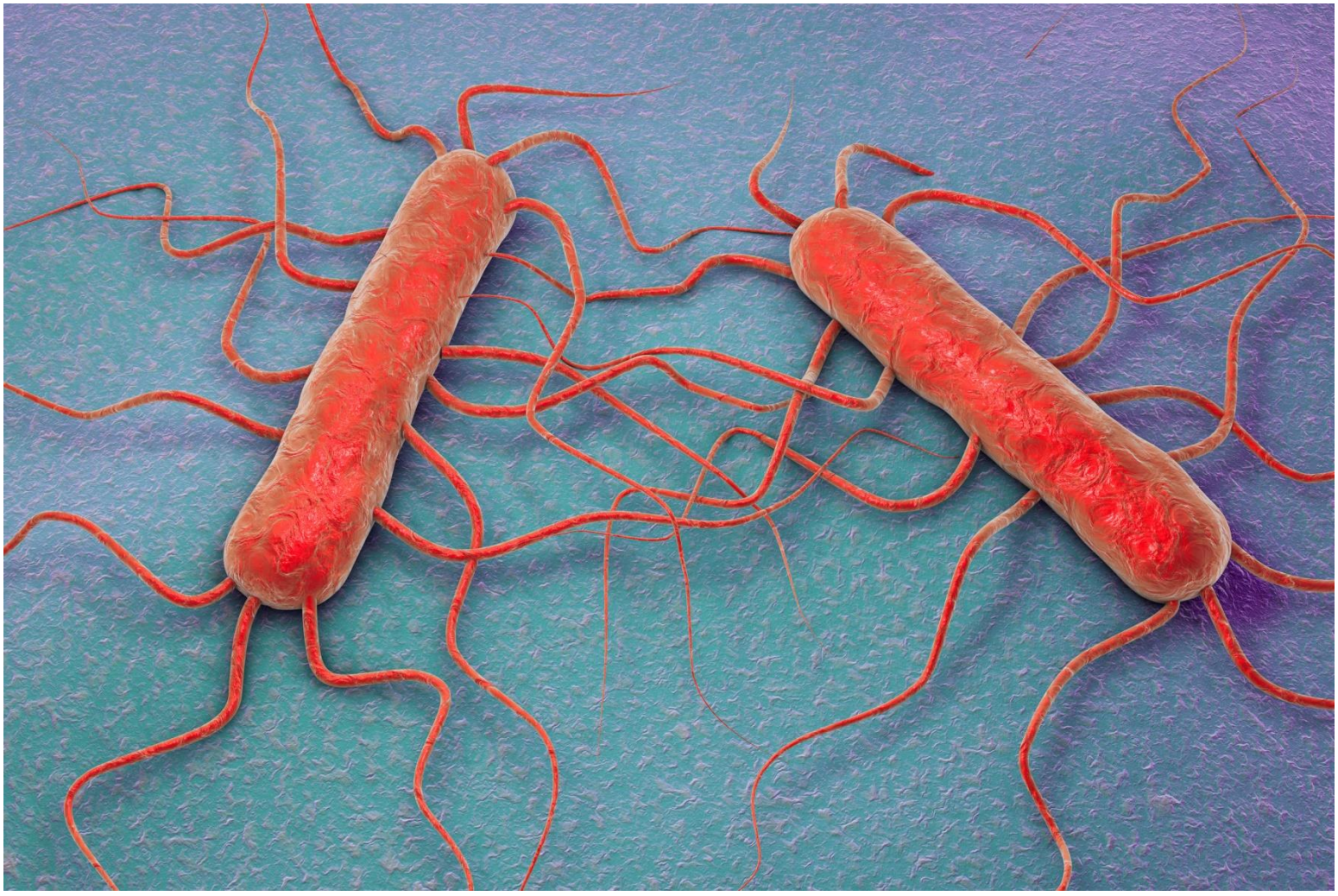
CONTROL OF *LISTERIA MONOCYTOGENES*

GUIDANCE FOR THE SOUTH AFRICAN DAIRY INDUSTRY



STANDARD DAIRY AGENCY

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1. Introduction

This *Listeria* Control Guidance Document has been prepared for the dairy industry and is intended to build knowledge and communicate best practices for role players in the dairy industry. The guideline is strongly supported by the Dairy Standard Agency *Code of Practice for the Secondary Industry*, which contains all the relevant prerequisites and Hazard Analysis and Critical Control Points (HACCP) principles to ensure the implementation of a food safety management system

In view of the current devastating effect of listeriosis in South Africa, the publication of this guideline document is considered most essential. The guideline is based on the core principles of *Listeria* pathogen control developed by the Innovation Centre for US Dairy and is intended to help identify focused practices which are critical to effective pathogen control. The following core principles are based on a pathogen control equation and considered essential and will be discussed in more detail further on in this document.

