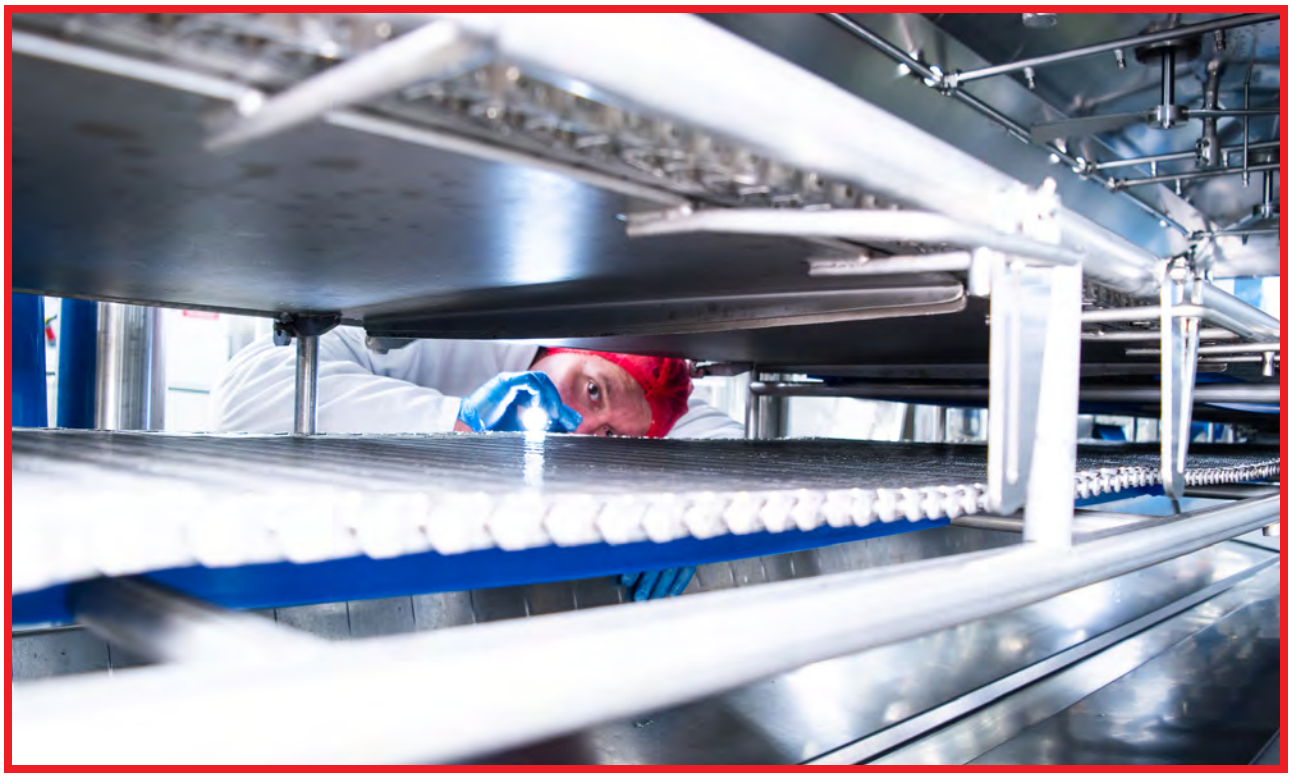
John Holah*
Kersia Group, Gateway House, Pilsworth Road, Pilsworth Industrial Estate Bury BL9 8RD, United Kingdom

PEER-REVIEWED ARTICLE
Food Protection Trends, Vol 42, No. 5, p. 383–395
https://doi.org/10.4315/FPT-21-038



A 5-Point *Listeria* Control Plan: A European Perspective

ABSTRACT

With an aging population and no reduction in *Listeria* cases, listeriosis is likely to become even more important in Europe, and all potential food industry control measures should be explored. A *Listeria* 5-point control plan to manage the occurrence of *Listeria* in high hygiene food manufacturing areas has been developed and trialed in the United Kingdom and Ireland since 2016; it comprises these points:

- Prevent entry of *Listeria* into high hygiene food manufacturing areas using effective barriers.
- Ensure that the high hygiene manufacturing infrastructure (building structure, equipment, and utensils) cannot harbor and/or allow the growth of *Listeria* (*Listeria* sources).
- Ensure that high hygiene good manufacturing practices limit the cross-contamination vectors that can carry *Listeria* from sources to product or product-contact surfaces.
- Design an effective cleaning and disinfection program that will kill or remove any *Listeria* that has entered the high hygiene area since the previous cleaning program.
- Provide an environmental monitoring and microbiological verification sampling program that monitors and verifies *Listeria* control procedures.

This review suggests that the plan develops a team ethos among factory technical, production, engineering, and hygiene functions and that success has been achieved in reducing the prevalence of *Listeria* in product and the environment.

INTRODUCTION

Listeria monocytogenes is a ubiquitous, environmental microorganism responsible for the human disease listeriosis (*7*). Listeriosis symptoms range from the mild flu-like and diarrhea to life-threatening infections such as septicemia and meningoencephalitis. More severe illness mainly occurs in developing fetuses, newborn infants, those with weakened immune systems, and the elderly (over 65 years of age) (*7*). Severe illness is characterized by high rates of hospitalization and high mortality rates, which equated to 17.6% of confirmed cases in the European Union in 2019 (*8*).

*Author for correspondence: Phone: +44 (0) 1706 2222444; Email: john.holah@kersia-group.com

Listeria has reservoirs in soil, forage, water, and infected domestic and wild animals; its main route of transmission is via the consumption of contaminated food. The main food types likely to give rise to infection in the EU remain fresh produce, raw milk products, and ready-to-eat (RTE) fish, meat, and dairy products, which have been primarily contaminated after processing *(8)*.

The number of confirmed cases of listeriosis in the EU from the latest available figures *(8)* and for the previous 10 years (compiled from previous annual European Food Safety Authority Zoonosis Reports), together with the infection rate per 100,000 people, are shown in *Table 1*. It is recognized that the confirmed case numbers are a slight underestimate of the actual total number of cases. Listeriosis is the most important food poisoning disease in Europe; in a typical year, there are more deaths from listeriosis than from all other notifiable food poisoning organisms combined (including *Salmonella*, *Escherichia coli* STEC infections, *Campylobacter*, and *Yersinia*) *(7)*.

The data in *Table 1* indicate that the number of listeriosis cases has leveled off over the last 5 years after significantly increasing during the previous 5 years. Between 2010 and 2020, the EU population increased from approximately 440 million to 447 million (approximately a 1.6% rise). However, the proportion of the population that are over 65 has risen from 17.6 to 20.6% (approximately a 17% rise) in the same period *(10)*. Although the overall incidence of listeriosis is low in Europe, its incidence expressed as a rate per 100,000 people is increasing, probably due to the expansion of the section of the population above 75 years of age, the age group with the highest incidence of listeriosis *(7)*. As the European population ages further, the importance of listeriosis will likely increase; and, thus, more effort is needed from all stakeholders, including the food industry and medical practitioners, to control this disease.

Historical control of *Listeria*

The control of *Listeria* in food manufacturing is multifaceted and has historically been achieved by product development, product decontamination, hygienic zoning of factories, effective cleaning practices, and management of the storage and distribution chain.

Product design challenges the formulation of a food product to minimize the presence of *Listeria* in the raw materials and/or reduce the chance for any *Listeria* present in the product after the decontamination process to survive and grow. Raw material risk assessment is undertaken to choose ingredients and suppliers so as to minimize the risk of agricultural and primary processing contamination. The majority of RTE products will have received a microbiological reduction treatment by the product manufacturer, either as a pasteurization (e.g., cooking) or a decontamination (e.g., produce washing) process. Food manufacturing facilities are built to contain hygiene zones such that, as the product is processed and microbiologically decontaminated, the hygiene of the process environment increases so that, after final product decontamination, any further manipulation of the product prior to packaging is undertaken in the highest hygiene zone. The high hygiene zone, primarily for the manufacturing of RTE products, is constructed to minimize the chance of cross-contamination of *Listeria* from the processing environment by reducing both potential *Listeria* harborage sites (sources) and cross-contamination vectors to the exposed product.

