

## Authors

## Industry Guidelines to Prevent Contamination from *Listeria monocytogenes*

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## Overview

Extensive efforts to control *Listeria monocytogenes* can reduce the frequency and level (CFU/g or cm<sup>2</sup>) of contamination, but it is not possible, given currently available technology, to eradicate it from the processing environment or totally eliminate the potential for contamination of finished products. Because of the serious nature of listeriosis in the susceptible population, industry must take stringent measures to control *L. monocytogenes* in ready-to-eat foods in which the organism can grow. This document provides practical guidelines for preventing recontamination of products with *L. monocytogenes*, including controls directed toward preventing contamination of product surfaces and preventing the establishment and growth of the organism in niches in the plant environment. Although this document focuses on refrigerated, ready-to-eat products that support the growth of *L. monocytogenes*, the guidelines may be applied to other products to minimize contamination. The guidelines, which cover General Considerations, Processing Operations, Packaging and Storage Operations, Equipment Considerations, General Plant Sanitation, and Employee Personal Hygiene, also provide general guidance on environmental monitoring programs that use indicator organisms such as *generic Listeria* to verify the effectiveness of the *L. monocytogenes* control program.

## Introduction

This document is intended to apply to refrigerated, ready-to-eat (RTE) foods that support the growth of *Listeria monocytogenes*, although the guidelines may be applied to other products to minimize contamination with *L. monocytogenes*. However, not all the guidelines listed below apply in all situations. The controls for *L. monocytogenes* will be product, process and plant specific; therefore, these recommendations should be considered only as guidelines. These guidelines may need to be adjusted as we gain new knowledge and better understand how to control *L. monocytogenes* in the plant environment.

Listeriosis is a serious disease that is caused by the bacterium *L. monocytogenes* and that results primarily from consumption of contaminated foods<sup>4,5</sup>. Although listeriosis can occur in otherwise healthy adults and children, certain populations—pregnant women, neonates, the elderly, and immuno-suppressed individuals are more susceptible to listeriosis<sup>4,5</sup>. Foods implicated in outbreaks and in sporadic cases have been limited to a few refrigerated products that supported the growth of the organism to high numbers<sup>4</sup>.

*L. monocytogenes* is widespread in the environment; it is found in soil, water, sewage, and decaying vegetation and can be isolated readily from humans, domestic animals (including pets), raw agricultural

commodities, food processing environments, and the home<sup>5</sup>. The organism is found in a wide variety of foods, including meats, poultry, vegetables, dairy products, and fishery products<sup>4,5</sup>; and, in fact, in just about any cool, damp environment. This is one reason why floor drains frequently contain high populations of *Listeria spp.* Because of its pervasiveness, the organism is constantly re-introduced into the plant environment. Extensive efforts to control *L. monocytogenes* can reduce the amount and level of contamination, but cannot, given currently available technology, eradicate it from the processing environment or totally eliminate the potential for contamination of finished products<sup>1,5,8</sup>. However, because of the serious illness, and even death, that it can cause in susceptible individuals, it is imperative that industry take stringent measures to control the potential for contaminated RTE foods. Because U.S. regulatory agencies consider *L. monocytogenes* in RTE foods an adulterant, they will request that companies recall product that is found to contain *L. monocytogenes*<sup>6</sup>.

**Table 1. Common sites of *L. monocytogenes* contamination**

- Filling or packaging equipment
- Conveyors
- Solutions used in chilling food
- Slicers, dicers, shredders, blenders, etc. used after heating or decontaminating and before packaging
- Collators used for assembling/arranging product for packaging
- Racks for transporting finished product
- Hand tools, gloves, aprons, etc. that contact exposed finished product
- Spiral freezers/blast freezers
- Containers such as bins, tubs, or baskets used for holding food while it is waiting to be further processed or packaged

Providing effective control of *L. monocytogenes* is challenging and, because it can be very resource intensive, management must be committed to expending the resources necessary to resolving the problem, protecting the business, and assuring consumer safety<sup>1,2</sup>. Employees must be trained to understand the problem, the potential sources of the organism, and the specific controls the plant is employing for control of *L. monocytogenes*<sup>2</sup>. This employee training will go far beyond the normal training in Good Manufacturing Practices (GMPs). Management should strive to instill a sense of personal responsibility for the safety and quality of the food that is being produced.

Because *L. monocytogenes* is present on raw ingredients, many processing plants have adopted steps to destroy or remove the organism to the extent possible within the operation. For cooked products, the plant should verify that the heat treatment is adequate to destroy *L. monocytogenes*. This document does not focus on how to establish and validate such a process; instead, the focus for heat-treated products will be on preventing recontamination of products that are subsequently handled or further processed (sliced, repackaged, etc.). Most of the risk of contamination with *L. monocytogenes* is from potential recontamination after heating; in general, there is a low risk of *L. monocytogenes* surviving a heat treatment.