1.1 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 pasteurisation. They can grow at refrigeration temperatures, survive freezing, and tolerate up to 20% salt.
- *Listeria* can grow quickly at ambient temperatures.
- *Listeria monocytogenes* is a pathogen that causes listeriosis, one of the most frequent and serious human foodborne illnesses. *L. monocytogenes.* is one of the many known *Listeria* species (*Listeria* spp.).
- The presence of *Listeria* spp., the broader genus to which *L. monocytogenes* belongs, is widely used as an indicator of conditions that also may be favourable for the pathogen *L. monocytogenes*.
- *Listeria* has the ability to form strong protective biofilms, which effectively protect bacteria cells and can be quite difficult to remove. Biofilms are more likely to form in difficult to clean areas within processing environments.

1.2 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 programme 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, adenosine triphosphate (ATP) testing (a swabbing method used to verify that proper cleaning has occurred) 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 the sanitary condition of product and processing 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 for *L. monocytogenes*.

1.3 The role of finished product testing

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.
- *Listeri*a spp. grows slowly under chilled conditions and tends to occur in very low concentrations.
- Even in a contaminated product, high enough numbers of *L. monocytogenes* may not be present to be detected at the time of production, potentially creating false negatives.
- Cross-contamination events are often sporadic in nature.

1.4 Hazard analysis and critical control points (HACCP)

Listeria monocytogenes should be identified as one biological hazard controlled by your HACCP plan. Pasteurisation is an effective control for all vegetative pathogens including *L. monocytogenes*. It should be noted that not all dairy products such as ready-to-eat (RTE) products have the same value chain, as 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).

1.5 Regulatory implications

Milk and other dairy products in South Africa are governed by the Foodstuffs, Cosmetics and Disinfectants Act (54 of 1972) and Regulations relating to milk and dairy products (R1555 of 1997). Regulations contained in R1555/1997 have a zero tolerance towards *Listeria* as it clearly states that milk and milk products shall be free from pathogenic organisms, extraneous matter or any inflammatory product or other substances which for any reason whatsoever may render the milk unfit for human consumption. Although the HACCP is provided for under R908 of June 2003 Regulations relating to the application of the Hazard Analysis and Critical Control Point (HACCP) System under the same Act, it is not yet mandatory in the case of the dairy industry. In this case

voluntary systems supported by South African National Standards of the South African Bureau of Standards (SABS) and the International Organisation for Standardisation (ISO) standards are widely used and enforced by stakeholders in the dairy value chain.

To effect proper food safety management with specific reference to *Listeria monocytogenes*, milk processors and manufacturers of dairy products will need to examine the rationale behind their monitoring and testing programmes. These programmes should be fully documented and management should be prepared to explain their choices. Manufacturers will also be required to establish and maintain appropriate documentation including written programmes and recorded results for all prerequisite programmes and preventive controls included in their Food Safety Management System to prove due diligence.

2. Control of *Listeria* using the pathogen equation

2.1 Principle #1: Separate raw from ready-to-eat (RTE)

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.

2.1.1 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. The role of hygienic zoning in controlling *Listeria monocytogenes* by managing incoming materials including ingredients, processing aids, utilities (water, air, gases), utensils, tools, lubricants, chemicals, and packaging materials as potential carriers are key proactive steps on the road to effective pathogen control.

2.1.2 Hygienic zoning to control cross-contamination

Hygienic zoning is used to control cross-contamination. Areas with raw, unprocessed materials should be physically separated from pasteurised product and sanitised 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. have 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 movement (via clothing, shoes, skin, tools, etc.).