Validated interim and end-of-production cleaning and disinfection programs, together with periodic deep cleans in which the equipment and building fabric is further dismantled prior to cleaning, ensure that any *Listeria* pathogens entering the high hygiene area during production periods are effectively removed. Following packaging, some RTE products will be designed to prevent *Listeria* growth (by the addition of preservatives or modified in-pack atmospheres) or eliminate the organisms in packed product via secondary, in-pack pasteurization treatments (e.g., high-pressure processing). For RTE products not preserved or in-pack treated, *Listeria* is likely to be controlled by a chilled distribution and retail chain with defined times and temperatures, within a shelf life determined from practical or modeled trials that ensures *Listeria* is unlikely to reach levels that are outside legislated values *(2)*.

As noted in *Table 1*, *Listeria* cases are not being reduced in the EU; and, thus, it can be argued that traditional control methods are not sufficiently robust and that a new approach to *Listeria* management is required. Hazard analysis and critical control point (HACCP) *(5)* remains the primary food control in Europe, and, in practice, any product decontamination steps will be identified as critical control points (CCPs). There is little or no evidence in published literature or the European Rapid Alert System for Food and Feed *(6)* of any failures in these CCPs giving rise to *Listeria* food poisoning incidents.

It would appear that, globally, the majority of *Listeria* cases are caused by an excessive load or challenge of *Listeria* prior to any decontamination process (e.g., in recent cantaloupe cases *(4, 11)*) and by instances in which the decontamination process may not be sufficiently effective at eliminating *Listeria* (e.g., produce washing that may have a 1- to 2-log reduction factor) or by cross-contamination after the decontamination process (e.g., the world's largest known *Listeria* outbreak in South Africa associated with cooked meats *(19)*). As such, *Listeria* is primarily controlled by HACCP prerequisite programs, and a better approach is required in which all identified prerequisites are risk assessed and managed according to their risk in a focused *Listeria* control plan.

Legislation on *Listeria* control

International and national legislation with respect to food pathogens is established with the best intentions of reducing the chance of a pathogen being present in foodstuffs at a level likely to cause harm when consumed. However, different approaches will be apparent with respect to guidance on regulated control measures and, particularly, limits for the

TABLE 1. Cases of listeriosis in the EU from 2009 to 2019

Year	2019	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009
No. of cases	2,621	2,545	2,475	2,500	2,183	2,242	1,883	1,720	1,516	1,643	1,675
Confirmed cases/100,000	0.46	0.47	0.48	0.47	0.43	0.47	0.45	0.42	0.36	0.37	0.36

pathogen in the finished product for sale to the final consumer. This may be a "zero tolerance" approach or a defined limit, usually expressed as CFU per gram of the foodstuff.

In Europe, there are no defined regulations on practical *Listeria* control plans, but all food business operators must establish food safety plans based on HACCP principles *(1)*. There is a zero tolerance for *L. monocytogenes* (defined as absence in 25 g) for RTE foods intended for infants, or for special medical purposes, at any time in their shelf lives. For RTE foodstuffs able to support the growth of *L. monocytogenes* throughout their shelf lives there is zero tolerance at the point of manufacture and a tolerance of 100 CFU/g at the point of consumption. For RTE foodstuffs unable to support the growth of *L. monocytogenes* throughout their shelf lives, there is a tolerance of 100 CFU/g at all points during their shelf lives *(2)*.

EC 2073/2005 *(2)* also mandates that food business operators must undertake, particularly for RTE foods, microbiological sampling of their processing areas and equipment and of their finished products throughout their shelf lives, for *L. monocytogenes*. In Europe, a dedicated *Listeria* control plan may be useful in helping meet the legislated requirements for *L. monocytogenes* sampling. In other regions of the world, sampling of the finished product and the processing environment for *L. monocytogenes* may not be legislated, and alternative measures, such as the sampling for indicator organisms or *Listeria* spp., as part of good manufacturing practices (GMPs), may be favored. As such, a *Listeria* control plan may have different areas of focus for different world regions, dependent on local legislation.

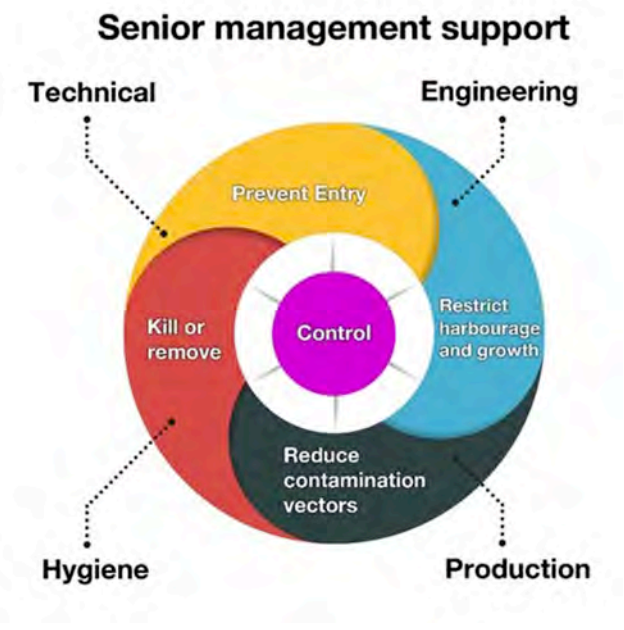


Figure 1. Schematic *Listeria* 5-point control plan.

LISTERIA CONTROL PLAN

A *Listeria* 5-point control plan has been developed by the author and trialed in RTE food factories in the UK and Ireland since 2016 *(Fig. 1)*. The plan seeks to prevent recontamination of RTE food products, after decontamination treatment, by managing the occurrence of *Listeria* in the high hygiene food manufacturing area and comprises the following five points.

- Point 1: Prevent day-to-day entry of *Listeria* into high hygiene food manufacturing areas using effective barriers. Barriers should be established to control the entry of *Listeria* at high hygiene area entrances and exits from carriage on or within items such as product, ingredients, packaging materials, manufacturing utensils and transport systems, waste products, people, the air, cleaning chemicals and equipment, and maintenance equipment
- Point 2: Ensure that the high hygiene manufacturing infrastructure (building structure, equipment, and utensils) cannot harbor and/or allow the growth of *Listeria* (*Listeria* sources). Harborage is exacerbated by damage to environmental surfaces and structures, the availability of water for microbial growth, and poor hygienic design or inaccessibility for cleaning of food production equipment.
- Point 3: Ensure that high hygiene production and GMPs limit the cross-contamination vectors (*Listeria* vectors) that can carry *Listeria* from sources to product or product-contact surfaces. Cross-contamination is exacerbated when, e.g., product, ingredient, packaging, transport, people, and waste flows cross over; when space for operations is limited; when the process or interim cleans use too much water; and when there is no demarcation of operative responsibilities, e.g., production, housekeeping, waste removal, product quality control.
- Point 4: Design an effective cleaning and disinfection program that will kill or remove any *Listeria* that has

entered the high hygiene area since the last cleaning program was undertaken. To facilitate this task, all surfaces that could harbor *Listeria* must be accessible to cleaning fluids, and all equipment should be periodically dismantled to ensure all surfaces are accessed. The cleaning program should be scheduled so that *Listeria* is actively decontaminated or flushed from the food processing environment rather than being moved from one surface to another (e.g., from the floor to food-contact surfaces) by the cleaning sprays.

