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 met.

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 FDA annually.
- Create a Food Safety Plan with science-based preventive controls based on a hazard analysis prepared by a Preventive Controls Qualified Individual (PCQI).
- Create a Food Defense Plan (Chapter 10) with science-based mitigation strategies based on a vulnerability assessment.

Meticulous record keeping is essential to the application of a Food Safety system. If records do not exist, it is assumed that it did not happen. Food Safety procedures should be documented, and all documentation and record keeping should correlate to the nature and size of the operation. Establish a record keeping system.

Documentation examples include:

- Hazard analysis
- Determination of preventive controls
- Determination of parameters and minimum/maximum values

Record examples include:

- Monitoring control point activities
- Deviations and associated corrective actions
- Verification activities
- Modifications to the food safety system

Records that support various attestations (sales and food safety related documentation) and required personnel training in 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.

I. Definitions

Prior to covering elements of FSMA legislation, a few terms need to be defined.

Facility

Under FSMA, a facility is a domestic or foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FDA 2018b), in accordance with the requirements of part 1, subpart H of the Code of Federal Regulations (US National Archives 2025a).

Small Business

FSMA defines small business in 21 CFR § 117.3 (US National Archives 2025a) as "a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees."

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).

Covered Facility

A covered facility is a business that is required to have and implement a written Food Safety Plan (FSP; US FDA 2025a).

Qualified Facility

A qualified facility is a business that, because of its very small size, is required to only meet modified requirements under FSMA (US National Archives 2025a). However, qualified facilities are subject to good manufacturing practices requirements (See Chapter 8; US FDA 2018a).

Qualified Facilities, as defined by the Rule in 21 CFR § 117 (US National Archives 2025a), are those businesses that meet one of the following two definitions:

- *A facility that is a very small business;* ***OR***
- *A facility to which both of the following apply:*
    - *During the 3-year period preceding the applicable calendar year, the average annual* monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
    - The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

To be a Qualified Facility, the Facility must submit two attestations:

- 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; US DHHS FDA 2024) 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 laws. 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 the 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.

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 and 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 CFR § 117.315 (a) (2); US National Archives 2025a).

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 CFR § 117, Subpart D (US National Archives 2025a).

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 Preventive Controls rule as prescribed 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.

Qualified Individual

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.

Preventive Controls Qualified Individual

The Preventive Controls rule (US FDA 2011) requires each plant have a preventive controls qualified individual (PCQI), which is a qualified 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. Training may be performed internally or through a 3rd party, online or in-person. Although the rule does not specify a specific training program, the FDA has funded the Food Safety Preventive Controls Alliance (US FDA 2018a) to develop a model curriculum that can be used in-house to provide the needed training as can online CGMP or other food safety courses.

Food Safety Hazard Analysis and Risk-Based Preventive Controls (HARPC)

Hazard Analysis 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 Food Safety Plan (FSP) to minimize or prevent hazards from arising. See 21 CFR § 117.130 (US National Archives 2025a).

In the first step, food companies must evaluate the product and its processing for hazards. This is the portion of a FSP 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 Preventive Controls rule (US FDA 2025a) 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."

The facility must designate control measures at each CCP, 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 identified hazards.

II. Food Safety Plan

Under FSMA, food facilities must prepare, or have prepared, and implement a written Food Safety Plan (FSP; US FDA 2025a) and conduct a hazard analysis. A hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. Depending on the outcome of the hazard analysis, risk-based preventive controls and monitoring procedures and timelines must be included in the FSP, along with oversight and management of preventive controls, a supply chain program, and a recall plan (21 CFR § 117.126; US National Archives 2025a).

The written FSP must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals (PCQIs), and include the following information:

- **Hazard analysis** as required by § 117.130(a)(2);
- **Preventive controls** as required by § 117.135(b);
- **Oversight and management of preventive controls** as required by subpart G of this part;
- **Procedures for monitoring the implementation of the preventive controls** as required by § 117.145(a);
- **Corrective action procedures** as required by § 117.150(a)(1);
- **Supply chain program** as required by § 117.139(a);
- **Recall plan** as required by § 117.165(b)

The following few pages are divided into specific sections of an FSP. It may help the reader to follow along with the *"Selected Sections of a Food Safety Plan for Pepper Jack Cheese: Teaching Example"* included in the **Appendix** of this ACS Best Practices Guide for Cheesemakers. Some sections of the FSP, those that require more depth of explanation, are elaborated upon in subsequent sections.

II.1. Company Overview

The company overview section is designed to describe basic information about the company as well as what the company produces. At minimum, it should contain:

- **Company name**
- **Facility address**
- **PCQI name**
- **Plan date**

II.2. Product Description

For each product in the company profile, a product description is required. Accurately describing the product (e.g., “Pepper Jack Cheese”, instead of “cheese”) 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:

Product Name

The product name needs to be concise but accurate. 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, “Pepper Jack Cheese”, as it may have a standard of identity.

Ingredients

A complete listing is required of all ingredients. The ingredients are required to be listed on packaging labels from largest to smallest quantity (see 21 CFR § 101.4). For example, for Pepper Jack Cheese, the ingredients list might include raw milk, red pepper flakes, salt, enzymes, and cultures.

Food Safety Characteristics

The information here should include any particulars directly related to safety. Each ingredient should be evaluated 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).

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.

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.

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). Do note that raw milk cheeses must be stored above 35°F for 60 days, as in the example stated above.

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).

Intended Consumer

For the raw milk Cheddar with chives, one might 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, elderly, pregnant women, immunocompromised).

Intended Use

Since cheese is a ready-to-eat (RTE) product, it should be stated that it is an RTE product and that it may be combined with other foods or used as an ingredient.

Shelf Life

Shelf life refers to the number of days, weeks or months, and temperature a product can be held before being considered “unfit for sale” based on a printed sell-by date. This typically corresponds to quality, not to its being “unsafe to consume.”

Company Details

On the product description page, the company’s address and contact information, such as phone, fax, or email, should be included.

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.

II.3. Flow Diagram(s)

Flow Diagram(s) can help you identify the process steps in your business, from receipt of the raw milk, through the production process, as well as packaging and distribution steps. By creating Flow Diagram(s) of your operation, you will be able to break your processes down into component parts – called process steps.

- The accuracy of the flow diagram is critical in conducting a hazard analysis.
- The hazard analysis should contain information to justify the identification of proper preventive controls.
- Information in the FSP 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 dangerous microorganisms. In raw milk cheese, the manufacturing 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. 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.

II.4. Process Narrative

The process narrative section of the FSP is, essentially, the text associated with the Flow Diagram(s), designed to explain every aspect of processing, product flow and packaging in the facility.

II.5. Hazard Analysis.

Section III covers this material in more detail.

II.6. Process Preventive Controls.

Section IV.1. covers this material in more detail

II.7. Allergen Preventive Controls.

Section IV.2. covers this material in more detail

II.8. Sanitation Preventive Controls.

Section IV.3. covers this material in more detail

II.9. Supply-Chain Preventive Controls.

Section IV.4. covers this material in more detail

II.10. 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.

III. Hazard Analysis

To complete the FSP, 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. The 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 Food Safety Plan.

The steps in creating a hazard analysis include:

- To identify a Preventive Controls Qualified Individual (PCQI) and assemble a Food Safety Team.
- Develop the product description and Flow Diagram.
- Follow the list of steps to complete the Hazard Analysis Worksheet.

III.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 CFR *§* 117.130 (US National Archives 2025a).

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?).

III.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 purposes. 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 CCP. 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.

III.3. Steps to Monitor Procedures

Monitoring

The Preventive Controls rule (REF) 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.

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 set by the facility. 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 control is lost, affected product should be put on hold to determine disposition.*

If monitoring is not continuous, then the 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.

III.4. Establish Corrective Action Procedures

As the risk-based preventive controls and control measures in a properly designed food safety system are monitored, any instances of deviation from the control measures must be identified, evaluated with respect to cause, and corrected.

Specific corrective actions must be developed for each control point in order to deal with deviations when they occur.

The Corrective Action steps of the Preventive Controls rule can be found in 21 CFR § 117.150. 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.

III.5. Establish Verification Procedures

The Preventive Controls rule requires that food facilities verify that the FSP preventive controls are consistently implemented and are effectively and significantly minimizing or preventing hazards. The frequency of verification should be sufficient to confirm that the Food Safety system is working effectively. Where possible, validation activities should include actions to confirm the efficacy of all elements of the FSP. See 21 CFR § 117.165 (b).

Verification activities 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:

- *Validation in accordance with 21 CFR § 117.160.*
- *Verification that monitoring is being conducted as required by 21 CFR § 117.140 (and in accordance with 21 CFR §117.145).*
- *Verification that appropriate decisions about corrective actions are being made as required by 21 CFR § 117.140 (and in accordance with CFR §117.150).*
- *Verification of implementation and effectiveness in accordance with 21 CFR §117.165; and*
- *Reanalysis in accordance with 21 CFR § 117.170.*

Verification and auditing methods, procedures, and tests (including random sampling and analysis) can be used to determine if the Food Safety system is working correctly:

- *Calibration of process monitoring instruments and verification instruments (or checking them for accuracy);*
- *Product testing, for a pathogen (or appropriate indicator organism) or other hazards;*
- *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.*

Requirement to Re-analyze

After developing and implementing an FSP, the food facility must periodically evaluate its Food Safety system. See 21 CFR § 117.170. You must conduct a re-analysis of the FSP as a whole at least once every 3 years.

You must conduct a reanalysis of the FSP, or the applicable portion of the FSP:

- *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 CFR § 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 FSP 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 PCQI must perform (or oversee) the reanalysis.

You must conduct a re-analysis of the FSP when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

Additionally, FDA 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 records. If no changes are necessary after a reanalysis of the Food Safety 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.

IV. Preventive Controls (§117.135; US National Archives. 2025a)

Preventive controls are risk-based proactive safety measures required under FSMA to prevent or significantly minimize potential food safety hazards. Facilities that produce human food have the flexibility to tailor preventive controls to address hazards that occur in their particular facilities. Written preventive controls must be implemented to ensure that hazards requiring preventive control will be minimized to ensure that food is not adulterated, including process controls, food allergen controls, sanitation controls, and other controls.