This document can also be applied to operations in which there is no heat treatment to destroy *L. monocytogenes*, but in which there is a need to minimize contamination of the product. These operations may include steps to remove the organism by peeling, washing, etc. Control in these operations must focus not only on reducing the numbers of *L. monocytogenes* on products by physical means, but also on preventing the establishment and growth of *L. monocytogenes* in the environment.

Because *L. monocytogenes* will continue to be introduced into a plant's environment, control must be directed toward preventing its establishment and growth in the environment. *L. monocytogenes* re-contamination can come from multiple sources, and control through Hazard Analysis and Critical Control Points (HACCP) CCPs is therefore usually impractical; prerequisite programs<sup>7</sup> are the foundation for *L. monocytogenes* control, with GMPs, sanitation, and training targeted toward specific control of this organism. While some may not agree with this position, the focus should be on having a program to control recontamination by *L. monocytogenes* rather than on what the specific controls are called.

To verify *L. monocytogenes* control, plants should implement an environmental monitoring program for an indicator such as *Listeria spp.*<sup>8</sup> This program, specific to the plant, should detail the areas to be sampled for *Listeria spp.* (*generic Listeria*), the frequency of sampling, and the action to be taken when *Listeria spp.* is detected. This aspect of a control program will be covered in detail later in the document.

## Control Guidelines

These guidelines are organized into General Considerations, Processing Operations, Packaging and Storage Operations, Equipment Considerations, General Plant Sanitation, and Employee Personal Hygiene.

### General Considerations

A control program for *L. monocytogenes* should emphasize the more common sources of direct product contamination. The greatest risk for product contamination occurs when a product contact surface is contaminated. This risk is highest between the point where a food is cooked, pasteurized, decontaminated, etc. and the point where the food is packaged. To effectively manage the risk of product contamination, it is necessary to assess where along the product flow the exposed food is most likely to become contaminated. This is generally wherever something has direct contact with the unpackaged product. Examples of some common sites of contamination are shown in Table 1.

Other areas of the environment can serve as indirect sources of *L. monocytogenes*. These areas may harbor the organism and under certain conditions lead to contamination of product contact surfaces or the food. Controlling the presence of *L. monocytogenes* in the environment can reduce the risk that product or a product contact surface will become contaminated. The significance of these areas will vary depending upon the facility, the process(es), the temperature and humidity of the room, and the food. Examples of places where *L. monocytogenes* may occur are shown in Table 2.

Consideration should also be given to the potential for *L. monocytogenes* to be brought back into the clean environment, which may occur because of traffic in the processing and packaging areas (people and equipment, such as trolleys and forklifts, entering from more contaminated points in the operation) or unscheduled equipment maintenance.

It should be recognized that, in a plant with an effective control program, *L. monocytogenes* contamination, when it occurs, is line or equipment specific. Although random isolated contamination with *L. monocytogenes* is possible in a controlled environment, contamination more likely will occur after the organism has become established in a niche, after which routine cleaning and sanitizing become ineffective. As the equipment is operated, the bacteria work their way out of the niche and become deposited onto the outer surfaces of the equipment. As product moves over or through the equipment, the contamination is spread downstream to other areas along the product flow. This situation can be corrected only by identifying the source or niche of *L. monocytogenes* growth and eliminating it. Some of the sites found to be potential harborage sites are shown in Table 3.

In addition to the possible establishment of *L. monocytogenes* in a niche, certain conditions that have led to product contamination deserve extra attention. Examples of conditions that have caused problems and should be viewed as “red flags”

**Table 2. Examples of *L. monocytogenes* reservoirs in the plant**

- Equipment framework and other equipment in the area
- Floors
- Drains
- Walls, especially if there are cracks that retain moisture
- Ceilings, overhead structures, catwalks
- Condensate
- Insulation in walls or around pipes and cooling units that has become wet
- Trolleys, forklifts, walk-alongs
- Cleaning tools such as sponges, brushes, floor scrubbers
- Maintenance tools

**Table 3. Potential harborage sites for *L. monocytogenes***

- Hollow rollers for conveyors
- Roller guards
- Slicers, dicers
- On/off switches
- Rubber seals around doors
- Damp insulation
- Fibrous or porous conveyor belts
- Conveyor scrapers, especially if frayed and in poor condition
- Open bearings within equipment such as slicers, strippers, etc.
- Hollow implements, including box cutters
- Trash cans and other such ancillary items
- Standing water in production areas
- Cleaning tools, including mops and sponges
- Poorly maintained in-line air filters through which compressed air must pass
- Wet rusting or hollow framework
- Motor housings
- Walls/crevices of spiral freezers
- Ice makers
- Cracked hoses

include the following:

- A packaging line is moved or modified significantly.
- Used equipment is brought from storage or another plant and installed into the process flow.
- An equipment breakdown occurs.
- Construction or major modifications are made to an RTE product area (e.g., replacing refrigeration units or floors, replacing or building walls, modifying sewer lines).
- A new employee, unfamiliar with the operation and *L. monocytogenes* controls, has been hired to work in, or to clean equipment in, the RTE product area.
- Personnel who handle RTE product touch surfaces or equipment that are likely to be contaminated (e.g., floor, trash cans) and do not change gloves or follow other required procedures before handling products.
- Periods of heavy production make it difficult to clean the floors of holding coolers as scheduled.
- A drain backs up.
- Product is caught or hung up on equipment, resulting in stagnant product in the system, which can be a major site of microbial growth during production; the equipment should be modified to eliminate areas where product stops moving along or through a processing line.
- Raw or underprocessed product is detected in a cooked product area. If this occurs, the process must be stopped, the unacceptable product removed, and the equipment recleaned and sanitized.
- Frequent product changeovers on a packaging line necessitate changing forming pockets, dies or molds, line speeds, etc.
- Personnel are used interchangeably for packaging raw and cooked products.
- Production increases, requiring wet cleaning of down lines in the same room as lines running product.
- Heat exchangers become compromised (e.g., with pinholes).
- Equipment parts, (tubs, screens, etc.) are cleaned on the floor.
- Waste bins in the RTE area are not properly maintained, cleaned, and sanitized; personnel handling product may contact these items and then contaminate product and/or product contact surfaces.
- Traffic flow between raw and ready-to-eat areas is not adequately controlled (e.g., maintenance personnel and their tools, outside contractors, etc.).

#### Table 4. Cleaning Chart

Drains = Daily  
Floors = Daily  
Waste Containers = Daily  
Walls = Once a week  
Coolers = Monthly

## Processing operations

As noted before, meat, poultry, vegetables, dairy products, seafood, and other raw ingredients may be contaminated with *L. monocytogenes*, although the presence of the organism and the levels of contamination vary widely<sup>4,5</sup>. These ingredients should be managed as if they are contaminated, and steps should be taken to prevent crosscontamination from raw ingredients to products that have been treated to eliminate or reduce the contamination. Separating raw products from semifinished and finished products is key to preventing cross-contamination.

1. Wherever possible, flow of product through the operation, from the raw ingredients to the finished product should be linear.
  - Plants and/or practices must be rearranged, if necessary, to improve the flow of product, equipment, and people to ensure separation of raw from cooked or treated product.
  - In some operations, it may be necessary to establish positive air flow on the “clean” side of the operation relative to the “dirty” side (e.g., maintain negative air pressures in raw product areas and positive pressures on the clean or finished product side).
2. Operations must be compartmentalized as needed to enhance the separation of raw ingredients and processed products.
  - Dedicated washing areas and CIP/COP (clean in place, clean out of place) systems should be provided for cooked or treated product equipment and raw processing equipment.
  - Rework and trash barrels for cooked or treated product areas should be labeled or color-coded and not be used elsewhere in the plant. They must be cleaned and sanitized daily, or more frequently if environmental sampling data indicate this is necessary.
  - Before the start of operation each day, hoses are to be removed if possible from the

- manufacturing areas where RTE products are exposed. Otherwise, they must be properly hung and controlled during production.
- Separate utensils, carts, racks, totes, equipment, cleaning utensils, etc., color-coded where practical, should be used for the RTE product area.
  - Where possible, overhead fixtures should be eliminated in the RTE area, especially over open product zones; overhead fixtures should be on a scheduled maintenance and cleaning program.
  - Where possible, wet process areas should be isolated from other production areas; at a minimum, standing water should be removed as soon as possible.
3. Traffic flow patterns between the raw ingredients and the processed products sides of the operation must be controlled to prevent transfer of *L. monocytogenes* from the “dirty” or “raw” side of the operation to the “clean” or “cooked” side. Some specific measures which should be considered for controlling the transfer of *L. monocytogenes* to clean areas are as follows:
- Equipment, utensils and people in raw and cooked areas should not be interchanged during the working day.
  - Drains from the “dirty” or “raw” side should not be connected to those in the “clean” or “cooked” side.
  - As an option, plant management may install foot baths; if they are installed, they must be properly maintained to prevent their becoming a source of contamination. Maintaining clean dry floors is preferred to the use of foot baths, unless there is a specific need that cannot be addressed otherwise. Foot bath solutions should contain stronger concentrations of sanitizer than would normally be used on equipment (e.g., 200ppm iodophor, 400-800ppm quaternary ammonium compound); minimum depth of 2 inches of solution is recommended. Chlorine is not recommended for this use as it becomes too quickly inactivated; if chlorine is used, attention must be given to monitoring and maintaining its strength. Foot baths will be ineffective if cleated boots are carrying large particles of dirt or plant waste.
  - As another option, a foam disinfectant may be sprayed on the floor as people or rolling stock (carts, forklifts, etc.) enter the room. Water used in processing operations in which it will come in contact with product, e.g., chill water for RTE products and for blanched vegetables to be used in RTE products, should contain an antimicrobial agent known to be effective against *L. monocytogenes* and approved for the specific application at the levels used.

