CONTROL OF *LISTERIA MONOCYTOGENES*

GUIDANCE FOR THE U.S. DAIRY INDUSTRY

INNOVATION CENTER FOR U.S. DAIRY

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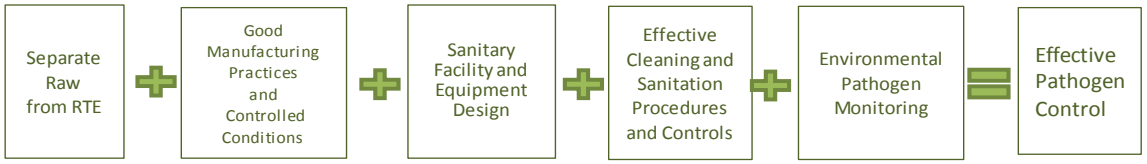
To the Reader

This *Listeria* Control Guidance Document has been prepared for the dairy industry by subject matter experts who work daily in the industry. It is intended to build knowledge and communicate best practices for a wide spectrum of food safety practitioners: hourly employees, engineers, quality professionals, senior staff, contractors, suppliers, and more.

With the diverse information needs of this group, and the obligation to present scientific principles and best practices in mind, the document employs a simple graphic to guide the reader. The graphic symbolizes the basic programs that are recommended to be employed in concert to establish effective pathogen control in a dairy manufacturing facility. This is the **Pathogen Control Equation**[1]:



Core principles of the Pathogen Control Equation will be discussed in depth to help identify focused practices which are essential to effective pathogen control. Years of experience and best practices from multiple food categories have been summarized as the following core principles:

Principle #1

Separate Raw from Ready-to-Eat

History has shown that there is a greater likelihood of finding spoilage organisms or pathogens in uncontrolled or raw manufacturing areas than in controlled production or Ready-to-Eat (RTE) areas. Governing the flow of personnel, supplies, and equipment significantly reduces the potential for cross-contamination.

Principle #2

Good Manufacturing Practices and Controlled Conditions

Following Good Manufacturing Practices (GMPs) is one of the most fundamental expectations in the food industry. If these practices are not followed, it could lead to contamination of products. GMPs apply to both personnel practices and, equally important, production practices. Surfaces in a dairy production facility can be wet from manufacturing conditions; this moisture can support microbial harborage and growth. Floors and other surfaces should be dry, well maintained, and free of cracks.

Principle #3

Sanitary Facility and Equipment Design

Sanitary design of equipment and facilities is one of the most important of the core Pathogen Control principles. Surfaces which are difficult to clean can be challenging and/or overlooked during a sanitation cycle, resulting in microbial harborage and growth. In order to more fully assess cleanability and identify improvements, quality, food safety, and engineering professionals should spend time observing and possibly performing cleaning duties during the sanitation process.

Principle #4

Effective Cleaning and Sanitation Procedures and Controls

Cleaning and sanitation must be effective, always. Effective sanitation is core to maintaining a clean plant environment. Enhanced cleaning procedures have been proven to compensate for weaknesses in facility or equipment design until improvements can be implemented.

Principle #5

Environmental Pathogen Monitoring

Environmental monitoring measures the success of dairy plant pathogen controls by verifying that preventive programs are effective. An environmental monitoring program helps you know your environment and make improvements as highlighted by the findings.

Focusing on these core principles provides early control and long-term stability for pathogen management programs. Users of this document will find it flexible enough to be studied completely or in sections, depending on the reader's interests and needs.

This *Listeria* Control Guidance is offered by the Food Safety Operating Committee of the Innovation Center for U.S. Dairy. It is part of a broad set of food safety education initiatives designed to strengthen manufacturing practices in all dairy processing facilities with the goal of reducing food safety risks. More information regarding hands-on workshops and user resources is available at www.usdairy.com/foodsafety.

Thank you for sharing in the industry's commitment to advance food safety performance, every day.

The Food Safety Committee
Innovation Center for U.S. Dairy

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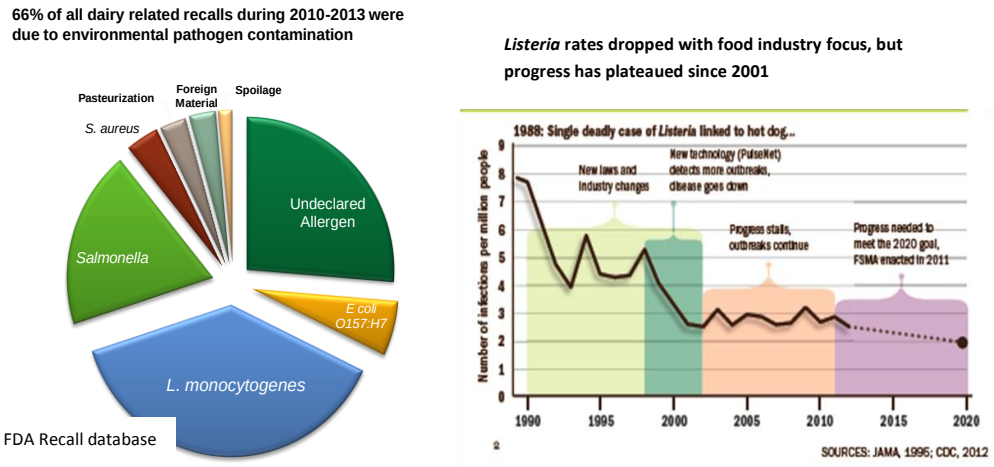
INTRODUCTION

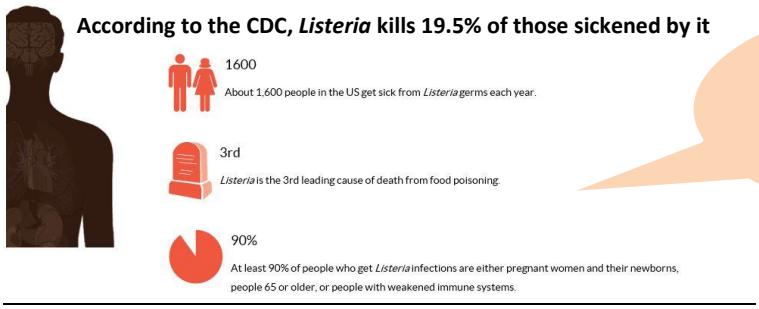
Listeriosis is a deadly foodborne illness caused by *Listeria monocytogenes (Lm),* which is estimated to affect 1,600 people every year in the U.S.[2] When diagnosed, the fatality rate of *Lm* is high at almost 20%, compared to 0.5% for *Salmonella.* Since the first widely recognized outbreak in 1985, *Listeria* has been responsible for a number of illness outbreaks across many food products including processed meats, ready-to-eat (RTE) meals, cheese, hummus, and ice cream. Dairy products, as a whole, have a very good food safety track record thanks in part to pasteurization and in part to the hard work and diligence of the industry. With the 1924 introduction of the Pasteurized Milk Ordinance (PMO),[3] a focus on sanitation, and the adoption of strict environmental pathogen controls, today's dairy products are among the safest foods produced.

One ongoing threat to this safety record is the risk of *Listeria monocytogenes* (*Lm)*, a virulent, disease-causing bacterium which can grow under refrigerated conditions. Controlling *Listeria* requires making a clean product (pasteurization, pathogen-free raw materials, etc.) and preventing environmental recontamination by keeping *Listeria* out of the manufacturing plant and away from finished product.

The industry has made great improvements since the 1985 soft Hispanic-style cheese outbreak sickened 142 people and resulted in 48 deaths,[4] but dairy foods, both refrigerated and frozen, continue to be implicated in outbreaks of listeriosis. Control of this organism is critical and urgent. In 2013, the Centers for Disease Control and Prevention (CDC) reported that after several years of impressive improvement, reductions of listeriosis cases had stalled—calling for a renewed focus on this front.[2]

Fig. 1 *Listeria* Background





Recent Example

In 2015, an outbreak attributed to ice cream was reported to have infected 10 people and claimed 3 lives. (http://www.fda.gov/Safety/Recalls/ucm439533.htm.)

A Few Facts About *Listeria*

- ✓ *Listeria* are bacteria widely present in nature and normally present in agricultural products including raw milk.
- ✓ *Listeria* do not survive pasteurization. They can grow at refrigeration temperatures, survive freezing, and tolerate up to 20% salt.
- ✓ *Listeria* can grow quickly at ambient temperatures.
- ✓ ***Listeria monocytogenes (Lm)*** is a pathogen that causes listeriosis, one of the most frequent and serious human foodborne illnesses. *Lm* is one of the many known ***Listeria* species (*Listeria* spp**.).
- ✓ The presence of *Listeria* spp., the broader genus to which *Lm* belongs, is widely used as an indicator of conditions that also may be favorable for the pathogen *Lm*.
- ✓ *Listeria* has the ability to form strong protective biofilms, which effectively protect bacteria cells and can be quite difficult to remove.[5] Biofilms are more likely to form in difficult to clean areas within processing environments.

Indicator Testing and Its Role in Controlling Pathogens

The majority of this guide will focus on monitoring for *Listeria* spp., but a good environmental monitoring program encompasses all relevant pathogens and also incorporates "indicator testing" to verify manufacturing environment cleanliness and the effectiveness of plant procedures. An indicator organism predicts the likely presence of a target organism or condition. While not specific for an organism, ATP testing (see Glossary) is widely used as an immediate verification of sanitation effectiveness before starting up production. In the dairy industry, coliform testing is also widely used to confirm sanitary condition of product and process conditions. These types of testing can alert processors that special action or deep cleaning is needed before more serious issues arise. Testing for indicator organisms in the environment and/or finished product can be used to show that sanitation and zoning controls are working and the environment is clean.

Indicator testing does not replace pathogen monitoring, it provides supplemental information. Verifying that a processing environment is under control requires independent testing for *Listeria* spp. Because it is a broader indicator group and more frequently found in the environment, using *Listeria* spp. as an indicator provides a more conservative, more inclusive approach for detecting *Lm*. See "Developing a Sample Plan" on page 34 for more details.

The Role of Finished Product Testing

Finished product testing alone does not ensure food safety. Experts advise that processors focus on preventive controls and employ pathogen environmental monitoring to verify their effectiveness.

Product testing alone is not considered effective as a means of control for many reasons, most notably:

- ✓ *Listeria* spp. is generally unevenly distributed within contaminated product and testing may miss pockets of contamination.[6]
- ✓ *Listeria* spp. grows slowly under chilled conditions and tends to occur in very low concentrations. Even in contaminated product, high enough numbers of *Lm* may not be present to be detected at the time of production, potentially creating false negatives.
- ✓ Cross-contamination events are often sporadic in nature.

Product testing can have a role in a comprehensive food safety system when used in conjunction with processing, preventive controls, and validation. When product contact or finished product pathogen testing is undertaken, there must be an effective sampling plan which is representative of production and be conducted under the guidance of a qualified food safety expert. Whenever product or product contact surfaces are tested for Lm *or other pathogens, all product must remain "on hold" and within your company control until all samples are reported as "negative."*

Hazard Analysis and Critical Control Points (HACCP) and Hazard Analysis Risk Based Preventive Controls

Listeria monocytogenes should be identified as one biological hazard controlled by your HACCP plan as part of your Food Safety plan. Pasteurization is an effective control for all vegetative pathogens including *Lm*. In addition, some products may incorporate hurdles to pathogen growth such as pH, live cultures, antimicrobials/inhibitors, or formulating within prescribed formula boundaries (i.e., processed cheese). This guide focuses on preventing recontamination, through the Pathogen Equation, and should complement or be part of existing HACCP / Food Safety Plan. For a more complete understanding of HACCP principles and application, resources are included on page 48, "Additional Resources." Additional information can also be found in the FDA's Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food[14].

Regulatory Implications

In the U.S., the Food and Drug Administration (FDA) has established a regulatory zero tolerance policy for the presence of *Lm* in any RTE food. This means that any RTE food that tests positive for *Lm* is deemed adulterated and cannot be shipped or sold. Further details can be found by reviewing FDA's Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry, *Draft Guidance*[7].

The FDA's final rule on Preventive Controls for Human Food, stemming from the Food Safety Modernization Act, includes requirements for environmental pathogen monitoring based on risk. Manufacturers will need to examine the rationale behind their monitoring and testing programs, document fully, and should be prepared to explain their choices. Manufacturers will also be required to establish and maintain documentation including written programs and recorded results for all prerequisite programs and preventive controls included in their Food Safety Plan.

CONTROL OF *LISTERIA* USING THE PATHOGEN EQUATION

PRINCIPLE #1: SEPARATE RAW FROM READY-TO-EAT

History has shown that there is a greater likelihood of finding spoilage organisms or pathogens in uncontrolled or raw manufacturing areas than in controlled production or ready-to-eat (RTE) areas. Governing the flow of personnel, supplies, and equipment significantly reduces the potential for cross-contamination.

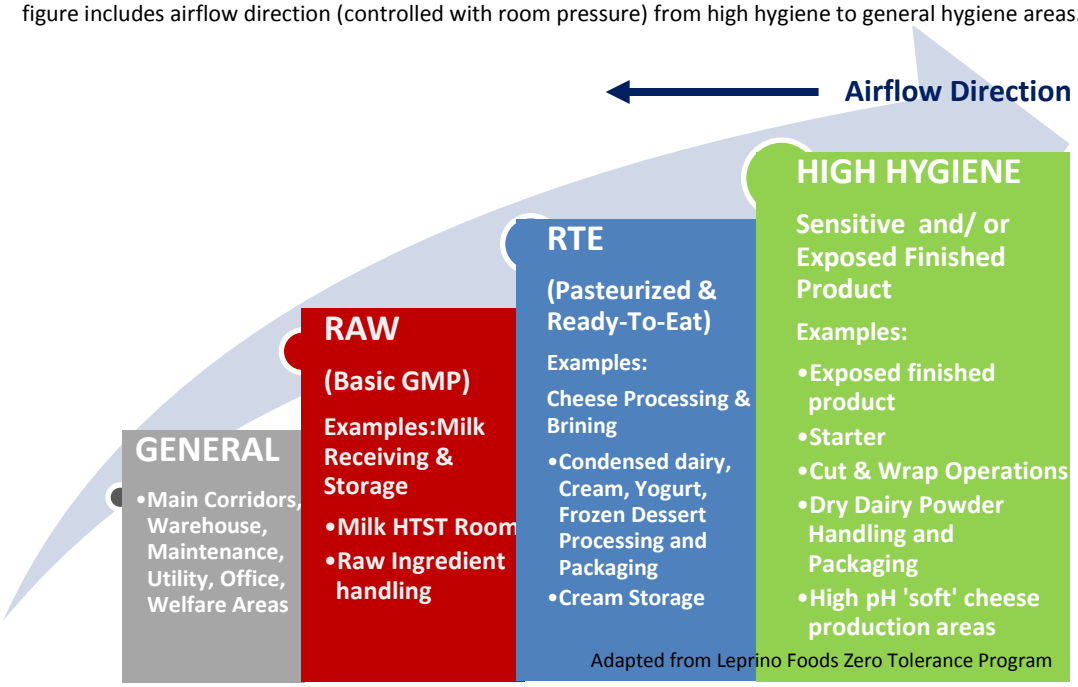
Prevent Entry into the Plant

It is possible for any incoming material to bring contaminants, including *Listeria,* into the plant. Therefore it is important to determine all potential routes of pathogen entry into the processing facility including direct access through personnel (employees, visitors, contractors, etc.), raw materials, supplies, and utilities all of which can be a source of contamination directly into finished product or indirectly through contact during processing. This section will explain the role of hygienic zoning in the controlling *Lm* and managing incoming materials including ingredients, processing aids, utilities (water, air, gases), utensils, tools, lubricants, chemicals, and packaging materials as potential carriers.

Hygienic Zoning to Control Cross-Contamination

Hygienic Zoning (Fig. 2 and 3) is used to control cross-contamination. Areas with raw, unprocessed materials should be physically separated from pasteurized product and sanitized equipment. Raw milk should always be presumed to be contaminated and *Listeria* spp. can also be present in other incoming materials. As materials move into and through the facility, any bacteria in/on those materials can potentially cause contamination. *Listeria* can be readily transported, transferred, and spread throughout a facility, where it can then find niches suitable for growth or biofilm formation. Failure to control the flow of materials can lead to direct contamination, growth and even persistence in the environment. *Listeria* spp. has been detected in processing and packaging equipment, facility structures, transportation equipment, bulk ingredient containers, water, and pallets. Transfer into facilities has been traced to insects, animal pests, and human (clothing, shoes, skin, tools, etc.) movement.

Fig. 2. Zoning. Facilities should be zoned to prevent cross-contamination from raw to finished product. This figure includes airflow direction (controlled with room pressure) from high hygiene to general hygiene areas.



Traffic Controls

Because *Listeria* spp. can be readily transferred, the movement of people and materials must be controlled by developing traffic patterns with strict controls.

A facility flow diagram should be developed to define areas by their hygienic requirements (e.g., general, raw/basic GMP, RTE, high hygiene, and transitional areas) and show human and material flows. Note: The terminology used may vary by individual company or with conformance to specific audit schemes (e.g. BRC, SQF). The diagram should include:

- ✓ Hygienic zone designations.
- ✓ Incoming materials and outgoing finished product.
- ✓ Personnel routes including job responsibilities, entry/exit, breaks.
- ✓ Equipment and conveyor positions.
- ✓ Drainage and floor slopes.
- ✓ Air flows and air handling systems.
- ✓ Rework handling.
- ✓ Usage and storage of cleaning equipment, utensils, spare parts, and tools.
- ✓ Waste collection and removal.

Separation of raw product areas from finished product areas can be achieved by using barriers to restrict traffic. Physical barriers (walls, railings, transition benches) are the most effective choice, but separation can also be achieved through floor markings, transition spaces, floor sloping, drainage barriers, and controlled airflow. It is also possible to create separation through the use of "scheduling." This involves removing finished product before handling raw and then performing cleaning/sanitizing before reintroducing finished product. Other techniques to help maintain separation include footwear and uniform changes, use of smocks, pallet exchanges, and removal of outer/exposed packaging materials.