2.1.3 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 Good Manufacturing Practice (GMP), ready-to-eat (RTE), high-hygiene, and transitional areas) and show human and material flows. The diagram should include:

- hygienic zone designations;
- incoming materials and outgoing finished product;
- personnel routes including job responsibilities, entry/exit, and 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; and
- 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 materials and then performing cleaning/sanitising 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, quality assurance (QA) personnel and trolleys, 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 trolleys, forklifts, and workers). Consider zone designations for transport equipment (forklifts, pallet jacks, trolleys) 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.

Colour coding of protective clothing such as 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.

2.1.4 Use of chemicals – 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 designated 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 sanitising 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 sanitiser. Footbath "mats" must be washed and sanitised 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 sanitiser chemical supplier can be an important resource for identifying appropriate chemical controls.

2.1.5 Heat treatment of milk and other products (ingredients)

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

For manufacturers adding post-pasteurisation inclusions (nuts, fruit, berries, spices, flavours, etc.) into ice cream, cheese, yoghurt, or other products, it is also critical to make sure that those inclusions do not contaminate the already pasteurised products. These controls could include treatment by the supplier to control *Listeria monocytogenes* and other pathogens.

2.2 Principle #2: Good Manufacturing Practice (GMP) and controlled conditions

2.2.1 Good Manufacturing Practice (GMP), personnel, and behaviours

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 programme, 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, including:

- 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-sanitised surfaces;
- after leaving the production area/line or visiting the restroom;
- after coughing or sneezing into hands or scratching/touching exposed skin; and
- after breaks.

The use of sanitary gloves is common in manufacturing environments. While gloves minimise human contact with foods and shield employees' skin from soil, they must be cleaned and sanitised 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 sanitised on a regular basis to avoid cross-contamination. Immediate cleaning and sanitising is required if they have contacted non-sanitised 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 sanitising 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 sanitise and can allow microbial harbourage 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 sanitised reusable footwear. There should be a documented sanitation programme for footwear that is reused.

2.2.2 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.

2.2.3 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 harbourage 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 harbourage 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 sanitised 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.
- *Listeria* requires moisture and nutrients to grow, so minimise 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*.

2.2.4 Controlling temperature and humidity

All time-temperature controls and protocols for ingredients, in-process materials, and finished products must be followed. Written programmes 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.

2.2.5 Training and documentation

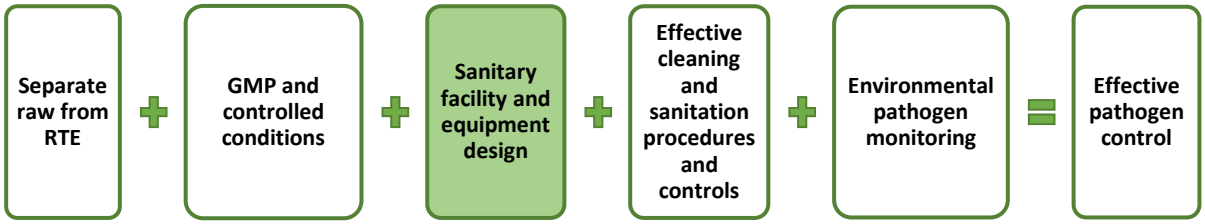
All dairy manufacturing employees should be aware of and trained on their role in controlling *Listeria* in the manufacturing environment and finished product. Training should occur upon initial hire, prior to new job assignments, and must be periodically reinforced. It is important to have a standard 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 harbourage points;
- preventing cross-contamination in the facility;
- identifying likely sources of *Listeria* in the processing/packaging facility and behaviours that might spread the pathogen in the plant environment;

- encouraging an effective environmental monitoring programme and detection of *Listeria* spp. in the environment when it is present; and
- *Listeria* control practices and GMPs relevant to the specific job the employee will be performing.

2.3 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 on-going efforts required to assure effective cleaning and sanitation. Ideally, facilities and equipment will be designed for optimal cleaning ability with minimal niches, sandwich joints, or other potential harbourage sites. Harbourage 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.

Without adequate control programmes, *Listeria* may grow and become entrenched in any equipment or plant areas that might trap moisture or food debris. Areas known to harbour *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 harbour *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 harbourage location.

2.3.1 Sanitary facility design considerations

Facility and equipment design considerations include:

- Equipment and facilities must be cleanable and resistant to deterioration by cleaning/sanitising 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 maintained well.
- Freezers and coolers must be cleanable after spills. Condensate must be minimised and controlled.

