



The Association of Food, Beverage
and Consumer Products Companies

***Listeria monocytogenes* Guidance on
Environmental Monitoring and
Corrective Actions in At-risk Foods**

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AUTHORS AND ACKNOWLEDGEMENTS

This document has been prepared by Richard Brouillette (Commercial Food Sanitation, formerly Mondelez International), David Aggen (retired, formerly Lakeside Foods), Brian Borchert (Sara Lee Corporation), Kurt Buckman (Pinnacle Foods Group LLC), Mark Domanico (retired, formerly Kellogg Company), Judy Fraser-Heaps (Land O'Lakes), Timothy Freier (Cargill), Melinda Hayman (GMA), Timothy Jackson (Nestlé NA), Ai Kataoka (GMA), Joseph Meyer (Covance Laboratories, formerly Kellogg Company), Emily Shoaf (WhiteWave Foods, formerly GMA), and Warren Stone (GMA).

The Grocery Manufacturers Association has worked to ensure that all information in this guidance is accurate as of the time of publication and consistent with standards of good practice. As laws and practices advance, however, standards may change. For this reason, it is recommended that readers evaluate the applicability of any recommendations in light of particular situations and changing laws and standards.

Grocery Manufacturers Association
1350 I Street, NW, Suite 300
Washington, DC 20005-3305
Phone (202) 639-5900
Fax: (202) 639-5932

TABLE OF CONTENTS

AUTHORS AND ACKNOWLEDGEMENTS	2
INTRODUCTION	4
COMPONENTS OF A <i>LISTERIA</i> ENVIRONMENTAL MONITORING PROGRAM.....	6
Management Commitment.....	6
Risk Consideration: Is an LEMP Recommended?.....	7
Risk Consideration: What Affects the Stringency of the LEMP?	8
Monitoring for <i>Listeria</i> spp.....	8
Designing the Routine Monitoring Program.....	8
Sampling Procedures and General Guidance.....	11
Sample Handling.....	12
Testing Methods.....	12
Evaluation of Results	12
INVESTIGATION & CORRECTIVE ACTIONS	13
Investigations	13
Response to an Initial <i>Listeria</i> spp. Finding (Zones 1, 2 and 3):	15
Additional Actions for a Single <i>Listeria</i> spp. Finding in Zone 2.....	16
Additional Actions for a Single <i>Listeria</i> spp. Finding in Zone 1.....	17
Response to Reoccurring Positives (all Zones)	18
Response to a Reoccurring Positive in Zone 3	18
Additional Actions for a Reoccurring Positive in Zone 2.....	19
Additional Actions for a Reoccurring Positive in Zone 1.....	19
Documentation	21
SPECIAL CIRCUMSTANCES.....	28
Roof and Water Leaks in Exposed RTE Product Areas	28
Plant Construction or Equipment Installation.....	29
Drainage Backups	29
Other Operational Issues.....	29
Recommended Practices	29
VERIFICATION OF A <i>LISTERIA</i> ENVIRONMENTAL MONITORING PROGRAM.....	31
Environmental Monitoring Program Validation	31
Environmental Monitoring Program Verification	31
CONCLUSION AND SUMMARY	33
REFERENCES	34

INTRODUCTION

Listeria monocytogenes is a bacterial pathogen that is widely distributed in nature. *Listeria monocytogenes* is psychrotrophic¹ and can tolerate high salt as well as a wide pH range. The organism has been isolated from many raw agricultural products, raw meat and poultry products, raw milk, and raw aquaculture products. *Listeria monocytogenes* has been associated with a number of foodborne outbreaks in a variety of refrigerated food products, such as ready-to-eat (RTE) meat, dairy products, processed vegetables as well as fish and seafood (1) (2) (3).

The presence of *L. monocytogenes* in RTE products is generally known to occur because; 1) there is no lethality step or an insufficient lethality step, so that incoming materials do not receive a process that would be sufficient to eliminate *Listeria* on outgoing products (e.g., fresh or fresh cut fruit and vegetables); 2) products are intended to undergo a listericidal treatment but are processed incorrectly (e.g., an insufficient thermal process); or 3) the product is exposed to the processing environment, and has been contaminated or recontaminated by from the processing environment. This guidance will focus on the latter point for refrigerated RTE foods that can support the growth of *L. monocytogenes*; for clarity, the term “at-risk foods” will be used throughout this document to describe these foods.

A number of the earliest listeriosis outbreaks in the US (late 1990s, early 2000s) were associated with frankfurters, deli meats and other ready-to-eat (RTE) meat products (1). A 2003 risk assessment conducted by the US Food and Drug Administration (FDA) and US Department of Agriculture Food Safety Inspection Service (USDA FSIS) identified deli meats as the food category most often associated with listeriosis (as compared to other RTE foods such as soft cheeses, and smoked seafood) (3). Due to the early association of listeriosis with RTE meat, the US meat industry was among the first to implement an industry wide program to address the presence on *Listeria* spp. in the processing environment and on product contact surfaces (PCS, also called food contact surface) as a verification tool to ensure that control programs were effective in preventing potential cross-contamination of finished products. Through collaborative efforts between food companies, industry associations, and regulatory agencies, industry was able to aggressively pursue a ‘seek and destroy’ approach to identify possible harborage site(s) of the organism (4). Recent data published by the Centers for Disease Control and Prevention (CDC) (1) shows that there has been only one outbreak involving *L. monocytogenes* contamination of RTE meat (associated with hogs head cheese, 2010) since this approach has been implemented. Although a number of factors have contributed to this outcome, such as formulating products to prevent the growth of *Listeria monocytogenes*, part of this success is attributed to the allowance for taking corrective actions without holding/implicating/recalling product in reaction to an isolated occurrence of positive² *Listeria* spp. on PCS.

To minimize listeriosis associated with at-risk foods, food manufacturers should consider processes and/or formulations designed to prevent growth of *L. monocytogenes* in the finished

¹ Capable of growth at low temperatures, including refrigeration temperatures.

² Either a presumptive or confirmed test result that is indicative for the target organism (in this case *Listeria* spp. or *Listeria monocytogenes*), as a result of either rapid or traditional test.

product. This could be accomplished by a number of techniques such as frozen distribution, post-packaging treatment, the addition of antimicrobials, etc.

The intent of this guidance document is to provide information to food manufacturers producing at-risk foods to help them design a *Listeria* Environmental Monitoring Program (LEMP), which will in turn verify the efficacy of the relevant prerequisite programs (such as sanitation, employee practices and sanitary design). The guidance will discuss the need to conduct extensive investigative sampling when a potential harborage is identified, when to escalate LEMP activities, and when to consider finished product testing. Using these techniques over time with appropriate data analysis and corrective actions will help to reduce the likelihood of contamination of product with *L. monocytogenes* and thus reduce overall incidence of consumer illness.

Microbiological testing serves as a verification activity rather than a control, therefore the LEMP is not a control program. The program should be designed to verify that other control programs, such as facility and equipment sanitation, facility (hygienic) zoning, equipment design, personnel practices, and traffic controls are effective in preventing post-process contamination. A well executed LEMP is a more preemptive and effective use of microbiological testing resources than ingredient or finished product testing. This is because contamination of a product is often sporadic and at low levels, whereas environmental niches may be expected to have higher levels that are more readily detectable (5).

A LEMP is a seek-and-destroy program; the aim is to find, eliminate, and prevent establishment of *Listeria* growth niches³ (6). The LEMP should focus on the detection of *Listeria* spp. rather than *L. monocytogenes*. Targeting this group of broader indicator organisms⁴ leads to more robust verification of environmental conditions, and more rapid identification of niche and harborage sites⁵. If *Listeria* spp. is detected, appropriate investigation and implementation of corrective actions can occur in order to prevent potential contamination of the product by *L. monocytogenes* and ultimately leads to greater protection of public health.

A successful LEMP is one that rewards aggressive investigation and does not penalize finding *Listeria* spp. These positive results are viewed as an opportunity to strengthen and improve manufacturing programs. Finally, a LEMP may not be appropriate for all production facilities. The decision to incorporate a LEMP should be based upon a thorough risk evaluation as discussed later in this guidance document. These principles can be used in other general EMP programs, to support the overall food safety of post-lethality exposed products.

³ A location that supports microbiological growth and is protected from the sanitation process; characterized by high microbial counts after cleaning and sanitation (4).

⁴ An indicator organism is an organism whose presence indicates a state or condition (that could contribute to the presence of a pathogen, whereas an index organism is an organism whose cell numbers or frequency correlate with the cell numbers or frequency of another microorganism of concern

⁵ A growth niche that contains the pathogen or its indicator (4).

