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Food Safety Authority of Ireland

45

GUIDANCE NOTE

Guidance on Environmental Monitoring of *Listeria monocytogenes* in Ready-to-Eat Food Business Operations

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Abbreviation/acronym	Explanation
ACC	aerobic colony count
ATP	adenosine triphosphate
BIM	Bord Iascaigh Mhara
BRCGS	Brand Reputation Compliance Global Standards
CCP	critical control point
CFU	colony-forming unit
DAFM	Department of Agriculture, Food and the Marine
E. coli	*Escherichia coli*
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EURL *Lm*	European Union Reference Laboratory for *Listeria monocytogenes*
FSAI	Food Safety Authority of Ireland
FSMS	food safety management system
g	gram
GHP	good hygiene practice
HACCP	Hazard Analysis and Critical Control Point
L. monocytogenes	*Listeria monocytogenes*
LEM	*Listeria monocytogenes* environmental monitoring
NEHS	National Environmental Health Service
PPE	personal protective equipment
PRP	prerequisite programme
SFPA	Sea-Fisheries Protection Authority
SMEs	small and medium-sized enterprises
spp.	species
TVC	total viable count
VBNC	viable-but-nonculturable
WGS	whole genome sequencing

1. Introduction

1.1 Scope

This guidance note applies to all food business operators of any scale involved in the production of ready-to-eat food products. Certain aspects are also applicable to food business operators that produce ready-to-heat food products, which are either intended to be reheated for palatability prior to consumption, or where evidence exists that they are not always cooked thoroughly by consumers (e.g. sausage rolls, panini sandwiches, soups, precooked composite ready meals). The extent and nature of food safety controls required for such ready-to-heat products should be based on a risk assessment conducted by the food business operator. This guidance note is not applicable to other non-ready-to-eat foods (e.g. raw meat labelled with valid cooking instructions that is to be fully cooked before eating).

This guidance note provides best practice advice on how to develop a *Listeria monocytogenes* (*L. monocytogenes*) environmental monitoring (LEM) programme. It provides recommendations to ready-to-eat food business operators on how to develop a risk-based approach to determine which locations should be swabbed in order to monitor the presence of *L. monocytogenes* in the environment of the food business operation (i.e. food contact and non-food contact surfaces and equipment). It also provides advice on when and how frequently these locations should be swabbed. It explains how the test results should be interpreted and what actions to take in the event of *L. monocytogenes* being detected.

This guidance note does not provide information on how to carry out swabbing of surfaces or equipment to detect *L. monocytogenes*. For further information on surface sampling methods, food business operators are recommended to consult ISO 18593:2018 and the specific guidance on *L. monocytogenes* detection on surfaces published by the European Union Reference Laboratory for *Listeria monocytogenes* (EURL *Lm,* 2023).

This guidance note does not provide information on designing a ready-to-eat food business operation, personal hygiene of food workers, equipment design, or implementing suitable hygiene programmes. For more information on this topic consult the Food Safety Authority of Ireland's (FSAI's) document '*The Control and Management of* Listeria monocytogenes *Contamination of Food* (Food Safety Authority of Ireland, 2005).

1.2 Definition of ready-to-eat food

Article 2 of Commission Regulation (EC) No 2073/2005, as amended (European Commission, 2005), defines ready-to-eat food as "food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern".

Cooking food thoroughly until the internal temperature reaches 75 °C (or an equivalent time-temperature combination), or thoroughly reheating food that has already been cooked to reach a core temperature of 70 °C before consumption, is regarded as an effective method to achieve a 6-log reduction in the number of *L. monocytogenes* cells (Food Safety Authority of Ireland, 2014). Food products that are labelled to be thoroughly cooked before consumption with validated cooking instructions, and for which there is no evidence that the consumer eats the food without following those instructions exactly, are considered non-ready-to-eat food (e.g. raw poultry meat).

Chilled precooked food products, such as sausage rolls, quiche, or soup, often have cooking instructions on the packaging to improve taste and texture. However, these instructions are not always designed to ensure that the product reaches a minimum core temperature of 70 °C prior to consumption. For other similar products, including certain precooked composite ready meals and frankfurter sausages, there is evidence that consumers may choose to eat them without fully cooking as recommended, even when cooking instructions are provided. Accordingly, such precooked chilled products should be regarded as posing a similar risk to ready-to-eat foods with respect to *L. monocytogenes* contamination. These are termed 'ready-to-eat by default' food products in accordance with Figure 1: Food business operator's decision tree for determining the ready-to-eat status of the food they produce, manufacture or package of FSAI *Guidance Note No. 27* (FSAI, 2014, p. 32).

The recommendations provided in the present guidance note apply to 'ready-to-eat by default' food products as well as ready-to-eat food products. Unless a risk assessment determines otherwise, stringent environmental control measures that are equivalent to those applicable to ready-to-eat foods should be implemented during the production of ready-to-eat by default foods in order to ensure food safety. This guidance note will use the term 'ready-to-eat' to refer to both types of food business operation. For more information on how to determine the ready-to-eat status of food, see *Guidance Note No. 27* (Food Safety Authority of Ireland, 2014, pp. 32–33).

1.3 Purpose of an LEM programme

The purpose of an LEM programme is to detect, investigate, manage and/or eliminate potential sources of *L. monocytogenes* contamination in the environment of a ready-to-eat food business operation. Controlling *L. monocytogenes* is essential at all stages of the food production process. An integrated approach is necessary to prevent the growth of this pathogen in the final ready-to-eat food product.

The challenges associated with controlling *L. monocytogenes* are significant, given its widespread presence; its high resistance to heat, salt, and acidic pH; and its capacity to grow and survive at or below standard refrigeration temperatures (Food Safety Authority of Ireland, 2011). The LEM programme should ensure that the control measures implemented by the food business operator are optimised in order to minimise the transfer of *L. monocytogenes* to ready-to-eat food products. Furthermore, the LEM programme provides information to identify and prevent harbourage sites and growth niches in the food business operation's environment that may allow *L. monocytogenes* strains to persistently survive and grow, thereby acting as a potential source of cross-contamination for ready-to-eat food products.

Article 17.1 of Regulation (EC) No 178/2002, as amended (European Commission, 2002), states that:

"Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met".

This means that primary responsibility for food safety rests with the food business operator.

Under Articles 4 and 5 of Regulation (EC) No 852/2004, as amended (European Commission, 2004), food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations are required to have a food safety management system (FSMS) consisting of good hygiene practices (GHPs)/prerequisite programmes (PRPs) and procedures based on the principles of Hazard Analysis and Critical Control Point (HACCP) appropriate to the size and nature of the food business. In ready-to-eat food business operations, an LEM programme is a key component of the FSMS.

1.4 Difference between *Listeria* species and *L. monocytogenes*

L. monocytogenes is a species (spp.) of *Listeria* that is pathogenic (i.e. can cause foodborne disease), and for that reason it is the main focus of the legal requirements in Commission Regulation (EC) No 2073/2005, as amended (European Commission, 2005). However, there are

other non-pathogenic spp. of *Listeria*[1] that are also widely distributed in the environment. *Listeria* spp. (including *L. monocytogenes*) have been isolated from a variety of habitats, including soil, vegetation, silage, sewage, water, and faeces of healthy animals and humans. They are capable of persisting on equipment and surfaces of food business operations if effective hygiene programmes are not in place (Food Safety Authority of Ireland, 2011).

While other *Listeria* spp. are not considered pathogenic, they serve as valuable indicators of environmental conditions that may support the potential presence of *L. monocytogenes*, as all *Listeria* spp. share the same ecological niche (Spanu and Jordan, 2020; Tompkin, 2002). In addition to *L. monocytogenes,* it is recommended that the LEM programme also monitors the presence of other *Listeria* spp. in the environment of the food business operation. This acts as a hygiene indicator of environmental conditions that may support the potential presence of the pathogen *L. monocytogenes* (Food Standards Australia New Zealand, 2018; Codex CXG 61-2007, Rev. 2009).

1.5 Components of an effective LEM programme

Article 5.2 of Commission Regulation (EC) No 2073/2005, as amended (European Commission, 2005), states that "Food business operators manufacturing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing area and equipment for *Listeria monocytogenes* as part of their sampling scheme".

This means that food business operators making ready-to-eat food products that are able to support the growth of *L. monocytogenes* are legally required to sample the processing area and equipment for *L. monocytogenes* as part of their sampling scheme.

A comprehensive environmental monitoring programme should include both an LEM programme and the environmental monitoring of hygiene indicators or monitoring for adenosine triphosphate (ATP) on surfaces in order to verify that cleaning and disinfection of food contact and non-food contact surfaces and equipment has been carried out to a satisfactory standard.

Both aspects should complement each other and work as one environmental monitoring programme, as follows:

[1] Throughout this guidance note, use of this term refers to other *Listeria* spp. that are considered non-pathogenic (e.g. *L. innocua, L. ivanovii, L. seeligeri, L. welshimeri,* and *L. grayi)*.

I. Identification and management of *L. monocytogenes* in the food business operator's environment, in particular to detect, manage and/or eliminate any potential harbourage sites and growth niches
II. Assessment of the efficacy of the hygiene programme by testing environmental monitoring swabs for hygiene indicators such as total viable counts (TVCs), which are also known as aerobic colony counts (ACCs); Enterobacteriaceae; generic *Escherichia coli* (*E. coli*); or using other indicators of hygiene, such as rapid alternative test methods including measurement of ATP on surfaces (see Section 3 and Appendix 4 for more information).

However, while Commission Regulation (EC) No 2073/2005 (European Commission, 2005) specifies that food business operators must sample the processing area and equipment for *L. monocytogenes* as part of their sampling scheme, it does not provide a microbiological criterion to assess the test results, nor does it provide information on what actions to take when *L. monocytogenes* is detected in the food business operation's environment.

This guidance note offers recommendations for ready-to-eat food business operators on establishing a risk-based framework to identify sampling sites for monitoring the presence of *L. monocytogenes*. It also provides guidance on the appropriate timing and frequency of sampling activities. Additionally, it outlines how to interpret test results and describes the necessary steps to be taken should *L. monocytogenes* be detected in the environment of a ready-to-eat food business operation.

1.6 Note for small and medium-sized enterprises

Food hygiene legislation places the responsibility of producing safe food on all food business operators, big and small. However, in comparison to larger food operations, small and medium-sized enterprises (SMEs) may have limited access to resources such as staff, technical knowledge, floor space and/or funds. This can lead to them being overwhelmed with the volume of food safety requirements they must meet. In particular, compliance with food safety legislation in relation to *L. monocytogenes* is complex. It can be difficult for SMEs to understand and challenging to implement. For example, while medium- to large-sized food business operators may have several staff working in teams that cover the roles of operations, engineering, quality/technical staff, and hygiene, some small food business operations may only have a low number of staff who have overlapping duties. Under these circumstances, the responsibility to design and implement the LEM programme may fall to one or two people, depending on the size of the food business operator and the number of people employed in it.

It is important to acknowledge that, although a food business operation may be of modest scale, there remains a potential risk for *L. monocytogenes* to be introduced and to persist within the environment from where it can cross-contaminate the food being processed. SMEs are as likely to find *L. monocytogenes* in their operation as a large multinational food business operation. Therefore, it is crucial that SMEs understand what the potential risk of *L. monocytogenes* contamination means for the type of ready-to-eat food they are producing, and the public health significance to consumers of that food.

Contamination of the food processing environment with *L. monocytogenes* must be identified as a hazard to the safety of the food produced, as it could serve as a source of cross-contamination for ready-to-eat products. This could potentially lead to illness (called listeriosis) in some people who consume the contaminated food, especially those in vulnerable groups (Food Safety Authority of Ireland, 2011). Consequently, it is essential to implement and maintain effective control measures for *L. monocytogenes* contamination in all ready-to-eat foods produced by using appropriate HACCP-based procedures within the FSMS in accordance with Regulation (EC) No 852/2004, as amended (European Commission, 2004). The LEM programme needs to be incorporated into the food business operator's procedures in accordance with HACCP principles and must be developed and managed by personnel who have received appropriate training.

There is no universal approach to developing and implementing a risk-based LEM programme, as space limitations and layout configurations can differ depending on the type of food business operation. For instance, some smaller-sized food business operators may use time separation rather than physical barriers. Nevertheless, the core principles for establishing an effective FSMS remain consistent (European Commission, 2022; 2004). The core advice given in this guidance note is applicable to food business operations of all sizes. The approach taken by each food business operation to develop its own LEM programme should be tailored to its own situation on a risk basis depending on the nature and size of the operation.

If a small food business operator determines that some of the necessary expertise is not currently available within its business, it may decide to employ additional external support to facilitate the work of the LEM team. In this case, such food business operators are advised to source a suitable external consultant to work with them who has the appropriate knowledge and expertise in ready-to-eat food business operations (Food Safety Authority of Ireland, 2023; 2008). External consultants can be used for their technical knowledge, but they should not design or write the LEM programme in isolation without the continued collaboration of the LEM team or the in-house responsible person(s) of a small SME (Holah, 2022). Instead, they can support the LEM team with their expertise in order to facilitate the design, documentation and implementation of the LEM programme, which is ultimately managed by the LEM team in the food business operation.

Additionally, food business operators may require the services of a private commercial laboratory to carry out microbiological testing of food samples and swabs. There are no specific legal requirements in Commission Regulation (EC) No 2073/2005, as amended (European Commission, 2005) for commercial laboratories conducting analysis on behalf of food business operators to be accredited to ISO/IEC 17025 standard. However, the FSAI strongly recommends that food business operators employ the services of accredited laboratories. The use of an accredited laboratory gives the food business operator confidence in the standard and quality of service provided. For more information, see the FSAI factsheet on testing foods for the microbiological criteria specified in Commission Regulation (EC) No 2073/2005 (Food Safety Authority of Ireland, 2021) and the Chilled Food Association's guidance on employing third-party laboratories (Chilled Food Association, 2021).

1.7 Reporting a food incident

If *L. monocytogenes* is detected in the food business operator's environment, appropriate actions should be taken as per Section 7 (Step 5) and Section 8 of this guidance note. If a food business is experiencing ongoing issues with *L. monocytogenes* environmental contamination in their operation that it finds difficult to manage, it is advisable that the food business discuss this with its competent authority inspector at the earliest opportunity.

If the food business operator finds the presence of any microbial hazard in a food product placed on the market that could be considered a risk to food safety (e.g. *L. monocytogenes* in a ready-to-eat food placed on the market that would support its growth to >100 colony-forming units (cfu) per gram (g) throughout the product's shelf-life), the food business should immediately report the finding to its own inspector in the official agency that supervises it. If it is an emergency or out of hours and the food business operator cannot get in contact with its own inspector, it should inform the FSAI directly using the food incident report form.[2]

The roles and responsibilities for food business operators, Official Agencies (e.g. the Department of Agriculture, Food and the Marine (DAFM), the National Environmental Health Service (NEHS), and the Sea-Fisheries Protection Authority (SFPA)) and the FSAI for managing food incidents at local and national level are provided in *FSAI Code of Practice No. 5* (Food Safety Authority of Ireland, 2004).