Floors

Floors are to be constructed to prevent harbourage, be impervious to chemicals and water, easily cleanable, resistant to wear, and resistant to corrosion. Proper design and maintenance of floors and drains are 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 (special bricks 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 harbourage spot for bacteria. Flooring professionals can perform a "tap-test," which is a technique where tiles are tapped with a solid object, resulting in audible differences in tone. Experience with this method allows the expert to assess floor conditions, including floor tile delamination 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 harbourage 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 underneath 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 should include the following questions:

- Are the current floor materials and/or 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 heavy equipment traffic (forklift, pallet jack, etc.) is present, and how often? 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 due to 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 harbourage 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 minimise 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 an 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.

An accurate drain map that includes all drainpipe 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 into the design to limit the potential for pooling. If using a wastewater treatment facility, chemical restrictions may change the amount of water used. Discharge from all equipment sinks and clean-out-of-place (COP) tanks 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 sanitised properly. Drain backups are a potential source of large-area contaminations, so procedures around special-cause cleaning, sanitising, 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 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 smooth, hard, non-porous, 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, sanitising, and identifying when and how the leak occurred. Environmental monitoring should be initiated after any leak to monitor contamination risk and determine product disposition.

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 the absorption of moisture 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 minimised, 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 sanitising underneath the equipment and aisles should allow sufficient space for maintenance and sanitation access.

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 sanitising 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 the correct water pressure to limit the overspray and aerosol creation that is possible at higher water pressures. Drums 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 vapour and humidity control.

Frequent repairs of rooms dedicated for cleaning and sanitising operations may be needed due to the infrastructure degradation. 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 on-going 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.

2.3.2 Utilities

Utilities interact with food products in many ways and must not be overlooked as potential contamination vectors.

Heat ventilation and air conditioning (HVAC)

As a general guideline, room pressure is used to cause air to flow from high-hygiene areas > RTE areas > raw areas to reduce the risk of dust and contaminants migrating to higher product risk areas. 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 mould, appropriate filters may be required.

Compressed air

Compressed air can also become a risk if not adequately designed for food manufacturing applications. The most critical aspects are the dew point (the atmospheric temperature below which water vapour begins to condense and water droplets can form, dependent on pressure and humidity), 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 at least 0,01 micron.

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 food grade approved chemicals. 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.

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 Recognised as Safe (GRAS) status unless specific design requirements are set forth in the Pasteurised Milk Ordinance (PMO). Reclaimed water from heat exchangers, evaporators, and membrane processes (condensate of whey) 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).

2.3.3 Special circumstances

In the course of operating manufacturing facilities, special circumstances will arise. Recognising and preparing for either planned or unplanned events 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.

Planned events require preparations including the creation of a food safety construction plan 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.

2.3.4 Equipment design

Following sanitary design principles is critical to ensure cleanability and to eliminate harbourage sites where microorganisms are protected from cleaning and sanitation. An equipment sanitary design checklist 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. The Regulations governing general hygiene requirements for food premises and the transport of food, R962 of 2012 Under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 0f 1972 and the SABS South African National Standard 10049:2017 Food Safety management systems – requirements for pre-requisite programmes are a good starting point for dairy equipment. It is important to verify that all production equipment is cleanable to a microbiological level and that it will survive repeated cleaning cycles.

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. For example, anodised or coated aluminium 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.

2.3.5 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 harbourage sites. All product-contact surfaces should maintain an acceptable floor clearance to minimise potential for contamination from the floor. The outer perimeter of equipment should have adequate clearance from the floor and from walls and other large equipment to allow for cleaning.

Self-draining surfaces

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

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.

No niches

Prevent accumulations of water, moisture, or soil by minimising overlapping surfaces, seams, recesses, sandwich joints, and dead spots. Equipment should be built from single pieces of material whenever possible to minimise assembly with bolts, press-fits, or other fasteners. Avoid threaded parts including threaded legs.

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 sanitised 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, sanitised, 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 (treating or coating the metal in order to reduce the chemical reactivity of the surface) for corrosion resistance and to enable cleaning.