COMPONENTS OF A *Listeria* ENVIRONMENTAL MONITORING PROGRAM

Management Commitment

In order for a LEMP to succeed, there must be a top management commitment to the LEMP program and the overall food safety management system. The success of a LEMP improves dramatically when senior management drives implementation by establishing regular reviews of key performance indicators, corrective actions, and continuous improvement results. Moreover, success depends on detailed planning that provides resources and definition of roles and responsibilities to empower trained employees to carry out their mission. Roles and responsibilities should be defined for both operational requirements and management framework to support the success and effectiveness of the LEMP.

While top management commitment to a LEMP to aid the firm in producing safe food is necessary for success, effective implementation within the organization is no less critical. Making a public commitment to all food safety preventive controls and programs is a decisive step in communicating the importance of such activities to every employee in the organization. Once food safety management systems become the expected mode in which people work within an organization, they will become the core to any initiative launched by that group including a LEMP. All levels of management, from the top down, should have job descriptions defining their responsibilities for food safety, including LEMP programs, furthered by training to set expectations for participation, along with how and what to communicate internally and externally.

Senior company officials must further recognize their responsibility to the LEMP by providing for on-going review and assessment of the program.

Industry success stories have shown that organizations with a strong food safety management system as a daily operating philosophy have an advantage in the deployment and implementation phase of programs like LEMP. One should not underestimate the importance of having both a strong management system, along with a robust food safety program, for the success of the deployment and implementation of the LEMP.

The International Organization for Standardization (ISO) defines a system as “a set of interrelated or interactive elements” and a management system as “a system to establish policy and objectives and to achieve these objectives”. Using these definitions collectively, a management system is recognized as “establishing policies and objectives to manage processes” so that each level of responsible manager and front line worker understands their role and responsibilities. Management commitment to the overall food safety system, including LEMP control practices, is vital to ensuring that food safety hazards that may be reasonably expected to occur are identified, evaluated, and controlled in such a manner that the product does not directly or indirectly harm the consumer. The importance of both cannot be overemphasized.

Risk Consideration: Is an LEMP Recommended?

When deciding to implement a LEMP, a risk consideration should be undertaken. The outcome will determine if a LEMP is recommended. The FDA defines risk as the likelihood of the occurrence and the magnitude of the consequences of exposure to a hazard on human health (3).

As stated previously, at-risk foods refer to refrigerated RTE foods that are exposed to the processing environment and support the growth of *L. monocytogenes* within the shelf life of the product. The rationale for differentiating foods that support the growth of *L. monocytogenes* from those that do not is based on the results of a 2004 risk assessment conducted by the World Health Organisation (7). This risk assessment concluded that the potential for growth of *L. monocytogenes* within the food strongly influences the risk of contracting listeriosis. For instance, *L. monocytogenes* cannot grow on low moisture foods (water activity <0.85); therefore this product category presents a very low risk of listeriosis (8). The use of LEMP in facilities manufacturing low moisture foods or other low-risk foods would not be a good use of food safety resources. A *Salmonella* EMP may be the focus in some these facilities, such as those producing low moisture foods exposed to the environment post-lethality.

Product categories NOT typically considered to be at-risk foods generally include:

1. Shelf-stable products (*e.g.*, canned, retorted, acidified, low water activity).
2. Perishable products that allow the growth of *L. monocytogenes* but have no or very limited exposure to the plant environment after a lethality step (for example, hot-filled or aseptically-filled product).
3. Perishable products with intrinsic characteristics or formulations that prevent the growth of *L. monocytogenes* (*e.g.*, acidified refrigerated, listeristatic/listeriocidal additives).

Product categories considered to be at-risk foods generally allow for the growth of *Listeria* spp. at some point prior to consumption and generally include:

1. Refrigerated, perishable foods that are exposed to the plant environment after the final lethality step.
2. Frozen foods exposed to the plant environment after the final lethality step and intended to be thawed for an extended time prior to consumption (*e.g.*, deli sandwiches, baked goods, salad ingredients).
3. Foods produced with no lethality step (*e.g.*, dips, spreads, salads, fresh produce).

The product categories above are not a comprehensive list; if the product is not discussed above the facility must undertake a risk assessment. Both food safety and regulatory considerations should be addressed.

Risk Consideration: What Affects the Stringency of the LEMP?

Factors that may increase the sampling frequency or the number of samples taken and/or more aggressive corrective action include:

1. A complex process (*e.g.*, extended run cycles, numerous pieces of equipment, multiple processing lines or multiple handling steps).
2. Marginal or incomplete segregation between pre- and post-lethality operations. Refer to the GMA Facility Sanitary Design Checklist for further information (9).
3. Lack of sanitary design of equipment. Refer to the GMA Sanitary Equipment Design Checklist to assess potential harborage sites (10).
4. Product which is being produced specifically for a high-risk group such as hospital patients, pregnant women, neonates, or the elderly.
5. Special circumstances, described later in this document.
6. Increased degree of post lethality product exposure to the environment.

The risk evaluation should be a written document where identified risks have been considered and scientifically linked to an overall environmental monitoring program. The risk assessment document provides a living history that should be kept current and updated frequently, including information such as: changes impacting prior risk considerations or risk decisions, special circumstances, or discovery of root cause not previously identified. Each risk assessment update typically has a corresponding LEMP update.

Monitoring for Listeria spp.

Listeria spp. are a broad indicator, which when detected provide a signal that conditions favorable for *L. monocytogenes* growth or survival could exist. The purpose of the monitoring program is to find where *L. monocytogenes* could potentially grow or survive. Using a broad indicator group, such as *Listeria* spp. increases the chances of finding these niches and reacting in an effective manner.

Designing the Routine Monitoring Program

The objective of the routine monitoring program is to detect niches in order to initiate corrective actions before *L. monocytogenes* can contaminate product contact surfaces (PCS) or product. The routine monitoring program will typically focus on surfaces in the processing area(s) where at-risk product is exposed to the environment. Sampling locations are typically designated into zones based on the proximity to the food (Table 1). The number of samples collected will differ by zone, the risk to exposed product and the complexity of the production system. The majority of the sampling locations are typically focused in Zones 2 and 3 to obtain early indication of

Listeria spp. presence in harborage sites or transfer points⁶. In order to make the best use of resources and collect relevant data, it is important that processors perform their own facility specific evaluation to determine the selection of number of samples and frequency of sample collection in each of the zones. Recommendations for sample numbers and frequency exist in other guidance, for example the USDA FSIS *Listeria* Guidance (11).

For at-risk products, it is recommended that facilities consider including Zone 1 testing in their LEMP program. In order to make this decision the facility should assess whether there is a risk of harborage of *Listeria* on PCS and whether information from other verification activities questions the hygienic status of a processing line or an increased potential for cross contamination of the line. Zone 1 sampling should be representative of all product contact surfaces on that line. The number of samples to take would be determined by the size and complexity of the line. Under most conditions Zone 1 testing for *Listeria* spp. can be implemented without the need for holding finished product (see section on Investigation and Corrective Actions). This allows facilities to more aggressively test for the indicator while minimizing disruption to production.

Typically Zone 4 monitoring is conducted less frequently or for investigational purposes. The sampling locations typically include surfaces outside the production areas in order to determine if there is a potential for *Listeria* spp. to be present in the non-production areas. Sampling non-production and raw areas may also help to assess the effectiveness of preventive controls between production areas with different level of risks (e.g., hallway between raw and or at-risk product areas).

In most circumstances a LEMP should not extend into raw processing areas (e.g., ingredients, raw meat and fish, and unpasteurized dairy products) as it is assumed these areas are likely contaminated. Some facilities may not have truly defined raw and RTE areas, in this case the all production room with exposed at-risk may be included (e.g. fresh cut produce, salad assembly).

In the risk evaluation, thorough consideration should be given to the process flow and nature and intended use of the product. The sampling of interfaces, transition areas or barriers between raw areas and at-risk product areas is recommended to verify the effectiveness of preventive controls at maintaining separation. Some examples include the curing area in raw milk cheese production or a the floor in front of a single door oven

Refer to Table 1 for examples of surfaces to include in a plant program.

⁶ Surfaces that are exposed to cleaning and sanitation and can serve as points of contact facilitating the transfer of an organism from one surface to another, e. g., gloved hands. Transfer points should not be growth niches when effective cleaning and sanitizing procedures are used (4).

Table 1 – Definition of sampling zones and examples of sample sites to include in a LEMP⁷.