## Packaging and storage operations

Pallets entering the packaging room must be clean, dry and in good condition, and exposed products must be stored and packaged in a clean, dry environment, for the following reasons:

- Bacteria cannot multiply without water, therefore, if the environment is clean and dry; *L. monocytogenes* remains dormant or perhaps dies.
- There is less transfer of bacteria from surfaces if the surfaces are clean and dry.
- The spread of contamination by vehicular and pedestrian traffic is reduced considerably if the floors are clean and dry.
- The cooling units in packaging room and coolers for exposed product should have dehumidifying capability. To facilitate the removal of humid air and to dry floors after cleaning, it may be necessary to exhaust air outside the plant. Heating air within a room can also be effective for removing moisture at the end of the cleaning/sanitizing process.

## Equipment considerations

Proper design and maintenance of equipment is essential.

- Equipment must be designed to facilitate cleaning and to minimize sites where microbial multiplication can occur. Acceptability of the design from a microbiological and sanitation standpoint should be reviewed before any new or replacement equipment is acquired.
- Previously used equipment, even though visually clean, may harbor pathogens; such equipment must be thoroughly cleaned and sanitized, disassembling as needed, prior to putting it into production.
- Equipment must be properly maintained to minimize breakdowns and the attendant risk of contamination during repair.

- Damaged, pitted, corroded, or cracked equipment should be repaired or replaced.
- Equipment or catwalk framework should not be hollow, which could allow water to collect and harbor *L. monocytogenes*.
- Lubricants that contain additives (e.g., sodium benzoate) that are listericidal should be used; lubricants can become contaminated with product residue and become a center for growth of *L. monocytogenes*.
- Conveyor designs and locations that are difficult to clean and sanitize must be avoided. Conveyors for product prior to packaging should not contain hollow rollers. Conveyors or other processing equipment in which product is exposed should not be located near the floor, as this is a likely source of *L. monocytogenes*. Overhead conveyors should be avoided if possible, as they are more difficult to clean, sanitize and inspect; a safety ladder should be provided, or the conveyor should be designed so it can be lowered for cleaning.
- Racks used for transporting exposed cooked product should have cover guards over the wheels to prevent spray from the wheels onto the rack and product as the racks are moved.
- Racks used in operations after products are cooked can be a significant source of contamination if not properly cleaned and sanitized before use; the most reliable method of sanitizing racks is with heat. Heat can be applied by
  1. a hot water (180°F) rinse in a rack washer in which the racks will reach a temperature of 160°F or higher,
  2. steam applied in a cabinet after cleaning in a rack washer, or
  3. placing the racks into an oven and applying moist heat to raise the temperature of the racks to 160°F or higher.

When heat is used to sanitize, it is essential that the equipment be thoroughly cleaned so the heat does not bake the soil on, making it more difficult to remove, and resulting in more contamination problems in the future.
- Regular maintenance schedules should be adopted and followed to minimize the potential for harborages and to reduce the potential for contamination due to unscheduled repair operations.
- For maintenance of equipment in the cooked, RTE product area it may be necessary to use tools dedicated to this area or to sanitize tools prior to use in this area. Maintenance personnel should wear clean smocks that are not used in raw material areas. Equipment should be re-sanitized after maintenance work on or around product contact surfaces.