[2] The online form for food business operators to report a food incident is available at https://www.fsai.ie/contact/fsai-incident-report-form.

2. *L. monocytogenes*

L. monocytogenes is a pathogenic bacterium that causes a group of diseases that are collectively known as listeriosis (Food Safety Authority of Ireland, 2011). *L. monocytogenes* is of major concern because of:

- Its ubiquitous nature
- Its ability to survive and grow at refrigeration temperatures (i.e. ≤5 °C)
- The severity of the disease it causes
- The high human fatality rate.

In addition to *L. monocytogenes,* there are 25 recognised other species of *Listeria* (Carlin *et al.,* 2021). Only *L. monocytogenes* is normally considered pathogenic to humans (Quereda *et al*., 2021). The consumption of food contaminated with *L. monocytogenes* is the main route of transmission of listeriosis (European Commission, 2025).

Foods most often associated with listeriosis include those that:

- Support the growth of *L. monocytogenes*
- Have a long shelf-life under refrigeration (*L. monocytogenes* can grow to significant numbers in food held at refrigeration temperatures when given sufficient time)
- Are consumed without further listericidal treatments (i.e. treatments that would kill *L. monocytogenes*, such as thorough cooking).

Examples of food products that have been involved in previous listeriosis outbreaks include certain meat, poultry and fish products (e.g. frankfurters, pâté, smoked salmon); dairy products (e.g. soft cheeses, unpasteurised milk); and prepared salads (e.g. coleslaw, bean sprouts) (Food Safety Authority of Ireland, 2011). It is estimated that levels of *L. monocytogenes* below 100 cfu/g of food represent a very low risk of listeriosis for all population groups (Scientific Committee on Veterinary Measures relating to Public Health, 1999).

Based on the Scientific Committee on Veterinary Measures relating to Public Health's scientific opinion (1999), the legal microbiological criterion limit of 100 cfu/g of *L. monocytogenes* in food category 1.2 and 1.3 of Annex I, Chapter 1 in Commission Regulation EC No 2073/2005 was set for ready-to-eat food products placed on the market during their shelf-life (European Commission, 2005). Considering this legal requirement, the potential of ready-to-eat food products and their raw materials/ingredients to support the growth of *L. monocytogenes* to levels above 100 cfu/g must be taken into consideration when designing an LEM programme.

2.1 Analytical method for detecting *L. monocytogenes* in environmental monitoring swabs

Environmental monitoring swabs are tested for *L. monocytogenes* using the analytical method in ISO 11290-1:2017, or an alternative testing method validated according to Article 5.5 of Commission Regulation 2073/2005 (European Commission, 2005). This is commonly referred to as the detection method. It is a qualitative test that is very sensitive. If confirmed *L. monocytogenes* colonies grow on the agar plate, it means that they were detected in the environmental monitoring swab tested. If this is the case, it will be stated on the test report.

If no colonies grow on the agar plate, the test result will be reported as 'not detected'. ISO 11290-1:2017 is also a detection method for other *Listeria* spp. that are considered non-pathogenic. If *Listeria* is detected in the environmental swab, the laboratory report should confirm if the microorganism(s) detected are *L. monocytogenes* and/or *Listeria* spp. Information Box 1 provides guidance on interpreting analytical test results for *L. monocytogenes* and/or *Listeria* spp. and actions to take based on those results.

Under the food safety criteria laid down in Chapter 1 of Commission Regulation (EC) No 2073/2005, as amended (European Commission, 2005), the analytical reference method for *L. monocytogenes* is ISO 11290-1:2017. Alternative analytical methods are permitted if they meet the requirements listed in Article 5.5 of Commission Regulation (EC) No 2073/2005, as amended (European Commission, 2005). Alternative or rapid methods may have advantages over the reference test method, such as a shorter time to result or being easier to use. However, the alternative method must be validated in order to show that it can provide at least equivalent guarantees of the relative accuracy, specificity, sensitivity and limit of detection compared with the relevant analytical reference method. It must be able to detect all target strains and not to have cross-reactions with non-target strains compared with the relevant analytical reference method (i.e. inclusivity/exclusivity testing). For more information, see the FSAI factsheet on testing foods for the microbiological criteria specified in Commission Regulation (EC) No 2073/2005 (Food Safety Authority of Ireland, 2021).

Information Box 1: Interpreting the reported results of environmental monitoring swabs tested using ISO 11290-1:2017 (i.e. the detection method) or an alternative testing method validated according to Article 5.5 of Commission Regulation 2073/2005[a]

Test parameter	Test result	Interpretation	Action
Listeria spp.	Not detected	*Listeria* spp. or *L. monocytogenes* was not detected in the swab. Some laboratories may report this as *Listeria* spp. (including *L. monocytogenes*). Where some laboratories do not specifically list a separate test result for *L. monocytogenes*, it can be interpreted as '*L. monocytogenes* not detected'.	No action required
Listeria spp.	Not detected	*Listeria* spp. or *L. monocytogenes* was not detected in the swab.	No action required
L. monocytogenes	Not detected		
Listeria spp.	Detected/not detected[b]	*L. monocytogenes* was detected in the swab.	*L. monocytogenes* was detected in the environment of the food business operation. See Section 7 (Step 5) and Section 8 for a list of suggested actions to take.
L. monocytogenes	Detected		
Listeria spp.	Detected	*Listeria* spp. was detected in the swab. The species may be identified on the laboratory report. While other *Listeria* spp. are not considered pathogenic (e.g. *L. innocua*), they are useful hygiene indicators of the potential presence of *L. monocytogenes* as they survive under the same environmental conditions (Spanu and Jordan, 2020; Tompkin, 2002). *L. monocytogenes* was not detected in the swab.	Another *Listeria* spp. was detected that is not *L. monocytogenes.* Although other *Listeria* spp. are not pathogenic, their presence may indicate the presence of *L. monocytogenes* as they occupy the same ecological niche. Food business operators are recommended to assess the risk and carry out any actions listed in Section 7 (Step 5) and Section 8 that are considered necessary.
L. monocytogenes	Not detected		

[a] There is no obligation for laboratories to format the laboratory report in a certain way. Thus, the format of the reported test result may differ slightly to the list above, which is not exhaustive.

[b] *L. monocytogenes* is also a species of *Listeria*, so it can be reported as 'detected' for both parameters depending on how the laboratory routinely reports the test results. It could also mean that another species of *Listeria* was detected in addition to *L. monocytogenes*. The other species of *Listeria* may or may not be identified on the laboratory report. If the laboratory report states *Listeria* spp. 'not detected' and *L. monocytogenes* 'detected', it means that *L. monocytogenes* was the only species of *Listeria* detected in the swab.

3. Hygiene programme

The FSMS is a holistic system of prevention, preparedness and own-check activities to manage food safety, including food hygiene, in a food business operation (European Commission, 2022). Under the FSMS, all food business operations must have adequate GHPs/PRPs in place in order to ensure the production of safe food. These are the basic conditions and activities necessary to maintain a hygienic food business operation environment.

Appropriate cleaning and disinfection of surfaces and equipment implemented under the hygiene programme is a critical PRP to manage food safety, including food hygiene, in a food business operation. All equipment and surfaces need to be kept clean, and some (such as those that are in direct contact with food) also require additional disinfection. Protocols and schedules for the hygiene programme should be developed and validated within the FSMS. The hygiene programme requires the implementation of adequate procedures for both cleaning and disinfection. This is because cleaning alone is not enough to kill all microorganisms, and disinfection alone is not enough to remove all dirt and debris.

There are no legal microbiological criteria to determine an acceptable level of contamination with hygiene indicators such as TVC/ACC, Enterobacteriaceae, coliforms, *E. coli* or ATP on food contact or non-food contact surfaces. As factors will vary between food business operations and the types of equipment used for the manufacturing of food, it is difficult to set standard microbiological criteria for the environmental monitoring of hygiene indicators or for ATP on surfaces after cleaning and disinfection has been carried out. It is recommended that food business operators set their own internal standards for hygiene indicators or ATP in order to assess whether the levels remaining on a surface after implementation of the hygiene programme are satisfactory. See Appendix 4 for an example of how to set microbiological criteria for hygiene indicators on surfaces that are appropriate for the specific needs of each food business depending on the size and nature of the operation.

Even with an effective hygiene programme in place, there may be harbourage sites and growth niches within the environment of the food business operation. *L. monocytogenes* can evade cleaning and disinfection procedures, persist, and potentially grow in these places. For example, this may be due to the poor implementation of the hygiene programme or an inadequate hygiene programme; poor training of staff; maintenance work being carried out; damaged areas in the fabrication of the buildings; or poor hygienic design of processing equipment. These areas may pose a risk of cross-contamination to ready-to-eat foods exposed to the environment and to food contact surfaces. The hygiene programme schedule should be frequent enough through the

production cycle to maintain hygiene standards and to eliminate microbiological contamination during each cleaning and disinfection cycle.

Inadequate cleaning and disinfection of drains, or poor drain design, is frequently identified as a source of *L. monocytogenes* contamination in the environment of a food business operation. Campden BRI (2020a) has produced a useful short video to demonstrate how to appropriately clean and disinfect a drain in a food business operation. It is also recommended to have detailed cleaning instruction cards and procedures available for staff or external hygiene crews to consult regarding the dismantling of equipment in order to enable the proper implementation of the hygiene programme (Campden BRI, 2020b: 2020c).

Information Box 2 provides guidance on typical areas and activities to monitor in order to avoid them becoming sources of environmental contamination with *L. monocytogenes* in a food business operation.

Information Box 2: Guidance on typical areas to monitor in order to prevent them becoming a source of *L. monocytogenes* contamination within the food business operation environment

Fabrication:

- Fabrication (i.e. the layout, design, and construction of food premises and processing equipment) in accordance with Regulation (EC) No 852/2004, as amended (European Commission, 2004) should be in good condition with no holes in walls or floors to allow water to ingress.
- Fixed and mobile equipment (e.g. slicers, vacuum packers, portable weighing scales) should be hygienically designed, cleanable, and constructed using appropriate materials. It should be maintained in good order and condition so as to minimise any risk of contamination.
- Drainage facilities must be sufficient for their intended purpose. They should be designed and constructed so as to minimise the risk of contamination of the processing area. In cases where drainage channels are partially or fully open, they must be engineered to prevent waste from flowing from contaminated areas towards or into clean areas, particularly those where high-risk food items are processed.

Water:

- Water is a common transmission vector of *L. monocytogenes* either directly (e.g. via water in use as an ingredient, or when used to rinse surfaces/equipment using a power hose) or indirectly (e.g. via aerosols/condensation). Care of the use of water and water potability is critical in controlling the presence of *L. monocytogenes* (British Frozen Food Federation, 2015).
- Ensure that floors are kept as dry as possible and avoid pools of water on the floor by regularly using a mop to dry it up or by using a squeegee to direct water into the nearest drain.
- Conveyor rollers have the potential to collect water that could then leak onto the conveyor belt during production, which may lead to cross-contamination of the product on the conveyor belt.
- Moisture may infiltrate emergency stop buttons, creating an environment that is conducive to the growth of *L. monocytogenes*. During production, this contaminated moisture can inadvertently be released when the emergency stop is activated, posing a risk of cross-contamination to any food products that come into contact with it.

Aerosols:

- Aerosols from cleaning (e.g. from using a power hose) or maintenance (or preventative maintenance) work could cause cross-contamination of ready-to-eat foods or food contact surfaces that are uncovered/open to the environment. The risk of cross-contamination can be higher when maintenance work is taking place.
- Air movement should be directed via positive air pressure in ready-to-eat areas in order to prevent any contamination coming in from non-ready-to-eat food areas.
- Air blown directly by fans onto a product to cool it should be filtered, and fans kept in clean condition.

Wheels:

- Wheels can be a vector of contamination. Any vehicles (e.g. forklifts, hand trucks) required in the ready-to-eat areas should be dedicated to those areas.
- Container wheels (e.g. on tote bins/racks/dollys/trolleys) should be cleaned daily.
- The equipment used to transport ready-to-eat food (e.g. racking trolleys) should have a solid base to prevent splash from the wheels cross-contaminating the product.

Touch points:

- Light switches and buttons on control panels are regular touch points and can act as a transfer point for cross-contamination to other vectors (e.g. gloved hand), surfaces and food products.

4. Vectors as sources of contamination

Vectors are transportation pathways – such as personnel, waste, or equipment – that can facilitate the transfer of *L. monocytogenes* between different areas within the food business operation. The pathogen can be transmitted via staff members (e.g. by contaminated footwear when moving across a high-hygiene barrier), items (e.g. wheels on carts or mobile equipment), or utensils (e.g. maintenance tools and cleaning equipment). Such vectors establish potential pathways for cross-contamination from a point source (i.e. original source) to transfer points, or directly to ready-to-eat foods and food contact surfaces.

High-touch-point surfaces that are frequently handled by staff (e.g. control panels, light switches, door handles) may serve as transfer points for cross-contamination of *L. monocytogenes* between surfaces by a vector such as a gloved hand. For example, consider a scenario where a gloved hand (the vector) comes into contact with a drain cover contaminated with *L. monocytogenes* (the point source) during cleaning and disinfection. The operative proceeds to open a door without changing their gloves between tasks, inadvertently transferring the same *L. monocytogenes* strain to the door handle. The door handle then becomes a transfer point, facilitating cross-contamination to the gloved hands of other personnel, as it is frequently touched. Subsequently, these staff members could spread the contamination to other surfaces and food products they handle if they do not change their gloves first.

4.1 Collector samples

Certain vectors may act as ‘collector samples’ in the LEM programme because they facilitate the accumulation of *L. monocytogenes* contamination over a period of time due to frequent contact with environmental surfaces, or because by their nature they concentrate hazards within the environment (Holah, 2022). These can include, for example, the footwear of personnel, wheels on mobile equipment, food debris accumulating on a slicer blade during processing, the contents of vacuum cleaners, or a floor drain designed to collect fluids from a wide surface area (Holah, 2022).

The advantage of collector samples is that a relatively small number of samples can provide an indication of the possible presence of *L. monocytogenes* in the food business operation environment. The disadvantage is that it does not specifically identify the point source of the detected *L. monocytogenes* but instead gives an indication of an issue that needs to be investigated further (Holah, 2022). For example, *L. monocytogenes* contamination detected on an operative’s footwear could have originated anywhere that the operative has walked since the footwear was last cleaned (Holah, 2022).