Preventive Controls cover five key areas in production of food:

1. ***Process Preventive Controls***
2. ***Allergen Preventive Controls***
3. ***Sanitation Preventive Controls***
4. ***Supply-Chain Preventive Controls***
5. ***Other controls***

Preventive Controls are a vital part of a Food Safety Plan (FSP), which manufacturers and processors, registered with FDA, are required to develop and implement. The FSP 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, *Listeria monocytogenes* has been known to be found in cheesemaking plants. The severity of the illness and high mortality rate ranks *Listeria monocytogenes* as a high-risk pathogen.

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.

The 21 CFR § 117 (US National Archives 2025a) and Chapter 8 cover Current Good Food Manufacturing Practices.

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 (US FDA 2017).

IV.1. Process Preventive Controls

Process Controls, as defined in 21 CFR § 117.135 (US National Archives 2025a), 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.

IV.2. Allergen Preventive Controls

Food allergen controls include procedures, practices, and processes to control food allergens. Allergen Preventive Controls specifically, proactively, address allergen labeling and allergen cross-contact (i.e., when an allergen comes into unintentional contact with another food). For some people, dairy is a food allergen, so it must be declared on a label even if it is obvious.

Nine food allergens (listed in order of the number of people affected) must be declared, including: Peanuts, Tree Nuts (e.g. almonds, pecans, walnuts), Crustaceans/Shellfish (e.g. crab, lobster, shrimp), Eggs, Milk and Dairy Products, Fish, Soybeans, Wheat, and Sesame.

Processing errors or oversights that result in allergen-containing product contamination include:

- 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 allergens)

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

- Ensuring protection of food from allergen cross-contact, including during storage, handling, and use.
- 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 (FD&C Act; US FDA 2018b).
- 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 products last.
- Implement a 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 annual 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 uses 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.

IV.3. Sanitation Preventive 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 unsanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

This is especially important when manufacturing high moisture or high-risk cheeses.

IV.4. Supply-Chain Preventive Controls

The FSMA rule on Preventive Controls for Human Food requires 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 these foods are received only from approved suppliers or temporarily from unapproved suppliers whose materials are subject to verification activities before being accepted for use.

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.

Conduct a hazard analysis to determine if any ingredient brought into the facility is a source of a biological, chemical, or physical risk. If a hazard is identified that (1) requires a preventive control and (2) the control will be applied in the facility's supply chain, the ingredient must be subject to supply-chain preventive control (US FDA 2025a). Document preventive controls applied by the supplier, verification activities, verification procedures, receiving procedures, and records (e.g., certificates of analysis (CoA) required for every lot of red peppers).

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 of the ingredients 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.

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.

Approved Vendor Lists

QA/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 all allergens.

Bear in mind that rework should be treated as a raw material. The FDA defines rework as "clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food" (21 CFR 117.3). 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 control hazards, do not need to have a supply-chain program for that hazard.
- Covered food facilities are responsible for ensuring these foods are received only from approved suppliers or temporarily from unapproved suppliers whose materials are subject to verification activities before being accepted for use. (Approved suppliers are those approved by the facility after 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

Any outside vendor should be assessed for its ability to supply high quality products and services. Document approved vendors (primary and back-up suppliers). Approval may be based on:

- Product quality
- Microbiological criteria
- Recall history
- Product and service availability
- Product price
- Compliance with traceability rules (unless vendor is exempt)

- Liability insurance sufficient to cover the business transaction

Supplier Audits

Annual onsite audits are required for suppliers of ingredients associated with hazards *that are not subsequently controlled (*e.g., a producer who receives raw milk is controlling its biological hazard if pasteurizing it. This producer is not required to collect annual site inspections of the source farm*)* that can cause serious adverse health consequences or death. Independent third-party audits are ideal, although second-party audits are acceptable if conducted by a trained auditor. Regulatory inspections may be adequate, but due diligence will include additional document review.

A supplier questionnaire can ask about the existence of various programs (food safety/HACCP, pest control, environmental monitoring, etc.) based on specific plant needs.

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).*

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 the 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.
- The 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 that indicates that the sheet was reviewed.

IV.5. Other Controls

Examples of other controls include hygiene training and other current good manufacturing practices. Additional information regarding processes and controls can be found in 21 CFR § 117.80.

Examples include but are not limited to:

- 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.
    - 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.

V. Traceability of Ingredients, Packaging, and Finished Product

The Traceability Final Rule is scheduled to go into effect in 2028, but it is a best practice to follow now.

The Traceability Final Rule (FSMA Sec. 204: Enhancing Tracking and Tracing of Food and Recordkeeping; US FDA 2024b) requires that any entity that manufactures, processes, packs, or holds foods on the food traceability list (FTL; US FDA 2024a) must establish and maintain a traceability plan. Hard cheeses as defined in 21 CFR 133.150 (US National Archives 2025a) are **not** currently included on the Food Traceability List (FTL), but fresh soft or soft unripened; soft ripened or semi-soft; and cheese made from unpasteurized milk (other than hard cheese) are on the FTL.

In addition to the FTL being subject to change, the traceability plan maximizes efficient execution of a recall, so best practice is to create a traceability plan for all cheeses.

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.

Cheesemakers must document the lot numbers of raw materials and the amount of each material used.

- 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.
    - Added ingredients.
    - Lot codes of ingredients.
    - Amount of each ingredient added.
    - Vat number.
- Record lot codes of packaging materials.

At the end of the shift, 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 finished product code should then be placed both on the product and on the master shipping cases.

Terms used in the Final Rule are listed and defined below:

- Critical Tracking Event (CTE): growing, receiving, transforming, creating, shipping.
- Key Data Element (KDE): recorded at each CTE. Examples of KDEs are batch number, lot number, or reference number.
- “Reference document”: a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the KDEs for a CTE in the supply chain of food. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.
- “Reference document number”: the identification number assigned to a specific reference document. In addition to being KDEs for certain CTEs, reference document numbers might be used in an electronic sortable spreadsheet requested by FDA to indicate the particular reference documents that contain information included in the spreadsheet.

The traceability plan must include:

- Description of the procedures used for maintaining records, including the format and location of required records.
    - Key Data Elements (KDEs) are required for specific supply chain activities (Critical Tracking Events, or CTEs).

- Description of procedures used to identify the FTL foods manufactured, processed, packed, or held.
- Description of how traceability lot codes are assigned to FTL foods
- e.g., a case GTIN + internal lot code based on date could represent the TLC assigned by the producer.
- Statement identifying point of contact for questions regarding the plan and records.
- The plan must be updated as needed, and the previous plan must be retained for 2 years after updating.
- Must maintain an electronic sortable spreadsheet.

Examples of CTEs and associated KDEs that would be considered in your Traceability Plan are listed below.

Critical Tracking Event	**Key Data Elements**
Receiving	• Traceability lot code for the food • Entry number assigned to the food (FSVP items) • Quantity and unit of measure of the food • Product description • Location description for the immediate previous source (other than a transporter) • Location description for where the food was received • Date the food was received • Location description for the traceability lot code source or the TLC source reference • Reference document type or reference document number (e.g., BOL, PO, invoice) • The producer sends these KDEs to the next recipient in the supply chain (us, or a distributor if applicable). A distributor only passes these KDEs along—it does NOT assign any new traceability lot codes
Transformation: FTL food(s) used as ingredient(s)	• KDEs must be linked to the new traceability lot for the food • Traceability lot code for the food • Product description for the food to which the traceability lot code applies • For each traceability lot used, the quantity and unit of measure of the food used from that lot

	• These KDEs relate to anything cut/packed, and anything given a new label that changes the identity (e.g., brand name). Transformation requires assignment of a new Traceability Lot Code.
Transformation: new food produced	• KDEs must be linked to the new traceability lot for the food • New traceability lot code for the food • Location description for where the food was transformed (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference • Date transformation was completed • Product description for the food • Quantity and unit of measure of the food • Reference document type and reference document number (e.g., batch code)
Shipping	• Maintain and provide these KDEs • Traceability lot code for the food • Quantity and unit of measure of the food • Product description of the food • Location description for the immediate subsequent recipient (other than a transporter) of the food • Location description for the location from which you shipped the food • Date the food shipped • Location description for the traceability lot code source or the traceability lot code source reference • Provide these KDEs to the next transfer or wholesale recipient. KDEs are NOT provided to final consumers. • Reference document type and reference type number (maintain only)

Exemptions to the Traceability Final Rule:

- Small retail food establishments and restaurants with average sold food value of no more than $250,000 (full exemption from the rule).
- If average sold food value does not exceed $1 million, these establishments are exempt from the sortable spreadsheet requirement.

- Because most state cottage food programs set a ceiling for participation at no more than $50,000 in annual sales, it is believed most cottage food producers will be exempt from this rule.
- When a retail food establishment or restaurant purchases food directly from the farm where it was produced, they are only required to maintain a record documenting the name and address of the farm that was the source of the food, and they must maintain that record for 180 days.

VI. Recall plan

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. Recalls may be initiated by the firm or the FDA (see CFR 21 Chapter 1 Part 7; US National Archives 2025b).

"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.

Recall policy (21 CFR 7.40; US National Archives 2025b)

A facility must have a written recall plan if the hazard analysis identifies a hazard requiring a preventive control. The recall plan must describe the procedures to perform a recall of the product and include procedures to notify consignees, to notify the public when necessary, to conduct effectiveness checks, and to appropriately dispose of the recalled product (US National Archives 2025b).

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.*

Firm-initiated recall (21 CFR 7.46; US National Archives 2025b)

Firms that initiate a recall should notify their FDA district office immediately. If the FDA deems the recall necessary, the following information should be provided by the firm (per 21CFR7.46; US National Archives 2025b):

- *Identity of the product involved*
- *Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered*
- *Evaluation of the risk associated with the deficiency or possible deficiency*
- *Total amount of such products produced and/or the timespan of the production*
- *Total amount of such products estimated to be in distribution channels*
- *Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts*
- *A copy of the firm's recall communication if any has been issued, or a proposed communication if none has been issued*
- *Proposed strategy for conducting the recall*
    - The recall strategy addresses how the recall will be conducted, e.g., its depth (consumer, retail, or wholesale level), the chosen method to notify the public, and level of effectiveness checks. See 21 CFR 7.42 (US National Archives 2025b) for FDA guidance regarding the recall strategy.
- Name and telephone number of the firm official who should be contacted concerning the recall.

Recall communications (21 CFR 7.49; US National Archives 2025b)

- 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
- Determine where this product will be kept once received. Place “Hold” tags on product once received
- Document quantity of product received
- Periodically visually audit the product is still on hold and the entire quantity is there until the final disposition is determined

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.