- Point 5: Provide an environmental monitoring and microbiological verification sampling program that monitors and verifies *Listeria* control procedures (for barriers, sources, vectors, and cleaning and disinfection programs) and maximizes early detection of *Listeria* in the production environment to facilitate immediate control.

Whereas there is undoubtedly a matrix of responsibilities to effectively control *Listeria*, *Fig. 1* indicates that the primary responsibilities are for senior management to coordinate the 5-point plan, for the technical department to establish and manage the barriers and environmental sampling plan, for engineering to hygienically specify and maintain the manufacturing infrastructure, for production to coordinate all manufacturing activities to manage potential cross-contamination vectors, and for the cleaning or sanitation department (hygiene) to establish and manage the cleaning and disinfection programs. Effective *Listeria* control can, thus, only be ensured if it is managed by a dedicated team, encompassing, at a minimum, senior management and these four departments.

Elements of the 5-point plan should already be established in RTE food factories as part of existing GMPs, though no attempt has currently been made to bring these elements together into a cohesive plan. Barriers to control *Listeria* entrance to the high hygiene area (point 1) should be well established, validated, monitored, and verified and could include the following:

- Food products: decontamination treatments (e.g., cooking, frying, washing).
- Other ingredients and rework: surface decontamination treatments (disinfectant spray and UV tunnels).
- Packaging materials: double bagging or manual surface decontamination.
- Operatives: personal hygiene practices, changing room procedures, boot washing.
- Air: filtration, air changes per hour, directional air movements.
- Items such as manufacturing utensils, transport systems, maintenance equipment, quality control sampling and measurement devices, and cleaning chemical containers: cleaning and decontamination procedures.
- Waste: solid and liquid waste management systems.

Similarly, cleaning and disinfection programs designed to control *Listeria* (point 4) should also be well established, validated, monitored, and verified *(9)*. Cleaning and disinfection programs include the following:

- Interim cleans to control cross-contamination between product stock-keeping units during production.
- End-of-production cleans to control cross-contamination between production days or batches.
- Periodic cleans in which equipment or building fabrics are further dismantled to expose poor hygienically designed features for cleaning, which could have harbored *Listeria*. Inaccessible harborage sites (*Listeria* sources) can in some instances be treated by dry heat (placing items in ovens) or steam.
- Decontamination or "firebreak" cleans, which seek to decontaminate the whole of the high hygiene production area, equipment, and utensils following a *Listeria* contamination incident.

An environmental monitoring and microbiological verification sampling program (point 5) will also be in place, though its objectives and focus may not be clear (addressed later in the text and in *Fig. 4*).

However, what is less likely to be in place is a systematic assessment of the food processing environment and production practices for potential *Listeria* sources and product vectors (5-point control plan, points 2 and 3), termed a processing environmental plan (PEP) *(13, 15)*. In practice, this can be undertaken as a complementary step to the HACCP study; the HACCP study considers the risks of *Listeria* at each of the processing steps, whereas the PEP considers the generic *Listeria* risks within the processing environment.

In the PEP, prerequisites are developed to control identified sources or vectors of *Listeria* contamination, and those that are deemed critical to food safety can be raised to the level of operational prerequisites (OPs) *(16)*, which can be then managed in the same way as CCPs (CCPs manage the product and process, OPs manage the processing environment). This concept has been recognized in U.S. legislation under the Food Safety Modernization Act, in which controls critical to managing food safety are known as "preventative controls." Preventative controls can include HACCPs and CCPs, but they also include traditional prerequisites, e.g., sanitation, allergen, and supply chain controls *(20)*. The following sections on the PEP (points 3 and 4) and the environmental sampling plan (point 5) provide further information on these points and how they are combined and developed to form an effective *Listeria* control plan via an environmental sampling plan journey.

PEP

The undertaking of the PEP follows the 14 steps of the HACCP plan as defined by Gaze *(12)* such that the same food safety management principles are used in addressing hazards in both the food process (HACCP) and processing environment (PEP).

Step 1. Obtain management commitment. Senior management must be committed to providing the necessary resource for the study to be planned, undertaken, implemented, and periodi-

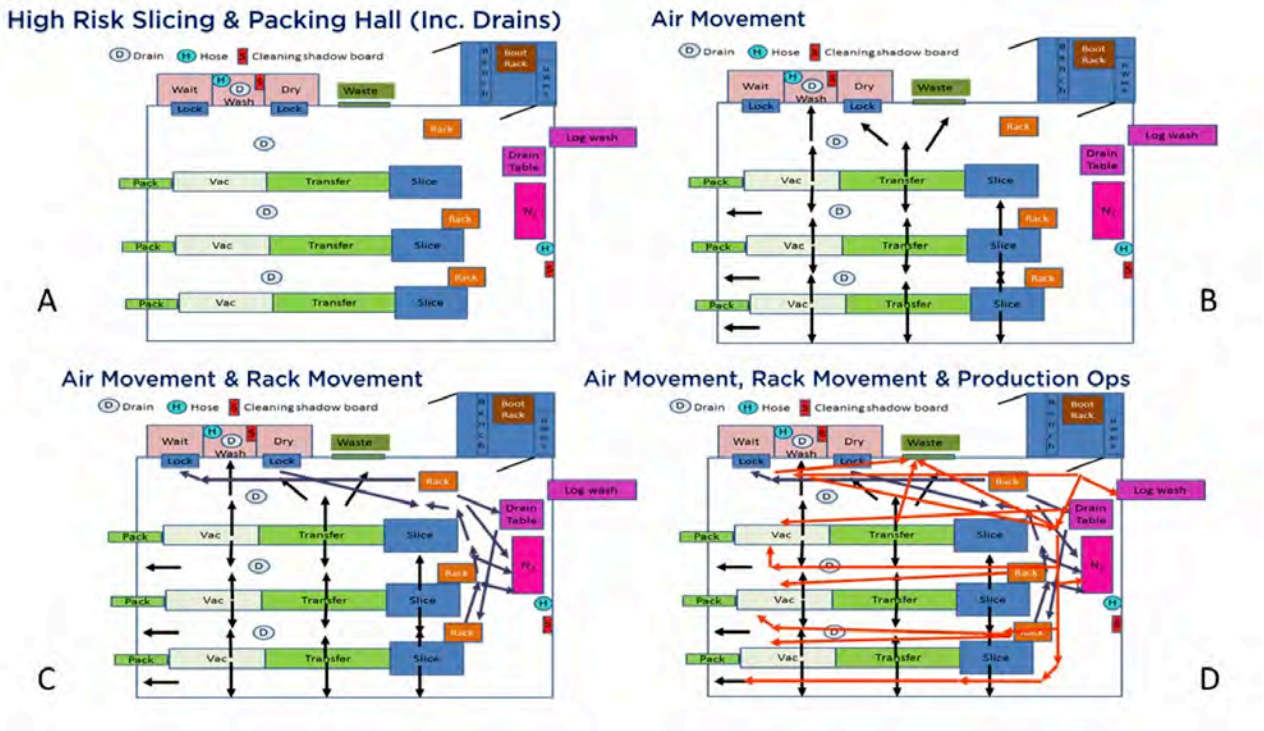


Figure 2. (A) Schematic diagram of a high hygiene meat slicing factory, where meat logs are brought into the high hygiene zone via log washer, stored on racks, nitrogen chilled prior to slicing, and packed. On top of this diagram can be added various flows, e.g., (B) air movements, (C) rack movements, and (D) production operatives, which can help identify potential *Listeria* environmental cross-contamination vectors.

cally reviewed. For RTE food manufacturers, this will be essential because the outputs of the PEP, particularly any requirements for capital expenditure projects such as building refurbishment, are likely to be critical in practically controlling *Listeria*.