Traffic flows should be designed to avoid having people and equipment from different zones travel on common paths whenever possible. Consider routine as well as occasional traffic including forklifts, waste

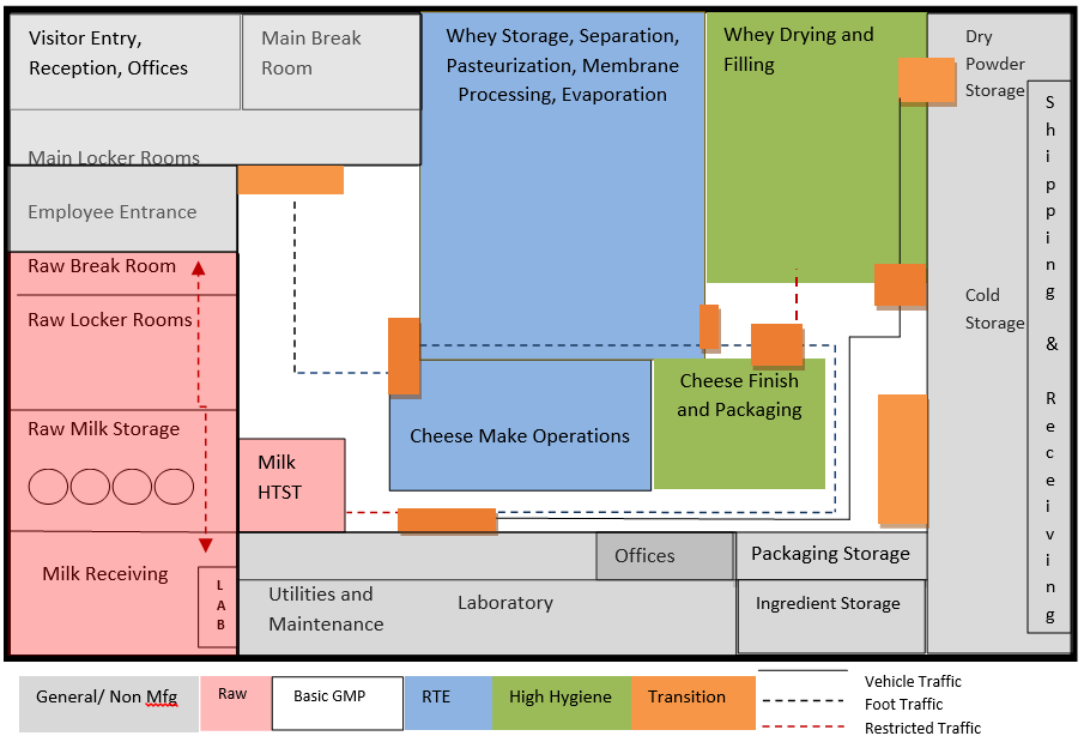
removal, QA personnel and carts, maintenance personnel, and sanitation activities. Include traffic flow on *all* shifts.

Finished product areas should be protected from potential cross-contamination sources of *Listeria* spp. such as raw materials, pallets, raw product bins, and cross traffic (product carts, forklifts, workers). Consider zone designations for transport equipment (forklifts, pallet jacks, carts) and using only "first time" pallets in high hygiene areas.

Storage areas should be separate and/or clearly marked to prevent co-mingling of raw and processed product. If storage space is constrained, processed product should always be positioned above raw to reduce the potential for contamination falling or dripping onto finished goods.

Color coding of smocks, hairnets, shoes, and tools is a best practice for visual verification of raw/RTE separation compliance and to prevent uncontrolled traffic flow through RTE areas.

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



Chemical Mitigation—Footbaths and Foamers

Foamers and footbaths can help to prevent contamination from outside the facility and between raw and RTE areas, but they must be properly designed and managed to be effective. Foamers can be very effective because they spray the fresh chemicals in a designed pattern at a designated frequency. Footbaths can be very effective but they can also become sources of contamination if not properly managed. Footbaths may be used where foamers are not an option, such as when a drain is not located nearby. Footbaths are designed to bathe the soles and sides of footwear as the employee walks through a pool of sanitizing solution. Chlorine and other chemicals dissipate and become ineffective from organic loads due to traffic through the footbath. Facility staff must ensure proper maintenance of the wash solution through frequent empty/clean/refill cycles with the proper-strength sanitizer. Footbath "mats" must be washed and sanitized on a regular basis and should be replaced if cracked or worn. For low water use areas, a dry floor treatment such as alkaline peroxide or granular quaternary ammonium can be effective. Your sanitizer chemical supplier can be an important resource for identifying appropriate chemical controls.

Manage doorways and transitions for foot and vehicle traffic with floor foamers or spraying devices that are timed or motion triggered. Sanitizer solutions should be controlled to assure:

- *Depth of foam (2 inches to cover soles of shoes)*
- *Width to cover entire transition area*
- *Length to cover at least one full wheel rotation*
- *Strength to be effective*
- *Proper foam structure to prevent rapid draining*

Thermal Inactivation

The first defense against *Listeria* is proper pasteurization, which kills the organism. Pasteurization often defines the transition of a material from "raw" to "RTE". Once pasteurized, it is important to prevent post-pasteurization contamination of in-process or finished product. Several listeriosis outbreaks have been attributed to post-pasteurization contamination from the processing environment and/or contaminated ingredients.

For manufacturers adding post-pasteurization inclusions (nuts, fruit, berries, spices, flavors, etc.) into ice cream, cheese, yogurt, or other products, it is also critical to make sure that those inclusions do not contaminate the already pasteurized products. These controls could include treatment by the supplier to control *Lm* and other pathogens. For further details about the supply chain preventive controls and supply chain programs please refer to FDA's Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food[14].

Dairy plant operators must ensure that in-process products are handled with appropriate time/temperature controls. This is especially important during equipment downtime and reworking processes.

PRINCIPLE #2: GOOD MANUFACTURING PRACTICES AND CONTROLLED CONDITIONS

Good Manufacturing Practices (GMPs), Personnel, and Behaviors

People are one potential source of cross-contamination as they interact with products or the manufacturing environment. Employees and visitors who enter production areas must be trained on GMP hygiene controls before entering production areas and everyone must comply with designated practices at all times. In addition, production facilities should have policies and procedures for identifying and excluding ill employees from working in food processing areas.

Hand-washing is a fundamental building block of any GMP program, as hands may come into contact with products and product contact surfaces. Hands must be washed before starting work, before entering production areas, when transitioning across hygienic zones, and whenever they become contaminated or soiled. Examples include:

- ✓ After touching unclean surfaces, e.g., floors, the bottom of items which have been on the floor, outer packaging layers, pallets, waste cans, or other non-sanitized surfaces.
- ✓ After leaving the production area/line or visiting the restroom.
- ✓ After coughing or sneezing into hands or scratching/touching exposed skin.
- ✓ After breaks.

The use of sanitary gloves is common in manufacturing environments. While gloves minimize human contact with foods and shield employees' skin from soil, they must be cleaned and sanitized in the same manner as hands. Soiled or damaged gloves should be replaced as they could be just as contaminated as unwashed hands.

Tools and utensils used in processing areas should be inspected, cleaned, and sanitized on a regular basis to avoid cross-contamination. Immediate cleaning and sanitizing is required if they have contacted non-sanitized surfaces including gloves, tables, equipment, walls, or floors.

Clean uniforms, smocks, and footwear should be worn when entering processing areas. Footwear and uniforms for use in processing plants should never be worn outside the plant. Employees should change their uniforms at the end of each shift or more frequently as necessary. Sanitation workers should change into clean uniforms or coverings when transitioning from heavy cleaning to the sanitizing phase.

Footwear requires special attention to ensure that contamination is not tracked into the production facility. Footwear should be designed to be easily cleanable, should be cleaned regularly, and replaced when cracked or worn. Avoid deep treads or cleats which are difficult to clean and sanitize and can allow microbial harborage or growth. Care must also be taken to balance cleanliness with functionality and personnel safety

(slips and falls). Visitors and contractors should be issued either disposable foot covers or sanitized reusable footwear. There should be a documented sanitation program for footwear that is reused.

Maintenance and Repair Activities

The maintenance and repair of equipment, storage areas, or infrastructure in and around processing rooms must be completed with adequate controls in place to prevent contamination. Maintenance staff and contractors who work in product zones, near product contact surfaces, and/or in areas leading to and from processing areas must follow GMPs and take extra precautions to protect products and the plant environment. See "Maintenance Best Practices" on this page and Appendix C – example construction plan and checklist.

Controlled Conditions

Floors, ceilings, walls, and other infrastructure should be clean, as dry as possible, and in good condition. Active care must be taken to reduce microbial harborage to prevent the growth and spread of pathogens:

- ✓ Floor grout, seals, and other joints must be maintained. Any deterioration should be repaired as soon as noticed to prevent creating pathogen harborage areas.
- ✓ Control and eliminate condensation. This is particularly important on or above equipment, tanks, or conveyors. Condensate could cause contamination of product or product contact surfaces.
- ✓ Overhead areas must be cleaned and sanitized at appropriate intervals.
- ✓ The use of high-pressure water hoses and compressed air during production should be avoided to prevent movement of debris from non-product contact areas such as floors to product contact surfaces such as conveyors, aging shelves/boards, contact packaging materials, or product vessels. Debris and spilled food should be physically removed or squeegeed to drains rather than pushed with a hose/water.
- ✓ Roof leaks can contaminate production areas and must be addressed as soon as evident.

Maintenance Best Practices

- ***Tools:*** *Implement a documented procedure to ensure tools are cleaned and sanitized regularly. Tools used in RTE areas must be properly cleaned and sanitized. A best practice is dedicated, color-coded tools for RTE areas to minimize the likelihood of cross-contamination.*
- ***Equipment:*** *Implement a documented "Clean Before Use" program to ensure that product contact surfaces and food handling equipment are cleaned, sanitized, and inspected before placing back into service.*
- ***Hygienic Zones:*** *Maintenance and contractor employees who have worked outside the facility, in "raw," or waste areas, must change into clean plant attire prior to entering production areas.*
- ***Construction/Maintenance:*** *Work on floors and walls in or near processing rooms must be done with contamination controls in place and/or rerouting of traffic. A "Food Safety Construction Plan" (Appendix C) should be developed and shared with affected employees prior to major construction or renovations.*
- *See* ***Appendix C*** *— Food Safety Construction Plan SOP and Checklist*

- ✓ *Listeria* requires moisture and nutrients to grow, so minimize the availability of both. Many dairy plants have adopted a "dry floor" policy whereby the use of water is severely limited to help with control of *Listeria*.

Controlling Temperature and Humidity

All time-temperature controls and protocols for ingredients, in-process materials, and finished products must be followed. Written programs should be in place to ensure compliance at all times including unplanned events, equipment downtime, and rework operations. Manufacturing plant temperature and humidity should be controlled at levels appropriate for each processing step and the products being produced.

Training and Documentation

All dairy manufacturing employees should be aware of and trained on their role in controlling *Listeria* in the manufacturing environment and finished product. Training should occur upon initial hire, prior to new job assignments, and must be periodically reinforced. It is important to have a standard operating procedure (SOP) for training and to maintain records that document employees have been trained. Key points include:

- ✓ Awareness of *Listeria* and other pathogens and the risk they pose to consumers.
- ✓ The importance of controlling the plant environment through effective cleaning and sanitation practices.
- ✓ Identifying, cleaning, and eliminating niche areas and potential harborage points.
- ✓ Preventing cross-contamination in the facility.
- ✓ Identifying likely sources of *Listeria* in the processing/packaging facility and behaviors that might spread the pathogen in the plant environment.
- ✓ Encouraging an effective environmental monitoring program and detection of *Listeria* spp. in the environment when it is present. Detection should never be discouraged.
- ✓ *Listeria* control practices and GMPs relevant to the specific job the employee will be performing.

PRINCIPLE #3: SANITARY FACILITY AND EQUIPMENT DESIGN

Proper sanitary design of facilities and equipment is an important, proactive step in environmental pathogen control. Proper design and maintenance will reduce risks and reduce the ongoing efforts required to assure effective cleaning and sanitation. Ideally, facilities and equipment will be designed for optimal cleanability with minimal niches, sandwich joints, or other potential harborage sites. Harborage points are locations where *Listeria* or other pathogens may survive, and they are usually difficult to reach with routine cleaning. Older plants and equipment may require modifications and upgrades to meet good sanitation standards and some equipment will require full disassembly for proper cleaning. Standard Sanitation Operating Procedures (SSOPs) must be written to compensate for any design/condition deficiencies. See **Appendices A & B** for Equipment Design and Facility Design checklists.

Without adequate control programs, *Listeria* may grow and become entrenched in any equipment or plant areas that might trap moisture or food debris. Areas known to harbor *Listeria* include drains, cracked floors, condensation on walls/ceilings/pipes, damp pipe insulation, hoist chains, unsealed electrical conduits, wrapped/bundled cords, and electrical/hydraulic junction boxes. Almost any equipment can harbor *Listeria*. Examples which have been historically associated with *Listeria* spp. include cooling units, drip pans, difficult-to-access surfaces, difficult-to-clean pieces of equipment such as conveyors, motor housings, bearings, undersides of equipment, pallet jacks, forklifts, and seasonal/limited-use equipment. Design details/workmanship considerations include weld seams, cracks in stainless steel, washers, bolt threads, hollow rollers, hollow framework/legs, overlapped materials, and press-fit parts. *Listeria* cells are very small (about 0.001 mm), making any crack, crevice, or gap a potential harborage location.[8]

Sanitary Facility Design Considerations

Both the 3-A Sanitary Standards[9] and the Pasteurized Milk Ordinance[3] provide good references for design. Both were developed by the dairy industry and offer excellent guidance, especially for fluid products and "inside the pipe" processing considerations. There are also a number of situations and equipment types that do not fit one of the formal standards. For these cases, a series of Sanitary Design Principles and checklists (Appendices A & B) have been developed and refined by industry professionals working with the American Meat Institute (AMI), Grocery Manufacturers Association (GMA), and the Innovation Center for U.S. Dairy (IC). Following these guides will help ensure that infrastructure and equipment can be cleaned, sanitized, and inspected with minimal degradation from repeated exposure to food and cleaning/sanitizing chemicals.

High-level design considerations include:

- Equipment and facilities must be cleanable and resistant to deterioration by cleaning/sanitizing chemicals.
- Facility design should facilitate separation of raw from RTE areas.
- Cleaning type (wet vs. dry) and frequency (daily, weekly, etc.) influence design. For example, packaging equipment placed in a wet-cleaned room must be completely wet-clean capable.

- Silo storage (e.g., raw milk) may need to be in well-ventilated, completely wash-down capable rooms. Silo/wall interfaces must be sealed and well maintained.
- Freezers and coolers must be cleanable after spills. Condensate must be minimized and controlled.

Guidance by specific design area includes:

✓ Floors

Floors are to be constructed to prevent harborage, impervious to chemicals and water, easily cleanable, resistant to wear, and resistant to corrosion. Proper design and maintenance of floors and drains is critical to prevent moisture accumulation and associated microbial growth.

Floors in wet-washed areas should prevent pooling and be appropriately sloped to a drain. All floor joints and cracks should be sealed. Tile, dairy brick, or vitrified tile (a special brick with smaller pores) are recommended in areas with heavy equipment traffic or high temperature liquid exposure. A minimal grout line is preferred as it prevents premature degradation when exposed to water and/or chemicals. Low or missing grout should be immediately addressed to protect the subfloor underneath and prevent water from seeping underneath and becoming a harborage spot for bacteria. Flooring professionals can perform a "tap-test," which is a technique where tiles are tapped with a solid object, resulting in differences in audible tone. Experience with this method allows the expert to determine floor conditions including floor tile delaminated from the subfloor. This information is mapped to set maintenance and replacement plans. Monolithic floors (e.g., urethane or epoxy-coated) require maintenance for any cracking or peeling, and deficiencies must be addressed quickly to eliminate harborage points. Expansion joints should be limited in number, but sufficient to prevent cracking. Closely monitor junctions and points where equipment is mounted to the floor. Pyramid bases around equipment legs and feet are not recommended because water, food, and bacteria could get trapped under and inside the pyramid.

The best flooring material for your application will vary based on multiple factors. A qualified professional should be consulted to determine the best type of floor for each situation. Flooring considerations include:

- Are the current floor materials/grout resistant to chemicals used in the area? Are they cleanable?
- How often is the floor wet? What chemicals are used? What temperatures are they exposed to?
- What kind of and how often is heavy equipment traffic (forklift, pallet jack, etc.) present? Are there safety concerns with the type of flooring (i.e., slip concerns on some monolithic floors without grit)?
- Will pallets be placed on the floor that may cause damage from nails or scraping?
- How much does equipment in the area vibrate and how often?
- How much does the equipment weigh and are special reinforcements needed?
- What kind and amount of maintenance is needed for the floor?

All vertical and horizontal joints, such as floor-wall junctions, coving, and pillars/beams must be sealed. These surfaces should drain freely and have no pockets, ledges, nooks, flat surfaces, or 90-degree angles. Columns wrapped in stainless steel should be sealed at the top and bottom; painted columns should also be sealed and no flaking paint should be present.

Design and maintenance of non-production floors is also important to prevent harborage points for bacteria. Concrete surfaces should be free of pits, erosions, and voids. Floors should be solid, smooth, and sealed at wall junctions. Exterior walls should have an 18-inch inspection zone at the floor/wall junction designated and cleared from obstruction. This zone is often painted white.