- Have a statement prepared with a list of necessary information to provide to reporters.
- Post similar information on your website and/or local news stations
- Pre-arrange legal representation and determine what documents may be required by insurance

Recall status reports (21 CFR 7.53; US National Archives 2025b)

Submit status reports to your relevant FDA district office. The interval will be specified by the FDA depending on the recall's urgency but is usually every 2-4 weeks. Status reports should contain the following information:

- *Number of consignees notified of the recall, and date and method of notification*
- *Number of consignees responding to the recall communication and quantity of products on hand at the time it was received*
- Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration)
- Number of products returned or corrected by each consignee contacted and the quantity of products accounted for

General industry guidance (21 CFR 7.59; US National Archives 2025b)

- 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.

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Section 4: Regulatory Compliance

Chapter 10: Food Defense, Complaint Management, and Crisis Management

As defined by the Food and Drug Administration (FDA), Food Defense is the effort to protect food from acts of intentional adulteration or tampering (FDA 2024). As a producer of foods for human consumption, you are required to prepare or have prepared an implement a written food defense plan to reduce the risk of tampering or other malicious, criminal, or terrorist actions on food. The US National Archives outline strategies for the mitigation of intentional adulteration in the Code of Federal Regulations (Title 21 Chapter I Subchapter B Part 121; US National Archives 2025).

Inclusions and Exclusions per FSMA

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, so dairy farms have been specifically included in FSMA's Intentional Adulteration Rule (US National Archives 2025); no other types of farms are included.

The dairy industry participates in this program voluntarily and is FDA-regulated against accidental contamination through the Pasteurized Milk Ordinance (PMO; US FDA 2023).

Very small businesses (less than $10,000,000 in annual sales) are exempt from this rule.

Food Defense Plan (§121.126)

The food defense plan addresses processes that are vulnerable to intentional adulteration.

The written plan must include:

- a vulnerability assessment (§121.130(c))
- mitigation strategies (§121.135(b))
- monitoring procedures (§121.140(a))
- corrective action procedures (§121.145(a)(1))
- verification procedures (§121.150(b))

To assist food producers, the FDA has created a Food Defense Plan Builder (US FDA 2024).

Steps

- Assemble your Food Defense Team and appoint a food defense coordinator. Any individuals performing activities associated with the plan must be qualified (via education, training, experience, or combination thereof).
- Conduct or have conducted a vulnerability assessment for each type of food manufactured, processed, packed, or held at your facility. The assessment must consider the possibility of an inside attacker. Explain why each point was or was not identified as an actionable step.
    - Potential public health impact
    - Degree of physical access to the product
    - Ability of attacker to successfully contaminate the product
- List mitigation strategies management components
    - Broad-based controls already in place may include: limited access, building security and lighting
- Monitor food defense according to implementation schedule
- Conduct food defense corrective actions appropriate to the nature of the actionable process step and the nature of the mitigation strategy
- Verify that appropriate decisions about food defense corrective actions are being made as required (and are significantly minimizing or preventing the significant vulnerabilities)
- Conduct reanalysis of the food defense plan every three years (at minimum)
- All staff should be trained in your plan.
- Maintain all records, including training records.
- The food defense plan must be retained for at least 2 years after its use is discontinued.

Complaint Management

Record any complaint information and complete an investigation at the facility and/or retail outlet. 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

Recording of the Initial Complaint Information

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 to 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

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.

his 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)

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

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

- Look for patterns in quality complaints. Even if a recall or withdrawal hadn't been prompted, there could be other sources of quality complaints benefiting from root cause analysis. For example, complaints that spike in the hot months could indicate issues with shipping temperatures.

Crisis Management

Unexpected events may be human or natural catastrophes like tornadoes, fire or flood, or even employee illness. These events may result in a loss of public trust and confidence. Develop a crisis management plan to handle unexpected events.

- Establish a team
- Assess the risk
- Determine the impact
- Plan the response
- Solidify the plan
- Review and update

The crisis plan should include:

- A coordinated response plan for food defense emergencies.
- Roles of staff involved in the plan.
- Establish who within the company and/or facility, is the key authority according to the plan
- Establish the alternate chain of command
- Train individuals in response plan
- Establish safety/defense partnerships with local, state and federal law enforcement agencies, other public safety and health agencies and surrounding community leaders.
- Define who maintains contact and contact information for these individuals
- Update information regularly
- Specify plan for emergency shut down.
- Define who has the authority to initiate an emergency shut down
- Specify who will notify authorities and the public
- Specify the criteria for initiating a shutdown
- Outline procedures for securing the facility following shut-down
- Outline a plan for emergency evacuation i
- Identify who has the authority to initiate an emergency evacuation
- Specify how employees are accounted for in the event of an evacuation
- Specify an offsite meeting place, if needed
- Establish emergency contact for employees
- Define mechanisms for employees to identify and refer suspicious incidents or site security breaches
- Outline how to handle these situations
- Identify point persons for incident identification and reporting
- Document training

References

U.S. Food and Drug Administration (US FDA). 2024. Food defense. Available at: https://www.fda.gov/food/food-defense. Date accessed: 5/26/2025.

US FDA. 2024. Food defense plan builder. Available at: https://www.fda.gov/food/food-defense-tools/food-defense-plan-builder. Date accessed: 5/26/2025.

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Section 4: Regulatory Compliance

Chapter 11: Inspections

The purpose of a food facility inspection is to protect public health by ensuring the safety and wholesomeness of the food supply. Inspections determine whether a facility is in compliance with applicable food safety regulations. These inspections aim to detect contamination, prevent foodborne illnesses, and enforce compliance with food safety standards throughout the entire food chain. Inspections and testing are routine in the operation of a dairy foods processing business, so you should expect to undergo both scheduled and unannounced facility and equipment inspections. FSMA emphasizes the shared responsibility between federal, state, and local authorities in ensuring food safety throughout the supply chain (US FDA 2017).

Inspections can originate with the local/state regulatory body and/or the FDA and they often have a different focus depending on the purpose of the inspection (quarterly pasteurizer checks, FSMA inspection, etc.). Regulatory officials are tasked with the responsibility of ensuring that you are manufacturing in a clean and safe facility utilizing proper procedures and producing a safe and wholesome product. Your facilities, equipment, raw inputs, and final products will all be subject to inspections or testing at various times.

You should set out in your value-added dairy processing venture with the mindset of developing a trusting relationship with your regulatory agencies built on open and clear communication. Enlist for their assistance in preventing or correcting problems as soon as they are identified. Regulatory officials are available for consultation, interpreting regulations, facility inspections, environmental monitoring and testing, and both raw milk and finished product testing. Remember, regulatory agency staff and inspectors are there to assist you in achieving your dairy processing goals. They are tasked, however, with ensuring that this is done in a safe manner that complies with applicable regulations. To prepare for an inspection, it is advisable for you to review the applicable regulations to identify (and correct) potential gaps in their facility and food safety and quality systems.

Because of the delicate nature of milk and a historical association with pathogens, the dairy foods industry has self-regulated for almost 100 years to ensure product safety and quality. Cottage food laws (for “non-potentially hazardous foods”) do not apply to dairy. Dairy as very targeted regulations and regulatory bodies that other small scale food items or processed foods do not. Dairy products can be regulated under two separate and distinct sets of regulations based on their grade. States can have separate regulations and/or adopt USDA regulations. Grade “A” dairy products are regulated by the "Grade 'A' Pasteurized Milk Ordinance" (PMO) (US FDA 2023a). Grade “B”, also called Manufacturing Grade, can be regulated by a separate set of regulations found in the Federal Code of Regulations (7 CFR 58) (US National Archives 2025c) and the USDA Guidelines for Milk Manufacturing Purposes (USDA AMS 2021). Dairy processing plants can be held to Grade “A” standards as described in the PMO; however, not all states simply adopt the PMO for their regulations. It is imperative to

speak with your local regulatory agency to be aware of the regulations that must be adhered to in your area.

One such special consideration is the ongoing FDA Food Safety Modernization Act (FSMA) requirements (US FDA 2017; See Section 4 Chapter 9). Some FSMA authorities have gone into effect, such as the FDA's new authority to order companies to recall food, while others require the FDA to prepare and issue regulations and guidance documents. As another example, FSMA Section 204(d), which deals with additional traceability records for certain foods, becomes effective on January 20, 2026.

FSMA emphasizes the shared responsibility between federal, state, and local authorities in ensuring food safety throughout the supply chain. In fact, many federal monitoring programs collaborate with state agencies for aspects of administration. For example, the FDA has a memorandum of understanding with the National Conference on Interstate Milk Shipments (NCIMS) a voluntary organization directed and controlled by the member states and open to all persons interested in its objective of promoting the availability of a high-quality milk supply. NCIMS is governed by an Executive Board whose members include representatives from state departments of health and agriculture, the FDA, the US Department of Agriculture (USDA), and industry. State NCIMS Milk Safety Regulatory Agencies are responsible for permitting, inspection and enforcement of sanitation requirements on NCIMS dairy farms and in NCIMS milk plants. The FDA's primary function within this voluntary National Cooperative Program is to provide technical assistance to the states in the implementation and enforcement of their milk regulations, which are to be substantially equivalent to the PMO.

Type of Inspections

Regulatory services typically perform three types of inspections:

- ***Surveillance inspections*** are conducted to assess compliance with a regulation or to focus on an emerging trend in food safety. Surveillance inspections fall into two categories:
  - *Routine inspections* are conducted to assess regulatory compliance.
  - *Targeted or Directed inspections* are based on specific food safety risks. Criteria for conducting a targeted inspection may include information related to an outbreak, risk factors that may lead to contamination, food consumption patterns, regional impacts, food safety trends and history of compliance.
- ***Compliance Follow-Up inspections*** serve to verify compliance and/or corrective actions in the wake of previous violative inspections, violative samples or following official agency action (e.g., a warning letter or enforcement action).
  - Prior observations of non-compliance, such as insanitary conditions or documented past failure on the part of a facility or a farm to implement an effective food safety plan, as required, may give rise to a compliance follow-up inspection.
- ***For-Cause inspections*** are a type of compliance follow-up conducted to evaluate a firm's actions in response to a specific issue, such as an outbreak of foodborne illness, consumer complaint, or a product recall. For-cause inspections are often expedited.

Frequency

Confirm your specific inspection protocols and frequencies with your state/local regulatory agency. States can have separate regulations and/or adopt USDA regulations. Dairy processing plants can be held to Grade “A” standards as described in the PMO, however not all states simply adopt the PMO for their regulations. PMO Section 5 outlines the inspection of Grade A dairy farms and milk plants. PMO Section 6 outlines the examination (sampling) of milk and/or milk products.