A certain amount of collector samples can be useful to test as part of the LEM programme to maximise the chances of detecting *L. monocytogenes* in the food business operation environment (see Section 7.3 (vi) and Table 4 for more information). Collector samples should be sampled following the use of the collector or towards the end of production periods, when the potential to detect *L. monocytogenes* contamination is at its highest (Holah, 2022).

4.2 Vector swabbing

As vectors transport contamination around the environment in various ways, detection of *L. monocytogenes* on a vector may not provide additional information on the point source of contamination. Additional investigative environmental swabbing may be necessary in order to determine the extent of the problem and to identify the point source. Vector swabbing is one such investigational procedure, which involves taking additional follow-up environmental swabs around the site that was initially positive. The objective is to follow possible contamination pathways to the initial detection point. This may be carried out in a 'starburst' pattern. This means that the area around the initial sampling site where *L. monocytogenes* was detected is investigated further by swabbing the surrounding area in a pattern that resembles diverging rays of light. See Figure 1 for an illustrated example of vector swabbing in a 'starburst' pattern.

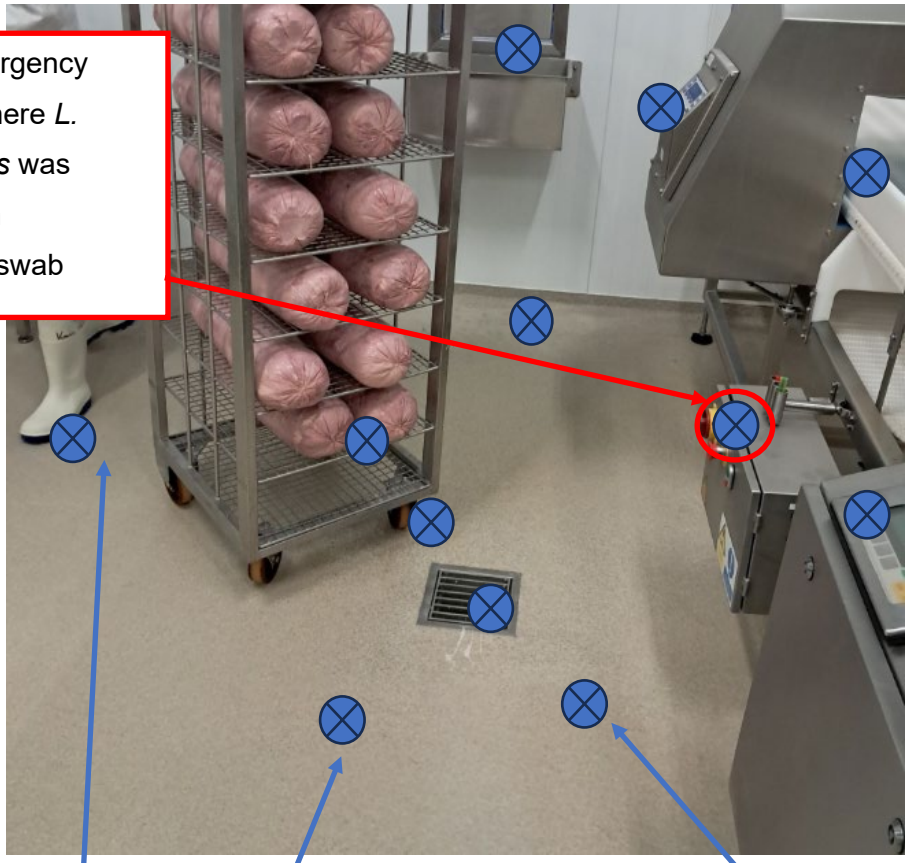


Figure 1 Example of how to vector swab in a 'starburst' pattern to identify the contamination point source

4.3 Control of vectors

The movement of vectors such as personnel, objects, and/or items around the food business operation should be considered when designing an LEM programme. When ready-to-eat food products are subjected to processes that eliminate potential contamination with *L. monocytogenes* (e.g. cooking raw cured ham), it is essential to establish and maintain effective controls in order to prevent post-process contamination during subsequent steps such as slicing and packaging. GHPs and effective controls should be implemented regarding access to the ready-to-eat area (Food Safety Authority of Ireland, 2005).

This may include designated changing areas equipped with dedicated footwear, handwashing stations, specific coat colours, and hairnets that are distinct from those used in non-ready-to-eat areas. As best practice, it is recommended that protective clothing for personnel, portable tools and cleaning equipment, etc. be visually distinctive (e.g. colour coded) and dedicated for use in the ready-to-eat area in order to minimise the risk of cross-contamination with *L. monocytogenes* from the non-ready-to-eat areas of the operation (Brand Reputation Compliance Global Standards, 2022b; Food Safety Authority of Ireland, 2005).

It is best practice to physically segregate ready-to-eat areas in the food business operation by means of a solid barrier in order to prevent the risk of microbiological cross-contamination (e.g. with *L. monocytogenes*). For example, physical barriers/partitions (e.g. walls, floors, ceilings, doors and windows) can be used between areas to separate the ready-to-eat area from other areas in the operation (Brand Reputation Compliance Global Standards, 2022a; 2022b; Food Safety Authority of Ireland, 2005). If this is not available for SMEs, alternative procedures must be implemented to segregate the ready-to-eat areas and prevent access by unauthorised personnel, transfer of objects or items (except via a controlled route), and microbiological contamination from airborne particles or water droplets. These procedures may involve time or space separation, movement controls, or other restrictions. When evaluating the suitability of the barrier controls, a risk assessment should be carried out by the food business operator. The chosen method must be validated in order to confirm that the controls are effective in preventing cross-contamination, and this validation must be documented (Brand Reputation Compliance Global Standards, 2022a; 2022b).

The risk of *L. monocytogenes* being spread in the environment of the operation by a vector could be greater where there is no solid barrier used. For example, SMEs that use time separation or a painted line on the floor instead of a walled barrier in order to ensure physical separation should consider the entire area as ready-to-eat, and tailor their LEM programme accordingly in order to manage the risk under their own FSMS. Information Box 3 provides some good practice

recommendations to control vectors and to prevent microbiological cross-contamination between ready-to-eat and non-ready-to-eat areas. For more detailed recommendations, consult the FSAI's document *The Control and Management of* Listeria monocytogenes *Contamination of Food* (Food Safety Authority of Ireland, 2005).

Information Box 3: Good practice recommendations to control vectors

Have procedures in place to carefully manage the movement of:

- Personnel between the ready-to-eat area and other areas through designated changing areas
- All objects and utensils into the ready-to-eat area through designated ports (e.g. hatches), with appropriate hygiene controls in place
- Water or other liquids on the floor that could ingress into the ready-to-eat area
- Airborne contaminants (e.g. dust particles or water droplets from using high-pressure hoses).

5. Raw materials as a source of contamination

It is important to consider whether any raw materials supplied as ingredients may already be potentially contaminated with *L. monocytogenes* on arrival to the food business operation. For example, *L. monocytogenes* has been previously linked to ready-to-eat cooked chicken used as an ingredient in sandwiches served in hospitals that resulted in a listeriosis outbreak (Public Health England, 2020), and in raw salmon intended for cold or hot smoking (Food Standards Agency, 2024b). It is recommended to have procedures in place to minimise the potential risk of cross-contamination from *L. monocytogenes,* if present, in raw materials in the environment of the food business operation, and in the final ready-to-eat food product(s), in accordance with GHPs and HACCP-based procedures taken under the FSMS (Food Safety Authority of Ireland, 2005).

Annex II General Hygiene Requirements for food business operators (except for those involved in primary production and associated operations), Chapter IX of Regulation (EC) No 852/2004, as amended (European Commission, 2004), lays down 'Provisions applicable to foodstuffs', which legally requires, among other things, that food businesses do not accept raw materials or ingredients if they are thought to be contaminated. It also requires storage of raw materials in appropriate conditions designed to prevent harmful deterioration and to protect them from

contamination, and procedures to ensure adequate pest control. Additionally, maintenance of the cold chain for raw materials, intermediate products and finished products is legally required if the products are likely to support the growth of pathogenic microorganisms, such as *L. monocytogenes*, in order to avoid a risk to health.

Raw materials (e.g. food ingredients, packaging) should be obtained from reputable and approved suppliers. The use of substandard raw materials can compromise the safety and quality of all food products (National Standards Authority of Ireland, 2007; 2022). It is recommended that food business operators establish microbiological specifications with their suppliers in order to ensure that *L. monocytogenes* is effectively controlled to an acceptable level upon receipt of raw materials. Having procedures in place to ensure good supplier control is essential in order to ensure the safety and overall quality of the ready-to-eat food products.

For example, it is useful to have a checklist of relevant points to address when selecting a supplier, a list of the hazards to be aware of, and the procedures that should be followed in order to minimise or eliminate the risk of these hazards under your HACCP-based procedures (European Commission, 2022; National Standards Authority of Ireland, 2007; 2022; Food Safety Authority of Ireland, 2005). Section 3.4 of the European Commission's (2022) *Commission Notice on the implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses* recommends that food business operators implement a comprehensive supplier control policy as part of their GHPs/PRPs and HACCP-based procedures under the FSMS.

The supplier control policy should include an agreement on specifications (e.g. microbiological parameters), hygiene assurance, and/or verification of a certified quality management system being maintained by the supplier. Section 3.3 of the FSAI document *The Control and Management of* Listeria monocytogenes *Contamination of Food* (Food Safety Authority of Ireland, 2005) provides guidance on the implementation of best practices for the procurement and delivery of raw materials, with particular consideration of the risks associated with *L. monocytogenes* contamination.

5.1 Specific concerns related to the potential contamination of raw materials with *L. monocytogenes*

Soil, in addition to animal manure often used as a fertiliser, is a well-known environmental source of *L. monocytogenes*, which in turn can cross-contaminate edible plants cultivated in it (Vivant *et*

al., 2013). Furthermore, the contamination of fresh produce with *L. monocytogenes* can occur through contaminated water sources used for irrigation or the reconstitution of plant protection products and biocides. Additionally, contamination may result from on-site washing and rinsing procedures, as well as from insufficient hygiene practices and human handling (Food Safety Authority of Ireland, 2016). Usually these raw ready-to-eat ingredients are not subjected to any further treatment, such as heat, to reduce or eliminate any *L. monocytogenes* contamination that may be present on them. Thus, fresh produce that is minimally processed for a ready-to-eat application can be challenging to manage in order to prevent it from becoming a potential source of *L. monocytogenes* contamination in the final end product and/or causing cross-contamination to food contact surfaces (British Sandwich & Food to Go Association, 2024; Chilled Food Association, 2022).

Other raw materials that have been subjected to processes such as a validated time-temperature treatment to reduce the risk of microbial contamination can be supplied to the final food business operator for use as a ready-to-eat ingredient in ready-to-eat food (e.g. chilled or frozen ready-to-eat cooked meats, pasteurised cheese, hot smoked salmon). Although these raw materials have undergone a heat treatment by the initial food business operator, there remains a potential risk of recontamination during subsequent processing steps (e.g. slicing) if the initial or subsequent food business operator does not adhere to its FSMS protocols effectively within its production facility.

Thus, it is important to consider whether certain raw materials that are used on-site as ready-to-eat ingredients in the final ready-to-eat product could be pre-contaminated with *L. monocytogenes.* It is recommended to have appropriate controls in place in order to minimise the risk, such as strict supplier controls. This includes having a microbiological specification in place for supplier *L. monocytogenes* testing, and occasionally carrying out verification testing of the raw materials as supplied (Food Safety Authority of Ireland, 2005). It is particularly important to have good supplier control of raw materials that are able to support the growth of *L. monocytogenes*. For example, leafy greens such as lettuce, spinach, kale and rocket are known to support the growth of *L. monocytogenes* if contaminated (Culliney and Schmalenberger, 2020).

In the case of a food business operation that frequently purchases and uses specific ready-to-eat ingredients that may be potentially contaminated with *L. monocytogenes*, and it is known that the ingredient and/or the finished ready-to-eat food product is capable of supporting *L. monocytogenes* growth, it is advisable to structure the production schedule accordingly. Specifically, it is recommended to organise production runs in a manner that progresses from the lowest-risk products at the beginning of the day to the highest-risk products towards the end of the production cycle. For example, if making a variety of pre-packed sandwiches, the sandwiches with the lowest-risk ingredients, which are unlikely to be contaminated with *L. monocytogenes,* should be made

earlier in the production schedule. Sandwiches containing ingredients that are considered to be of a higher risk because there is a higher chance they might be contaminated with *L. monocytogenes* (e.g. raw leafy greens that are grown in or in close proximity to soil) are recommended to be made towards the end of the production schedule in order to limit the potential of cross-contamination to other items made on the same production line (British Sandwich & Food to Go Association, 2024).

6. Ready-to-eat area

Several risk areas within processing and storage facilities may be relevant, depending on the specific food business operation. Some products will require handling in a high-risk, high-care or ambient high-care area (Brand Reputation Compliance Global Standards, 2022a; 2022b). The food safety controls implemented within the factory environment should be appropriate to the designated risk area in order to minimise potential contamination with pathogens, particularly for ready-to-eat food products that are open to the environment. The higher the risk associated with a particular product, the greater the controls required. For simplicity, all of these different types of production risk areas will be more generally referred to as the 'ready-to-eat area' in this guidance note. Figure 2 shows a simplified example of a ready-to-eat food business site floor plan that demonstrates a high-level overview of the different areas within the operation and an indication of the process flow.