Sampling Zone	Definition	Examples of Sample Sites
Zone 1	Product contact surface (PCS) in RTE areas	Conveyor belts and scrapers, tables, holding vats and tanks, utensils, gloves and aprons, pumps, valves, slicers, dicers, filling/packaging machines, transport racks, trays, scales, brine chillers, peeler tables, hoppers, overhead structures prone to condensation formation over product contact surfaces
Zone 2	Non-PCS in RTE areas with close proximity to product or PCS	Exterior of food contact equipment, control panels, lubrication points, sides of weigh scales, other areas where potential risk of contamination exists through human or equipment interaction
Zone 3	Non-PCS outside of Zone 1 or Zone 2, but still within the RTE processing area	Floors, walls, refrigeration units, drains, floor mats, doors, floor scrubbers, forklifts, traffic pathways into process area, overhead piping, wash stations, floor cleaning tools
Zone 4	Non-PCS outside RTE processing areas	Production area offices, locker rooms, restrooms, cafeteria, hallways, trash areas, maintenance shops, warehouses, corridors of production areas

⁷ Sampling zones that illustrate areas of highest risk (Zone 1) to lowest risk (Zone 4) for finished product contamination according to International Commission on Microbiological Specifications for Foods (ICMSF) (21). Examples of sampling sites were based on ICMSF recommendations and industry experiences. It is recommended that a facility assessment be done to identify sampling sites, in order to include potentially problematic areas. Final determination on Zone 1, 2, or 3 depends on ability for transfer to RTE product or PCS.

The food safety team (*e.g.*, a cross-functional team with technical knowledge of the plant's programs, processes and practices) may develop a list of sites that could be sampled in rotation and be completely covered in a given timeframe, for example, monthly or quarterly. The trained technician taking the samples should also have the freedom to sample additional sites. As mentioned earlier, the sites should be selected based on the potential to harbor *Listeria* spp. Examples of sites and potential sources of *Listeria* spp. are provided in Table 3.

Routine sampling should be performed during production. It is recommended that sampling of Zones 1-3 take place at a minimum of three hours after the beginning of production, and should be varied to cover times and shifts across the entire production schedule. Sampling days should also be varied to represent the entire production schedule. Some samples can only be collected safely when equipment is not running. In such a case sampling could be done at the end of production/before cleaning, or any other time the equipment is idle and can be locked out and safely accessed.

Sample site locations should be changed on a periodic basis and the LEMP should be designed to foster aggressive investigation. Sampling site locations and frequencies may be adapted to verify hygiene following specific events such as start up following a shut down, maintenance, or other events that could affect the environment or equipment hygiene.

Sampling Procedures and General Guidance

Environmental samples should be taken with the intent of finding *Listeria* spp., if it is present. Sampling should be done aggressively by covering a large surface and targeting sites that are most likely to be contaminated. Detailed procedures for collecting environmental samples are discussed in various references, for example the Compendium of Methods for the Microbiological Examination of Foods (12) and others (FSIS).

1. Swabbing procedures must be conducted aseptically by trained plant personnel using hygienic handling practices (hand sanitizing, wearing gloves, etc.). In general, sampling should proceed from the “cleanest” areas to the “dirtiest” areas to avoid cross-contamination of the facility (*i.e.*, PCS sites should be sampled first, followed by non-PCS). A separate sponge or swab should be used per each distinct site.
 - a. Up to five separate sponges may be combined into one sample (“compositing”). Typically this is done by using a separate sponge for each site, and then placing up to five sponges into one sample bag for analysis at the laboratory. This should only be done in a mature program where positives are rare, as this may delay or confuse corrective action.
 - b. PCS samples should not be composited with non-PCS samples.
 - c. Compositing of samples should not be performed during an investigation.
2. Sterile sponges are effective for sampling large areas for *Listeria* spp. testing. Swabs may be used for small or difficult to access areas. The sampling device should be moistened with an appropriate buffer solution. The choice of buffer should be made in consultation with a technical expert, such as the test-kit provider or a microbiologist, for example a buffer containing a neutralizing agent should be used if sanitizer residues are present and may interfere with the test methodology.

- a. When sampling large flat surfaces sponge an area as large as reasonably possible (*e.g.*, 12 x 12 inches).
- b. When sampling irregular or hard to access surfaces sample the entire area as indicated by the surface description. Some disassembly may be necessary for sampling.
3. When sampling small areas (*e.g.*, head screws, small water collection points, screw holes, threaded surfaces or interior corners of equipment) use of a swab may be appropriate. Swab the entire area as indicated by the surface description.
4. Other methods such as sampling of rinsate may also be utilized for difficult to reach areas.

Sample Handling

1. Procedures should be in place to avoid cross-contamination during sampling and handling, as well as to protect sample integrity.
2. After sampling, immediately return the samples to the lab and refrigerate (do not freeze) to maintain sample integrity until they are tested internally or shipped to an external testing laboratory.
3. During isolated situations when *Listeria* spp. swab samples are taken and it is not possible for the lab to start testing the next day, the samples should be placed immediately in the refrigerator. Samples should then be shipped with freezer packs and sent out at the next available shipping time on the next business day.

Testing Methods

Samples taken as part of a LEMP may include samples from PCS and non-PCS (Table 1). It is recommended that all environmental samples be tested for *Listeria* spp. following methods that are recognized by competent authorities for the intended product or environmental sample testing, such as the methods described in the US FDA Bacteriological Analytical Manual Online (BAM) (13), the USDA Microbiology Laboratory Guidebook (MLG) (14) or by the Organization for Standardization (ISO) methods (15) (16) (17) (18) (19). It is also suitable to use methods validated through recognized validation bodies, such as AOAC (20).

Evaluation of Results

1. Data should be reviewed by a qualified individual as soon as practical after receipt from the laboratory.
2. Positive results should lead to investigation and corrective actions.
3. A map of the plant is recommended to indicate where the sample sites are located and to map positive results.
4. The food safety team should monitor and review the LEMP data on a regular basis, looking for trends or patterns. The frequency and depth of review will depend on the facility.

INVESTIGATION & CORRECTIVE ACTIONS

Corrective actions should be taken any time *Listeria* spp. is identified in the processing facility. The purpose of investigating the results and implementing corrective actions or preventive measures is to try to identify the root cause and eliminate the condition that may have resulted in the presence of *Listeria* spp. Corrective actions should be initiated as rapidly as possible to eliminate the potential niche where *Listeria* spp. could grow or survive. The course of corrective action will depend upon the particular situation and actions may escalate depending on persistence. Here we will describe corrective actions for a first positive finding and repeat positive findings. The goal is “seek and destroy” *Listeria* spp. if it is found in the processing environment. In some cases, it may not be possible to identify a root cause due to the transient nature of the contamination or due to multiple simultaneous actions being taken to correct the problem. The key is to verify that the root cause has been eliminated as demonstrated by repeated negative samplings.

Some manufacturers may decide to confirm if a *Listeria* spp. result is in fact *L. monocytogenes*, in such cases initiating corrective actions should begin immediately and not wait until final test results are received. While speciation of *Listeria* can provide information on the relatedness of *Listeria* spp. isolated from the environment and assist in trending and root cause analysis, the manufacturer should not have a false sense of security even if *L. monocytogenes* is not confirmed. They should continue with the corrective actions and verifications recommended below.

Investigations

The depth of the investigation will depend on the historical association of the product type with listeriosis, which can be determined by performing risk assessment. This includes consulting scientific information and literature as such as outbreak data (*e.g.* data provided by the CDC), and published risk assessments (*e.g.* (3) (7)). In addition, the facility’s LEMP historical findings should be considered, assuming that the plan has been implemented with adequate robustness. While a positive finding of *Listeria* spp. does not automatically implicate finished product, particularly in a facility with no historical findings, an investigation followed by corrective actions should be conducted on all positive results in any of the four sampling zones. In facilities with historical findings on Zone 1, the manufacturers should conduct a risk assessment to determine if finished products may be implicated. It would be advantageous to have a pre-assigned team to assist in the investigation, as well as a general pre-determined documented procedure, to help direct corrective actions. The information below can help guide the content that could be included in this procedure. The investigation should include a review of records as well as direct observations of the positive site and surrounding areas. The size and extent of the investigation should be determined by the plant food safety team. It is important to remember that by the time the results of the testing are received, several days have passed since the samples were taken.

To illustrate potential actions to be taken following a Zone 1 positive(s) for *Listeria* spp., a number of scenarios have been developed (Table 2; Figures 1-3). These outline actions to follow

for holding and testing products, and other actions to take depending on the probability of finding *Listeria* in Zone 1 and in the product:

1. If a facility has had previous Zone 1 positives and the product type has a historical association with listeriosis, then a manufacturer would follow **Scenario C**. NOTE: If the facility falls under this category and does not have internal microbiological expertise it is strongly recommended that expert help is sought, *e.g.*, the use of an outside consultant to evaluate the food safety program.
2. If a manufacturer has not found *Listeria* spp. in Zone 1 in the past but the product type has had an historical association with listeriosis, or if the manufacturer has found *Listeria* in the past but the product has not been associated with listeriosis, then **Scenario B** would be followed.
3. If the manufacturer has not found *Listeria* spp. in the past and the product type has not been associated with listeriosis historically, **Scenario A** would be followed.