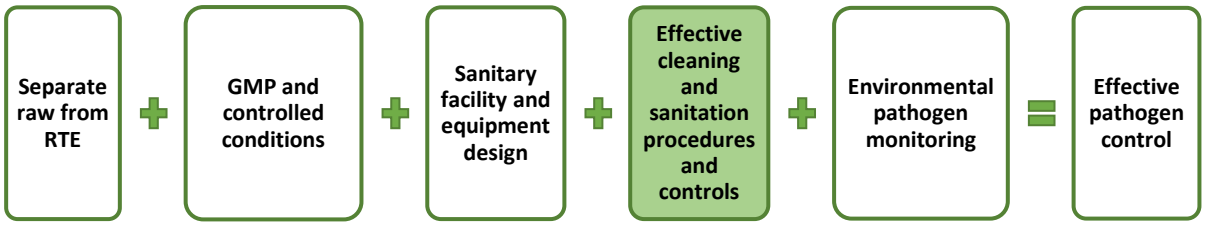
Other considerations

- 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.
- 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 have adequate clearance from the floor, not above open product, and be of cleanable design.

2.3.6 Existing equipment with design opportunities

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 harbour 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.

2.4 Principle #4: Effective cleaning and sanitation procedures and controls



Having a well-designed, effective cleaning and sanitising programme 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 sanitising 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, scrapers, tubs, mats, trolleys, transfer hoses, etc. All of these can harbour 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 harbourage, the risk of contaminating products or other equipment, and other environmental factors.

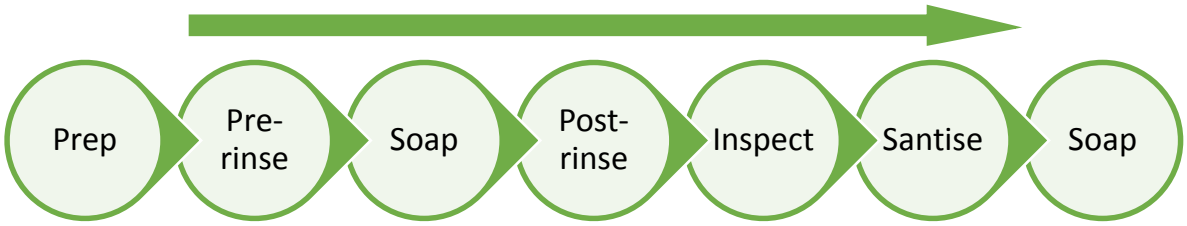
Effective cleaning requires balancing four basic variables:

- chemical concentration;
- mechanical/manual force or abrasion;
- temperature; and
- time.

These variables are adjusted based on the soil type, the surface being cleaned, and the 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.

2.4.1 Manual cleaning and sanitation

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



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 60^{o}C 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 colour-coded tools (scrub pad, brush, etc.) and apply mechanical action

to remove all product soil. Mechanical action is especially important in breaking up potential biofilms, allowing subsequent sanitising to be effective.

4. Post-rinse

Rinse away all chemical and remaining product residues with potable 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. Sanitise

Sanitising is only effective if equipment and other surfaces are clean and free of organic matter. Sanitise equipment, walls, floors, equipment framework, etc. from the bottom up to ensure all surfaces are covered. Only SABS-approved sanitisers with documented, validated activity against *Listeria* should be used.

7. Reassemble and room setup

Under sanitary conditions, wash and sanitise tools, hands and gloves. Remove any pooled sanitiser 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 sanitise again after equipment assembly.

2.4.2 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.

2.4.3 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

2.4.4 Sanitising

Sanitising can be accomplished utilising heat or chemical methods. Chemical sanitiser types include chlorine-based, iodine-based, quaternary ammonium compounds, and variations of acid and peracetic acid-based sanitisers. Sanitisers can be categorised as rinse-required or no-rinse.

Label instructions must be followed. Caution must be exercised to avoid recontaminating equipment after it has been sanitised.

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

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

2.4.5 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 build-up. Utensils should be monitored for wear and replaced when appropriate. Vacuums and dry-cleaning utensils should be part of the environmental monitoring programme. Alcohol-based sanitisers can be used to sanitise 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.

2.4.6 Sanitation effectiveness monitoring

Monitoring, corrective actions, and documentation activities are crucial for verification of the effectiveness of the facility's cleaning and sanitation programme. Key elements of pre-operational monitoring include: smell, touch, and visual inspection of equipment, ATP swabbing, and clean equipment swabbing for indicator organisms. Visual inspection and ATP swabbing provide immediate actionable feedback, while culture-based swab results are used to verify cleaning and sanitising at a microbiological level. The results of these monitoring activities should be tracked and trended to verify programme effectiveness and to determine the need for additional training

or SSOP changes. This will also aid in the identification of equipment design/integrity issues. For cleaning processes which utilise CIP or COP, temperature charts, cycle charts, and concentration checks should be monitored by trained personnel.