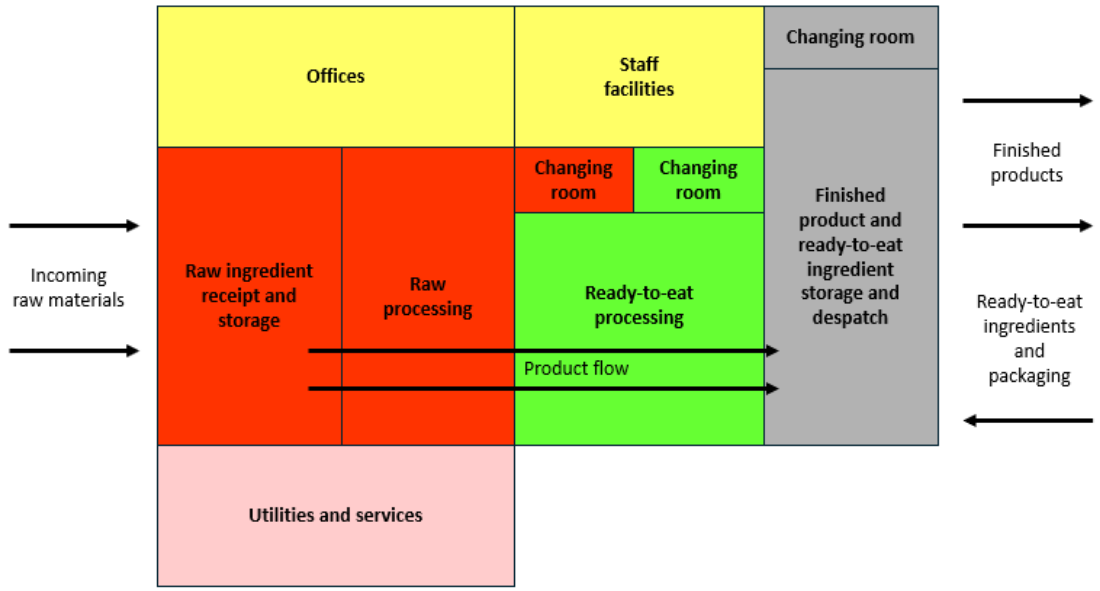


Figure 2 Simplified example of a ready-to-eat food business site layout with the operation areas and process flow indicated

6.1 Sampling locations in the ready-to-eat area

The specific locations in the ready-to-eat areas that should be considered for environmental monitoring for *L. monocytogenes* can be split into three categories, as shown in Figure 3. These three categories help to define the increasing risk of *L. monocytogenes* transfer from the environment to ready-to-eat food products:

1. At highest risk of transfer are food contact surfaces, which are areas where the food touches food processing surfaces or equipment. Examples are food preparation tables, conveyor belts, slicer blades, product utensils, and knives (Food Safety Authority of Ireland, 2005).
2. Indirect food contact surfaces are areas that do not touch the food directly, but where unintentional transfer can easily occur either directly or via transfer points such as hands (gloved or ungloved) or utensils. Indirect food contact surfaces could be the rollers of conveyor belts, control buttons on equipment, or parts of equipment very close to where food is in contact with the equipment.
3. Non-food contact surfaces are areas in the food production environment or parts of food processing equipment that are not in direct contact with the food. For example, this can be the outside of the food contact equipment, underneath the equipment, the framework of the conveyor, drains, door handles, light switches, extractor fans, ceilings, and hoods (due to contamination from condensation dripping on food or food contact surfaces).

Locations outside the ready-to-eat areas may also be considered, either to verify cleaning or to monitor the hygiene barriers. In the raw (non-ready-to-eat) manufacturing areas, the same three categories may be utilised in order to identify sampling locations for subsequent hygiene activities. As in the ready-to-eat areas, the highest risk of spreading contamination to other ingredients being processed will be from food contact surfaces. The surfaces in close proximity to the hygiene barriers are also significant, as they can provide insights into the level of contamination that the barriers are designed to manage. Examples are changing areas, openings between ready-to-eat and non-ready-to-eat areas, storage areas and maintenance workspaces.

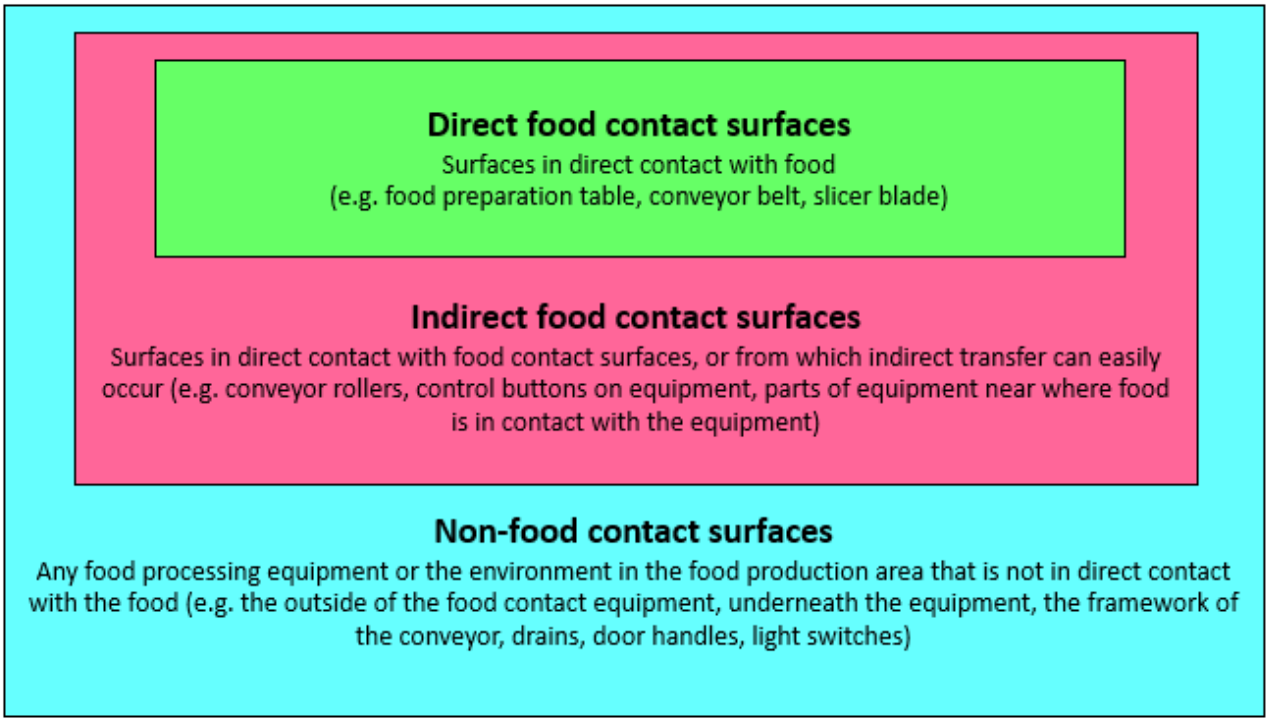


Figure 3 Types of surfaces that can be found in the food business operation environment

7. LEM programme

7.1 Food business operator management commitment

The senior management team should support the time and resources required to develop and implement an LEM programme. Under Chapter XIa of Regulation (EC) No 852/2004, as amended (European Commission, 2004), the senior management team shall encourage a food safety culture that drives the LEM team to find *L. monocytogenes* if present and enables them to complete the appropriate corrective actions to eliminate it. The LEM team also needs to be permitted to take proactive measures to prevent its recurrence when contamination of the food business operation environment is identified. This should cover any measures necessary to address and limit the spread of *L. monocytogenes* contamination.

7.2 How to create an LEM programme

The LEM programme limits the presence and survival of *L. monocytogenes* in the environment of the food business operation (i.e. on surfaces and in equipment) by identifying and appropriately managing or eliminating potential growth niches and harbourage sites, verifying the effectiveness

of the hygiene programme, and allowing for timely corrective actions. It involves systematic sampling and testing of surfaces, equipment, and processing areas to detect the presence of *L. monocytogenes*, and to ensure a hygienic production environment. In doing so, the potential for contamination of ready-to-eat food with *L. monocytogenes* will be minimised.

Microbiological testing functions primarily as a verification tool rather than a direct control programme; therefore, the LEM programme should not be regarded as a control programme (Grocery Manufacturers Association, 2018). Instead, it should be structured to assess the effectiveness of the GHPs/PRPs and HACCP-based procedures, under the food business operator's FSMS, in preventing cross-contamination of the finished product with *L. monocytogenes* from the food business operator's environment. An effectively implemented LEM programme offers a proactive approach to using the environmental monitoring data to pre-emptively detect and manage *L. monocytogenes* environmental contamination in various growth niches and harbourage sites before it cross-contaminates the finished product, which can possibly result in a withdrawal or recall of the food product from the market.

A successful LEM programme is one that rewards aggressive investigation to identify the root cause of the problem and implement appropriate corrective actions to address it. It does not penalise finding *L. monocytogenes* in the food business operator's environment. These positive results should be viewed as an opportunity to strengthen and improve the GHPs/PRPs and HACCP-based procedures under the food business operator's FSMS (Chilled Food Association, 2023; Grocery Manufacturers Association, 2018; Food Safety Authority of Ireland, 2005). Occasional positive results (i.e. for *Listeria* spp. and/or *L. monocytogenes*) should not be seen in isolation as a failure of control but as verification that the monitoring programme is effective. An LEM programme that is not capable of detecting contamination may be misleading, as the food business operator may believe that environmental contamination with *L. monocytogenes* is under control when in fact it may not be so (Food Safety Authority of Ireland, 2005).

Figure 4 demonstrates the six steps recommended to develop a successful LEM programme. More detailed information on how to carry out each step is provided on the pages that follow. It is recommended that the LEM programme targets the presence of both *L. monocytogenes* and other *Listeria* spp. While other *Listeria* spp. are not considered pathogenic (e.g. *L. innocua*), they are useful hygiene indicators of the potential presence of *L. monocytogenes*, as they survive under the same environmental conditions (Spanu and Jordan, 2020; Tompkin 2002).

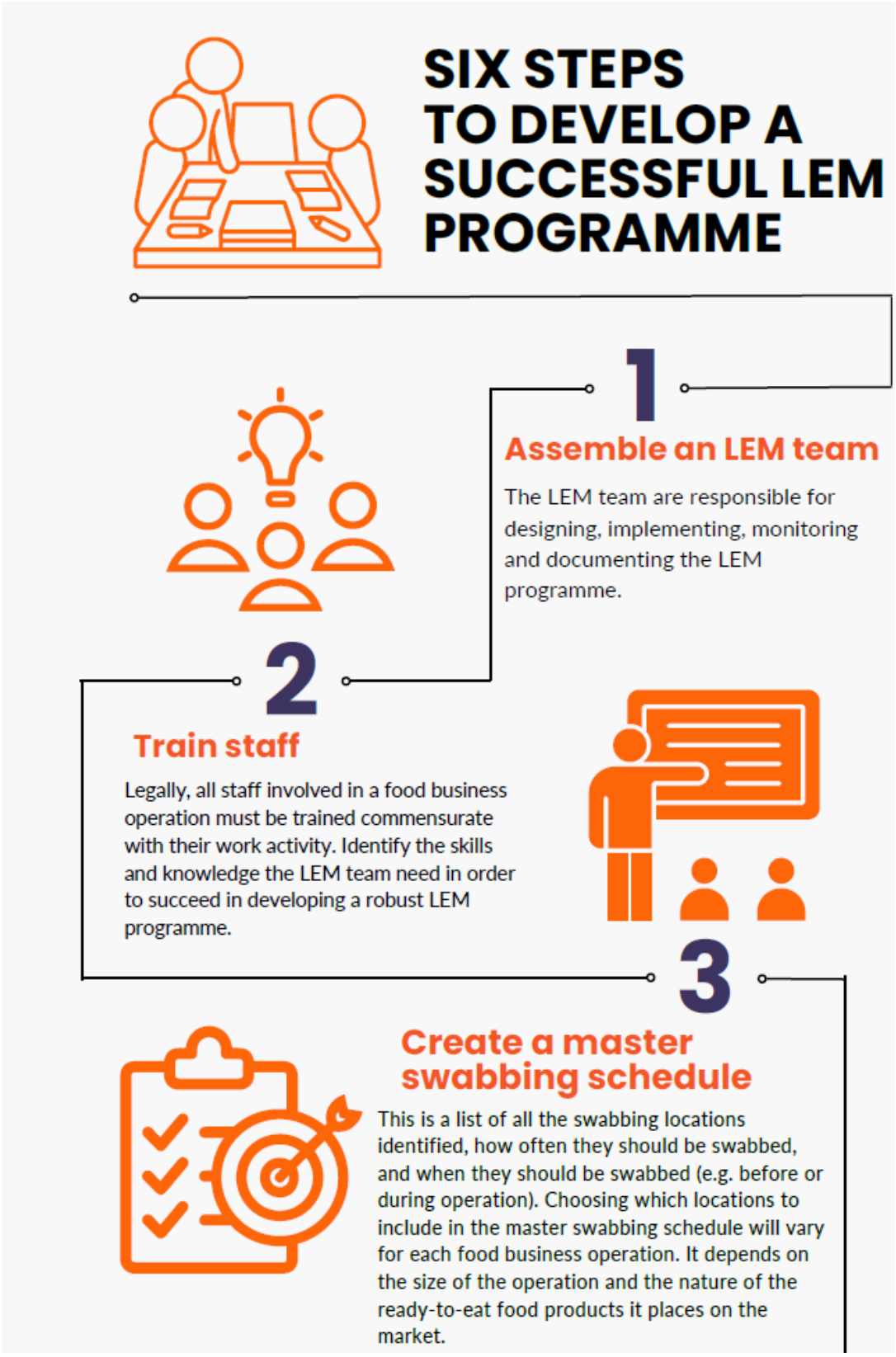

SIX STEPS TO DEVELOP A SUCCESSFUL LEM PROGRAMME
1
Assemble an LEM team
The LEM team are responsible for designing, implementing, monitoring and documenting the LEM programme.
2
Train staff
Legally, all staff involved in a food business operation must be trained commensurate with their work activity. Identify the skills and knowledge the LEM team need in order to succeed in developing a robust LEM programme.
3
Create a master swabbing schedule
This is a list of all the swabbing locations identified, how often they should be swabbed, and when they should be swabbed (e.g. before or during operation). Choosing which locations to include in the master swabbing schedule will vary for each food business operation. It depends on the size of the operation and the nature of the ready-to-eat food products it places on the market.

Figure 4 Six steps to develop a successful LEM programme

Step 1: Assemble an LEM team

The LEM team are responsible for designing, implementing, monitoring and documenting the LEM programme. As detailed in Table 1, the LEM team should include staff with applicable and useful knowledge of the day-to-day operations within the food business. It is recommended that the LEM team include representatives from the following areas: operations, engineering, quality/technical staff, and hygiene.

While large- to medium-sized food business operators may have departments for each of these roles, it is recognised that in small food business operations the same person may cover a number of these roles. Thus, the LEM team under these circumstances may consist of one to two people, depending on the size of the food business operator and the number of people employed in it. If the food business operator determines that some of the necessary expertise is not currently covered by staff within their business, it may decide that additional external support would be beneficial to facilitate the work of the LEM team. In this case, the food business operator is advised to source a suitable external consultant to work with it who has the appropriate knowledge and expertise of ready-to-eat food business operations (Food Safety Authority of Ireland, 2023; 2008; 2005).

Table 1 Suggested roles and responsibilities of the LEM team

Team member	Roles and responsibilities to develop and implement an LEM programme
Board member or senior manager	The board member or senior manager ensures that resources are made available to the LEM team. They are responsible for reporting back to the board on the progress and resources required in order to implement and maintain the LEM programme. They should be notified of any issues identified, investigations under way and actions taken.
Operations	The operations team member provides information about equipment used and staff movements around the food business operation when developing the LEM programme. If *L. monocytogenes* is detected in the food business operation environment, they have a key responsibility to investigate the root cause. For instance, they may monitor staff behaviours during operations, verify that staff training is current and sufficient, and ensure that equipment under investigation is available for thorough cleaning and disinfection. They may authorise additional disassembly for cleaning and disinfection, as well as further investigative swabbing if deemed necessary.
Engineering	The engineering team member provides insights into potential harbourage sites or growth niches within equipment or the food business operational environment. Additionally, it is important to inform the LEM team when planned preventative maintenance is scheduled.