Recommended corrective actions for each scenario are explained in this section and summarized in the decision trees (Table 2; Figures 1-3).

Table 2: Decision matrix to determine actions to be taken, including which hold and test scenario to implement, if a *Listeria* spp. positive is detected in Zone 1.

		Is the Food Category or Type Associated with Listeriosis?	
		NO	YES
Facility History of Zone 1 Positives?	YES	Scenario B	Scenario C
	NO	Scenario A	Scenario B

Recommended general activities may include:

1. The food safety team initiates a preliminary investigation to determine potential cause or possible source for the contamination (*e.g.*, water leaks, maintenance activity, construction). The suspect site and surrounding areas should be examined as part of the investigation.
2. Conduct investigational sampling by re-sampling the implicated area and other sites within the surrounding areas, as well as traffic pattern areas as soon as practical prior to cleaning. Select sites based on the issue at hand; do not necessarily use routine sample sites. For investigation purposes, single site swabs (*i.e.*, no composite sampling) should

be collected. Precaution should be taken to avoid spreading potential contamination from the suspect area to other areas in the plant.

3. Increase sampling frequency, *e.g.*, from weekly to once every two days in Zone 3, from weekly to daily for Zone 2. In order to resume routine sampling and consider the problem resolved, three consecutive follow-up samples of the problem site should yield negative *Listeria* results (or other number of sites, deemed suitable by the facility). Three consecutive samples has become the industry standard and has proven to be successful. The facility may choose to continue to monitor the site that yielded the positive test results on a routine basis for some time.
4. Sampling could be used to detect if *Listeria* has transitioned into the next zone. For example, if the positive is found in Zone 3, Zone 2 sites in the implicated area should be sampled and tested to verify that *Listeria* has not spread to areas closer to PCSs, if a positive is found in Zone 2, Zone 1 testing may be initiated or increased near the implicated area.
5. Review past test results from the affected area for previous *Listeria* findings and ascertain if any trends and/or patterns in the data can provide the root cause of the positive finding and hence guide the corrective actions. Include other data in this review, such as test results obtained during pre-operational sanitation verification sampling (*e.g.*, aerobic plate count (APC) and adenosine triphosphate (ATP) testing.
6. Corrective actions to be taken should be based on an assessment of the potential for finished product contamination given the location of the positive site in the plant environment. All activities and the outcomes associated with corrective action procedures should be verified and documented.
7. In some cases, another internal resource, third party consultant, or extension specialist may be able to provide “a fresh set of eyes” in reviewing the situation.

Response to an Initial Listeria spp. Finding (Zones 1, 2 and 3):

1. If feasible and appropriate, limit access to the area.
 - a. Re-examine traffic patterns. Where necessary and feasible, limit traffic flows (including employees, materials and mobile equipment as applicable) through the area, restrict fork truck movement, redirect high risk traffic patterns from adjacent areas, etc.
2. Review pertinent records, such as those related to sanitation, good manufacturing practices (GMP), maintenance, etc., to be sure that these activities did not contribute to the positive finding. Take immediate actions to correct any deficiencies based on findings. These may include:
 - a. Reviewing cleaning and sanitation practices and frequencies and revise as appropriate. More frequent spot cleaning and sanitization may be implemented
 - b. Reinforcing hygienic practices and retraining employees, if necessary.

- c. Reviewing production records including downtime, recent repairs, power outages, equipment changes, personnel changes, product changes and/or process changes, maintenance records, roof leaks or other special circumstances.
3. Visually inspect equipment for product build-up remaining after cleaning, condensate, cracks, bad welds, dead ends, etc. Inspect the environment in the area for pooling water and the condition of floors, walls and ceilings. Ask line workers to assess if there have been any potential issues.
 - a. Make any appropriate repairs. For example, repair damaged floors/walls and other structural damage.
 - b. Reduce water and eliminate water collection points, if present and practical.
4. Thoroughly clean/sanitize the positive site and the surrounding sampled area.
5. The application of heat (superheated steam, hot water, saturated steam) or validated sanitation process to the affected processing equipment can be an effective way to eliminate the contamination. This process may need to be conducted on a routine basis if recontamination could occur or is likely.
6. If the root cause identified a growth niche associated with a piece of processing equipment, the preferred action is to re-engineer or replace the equipment with a more appropriate design so that the growth niche is permanently eliminated.
7. In many instances, a root cause may not be apparent following the investigation, for example in the event of a single positive *Listeria* spp. finding. If a potential root cause can be identified following these steps, take corrective action, verify, and complete corrective actions.

Additional Actions for a Single Listeria spp. Finding in Zone 2

8. Stopping production for sampling, followed by sanitation may be appropriate under certain circumstances where finished product or PCS may be at-risk. Whether or not production is halted, conduct additional sampling of Zones 1, 2 and 3 sites; these should include sites upstream and downstream of the initial positive (vector sampling⁸ is a common approach).
9. Whether or not to disassemble the potentially implicated processing equipment depends on the equipment associated with the *Listeria* finding and how close the site is to finished product or a PCS. For example, the outside of a cooling tunnel and support frames may fall into a Zone 2 sampling category and these sites should not affect product contact surfaces or cause the equipment to be dissembled. Typically, complete equipment disassembly and sampling is reserved for repeat *Listeria* findings.

⁸ The original *Listeria* spp. positive sample is considered to be the center of a bullseye; investigational samples are taken from around this center point using a concentric ring like pattern. This pattern should be three dimensional.

Additional Actions for a Single Listeria spp. Finding in Zone 1

10. Production should be halted as soon as practical and corrective actions should be implemented.
11. The depth of the investigation and corrective actions for products supporting the growth of *L. monocytogenes* will depend on the historical results at the site and historical association of the product type with listeriosis.
 - a. When a manufacturing line has no history of Zone 1 positive and the product type has not been associated with listeriosis (Scenario A):
 - i. When a single Zone 1 *Listeria* spp. positive result is obtained, subsequent production lots manufactured on that line should be held. Whenever a product lot is tested, it should be held and only released if the test result is negative for *Listeria* spp. or *L. monocytogenes* (*i.e.*, hold and release). If lot acceptance testing for finished product is already conducted as part of the overall food safety program (*e.g.*, products with a *Listeria* specification), intensified product testing may be initiated following any Zone 1 *Listeria* spp. positive finding.
 - ii. If the product test results are negative for *L. monocytogenes* (or *Listeria* spp.), the product can be released. If positive for *L. monocytogenes* (or *Listeria* spp. if testing does not speciate), the product should be reprocessed by a method validated to eliminate *Listeria monocytogenes*, otherwise the product should be destroyed.
 - b. When a manufacturing line has a history of Zone 1 positives and the product category associated has not been associated with listeriosis (Scenario B):
 - i. When a single Zone 1 *Listeria* test result is obtained, subsequent production lots manufactured on that line should be tested. The recommended sampling plan is ICMSF case 12, n=20 (21), if the product is intended for a susceptible population, then additional sampling may be considered.
 - ii. Whenever a product lot is subjected to testing, the lot should be held and only released if the product test results are negative for *Listeria* spp. or *L. monocytogenes* (*i.e.*, hold and release). If a Zone 1 is positive, the food safety team should determine if the product should be released or if it would be more prudent to reprocess by a validated method to eliminate *L. monocytogenes* or if the product should be destroyed.
 - c. When a manufacturing line has no history of Zone 1 positives but the product category is associated with listeriosis (Scenario B):
 - i. When a single Zone 1 *Listeria* test result is obtained subsequent production lots manufactured on that line should be tested. The recommended sampling plan is ICMSF case 12, n=20.

- ii. Whenever a product lot is subjected to testing, the lot should be held and released only if the product tests results are negative for *Listeria* spp. or *L. monocytogenes* (i.e., hold and release). If a Zone 1 is positive, the food safety team should determine if the product should be released or if it would be more prudent to reprocess by a validated method to eliminate *L. monocytogenes* or if the product should be destroyed.
 - d. When a manufacturing line has a history of Zone 1 positives and the type of product has been associated with listeriosis (Scenario C):
 - i. Products made on that line should always be tested for *Listeria* spp. or *L. monocytogenes*. The recommended sampling plan is ICMSF case 12, n=20.
 - ii. When a Zone 1 is positive, intensified sampling should be initiated by increasing the number of samples taken, e.g., if there are ten Zone 1 samples collected on a routine basis, the number could be increased to 50 – 100 samples.
12. Obtain at least three consecutive negative follow-up samplings before returning to routine sampling, as per the facilities corrective action procedures.