2.4.7 Master Sanitation Schedule

A Master Sanitation Schedule (MSS) is a documented system for the managing and tracking of non-routine cleaning and sanitising 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. 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 programme should be re-evaluated when process or structural changes are made to the plant.

2.4.8 Special-cause cleaning (periodic deep 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 sanitising 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 sanitising 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 uniform and footwear changes, showers, hand-washing, and tool decontamination occur.

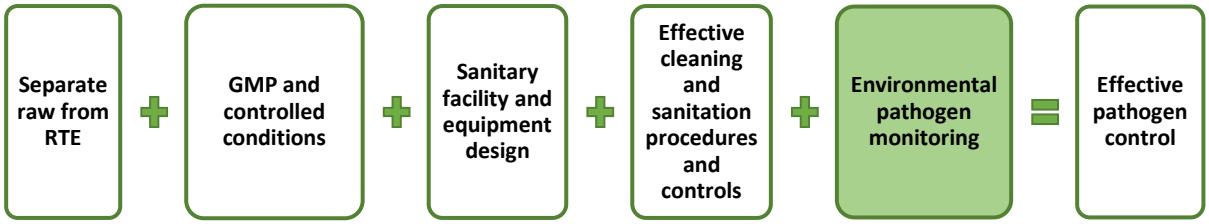
During special-cause cleaning or periodic deep cleaning, equipment should be disassembled to expose internal surfaces. Any overlapping parts are disassembled to expose all surfaces and bolted/fastened parts are separated. If the equipment is complex, the equipment manufacturer may be consulted to support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

- a sanitiser with oxidising 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; or
- steaming by shrouding the equipment and injecting live steam to ensure the coldest spot reaches 72^{o}c for a minimum of 30 minutes.

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 sanitised 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.

2.5 Principle #5: Environmental pathogen monitoring



A robust environmental monitoring plan designed to verify the effectiveness of the pathogen control programmes 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.

2.5.1 Facility-specific risk assessment

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 programme based on risk. A 24-month review of background information is ideal when building or updating a LEMP programme 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 pasteurisation 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; and
- equipment and facility design challenges.

2.5.2 *Listeria* monitoring programme

What to test for: Listeria spp. or L. monocytogenes

Listeria spp. are a broad indicator group which, when detected, signal that conditions are also favourable for *L. monocytogenes* growth or survival. The goal of a LEMP is to aggressively look for, find, and eradicate all *Listeria* spp. from the processing environment, ensuring the absence of *L. monocytogenes*. A programme based on detection of *Listeria* spp. is more conservative than one

monitoring for *L. monocytogenes* 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 sooner. 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 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 the potential risk of contamination. 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/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.

Additional information on zones and sampling:

	Description	Examples
Zone 1	Product-contact surfaces.	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 the following:

- Routine sampling is focused in Zones 2 and 3 to obtain early indication of *Listeria* spp. presence in the environment.
- 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 preventive controls.
- A cross-functional food safety team with knowledge of the plant's programmes, 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.
- Each company will need to design a plan appropriate for their own situation, but Zone 1 *Listeria* spp. testing is not routine in the dairy industry. It is conducted upon direction of your food safety expert, who determines a need for it and who will also ensure that product is held from shipment to customers pending results of such sampling. Testing for and finding *Listeria* spp. on a product-contact surface does not automatically mean that product is contaminated. However, product disposition of potentially exposed product must be determined considering likelihood of transfer, the ability of the product to support growth, and the intended use.