A key FSMA mandate 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 (establishment of your business) and no less than every three years thereafter. Non-high-risk facilities must be inspected at least once every five years.

The following are standard routine inspection frequencies:

- Milk Tank Truck-once every 24 months
- Bulk Milk Hauler/Sampler-once every 24 months
- Milk Plants-once every 3 months
- Equipment-every 3 months
- Milk & Milk Products-at least 4 samples during any consecutive 6 months
    - Seasonal/Sporadic Product-collected during each month of production.

Expectations and Preparation

The following is intended to be a walk-through of a cheese processing plant inspection. This walk-through is not all-inclusive but highlights some of the major areas of an inspection (Chapters 2, 3, 8 and 9 in this Best Practices Guide). Regulatory officials may reference PMO Section 7, Items 1P-22P. Each company should have in place a set of Good Manufacturing Practices (GMPs), which are read and signed by each employee outlining their responsibilities (Section 4 Chapter 8), and a Food Safety Plan (Section 4 Chapter 9).

Pictures may be taken as well for documentation purposes. There is no legal requirement for a producer to allow photographs to be taken. However, refusing to allow photography could be viewed as limiting the inspection, potentially leading to regulatory action such as warning letters or even an adulteration charge. It's important to be prepared to explain any restrictions on photography to regulatory services.

Regulatory officials will identify themselves to the owner, operator, or agent in charge. They will typically conduct a system-based inspection beginning with an interview, during which they verify and/or gather administrative information (e.g., legal name, size of business, number of employees, types of products produced). If there are previously observed conditions or practices of concern to public health, the regulatory officials will typically ask about corrective actions taken since the prior inspection and verify correction has been implemented. The regulatory officials also will select products to cover and collect operational information (e.g., hours of operation, production practices, sanitation schedules, raw ingredients sourcing, storage of raw materials and finished products, packaging, and distribution).

Subsequently, regulatory officials will typically conduct a full walk-through of your establishment – from the receipt of ingredients to the distribution of products while observing processes, manufacturing, procedures and employee practices. Generally, they will want to view all areas of your facility used to produce, pack, store, and ship 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 focus on learning the processes you use to produce artisan cheeses, the environment in which products are produced and stored, practices and procedures used for effective cleaning and sanitizing, and the controls in place to ensure the safety of the product you produce and distribute. Regulatory officials also may review written procedures and records and may speak with employees to help determine to what extent processes and procedures are being implemented.

Following the walk-through, regulatory officials may request additional records to review to help them examine specific operational areas. During the inspection, practices are evaluated, and documents are reviewed for compliance with applicable requirements. Flowcharts, photos, and schematics are encouraged to help simplify the process. Be prepared to review programs, procedures and have the ability to complete a traceability exercise for your product, packaging, and ingredients.

If a full-scope preventative controls inspection is done, a review of the food safety program, including hazard analysis, control of hazards, verification, and written programs will be conducted.

At the conclusion of the inspection, the regulatory officials may provide a written list of significant inspectional observations and may discuss labeling deviations as well as any lesser observations they may have made during the walk-through. This close-out discussion is an opportunity for you to ask questions about the investigators' observations, discuss any corrective actions they may suggest, and address corrective actions they plan to take going forward.

After the close of the inspection, the agency reviews the information gathered to assess compliance and consider further action, if warranted. Once the inspection is closed, a copy of the report will be sent to the individual identified at the start of the inspection as the owner, operator, or agent in charge.

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

Raw Milk Receiving

A dedicated area for raw milk receiving is required. State laws vary regarding 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 raw milk from outside contamination. The construction and design of this area is inspected to ensure compliance with regulations. 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.

Raw Milk Storage

Indicating thermometers used on raw milk storage tanks should comply with the requirements of the PMO (US FDA 2023a). 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 (PMO; US FDA 2023a). For more information, see Section 2 Chapter 3 of this guide. Beta lactam antibiotics test results should be available. The documentation for these test results will be reviewed daily.

Processing

No cross-connections are allowed between raw and pasteurized products, 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 inspected, timed, and sealed according to the PMO or your state's mandated frequencies. 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.

Time and temperature requirements will vary drastically when comparing batch or vat pasteurizers and continuous flow or HTST/HHST pasteurizers. When batch pasteurizing, the product must be held at or above minimum temperature (150°F) for at least 30 minutes. Vat pasteurization also requires the monitoring and recording of airspace temperatures, which must be 5°F above the minimum required pasteurization temperature during the holding period. Continuous flow pasteurization systems must meet the minimum 150°F (66°C) for not less than 30 seconds. However, these systems can vary widely in design and thus timing, so they should be tested and approved by regulatory officials. Regardless of the system type, recording and verification of pasteurization time and temperature is required and will be reviewed by regulatory officials. PMO Item 16P will often be referenced by regulatory officials.

According to the U.S. Code of Federal Regulations, 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.

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, such as culinary steam from airspace heaters, 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 regulatory official will determine air flow throughout the plant. They 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.

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. Plant personnel should be available to assist with the disassembly of equipment.

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.

All available storage and processing vessels will be inspected for cleanliness, including:

- Silo tanks
- Pasteurized storage tanks
- Pasteurizers
- Processing vats
- Balance tanks
- Transport tankers

A black light may be used to check for milkstone on or cracks in the equipment. The presence of milkstone is an indication of insufficient or poor cleaning.

Packaging

Since post-pasteurization contamination can be a 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 producing a pasteurized processed cheese food or spread, the filling of containers is also applicable. If packaging cheese, the product must be protected from environmental sources of contamination. In addition, air quality should be monitored.

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 (PMO Appendix N).

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

Water Supply

Water purity is extremely important, as water may be a source of contamination. See PMO Items 7P. 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 (US FDA 2023a).

Waste and Pest Management

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.

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.

A pest control plan including diagrams for traps should be reviewed.

Food and Drug Administration

Since the FDA regulates food products produced and shipped in interstate commerce, artisan cheese is under their purview. 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. Inspections are an important part of the FDA's food safety program. They are used to verify compliance with the laws administered by the FDA, as a surveillance tool in the wake of outbreaks, and to follow up on specific issues such as a product recall or when other risk factors have been identified (US FDA 2024a).

The FDA considers today's global food supply and markets and prioritizes inspections using a risk-based approach. The FDA's risk-based approach seeks to form a complete understanding of a farm's or a facility's food safety system. Thus, FDA investigators can

focus on significant observations that may adversely affect public health, and to, when appropriate, promote voluntary corrections. Sometimes state partnering agencies act on behalf of the FDA.

The FDA has created a web page called “Inspection References” (US FDA 2023c) that houses the Compliance Guides, Compliance Policy Manual, and the Investigations Operations Manual. All forms used during inspections are publicly available on this site.

When the FDA conducts an inspection, they will identify themselves by displaying their credentials and a Notice of Inspection (FDA Form 482) to the owner, operator, or agent in charge.

The management of the facility or farm is requested to submit to the FDA or other regulatory authority a written response addressing corrective actions within 15 working days of the inspection. The FDA highly recommends written responses to both documented observations listed on the FDA-483 or FDA 4056 as well as verbal observations discussed at the close-out meeting, as the FDA considers the written response and corrective actions when determining whether regulatory action should be taken.

At the conclusion of the inspection, the investigators may indicate No Action Indicated (NAI), Voluntary Action Indicated (VAI) or Official Action Indicated (OAI) (US FDA 2025b). The investigator may not (if NAI) or will provide (VAI or OAI) a written list of significant inspectional observations (known as an FDA-483 Inspection Observations and FDA-4056 Produce Farm Inspection Observations).

Sampling & Testing

In addition to the inspections listed above, environmental monitoring and raw milk and finished product testing may also take place. Some states may allow you to perform some of these tests yourself, while other states may perform this testing or require that you work through your department of agriculture or contract with a 3rd party laboratory. Communicate with your state regulatory agency to ensure that you know the type and frequency of sampling that is required. Regulatory services will collect 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. Producers MAY collect duplicate samples in order to test independently if desired, but be aware that FDA can request the sample results. PMO Section 6 outlines the examination (sampling) of milk and/or milk products.

Regulatory officials 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 (depending on zones). 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.

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; US FDA 2024a). Results of analysis: preliminary Cannot Rule Out (CRO) results may be available in as little as 3 days and full analytical results are usually completed within 14 days. It is a best practice to hold any product associated with a regulatory sampling event until results are recieved.

Raw Milk

- The raw milk used to manufacture your dairy food product(s) must be tested prior to processing.
  - Appendix N of the PMO (US FDA 2023a) outlines drug residue testing methods and required records.
  - While all tests are not required for all processors, some examples of the types of tests performed include the following:
    - Product Temperature
    - Growth Inhibitor (GI) for antibiotics
    - Somatic Cell Count (SCC)
    - Standard Plate Count (SPC)

Finished Product

- Samples of finished products are tested on an established frequency. The specific tests and frequency required vary based on product. Some states (e.g., Pennsylvania) outline requirements in their state Code. Review the requirements with your state regulatory officials.

  Tests may include the following:

  - Product temperature
  - Coliform count
  - Alkaline phosphatase
  - Aerobic plate count
  - Growth Inhibitor (GI) for antibiotics

Environmental

- Environmental monitoring (See Section 4 Chapter 9) also needs to be done, as required by FMSA's Preventive Controls for Human Food rule (US FDA 2017) when ready-to-eat products are exposed to the environment, such as in the packaging of cheese. The regulatory offical will review the plan for:
  - Results will inform if your personnel training and practices are successful, you have a good sanitary design of facilities and equipment, and your sanitation controls are performing correctly.
  - A strong environmental monitoring program will allow for documented corrective actions as soon as any concerns are identified to prevent product contamination.
  - In addition to the environmental monitoring that is performed at the facility, the FDA conducts environmental sampling to ensure that the processing facility environment does not contain harmful pathogens such as *Salmonella* spp. or *Listeria monocytogenes* that may contaminate the finished product. Test

results for samples taken will be communicated quickly, and for positive results for contaminants, the FDA will consider several regulatory and enforcement options such as product recall, public warnings, or citations.

Conduct

Every regulatory official should present themselves in a professional manner, both in dress and in action. They should comply with your facility's GMPs and food safety policies. For example, 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.