Response to Reoccurring Positives⁹ (all Zones)

When a sound control program for *Listeria* is in place, finding multiple and/or consecutive positives may indicate that the primary source is a growth niche, where the organism may have become established and is multiplying. This can lead to an increased risk for spreading the organism and ultimately process line contamination. Corrective actions outlined below may be followed for problem resolution.

Response to a Reoccurring Positive in Zone 3

1. It may be useful to map the contamination sites on a layout of the facility to aid in locating the source of contamination, or at least suggest additional sites to sample. It is critical that a harborage site, if one exists, be found and eliminated by appropriate cleaning and sanitizing. Also note and review shared pieces of equipment for different products.
2. Thoroughly re-inspect areas for potential niches (an area that is not easy to clean and provides the opportunity for nutrients, moisture and time). Intensify cleaning activities around these areas and consider use of a sanitizer according to manufacturer's instructions.
3. Observe handling practices (production, sanitation, maintenance, material handling) and correct non-hygienic employee practices.

⁹ When follow-up samples are taken for an investigation of an initial positive, and these follow-up samples (from the same or nearby location) test positive for *Listeria* spp.

4. When collecting additional environmental samples during an investigation to determine a general target in searching for the niche, it is recommended that the team evaluate (where applicable) water and drainage flow(s) and water use, where in the area. Following the water flow and investigative sampling along these routes can often lead to a root cause. Production areas should be maintained as dry as possible during production. Review conditions and practices for scenarios that could lead to the contamination of RTE products or the plant environment with *Listeria* spp. such as inappropriate traffic patterns, areas with persistent condensate, back-up of floor drains and other scenarios described in Table 3 (5).
5. The plant Hazard Analysis Critical Control Point (HACCP) and preventive programs may need to be reviewed to verify their effectiveness, *e.g.*, verify if the kill step is under control, verify segregation of raw and RTE.

Additional Actions for a Reoccurring Positive in Zone 2

6. If deemed necessary, disassemble the processing line starting from the site where the positive *Listeria* spp. result was located, through to the end of the line. Take apart equipment as necessary to ensure all PCs are accessible for cleaning and sanitation. Sample potential harborage areas, then eliminate or repair marginal design issues, and obvious defective parts (*e.g.*, cracked gaskets or condensation areas). Disassembly should be undertaken carefully as not to spread the contamination, and sampling should occur from the outside in, being extremely careful not to spread the contamination. Document the sample sites carefully to ensure that the growth niche can be identified. Thoroughly clean and sanitize the equipment and the surrounding areas as the equipment is reassembled, and conduct a final sanitation on the reassembled equipment.
7. Examine processing equipment and consider equipment redesign if necessary
8. In the case of reoccurring Zone 2 *Listeria* spp. test findings in related areas, escalated testing including Zone 1 in areas associated with the Zone 2 positive or product testing may be warranted. Sampling may need to be intensified in the case of repetitive positives. In some operations, investigation may involve testing of worst-case samples on the line, *e.g.*, sifter tailings on a spray dryer system. Line samples may be taken at various times and/or from various locations to help pinpoint potential contamination sites. Investigational samples should be analyzed individually, not as composites.
9. Molecular subtyping of isolates may be employed to help identify the source.
10. Quantitative analysis of environmental samples, such as (APC/total viable count, *Listeria* count, etc.) can be done in conjunction with the qualitative test to help identify the niche.

Additional Actions for a Reoccurring Positive in Zone 1

11. Conduct pre-operational inspections on the line equipment as necessary in the investigational sampling plan to re-qualify the line. Pre-operational test results should be obtained and confirmed negative prior to start-up.
 - a. When a manufacturing line has no history of Zone 1 positive and the product has not been associated with listeriosis (Scenario A):

- i. When a single Zone 1 *Listeria* spp. test result is obtained, subsequent production lots manufactured on that line should be placed on hold. If additional environmental samples are positive the product should be tested. The recommended sampling plan is ICMSF case 12, n=20.
 - ii. If lot acceptance testing for finished product is already conducted as part of the overall food safety program (e.g., products with a *Listeria* specification), intensified product testing may be initiated following any Zone 1 *Listeria* spp. positive finding.
 - iii. If the product test results and the Zone 1 are negative for *L. monocytogenes* (or *Listeria* spp.), the product can be released. If positive for *L. monocytogenes* (or *Listeria* spp. if testing does not speciate), the product should be reprocessed by a method validated to eliminate *Listeria*, otherwise the product should be destroyed.
 - iv. If there are more Zone 1 positives, but the product has tested negative it may be necessary to:
 - Suspend production and consider if product should be shipped in the event it tested negative, or if it should be destroyed
 - Perform a thorough sanitary design review by dismantling equipment and conducting intensified swabbing and testing.
 - Observe and re-assess sanitation practices
 - v. If the product is positive it should be destroyed or reprocessed using a validated *Listeria monocytogenes* kill process. In addition:
 - Perform a thorough sanitary design review by dismantling equipment and conducting intensified swabbing and testing.
 - Observe and re-assess sanitation practices
- b. When a manufacturing line has a history of Zone 1 positives and the product category associated is not associated with listeriosis (Scenario B):
- i. Continue to test subsequent production lots manufactured on that line. The recommended sampling plan is ICMSF case 12, n=20 (21).
 - ii. Whenever a product lot is subjected to testing, the lot should be held and only released if the product tests results are negative for *Listeria* spp. or *L. monocytogenes* (i.e., hold and release). If a Zone 1 is positive, the food safety team should determine if the product should be released or if it would be more prudent to reprocess by a validated method to eliminate *L. monocytogenes*, or destroy it.
 - iii. If the product test results and the Zone 1 are negative for *L. monocytogenes* (or *Listeria* spp.), the product can be released. If positive for *L. monocytogenes* (or *Listeria* spp. if testing does not speciate), the product should be reprocessed by a method validated to eliminate *Listeria*, otherwise the product should be destroyed.

- iv. If there are more Zone 1 positive or the product is positive, it may be necessary to:
 - Suspend production and consider if product should be shipped in the event it tested negative or if it should be destroyed
 - Perform a thorough sanitary design review by dismantling equipment and conducting intensified swabbing and testing.
 - Observe and re-assess sanitation practices
- c. When a manufacturing line has an history of Zone 1 positive and the type of product has been associated with listeriosis (Scenario C):
 - i. Products made on that line should always be tested for *Listeria* spp. or *L. monocytogenes*.
 - ii. Continue with activities previously provided in this guidance, and in addition, consider the following:
 - Suspend production and consider if product should be shipped in the event it tested negative or if it should be destroyed
 - Perform a thorough sanitary design review by dismantling equipment and conducting intensified swabbing and testing.
 - Observe and re-assess sanitation practices

Table 3 contains examples for meat products but the “Equipment or area” and the “Source” listed applies to other product categories.

Documentation

1. Each facility producing at-risk product should have a written facility specific LEMP that includes general steps to be followed in the event of positive findings.
2. Document all LEMP monitoring activities. These could include the date, time, zone, line, and sampling location (may include condition of location).
3. Documentation should be reviewed and maintained as per company policy.
4. Document corrective action activities and outcomes. Document all test results and corrective actions to close out the incident. The documentation demonstrates due diligence and can also serve as a reference should a similar incident surface.
5. Document updates and changes to the LEMP.

Figure 1 (next page). Scenario A: Actions to be taken following a Zone 1 *Listeria* positive in a facility that manufactures a product supporting the growth of *L. monocytogenes* with intrinsic / extrinsic properties preventing rapid growth of *L. monocytogenes* (*i.e.*, product not associated with outbreaks) and no historical re-occurring Zone 1 at the manufacturing location.