✓ Drains

Drains must be readily accessible for routine inspection, cleaning, sanitation, and environmental swabbing. Individual drains should have a cover that does not require tools for removal; access to the drainpipe should not be permanently blocked. Removable baskets may be used to catch particulates to minimize wastewater solids loading. Round drains (versus square or rectangular) are preferred because they do not have corners or edges that can collect soil. The inside of the drain must be structurally sound with no rough edges or pinholes. If a two-piece drain is used, it should be continuously welded. Trench or channel drains are not recommended due to increased surface area that must be cleaned, covers which are often difficult to remove, and multiple junctions which can collect debris or develop pinholes. Drains should be supported with a robust foundation to prevent settling. Where possible, cleanouts should be installed outside the processing area.

Fig. 4. Drains

An accurate drain map that includes all drain line distances, pipe diameters, and drain locations is an invaluable tool when researching operational problems. The map should be updated with facility expansions. This map is also helpful to ensure drains remain accessible when laying out equipment and other materials throughout the room. Raw process and RTE process sewers should be separated. All discharges from equipment in an area, such as from clean-in-place (CIP) skids and balance tanks, should be calculated and factored in the design to limit the potential for pooling. If using a wastewater treatment facility, chemical restrictions may change the amount of water used. All equipment sinks and COP tanks discharge should be piped directly to a drain with an appropriate air break or backflow prevention device instead of draining onto a floor.

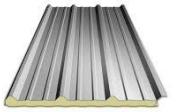
Maintenance of drains and drainage systems is extremely important as biofilms can form in the drains if they are not cleaned and sanitized properly. Drain backups are a potential source of large-area contaminations so procedures around special cause cleaning, sanitizing, and controlling future contamination should be established. Planned maintenance activities such as water jetting, snaking, pit pump-outs, and other drain repair work must have a "food safety construction plan" (see Appendix C) outlining control of aerosols, equipment used during the maintenance, foot and vehicle traffic, and the surrounding environment prior to work starting.

✓ Walls, Ceilings, and Junctions

Walls, ceilings, and structural supports should be constructed to avoid any moisture or nutrient accumulations. Construction materials should be hard, non-porous, smooth, and able to withstand the environmental, cleaning, and sanitation conditions in the area. Suspended ceilings should be smooth,

cleanable on both sides, and have a uniform height. Promptly address any roof or water leaks with containment, cleaning, sanitizing, and identifying when and how the leak occurred. Environmental monitoring should be initiated after any leak to gauge and monitor contamination risk and determine product disposition.

Table 1. Examples of infrastructure options commonly found in food manufacturing facilities

Material	Typical Use	Pros	Cons
Glazed Cement Masonry Unit (CMU, or a block wall with a glaze)	Walls 	High structural integrity, impervious to a wide variety of chemicals	Expensive, difficult to replace, regrouting necessary
Insulated Metal Panel (IMP)	Walls or ceiling 	Cheaper than glazed CMU, insulation properties, mid-range durability; can be used as a walk-on ceiling	Insulation is exposed if metal is damaged, floor/wall junctions can be challenging. Caulk must be replaced periodically due to significant panel flexing from wind shear or other building movement.
Fiberglass Reinforced Panel (FRP)	Walls or ceiling (whole panels or cut as part of a T-bar ceiling) 	Inexpensive, easy to install and replace	Backing wicks moisture, easily damaged; **not recommended**
Painted concrete, steel, etc.	Walls, ceiling, structural support	Easy to implement; durability dependent upon environmental conditions and paint type	Flaking paint could be a foreign material risk; various levels of maintenance required; can create niche harborage points
Stainless-steel filled with concrete or mounted against a wall	Walls, structural column support, silo/building interface	Stainless is cleanable and impervious to a variety of chemicals	Covering of wall or ceiling surface with stainless steel sheets creates harborages and is not recommended

Vertical surface-to-floor junctions should have a cove (rounded edge) and be free of pits, erosion, and voids. For tiled surfaces, grout must be maintained to an appropriate level to prevent moisture from wicking behind the tiles. If stainless steel is used on walls or pillars, such as in a tank alcove or behind a COP tank, seals must be maintained. Expansion joints in walls may be necessary for structural integrity, and should be maintained with an appropriate sealant. Closed cell or encapsulated insulation should be used where possible in infrastructure and pipes. All insulation must be sealed at the ends to prevent moisture from being wicked. Junctions should be seal-welded where possible, threaded surfaces should be minimized, and all-thread rods should not be used. All utility lines and supports should be accessible and cleanable.

✓ Interior Space Design

Several factors should influence the design of interior spaces including overall traffic flow, equipment locations, and utility placement. Controlled flow of employees, contractors, and visitors through the facility should be established. To prevent cross-contamination, the sanitary transport of packaging materials, ingredients, and rework into RTE/high hygiene areas should be consciously designed as discussed in Principle #2. Systems for the sanitary removal of trash from high hygiene areas should be established and followed. Trash collection should be properly located, maintained, cleanable, and cleaned regularly. It may be necessary to design specific employee access for this role to avoid potential cross-contamination. There should be sufficient access to clean building elements (columns, beams, bracings, etc.) and floor/wall interfaces. The equipment and facility layout should allow for access to overhead areas (ductwork, lights, etc.) for inspection and cleaning. Stationary equipment should be elevated sufficiently to allow cleaning and sanitizing underneath the equipment and aisles should allow sufficient space for maintenance and sanitation access.

Horizontal piping and conduits should not be installed above exposed product or processing equipment, because they could introduce foreign material hazards and may present cleaning and sanitizing challenges. Piping should be insulated to prevent condensation when its surface temperature is below the room's expected dew point.

✓ Cleaning and Sanitation Infrastructure

Automated cleaning systems, clean-in-place (CIP) and clean-out-of-place (COP), should be included in facility design to ensure effective cleaning and sanitizing of equipment. Water temperature, flow, and pressure must meet specified requirements at the point of use to be effective. Final rinse systems should be operated at city water pressure (generally 60–100 PSI) to limit the overspray and aerosol creation that is possible at higher water pressures. Barrels of stored chemicals should have spill containment present, and spills should be cleaned immediately. CIP skids should drain directly to a drain, not onto the floor. The backsplash behind COP tanks must be resistant to the chemicals used in the tank. For personnel and food safety reasons, rooms should be designed with sufficient ventilation and air exchanges for chemical vapor and humidity control.

Frequent repairs of rooms dedicated for cleaning and sanitizing operations may be needed due to the infrastructure degradation. Caulking, grout, and other sealing materials are weakened by elevated temperatures and chemicals. To obtain good seals, repairs should be scheduled when the area is completely dry and proper cure time is available. CIP units and circuits require ongoing inspection and repair of leaks (lines, gaskets, and valves) to ensure proper in-place cleaning is achieved.

✓ Exterior of the Facility

The outside of the facility must be maintained so that it does not become a potential source of environmental contamination. *Listeria* spp. and other contaminants can enter a facility through damaged infrastructure, leaks, and by animal/insect pests.

Table 2. Exterior facility design considerations

Structural	Traffic patterns	Additional considerations
Roads/walkways/parking lot surfaces—smooth, intact, no standing water, water drainage away from building	Employee entrance, break rooms, etc.	Vegetation control—nothing touching building, 18" minimum, vegetation on grounds chosen to not attract insects or rodents
Walls—solid, no cracks or voids, intact caulking from utility penetrations and between panels	Visitors, trucker, and construction contractors	Site security—fencing, adequate lighting
Roof—solid, flashing intact, canopies closed, no pooling of water	Controlled vendor delivery—uniforms, vending machines, chemicals, etc.	Pest control—no visible pests, no nests, insect-attractant lights away from building
Man & dock doors, windows, louvers, fans, vents sealed and locked	Accommodation for equipment that may go outside or into trucks/trailers	Garbage control—no loose trash on-site, adequate receptacles
Finished floor elevation higher than adjacent grades to prevent storm water ingress		On-site pallet and tractor-trailer control positioned to prevent unsanitary impact

Utilities

Utilities interact with food products in many ways and must not be overlooked as potential contamination vectors. The PMO[3] provides excellent guidance on the design needs and requirements of utilities setup and can be referenced for best practices.

✓ HVAC

To reduce the risk of dust and contaminants migrating to higher product risk areas. As a general guideline, room pressure is used to cause air to flow from high hygiene > RTE areas > raw areas (see Fig. 3). A pressure gradient of 0.1 inch or 15 Pa may be sufficient. Air filtration must be in place to reduce potential microbial contamination, with the micron size of filtration determined by the microbiological sensitivity of the product manufactured in the area. If the product is sensitive to mold, HEPA filters may be required. In areas where products may not be exposed or are hot processed, MERV 14 filters may be adequate. Seven to ten air exchanges per hour are recommended in most situations.

In some situations, dedicated HVAC/refrigeration systems may be needed to control specific zones:

- Dehumidification controls for high moisture areas (e.g., COP, batching/cooking areas) to reduce the potential for bacteria growth on surfaces.
- Portable HVAC/filtration units for areas with an increased likelihood of containing contaminants such as construction areas. These areas should be lower pressure than surrounding areas and the air should be vented or filtered.
- HVAC units may have a setting used to vent moist air to the outside during environmental sanitation cleanups.

✓ Compressed Air

Compressed air can also become a risk if not adequately designed for food manufacturing applications. The PMO and 3-A provide design standards for compressed air systems.[10] The most critical aspects are the dew point, coalescing filter, and point-of-use filters for removing microbial contaminants. For compressed air coming in contact with a RTE product the system should remove oil, water, smaller particulate matter down to 0.01 micron at greater than or equal to 99.99% dioctyl phthalate (DOP) efficiency, and microbial contamination down to 0.01 micron at least 99.9999% DOP efficiency with a sterile air filter.[11] This air will ideally have a dew point of -40^{o} F.

✓ Potable Water

Potable water can be sourced from a municipal or private well location. Typical potable water setups contain a main backflow prevention device that should be inspected at least annually. Additional point-of-use backflow prevention devices, or an air gap at least twice the diameter of the water supply inlet, should be set up to prevent cross-contamination of potable water supply. Boilers used for culinary steam production may be treated with chemicals to reduce water hardness, but they should only use chemicals approved by 21 CFR 173.310. Point-of-use filters should be used when water is added as an ingredient to the product. Periodic microbiological and heavy-metal testing of water collected at various sample points throughout the facility should be conducted. The PMO, local, state, or federal regulations may drive additional requirements.

✓ Cooling Water

Recirculated water used for cooling should be tested at least semi-annually to ensure it meets microbiological standards. Freezing-point depressant chemicals (salt, glycol, etc.) must be either USP food grade or have Generally Recognized as Safe (GRAS) status unless specific design requirements set forth in the PMO. Reclaimed water from heat exchangers, evaporators, and membrane processes (Condensate of Whey or "COW water") may also be used for cooling in some applications. Controls must be in place to prevent cross-contamination, such as maintaining pressure differentials between the product and cooling water streams (i.e., higher pressure on the product side compared to the cooling water side at all times).

Special Circumstances

In the course of operating manufacturing facilities, special circumstances will arise. Recognizing and preparing for either planned or unplanned events (Table 3) is key to controlling food safety risks. A major risk introduced by special circumstances is the potential for contamination because of non-routine traffic (people), traffic patterns (room segregation, alternate routes, etc.), infrastructure disturbances, or changed/sanitation procedures. Several illness outbreaks have been attributed to construction which introduced pathogens into the plant environment.

Table 3. Types of special circumstances

Type of event	Examples
Planned	Non-emergency construction; a different pool of employees due to an expansion; changes in sanitation following purchase of new equipment; or a new formula or product being produced at a facility
Unplanned	Natural disasters, flooding, water leaks (drain backups, burst pipes, leaking roofs, fire sprinkler, etc.), and hygienic zone breaches

Planned events require preparations including the creation of a food safety construction plan (see Appendix C) which details rigorous procedures for construction projects. A good construction plan clearly communicates the step-by-step work to be done, gives a timeline of events, identifies who will perform mitigation steps, and when mitigation steps will be taken. The depth of a construction plan should be based on the location and type of work being done in the plant, as well as the history of the area.

Unplanned events are typically urgent and challenging because time, personnel, and material resources may be constrained. Once the event or circumstance is contained, an assessment of the products and environment affected must be immediately conducted. Investigational environmental pathogen sampling is important to assess the impact of the event on production areas, as well as determining if other areas were affected through traffic. The Grocery Manufacturers Association (GMA) *Lm* guidance document provides valuable information on dealing with roof issues, water leaks or drain backups.[12]

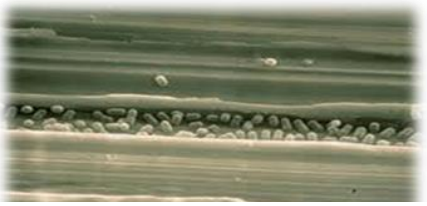
Equipment Design

Following sanitary design principles is critical to ensure cleanability and to eliminate harborage sites where microorganisms are protected from cleaning and sanitation. The equipment sanitary design checklist (Appendix A) can help identify areas of improvement on either new or existing equipment. Key principles of sanitary design for the dairy industry include:

- ✓ Microbiologically Cleanable
  - Equipment should be selected to eliminate the potential for survival of *Listeria* and other pathogens, as well as meet any regulations for the specific product. 3-A and PMO sanitary standards are a good starting point for dairy equipment, but they are most applicable to fluids and "inside the pipe" situations. It is important to verify that all production equipment is cleanable to a microbiological level and that it will survive repeated cleaning cycles.

Fig 5. Poor sanitary welds are not cleanable at a microbiological level

Fig. 6. Scanning electron micrograph of *L. monocytogenes* growing on stainless



Amy C. Lee Wong/ University of Wisconsin

- ✓ Made of Compatible Materials
  - Materials used to construct equipment must be compatible with the product, environmental conditions, cleaning methods, and chemicals. Most equipment in wash-down areas should be made of stainless steel or other corrosion-resistant, non-toxic, and non-absorbent material. Painted surfaces should be avoided. This applies to internal and external parts that may be exposed to product, cleaning chemicals, or moisture (Fig. 7 and 8). For example, anodized or coated aluminum should not be used with acidic products, high salt products, or when acid cleaners will be used. Similarly, some plastics deteriorate prematurely when exposed to chlorinated caustic cleaners.

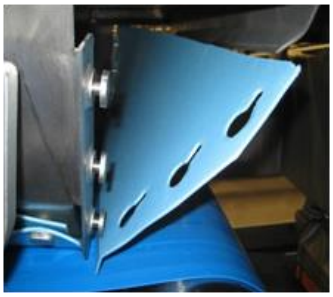
Fig 7. Example of material incompatible with cleaning solution / method

Fig 8. Example of compatible material covered with stainless steel

- ✓ Accessible for Inspection, Maintenance, Cleaning, and Sanitation
  - Any inaccessible surfaces (product or non-product zone) should allow for rapid, tool-free disassembly. Fillers, pumps, valves, catch pans, guards, and other equipment should be easily disassembled for routine cleaning. Instead of bolts, fasten guards and catch pans in place with pins or slots that don't require tools for disassembly. If parts of the equipment cannot be inspected after cleaning, they are likely to be difficult to clean and could serve as harborage sites. All product contact surfaces should maintain a minimum 18" floor clearance to minimize potential for contamination from the floor. The outer perimeter of equipment should have a 12" clearance from the floor and 36" from walls and other large equipment to allow for cleaning.

Fig 9. Splashguard requiring tool for disassembly and creating a catch point

Fig 10. Splashguard with keyhole attachment that can be removed



- ✓ Self-Draining Surfaces
  - Product contact surfaces should be designed to drain freely and not accumulate product/cleaning solutions, minimizing the availability of water and nutrients to microbes. Product and CIP lines should not have dead-ends that allow liquid to collect.

Fig. 11. The square tubing on the left will accumulate soil on the flat horizontal surface. By rotating 90^0, or using round tubing, flat surfaces are minimized.

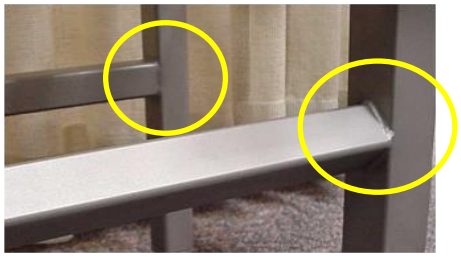
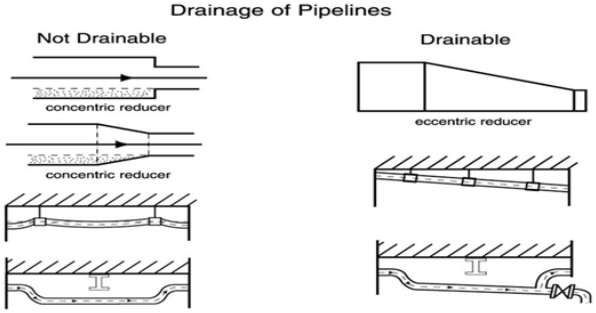


Fig. 12. Non-drainable and drainable designs of pipelines



- ✓ Hollow Areas Hermetically Sealed
  - Tubular framework, rollers, adjustable legs, and other hollow structures must not be penetrated in order to prevent soil and moisture from getting inside. It is often possible to replace a tubular structure with angle iron, which provides open access for cleaning and inspection. The integrity of double-walled vessels, such as tanks, silos, and mixers, should be monitored periodically for pinholes and small cracks. Mobile equipment (tables, stairs, ladders, and their wheels) should also be inspected and repaired where necessary.