When to sample

Routine environmental sampling is performed during production, at least four hours into the production cycle. Longer production cycles may warrant sampling later in the run, starting at least halfway between sanitation cycles. This timing is recommended because harbourage 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 with a minimum frequency (e.g., daily, weekly, biweekly) 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-cause 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 programmes 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:

- Facility size: Some companies use a general guideline of 1 sample/90 m^2/week.
- Processing conditions, including the degree of RTE product exposure to the plant environment, human handling prior to packaging, and 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, including floors, overhead conditions, wall conditions, age, product flow, etc.
- Sanitary condition of processing equipment, including welds, cracks, material, and cleanability.
- External historical data and recent outbreaks, including industry environmental monitoring norms, recent product or ingredient concerns, inherent risk profile of product type, etc.
- Other factors, including distribution conditions, shelf life, intended use, target distribution channel, if product is for higher risk consumers (young, old, pregnant, immunocompromised, etc.).
- Flexibility: The plan should accommodate routine as well as investigational, validation, and verification objectives.

Where and when samples will be collected

- 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 product-contact surface (PCS) swabs are taken before non-PCS swabs and RTE area swabs before non-RTE areas.
- Sterile sponges are effective for sampling large areas (e.g. 30 x 30 cm) 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 sanitisers may be present on sample sites, a buffer containing a neutralising 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 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 programmes 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.

Sampling and testing methods

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, including:

- staff competency and documented training;
- test methods documented and based on accepted standards;
- equipment fit for purpose and appropriately calibrated;
- documented QA programme including proficiency testing;
- internal audits of lab operations; and
- 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 recognised or accredited for product or environmental testing. These methods are described in the United States Food and Drug Administration (FDA) Bacteriological Analytical Manual, ISO methods, or validated through recognised validation bodies, such as AOAC International.

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. 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.

2.5.3 Response to results and corrective actions

Responding to a positive result requires the following action:

- 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 better determine the contamination source.
- Clean the affected area.
- Determine root cause and implement long-term corrective actions for the root and contributing causes. 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 exposed finished product.

The immediate response to a positive result is to resample the area or equipment extensively in order 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 in order to be fully inspected and cleaned. Then thoroughly clean and sanitise 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.

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 tiles, 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.

Corrective actions must always include re-swabbing 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 three, but may vary based on the zone and general environment. If the zone has multiple traffic patterns, re-swabbing 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.

2.5.4 Special considerations and documentation control

- If repeated positive *Listeria* spp. or *L. monocytogenes* 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 *L. monocytogenes* 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.
- 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.

2.5.5 Programme verification and documentation verification

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

- Review methodology
  - Does the monitoring programme 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 being used?
  - Are methods followed correctly?
- Review records and results
  - Are documents, records, and reported results (including required review/sign-offs) accurate and complete?
  - Are there documents and 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 utilised. Other activities may include engaging an outside expert consultant or reviewing published materials.

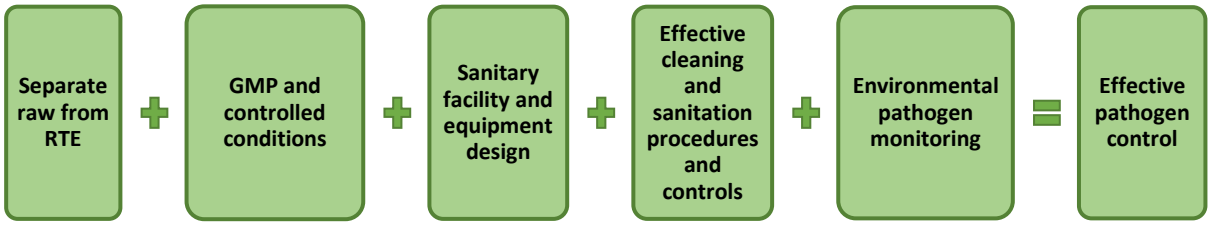
2.5.6 What if *Listeria* spp. are never detected?

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

- sampling and/or testing procedures may not be rigorous or sensitive enough;
- likely harbourage points have not been identified and sampled;
- sampling times and frequencies were not selected to detect the *listeria*;
- sampling procedures were not followed and that the size of area sampled was not adequate;
- failure to neutralise residual sanitiser in sampled areas;
- poor sample handling prior to testing;
- faulty detection methods or low technician competency; and
- manipulation of sampling or testing to obtain negative results.

3. 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 organised and integrated approach. This approach is symbolised by the pathogen control equation.



This document is intended to provide the reader with educational materials organised 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 organise 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 on-going success advancing food safety performance.

As stated, this guide is based on the *CONTROL OF LISTERIA MONOCYTOGENES – GUIDANCE FOR THE US DAIRY INDUSTRY* (October 15, 2015).

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