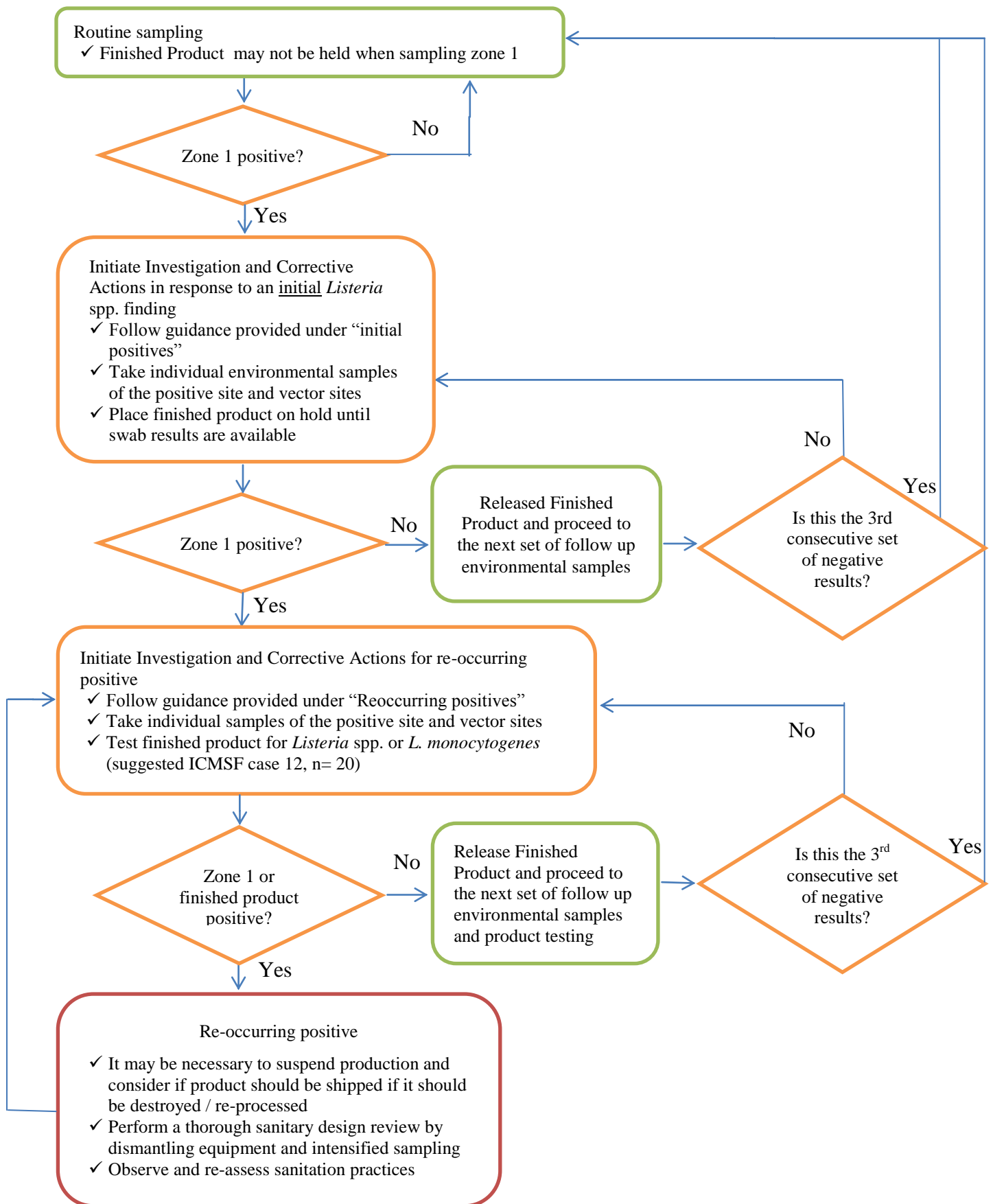


Figure 2. Scenario B: Actions to be taken following a Zone 1 *Listeria* spp. positive in a facility that manufactures a product supporting the growth of *L. monocytogenes*, or in a facility with historical re-occurring findings of *Listeria* spp. on Zone 1 at the manufacturing location.

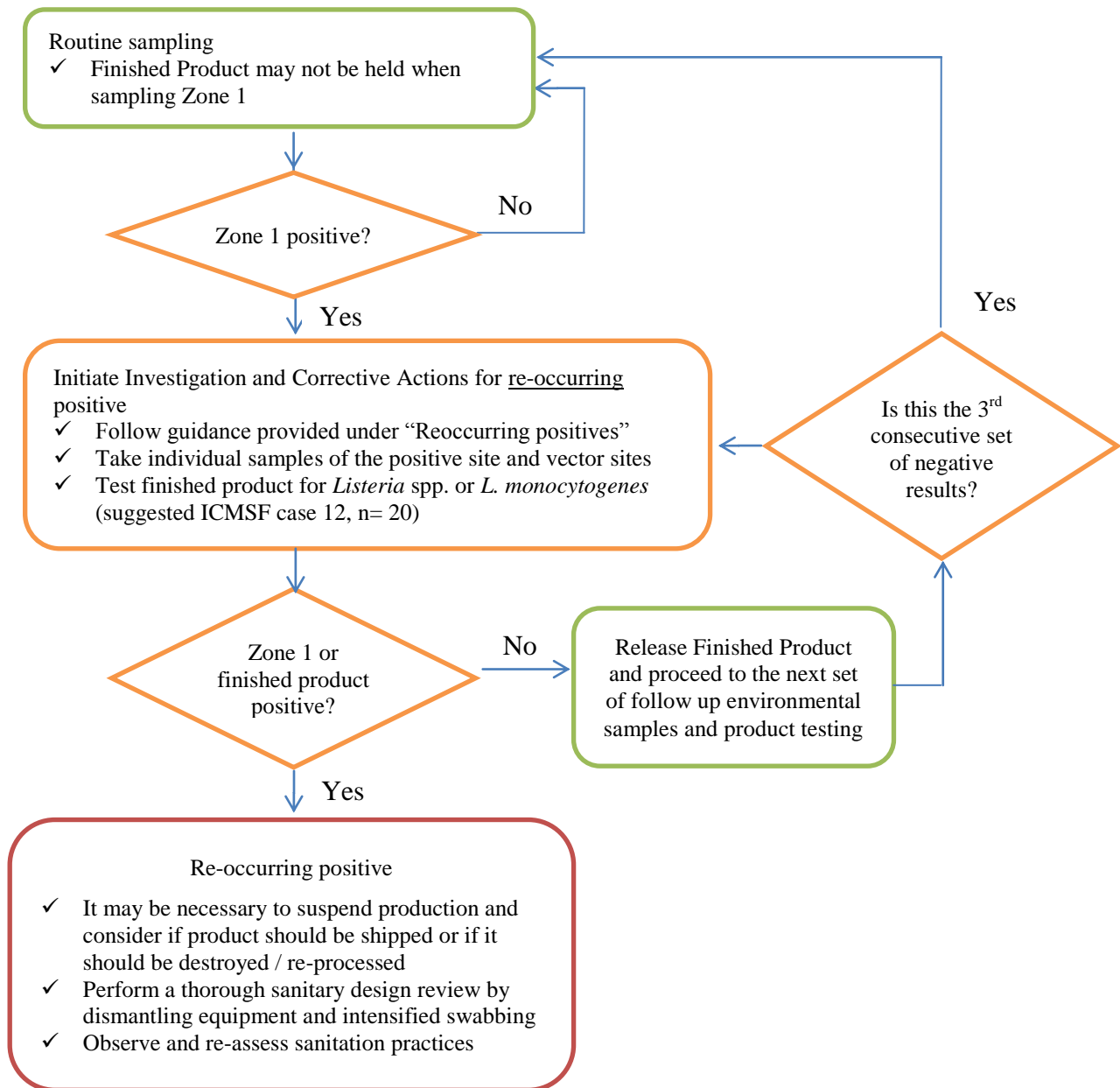


Figure 3. Scenario C: Actions to be taken following a Zone 1 *Listeria* spp. positive in a facility that manufactures a product supporting the growth of *L. monocytogenes* that are associated with outbreaks, and the facility has historical findings of *Listeria* spp. on Zone 1 at the manufacturing location.