Team member	Roles and responsibilities to develop and implement an LEM programme
	This maintenance may involve the removal of panels from equipment to facilitate deep cleaning and swabbing in harder-to-access areas. If *L. monocytogenes* is detected in the food business operation environment, the engineering team member's expertise will be instrumental in identifying possible harbourage sites within the equipment and assessing the time and resources required for disassembly.
Quality/technical	The quality/technical team member coordinates all the information required in order to develop and implement an LEM programme. They review and analyse all LEM test results in order to identify trends. They also ensure that appropriate actions are taken in consultation with the LEM team when *L. monocytogenes* is detected in the environment.
Hygiene	The hygiene team member provides information and staff training on the hygiene programme. They review data trends from the LEM programme in order to assess if the hygiene programme is fit for purpose, and they review hygiene team training needs in order to continuously support and improve it. The hygiene team member also supports the LEM team with knowledge of equipment and potential harbourage sites or growth niches in the operation.
Sample collector	The sample collector takes LEM swabs according to the master swabbing schedule for laboratory testing. If *L. monocytogenes* is detected in the food business operation environment, they take targeted investigative swabs in order to identify the point source of contamination in consultation with the LEM team.

Step 2: Train staff

Under Regulation (EC) No 852/2004, as amended (European Commission, 2004), it is a legal requirement that staff involved in a food business operation are trained and/or supervised commensurate with their work activity. The responsibility for the supervision and training of staff lies with the proprietor of the food business. It is recommended that the LEM team members receive specific training regarding the risks from *L. monocytogenes,* if they are not already knowledgeable on the topic.

For example, the training should cover aspects such as:

- An overview of *L. monocytogenes*
- Symptoms of listeriosis
- Vulnerable groups who are most at risk
- Relevant food safety legislation
- Intrinsic and extrinsic characteristics of ready-to-eat food that is able and unable to support the growth of *L. monocytogenes*

- Relevant case studies, where these are available (for example, Belias *et al.* (2021) presents a case study on root cause analysis of *L. monocytogenes* in an apple packing house that can be broadly applicable to different products and food processing operations).

In addition, all employees who work in the ready-to-eat areas of the food business operation are recommended to have a specific induction prior to them starting work in that area (see Information Box 4). Staff should be trained in the HACCP-based procedures implemented to prevent contamination of ready-to-eat food within the operation, and they should understand the importance of strictly adhering to these procedures. There are learning resources on food safety training and running a business that may be useful to prepare staff training sessions on the Food Safety Authority of Ireland (FSAI) website (www.fsai.ie). Appendix 1 also lists a number of other learning resources that may be useful when designing a targeted practical training programme on controlling *L. monocytogenes* to meet the needs of the food business operation.

If food business operators decide to employ the services of an external provider to assist them in developing the training session, the FSAI has a list of points to bear in mind when employing an external food safety trainer (Food Safety Authority of Ireland, 2023). It is recommended that annual refresher training for staff include material on controlling microbiological risk in food, including the risk from *L. monocytogenes.*

Information Box 4: Suggested points to be covered by a specific induction programme for production and hygiene operatives working in ready-to-eat areas

- Comprehensive training on their roles in preventing microbiological cross-contamination of ready-to-eat food by adhering strictly to the established procedures
- The importance of proper handwashing and the procedures around glove wearing/use
- Training on the exact procedures for moving between ready-to-eat and non-ready-to-eat areas and the use of dedicated personal protective equipment (PPE)
- Procedures on bringing any items into the ready-to-eat area
- The role of harbourage sites and growth niches and why it is important to precisely follow the hygiene programme procedures in order to eliminate *L. monocytogenes*
- Procedures on water management
- Procedures on waste management
- Cleaning and disinfection of equipment and the surrounding environment.

A dedicated learning session will also be required for any staff member(s) within the food business operation who have the responsibility to act as the sample collector(s) by swabbing the locations identified according to a precise swabbing protocol that is documented as part of the LEM programme. It will be their responsibility to take the LEM swabs according to the master swabbing schedule and to send these samples to the laboratory for testing.

Guidance on how to carry out swabbing of processing areas and equipment used in food production for the detection of *L. monocytogenes* is not in the scope of this guidance note. Information on how to develop factory-specific procedures for the sample collector(s) to follow are available in the specific guidance on *L. monocytogenes* detection published by the European Union Reference Laboratory for *Listeria monocytogenes* (EURL *Lm*) in *Technical guidance document on sampling the food processing area and equipment for the detection of* Listeria monocytogenes (EURL *Lm,* 2023), in ISO 18593:2018 *Microbiology of the food chain — Horizontal methods for surface sampling,* and in *Guide on best practices for surface sampling in the food industry* (Actia Chlean Joint Technological Network, 2021).

The quality of surface sampling to detect *L. monocytogenes* in the food business operation environment depends on how well the sampling is carried out according to a precise swabbing protocol that is documented as part of the LEM programme. It is important that the sample collector(s) are trained to a high standard in order to ensure that the influence of the person(s) taking the swabs is negligible (Actia Chlean Joint Technological Network, 2021). It is recommended to consistently use the same type and brand of swab from the same supplier for repeated swabbing of the same locations in order to ensure reproducibility of test results over time. Some specific points to consider when documenting the LEM swabbing protocol and training the sample collector(s) are provided in Information Box 5.

Information Box 5: Suggested points to include in the documented swabbing protocol and the associated training on how to swab surfaces and equipment in the food business operation

- Aseptic technique
- When the swabbing should be carried out (i.e. during or after production) depending on the objective of the sampling session (e.g. to identify environmental contamination in the food business operation or to verify that the hygiene programme was effective)
- How to know if a stick or sponge swab should be used, depending on the location
- What size surface area is to be swabbed, depending on the location
- How to know if a neutralising diluent is required
- How to know if the surface area is to be sampled using a wet or dry swab
- How to identify potential harbourage sites for swabbing that are outside the master swabbing schedule
- The precise technique to be used for the specific swab type used, such as:
    - The swabbing pattern
    - The number of times the area is to be swabbed in each direction
    - The pressure to be applied on the swab when sampling
    - The duration and intensity to be used when swabbing.

Specific guidance is available on the following topics:

- Timing and frequency of swabbing – Clause 7.4 of ISO 18593:2018 *Microbiology of the food chain — Horizontal methods for surface sampling* and Section 4 of *Technical guidance document on sampling the food processing area and equipment for the detection of* Listeria monocytogenes (EURL *Lm,* 2023)
- Use of neutralising diluents – Clause 5.3 and Annex A of ISO 18593:2018 *Microbiology of the food chain — Horizontal methods for surface sampling*
- How to swab – Clause 7.5.3 (for the stick swab method) and Clause 7.5.4 (for the sponge swab/cloth method) of ISO 18593:2018 *Microbiology of the food chain — Horizontal methods for surface sampling*.

Other useful training resources include the following:

- The EURL *Lm* has three short videos that show sampling techniques for stick, sponge and cloth swabbing of surfaces. These are available to view at https://sitesv2.anses.fr/en/minisite/listeria-monocytogenes/tutorials-implementation-sampling-techniques.
- The Actia Chlean Joint Technological Network guidance (2021) provides specific protocols for use of stick swabs and sponge/gauze swabs in descriptive sheets 4 and 5, respectively. These are available to download at: https://www.actia-asso.eu/en/surface-sampling/.

Step 3: Create a master swabbing schedule

The master swabbing schedule is a list of all the swabbing locations identified and the frequency of swabbing these locations. The frequency of swabbing for each location should be determined by the LEM team depending on the level of risk associated with it (e.g. weekly, monthly, or quarterly). The master swabbing schedule also states the time during the food operation schedule at which the locations are to be swabbed (e.g. at least 2 hours into production). The locations to be included in the master swabbing schedule should be chosen on a risk basis in agreement with the LEM team. The chosen locations will be different for every food business operation depending on its size, the nature of the ready-to-eat food products it places on the market, and its operation schedule.

An example of how to determine which locations should be included in a robust master swabbing schedule is outlined below in points i–viii. The swabbing frequency for the locations chosen should be rotated so that the entire master swabbing schedule is covered over a certain period of time, as defined by the food business operator on a case-by-case basis, depending on the risk and the nature and size of the food business operation (e.g. within 3 months/6 months/1 year).

i. Develop an LEM site floor map

The LEM site floor map should represent the food business operation's environment as accurately as possible. As there is a lot of information to include that could make the final map cluttered, the LEM team may wish to use a stepwise approach to capture the relevant information on a number of maps. Appendix 2 shows an example approach to producing a series of LEM site floor maps. This information can then be used to determine which locations should be included in the master swabbing schedule and how frequently these locations should be swabbed. The following non-exhaustive list is a suggestion of points to consider when developing an LEM site floor map:

- Obtain a copy of the food business operation's site floor plans, along with a list of permanent and mobile equipment by line or area.
- Highlight the ready-to-eat and non-ready-to-eat areas.
- Using the list of equipment, mark the location of each permanent item on the site map. Some or all of the mobile equipment could be listed too, if space allows.
- Consider the product, people, packaging and waste flows in the operation in the context of possible cross-contamination routes. Marking relevant flows on the LEM site floor map may be useful to consider where the transfer points may occur (see Information Box 6).
- Add in information to capture the points in the operation that act as barriers to prevent microbial contamination from moving from the non-ready-to-eat areas to ready-to-eat areas.

- Indicate the location of wall openings/hatches, doors, drains, sinks, condensate pipes, air vents, air lines, etc. on the LEM site floor map.

ii. Assess the potential for transfer points across any barriers segregating ready-to-eat and non-ready-to-eat areas

Transfer points are locations in the food business operation where environmental cross-contamination of *L. monocytogenes* may be transferred by a vector from a point source of contamination to ready-to-eat food that is open to the environment and/or to food contact surfaces. Walk the barrier in both the ready-to-eat and non-ready-to-eat areas to consider all of the possible transfer points across the barrier so these can be marked on the LEM site floor map. The LEM team should try to understand where all the gaps are and what items, activities and/or routes can occur through the gaps. If there is a walled barrier, look for all gaps in the barrier. If there is no walled barrier, but instead the barrier is marked out on the floor by a painted line or a change of floor colour, look for where the transfer points may occur.

Information Box 6 lists suggested items, activities and routes that could act as vectors of *L. monocytogenes* by transferring environmental cross-contamination from one location to another across a segregating barrier. The LEM team should determine which of these transfer points would be useful to include in the master swabbing schedule on a risk basis.

Information Box 6: Suggested items, activities and routes that could transfer *L. monocytogenes* contamination across a barrier from non-ready-to-eat to ready-to-eat areas:

- Incorrect design of, or practices in, changing rooms used to put on dedicated PPE, boot washers, or handwashing stations
- Racks used to transfer items to/from ovens/tunnels/batch cookers
- Areas where the floor often gets wet and there is staff or mobile equipment traffic over it
- Transfer/sharing of items or utensils between non-ready-to-eat and ready-to-eat areas, such as:
    - Quality control sampling tools (e.g. temperature probes, utensils)
    - Cleaning chemical containers and equipment (e.g. foaming machines)
    - Maintenance tools and maintenance activities.

Other items may also cross the barrier, such as:

- Pipework, air ducts
- Waste and packaging hatches/airlocks
- Sanitising tunnels.

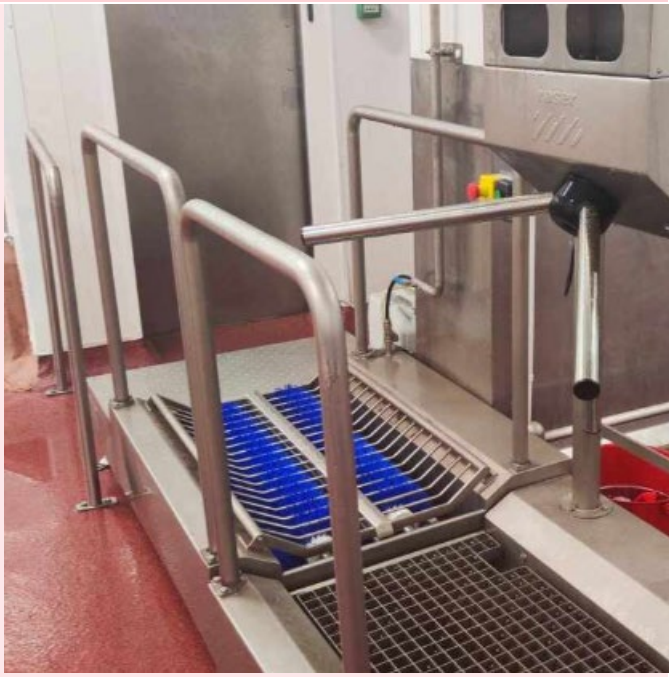
iii. Documenting the master swabbing schedule

When the LEM team agrees a list of all swabbing locations that merit inclusion in the master swabbing schedule, these should be listed in a suitable document that is in a user-friendly format (see the example master swabbing schedule template in Appendix 3). Table 2 outlines some examples of locations to consider for inclusion when designing the master swabbing schedule.

Table 2 Suggested locations to consider for inclusion in the master swabbing schedule

Potential issues		Picture
Damage in fabrication	Consult the maintenance list for fabrication items that are currently due attention. Inspect all parts of the building fabrication and list any areas that have damage, crevices or niches. Areas to consider include crevices between drains and flooring, cracks in concrete kerbing in the factory environment, blast chillers, chillers, damage to floors where pooling of water occurs, wall–floor junctions, leaking pipes, damage to ceilings, potential for dripping condensate from ceilings or equipment located overhead, etc.	
Conveyor belts	Check the design of the end rollers on conveyor belts to see if they are hollow and if water can seep inside. Some conveyors are boxed in at the end. It is recommended to always remove the end of the conveyors for easier access during cleaning and disinfection, and to release the conveyor so it can be lifted for easier access to the conveyor belt and the framework.	

Potential issues		Picture
Equipment that is difficult to clean and disinfect properly due to poor hygienic design and may act as harbourage sites or growth niches for *L. monocytogenes*	Slicing machines can be complex pieces of equipment with hard-to-reach areas that are difficult to hygienically maintain. Disassemble these machines as far as possible in order to thoroughly swab, clean and disinfect them.	
	Damaged gaskets and seals, as well as spaces between interfaces (such as metal-to-metal, metal-to-plastic, plastic-to-plastic) may harbour *L. monocytogenes* and become a growth niche.	