Fig. 13. Hollow square tubing not hermetically sealed (missed weld on one side of the leg)

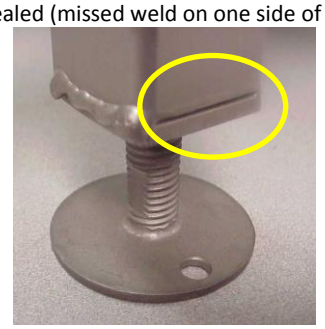
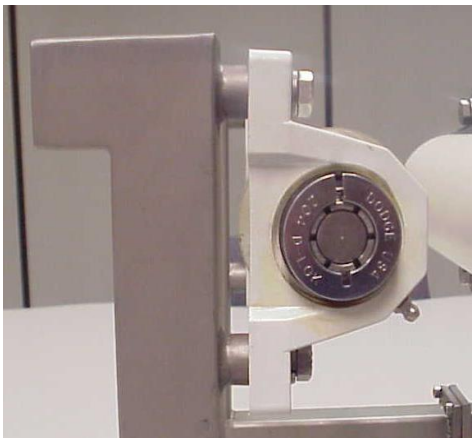


Fig. 14. Hermetically sealed hollow tubing

- ✓ No Niches
  - Prevent accumulations of water, moisture, or soil by minimizing overlapping surfaces, seams, recesses, sandwich joints, and dead spots. Equipment should be built from single pieces of material whenever possible to minimize assembly with bolts, press-fits, or other fasteners. Avoid threaded parts including threaded legs.

Fig. 15. Accumulation/niche created by reassembling the probe facing down instead of up

Fig. 16. Minimize overlapping surfaces with spacers



- ✓ Newly Acquired Equipment
  - When receiving new or used equipment, precautions must be taken to prevent introducing contamination. All equipment new to the facility must be cleaned and sanitized before it enters any production zone. Cleanliness and microbiological condition of the equipment should be confirmed

by taking indicator and/or pathogen swabs. The equipment may need to be re-cleaned, sanitized, and checked before being placed into service. A best practice is to have a policy and SOP to handle new equipment entering the plant.

- Similar precautions should be taken when used or existing equipment is moved to different RTE areas.
- Used equipment presents a greater risk because its history may be unknown and older designs tend to be less cleanable. Additional precautions are prudent.
- New stainless steel equipment must be passivated (see Glossary) for corrosion resistance and to enable cleaning.

✓ Other Considerations

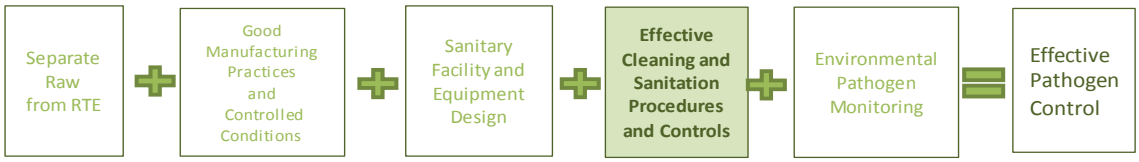
- Non-product contact surfaces in close proximity to the product (Zone 2) and surfaces which will be touched by operators (e.g., control panel buttons, valves, switches) should be designed using sanitary design principles as if they were product contact surfaces (see Fig. 20 for zone descriptions).
- Maintenance and safety enclosures (e.g., motor, drive, guards, electrical boxes, etc.) should never be located over open product. Motor-cooling fans should not blow onto exposed product. Utility lines and maintenance enclosures should be at least 12 inches off the floor, not above open product, and of cleanable design.

<u>Existing Equipment with Design Opportunities</u>

Many facilities have older equipment that may not have been built with current sanitary design best practices in mind. Using the equipment design checklist, it is possible to identify parts of older equipment that may be modified for easier cleaning and to eliminate niches. Examples include replacing the piano hinges common on older mixers with more sanitary ones, and replacing hollow rollers on conveyors with solid ones. Routine inspections are required to ensure that the sanitary design of equipment is maintained as it ages or becomes modified. There are many examples where teamwork between maintenance, sanitation, operations, and engineering have identified opportunities to eliminate niches that were difficult to clean, inspect, and which could harbor pathogens. At a practical level, many upgrades may be justifiable when the cost of incremental time for disassembly and proper sanitation is considered as a recurring expense.

It is important to remember that equipment which was initially properly designed may become insanitary with wear. Additionally, repair parts, modifications, and maintenance techniques can compromise sanitary designs. Routine checks should be conducted in order to promptly identify and remedy issues.

PRINCIPLE #4: EFFECTIVE CLEANING AND SANITATION PROCEDURES AND CONTROLS



Having a well-designed, effective cleaning and sanitizing program is an essential element of the full Pathogen Control Equation. Enhanced cleaning procedures have been proven to compensate for weaknesses in facility or equipment design until improvements can be implemented. Both *routine* and *non-routine* cleaning regimens are essential to remove bacteria and prevent bacteria from potentially becoming persistent.

Routine cleaning is defined as the cleaning and sanitizing that is performed at the end of a pre-determined production cycle. It includes fixed and moveable items including processing equipment, hand-held tools, product catch pans, "pigs" for pushing product, scrapers, tubs, mats, carts, transfer hoses, etc. All of these can harbor bacteria if not cleaned routinely, and therefore must be identified and assigned for sanitation. A process to identify, tag, and store clean equipment should also be established.

Non-routine or periodic cleaning is defined as cleaning that is managed through the use of a Master Sanitation Schedule (MSS) and may include floors, walls, drains, ceilings, other plant infrastructure, and non-food-contact portions of equipment. The frequency of cleaning is determined by the risk of harborage, the risk of contaminating products or other equipment, and other environmental factors.

Effective cleaning requires balancing four basic variables:

- ✓ Chemical Concentration
- ✓ Mechanical /Manual Force or Abrasion
- ✓ Temperature
- ✓ Time

These variables are adjusted based on the soil type (Table 4), surface being cleaned, and cleaning method (manual or automated). For example, manual cleaning at lower temperatures requires more force than cleaning with an automated system at higher temperatures and chemical concentrations.

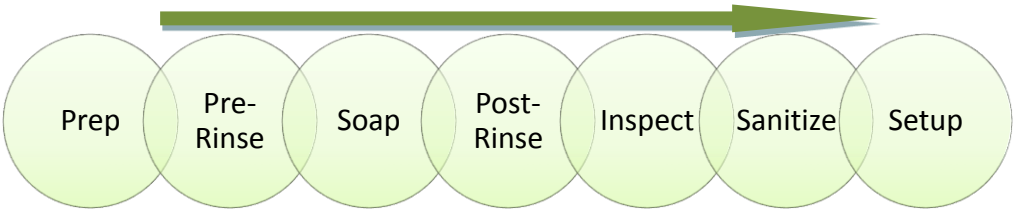
Table 4. Common dairy soils

Soil	Cleaning Temperature	Cleaning Chemical
Butterfat	100–130 °F	Alkaline
Protein	120–150 °F	Alkaline
Denatured Protein	140–170 °F	Alkaline
Mineral (e.g., milkstone)	130–150 °F	Acid
Carbohydrate (e.g., lactose)	130–150 °F	Alkaline

Manual Cleaning and Sanitation

Cleaning and sanitation is most effective when the proper sanitation sequencing is followed. Many companies follow a seven step process:

Fig 17. Seven Steps of Sanitation



1. Pre-Sanitation Preparation
   Remove all production supplies and waste, dry clean and remove as much product debris as possible. Do not use high-pressure water hoses or compressed air to remove solid food residue, because this may move debris around the facility as dust and aerosols which could contaminate additional surfaces.

2. Pre-Rinse
   Using water at an appropriate temperature for the product soil, pre-rinse to remove as much soil as possible from the equipment and surrounding area. Water should be hot enough to melt fats, but temperatures above 130^{o} F can denature proteins and cause soils to adhere to surfaces. High-pressure water or compressed air should be avoided to avoid spreading contamination. High pressure can also drive soils deeper into equipment where removal is problematic. It may also damage bearings or electrical equipment.

3. Soap Scrub
   Apply an appropriate detergent to walls, floors, and equipment. Do not let detergents dry on surfaces. Using the proper color-coded tools (scrub pad, brush, etc.), apply mechanical action to remove all product soil. Mechanical action is especially important in breaking up potential biofilms, allowing subsequent sanitizing to be effective.

4. Post-Rinse
   Rinse away all chemical and remaining product residues with water from the top down. Certain products may require a repeat of steps 3 and 4 with an alternative type of detergent.

5. Inspection
   Inspect and verify that the previous steps were effective. Repeat steps 3 and 4 if necessary. Inspection is best undertaken using strong illumination such as a flashlight.

6. Sanitize
   Sanitizing is only effective if equipment and other surfaces are clean and free of organic matter. Sanitize equipment, walls, floors, equipment framework, etc from the bottom up to ensure all surfaces are covered. Only EPA-registered sanitizers with documented, validated activity against *Listeria* should be used.

7. Reassemble and Room Setup
   Under sanitary conditions, wash and sanitize tools, hands and gloves. Remove any pooled sanitizer and condensation. Bacteria need moisture to grow, so the production environment should be kept as dry as possible. Under certain circumstances it may be necessary to sanitize again after equipment assembly.

Clean-In-Place (CIP)

Clean-In-Place (CIP) is a common routine cleaning regimen which is used for enclosed surfaces such as pipelines, heat exchangers, tanks, and processors. CIP involves the circulation of cleaning solution through pipes at a prescribed flow rate or through spray devices/balls for vessels and equipment. CIP systems use time, temperature, chemicals, and mechanical force to achieve maximum cleaning. CIP use requires that the equipment is of sanitary construction, with smooth, cleanable surfaces, and is drained. As with manual cleaning, following proper sequencing is necessary to ensure that equipment is clean.

Clean-Out-of-Place (COP)

A third cleaning system is clean-out-of-place (COP). With COP, parts that require manual cleaning are disassembled and submerged in a horizontal vessel which uses circulating detergent, heat, and agitation to remove product soil. COP tanks must be large enough so that parts are fully submerged and are not crowded. Overloading a COP tank inhibits flow of cleaning solutions, rendering the process ineffective. All parts should be reassembled or properly stored at the end of the COP cycle (Fig. 18 and 19).

Fig. 18. Incorrect storage of parts in a COP tank. They should be stored in designated areas

Fig. 19. Equipment must be fully submerged for appropriate cleaning

Sanitizing

Sanitizing can be accomplished utilizing heat or chemical methods. Chemical sanitizer types include chlorine-based, iodine-based, quaternary ammonium compounds, and variations of acid and peracetic acid-based. Sanitizers can be categorized as rinse-required or no-rinse. Label instructions must be followed. Caution must be exercised to avoid recontaminating equipment after it has been sanitized.

It is important to sanitize only clean equipment—excess food soil will make sanitizers ineffective. Sanitizer solution must be tested to verify that the desired concentration is consistently present. Too little sanitizer is unacceptable, but too much can also have diminished efficacy and may result in surface residues. For floors, walls, and drains, a sanitizer with residual properties should be used. Check with your chemical supplier for guidance on the appropriate products to use in each situation.

Heat sanitization should be controlled to ensure it is adequate to kill the target organisms while being mindful that excessive heat can damage equipment. Heat sanitizing using dry steam or hot water is only effective when appropriate temperatures can be maintained throughout the entire item being sanitized for the appropriate amount of time. Heat sanitizing procedures should be verified for each piece of equipment and surface.

Cleaning in Dry Environments

A key rule in dry dairy production areas is that "dry needs to stay dry." Plants that process dry dairy products and powders frequently have some wet processing, so it is important to maintain a high level of hygiene in wet areas and good separation to keep moisture out of the dry areas. Traffic from wet to dry should be controlled with transition areas. *Listeria* spp. can survive but not grow in dry (low water activity) environments. Most dairy powders are hygroscopic and will absorb moisture from the environment if it is allowed to accumulate which can lead to the survival and growth of *Listeria* or other contaminants. Cleaning plans should include preventing powder accumulation, proper air circulation, and humidity control. Relative humidity that is either too high or too low allows particles to stick to surfaces. Relative humidity should be no greater than 30%.

In dry areas, cleaning is commonly carried out using High Efficiency Particulate Arrestance (HEPA) filter vacuums, brushes, brooms, or other means to dislodge and remove soil. These cleaning utensils should be kept clean and stored in a manner which prevents contamination and moisture buildup. Utensils should be monitored for wear and replaced when appropriate. Vacuums and dry-cleaning utensils should be part of the environmental monitoring program. Alcohol-based sanitizers can be used to sanitize dry product contact surfaces. If periodic wet-cleaning is done anywhere in the dry processing plant, all product and packaging material should be removed from the area and dry processing equipment not being cleaned should be isolated to ensure it stays dry. The area should be completely dry prior to resuming dry processing or packaging.

Sanitation Effectiveness Monitoring

Monitoring, corrective actions, and documentation activities are crucial for verification of the effectiveness of the facility's cleaning and sanitation program. Key elements of pre-operational monitoring include: smell, touch, and visual inspection of equipment, ATP swabbing, and clean equipment swabbing for indicator organisms (see page 7). Visual inspection and ATP swabbing provide immediate actionable feedback, while culture-based swab results are used to verify cleaning and sanitizing at a microbiological level. The results of these monitoring activities should be tracked and trended to verify program effectiveness and to determine the need for additional training or sanitation standard operating procedure (SSOP) changes. This will also aid in the identification of equipment design/integrity issues. For cleaning processes which utilize CIP or COP, temperature charts, cycle charts, and concentration checks should be monitored by trained personnel.

Master Sanitation Schedule

A Master Sanitation Schedule (MSS) is a documented system for the managing and tracking of non-routine cleaning and sanitizing tasks. This targets areas of the plant (both infrastructure and equipment) that are not typically cleaned after each use or production cycle. Because these tasks are non-routine, it is important to

have a comprehensive list and set cleaning frequency based on pathogen risk, cleaning history, and proximity to exposed product. Master Sanitation tasks can be categorized as Periodic Infrastructure Cleaning (PIC) or Periodic Equipment Cleaning (PEC).

PIC Examples
- ✓ Walls
- ✓ Floors
- ✓ Ceilings
- ✓ HVAC ductwork
- ✓ Overhead equipment (hoists, beams)
- ✓ Pallet jacks
- ✓ Forklifts
- ✓ Floor scrubbers

PEC Examples
- ✓ Conveyors
- ✓ Dryers
- ✓ Chillers
- ✓ Heat exchangers
- ✓ Scales
- ✓ Wear strips
- ✓ Pumps
- ✓ Valves
- ✓ Spray devices

Each task on the MSS should have an associated SSOP and should be assigned to trained personnel. Each task area should also be inspected periodically before and after cleaning to ensure that the frequency is appropriate and that the task is being completed properly. The MSS program should be re-evaluated when process or structural changes are made to the plant.

Special Cause Cleaning

There are occasions due to construction, specific activities in the plant, positive environmental swab results, or other issues when it becomes necessary to perform deep or special cause cleaning. During special cause cleaning, equipment is disassembled for cleaning beyond what is routine and enhanced sanitizing procedures/chemicals are used.

The area around the issue should be isolated to prevent unnecessary access until the special-cause cleaning can be performed. If there is potential for cross-contamination of product due to adjacent traffic, the area should be roped-off or restricted until special cause cleaning is completed. Additional floor sanitizing barriers may be necessary to prevent potential spread to other areas of the production plant. If there are adjacent lines, it may also be necessary to put temporary walls in place to prevent cross-contamination. During the cleaning process, employees should take precautions to prevent cross-contamination. The employees performing the cleaning should not return to their normal production tasks until steps such as a uniform change, footwear changes, showers, hand-washing, and tool decontamination occur.

During special cause cleaning or periodic deep cleaning, equipment should be disassembled to expose internal surfaces. Any overlapping parts are disassembled to expose all surface and bolted/fastened parts are separated. If the equipment is complex, the equipment manufacturer may be consulted to support the teardown. After removal of any soil and subsequent deep cleaning, different sanitizing methods should be considered based on access to surfaces, presence of electronic components and motors, and other factors. Some options are:

- ✓ A sanitizer with oxidizing capability, such as chlorine dioxide or peracetic acid.
- ✓ Alcohol wipes for electrical boxes or control panels that must remain dry.

- ✓ Chlorine dioxide gas may be used if the area can be safely contained.
- ✓ Steaming by shrouding the equipment and injecting live steam to ensure the coldest spot reaches 160 ^{o}F for 30 minutes minimum.

The last two methods are effective for complex equipment with poor access to all surfaces. After the deep cleaning is completed and the equipment is reassembled, the entire area, including floors and any nearby drains, should be sanitized prior to returning to production. A swabbing regimen should be put into place to confirm that the cleaning was successful and that the area no longer poses a contamination risk.

PRINCIPLE #5: ENVIRONMENTAL PATHOGEN MONITORING

A robust environmental monitoring plan designed to verify the effectiveness of the pathogen control programs is an important component of any food safety plan. Top management commitment and involvement in the design and execution of this plan is critical and should include regular reviews of environmental results, trends, corrective actions, and driving continuous improvement. A successful plan also depends on detailed planning, proper resourcing, definition of roles, and empowerment of the responsible personnel.