The regulatory officials should review their inspection plans with the owner and/or appropriate team members at the start and end of the inspection. This includes the reason for the inspection and the approximate length of time that the inspection will take place. Depending on the nature of the inspection, they may also describe the path of travel through the facility, and what and where samples and measures will be taken. This will ensure access where necessary, safety of the investigator, and attention by the operator.

It is important that the regulatory official provides comments on the inspection during its progress. This permits timely questions and answers and provides a valuable teaching point, but moreover, it helps to clarify any misunderstandings or disagreements. At the exit meeting, they should ask if the findings are fully understood and if there are any questions. The regulatory official will thoroughly explain all findings and answer any questions that may arise. Please note that all employees are subject to interviews by regulatory officials.

FDA 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; US FDA 2018) 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. It is strongly advised that you voluntarily hold your product pending analysis of the investigator-collected environmental samples. FDA will provide the results of analysis when they are available. If a product is found to be contaminated with a pathogen, a mandatory recall will be issued. You should tell the investigator that you intend to voluntarily hold the product pending the results.

If analytical results are negative for contaminants, you may resume shipping your products. If analytical results are positive for contaminants, the local FDA district office Compliance or Investigations Branch management will contact 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 marketplace. The FDA also works closely with its state partners and will share results of analysis with Integrated Food Safety System (US FDA 2024b) partners, and the state regulatory authority may participate in follow-up activities.

Enforcement Actions

Regulatory officials have 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. Judicial actions are decided upon and taken by federal courts.

State and Federal inspections are typically based on the Current Good Manufacturing Practices (cGMPs) (US National Archives 2025b; see Section 4 Chapter 8), which require that facilities (manufacturing, processing, packing and holding food) are clean, cleanable, sanitary, and functional. Depending on state/local regulations and the type of inspection, regulatory services could enforce violations based upon a variety of regulations such as FSMA (see Section 4 Chapter 9), the PMO, and/or GMPs.

Additional regulations may apply, based on a facility's size and type of operation. For example, if a food facility is manufacturing cheese that meets the definition of a low acid, canned food, the facility is subject to additional Good Manufacturing Practices (US National Archives 2025b). Also, facilities selling human food by-product or feed to animals are subject to the Preventive Controls for Animal Food rule (US FDA 2023b).

The following are relevant FSMA key authorities and mandates:

- ***Records access:*** FDA will have access to records, including food safety plans, and the records firms will be required to keep documenting implementation of their plans. It is recommended to review FSMA key new authorities and mandates (see Section 4 Chapter 9).
- ***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. *(Establishment of accreditation program due 2 years after enactment).*
- ***Enhanced product tracing abilities*****:** The FDA is directed to establish a system that will enhance its ability to track and trace both domestic and imported foods. In addition, the FDA is directed to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a foodborne illness outbreak. *(Implementation of pilots due 9 months after enactment).*
- ***Additional Recordkeeping for High-Risk Foods*****:** FDA is directed to issue proposed rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that the Secretary designates as high-risk foods. *(Implementation due 2 years after enactment).*
- ***Reliance on inspections by other agencies:*** FDA is explicitly authorized to rely on inspections of other Federal, State and local agencies to meet its increased inspection mandate for domestic facilities.

Repeated Violations

Repeated violations (of the same finding) will result in a warning letter being issued. Continuation of the circumstances that lead to further violations can result in citations, permit suspension, or other enforcement actions until the finding has been corrected.

- 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.

Import Actions (US FDA 2015)

The following are import actions the FDA may consider:

- Import refusals are actions taken to deny admission into the US imported foods that 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.

Administrative Actions *(National Archives 2025a)*

The following are administrative actions that regulatory services may consider for enforcement:

- Suspension of Food Facility Registration-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 immediate control over food when there is reason to believe the food is adulterated or misbranded (US National Archives 2025a).
- Mandatory Recall allows regulatory services 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.

Advisory Actions

The following are advisory actions the regulatory services 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.

Judicial Actions

FDA may consider the following judicial actions which involve a court of law:

- Seizures
- Injunctions
- Inspection Warrants
- Search Warrants
- Criminal Prosecutions

Media and Issuance of Public Notification

The FDA publishes ongoing recall notifications on their website (US FDA 2025c) and bad press becomes a part of public record.

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Section 5: Selling Cheese
Chapter 12: Sales Channels

This section covers the final stages before cheese leaves the production facility. Considerable effort, resources, and skill have brought the cheese to the point where it is ready to be packaged, sold, and shipped out, and while the cheesemaking process may be complete, correct implementation of these last steps ensure 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 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.

Supplier Verification 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. For a description of audits, see Section 4 Chapter 9.

Sales Channels

Whether a cheesemaker is selling everything through a local farmers' market, working exclusively with distributors, selling directly 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 preventive control-based food safety 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:
• 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 (e.g., milk, culture, packaging) 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 understand what price is needed to make a sale worthwhile.* ***Shelf-life is not arbitrary. It should be set based on actual in-house storage studies to ensure that quality meets the cheesemaker's standards for approximately 7-10 days beyond the stated code date on the package.*

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
• Review the food code or local health department requirements for what is required by your state for selling/serving food/samples. • Review the ACS Retailers Toolkit (ACS 2017) for best practice in food service. • The cold chain below (41°F(5°C) and above 32°F(0°C) 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). Be aware, temperature abuse will deteriorate shelf life of the cheese. • 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.

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 is 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 is 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 for 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.

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.

Furthermore, retailers and restaurants in turn have the responsibility to comply with the FDA Food Traceability Rules for fresh soft, soft ripened and semi-soft cheeses made from pasteurized milk and non-hard cheese made from unpasteurized milk (FDA 2025) beginning at time of receipt of the cheese product as follows:

- Product temperature = 41°F(5°C) and above 32°F(0°C).
- Packaging is undamaged and is marked with visible expiration dates and Lot codes.
- Product is intact and unspoiled.
- Product is promptly placed in refrigerated storage with a temperature of 41°F(5°C) and above 32°F(0°C).

Portioning and packaging of cheese for retail sale and consumption must be performed within the parameters of FDA Food Traceability Rules and the FDA Food Code (FDA 2022).

Cheese products packaged by the manufacturer for retail sale and consumption with an expiration date must be sold or properly disposed of by the same date.

All cheeses cut by a retailer and packaged using ROP (Reduced Oxygen Packing) must be conducted within the regulations of an approved Food Safety Plan (Section 4 Chapter 9).

Most cheese that is cut and wrapped at a retail facility or restaurant for retail sale and/or consumption is exempt from date marking per Food Code (FDA 2022) Section: 3-501.17 Ready-to-Eat, Potentially Hazardous Food, Date Marking, stating: “Hard and semisoft aged cheeses and pasteurized process cheese, each manufactured according to 21 CFR 133... and maintained under refrigeration, are exempt from the Food Code's date marking provision relating to refrigerated, ready-to-eat, potentially hazardous food.” Non-exempt cheeses include Brie, Camembert, Cottage, Ricotta and Teleme, and while specifics for date marking these cheese products are not given, a maximum of 14 days from the cut and wrap date is recommended as a use by date.

Additionally, retailers must be familiar and comply with local and state food code regulations.

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.

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 of 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	Disadvantages
• 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.	• Cheesemakers effectively relinquish control of the maturing, sensory aspects, safety, and sales 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. Potential contaminants include, but are not restricted to: mites, pathogens and other unwanted microbes, and allergens. • Real product loss (yield loss) could become an issue and appropriate preventative steps

	must be taken to ensure risks are minimized and product loss is prevented.

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 (i.e., is this covered by insurance?). • How the cheese will be marketed and sold (i.e., 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 be available to retailers even if it is not necessarily in the marketing. • When the cheese is sold, how the proceeds will be distributed. • Both cheesemaker and affineur may want to document and agree upon key steps of the recipe in both cheesemaking and affinage. • Aging guidelines/expectations for the style of cheese.

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Section 5: Selling Cheese

Chapter 13: Packaging, Cutting and Wrapping Cheese

How well a cheese is packaged, cut and wrapped influences how its quality is perceived and how well it will meet its expected shelf life.

Packaging and Shipping Facilities

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

Placement of Packaging and Shipping Rooms within the Facility

In terms of optimal layout for a creamery, the flow of products should always be "forward" (from raw materials, through production, aging, and into packaging and shipping), and it is highly recommended that they never backtrack or go through the same area twice. For example, 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 from lower risk areas to higher risk areas. 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 packaging room from other rooms, particularly from the outside. All packaging 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. It is recommended to have a good manufacturing practice (GMP) for verifying this process (see Section 4 Chapter 8).

Separation of time between processes can also be used for food safety in flow. For instance, the same room can be used for different parts of the process as long as there is a clean down period before starting the next step.

Layout and Design of Packaging Room

Equipment in the packaging room must be constructed from materials suitable for food production areas (e.g., cleanable). Tables and work surfaces should be made from suitable materials including stainless steel, wall and ceiling surfaces should be covered in suitable materials including fiberglass reinforced panels (FRP), or tile. 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 packaging room, a sanitation plan specific to the space needs to be created. In addition, the following should be taken into consideration (are recommended) 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
- Foot baths (foaming or liquid), or dedicated footwear in clean spaces for workers.
- A three-part sink or similar system, like COP tanks, that allow equipment to be effectively washed, rinsed, and sanitized.
- Lighting in the room should incorporate safety coverings (i.e. shatterproof)..
    - “All rooms in which dairy products are manufactured or packaged or where utensils are washed shall have at least 30 foot-candles of light intensity on all working surfaces. Rooms where dairy products are graded or examined for condition and quality shall have at least 50 foot-candles of light intensity on the working surface (USDA 2012).”
- 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. Ventilation systems should be in good repair and cleaned periodically (USDA 2012).

It is important to separate the space between the process of packaging ready to eat cheese products from the area where packaged products will be boxed up for shipping out of the facility. It is also important to ensure there is adequate space for the temporary storage of shipping materials: boxes, labels, filler materials, ice packs, tape guns, etc. Shipping materials should not be permanently stored in the packaging room, as they pose a potential hazard by bringing in contaminants from outside, including attracting pests. Shipping materials should be stored in a separate, designated area at the facility and only brought into the packaging room in sufficient quantities to complete the packaging tasks taking place that day. After packaging is complete, the materials should be returned to their designated storage area each day.

When working in the packaging 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 a 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.

Ideally, the packaging room should include adequate space for products to be held prior to being packed into boxes, 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.