Potential issues		Picture
Cleaning equipment such as boot washers, floor cleaning machines, brushes, squeegees	Boot washers can harbour *L. monocytogenes* in pooling water and in the bristles. The disinfection chemicals can also run out if not monitored and maintained properly.	
	Cleaning tools such as brushes and squeegees can be a source of cross-contamination if they are not cleaned and maintained properly. Mops with hollow handles can be a source of contamination. Cleaning equipment should be dedicated to each area in the food business operation in order to limit cross-contamination.	

Potential issues		Picture
Wheels	Vehicle and container wheels (e.g. forklifts, hand trucks, tote bins, rack trolleys) can act as vectors that transport contamination around the food business operation's environment.	
Cables	Machine cables should be off the floor, as it can get dirty under the equipment. Mats that are used to cover cables on floors in order to control a trip hazard can become sources of contamination. Conduit pipe for cables can fill with water if damaged.	
Personnel	Footwear can act as a vector of contamination around the food business operation's environment if it is not hygienically maintained.	

Potential issues		Picture
Touch points	Control panels on equipment, door handles, light switches, emergency stop buttons, etc. are regular touch points and can be a source of cross-contamination.	
Waste management	Surfaces where waste hatches and bins are stored can become sources of contamination. Ensure that bins are foot operated.	

Assign each individual swab location a unique swab reference number, as shown in Table 3. This will ensure repeatability of the same sample location if different people act as the sample collector within a food business operation. It is recommended to document if the swabbing locations are in the ready-to-eat or non-ready-to-eat areas of the food business operation (see Figure 2), and what type of food contact surface they are (see Figure 3).

The type of swab that should be used to take the sample (e.g. sponge or stick) is also useful information to include on the master swabbing schedule in order to ensure consistency. The decision to use a stick or sponge swab is determined based on what would be best suited to the surface area that needs to be swabbed, the nature of the materials, and the area's accessibility. For example, sponges may be used for large flat surfaces, whereas stick swabs may be more appropriate for cracks and crevices and areas that are hard to access (Chilled Food Association 2023; Actia Chlean Joint Technological Network, 2021).

When the swabbing locations have been identified, it is recommended to mark them on the LEM site floor map with their swab reference number (see example maps in Appendix 2). This will assist the sample collector to know the exact location of the swab sampling points. An example master

swabbing schedule template is available to download in an Excel file to support this guidance note (see Appendix 3).

Table 3 Example of a master swabbing schedule

Swab reference number	Swab location description	Area	Food contact surface	Type of swab
S1	Pipe interior	Ready-to-eat	Direct food contact	Stick
S2	Slicer blade	Ready-to-eat	Direct food contact	Sponge
S3	Conveyor rollers	Ready-to-eat	Indirect food contact	Sponge
S4	Conveyor framework	Ready-to-eat	Non-food contact	Sponge
S5	Boot washer brushes	Ready-to-eat	Non-food contact	Sponge
S6	Production office floor	Non-ready-to-eat	Non-food contact	Sponge

iv. Frequency of swabbing and number of swabs to take

Under Article 5 of Commission Regulation (EC) No 2073/2005, as amended (European Commission, 2005), food business operators manufacturing ready-to-eat foods that may pose an *L. monocytogenes* risk for public health shall sample the processing areas and equipment for *L. monocytogenes* as part of their sampling scheme. However, the Regulation does not provide any information on how frequently a food business operator should carry out a monitoring programme for *L. monocytogenes* in the environment of its operation.

Routine swabbing to monitor contamination with *L. monocytogenes* in the food business operation's environment may be performed daily, weekly, fortnightly, monthly or quarterly, depending on the size and nature of the operation. It will depend on the amount of ready-to-eat food produced, the risk of *L. monocytogenes* harbourage in equipment or surfaces, the risk of contaminating ready-to-eat food that is open to the environment and/or other equipment in contact with food, and historical data for the food business operation.

In general, swabbing should take place more frequently when the food business operator first implements the LEM programme. Reviewing the trends in the test result data over the first 12–24 months of implementing the LEM programme can provide a good indication of whether to expand or reduce the number of swabs taken in certain locations of the operation based on the information generated (more information on how to trend testing data is provided in Step 4). Sampling sites and frequency will change and develop over time. For example, the detection of *L. monocytogenes* at a certain swabbing location should lead to an increased amount of investigative swabbing in

order to determine the root cause (see Step 5 and Section 8 of this guidance note). This could possibly lead to the introduction of another swabbing location into the master swabbing schedule over time as an outcome from the investigation. Alternatively, repeated negative results can indicate that a certain sampling location is of lower risk than previously thought, and swabbing of this location could be reduced or removed from the master swabbing schedule in favour of a different swabbing location known to be of higher risk.

The number of swabs routinely taken per swabbing session will vary depending on the nature and size of the operation and should be considered on a risk basis. For example, some pieces of equipment may require multiple sites to be swabbed during one session (e.g. a large conveyor belt or a complex piece of equipment that has several stationary and moving parts that come into contact with the food product). Some guidance documents recommend that small food business operations take approximately 5–10 swabs per LEM swabbing session to cover food contact and non-food contact surfaces in both the ready-to-eat and non-ready-to-eat areas of the operation (NSW Food Authority, 2019; United Fresh Produce Association, 2018; United States Food and Drug Administration Center for Food Safety and Applied Nutrition 2017). Medium- to large-sized food businesses that are more complex should consider taking a larger number of swabs per LEM swabbing session, according to their own needs based on the LEM team's assessment of the risk.

A risk-based approach is also used to determine the frequency of the swabbing sessions, which can vary for each food business operator depending on its needs. It is based on the characteristics of the ready-to-eat food it produces (i.e. the risk is greater if the product supports the growth of *L. monocytogenes*) and the methods used to produce those products (e.g. whether there is a listericidal process such as a heat treatment that has been validated and verified to remove microbial contamination in the raw materials). The LEM team should also consider if there is an opportunity for the food to be contaminated via the food business operation's environment, especially if the food has already been subjected to a listericidal process (e.g. post-process contamination of cooked deli meat via handling and slicing before putting it into the final package). In general, the greater the risk that a ready-to-eat food could become cross-contaminated with *L. monocytogenes* and support growth of the organism, the greater the frequency of environmental monitoring should be.

The LEM team may opt to keep a limited number of additional swabs available each week for flexible use, depending on the experience of the sample collector(s) with specific locations or events that may be deemed higher risk under certain circumstances. These additional swabs may not be specifically listed on the master swabbing schedule. If this is the case, the sample collector must be sure to precisely document the additional locations chosen on the master swabbing

schedule for each swabbing session in order to ensure accurate trending of the test results (see Step 4).

This allows the LEM programme to be dynamic and flexible in response to any changes to the operation's environment or production schedule that may increase the risk of *L. monocytogenes* contamination. Examples include repair or maintenance of equipment, new equipment being added to the operation, construction work to repair or extend the existing facility, or an increase in production capacity resulting in faster line speeds and/or increased staff numbers on the production floor. For instance, the sample collector may choose to monitor areas of pooling water, new cracks in the floor, or drain back-ups that may be evident at the time of swabbing. It should be noted that drain back-ups are particularly high risk. While it is appropriate to swab them at the time, they must also be addressed immediately according to a strict biosecurity protocol in the food business operation.

It is recommended to rotate the time period during the day that the locations are swabbed (e.g. morning, afternoon, evening) to get an idea of any potential contamination issues that may be emerging at different time points during the operation schedule. The LEM swabbing days should be rotated in order to cover all shifts during the production schedule and different days of the week (e.g. Monday on week/month 1, Tuesday on week/month 2) (EURL *Lm*, 2023).

Record any relevant details (such as swab location, production line number, time of day/shift) for each swab taken in order to allow good trending of the data generated (see Step 4). The timing should be varied to represent the entire schedule of the operation and to capture events that only occur periodically. This will help in investigating any issues that may occur (e.g. product and ingredient movement, activities before and after breaks, shift changeovers). The locations chosen for the routine swabbing schedule should be rotated so that the entire master swabbing schedule is covered over a certain period of time as defined by the food business operator on a case-by-case basis, depending on the nature and size of its food operation (e.g. within 3 months/6 months/1 year). Ensure that all of the necessary information is documented in the master swabbing schedule.

v. Time at which swabbing should be carried out

Typically, LEM swabs should be taken during production towards the end of a shift to get a sense of the worst-case scenario for environmental contamination in the food business operation, unless they are being taken with the specific aim of verifying the effectiveness of the hygiene programme. This is because it allows an adequate time period for *L. monocytogenes* (if present) to work its way

out of harbourage sites and to contaminate surfaces and equipment, thus maximising the chance of detecting the pathogen in the food business operation (PROFEL, 2020).

In some cases, the chemical agents used for the hygiene programme might have caused cell injury but failed to completely eradicate the pathogen. This means that the cells are still alive and could begin to grow again if they are exposed to the right conditions. This is known as a viable-but-nonculturable (VBNC) state, which means that the sub-lethally damaged cells may not be easily detectable if the swabs are taken too soon after the hygiene programme was implemented (EURL *Lm*, 2023; (International Organization for Standardization, 2018). Thus, the EURL *Lm* guidance (2023) and ISO 18593:2018 (Clause 7.4) recommend swabbing **after 2 or more hours into production or at the end of production runs** (i.e. before the hygiene programme is implemented).

vi. Use of neutralising diluents

In accordance with Clause 5.3 and Annex A of ISO 18593:2018, neutraliser **should not be added** to the diluent used to moisten swabs **when swabbing of surfaces or equipment is carried out during or at the end of production**, prior to the implementation of the hygiene programme. This is because the use of a neutraliser when no disinfectant residue is expected to be present on surfaces or equipment may in fact reduce the sensitivity of the swab to detect *L. monocytogenes* contamination. This unfavourable effect can be more pronounced when the cells are under stress (i.e. sub-lethally damaged cells in a VBNC state). Instead, simple diluents containing no neutraliser, as listed in Clause 5.1 of ISO 18593:2018, should be used to moisten the swabs prior to sampling if required.

While swabbing for additional hygiene indicators (as discussed in Section 3 and Appendix 4) can be valuable for verifying the overall effectiveness of the hygiene programme, only a limited number of LEM swabs should be used to confirm that cleaning and disinfection procedures specific to *L. monocytogenes* have been properly implemented as discussed in point vii and Table 4. If post-hygiene swabbing is carried out prior to the start of production, residual disinfectants on surfaces and equipment could reduce the sensitivity of the test to detect *L. monocytogenes*. **For post-hygiene swabs,** it is recommended to **add an appropriate neutraliser to the diluent** used to moisten the swabs in order to prevent any inhibitory effect of residual disinfectant on the growth of *L. monocytogenes* during analysis of the swab as per Clause 5.3 and Annex A of ISO 18593:2018.

It is recommended that the LEM team consult with the relevant third-party supplier (e.g. commercial laboratory) regarding the use of a neutraliser in the swab diluent, depending on

whether the purpose of the swabbing session is to detect *L. monocytogenes* before or after the implementation of the hygiene programme.

vii. Division of swabs pre- and post-implementation of the hygiene programme

The LEM team should determine an appropriate allocation of resources for the monitoring of direct and indirect food contact surfaces, non-food contact surfaces, finished food products, and raw materials on a risk basis depending on the nature and size of the operation. The LEM team may also consider including certain collector samples that could help identify potential issues with known point sources and vectors capable of transmitting *L. monocytogenes* to ready-to-eat food products or food contact surfaces (Campden BRI, 2022; Holah, 2022).

Monitoring to verify the efficacy of the hygiene programme specifically for *L. monocytogenes* is only recommended to be performed for a small number of swabs. However, if the product and/or raw ingredients are known by the LEM team to be a potential source of environmental contamination with *L. monocytogenes* during production (e.g. washed or unwashed salad leaves with no thermal decontamination), the LEM team may decide based on its own experience that it is more beneficial to know post-hygiene that *L. monocytogenes* has been removed from the high-care area (United Fresh Produce Association, 2018).

The detection of *L. monocytogenes* on food contact surfaces post-implementation of the hygiene programme indicates a serious failure in cleaning and disinfection procedures that requires immediate investigation (EURL *Lm*, 2023). The LEM team should assess whether the overall hygiene programme has failed, as indicated by associated unsatisfactory levels of hygiene indicators at the same location, or if the hygiene programme is specifically insufficient in controlling *L. monocytogenes* contamination in the food business operation. If the hygiene programme's performance was acceptable to control the presence of hygiene indicators but not of *L. monocytogenes*, action should be taken to rectify this; for example, retraining of hygiene operatives, reviewing and updating of cleaning instruction cards, the use of additional chemicals that have targeted action against *L. monocytogenes*, and/or additional dismantling of the equipment prior to cleaning and disinfection (Holah, 2022; Campden BRI, 2022; 2020b; 2020c).

Table 4 shows a suggested example of how to split the percentages of swabs taken during an LEM swabbing session for both routine and investigational swabbing (adapted from Table 2 in Holah, 2022, p. 394). Table 5 shows an example master swabbing schedule that shows the division of swabs pre- and post-implementation of the hygiene programme, along with the recommended frequency of swabbing at each designated location.

Table 4 Suggested percentages of swabs to be allocated for swabbing pre- and post-hygiene programme implementation for routine and investigational swabbing

Sampling point	Routine swabbing according to the master swabbing schedule		Investigational swabbing to determine a point source	
	Percentage of swabs taken	Comments	Percentage of swabs taken	Comments
Barriers	30%	The number of swabs depends on the number of low/high hygiene barriers.	20%	Focus on barriers that the root cause investigation indicated may have been compromised.
Sources and vectors	40%	This should include swabbing barrier controls, known sources and vectors, plus additional resources for flexible swabbing of potential sources and vectors.	65%	Repeat swabbing of potential sources and vectors to assess their risk.
Collector samples	20%	The number of swabs is dependent on the type of food process and the number of potential collectors.	5%	The allocation of swabs is intentionally kept at a reduced level to prioritise increased capacity for source and vector assessment.
Post-hygiene	10%	The number of post-hygiene swabs should always be low. Other monitoring information may be available, such as visual assessments, sign-off sheets, rapid hygiene tests.	10%	The allocation towards post-hygiene swabbing should be low.

Note: Table adapted from Table 2 in Holah, 2022, p. 394.

Table 5 Example master swabbing schedule with sampling frequency incorporated

Swab reference number	Location description	Area	Type of swab	Sampling frequency[a, b, c]			
				Week/ month/ quarter 1	Week/ month/ quarter 2	Week/ month/ quarter 3	Week/ month/ quarter 4
S1	Pipe interior	**Ready -to-eat**	Stick	**Post-hygiene**			
S2	Slicer blade	**Ready -to-eat**	Sponge		**During production**		
S3	Conveyor rollers	**Ready -to-eat**	Sponge			**Post-hygiene**	
S4	Conveyor framework	**Ready -to-eat**	Sponge				**During production**
S5	Boot washer brushes	**Ready -to-eat**	Sponge	**During production**			
S6	Production office floor	**Non-ready-to-eat**	Sponge		**During production**		

[a] The sampling frequency will be determined by the LEM team on a risk assessment basis. It will vary depending on the nature and size of the food business operation.