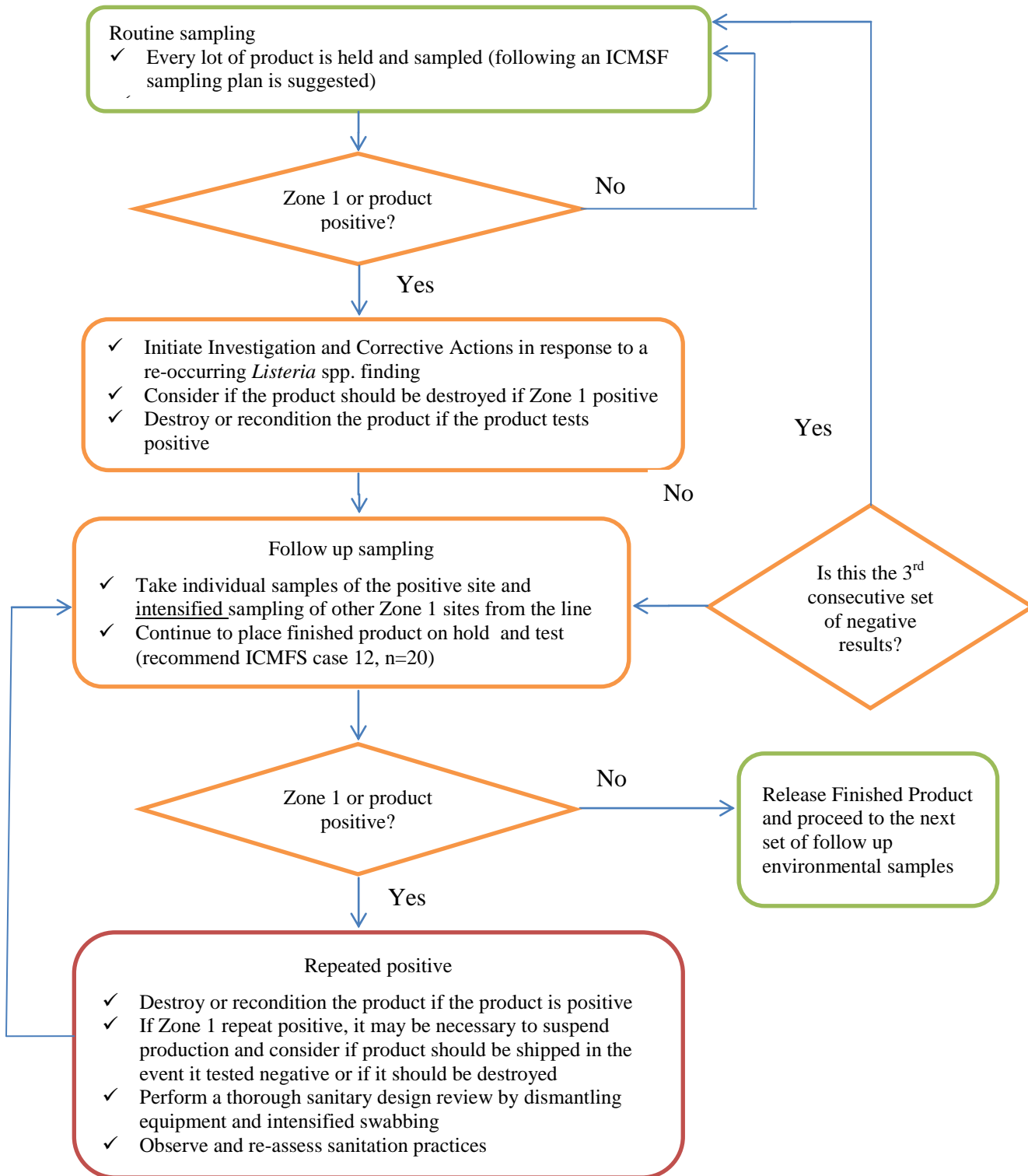


Table 3 - Examples of sources of contamination by *Listeria* species or *Listeria*-like¹⁰ organisms in RTE-food-processing operations and corrective actions that were taken (1989-2000) (5).

Equipment or area	Source(s) of contamination (i.e., niches or other sites of growth)	Corrective action(s) taken
Continuous brine chill chamber for product suspended from smoke sticks	Sponge rubber seals around edge of doors at top and side of chill unit	Rubber seals were removed; doors were redesigned so that seals were not needed
Hopper that catches franks after peeling	Cinder blocks around opening in wall between peeler room and packaging room	Cinder blocks were sealed to prevent moisture from accumulating in the blocks; stainless steel lip was installed around top of opening to divert moisture down the side
Continuous brine chill chamber for product on racks with wheels	Doors made of rubber-coated fabric, large metal hinges extending the width of the door, and hollow bump guards at bottom of door	Doors were replaced with rigid clean-able plastic material; large hinges and bump guards were removed
Ammonia unit used to chill brine solution	Fiberglass insulation on ammonia line to brine chilling unit became saturated with brine splashing from chilling unit	Contaminated insulation was removed; pipe and area were cleaned and sanitized; insulation was not placed too close to pipe to brine chiller
Refrigeration unit near ceiling of holding cooler before peeling	Condensate from refrigeration unit	Refrigeration unit was cleaned and sanitized. To prevent reoccurrence, the unit was placed on the master sanitation schedule
Area of brine chill exit and peeler	Hoses and spray nozzles at exit end of brine chill tunnel used to spray down franks for easier peeling	Hoses and nozzles were replaced; daily cleaning was initiated
Collator and conveyor	Undetermined	Equipment was covered with large tarp and steam was injected. To prevent reoccurrence, the equipment was re-designed to facilitate cleaning and inspection
Peeler area	Overhead on/off valves for steam and water lines near peeling equipment	Area was included in daily sanitation program

¹⁰ A colony that displays *Listeria*-like colony morphology on selective agar such as Modified Oxford Agar, however the colony is not confirmed as *Listeria* spp. or *L. monocytogenes*.

Equipment or area	Source(s) of contamination (<i>i.e.</i>, niches or other sites of growth)	Corrective action(s) taken
Peeler area (multiple events)	Peeler	Peelers were modified for ease and effectiveness of cleaning; centralized casing removal systems were installed to avoid operator contact with spent casings; metal boxes with steam ports were built so that peelers could be steamed each day before start of operation
Incline conveyor leading out of peeler room into packaging area	Two-ply Plexiglas shield guard on underside of conveyor had a crack where meat particles became entrapped	Plexiglas was replaced with stainless steel guard
Brine chill	Construction of brine chill tunnel had stainless steel framing with metal touching metal, causing an unclean-able space	Framing was modified to facilitate cleaning and to prevent material from getting into the space
Incline conveyor leading from peeler room to packaging area	Contaminated liquid was discovered within a hollow split sprocket	Hollow sprocket was replaced with solid sprocket
Wall in peeler room	Insulation behind fiberglass wall was contaminated by condensate from overhead pipe(s)	All fiberglass/insulation was removed from wall; concrete wall was cleaned with an acid base cleaner, sanitized, and sealed; overhead pipes were rerouted to be closer to the floor
Casing removal system (a long pipe through which vacuum conveys casings from the peeler to a canister in another room)	Design made cleaning difficult; inadequate cleaning and sanitizing	System was rebuilt to shorten length, replace existing pipe with stainless steel, and remove deadends and 90° angles; training and education were provided to supervisor and cleaning person
Slicer	Worn hydraulic seals at base of slicer, oil with water and product residue	Slicer was stripped, cleaned, sanitized, and placed into oven, where moist heat was applied; seals were replaced; slicer was put on preventive maintenance schedule; oil was used with listericidal additive (sodium benzoate)
Slicing/package line	Can opener with heavy wire safety cover	Cover was modified so that it could be removed daily for cleaning (Occupational Safety & Health Administration (OSHA) had required that it not be removable for employee safety)

Equipment or area	Source(s) of contamination (<i>i.e.</i>, niches or other sites of growth)	Corrective action(s) taken
Slicer	Buildup inside safety cover over gear and drive belt; material from this site contaminated product conveyor located below	Cover was changed so that it could be removed for cleaning each night
Dicer (multiple events)	Undetermined	Dicer was placed into oven and moist heat was applied, or dicer was covered with tarp and steam was applied
Packaging machine	Crack in stainless steel covering on top edge of the packaging machine near loading area	Area was cleaned, sanitized, and welded
Conveyors (multiple events)	Hollow rollers	Hollow rollers were replaced as detected; where possible, conveyors were replaced with sloping stainless steel slides
Brine chill tunnel for product on hanging racks	Damaged rubber seals on stainless steel door at exit of tunnel	Damaged door seals were replaced; cleaning procedure was modified
Conveyor between shrink tunnel and boxing	Worn conveyor made of rubber-coated fabric	Conveyor was replaced with one of new material
Conveyor leading to packaging machine	Fabric conveyor belt material	Belt was replaced with stainless steel slide
Cooked product stripping area	Hand-held knives for opening product	Knives were cleaned and sanitized daily in an automatic washer and were not stored in lockers
Bagging table	Air duct at base of table for blowing bags open	Table was modified to make duct accessible for nightly cleaning
Exit conveyor from spiral freezer	Wheel bearings for conveyor belt	Wheel bearings were removed and replaced
Spiral freezer	Undetermined	Cleaning frequency was increased and equipment was allowed to defrost before cleaning
Between freezer and packaging machine	Overhead conveyor	Safety ladder was provided so that conveyor could be cleaned from above rather than from below
Wire mesh conveyor between oven and freezer	Hollow support rods for conveyor	Hollow support rods were replaced with solid support rods
Packaging machine	Stainless steel rods for pushing product into carton	Push rods were removed, cleaned, and sanitized on daily basis

SPECIAL CIRCUMSTANCES

Environmental monitoring may need to be intensified to verify *Listeria* spp. control is effective when a special event or circumstance occurs. All operations will experience both planned and unplanned production interruptions. Such circumstances include, but are not limited to:

1. **Planned events:** such as construction, equipment installation, major repair, a high number of temporary workers, the change of sanitation from in-house to a third-party sanitation crew or vice versa, major change in production system or startup of different types of products in the facility.
2. **Unplanned events:** may include water leaks (drain backup, burst pipes, leaking roofs, fire sprinkler, etc.), major hygienic zones breach, fires, natural disasters, etc.