A good *Listeria* Environmental Monitoring Plan (LEMP) has various components that work together:

- ✓ Facility-Specific Risk Assessment
- ✓ *Listeria* Monitoring Plan
    - What organisms to monitor for
    - Sampling frequency
    - Number of samples to be collected
    - Where and when samples will be collected
    - Sampling and testing methods
- ✓ Evaluation of Results: When is action to be taken and corrective action confirmatory sampling?
- ✓ Documentation and Follow-up

<u>Facility-Specific Risk Assessment</u>

In order to identify areas of vulnerability, each facility must collect relevant background information and perform a facility-specific evaluation. This will aid in determining the number, location, and frequency of sample collection and provides a valid foundation for the program based on risk. A 24-month review of background information is ideal when building or updating a LEMP program because it will include seasonal environmental changes, production volume/mix changes, personnel vacations, holidays, and other cyclical factors which impact the plant environment. Facility assessment considerations include:

- Product exposure to the processing environment after pasteurization but prior to packaging.
- Human handling of product prior to packaging
- Traffic flows and human interactions with products and equipment
- Physical separation of raw and RTE
- Extended processing and its impact
- Equipment and facility design challenges

Developing a Sampling Plan

According to the FDA, "It is recommended that your environmental monitoring procedures use a risk-based approach in which you establish strategies for environmental monitoring (e.g. environmental sampling, sampling sites and frequency, test procedures, and corrective actions) based on both the characteristics of your RTE food products and the processing methods used to produce those products. In general, the greater the risk that a RTE food could become contaminated with *L. monocytogenes* and support growth of the organism, the greater the frequency of environmental sampling and testing[7]"

✓ What to Test For: *Listeria* spp. or *L. monocytogenes*

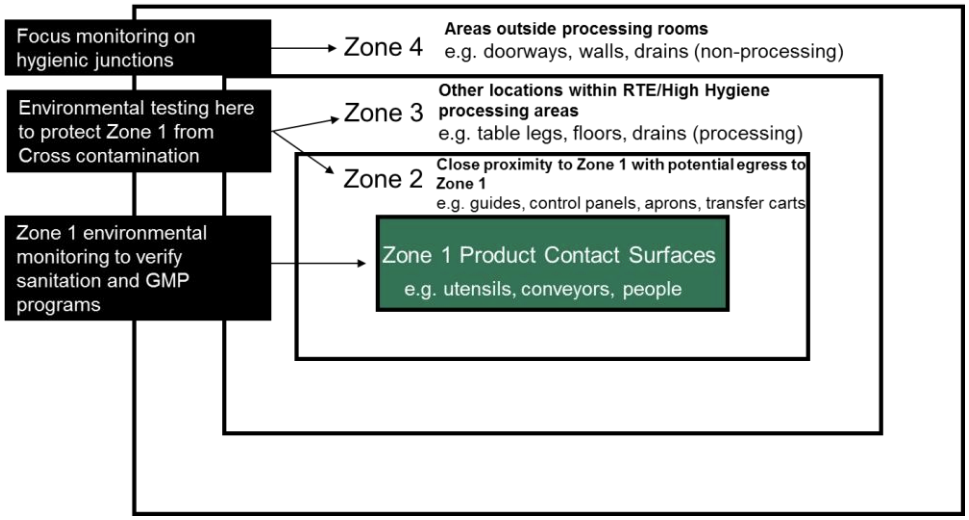
Listeria spp. are a broad indicator group which, when detected, signal that conditions are also favorable for *Lm* growth or survival. The goal of a LEMP is to aggressively look for, find, and continuously eradicate all *Listeria* spp. from the processing environment, ultimately ensuring the absence of *Lm*. A program based on detection of *Listeria* spp. is more conservative than one monitoring for *Lm* specifically; *Listeria* spp. will be found much more frequently in the environment. Another advantage of *Listeria* spp. monitoring is the time to results—environmental swab test results may be available in less time. Faster results will drive a more rapid response and intervention actions. It is considered a best practice to monitor for the presence of *Listeria* spp.

✓ Where to Sample

The goal of a good LEMP is to aggressively seek and find any *Listeria* spp. present in a facility so that it can be eliminated. Product contact surfaces, processing rooms, and areas adjacent to processing areas are referred to in a series of successively larger "zone" rings starting from product contact surfaces and moving outward, where "Zone 1" is a product contact surface and "Zone 4" might include a floor in a warehouse. The objective of the zone designations is two-fold: 1) developing a mindset of taking actions to prevent pathogen travel through adjacent zones to product contact surfaces, and 2) establishing a common set of terms for discussions among practitioners. Zones are defined based on the proximity to the product and potential risk of contamination[13] (Fig. 20). Zone designations are generally fixed, but could be dynamic depending on the facilities layout, personnel activity, or equipment conditions.

There is an important difference between "zones" and "sampling sites or locations." Swab sampling "sites" are the specific physical location of the sample (e.g., shaft of motor #43, handrail on blender deck, left guide on product conveyor), which must be recorded with each sample. For example, your sampling plan for monitoring Zone 2 on a particular manufacturing line would contain a list of all specific sampling sites that are non-food contact surfaces immediately adjacent to Zone 1. The Zone 3 list would contain sampling sites further from Zone 1 and adjacent to Zone 2, and so on (see Table 5).

Fig. 20. Environmental monitoring zones



REMEMBER
Raw Areas

- ***Covered by basic GMPs***
- ***Are not typically considered Zone 4***
- ***Environmental Monitoring activities focus on hygienic junctions with other hygienic zones***
- ***Examples:***
  - ***Milk Receiving***
  - ***Milk Storage***
  - ***Milk HTST Room***
  - ***Raw Ingredient areas***

Table 5. Additional information on zones and sampling

	Description	Examples
Zone 1	Product contact surfaces – direct and in-direct (includes any surfaces that can drip, drain, draw, or diffuse onto/into the product or product container)	Filling heads, hoppers, scrapers, utensils, packaging equipment surfaces, product contact conveyors, brine
Zone 2	Non-product contact surfaces near Zone 1 which, if contaminated, could reasonably contaminate product contact surfaces through normal operations	Sites near Zone 1 which might include: items above exposed product, package guides, equipment legs, framework, motor housings, tank lids, control panels, scrap carts, conveyors, HVAC vents, air filters, floor mats at packaging
Zone 3	Other locations within RTE or High Hygiene processing areas. Remote chance of contaminating product or product contact surfaces under normal practices without mechanical or human intervention	RTE or High Hygiene processing room floors, walls, surfaces, wall/floor junctions, cleaning tools (brooms, squeegees), floor scrubbers, forklifts, floor drains, ceiling drainpipes, wash stations, ingredient storage areas, transition rooms, etc.
Zone 4	Areas outside processing rooms	Warehouses, laboratory, lockers, break rooms, compactor areas, offices, maintenance shops

(Adapted from ICMSF 2002)

A sampling plan should be dynamic and robust, incorporating static, rotating, and random sites with planned quantities that take into consideration risks such as raw/RTE crossover, facility/equipment age and condition, history, and product type. Sampling Plan considerations include:

- Routine sampling of Zones 2 and 3provides an early indication of *Listeria* spp. harborage sites, helps prevent Zone 1 cross-contamination, helps verify corrective actions have eliminated *L. monocytogenes* from harborage sites, and verifies the effectiveness of your non-FCS control programs for *L. monocytogenes*.

- Areas historically associated with *Listeria* spp. growth (e.g., hollow rollers on conveyors, gasket material around doors, hollow support structures, grease inside bearings, slicers, dicers, drip pans, condensate) should be preferentially included in the plan.
- Focus on the most critical areas of the plant including the area between the kill step and final packaging.
- Check interfaces, transition areas, and barriers between raw areas and RTE areas to verify the effectiveness of separation.
- Sample collection personnel should have the freedom to sample additional sites based on observations.
- Zone 4 sampling is less frequent, used to determine whether transient microorganisms are present that may pose an eventual risk to the RTE areas or for investigational purposes. Sampling non-production and transition areas may also help to assess the effectiveness of sanitation and GMP controls.
- A cross-functional food safety team with knowledge of the plant's programs, processes, and practices is in the best position to develop a list of sampling sites. A site map identifying facility layout, traffic flow and hygienic zoning areas should help drive site selection.
- If Zone 1 testing is included as part of your monitoring program, it is used to verify the effectiveness of your control programs for *L. monocytogenes*.

- A facility specific plan, based on product, process, condition of the plant and equipment, will aide in determination of appropriate Zone 1 monitoring parameters including, sites and frequency. More information on Zone 1 monitoring can be found in the FDA's Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry, *Draft Guidance*[7]. You should involve an internal or external food safety expert to develop your Zone 1 monitoring program to determine which specific sites to sample and how product will be controlled pending sampling results from routine and non-routine sampling of zone 1. As the new FDA Listeria control guidance describes, only test for *Listeria* spp. in zone 1, not *L. monocytogenes*. Testing for and finding *Listeria* spp. on a product contact surface does not automatically mean that product is contaminated, but appropriate and aggressive corrective actions need to be taken and documented. In addition to *Listeria spp.* Monitoring, facilities may use other indicators of zone 1 sanitation effectiveness such as ATP and/or APC test on a more frequent basis than Listeria testing.

✓ When to Sample

Routine environmental sampling is performed during production, at least 3-4 hours into the production cycle. Extended runs may warrant sampling later in the run, starting at least halfway between sanitation cycles. This timing is recommended because harborage sites may not be identifiable immediately after cleaning and sanitation. *Listeria* spp. established in a niche may work their way out with vibration and moisture as equipment is operated. Some samples can only be collected safely when equipment is not running, these samples can be collected at the end of production before cleaning or any other time the equipment is idle and can be safely accessed.

Routine sampling should be conducted on aset frequency (e.g., daily, weekly, bi-weekly) based on individual facility conditions, circumstances, and history. Timing should rotate to ensure situations are monitored across all days, shifts, plant areas, and zones. Varying timing to represent the entire production schedule and to capture events that only occur periodically will help in investigating any issues. Some Zone 4 sites may only be sampled monthly or quarterly.

For non-routine, investigational, or special events swabbing, timing is determined by the specific circumstance. Sample when conditions are not typical, such as during audits, tours, construction, etc. Always sample when a drain backup or roof leak occurs. Additionally, a process should exist for swabbing all new incoming equipment, and pre- and post-swabbing for construction.

Beyond your routine sampling sites, it is also a good practice to perform some random sampling as a further check that the facility's pathogen control programs are working as intended.

✓ How Often and How Many Samples

The number of samples collected will differ by zone, the risk to exposed product, and the complexity of the production system. The overall number of samples taken each week is facility- and product-specific. Considerations include, but are not limited to:

- Generally, it is recommended that a minimum of 5 samples be collected for FCS and non-FCS per line for small facilities. Facility size and layout as well as history will inform sampling numbers. For more details refer to FDA's Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry, *Draft Guidance*[7].
- Process conditions: degree of RTE product exposure to the plant environment, human handling prior to packaging, product temperature at packaging (hot fill vs. cold fill).
- Product risk assessment: does the product support survival or growth of pathogens?
- Condition of the processing facility: floor, overhead, wall conditions, age, product flow, etc.
- Sanitary condition of processing equipment: welds, cracks, pitted, material, easily cleaned, etc.
- External historical data and recent outbreaks: industry environmental monitoring norms, recent product or ingredient concerns, inherent risk profile of product type, etc.
- Other factors: distribution conditions, shelf life, intended use, target distribution channel, if product is for higher risk consumers (young, old, pregnant, immunocompromised)
- Flexibility: plan should accommodate routine as well as investigational, validation, and verification objectives.

✓ Sampling and Sample Transport

- Trained plant personnel should collect samples aseptically using hygienic handling practices.
- Individuals sampling should proceed from "clean" areas to lower hygiene areas to avoid cross-contamination of the facility. This means Zone 1 FCS contact surface swabs are taken before non-FCS swabs and RTE area swabs before non-RTE areas.
- Sterile sponges are effective for sampling large areas (e.g., 12 x 12 inches) and smaller "swabs" may be used for small or difficult-to-access areas. Sponges and swabs must be moistened with an appropriate buffer solution. If residual cleaners or sanitizers may be present on sample sites, a buffer containing a neutralizing agent must be used. Consult with your testing laboratory or technical expert regarding the choice of buffer solution.
- A separate sponge or swab should be used for each distinct site. For sponges, sample as large an area as reasonably possible using firm rubbing/abrasion to enhance the chances of finding organisms

It is important to recognize that swabbing requires abrasion/firm rubbing, in areas where biofilms may have been established, to enhance the chances of finding embedded Listeria and established biofilms.

where biofilms may have established. For long pipelines or inaccessible assemblies, rinsing with a buffer solution and then testing the rinsate is an acceptable practice.

- Compositing samples to reduce testing costs should be considered only in mature LEMP programs where positive results are rare. Compositing can cause delayed or confused corrective action. Up to five separate sponges may be combined into one "composite sample" for testing. Do not composite swabs from different zones. Sample compositing should not be done during an investigation. In the event of a suspect result on a composite, each site must be treated as suspect. Consult with your testing laboratory regarding compositing protocol.

✓ Selection of Testing Laboratories

It is important that your testing laboratory is accredited and reliable for the desired tests. It is recommended that the laboratory be accredited to ISO 17025 or have a management system to address the key components of an accredited laboratory:

- Staff competency and documented training.
- Test methods documented and based on accepted standards.
- Equipment fit for purpose and appropriately calibrated.
- Documented QA program including proficiency testing.
- Internal audits of lab operations.
- Internal environmental monitoring to help evaluate if conditions are impacting client results.

The laboratory should be experienced in testing of environmental monitoring samples for *Listeria* spp. and should use only test methods that are recognized or accredited for product or environmental testing. These methods are described in the FDA Bacteriological Analytical Manual, ISO methods, or validated through recognized validation bodies, such as AOAC.

Results Tracking and Trending

Results should be reviewed as soon as practical after receipt. It is recommended that a facility map be used to indicate where sample sites are located and to indicate where positive results occur. Mapping gives a visual depiction of the sites in relation to equipment, traffic routes, and convergence areas and may lead to identifying patterns not otherwise apparent (Fig. 21). Indicate sampling time to identify shift, before/after sanitation, etc. A food safety team should monitor and review LEMP data on a regular basis, looking for trends or patterns (Fig. 22).

Fig. 21. Example map format for tracking and trending

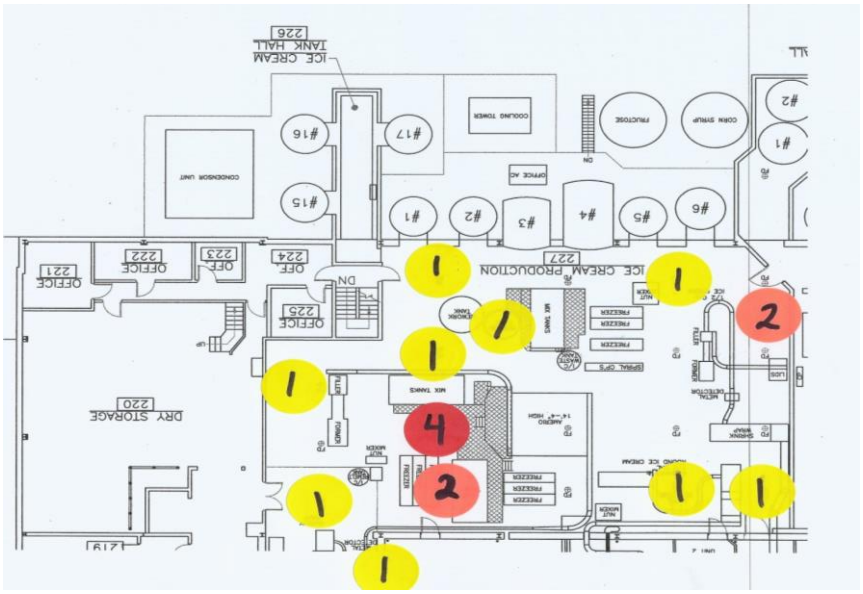


Fig. 22. Example spreadsheet format for tracking and trending

LISTERIA SURVEILLANCE TRACKING + - Down/Day Non operational Not sampled

Sampling Location	12/22	12/23	12/29	12/30	12/31	1/1	1/2	1/3	1/4	1/5	1/6	1/7	1/8	1/9	1/10	1/11	1/18	1/25	1/29	2/1	2/3	2/4	2/5	2/6	2/7	2/8	2/9	2/10	2/11	2/13	2/15	2/22	2/28	3/6	3/13	3/20	3/
Milk Silo corridor		+	+																																		
Steps up to HTST Room		+																																			
Floor/Wall Junction by Separator																																					
Milk Balance tank --bottom side		+																																			
Drain 52 in HTST Room		+																																			
Control Panel HTST																																					
Separator Desludge floor area																																					
Cream Pot																																					
Standardization Instrumentation station																																					
Red line room entryway floor																		+	+																		
Door Handle HTST to Vat area																																					
Vat Operator workstation surface																																					
Vat Sampling Scoop Holder Frame																																					
Floor Vat room																																					
Drains in Vat room																																					
Wall behind curd discharge Valves																																					
Floor under curd discharge lines																																					
DMC exterior wall north																																					
DMC exterior wall south																																					

Case Study 1—Eliminating a Growth Niche

During routine sampling in a processing room, a floor sample under a conveyor and near a metal detector came back with a presumptive positive for *Listeria* spp. during operation.

The food safety team immediately conducted investigational swabs on nearby sections of the floor, on equipment framework, legs, guards, and bearings/shafts. Investigational swabs were taken after cleaning and during operations.

All post-cleaning swabs came back negative with the exception of one near a bearing housing (Fig. 23). During operation, other sites adjacent to the bearing housing were also positive.

Fig. 23. Sandwich area formed by the bearing housing and framework where *Listeria* spp. had established a niche and the framework had rusted

Maintenance disassembled the bearing housing and noticed rust on the housing and the framework. They changed the housing and asked sanitation to clean and sanitize (quaternary ammonium) the framework. To verify the effectiveness of their actions, the new housing and the sanitized framework were sampled for *Listeria* spp. The results were negative for the new housing but presumptive positive for the framework.

Maintenance removed the housing and used a different type of sanitizer (alcohol-based). The swab still came back presumptive for *Listeria* spp.

At that time, maintenance decided to remove all the rust on the framework by buffing and sanitizing it. Following these actions, the results were negative for *Listeria* spp. on all surfaces adjacent to the housing including the floor.

This case study highlights the importance of vectoring to identify a niche and the importance of verifying the effectiveness of the actions taken.