[b] Blue cell = swabs taken at least 2 hours into the food business operation's production schedule.

[c] Purple cell = swabs taken after the hygiene programme has been implemented.

viii. Changes to the environment

The master swabbing schedule should be dynamic and reviewed regularly in order to consider any relevant changes to the environment that could then become a source of contamination. Any change from the standard operating procedures and/or practices will require a review of the LEM programme by the LEM team. The following activities in the food business operation environment may trigger a change to the master swabbing schedule in order to manage the risk of *L. monocytogenes* contamination:

- Significant changes to raw materials or the suppliers of the materials, or new product development
- Different operation hours
- Changes in the hygiene programme
- Introduction of new equipment
- Building work to extend, repair or replace structural parts of the building

- Line maintenance, which can disturb potential harbourage niches of *L. monocytogenes* that may be deep within the equipment
- Breaches to the ready-to-eat area, such as roof leaks, blocked drains or flooding.

Step 4: Trend test results

Analysing trends in test results is a legal requirement under Article 9 of Commission Regulation (EC) No 2073/2005, as amended (European Commission, 2005). It can also provide the LEM team with useful data to identify the areas of the operation that are most problematic in terms of *L. monocytogenes* environmental contamination. All newly reported test results should be promptly incorporated into the dataset in order to ensure that the information remains as current and accurate as possible. The LEM team should regularly review the trends in test result data. If the LEM team observes a trend towards unsatisfactory results, it must take appropriate actions without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks (Food Safety Authority of Ireland, 2005; 2014). In addition, trending of LEM test result data is important in order to monitor the effectiveness of actions taken.

The master swabbing schedule could be utilised to trend LEM test result data by changing the boxes to green for not detected and red for detected, as shown in Table 6. A further example is provided in the Excel file template provided as supporting documentation to this guidance note (Appendix 3). The trends could also look at different areas of the food business operation, different times of day, post-hygiene versus during production, different shifts or teams, etc. This largely depends on the data collected and what the LEM team decides would be most beneficial for the food business operation.

i. Trending data using a hot spot map

Another option to visually trend LEM data, along with test results for environmental monitoring of other hygiene indicators (e.g. *Listeria* spp., Enterobacteriaceae, aerobic colony counts (ACCs), adenosine triphosphate (ATP)), is to utilise the LEM site floor map to generate a hot spot map. This can be done by placing coloured dots at the relevant locations on the LEM site floor map to correspond to all instances of *L. monocytogenes* detection in the environment over a certain period of time, as defined by the LEM team. For example, this time period could correspond to the duration required for the food business operation to complete the entire master swabbing schedule. A different coloured dot could be used to represent other test parameters for environmental hygiene indicators on surfaces/locations that are out of specification. An example of an LEM site floor hot spot map showing routine detections of *L. monocytogenes,* along with other

test parameters for environmental hygiene indicators that were unsatisfactory, is provided in Appendix 2 (Figure 8). See Appendix 4 for information on how to determine microbiological criteria for hygiene indicators on surfaces.

Table 6 Example of how the master swabbing schedule could be used to trend LEM test results

Swab reference number	Location description	Area	Swab type	Sampling frequency[a, b]			
				Week/ month/ quarter 1	Week/ month/ quarter 2	Week/ month/ quarter 3	Week/ month/ quarter 4
S1	Pipe interior	**Ready-to-eat**	Stick	**Not detected**			
S2	Slicer blade	**Ready-to-eat**	Sponge		**Detected**		
S3	Conveyor rollers	**Ready-to-eat**	Sponge			**Detected**	
S4	Conveyor framework	**Ready-to-eat**	Sponge				**Not detected**
S5	Boot washer brushes	**Ready-to-eat**	Sponge	**Not detected**			
S6	Production office floor	**Non-ready-to-eat**	Sponge		**Not detected**		

[a] The sampling frequency will be determined by the LEM on a risk assessment basis. It will vary depending on the nature and size of the food business operation.

[b] Pink cell = Location not swabbed for testing.

ii. Continuous 'not detected' test results

Environmental contamination is a major source of post-processing contamination of food products. Managing *L. monocytogenes* contamination is challenging because this pathogen is common in various environments outside processing plants and can persist in the environment of food business operations for years (Malley *et al.*, 2015). If the test results obtained for *L. monocytogenes* in the environmental monitoring swabs tested by a food business are always returning a 'not detected' test result, it is recommended that the suitability and sensitivity of the LEM programme is reviewed in order to ensure that a source of possible environmental contamination is not being missed.

As *L. monocytogenes* is known to be commonly found in the environment of food business operations and in certain raw materials, both of which may cause cross-contamination of surfaces and equipment within the operation, it can be expected that both transient and persistent strains of the pathogen will be occasionally detected if food business operator has a robust LEM programme in place. It would be considered unusual if a food business operation did not detect *L. monocytogenes* in the environment from time to time considering these factors.

Thus, it is more beneficial if the LEM programme is successful in seeking out potential sources of *L. monocytogenes* environmental contamination so the LEM team within the food business operator is aware of them and can take actions to manage the possible risks to public health appropriately. If a food business operation is always obtaining 'not detected' test results for its LEM programme, this can lead to a false sense of security, when in fact a possible source of environmental contamination may have been missed due to inadequacies in the LEM programme (Food Safety Authority of Ireland, 2005). Instead, food business operators are encouraged to take a seek-and-destroy approach when designing, implementing and reviewing the LEM programme, with the goal of either eradicating or mitigating the effects of any *L. monocytogenes* strains detected in the food business operation, as described by Malley *et al.* (2015) and Butts (2003).

It is also advised to assess whether the analytical method being used to test the swabs is suitably sensitive and fit for purpose. It is recommended to check that the testing laboratory is accredited to use the test method for the types of swabs the food business operator uses (Food Safety Authority of Ireland, 2021). The analytical reference method is ISO 11290-1:2017. Alternative analytical methods are permitted if they meet the requirements listed in Article 5.5 of Commission Regulation (EC) No 2073/2005, as amended (European Commission, 2005). Alternative or rapid methods may have advantages over the reference test method, such as a shorter time to result or being easier to use. However, the alternative method must be validated in order to show that it can provide at least equivalent guarantees of the relative accuracy, specificity, sensitivity and limit of detection compared with the relevant analytical reference method. It must be able to detect all target strains and not to have cross-reactions with non-target strains compared with the relevant analytical reference method (i.e. inclusivity/exclusivity testing).

Step 5: Establish corrective action procedures

If a food business has a robust LEM programme in place, it can be expected that *L. monocytogenes* will be occasionally detected in the environment of the operation. When this occurs, it is crucial for public health that the consequences of *L. monocytogenes* detection in the environment, and the potential for cross-contamination of the final ready-to-eat food product(s)

produced, are risk assessed and investigated thoroughly in a timely manner. The LEM team must work together in order to determine the potential root cause of the contamination event, to eliminate the pathogen from the environment, and to appropriately manage the risk to public health.

Corrective actions in response to a positive *L. monocytogenes* detection in the environment should be established by the LEM team in advance of a contamination event. The LEM team must document these corrective actions as part of the LEM programme under the food business operator's food safety management system (FSMS). Table 7 provides examples of areas to review and corrective actions to consider when investigating detections of *L. monocytogenes* in the environment of a food business operation. Information Box 7 provides an example of corrective actions taken after a root cause analysis identified a drain as the source of the *L. monocytogenes* contamination.

Section 8 of this guidance note also outlines additional investigational procedures to consider if a more comprehensive investigation is needed. This is particularly relevant when the LEM team are managing an ongoing persistent contamination issue, as indicated by repeated detection of *L. monocytogenes* in the final product and/or the environment of the food operation, despite the implementation of corrective actions, and when the team are unable to sufficiently identify the root cause of the contamination event.

Table 7 Suggested corrective actions for the LEM programme that would be triggered if *L. monocytogenes* is detected

Aim of corrective action	Suggested corrective actions to include in the LEM programme
Manage the potential risk to ready-to-eat food	• Assess and document the *L. monocytogenes* cross-contamination risk to all batches of ready-to-eat food produced during the relevant time frame. • In accordance with Article 19 of Regulation (EC) No 178/2002 (European Commission, 2002), notify the relevant competent authority **immediately** if any food placed on the market is deemed unsafe in accordance with Article 14 of Regulation (EC) No 178/2002 (European Commission, 2002). See Section 1.7 for more information. • If unsafe ready-to-eat food has been placed on the market, conduct a traceability exercise to identify onward supply of the suspect product(s), batch number(s), use by/best before dates, quantities, etc. See *Guidance Note No. 10* for guidance on product recall and traceability (Food Safety Authority of Ireland, 2013). • If all, or some, of the potentially contaminated food products are under the control of the food business operator, place these on hold pending further investigations. This is especially important for ready-to-eat food products that can support the growth of *L. monocytogenes* that are food category 1.2 under Commission Regulation (EC) No 2073/2005. Notify your inspector regarding a batch of potentially contaminated food product even if it is still within your control.
Ensure that the FSMS is functioning and fit for purpose	• Review Hazard Analysis and Critical Control Point (HACCP) records and talk to production staff to determine whether all operational parameters were within specification during the time period under investigation. • Carry out a detailed analysis and review of all microbiological test results for raw materials, finished product testing and environmental monitoring. Use trending to understand where and when test results are out of specification (see Step 4). • As part of the investigation, determine whether the current good hygiene practices (GHPs)/prerequisite programmes (PRPs) and HACCP-based procedures are fit for purpose. If not, ensure that the necessary modifications are made to prevent recurrence.
Ensure that the hygiene programme is adequate	• Assess if any other hygiene indicators were unsatisfactory for the area under investigation during the corresponding time period. This may

Aim of corrective action	Suggested corrective actions to include in the LEM programme
	indicate an entire failure of the hygiene programme (e.g. due to complex equipment requiring further disassembly) or, if only *L. monocytogenes* was detected after the hygiene programme was implemented, it may indicate a specific failure related to its control (e.g. cleaning and disinfection chemicals do not have appropriate targeted action for *L. monocytogenes*). • Deep clean and disinfect any surfaces or equipment under investigation. Dismantle any implicated equipment as much as possible in order to assess if it could be a potential source of contamination. • Implement improvements to the hygiene programme procedures as necessary (e.g. review efficacy of chemicals, sufficiency of staff training).
Evaluate the role of barriers and vectors in the contamination event	• Review test results for all barriers and vectors that move across the area during the time period under investigation. • Consider and rectify any possible weaknesses in vector and/or barrier control (e.g. poor maintenance of boot washers, drains). • Review staff movement, waste removal, staff training, etc. to determine whether any breaches to operational procedures may have occurred. • Consider if any recent changes or events in the food business occurred that might have introduced contamination to the operation.
Determine the root cause of the contamination event	• Carry out a thorough investigation to identify the root cause of contamination • Increase environmental swabbing for *L. monocytogenes* in the area under investigation and final product testing until the root cause is determined and appropriate corrective actions implemented. • If the LEM team are unable to sufficiently identify the root cause of the contamination event, or if *L. monocytogenes* is detected repeatedly despite the implementation of corrective actions, consider if more comprehensive investigative procedures are necessary (see Section 8 of this guidance note).
Evaluate the long-term implications of the contamination event	• Consider if further molecular characterisation by whole genome sequencing (WGS) of the *L. monocytogenes* strains isolated would be useful to determine whether the same strain of *L. monocytogenes* is persistent throughout the factory. This can also help provide clues as to the potential root cause(s) of contamination and implications for future safe processing (see Section 10).

Information Box 7: Example of actions taken to manage an environmental source of *L. monocytogenes* contamination in a food business operation

In this example scenario, the LEM team carried out a root cause analysis following the detection of *L. monocytogenes* in environmental swabs and in ready-to-eat food products.

The LEM team identified a drain located in the ready-to-eat area as the source of the *L. monocytogenes* contamination. By reviewing operational procedures in the vicinity of the drain, the LEM team identified that the wheels of a certain tote bin frequently moved over the drain, thereby acting as a vector of contamination. Analysis of *L. monocytogenes* isolates that originated from the drain, the tote bin wheels, and ready-to-eat finished product by WGS demonstrated that they were all contaminated by a genetically similar *L. monocytogenes* strain.

The LEM team determined that an intervention needed to be put in place in response to the point source contamination (i.e. the drain) and vector (i.e. the tote bin wheels) identified.

The following actions were taken to prevent recurrence of the issue:

- The drain was cleaned and disinfected thoroughly (Campden BRI, 2020a). It was re-swabbed post-hygiene in order to ensure that the *L. monocytogenes* contamination identified was removed.
- The hygiene procedure for the drain was updated. The responsible staff were retrained. New hygiene cards were produced to support the correct implementation of the updated procedure (Campden BRI, 2020a; 2020c).
- The wheels of the tote bin were thoroughly cleaned and disinfected.
- A new hygiene procedure was agreed that allowed the hygiene team to spray the drain and the wheels of the tote bin with an appropriate chemical during production, which was validated to show it would suppress the growth of *L. monocytogenes.*
- In order to establish how frequently this procedure should take place, the drain was swabbed post-hygiene to ensure that the *L. monocytogenes* is removed through routine cleaning, then every 2 hours to understand at what point *L. monocytogenes* re-emerges.
- Deep cleaning of the drain and the tote wheels was completed at 6.00am; thus, the area where the tote bin wheels pass over the drain was swabbed at 8.00am, 10.00am, 12.00pm, etc.
- After deep cleaning at 6.00am, *L. monocytogenes* was first detected again at 10.00am. The LEM team used this information to implement the new hygiene procedure of spraying the drain and wheels of the tote bin with an appropriate chemical every 4 hours in order to suppress the re-emergence of *L. monocytogenes* after deep cleaning.
- The new hygiene procedure was implemented during production hours to prevent the risk of cross-contamination to ready-to-eat food, which could occur if the drain is dismantled for deep cleaning during the manufacturing hours when ready-to-eat food was being produced.

Step 6: Review

The LEM team member(s) with responsibility for reviewing and trending test results (e.g. quality/technical staff) should do so as soon as possible after receiving the results from the laboratory. They should also ensure that any necessary corrective actions required for the detection of *L. monocytogenes* in either food products or the environment are carried out in accordance with the food business operation's documented corrective action procedures.