Supply Room

If a separate supply room is available, ti may be used for packaging materials, containers, and miscellaneous ingredients. It should be kept clean, dry, orderly, free from insects, rodents and mold, and maintained in good repair. The items should be protected from dust, dirt, and arranged on shelves or pallets that permit access for cleaning and inspection. Insecticides, rodenticides, cleaning compounds and other nonfood products shall be properly labeled and segregated and stored in a separate room or cabinet away from milk, dairy products, ingredients, cheese or packaging supplies (USDA 2012).

Operation of the Shipping Room

The shipping room should include adequate space for the packed boxes or pallets to be temporarily stored at the correct temperatures. 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.

The scale and type of operation will determine the number and variety of items and equipment needed in the packaging room and shipping room. A good place to start is to identify the number of packing station(s) that will be required within each 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.

Training on Packaging

Workers must receive thorough and continuous training in how to use the equipment in the packaging 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.

GMPs (Good Manufacturing Processes) documentation should be used in training, and the GMPs should be part of the overall Food Safety Plan for the facility (see Section 4 Chapter 9).

Cutting Cheese

To safely and efficiently cut and package cheese, it is necessary to have a selection of cheese knives, countertop cheese cutters, cheese wires, and cutting boards. To avoid potential cross contamination, these items should be specific to the packaging room and identified as such. The key objective when selecting tools is to ensure they can be effectively cleaned and sanitized. All employees should wear proper PPE (personal protection equipment).

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, cutters, and wires 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 easier and will result in a cleaner cut with less waste.

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. Should you encounter this situation, a thorough visual inspection should be performed to make sure that no pieces of the broken wire remain lodged in the cheese. If you have a rare earth magnet, you may want to use this very strong magnet to help remove any lost pieces.

Some facilities will run finished packaged cheeses through a metal detector to ensure that no metal fragments (physical hazards) are present in cheeses prior to release.

Cutting Boards

Cutting boards are an essential part of any cutting station. Boards should always be in good condition and be cleanable. 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 cheese. 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 sanitary paper towel can be placed between the board and the countertop. Paper towels should be discarded and replaced as a worker switches the station between batches of cheese.

Equipment for Shredding and Grating

Specialized shredding equipment 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, and for Swiss (gas producing) items. 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 stiff, 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 (CO_2) during aging.

Employees should be fully trained on the proper use and sanitation of shredding machines.

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-caking 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—2% is the legal limit for shredded Cheddar (USDA 2001). The amount might be adjusted lower based on specific customer requests, within limits. Check current with the manufacturer of the anti-caking 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.

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.

In addition, it is important to consider the cheese’s exterior. A disruption of the cheese surface, such as removing a bandage, cutting, or other handling, will cause a release of mold spores. Mold spores are easily transmitted through the air, and such airborne mold spores are a very effective transport mechanism for bacteria and pathogens.

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. It is recommended that a cheesemaker 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, storage of the 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. Under the Traceablity Rule (Section 4 Chapter 9) it is required to maintain records of batch/lot numbers of packaging materials that come into direct contact with the cheese, noting when they are used and with which batches of cheese.

Wrapping Materials

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.

Vacuum Packaging

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.

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 (CO_2) gas can be used. However, to have a truly loose package without a crush effect, the CO_2 gas should be blended with nitrogen. CO_2 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 errant 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. Avoid introduction of anaerobic pathogens in vacuum packaging materials**.**

Storing Wrapped Cheese

All cut and wrapped cheese that is stored by the producer should be stored at a consistent temperature below 41° F (5°C) (FDA 2022). The maximum storage/display temperature should not exceed 86° F (30°C) (Johnson and Smukowski 2019)

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 (see Section 4 Chapter 9).

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
- Storage instructions such as “keep refrigerated”
- Producers Permit Number and Location
- Pieces per case
- Date Marking

If you are naming your cheese that is regulated by the Code of Federal Regulations (US National Archives 2024), make sure it properly meets the requirements of the Standards of Identity (see Section 3 Chapter 5).

Additional Information Regarding Date Marking

The Institute of Food Technologists (IFT) published recommendations to help harmonize labeling practices, avoid confusion, and minimize food waste (IFT 2019).

- “Best if used by” is for quality. Contents are safe to eat after the date but may not meet quality standards.
- “Use By” may refer to quality or safety. Products with these dates should be consumed or frozen by this date or discarded afterwards.
- If used, “sell-by” dates are for the attention of those working at the retail level, not the consumer.

The printed date is for “first-in-first-out" inventory rotation and is the last day that the product may be sold at full price.

Many large distributors are moving to special inventory labels (GS1 barcodes). Be sure to use labels that remain adhered to the boxes in colder temperatures. With specialized labeling computer programs, these can easily be printed for each carton. (GS1 barcodes will be requited by January, 2027.)

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.

Recording Cheese Information

To maintain an effective Traceability for a Food Safety Plan:

- Establish an effective plan and write it down. In the eyes of regulators, if it is 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.

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 standard operating procedures for a mock recall online (Cornell 2016). In addition, the Food and Drug Administration provides guidance for recall procedures in the *Regulatory Procedures Manual* (US FDA 2013).

A facility should be able to pick a random batch ID and find the location and/or destination of 95% of the batch within a two-hour timeframe.

Summary of Risks to Quality and Safety

- 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.
- Metal fragments are physical hazards.

Summary of Best Practices for Mitigating Risks to Quality and Safety

- Handle cheese with visible mold in an isolated area.
- Dispose of contaminated materials.
- Clean and sanitize all equipment.
- Provide protection for personnel handling cheese.
- Store all packaging materials in clean conditions.

- Replace damaged equipment and wires.

Records to maintain and required documents

- Cleaning logs indicating cleaning and sanitizing dates, times, and personnel. (i.e., Daily and Monthly Sanitation Logs, etc.)
- Temperature Logs for all refrigerators and cave aging spaces.
- Cutting logs identifying dates, times, batch numbers, product temperature, personnel, and any non-conformities
- Brittle Plastics Logs.
- Receipts,storage, and lot tracking logs for packaging materials.
- Letters of guarantee from packaging suppliers and/or Certificates of Authenticity
- Scale weight calibration records.
- Equipment training records for personnel.

Facilities are required to have the following up-to-date documents: Food Safety Plan or HAACP Plan, Recall Plan, Food Defense Plan, and Traceability Plan. Each of these are separate documents and need to be reviewed regularly.

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Section 5: Selling Cheese

Chapter 14: Transporting Cheese

A cheesemaker should carefully consider the various packing and transportation options so that the cheese is protected during shipping and reaches customers in peak condition.

The Food Safety Modernization Act (FSMA) Rule on Sanitary Transport of Human and Animal Food (US FDA 2018) legislation works to protect food from contamination during transport. 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 was published for shippers, carriers, and receivers that are inspected under the NCIMS Grade A Milk Safety Program (US FDA 2020). 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 (US FDA 2017).

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 (US FDA 2018).

Packing Cheese for Transport

Packing Materials

A bewildering array of packing materials are 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.

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.

Transportation

Since producers know best how their products are to be handled, the onus is on the shipper/producer to tell the carrier simply transports the product as instructed (e.g.,

refrigerated, separated from meat, etc.). Choose wisely and vet your carrier (verify that they pre-chill trucks, control temperatures, maintain cleanliness).

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. Lock tags are not required but may be a tamper-evident lock tag part of your Food Safety Program. In such cases, the onus is on you to document their requirement and use.

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 food safety 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 in 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 a 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 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.

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 it 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 possible, leave a “chimney” in the middle of the pallet for complete cooling.

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.

Hand Delivery (Cheesemaker Transportation to 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 (ACS 2025).

Summary of risks to quality and safety

- Cheese may become contaminated with undesirable microbes during transport from personnel, other goods, or a contaminated vehicle.
- Undesirable microbes may grow if cheese is not maintained at a chilled temperature during transport, or if the transit time is longer than expected.
- Certain cheese types may experience "huffing" of packaging, the expanding with gas if temperature exceeds cheese type temperature range.

Summary of best practices for mitigating risks to quality and safety

- Cheese should be adequately wrapped and protected for transport.
- Ensure a sufficient number of ice packs are used relative to the quantity of cheese or time of delivery.
- Reputable haulers should be used to transport cheese.
- Hauler and transport vehicles should be inspected for adequate maintenance and cleanliness.
- Verify that tamper-resistant procedures are in place, such as lock tags.
- Tamper-resistant procedures should be in place when self transporting, such as locking the vehicle if/when exiting.
- Ensure that haulers maintain temperature control, monitoring, and corrective action logs in the event of failure.
- Hauler (including self) should have a plan in place, in case the vehicle breaks down.

Records to maintain

(ensuring a carrier has these records is a way to vet them when making a decision which carrier to contract with)

- Bill of loading.
- Contracts with haulers.
- Contracts with customers, if applicable.
- Sanitation records including transport vehicle inspections.

- Temperature control, monitoring, and corrective action logs.
- Tracking of time of departure/arrival for deliveries.
- Vehicle registration and insurance documents are on hand at all times.
- Mileage record if needed for business purposes.

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Appendix: Teaching Example: Selected Sections of a Food Safety Plan

Adapted from: Mathison, M. and M. Smukowski. 2017. **Sections of a Food Safety Plan for Pepper Jack Cheese: Teaching Example**. Wisconsin Training Model.

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

Table of Contents

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.