Step 2. Define the scope or the terms of reference. The processing area(s) for the study should first be determined, typically the high hygiene area. The types of potential sources and routes (vectors) of environmental contamination transfer may need defining, particularly if these have already been considered at the generic prerequisite stage of the HACCP study, e.g., compressed air or the potable water supply.

Step 3. Select the PEP team. Because the study will assess *Listeria* sources and vectors within a given process area, many activities and events may occur in this area at different times of the day, week, year, or other frequency; and the selection of team members should reflect all of these activities. A PEP team (which may be the HACCP team) is likely to consist of members of engineering, production, technical, quality, and hygiene; hazard specialists such as microbiologists; and a scribe. Consultants can be used for their technical knowledge, but they should not write the plan. The PEP should be owned, written, implemented, and managed by the food manufacturer.

Step 4. Describe the environment. All physical and operational parameters of the processing environment under study should be recorded and/or measured with due regard to activities in adjoining processing areas, adjacent to, below, or above the area of study. The physical properties will include the size and layout of the processing area; any zones of segregation; entrance barriers into the area; services flowing through or above the area; air flows, temperatures, and humidity; personnel flows; transport flows for product and packaging and solid and liquid waste streams. Operational activities will include products processed, production lengths, and seasonality; housekeeping, end-of-production, and periodic cleaning and disinfection practices; quality control inspection and sampling activities, maintenance activities, and shut down periods.

With respect to *Listeria* detections, any historical data from previous routine sampling should be recovered and reviewed.

Step 5. Susceptibility of the product to be cross-contaminated. This clause has been modified from the original step 5 of the Gaze HACCP study, which was "identify intended product use." For this clause, any properties of the product should be determined that would prevent or restrict *Listeria* cross-contamination from the environment. For example, for hot product entering the high hygiene area from a cooking process, when does the product cool sufficiently so that any *Listeria* cross-contamination would survive on the product surface?

Step 6. Construct flow diagrams. All information collected during step 4 should be recorded in the form of physical maps or diagrams of the processing area. Ideally, this should start

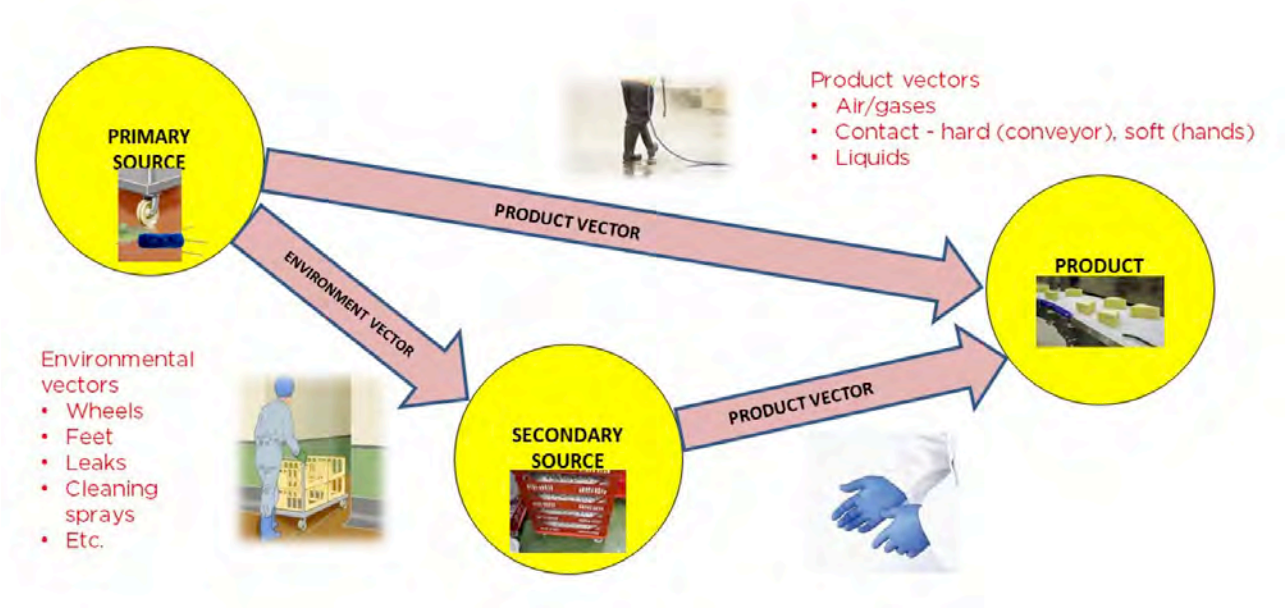


Figure 3. Schematic of product and environmental *Listeria* transfer vectors.

with a map of the processing area showing the layout of food processing equipment and services. Overlying this map can be specific diagrams of, e.g., alternative production equipment set-ups, air flows, personnel flows, transport flows, and waste flows. At a simplistic level, this plan can be achieved by the use of colored acetates, which can be overlaid to build up a "3-D" picture of the processing environment; or it can be undertaken more structurally in, e.g., CAD software packages *(Fig. 2)*. The diagrams' prime purpose is to be used in step 8 to help in the identification of potential cross-contamination vectors.

Step 7. On-site confirmation of flow diagrams. The PEP team should audit the processing area at all processing, sanitation, maintenance, and down times to ensure that the flow diagrams produced are accurate and representative. The flow diagrams can then be signed off as a true record of the processing area.

Step 8. List all potential hazards, conduct a hazard analysis, and consider any measures to control the identified hazards. Within this step, the PEP team conducts a thorough investigation, via physical examinations and microbiological sampling, to identify any *Listeria* sources and any mechanisms or vectors via which *Listeria* could enter the food product directly or indirectly.

Sources may be harborage sites or growth niches. Harborage sites are physical areas in which *Listeria* can lodge and be protected from external forces, such as cleaning and disinfection actions, e.g., poor hygienic design features of processing equipment or damaged areas of the factory's building structure. Growth niches are also harborage sites, but they also provide an environment for growth, e.g., nutrients, temperature, oxygen, water or humidity, and lack of competition from other microbial flora.

The processing environment and equipment are sampled following a hygienic design risk assessment that may indicate areas of the building fabric and equipment that could be difficult to effectively clean. Areas to sample could include the following:

- Around thermal movement joints, usually associated with oven installation
- Damaged floors and coving
- Damaged building fabric, particularly areas that could allow the ingress of cleaning and rinsing fluids
- Poorly adhered structures to surfaces, e.g., panels or checker plating that are not effectively sealed
- Poorly adhered structures to floors, e.g., equipment legs, platform legs, access equipment legs, posts, and crash bars
- Drainage systems
- Areas subject to condensation build-up
- Poorly designed processing equipment that cannot be effectively dismantled
- Poorly designed equipment framework that is not sealed or whose integrity has been penetrated by, e.g., fixing holes
- Equipment producing condensate, e.g., evaporative condensers

Potential environmental sources should be sampled toward the end of production periods, when the chance for *Listeria* movement out of such sources may be greatest. Additionally, and particularly for equipment, samples can be taken either after the rinsing stage of the cleaning program, when *Listeria* may be flushed out of the equipment, or on initial start-up of production, when *Listeria* may be driven out of equipment by its return to operation.