## General plant sanitation

- Sanitation procedures designed to control *L. monocytogenes* should be used. The frequency of cleaning and sanitizing the equipment and environment of a plant depends upon experience and microbiological data. Visual inspection is very important in verifying equipment cleanliness. Routine microbiological testing (e.g., Aerobic Plate Count) allows the plant to develop a baseline for comparison purposes, observe trends, and detect a developing sanitation problem. ATP monitoring systems can also be useful tools for monitoring overall sanitation in the plant. However, these procedures (visual inspection, APC counts, ATP monitoring) do not give the same degree of assurance that *L. monocytogenes* is not present as does environmental testing for *Listeria spp.* (as outlined later in this document).
- Successful control of *L. monocytogenes* requires consistency and attention to detail, following these steps: (1) dry clean, (2) pre-rinse the equipment, (3) visually inspect the equipment, (4) foam and scrub the equipment, (5) rinse the equipment, (6) visually inspect the equipment, (7) clean the floors, (8) sanitize the equipment and floors, (9) conduct post-sanitation verification, (10) dry the floors, (11) clean and put away supplies. Some equipment may require disassembling prior to cleaning and sanitizing and may need to be re-sanitized after reassembling.
- Quaternary ammonium compounds (quats) have been found to be effective against *L. monocytogenes* and leave a residual germicidal effect on surfaces. In addition, sanitizers containing peracetic acid and peroctanoic acid have been shown to be effective against biofilms containing *L. monocytogenes*. Areas that should be sanitized with such compounds and a suggested frequency are shown in Table 4.
- The cleanup crew should receive special training in proper procedures to control *L. monocytogenes*, as well as close monitoring and correction to improve and maintain a high level of performance.
- Priority must be given to rooms and equipment used for holding and packaging exposed ready-to-eat product. Areas where products are stored or processed are of lower priority because inadequately cleaned equipment in raw processing areas has not been associated with a problem of *L. monocy-*

*genes* in finished product. Consideration should be given to assigning the most capable and experienced personnel to areas where RTE products are handled and packaged.

- It is very desirable, even necessary in some cases, to have a person on the staff whose primary responsibility is to monitor the cleaning and sanitizing process whenever it occurs to be certain it is done correctly. This person should recognize the urgency of having the plant ready on time for startup, but this concern must be secondary to the necessity that the plant is correctly cleaned and sanitized. Extensive experience indicates that, if the equipment is properly cleaned and sanitized before start-up, then the risk of contamination from equipment during production through two shifts is minimal.
- Mid-shift cleanups should be eliminated wherever possible, because they produce aerosols and add water to the environment, which can spread *L. monocytogenes*; they are therefore counter-productive in that they increase the risk of *L. monocytogenes* contamination and make it more difficult to control *L. monocytogenes*.
- Some plants have found the following sanitizing procedure to be helpful: After cleaning the equipment, apply a high level of sanitizer (e.g., 800ppm quat), allow it to stand for about 20 minutes, rinse thoroughly, and then apply the normal level of sanitizer (e.g., 200ppm quat or chlorine). At the end of the production week, the high level of sanitizer can be left on the equipment until shortly before start-up. The sanitizer is then rinsed off, the normal level is applied, and the room is prepared for start-up. Under certain circumstances, it may be beneficial to spray an aerosol of 200ppm quat into a room as a final step in the cleaning and sanitizing process; weekly or monthly fogging may be useful.
- Rotating other sanitizers (e.g., chlorine, acid-anionic, peracid and iodophors) into the sanitation program may provide for greater effectiveness. Consideration can be given to using new peracid-based sanitizers and others that have been demonstrated to be effective against *L. monocytogenes*.
- Equipment should be modified so it is simple in design, is easy to clean, and has fewer maintenance problems, because breakdowns during production increase the risk of *L. monocytogenes* contamination.
- Sanitizing with high temperatures, if manufacturers' instruction permit such application, may be particularly useful for biofilms.
- Hot water/steam sanitation is an especially effective alternative to chemical sanitation where equipment is difficult to clean. Wherever possible, steam should be applied as a final step for difficult to clean equipment. One method is to place a metal cover over the equipment and then inject steam. In some cases, equipment can be steamed in a cook oven. The goal is to heat the equipment so it reaches at least 160°F throughout. A holding period of an hour or more is desirable. For equipment that is more sensitive to heating, it is necessary to use a lower temperature (e.g., 145°F) and a longer holding time. (See earlier cautions about thorough cleaning prior to application of heat.)
- Plastic tubs that can be stacked have been a chronic problem if they are not cleaned and sanitized daily; they must not be put on the floor, unless placed on a clean plastic mat.
- Because infrequent cleaning of coolers used for holding cooked product commonly causes increased *L. monocytogenes* problems, particularly in the busy summer season, these coolers should be emptied and cleaned at least once per week (or month) depending upon level of use and conditions of the coolers, and floors should be kept dry.
- Spiral freezers used for freezing unpackaged product should be cleaned twice a year; infrequent defrosting, cleaning, and maintenance of these can be sources of *L. monocytogenes* problems.
- Condensate that accumulates in drip pans of refrigeration units should be directed to a drain via a hose, with care taken to ensure that the hose does not become blocked. Solid forms of sanitizers (e.g., blocks or donuts of quats) can be placed in the drip pan to control microbial growth; in addition to the routine use of sanitizers, drip pans should be cleaned regularly.
- If compressed air is used to remove debris from equipment during production, it should be recognized that this can increase the risk of contamination by being a source of *L. monocytogenes* when in-line filters are not maintained or replaced with regularity. Thus, when compressed air must be used directly on product or product contact surfaces, the air should be filtered at the point of use and the filters maintained. This practice should be restricted, preferably, to cleaning certain equipment (e.g., packaging machines) at the end of production before cleaning begins.
- Coolers or other rooms should never be cleaned when exposed RTE product is present. Covering the product with plastic or paper cannot be relied on; all unpackaged product should be removed from the room before cleaning begins.
- Equipment should not be dismantled and washed on the floor.
- The best method for cleaning floors is to use a powdered caustic cleaner, apply water as needed, use a dedicated, color coded brush to clean the floor, and then thoroughly rinse, using a low volume hose, and sanitize the floor. New cleaners and sanitizers may be more effective for controlling *L. monocytogenes* on the floor. Floor scrubbers can be helpful, particularly for cleaning large open spaces such as