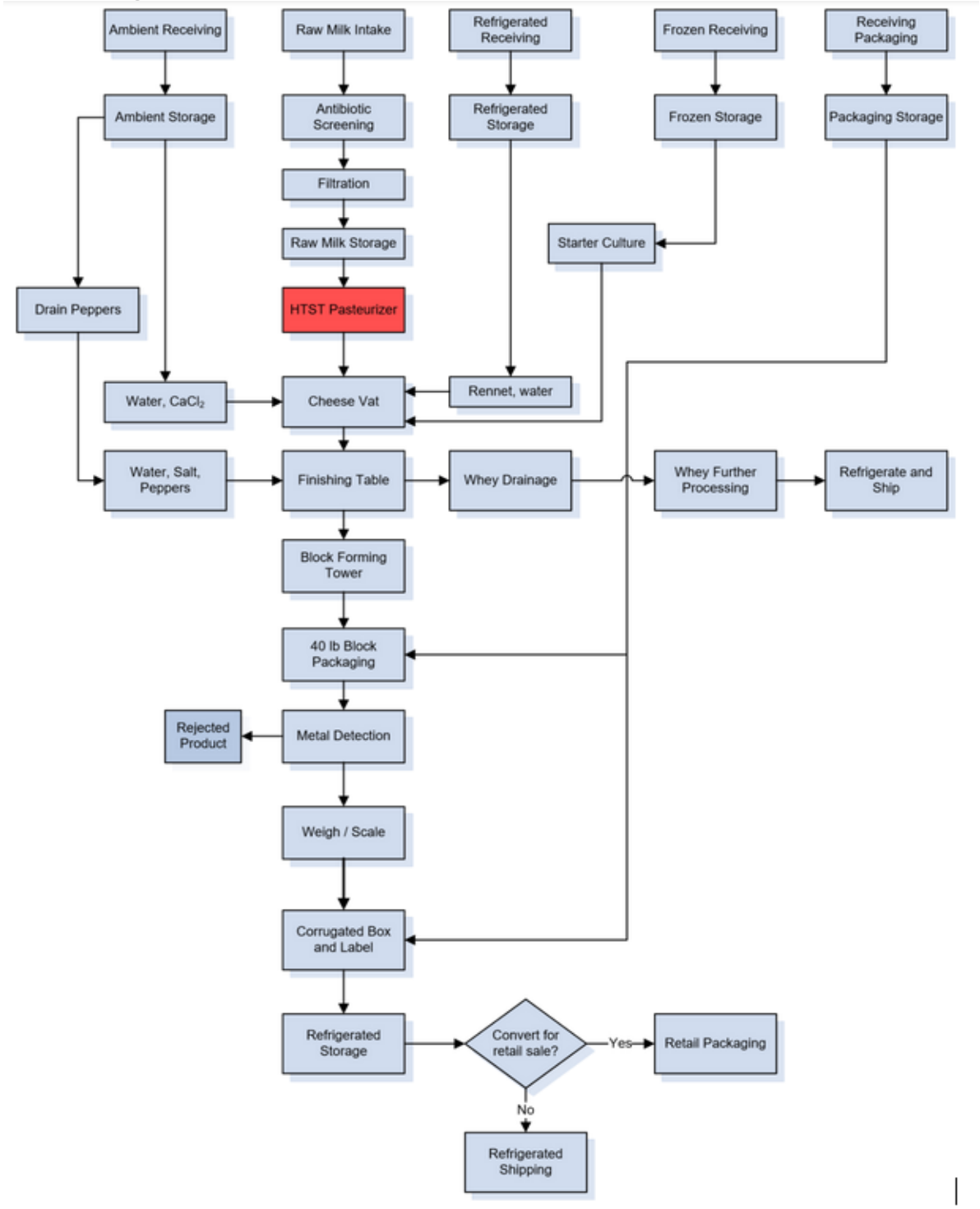
The Food Safety Team members include:

- **Director, Quality Assurance [company trained PCQI]**
- **Operations Manager [PCQI back up]**
- **Head cheesemaker**
- **VP, Sales and Marketing**
- **Maintenance Manager**

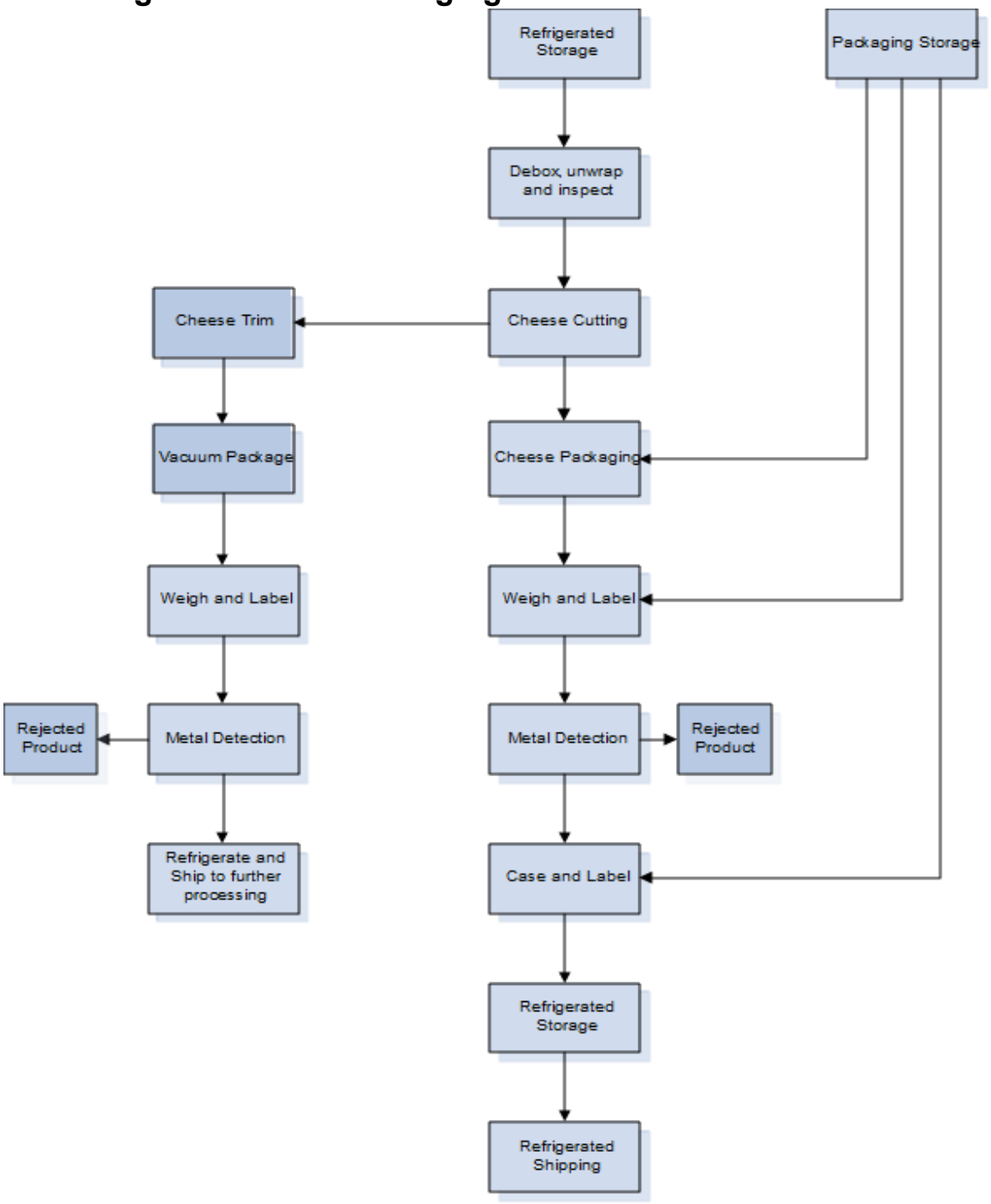
Product Description

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.

Flow Diagram – Cheese Make



Flow Diagram – Retail Packaging



Process Narrative

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

- **Receiving packaging:**
  - Cryovac 40 # block bags: blue bags with specifications for product contact use
  - Cryovac 1 # chunk bags: clear with specifications for product contact use o Labels are reviewed for conformance with product allergen requirements and ingredients
  - Corrugated boxes: received in bulk and meets specification
- **Receiving ambient [shelf stable] ingredients**: o Salt: received in 2000 # tote
  - Calcium chloride: received in 55 gallon drums o Diced peppers in brine: received in 380 # drums
- **Raw milk intake:**
  - Raw milk: received at temperature ≤ 45 °F, tested for antibiotics prior to unloading in the receiving bay and filtered prior to transfer to milk silo
- **Receiving refrigerated ingredients:**
  - Rennet: received at ≤ 41 °F in 5 gallon cubes
- **Receiving frozen ingredients:**
  - Dairy cultures: received at minimum – 70 °F

Storing Ingredients and Packaging:

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

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

- **Cheese vat**:
  - Milk pasteurized at ≥161 °F for 15 sec. prior to addition to the cheese vat
  - Frozen culture, calcium chloride [with water dilution] and rennet [with water dilution] added after pasteurization
  - Vat cut, cooked and curd/whey transferred to Finishing Table
- **Finishing table:**
  - Whey drained from curd, cooled and stored for further processing o Cold water added to cool the curd, then drained off o 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 [5.0mmferrous/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 o Block deboxed and unwrapped o 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

PRODUCT(S): Pepper Jack Cheese – Ready-to-Eat		PAGE < 9 > of 25
PLANT NAME: Wisconsin Cheese Company	ISSUE DATE	1/27/2017
ADDRESS: 123 Main Street, Monterey, USA	SUPERSEDES	11/11/2016

Hazard Analysis

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

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

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Receiving packaging – Bags, corrugated boxes, labels	B	none						
	C	Allergen - milk	X		Milk is considered a major food allergen	Allergen control - for pre-printed label review	X	
	P	None						
Ambient receiving - salt, calcium chloride, peppers	B	Pathogens	X		Peppers may contain pathogens. Supplier has validated blanching/brining process to kill vegetative pathogens	Supply chain control - for pathogens in peppers in brine/receiving check for proper documentation	X	
	C	None						
	P	None						
Refrigerated receiving – rennet	B	None						
	C	None						
	P	None						

PRODUCT(S): Pepper Jack Cheese – Ready-to-Eat		PAGE < 10 > of 25
PLANT NAME: Wisconsin Cheese Company	ISSUE DATE	1/27/2017

ADDRESS: 123 Main Street, Monterey, USA						SUPERSEDES	11/11/2016		
(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential hazards require a preventive control?		(4) Justify your decision for column 3		(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No				Yes	No
Raw milk intake	B	Pathogens	X		Raw milk received <45 ˚F as per PMO. Raw milk may contain pathogens that must be subjected to 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
Frozen receiving – cultures	B	None							
	C	None							
	P	None							
Packaging storage – packaging, corrugated boxes, labeling	B	None							
	C	None							
	P	None							
Ambient Storage (salt, calcium chloride, peppers)	B	None							
	C	None							
	P	None							
Refrigerated storage – rennet	B	None							
	C	None							
	P	None							
Frozen storage – cultures	B	None							
	C	None							
	P	None							

PRODUCT(S): Pepper Jack Cheese – Ready-to-Eat								PAGE < 11 > of 25	
PLANT NAME: Wisconsin Cheese Company						ISSUE DATE	1/27/2017		
ADDRESS: 123 Main Street, Monterey, USA						SUPERSEDES	11/11/2016		
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						
Weigh/Scale	B	None						
	C	None						
	P	None						

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any potential hazards require a preventive control?	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen,*	(6) Is the preventive control applied at this step?