Response to Results and Corrective Actions

Responding to a positive result requires:

- ✓ Isolate and limit traffic in/around the area. Resample areas represented by the positive sample.
- ✓ Conduct a thorough investigation/risk analysis of area.
- ✓ Complete vector swabbing at the first opportunity, before cleaning if possible, to try to determine the contamination source.
- ✓ Implement intensified cleaning and sanitizing, possibly including equipment disassembly (i.e., a "deep clean")
- ✓ Intensified sampling and testing to confirm the effectiveness of corrective actions
- ✓ Determine root cause and implement long-term corrective actions for the root and any contributing causes identified. In the event long-term correction must be delayed, mitigation steps/temporary actions must be taken to prevent spreading and/or contaminating product/product contact surfaces.
- ✓ Determine if finished product testing is warranted based on proximity of positive result to a FCS to exposed finished product.
- ✓ Further details on Zone 1 mitigation and corrective action steps can be found in FDA's Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry, *Draft Guidance*[7].

The immediate response to a positive is to resample the area or equipment extensively to isolate the specific site, especially if the test sample had been composited. If possible, limit access to this area to prevent moving the pathogen to other areas of the facility. It is possible that equipment may have to be disassembled to be fully inspected and cleaned. Then thoroughly clean and sanitize the affected area. When cleaning the area, verify that the standard procedures are adequate for the equipment/area to be cleaned. Mechanical action (elbow grease) is necessary for the removal of biofilms that may harbor pathogens and protect them from cleaners and sanitizers.

Complete a vector analysis of the area to determine how the organism may have been introduced, but be careful not to spread any potential contamination. Look up, down, and in all directions (360 degrees) for potential sources. The investigation should include a review for leaks, crevices, metal joints (welded and bolted), broken or loose tile, hollow areas, air handling units, and air flow. Include both stationary and transient equipment in the investigation. Be sure to include traffic patterns in the area, as they are a potential source as well as a risk of tracking the organism to additional areas. The analysis should include inspections using your senses (sight, smell, touch) as well as a regimen of investigational swabs to assist in locating the source. Follow-up sampling is performed after cleaning (see sidebar).

Corrective actions must always include reswabbing of the area under similar conditions to verify that remediation efforts have been successful. Each facility should establish a required number of consecutive negative results before considering the area "clean." This number is often 3, but may vary based on the zone and general environment. If the zone has multiple traffic patterns, reswabbing should be conducted based on a complete cycle of traffic or processing. It is critical to document all investigations and corrective actions as well as follow-up testing.

Special Considerations

- **If repeated positive *Listeria* spp. or *Lm* results** are encountered within an RTE area, close to or in Zone 1, for which the cause has not been identified, **it is strongly recommended that the facility cease production**, identify causes, and take correct actions before resuming production.
- When a test reveals the presence of *Lm* in product, the product is considered adulterated and must be withheld from commerce. If any part of the production lot has already been shipped, it must be recalled and reported through FDA's Reportable Food Registry, if the affected lot is no longer within the company's control.
- The above conditions may indicate a loss of control and the facility should engage internal or external food safety professionals to lead and facilitate troubleshooting and corrective actions.
- Cheese brines directly contact product and should be considered Zone 1. *Listeria* can survive in the cold, salty conditions of cheese brines, so they deserve special attention. Brines and brining equipment must be clean and in sanitary condition.
- Shelves, boards, and other surfaces that are used to age or drain unpackaged cheeses and other dairy products are considered Zone 1 and must be maintained in a sanitary fashion.
- When brines, aging shelves, boards, and other product-contact surfaces are tested for an indicator such as *Listeria* spp., company management should have a clear understanding of the product implication in the event of a positive test result. Product should be held until negative results are received.

Program Verification and Documentation

Verification of the LEMP should be a routine process involving the review of all program elements, results, corrective actions, and documentation. It includes visual observation of the program execution to ensure that all required steps are performed properly and completely. Verification of the LEMP may include activities applicable to the overall program or to a specific line/area. Items to be reviewed include:

- ✓ Review methodology
  - Does the monitoring program include the appropriate numbers of samples, site locations, and timing of sampling?
  - Is the proper sampling procedure being followed and correct location being sampled?
  - Are samples handled and delivered to the lab in an appropriate manner?
  - Are the correct (analytical methods) methods being used? Are they followed correctly?
- ✓ Review records and results
  - Are documents, records, and reported results (including required review/sign-offs) accurate and complete?
  - Are there documents, records of response for all findings and corrective actions?
  - Have periodic reviews of results identified any trends or repeat issues?
  - Were corrective actions implemented and followed?
  - Do records show that the corrective actions effectively re-established control?
- ✓ Identify modifications to the sampling plan in response to:
  - Results/trends/repeat issues
  - Special circumstances
  - Changes to product, process, equipment, and/or plant environment

Records of sampling maps, plans, results, and corrective actions must be maintained. These are valuable when evaluating effectiveness of the plan and enable valid reviews for improvement. As with all records, they must be dated, signed, and traceable to the facility and processing line.
During the verification, additional sampling may be conducted at additional and/or different sites to demonstrate that routine sampling has been effective. Finished product testing may also be utilized. Other activities may include engaging an outside expert consultant or reviewing published materials.

Case Study 2—Environmental Contamination Leading to Presumptive Positives

The facility receives different natural cheeses and other microbiologically sensitive material to make process cheese. Blending and packaging takes place in a high hygiene room where the product is cold packed. The packing line is wet-cleaned daily. Because the product is cold packed and exposed during packaging, the pathogen environmental monitoring program includes Zones 1, 2, 3, and 4 sampling for *Listeria* spp. during operation (minimum 4 hours after the beginning of production). When Zone 1 surfaces are sampled, all product is held pending negative results.

One of the Zone 3 samples, a floor sample from the packing room, was presumptive positive for *Listeria* spp. Corrective action was taken by cleaning with foam and scrubbing the entire floor followed by application of peroxyacetic acid sanitizer. Follow-up swabs were all negative (three consecutive sets) for *Listeria* spp.

Then, about a month later, another floor result was presumptive positive for *Listeria* spp. Similar corrective actions were taken, and investigational swabs revealed an additional Zone 3 positive for *Listeria* spp. All investigational Zone 2 results were negative. After the corrective actions, the first two sets of follow-up results were negative; however, on the third set, one swab was presumptive positive for *Listeria* spp., which led to more investigational swabs. Some Zone 3 investigational swabs taken during operation came back presumptive positive for *Listeria* spp. All *Listeria* spp. environmental samples taken after cleaning, but before operation, were negative.

When mapping the results and observing production, the food safety team noticed that water was dripping onto the floor and across a piece of peripheral equipment before draining near exposed product. The sanitation team had minimal access to clean under the peripheral equipment and the epoxy floor showed some damage in that area.

For preventive actions, the team installed a temporary barrier during production preventing water from dripping onto the floor and performed periodic sanitizing of the floor with a peroxyacetic sanitizer during operation (note: hydrogen peroxide powder would also be an option that would help keep the area dry). Following the implementation of these preventive measures, all environmental *Listeria* spp. samples were negative.

For corrective actions, maintenance fixed the leak, sealed the peripheral equipment with the floor, and resurfaced the floor.

What If *Listeria* spp. Is Never Detected?

It is unlikely that an effective LEMP in a dairy facility would never yield positive *Listeria* spp. results. If *Listeria* spp. is never detected, then the sampling program should be revisited. Potential reasons for not detecting *Listeria* spp. include:

- ✓ The sampling and/or testing procedures may not be rigorous or sensitive enough.
  - Ensure likely harborage points have been identified and sampled.
  - Ensure sampling times and frequencies are selected to increase the chances of finding *Listeria.*
  - Ensure sampling procedures are followed and size of area sampled is adequate.
- ✓ Failure to neutralize residual sanitizer in sampled areas.
- ✓ Poor sample handling prior to testing.
- ✓ Faulty detection methods or low technician competency.
- ✓ Manipulation of sampling or testing to obtain negative results.

Case Study 3

A specialty cheese manufacturer was notified that a random regulatory test had identified *Lm* in product sampled at retail. The product was still within shelf life and was obtained as unopened containers. Further sampling at the manufacturer's stock cooler identified additional packages with *Lm*-positive tests. A full product recall was initiated. The manufacturer had several very good controls in place and appeared to be very conscientious in their sanitation procedures.

Investigation and Observation

After extensive investigational swabbing, *Lm* was identified in a small crack in the ceiling above the open brine pit. An isolate from the crack had the same genetic fingerprint as the *Lm* isolated from the contaminated cheese. The crack could only be seen from a ladder above the brine area. The ceiling was reportedly cleaned every day after packing cheese. The brine was tested and it showed presence of the same *Lm* identified in product and the crack. Additionally, one spot on the floor below the brine tank had a positive with the same isolate from the product, the ceiling crack, and the brine.

A thorough review of the environmental monitoring program identified overhead areas as the problem, including the ceiling in the RTE room, and it was added to the routine monitoring plan. It was also discovered that during sanitation, the ceiling was being washed using a high-pressure water hose, with spray/drips falling into the uncovered brine. This was identified as the probable source of the *Lm* contamination. The brine also splashed onto the floor sometimes and likely contaminated the floor.

Corrective Actions and Preventive Actions

- ✓ Recalled the product.
- ✓ Identified an infrastructure breach—the ceiling crack (which regular inspections would have identified) as a critical breach since it was over open brine. The owner immediately instituted regular inspections of overhead areas.
- ✓ Workers were provided with proper cleaning brushes and mops for the ceiling and overhead areas and use of high-pressure water hoses was prohibited. Furthermore, the pressure was turned down on all cleaning hoses. A long-lasting sanitizer is now used after cleaning the overhead areas.
- ✓ A new preventive measure of covering the brine during sanitation was instituted to prevent contamination with cleaning fluids or splashing from non-food contact areas.

PUTTING IT ALL TOGETHER

The control of *Listeria monocytogenes* in a dairy manufacturing environment has been proven possible, using best food safety practices and an organized and integrated approach. This approach is symbolized by the Pathogen Control Equation.

This document is intended to provide the reader with educational materials organized in sections that correspond to the Pathogen Control Equation.

It is the experience of seasoned dairy industry food safety practitioners that:

- Proactive work in each of the equation elements will advance overall dairy plant pathogen control.

AND

- The equation serves as a simple tool to organize thoughts and actions should pathogen challenges occur.

In essence, the Pathogen Control Equation can lead the food safety expert in determining what is important, where to focus resources, and how to create an integrated plan for remediation.

Food safety professionals using this knowledge have had ongoing success advancing food safety performance.

Thank you for sharing the dairy industry's commitment to protecting consumers and advancing food safety performance every day.

Glossary and Acronyms

3-A Sanitary Standards – Standards from 3-A, a non-profit corporation dedicated to advancing hygienic equipment design for the food, beverage, and pharmaceutical industries.

Aseptic Technique – Ensuring samples collected for microbiological testing are not contaminated by the sample collector.

AOAC – An organization that develops official analytical testing methods.

ATP – Adenosine triphosphate, swabbing method used to verify proper cleaning has occurred. Detects the presence of organic matter or bacteria.

Biofilm – A protective layer shielding the pathogen from destruction by routine cleaning and sanitizing chemicals.

CAPA – Corrective Action, Preventive Action.

CCP – Critical Control Point, a process step at which control can be applied, which is essential to eliminating a product safety hazard or reducing it to an acceptable level.

CIP – Clean-In-Place, a cleaning method that circulates cleaning solutions and water, used for pipelines, large tanks.

COP – Clean-Out-of-Place, equipment is dismantled and cleaned in a central washing area, normally a COP tank with temperature controls and agitation of cleaning solution.

COW Water – Condensate of Whey, water that is extracted from dairy products. Often used for heat recovery or as a cooling media.

EMP – Environmental Monitoring Program.

FCS – Food Contact Surface, may also be referred to as a Product Contact Surface (PCS).

Food Safety Construction Plan – A plan that identifies timelines and roles/responsibilities for specific actions during planned downtime activities.

Food Safety Plan – A plan to describe handling, preparation, and storage of food to prevent foodborne illnesses.

GMA – Grocery Manufacturers Association, a trade group.

GMP – Good Manufacturing Practices, best practices employed by food manufacturers to ensure sanitary handling of food and food environments.

Grade A – Dairy products produced under sanitary conditions sufficient to qualify for fluid consumption

HACCP – Hazard Analysis and Critical Control Points, a systematic approach to the identification, evaluation and control of food safety hazards.

HARPC – Hazard Analysis and Risk-Based Preventive Controls.

Harborage – A place of refuge or safety for microorganisms where they can grow and/or remain dormant/hidden until conditions for growth occur.

HEPA – High Efficiency Particulate Arrestance, air filtration capable of removing 99.97% of 0.3 micron–size particles.

HVAC – Heating Ventilating and Air Conditioning.

LEMP – *Listeria* Environmental Monitoring Program.

Listeria monocytogenes – Facultative anaerobic bacterium causing listeriosis.

***Listeria* spp**. – Genus of bacteria that currently contains 10+ species including *L. monocytogenes*. Gram-positive, rod-shaped, facultative anaerobe, and non-spore forming.

Listeriosis – An invasive bacterial infection most commonly caused by *L. monocytogenes.* It normally affects the immunocompromised, pregnant women, fetuses, newborns, and elderly. It is characterized by fever, meningitis, encephalitis, and may result in death.

MERV – Minimum Efficiency Rating Value, an air filtration rating scale used to describe filter efficiency and capability.

MSS – Master Sanitation Schedule, a documented system for managing and tracking non-routine cleaning tasks.

NACMCF – National Advisory Committee on Microbiological Criteria for Foods, provides impartial, scientific advice to food safety authorities and industry.

Passivation – The process of chemically creating a corrosion-resistant barrier on stainless steel. Prevents or retards degradation which could result in the inability to properly clean the surface.

PC – Preventive Control, risk-based, reasonably appropriate procedures, practices, and processes that significantly minimize or prevent hazards.

PCS – Product Contact Surface; may also be referred to as a Food Contact Surface.

PEC – Periodic Equipment Cleaning, a portion of an overall Master Sanitation Schedule dealing with equipment that is not routinely cleaned after each use.

PEM – Pathogen Environmental Monitoring, plan designed to verify effectiveness of all pathogen control programs.

Persistent Microorganism – Organism which has become established in an environment's niches and cannot be removed through normal sanitation; special cleaning and sanitizing are required for removal; may also be referred to as a Resident Microorganism.

PIC – Periodic Infrastructure Cleaning, the portion of an overall Master Sanitation Schedule that deals specifically with floors, walls, ceilings, and other infrastructure elements.

PMO – Pasteurized Milk Ordinance, the collection of minimum public health standards governing all aspects of Grade "A" milk and milk products. Includes standards for sanitation, equipment, farms and processing facilities, processing, transportation, storage, testing, and labeling of Grade "A" milk and milk products.

Presumptive Positive – A test indicating a positive result which has not been confirmed by additional specific methods.

PRP – Pre-Requisite Programs, set the stage for a HACCP system and provide ongoing support for the establishment's food safety system.

Raw – Dairy products or other ingredients that have not been pasteurized.

Refrigeration – An environment with temperatures below 45° F and above freezing.

RTE – Ready-to-eat, a food that is designed to be consumed with no consumer cooking step.

SOP – Standard Operating Procedure.

SSOP – Sanitation Standard Operating Procedure.

Transient Microorganism – An organism brought into a plant which is removed during normal sanitation.

USP – U.S. Pharmacopeia Convention, scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide.

Vectoring – The process of inspecting and swabbing locations in all directions around a location that has tested positive for a pathogen or indicator bacteria. It is also referred to as a 360-degree review.

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Additional Resources:

1. FDA—Memorandum of Information (M-I-86-17): Preliminary Status Report on FDA's Dairy Product Safety Initiatives Recommended Guidelines for Controlling Environmental Contamination in Dairy Plants
2. FDA 2008—Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen-Ready-To-Eat Foods, Draft Guidance.
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5. Online resources, check sheets, and tools provided by The Innovation Center for U.S. Dairy can be found at www.usdairy.com/foodsafety

Appendix A—Sanitary Design Checklist *

Electronic versions available at www.usdairy.com/foodsafety

	Dairy Products -- Outside of the Pipe			Review Date:			
	Sanitary Design Checklist			Review Completed By:			
				Review Location:			
				Review Description:			
#	Description		S	M	U	NA	Comments
PRINCIPLE #1 - MICROBIOLIGICALLY CLEANABLE							
1.1	Equipment is designed & constructed to be maintained in a cleanable condition.						
1.2	Surfaces can be cleaned to visually clean standard and meet pre-op inspection requirements.						
1.3	Representative surfaces can be monitored prior to start up for allergen residue or microbiological activity.						
1.4	Construction of equipment meet the GMP definition of "easily cleanable".						
1.5	A HACCP based product risk assessment was completed during the design phase to understand risks associated with the product type.						
1.6	Method of cleaning needed for the product risk was incorporated into the chosen design of the equipment.						
1.7	Equipment design meets efficiency requirements in equipment specifications.						
1.8	Equipment has no apparent flaws that will fail over its life and make it uncleanable.						
			100	out of	100		
PRINCIPLE #2 - MADE OF COMPATIBLE MATERIALS							
			S	M	U	NA	Deficiency
2.1	Product Contact Surfaces are made with materials which are corrosion resistant, non-toxic, and non-absorbent and approved as an acceptable product contact surface by regulatory agencies.						
2.2	Composites & plastics used will remain intact without changes in shape, structure & function through cleaning & sanitation protocols. These should be easily removed and replaced as needed.						
2.3	Plated, painted & coated surfaces are not used for food contact surfaces or for process equipment surfaces directly above the product zone areas.						
2.4	Coatings and plating if used on non contact areas away from product zones, must be designed to remain intact throughout life of equipment.						
2.5	Cloth back belts are not used.						
2.6	Materials not permitted for use include wood, enamelware, uncoated aluminum, un-coated anodized aluminum.						
2.7	Metals used are compatible with one another.						
2.8	Seals and O-rings should be chosen to be compatible with the products and cleaners used on line.						
2.9	Materials used in construction are compatible with the product, the environmental conditions they will be exposed to, as well as the cleaning methods & chemicals						
			90	out of	90		