hallways. The equipment used for cleaning must be maintained and properly cleaned so that it does not become a source of contamination. Application of powdered citric acid to certain areas of the floor may be effective for controlling *L. monocytogenes*, provided the floor has been properly cleaned and dried before applying the citric acid. For maximum effectiveness, the surface of the floor should be maintained at pH 5.0 or below with litmus paper used to check the pH. Although this may help control *L. monocytogenes*, the condition of the floor should be monitored, as the acid condition will cause deterioration that eventually will necessitate replacing the floor.

- Floor drains must be designed and maintained to prevent backups. If a backup occurs, production must cease, open product removed from the room for disposition, the drain cleared, and the area carefully cleaned with caustic, and then rinsed and sanitized. Splashing of solutions onto equipment during the process must be avoided. The floor should then be dried. A high pressure hose must never be used to clear a drain; the aerosol created will spread contamination through the room.
- Whenever possible, trench drains should be eliminated.
- Bactericidal drain rings are recommended.
- Floor drains should be cleaned and sanitized in a manner that prevents contamination of other surfaces in the room. Floor drain brushes must be at least 1/4 inch smaller than the diameter of the drain opening, or a splash guard must be used to prevent splashing during cleaning. Utensils for cleaning drains should be dedicated to that purpose to minimize the potential for contamination. If floor drains are cleaned first, it may be necessary to clean and sanitize them again at the end of the process.
- Cleaning tools should be sanitized using 600-1000ppm quat solutions and stored either dry or in quat solutions maintained at 1000ppm.

## Employee personal hygiene

Personal hygiene practices with *L. monocytogenes* control as a major objective should be established. The following information should become part of employee training for *L. monocytogenes* control.

- Clean gloves, smocks, and aprons are essential to protect against product contamination. Ideally, there should be one color smock for the raw side of the operation and one for the processed side. Disposable gloves and aprons should be used wherever possible in cooked product areas. Disposable paper sleeves (arm covers) can provide another barrier for those who handle exposed product. Disposable items should be discarded when the work area is left and replaced with new when the employee returns. Some garments (e.g., smocks) may be left in the department and re-used, provided they are still clean. Gloves should be replaced if damaged. The use of gloves does not preclude the need for employees to wash hands regularly.
- Everyone working in areas where RTE products are exposed must clearly understand that the purpose of wearing clean garments and disposable gloves is to protect the product from contamination, not to protect employees from getting dirty.
- If an unclean surface is touched, then hands should be washed and gloves changed.
- Equipment and soiled clothing must not be stored in lockers.
- If possible, a person in the packaging room should be assigned to pick up material from the floor, remove trash, and perform other housekeeping tasks. This person must not work on a packaging line or handle product that will be packaged or replaced on the line.
- Rubber boots that are nonporous and easily cleaned, which experience indicates are better for *L. monocytogenes* control than other footwear, are necessary where foot baths are used.

## Environmental Monitoring Program to Verify Control

An environmental monitoring program is necessary to assess the need for additional pathogen control measures for products that may be recontaminated by *L. monocytogenes*<sup>9</sup>. Industry experience has shown that an ongoing monitoring and control program that uses *Listeria* species (*Listeria spp.* or *generic Listeria*) as an indicator of potential *L. monocytogenes* contamination reduces the possibility of finding not only *L. monocytogenes* in finished product, but other pathogens as well<sup>2</sup>. Industry experience also shows that reentry of *Listeria spp.* into the production environment cannot be reliably prevented. Thus, ongoing monitoring to detect the organism in the environment is necessary. Each company should establish its own *L. monocytogenes* monitoring program considering the guidelines that follow. The actions to be taken when environmental or product contact surfaces give positive results will vary with each company's policy and action plans, which may change over time based on knowledge of the operation and its controls, the risk of contaminating product, regulatory requirements, and other factors. It must be emphasized that there are many approaches to controlling *L. monocytogenes*; and that what works for one company may not be appropriate for another.