			Yes	No		*Sanitation, Supply-chain, other preventive control*	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						
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

(1) Ingredient/ Processing Step	(2) ID potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Cheese packaging	B	None						

	C	None						
	P	None						
Weigh and label	B	None						
	C	Allergens	X		Milk is considered a major food allergen	Allergen control - for label review	X	
	P	None						
Metal Detection	B	None						
	C	None						
	P	Metal	X		Metal could be present in finished product	Process control – metal detection	X	
Case and label	B	None						
	C	Allergens	X		Milk is considered a major food allergen	Allergen control - for case label review	X	
	P	None						
Refrigerated Storage – Finished product	B	Pathogen	X		Temperature control will minimize growth of pathogens present	Process control – temperature control	X	
	C	None						
	P	None						
Refrigerated Product Shipping	B	Pathogen	X		Temperature control will minimize growth of pathogens present	Process control – temperature control	X	
	C	None						
	P	None						

Process Preventive Controls

Process Control(s)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

Milk 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

PRODUCT(S): Pepper Jack Cheese – Ready-to-Eat							**PAGE < 15 > of 25**		
PLANT NAME: Wisconsin Cheese Company						**ISSUE DATE**	1/27/2017		
ADDRESS: 123 Main Street, Monterey, USA						**SUPERSEDES**	11/11/2016		
Process Control(s)	**Hazard(s)**	**Critical Limits**	**Monitoring**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			

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

Process Control(s)	**Hazard(s)**	**Critical Limits**	**Monitoring**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			

Tempera-ture Control	Biological – pathogens	≤ 45 ˚F	All milk stored in raw milk silos	Continuous chart recorder	Continuous or twice daily	Trained and designated employee per SOP	Evaluate raw milk suitability for cheese making based on time and temperature held above 45 ˚F. Determine cause of temperature deviation and correct. Document corrective action.	Review of charts and temperature logs and signed by PCQI or designee within 7 working days PMO 2013 for validation of product holding temperatures Annual calibration of thermometers	Milk silo charts Thermometer calibration records
Tempera-ture Control	Biological – pathogens	≤ 45 °F	All refrigerated storage coolers	Continuous chart recorder or calibrated thermometer	Continuous or twice daily	Trained and designated employee per SOP	Place product on hold, evaluate product based on time and temperature held above 45 ˚F. Determine cause of temperature deviation and correct. Document corrective action.	Review of charts and temperature logs and signed by PCQI or designee within 7 working days PMO 2013 for validation of product holding temperatures Annual calibration of thermometers	Cooler charts Thermometer calibration records

Process Control(s)	**Hazard(s)**	**Critical Limits**	**Monitoring**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			

Tempera-ture Control	Biological – pathogens	≤ 45 °F	All refrigerated shipping and receiving trucks	Continuous chart recorder or calibrated IR thermometer	Every truck	Trained and designated employee per SOP	Rejection of truck or receive and hold product for retest/release or reject	Review of charts and temperature logs and signed by PCQI or designee within 7 working days PMO 2013 for validation of product holding temperatures Annual calibration of thermometers	Receiving and shipping logs Thermometer calibration records

Allergen Preventive Controls

	Hazard(s)	Criterion	Monitoring	Corrective Action	Verification	Records

Allergen Controls			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

Product Name	Production Line				Intentional Allergens				
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	
Pepper Jack Cheese	1		×						

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

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

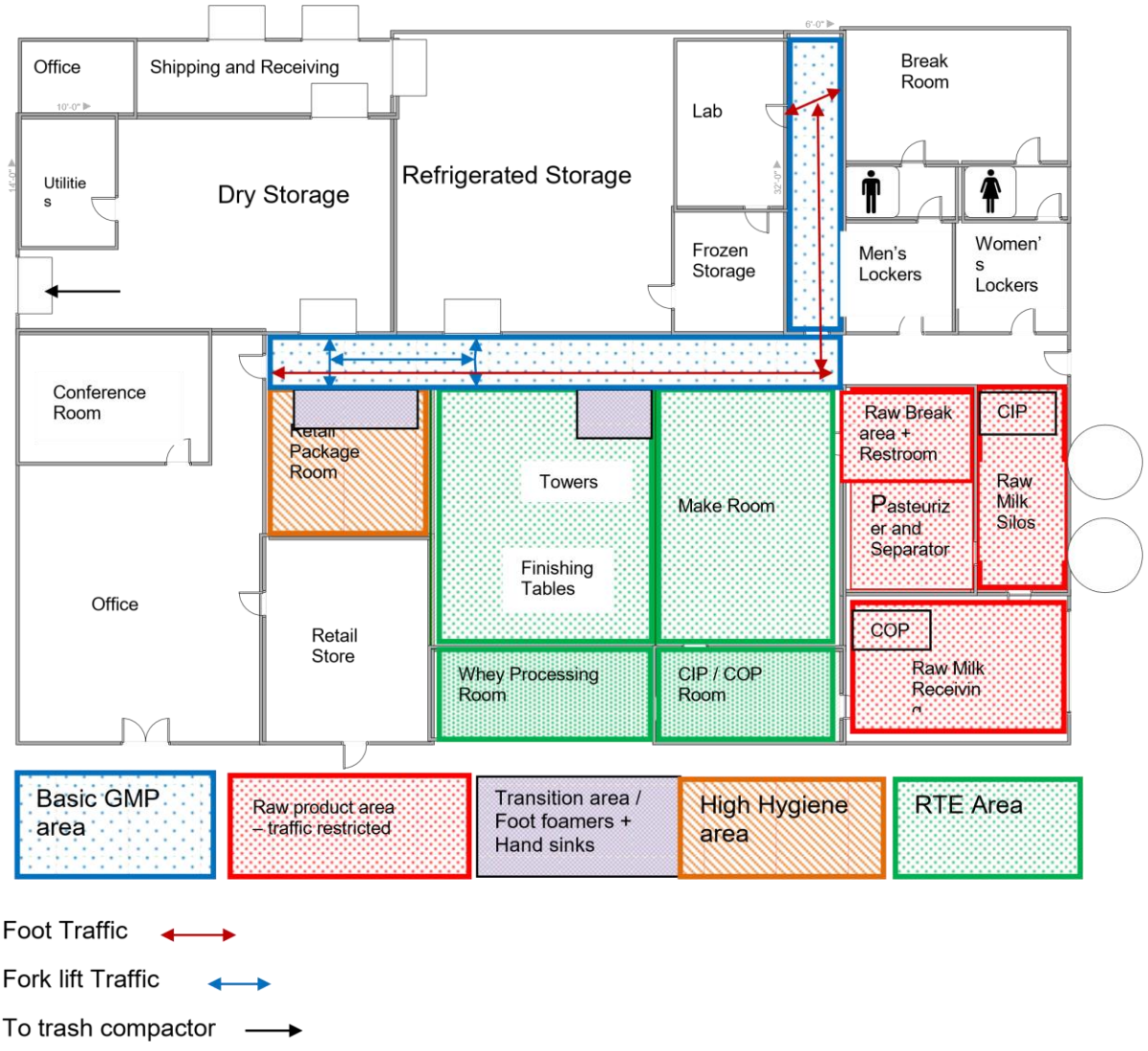
Sanitation Preventive Controls

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

Hygienic Zoning/ Environmental Monitoring

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

Cheese Plant Diagram



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.

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.

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

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 (Figure 1) to control environmental pathogens such as *L. monocytogenes* and *Salmonella.*

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

Sampling procedure: The primary pathogen control area is tested weekly for the presence of *Listeria* species. Sponge swabs are collected during production at least 3 hours after production starts. Sampling time is not uniform to avoid bias of results. Samples are shipped to the laboratory using the sampling kit provided

by the laboratory. Samples are refrigerated and shipped in an insulated cooler with a gel pack with next day delivery. Samples are NOT frozen.

Samples are collected by trained personnel in zoned areas (see diagram). Most samples are taken in zones 2 and 3 and include pre-identified sites as well as random sites based on observed conditions. Total number of samples collected each week:

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

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

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

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

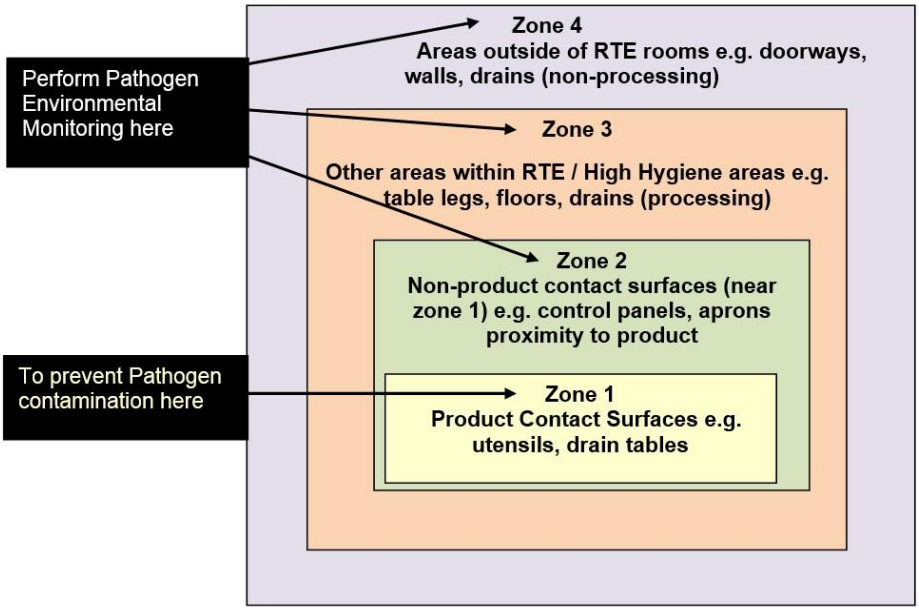


Figure 1. Zone chart for Food Production Facility.

Interpretation of results:

Action for a negative result – continue routine operations.

Corrective action for a positive result:

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

Supply-Chain Preventive Controls Program – Diced Peppers

Determination of Verification Procedures

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

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

Verification activities:

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

Verification procedures:

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

Records:

- Specifications Sheet
- Supplier Letter of Guarantee
- Copy of 3rd party audit
- Quarterly testing results

Validation study for blanching/brining process

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

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

Receiving Procedure for Ingredients Requiring a Supply-chain applied Control

For each shipment received, the receiving department:

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