Listeria may transfer from sources directly to the food product, on product vectors, or indirectly to other parts of the processing environment via environmental vectors, from which they could then contaminate the product *(Fig. 3)*. Product contamination occurs through three main vectors:

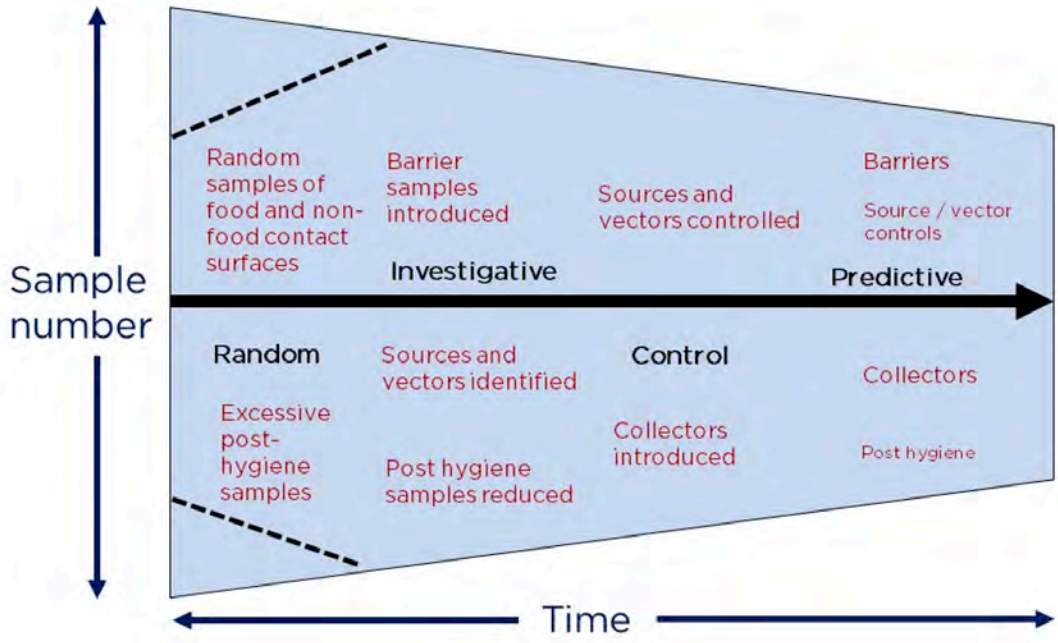


Figure 4. The four stages of an environmental sampling journey: random, investigative, control, and predictive.

- Contact between the product and surfaces
  - ◊ Hard surfaces such as equipment food-contact surfaces, utensils, probes, sampling equipment
  - ◊ Soft surfaces such as an operative's hands or gloves or personal protective equipment
- Contact between the product and the air or gases
  - ◊ Sedimentation of *Listeria* from the air if the air is stationary
  - ◊ Entrained into the product if the air or gas is moving, e.g., blast chillers, transport air, gas packing equipment
- Contact between the product and liquids
  - ◊ Via a defined process, e.g., a cooling water, fluming water
  - ◊ Via ad hoc fluids such as lubricants, cleaning aerosols, splashes from vehicle wheels, or poorly drained surfaces

Environmental contamination vectors move *Listeria* from a primary source to a secondary source, from which they may be able to cross-contaminate the food product via a product vector. Environmental vectors can be predictable, e.g., the movement of wheeled equipment or product containers, or ad hoc, e.g., the leaking of water between factory floors or negative air pressures in high hygiene areas due to, e.g., high air extract rates from tray wash areas.

Environmental vectors, thus, include the following:

- Footwear
- Vehicle wheels (forklift trucks, pallet trucks)
- Container wheels (totes, Dolavs, racks)
- Adverse air movements
- Aerosols

Potential product vector sources should be sampled as they occur and environmental vectors toward the end of production periods, when the chance for *Listeria* movement out of any related sources may be greatest.

All identified sources and vectors and any control actions identified should be recorded and, if not present, control actions should be assigned.

Source control may be of a permanent nature, often involving capital expenditure:

- Building refurbishment
- Equipment replacement or modification

However, controls may also be temporary until, e.g., building refurbishment can take place, or more permanent if this may be impossible. Such controls could include the following:

- Periodic spraying of environmental surfaces with oxidative biocides such as peracetic acid or sodium hypochlorite
- Additional equipment dismantling
- Periodic dismantling and/or heating of equipment via steam or in ovens
- Vector control may be of a permanent nature, for example:
- Removing the vector
- Reducing its frequency

However, controls may also be temporary until, e.g., a change in the process or manufacturing infrastructure can take place, or more permanent if this may be impossible. Such controls could include the following:

- Cleaning and disinfecting of, for example, product temperature probes or sampling equipment
- Periodic spraying of environmental surfaces with oxidative biocides such as peracetic acid or sodium hypochlorite in heavily trafficked areas for operatives and for wheeled containers for product, packaging, and waste

It is then possible to undertake a risk assessment of the sources and vectors, both before and after controls have been applied, to understand the severity of the risk of *Listeria* contamination from these sources or vectors and the adequacy of the controls. A risk assessment for a source is the risk of *Listeria* being present at the potential source and the ability of the *Listeria* to be transferred from this source via an environmental and/or product vector. A risk assessment for a contamination transfer vector is the potential for *Listeria* to be present on the product vector and the frequency of the vector. At its simplest, a risk assessment can be undertaken using, e.g., a 3-point scale of low (1), medium (2), or high (3); and the presence or spread, or presence or frequency, scores can be multiplied together to obtain an overall risk score *(15)*.

Step 9. Determine operational prerequisites. Control of food product contamination with *Listeria* is a combination of eliminating or controlling the number of possible harborage sites and niches and removing all unnecessary contamination vectors and controlling those that remain or are intrinsic to the food production process.

However, the control of some sources or vectors (prerequisites) may be more critical to the safety of the food product than others, dependent on the precontrol risk score, particularly if controls failed. For sources or vectors that cannot be eliminated and have high precontrol risk scores, but effective controls, the control of these prerequisites can be elevated to the level of OPs. OPs may also be established on a temporary basis until a source or vector is eliminated. For example, a broken floor that is known to be a source of *Listeria* and that is currently controlled by spraying it with disinfectant every 8 h may be elevated to an OP until it is replaced or repaired. As noted previously, OPs can be managed to the same level as CCPs.

Step 10. Establish control or operating limits. Wherever possible, control or operating limits should be identified for each OP. These may be defined in legislation, codes of practice, and other guidance documents, though the majority are likely to be determined from collection of experimental data during trials, e.g., cleaning validation data. The specific control limit for each OP must be a measurable (e.g., ATP or protein level after cleaning, disinfectant concentration, flow rate, pH, temperature, pressure, contact time) or an observable parameter related to the control option. Measurements are preferred; but, where control limits are based on subjective data (e.g., visual observations), clear guidance should be provided (e.g., photographs to define clean surfaces or appropriate wearing of protective clothing). The PEP team should record details of how the control limit was determined, including relevant sources of information or experimental and validation trial data.

Step 11. Establish a monitoring system. Monitoring systems describe the methods by which the food processor ensures that the OPs are operating within their defined control or operating limits and are, thus, "in control" and, as a corollary of this, produce an accurate performance record that can be used for process verification (step 13). The monitoring system must be able to detect loss of control at the OP in a time frame sufficient to provide corrective actions that will regain control.

Monitoring systems should ideally be on-line and could include air and gas pressure, humidity, temperature, chemical concentration, redox, conductivity or pH probes; UV intensity, flow rate, and rapid hygiene checks such as ATP and protein tests. Some on-line monitoring systems have a direct feedback system with the ability to directly control (and record) any drift in the control limit, and these are preferred. Other monitoring checks may be visible and could include an assessment of cleanliness, an assessment of a personnel clothing changing procedure, or whether a procedure is correctly being followed.

Step 12. Establish a corrective action plan. Practical and achievable corrective actions should be undertaken when the results of monitoring at an OP detect a situation in which a control limit has not been met (deviation) or when a treatment system is drifting out of control. Responsibilities for corrective actions should be clearly defined, and any product that could have been contaminated through any loss of control should be placed on hold following company quarantine procedures to allow authorized personnel to determine its fate.