## General principles for verification of environmental monitoring

Environmental monitoring (microbiological testing) should focus on a nonpathogenic indicator such as *Listeria spp.* or *Listeria*-like organisms (e.g., organisms that blacken Fraser broth or produce black colonies on a *Listeria* selective-differential agar), because these indicators will be found more frequently in the environment than *L. monocytogenes* and because test results are available more quickly. Monitoring results should alert the plant to potential problem areas, prompting further investigation and focusing of additional control efforts, as necessary. Corporate goals for reduction of positives should be established to encourage continuous improvement<sup>8</sup>. A detailed set of action plans should be developed to control the risk of *L. monocytogenes* in the event that the corporate goals are not met.

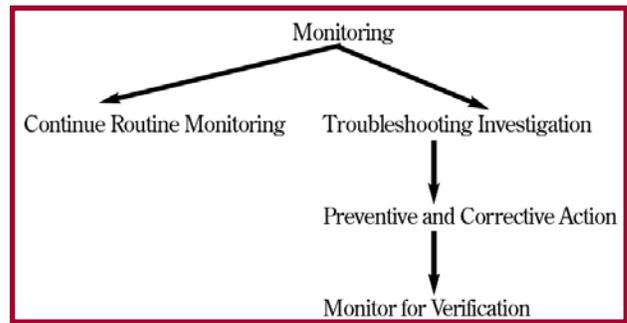


Figure 1. Non-product contact surface testing for indicators of *Listeria* contamination

Each plant, product, and process must be evaluated to determine the appropriate monitoring points. Each packaging line should be regarded as an independent unit for *L. monocytogenes* monitoring and control. It is recommended that both food contact surfaces and non-food contact surfaces that have the potential to contaminate product be tested. One approach might be to separate testing into environmental sites, product contact sites, and product itself, keeping in mind that because *L. monocytogenes* will not be found frequently in products in operations following these control guidelines, and because it will not be uniformly distributed, product testing will not be a reliable indicator that *L. monocytogenes* contamination has not occurred. Thus, the emphasis of the program discussed here is on testing for *Listeria*-like organisms in the environment to verify control. There can be many variations on how this is done. Some guidelines, which follow, are illustrated in Figures 1 and 2.

## Environmental testing

Plants should determine the points to sample and the frequency of sampling based on knowledge of their specific operation and the controls that have been put into place, as well as any microbiological data available. Suggested areas include support structures, overhead areas or structures, walls, floors, drains, and room air. Weekly sampling is recommended initially for most wet areas, where *L. monocytogenes* can grow; in drycleaned areas sampling may be less frequent.

The number of sampling points and the frequency of sampling may be adjusted based on results over time. For example, repeated negative findings may suggest that a sampling site may be eliminated or frequency of sampling for a particular area may be decreased. Statistical Process Control (SPC) may be used to track results and identify the need to take action.

Plants should determine the action to be taken if *Listeria spp.* is detected at frequencies exceeding the upper control limit, target, or “trigger” that the plant has set (although some attention should be given to cleaning and sanitizing an area when any positive result is found). Because the reasons for a positive finding are likely to be plantspecific, remedial actions will vary; the following points should be considered in determining remedial actions for environmental positives:

- Detection of *Listeria spp.* in an environmental monitoring sample does not necessarily indicate a microbiological control problem; it does indicate that additional investigation should be undertaken. Thus, a positive environmental monitoring sample does not mean that plants must shut down the line and take immediate remedial action.
- When environmental monitoring results indicate a trend toward an increased incidence of *Listeria spp.*, plants should investigate to determine the reason(s) for the increase and should take action to reduce the level again. Increased environmental positives may trigger a shift to the troubleshooting or problem-solving mode, depending on the company’s specific action plan.
- If a positive sample is detected, and the sample was a composite sample, the individual samples should be tested to pinpoint the location of the positive.
- Additional samples should be taken from the environmental area where the positive was detected. These samples may indicate that additional remedial actions are needed in this area. Again, this may trigger a shift to the troubleshooting or problem-solving mode, depending on the company’s specific action plan.

- If, after remedial actions have been applied, additional samples are positive, the environment should be intensively cleaned and re-tested.
- Sampling of (additional) food contact surfaces in the areas where environmental positives are detected should be considered.
- If, after remedial actions have been applied, additional samples yield negative results, the plant would return to routine monitoring.

## Food contact surface testing

Food contact surfaces may be sampled routinely for *Listeria*-like organisms as a verification that environmental controls are preventing *L. monocytogenes* contamination of surfaces; alternatively, they may be sampled only when environmental monitoring suggests a possible problem.

As with environmental sampling, plants should determine the points to sample, the time of day for sampling, and the frequency of sampling based on knowledge of their specific operation and the controls they have put into place, as well as any microbiological data available.