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

PRINCIPLE #3 - ACCESSIBLE FOR INSPECTION, MAINTENANCE, & CLEANING/SANITATION							
			S	M	U	NA	Deficiency
3.1	All surfaces in the product zone are readily accessible for cleaning and inspection						
3.2	Product zone components with inaccessible surfaces shall allow for tool free equipment disassembly (compliant with local personnel safety laws).						
3.3	Where access or disassembly is not possible, the entire assembled unit is cleanable using techniques that assure cleaning to address product risks.						
3.4	Parts remain attached or are hung on the equipment for easy cleaning & to prevent damage or loss. Separate parts carts are supplied as an alternative.						
3.5	Machinery and chain guards slope away from product zones and are easily removed (compliant with local personnel safety						
3.6	Product catch pans or drip pans are easily removable (compliant with local personnel safety laws) for clean-up so that they are not lost or separated from the equipment.						
3.7	All belting is easily removable or the belt tension is removed easily without tools so the surfaces underneath can be cleaned.						
3.8	All surfaces in non-product zone shall be readily accessible for cleaning and inspection.						
3.9	Installation for product contact areas and conveyor travel paths will maintain at minimum a 18" floor clearance.						
3.91	Equipment design provides a 12 inch clearance to the floor to allow for cleaning and inspection.						
3.92	Equipment is located 30 inches from overhead structures and 36 inches from the nearest stationary object.						
3.93	All air, vacuum, & product hoses, & their assemblies, on the equipment are easily removable for cleaning.						
3.94	All air, vacuum, & product hoses are transparent or opaque, & the interior surfaces meet product contact surface guidelines.						
3.95	All utility (electric, air, vacuum) lines should be separated (not bundled) or enclosed in smooth conduit or dust free enclosures to avoid soiling and / or allow for cleaning.						
			140	out of	140		
PRINCIPLE #4 - NO LIQUID COLLECTION							
			S	M	U	NA	Deficiency
4.1	All surfaces should be designed to eliminate product collection or water pooling (if water is used during cleaning & be self-draining).						
4.2	Materials used in construction shall be non-absorbent						
4.3	Round framework is used for horizontal members wherever possible.						
4.4	Where square or rectangular tube is used, the flat surface is turned 45 degrees to horizontal where possible.						
4.5	All open surface areas are made of sufficient strength to prevent warpage & subsequent pooling of water.						
4.6	Moisture does not drip, drain, or draw into product zone areas.						
			70	out of	70		

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

PRINCIPLE #5 - HOLLOW AREAS HERMETICALLY SEALED							
			S	M	U	NA	Deficiency
5.1	All rotating members, such as drive sprockets or belt pulleys, are to be solid or filled with dye and fully sealed with continuous welds.						
5.2	All stationary hollow tube construction, such as frame members or blade spacers, are fully sealed with continuous welds to prevent interior contamination.						
5.3	There are no fastener penetrations into hollow tube construction.						
5.4	Threaded leg adjustments (for equipment) are internal and do not penetrate the tube frame members.						
5.5	Name plates & tags are minimized. When attached, plates & tags are continuously welded. Rivets or screw attached plates (often sealed with caulk) are absent.						
5.6	Void areas do not exist that would allow infestation activity to gain and maintain harborage and growth.						
			150	out of	150		
PRINCIPLE #6 - NO NICHES							
			S	M	U	NA	Deficiency
6.1	Equipment is designed to prevent the ingress, survival & multiplication of microorganisms, insect activity or allergens in void or niche areas.						
6.2	There are no lap joints. Examples include standing off flanged bearings versus mounting directly to side of a conveyor.						
6.3	Seals and O-rings will be designed to minimize product contact.						
6.4	All surfaces near the product contact zone areas are designed as if they were product contact zone areas.						
6.5	Piano hinges, knurling, braided covers, exposed threads, and socket head cap screws are not approved designs.						
6.6	Belt scrapers do not have lap joints and are removed without tools.						
6.7	Belts supports are constructed from single pieces of material.						
6.8	Product zones and adjacent zones are free of open seams, recess, inside threads, rivets, etc.						
6.9	All surfaces should be designed to eliminate water pooling & be self-draining.						
6.1	No dead ends or spaces are permitted. All equipment areas are accessible for cleaning & treatment to enable removal of allergen residues, microbiological activity or evidence of insects.						
6.11	Fasteners are not used in or above the product zone.						
6.12	Fasteners which may be a product contact surface must utilize the ACME 60º stub thread						
6.13	If fasteners are necessary, they do not have exposed threads and have a positive locking method to prevent falling- or vibrating-off.						
			150	out of	150		

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

PRINCIPLE #7 - SANITARY OPERATIONAL PERFORMANCE							
			S	M	U	NA	Deficiency
7.1	Buttons on control panels are easily cleaned & sanitized during operations.						
7.2	All compressed air used for blowing on the product or contact surfaces is filtered to a minimum of a 0.3 micron level and dried to prevent the formation of moisture in the piping system.						
7.3	No bearings are present in product contact zone areas.						
7.4	Separation between product contact & non-product contact areas prevents cross contamination during operations.						
7.5	All surfaces near the product contact zone areas are designed as if they were product contact zone areas.						
7.6	Product contact surfaces are made to prevent build-up of product residue during operations.						
7.7	Shafts passing through a product zone shall have a air gap to prevent product contamination						
			100	out of	100		
PRINCIPLE #8 - HYGIENIC DESIGN OF MAINTENANCE ENCLOSURES							
			S	M	U	NA	Deficiency
8.1	Drives, chain guards, electrical control boxes, and bearings are not located over open product zones.						
8.2	Control and junction boxes are fastened to the frame in a manner consistent with the sanitary design principles.						
8.3	Utility supply lines & pipes are separated to prevent catch points and to allow for cleaning.						
8.4	Utility lines are 12 inches off of the floor and cleanable .						
8.5	Conduit & supply lines are not routed above product contact areas.						
8.6	Maintenance enclosures in direct wash down areas must be able to be exposed to water and chemicals used in cleaning & sanitation (securing with a plastic bag is not acceptable).						
			50	out of	50		
PRINCIPLE #9 - HYGIENIC COMPATIBILITY WITH OTHER SYSTEMS							
			S	M	U	NA	Deficiency
9.1	Exhaust systems have welded seams with adequate access for cleaning and inspection.						
9.2	Vertical duct sections have a drain (e.g., to the floor) to prevent drainage from going back into the equipment.						
9.3	Separate exhausts are supplied for raw and RTE product zones.						
9.4	C.I.P systems are designed, installed & validated (using a recognized third party), in sections of ductwork that are not easily cleaned through access openings.						
9.5	Equipment is designed to meet criteria of waste water infrastructure capability to assure no backups of drainage lines result under normal operations.						
			50	out of	50		

PRINCIPLE #10 - Sanitation Integrated Into Facility Design							
			S	M	U	NA	Deficiency
10.1	Water temperature, flow and pressure meets specified requirements at point of use						
10.2	Cleanup hoses are stored outside of process areas when not in use.						
10.3	Rinse systems are operated at city water pressure to limit overspray and creation of aerosols.						
10.4	Hand washing and sanitizing sinks (hands free) are provided in transition areas.						
10.5	Hurdles are installed (foot baths, doorway foamers, boot washers) at locations as required to maintain zones of control.						
10.6	Cleaning systems (e.g., COP, CIP, equipment washers) are provided to facilitate proper cleaning and sanitizing of equipment based on sanitation needs.						
			0	**/**	**100**		

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

Appendix B—Dairy Facility Design Checklist *

Electronic versions available at www.usdairy.com/foodsafety

	Dairy Facility Design Checklist				Review Date:		
					Review Completed By:		
					Review Location:		
					Review Description:		
#	Description		S	M	U	NA	Comments
PRINCIPLE #1 - Distinct Hygienic Zones Established In The Facility							
1.1	Facility is divided into hygienic zones and facility drawings accurately reflect hygienic zones						
1.2	Active control barriers prevent uncontrolled movement between RTE / high hygiene and non-RTE / lower hygiene areas.						
1.3	Transition areas with hurdles exist between raw and RTE areas or from lower to higher hygiene areas.						
1.5	Restrooms are located outside of from RTE / high hygiene areas						
1.6	Separate equipment and tool storage areas exist for RTE/ high hygiene versus non-RTE / lower hygiene areas.						
1.7	Separate QA labs exist for RTE / high hygiene and non-RTE / lower hygiene areas						
1.9	Space is provided for clean equipment storage						
1.91	Soiled laundry collection locations are established						
1.92	Trash collection is properly located, and locations are cleanable and maintainable						
1.94	Color codes (e.g., garments, helmets) are used to identify hygiene areas						
			0	**/**	**120**		
PRINCIPLE #2 - Personnel & Material Flows Controlled to Reduce Hazards							
			S	M	U	NA	Deficiency
2.1	Movement of employees, contractors, and other visitors through the facility is predetermined and controlled						
2.2	Systems are in place for sanitary transportation of packaging materials and ingredients into RTE / high hygiene areas to minimize cross contamination						
2.4	Systems are in place for sanitary transportation of rework into RTE / high hygiene areas						
2.5	Systems are in place for sanitary removal of trash from RTE / high hygiene areas						
			0	**/**	**100**		
PRINCIPLE #3 - Water Accumulation Controlled Inside Facility							
			S	M	U	NA	Deficiency
3.1	Floor design and drainage systems prevent standing water and wet floors						
3.2	All floor joints and cracks are sealed						
3.3	Wall and curb surfaces drain freely without pockets, ledges and nooks						
3.4	Areas above ceilings do not accumulate water						
3.5	Equipment wastewater discharges are piped directly to drains						
3.6	Drain pans are sloped to be free draining						
			0	**/**	**100**		

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

PRINCIPLE #4 - Room Air Flow and Room Air Quality Controlled							
			S	M	U	NA	Deficiency
4.1	Room temperature meets process requirements						
4.2	Controls are in place to prevent condensation						
4.3	All rooms have their pressures controlled to ensure the airflow will be from clean to less clean areas						
4.4	Critical process air is adequately filtered to protect micro sensitivity of the product based on quality and pathogen control risks.						
4.5	Makeup air is sufficient to maintain specified clean areas positive to adjacent rooms.						
4.6	Air handling system components for RTE / high hygiene areas meet the 10 Principles of Equipment Sanitary Design						
4.7	Provision is made to capture high concentrations of heat, moisture and particulates at the source						
4.8	HVAC/refrigeration system components are located to avoid risks of product contamination through air flow or condensation.						
4.9	HVAC/refrigeration systems are dedicated appropriately to specific control zones to prevent cross-contamination						
			0	**/**	**100**		
PRINCIPLE #5 - Site Elements Facilitate Sanitary Conditions							
			S	M	U	NA	Deficiency
5.1	Driveways, parking lots and pedestrian walkways are paved and drain to prevent standing water						
5.2	Landscaping and grounds are designed to minimize attraction and harborage of insects and rodents						
5.3	Adequate trash receptacles in pedestrian traffic areas are provided						
5.4	Insect attractant lighting is positioned to draw insects away from the building						
5.5	Grading provides positive drainage away from building						
5.6	Finished floor elevation is higher than adjacent grades to prevent storm water ingress into building						
5.7	External operations (e.g., trailer cleaning, bulk storage, trash and waste management) are designed and positioned to prevent unsanitary impact on the facility						
5.8	Storm water system is properly designed and maintained to prevent standing water on the site with retention basins.						
5.9	A minimum of 18" of asphalt, gravel or concrete borders are present on all exterior sides of the facility						
			0	**/**	**100**		

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

PRINCIPLE #6 - Building Envelope Facilitates Sanitary Conditions							
			S	M	U	NA	Deficiency
6.1	Building envelope (i.e., shell, skin) is constructed of materials that are solid, impervious, and free of cracks and voids						
6.2	Roof flashing systems prevent harborage of insects, birds and rodents and roof is sloped and drains freely.						
6.3	Canopies are totally closed						
6.4	All louvers, fans, vents and openings have insect screens and vents prevent pigeon harborage.						
6.5	Doors are impervious, fully weather stripped and fit well						
6.6	All door and window sills are firmly anchored to the slabs and set in full beds of sealant						
6.7	All voids associated with utility penetrations (e.g., electrical weather heads, gas mains, sprinkler risers) are sealed.						
6.8	Concrete wall panels are caulked from roof to footing						
6.9	Dock doors have a dock seal or shelter and are weather stripped and rodent proofed.						
			0	**/**	**100**		
PRINCIPLE #7 - Interior Spatial Design Promotes Sanitation							
			S	M	U	NA	Deficiency
7.1	Aisles are sufficiently spacious for maintenance, sanitation to access with equipment and materials movement						
7.2	There is sufficient access to clean building elements (e.g., columns, beams, bracing) and wall / floor interfaces.						
7.3	Stationary equipment is elevated sufficiently to allow cleaning and sanitation underneath the equipment						
7.4	The equipment and facility layout allows access to overhead areas (ductwork, lights, etc.) for inspection and cleaning.						
7.5	There is an interior perimeter inspection zone of 18 inches to allow for inspection and cleaning.						
			0	**/**	**80**		
PRINCIPLE #8 - Building Components and Construction Facilitate Sanitary Conditions							
			S	M	U	NA	Deficiency
8.1	Suspended ceilings are smooth, cleanable (both sides) and at a uniform height						
8.2	All vertical surface to floor junctions have a cove and surfaces that are free of pits, erosion and voids						
8.3	Concrete surfaces are free of pits, erosions and voids, solid and smooth						
8.4	All vertical and horizontal wall joints are sealed appropriately						
8.5	Closed cell or encapsulated insulation is used						
8.6	Horizontal structural members have no flat surfaces where dust or soil could accumulate.						
8.7	All-thread rods are not used and other threaded surfaces are minimized						
8.8	Expansion joints are adequate to avoid irregular cracking in floors and are limited to the extent possible						
8.9	Bases of drains are supported with a robust foundation to prevent settling						
8.91	Items attached directly to a building surface such as electric conduit, water lines, have at a minimum 1 inch standoff from wall surface.						
8.92	Floors are constructed to prevent harborage, impervious, easily cleanable and resistant to wear and corrosion						

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

PRINCIPLE #9 - HYGIENIC COMPATIBILITY WITH OTHER SYSTEMS							
			S	M	U	NA	Deficiency
9.1	Exhaust systems have welded seams with adequate access for cleaning and inspection.						
9.2	Vertical duct sections have a drain (e.g., to the floor) to prevent drainage from going back into the equipment.						
9.3	Separate exhausts are supplied for raw and RTE product zones.						
9.4	C.I.P systems are designed, installed & validated (using a recognized third party), in sections of ductwork that are not easily cleaned through access openings.						
9.5	Equipment is designed to meet criteria of waste water infrastructure capability to assure no backups of drainage lines result under normal operations.						
			50	out of	50		
PRINCIPLE #10 - VALIDATED CLEANING & SANITIZING PROTOCOLS			S	M	U	NA	Deficiency
10.1	Cleaning & sanitizing are considered in the design process.						
10.2	Cleaning protocols must be safe, practical, effective and efficient						
10.3	Cleaning and sanitation protocols are have been developed by the manufacturer, validated by a third party, and provided in a training manual that is easily read and understood by cleaning and sanitation employees.						
10.4	Equipment design and materials are capable of withstanding standard clean-up procedures. Equipment materials have been reviewed with the MSDS for the cleaning and sanitizing chemicals to assure compatibility.						
10.5	All belts should withstand heating to 160ºF for up to 30 minutes.						
			50	out of	50		
	* Dairy specific checklist built on earlier work by AMI and other individual experts						

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

Appendix C—Food Safety Construction Plan SOP and Checklist Example

1.0 PURPOSE

1.1. Analyze the nature of the project to determine the risk level.

1.2. Identify steps required to manage construction and maintenance activities and maintain a sanitary plant environment during construction projects.

1.3. Establish a Food Safety Construction Plan (FSCP) outlining steps to ensure proper management of construction and maintenance activities and verification of sanitary conditions prior to resumption of operations.

1.4. Define key roles responsible for specific activities within the project scope.

2.0 SCOPE

2.1. This policy applies to the removal, installation, or modification of equipment or infrastructure components that could negatively impact food safety.

2.1.1. Temporary equipment or infrastructure will also require a construction plan, depending upon use and conditions.

2.1.2. Medium- and high-risk projects require a Food Safety Construction Plan to be developed by the project manager and approved by the plant/distribution center quality manager and corporate quality before construction activities begin.

2.2. All projects will be reviewed to assess Food Safety risk and intervention requirements prior to implementation.

2.2.1. Physical, chemical, and microbiological hazards should be considered.

2.2.2. Considerations of how a project will affect the entire plant, particularly air, water, and traffic routes, will be considered.

3.0 DEFINITIONS

3.1. Low-risk projects can be controlled through preventive or general maintenance processes. See matrix in Reference 6.1 for categories.

3.1.1. This encompasses projects or activities where precautionary safety processes exist and/or there is a proven history of success.

3.1.2. Special-Cause Cleanup requirements should typically suffice.

3.1.3. Examples of projects in ready-to-eat (RTE) production areas (no environmental history).

3.1.3.1. Normal preventive maintenance.

3.1.3.2. Modification of an equipment guard requiring welding.

3.1.3.3. Installation of electrical conduit during downtime.

3.1.4. Examples of projects outside of RTE areas.

3.1.4.1. Normal preventive maintenance.

3.1.4.2. Removal of ammonia lines.

3.1.4.3. Maintenance work done in palletizing.

3.2. Medium-risk projects can be controlled through specific intervention and controls to prevent contamination.

3.2.1. This encompasses activities in or near production environments where enhanced monitoring has not revealed any microbiological issues. Depending upon circumstances, this may include both pathogen swab data as well as indicator organism (yeast/mold, coliform, APC) results.