Step 13. Verification. The verification stage is concerned with three activities: validation, verification, and review. The objective of the validation stage is to ensure that all sources and contamination vectors for *Listeria* that could be present in the processing environment have been considered and that the controls put in place to reduce or eliminate them are technically sound and effective. Identified control actions should then be validated as appropriate, using best practice techniques.

Verification of the PEP gathers information from routine analytical tests that are used to demonstrate the effectiveness of the *Listeria* controls and OPs in a time frame beyond that of monitoring (step 11). Verification can include microbiological sampling; internal and external auditing; analysis of customer complaints; trending of monitoring and verification results; and a review of any deviations, corrective actions, and any resulting foodstuff disposal.

In accordance with the general practices of food-safety management, the PEP should be reviewed at least annually and following any significant change to the food production process or the processing environment.

Step 14. Establish documentation and record keeping. Accurate, timed, and dated records, including the actual as well as any calculated results, should be retained for at least the shelf life of any foodstuffs and be sufficient to enable records to be available to support a defense of due diligence. In Europe, due diligence applied to food safety refers to being able to prove (to a court) that the food business operator has done everything reasonably possible to prevent food safety breaches.

Environmental monitoring and microbiological verification sampling program

Existing *Listeria* prerequisite controls, and those identified in step 8 of the PEP, should be appropriately validated. To ensure their subsequent control, they then should be monitored and verified.

Monitoring is carried out in real time and involves observations, gathering data and measurements, and making appropriate corrective actions to the barriers, sources, vectors, and cleaning program prerequisite to ensure that all activities and parameters are brought under control should there be any nonconformances identified. In addition, all observations, measurements, data analysis, and corrective actions should be recorded.

Monitoring frequencies and methods will vary according to the prerequisite type. For example, the monitoring of a high hygiene barrier entrance spray tunnel, through which ingredient containers could be decontaminated by chemical disinfectants, could include the following:

- Measuring the disinfectant concentration
- Ensuring all spray nozzles are in place and working
- Measuring the speed of the conveyor to ensure a determined disinfectant contact time
- Observing the loading of the containers on the conveyor to ensure that all aspects of the containers are accessible to the chemical spray
- Observing the cleanliness of the containers exiting the spray tunnel

The monitoring of the use of gloves, where gloved handling of the food product is a vector, could include the following:

- Observation of the cleanliness of glove storage facilities
- Observation that the correct glove and glove color is being used for a particular process time or product
- Assessment of the handwash facilities (e.g., dispensers and hand dryers in good condition, correct water temperatures, clean taps and wash basins, well stocked soap and towels)
- Observation of individual handwashing procedures prior to glove application
- Review or observation of any closed-circuit television monitoring
- Observation that any required glove decontamination step is undertaken correctly (correct disinfectant product type, stock rotation, recorded usage)

The monitoring of an end-of-production clean could include the following:

- Ensuring that the correct resources are in place, that the area has been prepared ready for cleaning, and that there is a sufficient hygiene window in place
- Equipment dismantling standards
- Rinse water conditions (e.g., visual assessment, water hardness, temperature, pressure, flow)
- Equipment (dosing, application, cleaning tools)—suitability, hygienic design, condition, and color coding
- Detergent and disinfectant chemicals (correct type, concentrations, temperature, method of application, coverage, and contact times)
- Visual inspection of postclean cleanliness
- Rapid hygiene assessment of visually clean surfaces (e.g., ATP, protein, chemical residues)
- Equipment reassembly standards
- Draining and drying times

Verification of prerequisites determines that the control measures are still working as designed (validated) and are consistently generating successful results. Verification may include the following:

- Microbiological testing
- Analysis of customer complaint trends
- Trend analysis of monitoring results
- Ensuring operative adherence to specific work instructions
- Ensuring operative training records and competency
- Analysis of results of internal and external audits
- Record reviews

With respect to *Listeria* control, the most direct verification of prerequisite controls is via microbiological sampling and the design of the environmental microbiological sampling plan. The routine environmental sampling plan is directly related to the first four points of the *Listeria* 5-point control plan and is undertaken for these purposes:

- Verify the high hygiene area barrier prerequisite controls. Sampling around barriers should be undertaken during production and at all times when barriers might be challenged, e.g., during cleaning or maintenance activities.
- Verify the prerequisite controls applied to known or potential *Listeria* sources. Sampling of source controls should be undertaken during production.
- Verify the prerequisite controls applied to known or potential *Listeria* vectors. Sampling of vector controls should be undertaken during production.
- Verify the efficacy of the cleaning and disinfection program, applied to both equipment and environmental surfaces. Sampling of cleaned and disinfected surfaces should be undertaken after the cleaning program has finished, allowing sufficient disinfectant contact time.
- Via "collector" samples, establish any presence of *Listeria* in the high hygiene area.

Collector samples are those samples that maximize the detection of a pathogen. Such samples could be of objects that have high environmental sampling surface contact, e.g.:

- Cleaning equipment
- Operatives' footwear
- Wheels of racks, totes, bins, and other equipment

Or samples could be of objects that, by their nature, "concentrate" hazards within the environment, e.g.:

- A floor drain that draws in fluids from a large surface area
- A condensate discharge from an evaporative condenser or freezer
- Food debris on a slicer blade that builds up through the processing period
- Dust and debris building up on motor fans
- Vacuum cleaner contents

Collector samples should be undertaken after the use of the collector, e.g., cleaning equipment, or toward the end of production periods, when the chance for *Listeria* movement out of any sources may be greatest.

The advantage of collector samples is that a relatively few samples can give an indication of the likely presence of *Listeria* in a processing area. The disadvantage of collector samples is that they do not reflect the source of the *Listeria* found. For example, *Listeria* present on an operative's footwear could have originated anywhere that the operative has walked since the footwear was last cleaned.

For all sample points, a direct action plan should be detailed if a *Listeria* positive is detected. These could include the following:

- For *Listeria* found at barrier sampling points, review the barrier performance. For example, if *Listeria* is found at the exit of a disinfectant spray tunnel, review whether the disinfectant concentration is correct, whether the speed of the tunnel conveyor is unchanged, whether all spray nozzles are present and working, whether products are placed on the conveyor correctly (i.e., the previously noted monitoring parameters).
- For *Listeria* found on known sources and vectors, review source and vector controls and frequencies. For example, if *L. monocytogenes* is found on the surface of a floor crack, which is known to harbor *L. monocytogenes* and which is controlled by disinfecting the floor every 8 h, increase the disinfection frequency to every 6 h.

For *Listeria* found on collectors, establish the following:

◊ Where has the *Listeria* come from?
◊ Where could it be spread to via environmental or product vectors?

- For *Listeria* found on food processing equipment posthygiene, review the cleaning and disinfection program. Has the cleaning program generically failed, e.g., are there accompanying high ATP, total viable count, or *Enterobacteriaceae* levels? Or was it working correctly but unable to control *Listeria*? If the cleaning program performance was ostensibly acceptable, the cleaning program could be further improved by additional energy inputs from chemicals, temperature, or mechanical action, or by additional dismantling of the equipment prior to cleaning.

For *Listeria* found on collectors (probably the most likely indicator of *Listeria* presence in the environment), what is the *Listeria* strain?

- Is it a random strain that might be indicative of sporadic isolation? This may be a temporary or transient strain that would be removed with cleaning and disinfection.
- Is it a recurring strain that may be indicative of strain persistence? This may indicate an unknown or uncontrolled *Listeria* source within the manufacturing infrastructure.

All sample points, their purpose, and the actions that should be taken if they test positive should be described in a sampling plan. In addition, the position of all sampling points should be detailed on a map of the food processing area.