Plants should investigate to determine the reason(s) for all positives on food contact surfaces. Investigational sampling (which may be termed the troubleshooting or problem-solving mode for some plants) must be capable of identifying equipment that contains niches where *L. monocytogenes* has become established. Until these sites are located, it is not always possible to correct an ongoing problem.

Remedial actions should be taken for all food contact surface positives, based on a pre-determined plan of action, and the actions should be documented. Contamination of some product contact surfaces is of greater concern than others. Examples of remedial action include modifying cleaning and sanitizing procedures, re-design of equipment, improved GMPs., employee re-training, etc.

Plants should consider whether finding *Listeria*-like organisms on food contact surfaces should necessitate product testing.

## Product testing

Plants may decide to test product as a result of positive food contact surfaces. In addition, random product testing may be considered as a component of a verification program to assess that the control/monitoring program is effective in preventing product contamination. Effective programs do not necessarily require product testing; finished product testing has limited utility (for reasons indicated previously), even as a verification tool. Whenever product is sampled, the lots should be held until the laboratory results are available. Plants must determine the action to be taken in the event that *L. monocytogenes* is detected in a product sample.

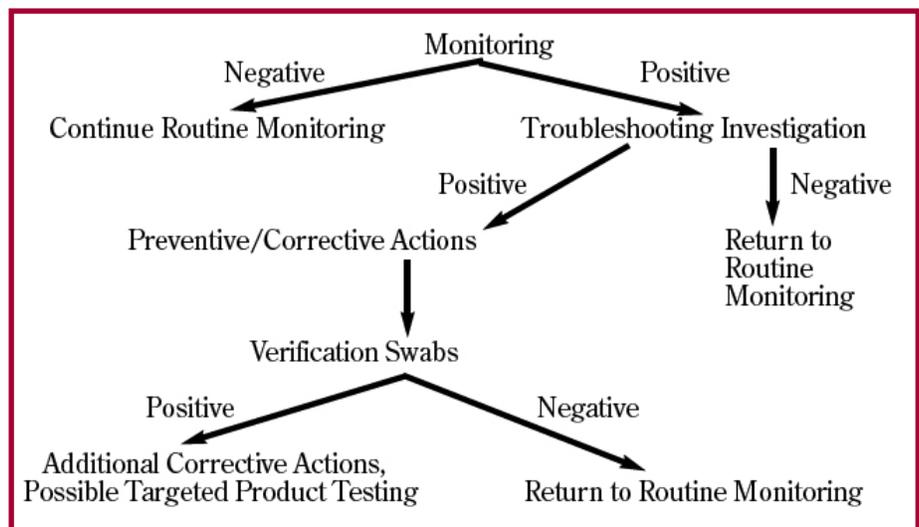


Figure 2. Product contact surface testing for indicators of *Listeria* contamination.

## Environmental sampling guidelines

When taking swab or sponge samples, a scientifically acceptable method must be used. Samples may be composited where scientifically appropriate; where possible, the remaining portion of each individual sample should be retained until composite results are obtained, in case additional testing of individual samples is necessary.

Packaging line samples (product contact surfaces) should be from areas as large as practical. Environmental samples should represent a constant area (e.g., 1.5 ft. x 1.5 ft., 2 ft. x 3 ft., etc.)

Floor drains represent an almost constant problem area; a corporate decision should be made on whether or not to include drains in the environmental sampling program. A separate goal for drains may be appropriate.

Any testing for *Listeria*, whether it be environmental or finished product testing, should be conducted by a laboratory adhering to Good Laboratory Practices<sup>3</sup>. It is recommended that the laboratory participate in a proficiency or check sample program for *Listeria*, where possible. It should be recognized that error rates occur with any laboratory test, and controls should be in place to help detect laboratory errors and to assure that the laboratory can properly identify the organism.

## Problem solving

When an effective control program for *L. monocytogenes* is in place, the primary source of contamination is often a niche where the organism has become established and is multiplying. When *L. monocytogenes* finds a niche, the contamination will be line-specific. In general, the contamination will flow downstream along a packaging line. When seeking the source of a niche, sponge samples should be collected and analyzed individually, not as composites. Additional sites should be sampled along the line and sampling should be done more frequently throughout the day. Suspected pieces of equipment should be torn down, collecting samples of suspicious sites and materials. The equipment should be cleaned and sanitized as it is being reassembled. If cleaning and sanitizing are unsuccessful, it may be necessary to remove sensitive electronics, oil and grease and apply heat to 160°F. Small parts can be placed in an oven; larger equipment can be shrouded and steam applied under the tarp. Lower temperatures for longer times may also be effective. The possibility that employee practices may be involved in the contamination should also be considered, in which case refresher training in the controls necessary to prevent *L. monocytogenes* contamination may be necessary or advantageous.

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