When a special circumstance occurs, the facility should consider increasing the intensity of the environmental monitoring program by selecting additional sampling sites, increasing the number of samples and/or increasing the frequency of sampling. Refer to the Investigation and Correction Action section for guidance on increased sampling. Such an increase in sampling (the number of sites, the number of samples and frequency) would depend on the risk assessment. Environmental monitoring should be initiated in the area where the events or activities occur (if the area is not already included under routine monitoring). Several examples of approaches taken to address special circumstances are provided below.

Monitoring the area for special circumstances:

1. Consider taking additional *Listeria* spp. environmental samples within or adjacent to the activity site. Samples can be taken while the activity is occurring throughout the duration of the activity. If any of the swabs are positive for *Listeria* spp., the plant food safety team should determine, carry out and document appropriate corrective actions (See Investigations and Corrective Actions section).
2. Take preventive action(s) to prevent the event from reoccurring.
3. When the special circumstance is completed and the food safety team has determined that it is appropriate to return to routine monitoring, the team may want to continue some monitoring to verify that the event has not created any long term issues.
4. For unplanned events, consider investigational sampling to assess the impact on production areas and evaluate the effectiveness of those interim mitigation actions until permanent corrective action(s) can be implemented.

Roof and Water Leaks in Exposed RTE Product Areas

In the event of roof and/or overhead water leaks occurring in close proximity to product contact areas or exposed product, plant employees should report the conditions immediately to appropriate management personnel. The plant food safety team will identify the need for additional environmental monitoring, if any (e.g., product and/or non-product contact *Listeria*

spp. testing), based on the assessment of contamination risk. The product should be evaluated for potential contamination and actions taken accordingly.

Plant Construction or Equipment Installation

In the event of plant construction and/or equipment installation or recommissioning of equipment that has been idles for a while, in RTE areas, increased environmental control procedures and action steps may be required.

When sampling for *Listeria* spp. while the plant is undergoing construction, consideration should be given to sampling during construction and adjacent areas. Increased frequency of sampling and number of sample sites should be considered following construction, after equipment installation and after major repairs are completed. In order to determine sampling sites and swabbing frequencies, the plant food safety team may assess items such as:

1. Plant traffic controls
2. Sanitation activities during construction
3. Plant location of construction activities
4. Type of construction (*e.g.*, installation, demolition, material removal, etc.)
5. Time duration of construction activities
6. Types of environmental controls implemented

Drainage Backups

Drains backing up in RTE areas may increase the risk for environmental contamination in sensitive areas from two sources. First, drains are inherently dirty and liquids seeping from drains into a processing area could carry microbial contaminants. Secondly, if the facility is not designed such that all drain water flows from cleanest to the dirtiest portions of the factory, non-RTE wastes could also back up into RTE areas. In such situations food safety management should consider, in addition to other control measures, increasing environmental monitoring in an affected area after the situation has been corrected.

Other Operational Issues

Both planned and unplanned events may further express the need for increased LEMP activity. These can include, but are not limited to, changes in SSOPs, non-RTE ingredients being discovered in RTE areas, breakdown in zoning practices and traffic pattern disruptions.

Recommended Practices

All operations will experience both planned and unplanned production interruptions. Unfortunately, some special circumstances such as fire sprinkler malfunctions or drains backing up are unforeseen events that can impact food safety during processing and storage. However, in other instances the special circumstance may be a planned event such as construction, major equipment overhaul(s) or major changes in production systems. When the interruptions are a

planned event, food safety management should ensure that a microbial baseline of the appropriate area exists. If such a baseline does not exist, they should take steps to establish that baseline before the special circumstance ensues. Baseline data should be collected over a series of different production days and at different times of the day. During and/or after the special circumstance, environmental monitoring results can then be compared against the baseline to detect if an unusually high amount of *Listeria* spp. positives are occurring and apply corrective actions as appropriate.

Natural disasters such as hurricanes and tornadoes can have a significant effect on environmental systems and infrastructures. When the food manufacturing facility has been impacted by such a disaster, the food safety team should assess the situation and determine if a change in environmental monitoring procedures is warranted. This assessment could include factors such as structural damage, waste stream efficiency, flood damage and the availability of power and potable water. From this assessment, the food safety team can determine the steps for environmental evaluation, if any. Each case may be slightly different and may require more or less environmental testing.

VERIFICATION OF A *Listeria* ENVIRONMENTAL MONITORING PROGRAM

The adequacy of the LEMP should be reviewed on an ongoing basis (e.g., every 1-2 years) to assure that the program is effective and to drive continuous improvement.

These validation and verification activities should be documented. In the U.S., the proposed regulations on *Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Human Food* (78 FR 11, 2013) and “*Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals*” (78 FR 209, 2013), include specific requirements for verification and validation activities related to food safety controls. The Food Safety Modernization Act (FSMA) statute specifically includes environmental monitoring, hence it is anticipated that there may be increased US FDA interest in these activities in the future.

Environmental Monitoring Program Validation

Typically, validation activities include those that would be used to demonstrate that the mitigation employed at a HACCP critical control point is effective. In the strictest sense/definition, validating a LEMP would involve inoculating the environment with the target pathogen or suitable surrogate and demonstrating that the monitoring program is effective in identifying the presence of the target organism and that corrective action can eliminate it. In the typical manufacturing environment this is not a practical approach.

Other validation strategies may also include referencing existing scientific literature, the use of predictive modeling, or historical data. Certain elements of the program can be validated in a traditional sense, such as testing methodology. GMA suggests that when traditional validation is not feasible procedures implemented as part of a LEMP should be technically sound, *i.e.*, based on industry best practices. For example, environmental sampling plans, such as sample number and location, may not be statistically designed and are based on facility history and experience and knowledge of the sites most likely to detect a failure in good hygiene practices (GHP) (21).

Environmental Monitoring Program Verification

Verification of the LEMP is a routine process involving the review of all program elements, results, corrective actions and documentation. It includes visual observation of the program execution to ensure that all required steps are performed properly and completely.

Verification of the LEMP may include activities specific to a line/area or to the overall program:

1. Methodology Review
 - a. Does the monitoring program include the appropriate numbers of samples, site locations and time of sampling?
 - b. Is the proper sampling procedure being followed and correct location being sampled by the technician[s]?

- c. Were samples handled and delivered to the lab in an appropriate manner?
 - d. Review of analytical methods (*e.g.*, is the correct method used, is the method being followed correctly?)
2. Record and Results Review
- a. Are documents/records and reported results (including required review/sign-offs) accurate and complete?
 - b. Are there documents/records of appropriate response to findings and corrective actions?
 - c. Have periodic reviews of results identified any trends or repeat issues?
 - d. Were corrective actions implemented and followed?
 - e. Do records show the corrective actions effectively reestablished control?
3. Are Sampling Tactics Modified in Response to:
- a. Results/trends/repeat issues?
 - b. Special circumstances?
 - c. Changes to product, process, equipment and/or plant environment?

During the verification activities, additional sampling may be conducted to look at more and/or different sites to demonstrate that routine sampling has been effective. Finished product testing may also be utilized. Other activities such as use of an outside expert consultant or reliance on published materials can also be of value.

CONCLUSION AND SUMMARY

Listeria monocytogenes, being widely distributed in nature, has the potential to find harborage in many types of food processing facilities and has been associated with outbreaks across various food categories. Therefore, manufacturers of all types of food products should conduct a risk assessment to determine if a *Listeria* Environmental Monitoring Program is appropriate for the specific operation. Following the risk evaluation, manufacturers should consider a LEMP if the processing/sanitation conditions may be favorable to the survival/growth of *L. monocytogenes* in *at-risk foods*.

In the US, the meat industry was among the first to implement an industry wide program to address the presence of *Listeria* spp. in the processing environment as a verification tool to ensure that control programs are effective in preventing potential cross-contamination of finished products. Through collaboration with industry associations and regulatory agencies, the meat industry was able to aggressively pursue a ‘seek and destroy’ approach to identify possible harborages of the organism. Recent data published by the CDC show a reduction in the number of outbreaks involving *L. monocytogenes* contamination of RTE meat since this approach has been implemented (1).

One of the key factors for the success of the meat plants was to take corrective actions once *Listeria* spp. is found in the manufacturing environment and monitor the effectiveness of the corrective actions. Due to its ability to form biofilms, *Listeria* spp. may be difficult to remove and incremental actions may be required to completely eliminate the source.

This guidance is based on industry practices that have demonstrated good results. Manufacturers should stay informed and modify their programs as new information arises.

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