Environmental sampling journey

Many factory environmental sampling plans have been built up over a number of years and have been influenced by staff changes, product and process changes, customer (retailer) requirements, and legislation. Their original purpose may have been lost, and they may essentially be random in nature with no clear purpose. The adoption of a new environmental sampling plan, such as to facilitate the *Listeria* 5-point system, is really a sampling journey and consists of four stages *(Fig. 4)*:

Stage 1: Adoption of a pathogen management system such as the 5-point system outlined above. Many existing environmental sampling plans have aspects of source and vector identification, collector, and posthygiene samples. The source, vector, and collector samples are usually not structured, and there may be a preponderance of samples from after cleaning and disinfection (posthygiene).

Cleaning procedures used to control *Listeria* are part of a defined prerequisite plan to control the risk of a specific hazard, and GMPs and EU legislation require that the cleaning and disinfection procedures and their frequency thus need to be validated, monitored, and verified. This is also a requirement of the Global Food Safety Initiative endorsed audit standards, such as the British Retail Consortium Global Standard for Food Safety version 8, which specifically mentions the need for verification after cleaning and disinfection *(3)*. The presence of this requirement in auditing standards leads to perhaps excessive posthygiene sample numbers. In addition, there is usually a wealth of monitoring evidence concerning the success of the cleaning operation (visual assessment, ATP or other rapid method assessment of cleanliness prior to disinfection, operative and supervisor check-off sheets) that should diminish the need for verification samples.

The major omission in many existing sampling plans is barrier samples. In stage 1, therefore, barrier samples are usually added, posthygiene samples reduced, and collector samples refocused.

Stage 2: "Seek and destroy." The term "seek and destroy" was first coined by Dr. John Butts in the United States and is described in Malley et al. *(18)*. The prime purpose of stage 2 is to identify potential sources and vectors of *Listeria* with the aim of eliminating or controlling them. This process can take a long time and involve hundreds of samples. There are three key factors involved:

- A formal assessment of the high hygiene area for likely sources and vectors by the site PEP team (step 8 of the PEP). This should be undertaken during all types of processing conditions, such as production, cleaning windows, downtime, and maintenance work.
- Assessment of the risk of each source or vector. For a source, this is based on the likely presence of *Listeria* at the source and its ability to spread from the source; for a vector, it is based on the likely presence of *Listeria* at the vector and the vector frequency. The determination of *Listeria* on the potential sources and vectors with the highest risk should be established first.
- It is very unlikely that *Listeria* will always be present in samples taken from a source or vector, even though it

is known to be contaminated (e.g., *Listeria* in a wall or coving). It is also recognized, however, that the potential detection of *Listeria* from a known source or vector will have higher incidence than for general environmental samples. Agreement of the number of samples to be taken at each potential source or vector to detect the presence of *Listeria* is, thus, required.

Stage 3: Determining the efficacy of source and vector controls. For every source and vector detected, a control action should be established, e.g., if a crevice between a drain and the surrounding flooring material has been found to harbor *Listeria*, it should be sprayed with an oxidizing biocide at a suitable time period, e.g., every 8 h. An environmental sample to assess the disinfectant control action would be to sample the floor around the crevice 7 h, 55 min after disinfectant application. If the sample is negative for *Listeria*, the 8-h disinfectant application is working. If it is positive, the application time should be reduced. Again, it is necessary to be conscious of the number of samples that might need to be taken to verify that the control is working adequately.

Stage 4: Maximize the detection of *Listeria*. Once controls have been ensured to be working for high hygiene barriers, the control of identified sources and vectors, and end-of-production cleaning and disinfection, the final focus of the environmental sampling plan is to try to actively detect *Listeria* in the high hygiene area. This is undertaken by refocusing on the choice of collector samples in relation to known or potential sources and vectors.

Environmental sample numbers

The number of product and environmental samples taken for *Listeria* is dependent on a number of factors, primarily defined by the nature of the RTE food product. RTE products that are fully pasteurized (e.g., cooked meat products), because of the nature of this pathogen reduction step, tend to have fewer raw material, product intermediate, and finished product samples. More samples may be taken, however, dependent on the degree of postpasteurizing product processing (e.g., slicing, dicing, freezing) and the complexity of the process. Conversely, RTE products that are a mixture of pasteurized and decontaminated ingredients (e.g., sandwiches) will have more (risk assessed) raw material, intermediate, and finished product samples. The number of product lines or stock-keeping units will also be important, with many retail customers suggesting finished product sampling frequencies such as one sample per stock-keeping unit per week.

The number of environmental samples taken for *Listeria* will depend on the stage of the environmental journey and the RTE product. With the adoption of the *Listeria* 5-point system, the sample numbers may increase (dotted lines in *Fig. 4*) as the hunt for sources and vectors increases and will then decrease as the plan matures toward a predictive state. Sample numbers will also be higher in the environments of more complex fully pasteurized RTE and pasteurized or decontaminated ingredient RTE product sites.

The likely incidence of *L. monocytogenes* in the product or environment also influences sample numbers. For example, if the typical *Listeria* isolation rate is 10% of environmental samples, more than one detection of *Listeria* in 10 samples from the same site might be indicative of a contaminated source or vector. If, however, the isolation rate is typically 1% of all environmental samples, more than one sample in a hundred taken at the same site might be needed to identify a contaminated source or vector. In the UK, the author has observed little change in the estimation of average *L. monocytogenes* incidence in finished product since the suggestion that levels of <1% of samples should be positive for *L. monocytogenes* in the early 1990s *(14)*. Best practice remains approximately 0.1% detection of *L. monocytogenes* in fully pasteurized RTE products and 0.2 to 0.3% detection in products containing decontaminated ingredients. Detection of *L. monocytogenes* in the environment is a factor of 1 to 3 times this product level, dependent on whether pasteurized or decontaminated ingredients are used in the high hygiene area.

In summary, it is not unusual for small- to medium-size RTE food manufacturers to undertake 100 to 200 product samples and, similarly, 100 to 200 environmental samples, for *L. monocytogenes*, per month. Larger RTE manufacturers may take 300 to 500 product samples and 300 to 500 environmental samples per month.

The type of sample may also change during the evolution of the *Listeria* sampling journey, and the percentages of samples that should be taken in the investigational and predictive stages are suggested in *Table 2*. Whereas the percentages may change, the actual number of samples may be the same, e.g., for barrier samples, the percentage has gone from 20 to 30% between the investigational and predictive stage, but this may be reflective of the fewer samples taken at the predictive stage.

The endpoint of the environmental sampling journey asks these questions:

- Are my high hygiene area barriers working—are they stopping *Listeria* from getting in? This is particularly useful for high hygiene areas in which fully pasteurized RTE products are manufactured.
- Are my potential *Listeria* source and vector controls, and cleaning and disinfection programs, working effectively?
- Is there any evidence of *Listeria* in my high hygiene area? If no *Listeria* is found in the collectors, and source, vector, and equipment cleaning controls are effective, there is a reasonable probability that *Listeria* is not present in the high hygiene area.