3.2.2. Work zones must be defined and segregated.

3.2.3. Examples in RTE environments.

3.2.3.1. Installation of a new line in an isolated production room where no soil or outside elements will be exposed.

3.2.3.2. Installation of shred scale platform.

3.2.4. Examples of projects outside of RTE areas.

3.2.4.1. Installation of new auto palletizing equipment in warehouse.

3.2.4.2. Shipping floor repair.

3.3. High-risk projects must be controlled through special intervention and controls to prevent contamination.

3.3.1. This encompasses activities in areas where microbiological issues are known to exist or the potential risk of product contamination (safety or quality related) is elevated. Examples include:

3.3.1.1. Any time soil is exposed/broken (drain repair/installation, bollard installation, etc.).

3.3.1.2. When any production area (including Zone 4) is exposed to the outside environment (roof projects, infrastructure repair).

3.3.1.3. When air circulation is shared between construction zones and production and/or storage areas and dust generation or moisture migration is a concern.

3.3.2. The length of the project should also be taken into consideration, with longer projects being a higher risk because temporary structures are often more difficult to maintain effectively. Work zones must be defined and isolated from the rest of the facility.

3.4. An enhanced environmental monitoring scheme must be developed and deployed by plant quality manager or designee.

3.5. Negative pressure within the construction site should be established whenever possible.

4.0 PROCEDURE

BEFORE CONSTRUCTION

4.1. The project manager will submit a written FSCP to the plant/distribution center quality manager and corporate quality for medium and high-risk projects outlining controls and safeguards that will be implemented before, during, and after construction activities (Form 6.1).

4.1.1. An enhanced environmental monitoring scheme will be deployed to assess microbiological risk in the site, surrounding areas, and traffic routes prior to initiating the project.

4.1.1.1. Monitoring will incorporate Zone 2, 3, and 4 locations as well as potential traffic routes and vectors (carts, pallets, etc.).

4.1.1.2. Swabs on incoming equipment are required.

4.1.1.2.1. Equipment swabs should be taken at the plant upon arrival if the equipment is sequestered in the facility, until favorable results are obtained.

4.1.1.2.2. Swabs may also be taken at the manufacturer on incoming RTE and non-wash-down equipment if shipping and storage conditions limit exposure to the outside environment.

4.1.1.2.3. New construction areas or areas that will undergo substantial reconstruction activities do not need to be swabbed upon arrival, because extensive cleaning and validation will be performed before startup.

4.1.2. Potential problems should be identified and addressed by a cross-functional team and integrated into the Food Safety Construction Plan. Team members minimally include QA/sanitation, production leadership, and maintenance.

4.1.3. Additional precautions will be taken if microbiological activity is identified.

4.2. It is the responsibility of the project manager to review the food safety construction plan with plant leaders, incorporating feedback from sanitation, operations, maintenance, and other plant or corporate functions. Plant/distribution center quality manager and corporate quality will then review and approve each plan.

4.3. Impact on customer ordering and scheduling will be accessed and communicated prior to initiating the project.

PRE-CONSTRUCTION

4.4. All contractor personnel will be trained on plant Good Manufacturing Practices before beginning work. A record of trained personnel will be maintained. It is permissible to train the owner or designee of the contractors and have them train their personnel.

4.5. Equipment will be assessed to evaluate and remediate any food safety risks of design or condition.

4.5.1. Product will not be released until receipt of acceptable results.

4.5.2. All equipment defined as high-risk should have a construction plan associated with any work performed.

4.6. Traffic patterns for supplies, construction materials, waste, lunchroom, and toilet facilities must be established and clearly identified. The project manager will ensure traffic routes are dedicated, appropriately cleaned and sanitized, and adhered to.

4.7. Steps will be taken to prevent accumulation of humidity, dust, fumes, vapors, or gases from construction sites. The condition of the site must not cause condensation on temporary walls or adjacent areas.

4.8. Exhausts from the construction site will be blocked from other plant areas.

4.8.1. Air quality (indicator organism) and appropriate air pressure should be monitored by the QA department as outlined in the FSCP.

4.8.2. Negative pressure within the construction site should be established whenever possible. This is required for high-risk projects.

4.9. Storage of idle equipment, contractor supplies, or other items should be minimized; if necessary, covered and neatly stored off the ground.

4.10. Equipment and tools will be cleaned and sanitized prior to entry into the facility. Swabs should be taken of non-plant equipment that may be a vector (forklift, wheelbarrow, etc.) within plants, and special precautions should be taken to minimize areas affected.

4.10.1. External tools and equipment will be swabbed after sanitizing (and after the sanitizer has dried).

4.10.2. Clean, sanitize, and swab traffic pattern of equipment coming in if the equipment is brought in to clean and sanitize.

4.11. Durable dust and watertight partitions will be provided at all construction sites to prevent migration of contaminants such as dust, filth, debris, and moisture from the construction site to non-construction areas. Doors to areas with exposed product will be provided with seals and will be self-closing.

4.11.1. Plastic or Visqueen can be punctured and is not considered a durable alternative in production environments.

4.11.1.1. Long-term (>2 weeks) projects located in a functioning Zone 3 should have a temporary solid-structure wall (IMP, etc.) when possible. Wood should be avoided whenever possible.

4.11.1.2. Zone 3 projects of less than 2 weeks should have triple-layer plastic with metal studs or a solid-structure wall with triple-layer plastic.

4.11.1.3. Long-term projects located in Zone 4 should have a wall type that takes into consideration the length of the project, the type/amount of traffic, and the type of work being done in the area.

4.11.2. Equipment that cannot be removed from the construction site will be thoroughly covered during pre-construction and construction activities.

4.11.2.1. Double layers of plastic will be used. Tape will be adhered to the plastic overwrap, not to the equipment, where possible.

4.12. Any tape residue must be removed prior to resumption of production. Reaction plans will be developed by the project manager and outlined in the FSCP to address potential breaches or changes to the plan.

DURING CONSTRUCTION

4.13. Production areas must be maintained in a sanitary condition to ensure products are manufactured in a Good Manufacturing Practice (GMP) compliant environment. During construction (demolition, installation, remodeling, etc.) steps will be taken to ensure that contaminants are kept out of the production environment. Equipment and handling devices that move between the construction site and various locations in the facility (e.g., scissor lifts, welders, supply carts, pallets) will only enter process and storage areas if they are cleaned and sanitized prior to entry.

4.13.1. Devices dedicated to construction activities should not enter manufacturing areas during production periods.

4.13.2. Wheels should be cleaned and sanitized on a routine basis throughout the project. This should be done at a minimum of each shift, but may be more often depending upon the project.

4.14. All plant doors and entrances must:

4.14.1. Remain closed when they are not in use.

4.14.2. Form an adequate seal when closed.

4.14.3. Not be left propped open unattended.

4.14.4. Be repaired immediately if damaged.

4.15. All partners and contractors will wear appropriate clean clothing, hair restraints, and footwear as defined in the contractor briefing document when entering production areas.

4.15.1. Projects may require extra PPE to be worn by partners or leaders while on the construction site as defined in the FSCP.

4.15.2. Contractors must put on new GMP PPE when entering or re-entering the facility.

4.16. Special projects may have a non-GMP area in the plant due to special construction activities. In these circumstances, GMP apparel is still required when going through the plant when not in these construction areas. Examples may include:

4.16.1. Roof work.

4.16.2. Drain work (non-GMP area inside of construction vestibule).

4.17. The site must be free of standing water.

4.17.1. Adequate exterior drainage or grading must be provided.

4.17.2. Wet-vacs are not preferred but may be used if they are equipped with a HEPA filter. The use of a vacuum to remove water or other debris must be approved by the quality manager or the project manager.

4.17.3. The filter must be routinely visually inspected and secured.

4.17.4. Wet-vacs used in high-risk projects must be cleaned, sanitized, and swabbed before being used again.

4.18. Water hoses will not be used to clean the floor or equipment when product or packaging material is exposed due to the formation of aerosols. Cleaning will be coordinated with plant sanitation and production staff.

4.19. Waste materials and rubbish will be removed from the construction site on a minimum daily basis.

4.19.1. All waste containers taken through the plant must be covered and adhere to a designated traffic route. All garbage and debris will be removed prior to closing the space.

4.19.2. Materials associated with microbiological issues will be subject to special handling precautions prior to and during removal.

4.20. Reaction plans will be developed by the project manager and outlined in the FSCP to address any unanticipated breaches or changes to the plan.

POST-CONSTRUCTION

4.21. After the temporary partition is dismantled, all construction materials will be removed and the entire area cleaned and sanitized without disrupting existing operations.

4.21.1. The partition should be cleaned and sanitized before being removed from the area.

4.21.2. Waste should be double-bagged when removed from the facility, especially for high-risk projects.

4.21.3. Special-cause cleanup will be documented where applicable.

4.22. HVAC ductwork that was subjected or exposed to construction activities will be thoroughly cleaned and sanitized.

4.22.1. New, refurbished, or modified ductwork will be cleaned and sanitized by a qualified contractor.

4.22.2. Proper pressure and air balance must be verified prior to any manufacturing activities.

PRIOR TO STARTUP

4.23. Prior to startup, the sanitary condition of the site and all equipment must be verified. This will be documented through a checklist specific to each project and encompass the following elements:

4.23.1. The manufacturing department, equipment, and support areas will be thoroughly inspected for sanitary operating conditions. Findings will be documented and subsequent corrective actions noted.

4.23.2. The manufacturing area and all equipment will be subject to a full cleanup and a deep sanitizing treatment appropriate for the area as determined in the plan and verified at the conclusion of construction activities.

4.23.3. Effectiveness of cleanup and sanitary condition will be verified by bioluminescence and microbiological monitoring.

4.23.4. An enhanced pathogen monitoring scheme will be conducted in the post-construction area and surrounding locations. Zones 2 to 4 will be monitored.

4.23.5. Air quality will be measured and verified.

4.23.6. HVAC ductwork subject to construction will be monitored for positive pressure and yeast & mold at enhanced frequencies.

4.23.6.1. Abnormalities will prompt immediate corrective action and product evaluation where appropriate.

4.23.6.2. Frequencies may be modified depending on findings if approved by the plant quality manager and corporate quality.

4.24. The plant quality manager and corporate quality will provide approval to resume manufacturing activities after completion of the project.

4.25. Any questionable issue(s) will be forwarded to corporate quality and operations management for further evaluation.

SPECIAL CIRCUMSTANCES

4.26. Projects involving water line modification: Water quality will be confirmed to meet chemical and microbiological criteria.

5.0 DOCUMENTATION

5.1. A list of trained contractors will be maintained; non-conforming contractors will be identified and documented to prompt subsequent action.

5.2. The construction site plan and related documentation will be readily available.

5.3. Special-cause cleanup documentation following construction will be available where applicable.

6.0 FORMS

6.1. Construction Form Checklist

CONSTRUCTION FORM CHECKLIST (Example)

Tailored to each Circumstance

PROJECT **SUBMISSION DATE:**

PLANT: **IMPLEMENTATION DATES:**

DEPARTMENT: **PROJECT MANAGER:**

DESCRIPTION OF CHANGE:

Project resources, including contractors:

Key assumptions:

CONSIDERATIONS

BEFORE CONSTRUCTION

- Environmental Assessment—Highlight or bold the risk level that most closely matches the project. The risk level defaults to the highest category unless otherwise explained below.

	High risk	**Medium risk**	**Low risk**
Pathogen/pest history	History in room within the past 6 months	History before an effective mitigation effort or no history in past 6 months	No history in past 6 months
Location in plant	RTE with exposed product or cultured dairy post-pasteurization	RTE or raw with good isolation throughout project; Zone 4 with limited isolation	Zone 4 with good isolation
Type of work	Exposed soil, exposure to outside elements, shared air circulation with production, long term project (>2 weeks)	Risks controlled through specific, but limited, intervention measures	Proven history of success for similar projects, small precautionary processes sufficient

PROJECT RISK: High ☐ Medium ☐ Low ☐

COMMENTS ABOUT RISK: _____

Italicized items should be modified/changed for each project. List who is responsible for each action on the construction plan. "Typical requirements" are basic minimum requirements for each section that should be modified to meet the specific needs of the project.

- Scheduling implications
  - *Will production be running in the room?*
  - *Will aspects of the construction (cleaning/traffic) affect other parts of the plant?*
  - *What is the timeline of the project, start to finish?*

PRE-CONSTRUCTION

- Contractor Training—**Typical Requirements**
  - Basic contractor training will take place when they arrive at the plant on a per contractor basis.
  - The training will consist of a GMP and traffic pattern review as well as safety and security requirements.
  - Contractors will adhere to all standard plant contractor procedures and wear appropriate gear including hair nets/beard nets, hard hats, ear plugs, safety glasses, shoe covers, and smocks at all times during the work.
  - All parts, equipment, and tools brought into this area will be clean and thoroughly sanitized prior to entry into the plant.
    - No visible dirt will be allowed on any parts, tools, and equipment entering this area.
    - Tools with wheels (forklifts, wheelbarrows, scissors lifts, etc.) should be sanitized when brought in and swabbed once dry.
    - Once tools and equipment are in the plant, they should remain inside, if possible. Tools/equipment will have to be cleaned/sanitized upon reentry into the plant.
  - Access to any area beyond the construction/work areas without prior consent is not allowed.
  - Contractor should work with plant to ensure that plant access clothing and accessories, as well as cleaning and sanitation chemicals, are present in sufficient quantities at all times.
  - Establish requirements for break room/restroom use and GMPs required for this project.

- Isolate Site
  - Short term projects (<3 days)–triple-layer plastic with wood or metal studs:
    - Metal studs should be used if the area will have wet-cleaning routinely done in area.
    - Absorbent pads/dikes should be used as necessary to divert water away or contain within a construction site.
    - Ensure there is a good seal along the wall/floor.
    - If production is not running in the area, Zone 1 areas should be protected with plastic, but a containment may not be necessary (depending upon project).
  - Long-term projects (>2 weeks)—IMP wall or plywood containment with at least double layers of plastic inside and a single layer outside.
  - Isolation of any production areas from construction sites—may include covering equipment with plastic, removing non-essential equipment from area, HVAC considerations.

- Traffic Plan
  - Include a map with mitigation steps.
  - Identify construction traffic route.
  - Partner traffic route (if applicable).
  - Trash traffic.
  - Equipment traffic route, including staging and/or cleaning areas.
  - Include current or added mitigation steps (footbaths, foamers, sanitizer stations, etc.).

- Dust and Fume Control
  - Isolate HVAC in construction site from production areas.
  - Cleanup mode should be used when possible.
  - Establishing negative pressure in the construction area is necessary if dust, soil, outside environment exposure, and/or environmental history is present.

- Reaction Plan**—Typical Requirements**
  - Plant QA and/or project manager is responsible for adherence to the plan with cooperation from all team members.
  - Any significant deviations to the plan will be reviewed with corporate quality for concurrence prior to action/reaction.
    - If due to time or urgency, the plant can make the call, but corporate quality must be notified to review actions as soon as possible.
    - Any environmental deviations will be reported to members of the corporate quality department.

DURING CONSTRUCTION

- Condition of Site and Surrounding Area**—Typical Requirements**
  - Plant employees and/or leadership will monitor the construction area for compliance.
  - Sanitation employees will monitor sanitizer stations, footbaths, etc.

- Partner and Contractor GMP Compliance
  - Contractor requirements for going in/out construction site.
  - Special GMP apparel needed for plant employees/leaders in construction area.

- Traffic Flow
  - Contractor traffic flow.
  - Trash traffic flow.
  - Traffic patterns will be cleaned and sanitized on a routine basis.

- Site Integrity (breaches)—**Typical Requirements**
  - Any breach from the construction areas will be dealt with by the quality manager and could include contractor removal from site or cost penalties for increased sanitation and/or food safety inspection.
  - Any breaches in temporary walls will be repaired, reported to the quality manager or designee, and addressed with a special-cause cleanup.

- Waste Removal—**Typical Requirements**
  - Any waste generated will be tightly controlled with double-layer plastic bags as soon as generated; the bags will be tied and removed from operations area to the waste handling area as required.
  - Bags will be spritzed with sanitizer before being removed from the construction site.

- Environmental monitoring—**Typical Requirements**
  - Air monitoring (yeast/mold, air velocity) should be conducted during the construction project.
  - Pathogen swabs (*Listeria* spp., *Salmonella* spp.) should be conducted during and after the construction. Minimum areas to be included are traffic patterns and just outside of the construction area.

POST-CONSTRUCTION

- Material Removal**—Typical Requirements**
  - All waste and construction materials will be removed from site.
  - They will all be placed in plastic bags and sealed when passed through plant areas.
  - Temporary walls/floors should be cleaned/sanitized before being removed from the construction site. Plastic will be put in bags before being discarded.
  - Contractor tools will be removed from area after completion of work.

- HVAC Cleaning/Balance
  - HVAC in the construction area should be cleaned and sanitized if dust is generated from construction activities.

PRIOR TO STARTUP—**Typical Requirements**

- Cleaning/Sanitation Plan
  - System flush and deep clean—documented special cause cleanup.
  - Traffic patterns will be included in special cause cleanup.

- Verification
  - Inspection—visual inspection will be performed following sanitation.
  - Swabbing
    - Equipment swabs (ATP, APC, coliform) will be conducted following special cause cleanup.
    - Air monitoring (yeast/mold, air velocity) will be conducted for several weeks following the construction project.
    - Pathogen swabs (*Listeria* spp., *Salmonella* spp. depending on project) will be conducted during and after the construction. Minimum areas to be included are traffic patterns and the construction site.

APPROVAL: _____

The Innovation Center for U.S. Dairy® (IC), formed in 2008, provides a forum for the dairy industry to work together pre-competitively. Collectively, the IC represents over 500 dairy manufacturers and over 80 percent of the U.S. milk supply. One important IC initiative is the Food Safety Team, which helps assure dairy products are safe by providing resources and training in all facets of dairy manufacturing. The IC Food Safety Team is very active with over 65 experts from 30 organizations involved across seven platforms. Learn more at: www.usdairy.com/foodsafety

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