Finally, environmental sampling plans should be reviewed at least annually, usually in conjunction with reviews of other food safety programs such as HACCP. In addition, environmental sampling plans should be reviewed if there are any changes in the following:

- Raw materials (particularly in high hygiene areas where equipment and environmental areas may harbor any *Listeria* related to the raw materials)

TABLE 2. Suggested balance of environmental samples during the investigational and predictive stages of the environmental sampling plan development journey

Sampling point	Investigational phase		Predictive phase	
	% of samples taken	Comments	% of samples taken	Comments
Barriers	20	Barrier samples are introduced to the sampling plan	30	The number of samples is dependent on the number of low/high hygiene barriers
Source and vector controls	65	Repeat sampling of potential sources and vectors to assess their risk	40	This should include sampling the controls of known sources and vectors plus additional sampling for potential sources and vectors (in line with the need for large sampling numbers as indicated in stage 2 of the sampling journey)
Collectors	5	Collector samples are introduced to the sampling plan but at a low level to allow source and vector assessment	20	The number is dependent on the type of food process and the number of potential collectors
Posthygiene	10	Posthygiene sampling substantially reduced from the initial, random phase	10	The number of posthygiene samples should always be low. Other monitoring information may be available, such as visual assessments, sign-off sheets, rapid hygiene tests

- The production environment, e.g., equipment or new build or refurbishment (which may change the ease or difficulty of cleaning)
- The cleaning program's parameters (which may change cleaning and disinfection performance)
- Assessment methods (which may be more cost effective or more sensitive)
- Any sustained increase in *L. monocytogenes* detection

CONCLUSION

The *Listeria* 5-point plan has now been embedded into *Listeria* training courses for the food industry *(17)* and, following training, has been established into more than 10 European RTE food companies, together with PEPs, to focus on the detection and control of *Listeria* sources and (product and environmental) vectors.

The majority of the companies who have adopted the concept of the 5-point plan were already proactive in the management of *Listeria* in their sites and, thus, already had low rates of *Listeria* detection in food products and the environment. For companies starting on their *Listeria* control journey, the focus of the PEP has been to identify and control the major *Listeria* environmental sources and vectors, and the plan has been found to reduce *Listeria* environmental isolation levels to 1% or below. Some success has also been achieved in reducing the prevalence of *Listeria* in product and the environment, particularly when *Listeria* environmental levels were, on occasions, high (5% or greater).

For companies that were already working to *Listeria* incidence levels of best practice, value has been seen in reducing the incidence of sustained *Listeria* isolations in the environment, primarily due to more attention given to the development, control, and sampling of high hygiene area barriers to prevent the entrance of *Listeria*. These companies also managed to reduce their environmental sampling numbers and costs, while still maintaining effective *Listeria* control.

Comments from the factories using the 5-point plan suggest that it has been useful in three main areas. First, bringing together existing and new prerequisites and their controls into one plan has allowed them to better focus on *Listeria* control and demonstrate this to interested external stakeholders. Second, when companies have had *Listeria* incidences, the

logical nature of the environmental sampling plan, and its focus on predetermining responses if *Listeria* is found at each of the sampling points, has allowed a rapidly implemented follow-up and investigative program. Third, and perhaps most importantly, it has also developed a team ethos among (particularly) technical, production, engineering, and hygiene functions in the companies to jointly own (and control) *Listeria* management. Prior to this, *Listeria* control was thought to be the domain of the hygiene function, who were often blamed for, and required to correct, *Listeria* incidences. The model demonstrates that the hygiene function has no control over the entry of *Listeria* into the facility or its harborage in poorly hygienically designed infrastructures and also has no impact on the cross-contamination vectors to food products. Poor cleaning and disinfection does, however, exacerbate existing *Listeria* issues if surfaces on which *Listeria* resides are not effectively accessed and cleaned and disinfected.

Whereas this 5-point control plan focuses on *Listeria*, in principle it could be applied to the control of any pathogen in a high hygiene environment or other defined manufacturing area, where the entrance to such an area and the potential harborage and cross-contamination of pathogens to food product needs to be controlled.

REFERENCES

1. Anonymous. 2004. Commission Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005R2073-20200308&from=EN. Accessed 16 November 2021.
2. Anonymous. 2005. Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/ ?uri=CELEX:02005R2073-20200308&from=EN. Accessed 16 November 2021.
3. BRC Global Standards. 2018. Global standard food safety issue 8. BRC Global Standards, London. Free download at: https://cdn.scsglobalservices.com/files/program_documents/brc_food_standard_8.pdf
4. Centers for Disease Control and Prevention. 2011. Multistate outbreak of listeriosis linked to whole cantaloupes from Jensen Farms, Colorado (final update). Available at: https://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html. Accessed 16 November 2021.
5. Codex Alimentarius Commission. 2020. Recommended international code of practice: general principles of food hygiene. CAC/RCP 1-1969. Available at: http://www.fao.org/ fao-who-codexalimentarius/shproxy/en/?lnk=1&url=https%253A%252F%252Fworkspace. Fao.org%252Fsites%252Fcodex% 252Fstandards%252FCXC%2B1-1969%252FCXC_001e.pdf. Accessed 16 November 2021.
6. European Commission. Rapid Alert System for Food and Feed (RASFF). Available at: https://ec.europa.eu/food/safety/rasff-food-and-feed-safety-alerts/rasff-portal_en. Accessed 25 January 2022.
7. European Food Safety Authority. 2018. *Listeria monocytogenes* contamination of ready-to-eat foods and the risk of human health in the EU. EFSA J. 16(1):5134.
8. European Food Safety Authority. 2021. The European Union One Health 2019 Zoonoses Report. 27 February 2021. Available at: https://efsa.onlinelibrary.wiley.com/doi/pdf/ 10.2903 /j.efsa. 2021.6406. Accessed 16 November 2021.
9. European Hygienic Engineering Design Group. 2015. Cleaning validation in the food industry—general principles, part 1. Document 45 (free download) Available at: https://www.ehedg.org/guidelines/. Accessed 16 November 2021.
10. Eurostat. 2021. Population structure and ageing. Available at: https://ec.europa.eu/urostat/statistics-explained/index.php?title=Population_structure_ and_ageing# The_share_of_elderly_people_continues_to_increase. Accessed 16 November 2021.
11. Food Standards Australia New Zealand. 2018. Trade recall of rock melons linked to *Listeria*. 28/02/2018. Available at: http://www.foodstandards.gov.au/media/Pages/Trade-recall-of-rockmelon-linked-to-Listeria-.aspx. Accessed 16 November 2021.
12. Gaze, R. 2009. Guideline no. 42. *In* HACCP: a practical guide, 4th ed. Campden BRI, Chipping Campden, UK.
13. Holah, J. T. 2013. Hygienic practice in food processing and manufacturing, chap. 24. *In* Y. Motarjemi and H. L. M. Lelieveld (ed.). Food safety management. Elsevier, Amsterdam.
14. Holah, J. T., J. Bird, and K. E. Hall. 2004. The microbial ecology of high risk, chilled food factories; evidence for persistent *Listeria* spp. and *Escherichia coli* strains. *J. Appl. Microbiol.* 97:68–77.
15. Holah, J., E. T. Margas, R. Hagberg, B. Warren, J. Fraser-Heaps, and S. Mortimore. 2012. Identifying and controlling microbiological cross-contamination: a risk-based approach to understanding the critical role of prerequisite programs. *Food Safety Mag.* 18(1):54–61.
16. International Organization for Standardization. 2018. Quality management systems—requirements for any organisation in the food chain. ISO 22000:2018. International Organization for Standardization, Geneva.
17. Kerisa. 2022. L4 Listeria management training course. Available at: https://www.holchem.co.uk/shop/training-courses-2022/l4-listeria-management/l4-listeria-management-2022/. Accessed 27 February 2022.
18. Malley, T., J. Butts, and M. Wiedmann. 2015. Seek and destroy process: *Listeria monocytogenes* process controls in the ready-to-eat meat and poultry industry *J. Food Prot.* 78:436–445.
19. National Institute for Communicable Diseases. 2018 Situation report on listeriosis outbreak, South Africa, 12 March 2018. Available at: https://www.nicd.ac.za/wp-content/uploads/2018/03/Listeria-Sitrep-13Mar2018_finalapproved.pdf. Accessed 16 November 2021.
20. U.S. Food and Drug Administration. 2018. Hazard analysis and risk-based preventive controls for human food: guidance for industry (draft guidance). Available at: https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM517610.pdf. Accessed 16 November 2021.