Additionally, the LEM team should agree a regular frequency to meet (e.g. monthly/quarterly) in order to review and discuss test result data, trends, effectiveness of any corrective actions taken, and any changes to the environment such as the introduction of new equipment, building work, etc. The master swabbing schedule is a living document that can be adapted and changed based on the experience of the LEM team and what would suit the needs of the food business operation best. It is advisable for the LEM team to routinely evaluate the effectiveness of the master swabbing schedule. If it is determined to be inadequate, appropriate amendments and updates to the document should be made accordingly.

7.3 Documentation requirements

Once the LEM programme is finalised, all relevant details must be documented as part of the food business operation's FSMS. This documentation should include information regarding the members of the LEM team, their respective roles and responsibilities, and staff training protocols. The master swabbing schedule should be documented and should include detailed information on the locations to be swabbed, the frequency and timing of the swabbing procedures, etc.

Additionally, the swabbing procedure, analysis and trending of test results, and the actions to be taken in the event that *L. monocytogenes* is detected in the food business operation environment should be clearly documented. An implementation project plan should be established in order to ensure that the LEM programme is carried out as planned by the LEM team.

8. Investigational procedures for persistent detections of *L. monocytogenes*

Ongoing persistent issues with *L. monocytogenes* contamination within the food business operation's environment requires a comprehensive investigation into the matter. The LEM team's role during this investigation is to identify and effectively manage the problem to prevent future recurrence. To initiate this process, it is recommended that the LEM team meet to discuss and identify the primary reasons that may have led to the contamination issue occurring. For example, this could be done by using structured problem-solving techniques such as root cause analysis (Belias *et al.,* 2021; Juran, 2018). The Food Standards Agency in the United Kingdom has an eLearning module on how to carry out root cause analysis targeted to food businesses (Food Standards Agency, 2024a).

To prepare for the meeting, the LEM team should gather as much information as possible about the issue under investigation. For instance, it is important to consider recent test result data and the trends of historical data for the area or location under investigation. Additionally, information regarding the performance of the hygiene programme in that specific area is essential. Details should also be gathered on any relevant changes or issues that may have contributed to the contamination event, such as an increase in production volume, the introduction of new equipment or personnel, related problem areas identified under the hygiene programme, and recent building or maintenance activities.

The food business operator needs a clear understanding of all factors that may have caused the contamination event in order to determine where to focus their investigation. It is recommended that the LEM team begin the investigation process by reviewing the HACCP-based procedures to verify that the critical control points (CCPs) are being implemented as they should be, and that the food safety of the manufacturing process has not been compromised. It is also advised to review historical data trends to establish if a contamination event similar to one under investigation has occurred before, and if so, was the root cause determined and appropriately managed to prevent recurrence.

While recognising that the contamination issue may be unique to each food business, and the situation may vary depending on the nature and size of the operation, the LEM team are recommended to conduct a joint visit to assess hygiene practices and operational procedures in the food business. Special attention should be given to certain areas of the food business operation during this assessment in order to aid in gathering additional information for the investigation. Table 8 provides some practical suggestions for areas to focus on when conducting the investigation process.

Once the potential root cause(s) are identified, corrective actions should be developed and implemented to adequately manage the problem identified, and to prevent recurrence. Depending on what was identified as the root cause of the problem, the corrective actions may include changes or improvements to procedures, upgrades to equipment and/or fabrication, and/or improvements to staff training procedures (Table 8). Any remedial actions put in place must be monitored appropriately to verify the effectiveness of these actions (e.g. by carrying out follow-up swabbing to verify effectiveness). Lessons learned from the root cause analysis should be incorporated into ongoing quality control and operational practices. By systematically addressing root causes, a food business operation can enhance its overall FSMS, thereby reducing the risk of contamination issues with *L. monocytogenes* recurring.

Table 8 Suggested areas to review and questions to ask during the investigation process

Area	Suggested topics for discussion
Operations	• Review any recent changes to the environment (e.g. increased production volume, new equipment, changes to fabrication or building, maintenance work, new chemicals, new ingredients, new supplier, new staff). • Review staff training and establish if correct procedures were followed. • Assess if any breaches of barriers segregating ready-to-eat and non-ready-to-eat areas could have occurred. • Review flows of people, product and equipment, along with the hot spot map. For example, are there any routes which are heavily used that pass by the possible source of contamination (e.g. a drain), which could act as a vector, and can it be rerouted?
Engineering	• Check if there was any planned maintenance or unexpected engineering issues (e.g. breakdown of equipment) in the area during the time frame under investigation. • Consider if sufficient hygiene procedures can be established to effectively manage and mitigate the risk of *L. monocytogenes* cross-contamination from any suspected equipment, or if it would be more appropriate to replace the equipment.
Quality/ Technical	• Conduct a traceability exercise to establish all food products that may have been in contact with the area/location during the time frame under investigation. • Review all raw materials that were used to make these products, including the results of any microbiological tests that may have been carried out. • Review if there is a correlation between detection of *L. monocytogenes* in the final product and in the equipment used, and/or in food surfaces it was in contact with during the manufacturing process (e.g. *L. monocytogenes* detected in sliced cooked deli meat, and in the environmental swabs of the slicer that was used to slice the cooked meat).

Area	Suggested topics for discussion
	• Consider if there was any potential cross-contamination of *L. monocytogenes* from environmental sources to food products open to the environment (e.g. risk of splashes from standing water or a wet floor coming into contact with open products transported via a racking trolley without a solid base, air from fans used to cool down product, condensation drips on to open product, dust from building or maintenance work taking place nearby).
Hygiene	• Review hygiene schedules, hygiene procedures and staff training in area where *L. monocytogenes* was detected. Observe the hygiene team to assess if the correct procedures are being followed, such as correct use of chemicals and hygiene equipment. • Consider if any recent hygiene issues occurred in the area and time frame under investigation (e.g. drains blocked or backed up). • Review the hygiene procedure for any equipment suspected of being a harbourage point or growth niche for *L. monocytogenes*. Assess whether the current level of disassembly for that piece of equipment prior to implementing the hygiene programme is sufficient. If not, determine whether further disassembly of that piece of equipment can be conducted in-house or if a qualified specialist is necessary, such as a manufacturing engineer from the equipment manufacturer. • Assess if the frequency of cleaning and disinfection for any equipment or surfaces suspected of being a harbourage point or growth niche for *L. monocytogenes* is adequate and/or has been implemented correctly. Consider if the *L. monocytogenes* contamination could be protected by a biofilm that needs physical removal (e.g. through vigorous scrubbing actions or use of an acidic chemical). • Consider if contamination could have been spread through use of cleaning water hoses in the ready-to-eat areas, as they can create aerosols and spread contamination.
Sample Collector	• Take additional swabs as agreed with the LEM team to investigate the root cause of the contamination issue. • If a new location is being swabbed as part of the investigation, assign it a new swab reference number and log all the relevant information (e.g. swabbing point description, time, shift) to the master swabbing schedule. • Trend data related to all investigative LEM swabs should be analysed separately from data related to the routine swabs, so that the progress in identifying and tackling the source and/or vectors of the contamination can be monitored.

8.1 Trending investigative data

As previously discussed in Section 7.2, Step 4, it is a legal requirement under Article 9 of Commission Regulation (EC) No 2073/2005 to trend test result data (European Commission, 2005). Trending of *L. monocytogenes* detection data is also very valuable when investigating the potential root causes of a contamination event in the environment of the food business operation. Obtaining a clear and thorough understanding of the data is the most important part of performing a trend analysis (European Centre for Disease Prevention and Control, 2024). To maintain the integrity of the routine testing data and to avoid sampling bias, it is recommended to trend investigative data separately from the data generated by routine swabbing conducted in accordance with the LEM master swabbing schedule.

When reporting the detection of *L. monocytogenes* during a complex investigation of contamination within the food business operation environment, it may be more beneficial to present a rolling summary of weekly percentage pass rates instead of a monthly total. This approach offers a more current view of contamination levels within the factory environment. It can also help to determine whether the numbers of positive environmental detections of *L. monocytogenes* are increasing in certain locations known to be problematic, which may suggest that additional adjustments to the LEM programme may be necessary (e.g. improvement of the hygiene procedures). An illustrative example is provided in Table 9.

Appendix 3 outlines the contents of an Excel file template which is provided as a supporting document to accompany this guidance note. Tab 5 of the Excel file contains an example of how investigative LEM data can be trended. Tab 6 of the Excel file contains an example blank template that food business operators may modify and edit as required to enable them to trend investigative LEM data.

8.2 Trending investigative data using a hot spot map

If during an investigation, the food business operator frequently detects *L. monocytogenes* within shorter time frames, it may be more suitable to represent the findings as a cumulative percentage pass rate, as outlined in Table 9, on the LEM site floor map instead of using coloured dots. This approach may enhance the visual clarity of the map. An example of an LEM site floor hot spot map with cumulative percentage pass rates for environmental detection of *L. monocytogenes* is provided in Appendix 2 (Figure 9).

Table 9 Percentage pass rates for *L. monocytogenes* investigative swabs

Swab reference number	Location description	Area	Swab type	Week number[a]						Cumulative pass rate[b]
				1	2	3	4	5	6	
S1	Pipe interior	RTE	Stick	**Not detected**	**Not detected**	**Detected**	**Not detected**	**Not detected**	**Detected**	**67%**
S2	Slicer blade	RTE	Sponge	**Detected**	**Detected**	**Detected**	**Not detected**	**Detected**	**Not detected**	**33%**
S3	Conveyor roller	RTE	Sponge	**Not detected**	**Not detected**	**Not detected**	**Not detected**	**Not detected**	**Not detected**	**100%**
S4	Conveyor framework	RTE	Sponge	**Not detected**	**Not detected**	**Not detected**	**Not detected**	**Not detected**	**Not detected**	**100%**
S7	Blade holder	RTE	Sponge	**Not detected**	**Detected**	**Not detected**	**Not detected**	**Detected**	**Not detected**	**67%**
S8	Tote bin wheel	RTE	Sponge	**Not detected**	**Not detected**	**Not detected**	**Not detected**	**Not detected**	**Not detected**	**100%**
Weekly pass rate[c]				**83%**	**67%**	**67%**	**100%**	**67%**	**83%**	

[a] *The frequency of increased swabbing in the area under investigation will be determined by the LEM on a risk assessment basis and may vary from the example provided in Table 9.*

[b] *In this example, the cumulative pass rate (%) is calculated as a rolling percentage pass rate that is updated on a weekly basis once the latest test results become available. Cumulative pass rate (%) = [**number of swabs where L. monocytogenes was not detected ÷ total number of swabs tested** per location during the cumulative investigative time period] x 100. This cumulative pass rate (%) could also be updated weekly on the hot spot map for each location if the LEM team decide to visually trend data in this way (see Figure 9 in Appendix 2 for an example of a hot spot map displaying the cumulative pass rate (%) for L. monocytogenes investigative swabs).*

[c] *Weekly pass rate (%) = [**number of swabs where L. monocytogenes was not detected ÷ total number of swabs** tested per week] x 100*

8.3 When to consider employing external expertise

When the LEM team are unable to identify the root cause of contamination and subsequently address the presence of *L. monocytogenes* in the food business operation, it may be beneficial to engage an independent external food safety expert who possesses specialised knowledge in hygiene and *L. monocytogenes* (Food Safety Authority of Ireland, 2023; 2008). A suggested agenda for an initial meeting with an external provider is outlined in Information Box 8.

9. Internal auditing and continuous improvement

Both the LEM and the hygiene programme should be regularly reviewed under the food business operator's internal audit programme to determine whether they are fit for purpose. The food business operator should demonstrate a commitment to continuous improvement by effectively addressing any findings identified and ensuring timely resolution. The frequency of the review should be appropriate for the scale and nature of the food business operation and be agreed by the LEM team. For example, in SMEs, the internal audit may be annual, while a larger operation may carry it more frequently (e.g. one area of the operation each month).

During the review of the LEM programme, the audit should evaluate whether the number, location, and timing of samples collected weekly, in accordance with the master swabbing schedule, remain appropriate and aligned with the current risk assessments. The analysis and documentation of the LEM test results should be incorporated into the review process. For example, an occasion could be selected where *L. monocytogenes* was detected in the environment to assess whether appropriate corrective actions were implemented in accordance with the procedures documented in the LEM programme.

The audit may include an assessment of the laboratory's accuracy in reporting information on the laboratory report. This may involve verifying consistency between the metadata provided on the sample submission form – such as collection date, sample location, and sample type – and the information documented on the laboratory report for the corresponding sample. Additionally, the audit should evaluate whether test results are recorded systematically and promptly to support effective monitoring of data trends. To maintain high hygiene standards, it is also recommended that procedures established under the hygiene programme are audited internally on a frequency appropriate for the scale and nature of the food business operation. This is in order to verify that there is no opportunity for environmental cross-contamination while the hygiene programme is being implemented, that the hygiene team are adequately trained, and that they are following the hygiene procedures correctly.

Information Box 8: Example agenda for initial meeting with an external expert with specialised knowledge on hygiene programmes and *L. monocytogenes*

- **Opening meeting**
  - Introduction of the LEM team
  - Outline commitment of senior management to the LEM programme
- **LEM programme**
  - Provide an update on the activities completed by the LEM team to date.
  - Overview of LEM programme implemented in the food business, including master swabbing schedule, corrective action procedures, root cause analysis under investigational procedures, and staff training.
  - Discuss where positive detections of *L. monocytogenes* have been identified (e.g. in environment, food or raw materials), along with the trends observed in the test results.
  - Discuss the hygiene programme, including relevant documentation such as hygiene schedules, cleaning instruction cards, and training of hygiene staff.
- **Management of recurring contamination challenges**
  - Define the objectives for engaging the services of an external expert.
  - Provide a summary of the key contamination issues regarding *L. monocytogenes* in the food business operation.
  - Explain the rationale behind the LEM team's assessment regarding these ongoing challenges and why external expertise is required to assist in bringing the contamination issue under control.
  - Provide a detailed overview of the corrective actions and investigative procedures that have been implemented to date.
  - Discuss any recent changes that may have occurred in the food business operation (e.g. introduction of new equipment and/or new raw materials, building or maintenance work, increased production volumes, increased staff turnover).
- **Tour of food business operation – opportunity to observe:**
  - Food business operator practices
  - Layout of ready-to-eat and non-ready-to-eat areas
  - Barrier and vector controls implemented
  - Fabrication condition
  - Equipment design
  - Hygiene programme in practice
  - Inspect hygiene standards before and during production
- **Closing meeting**
  - Recommendation(s) from external expert to address *L. monocytogenes* contamination issue
  - Agreement on follow-up actions to be undertaken by the food business operator and/or external expert.

10. WGS of *L. monocytogenes* isolates

L. monocytogenes can be separated using molecular subtyping methods into different lineages, serotypes, clonal complexes and sequence types (Unrath *et al*., 2021). Further characterising the isolates recovered from the environment of the food business operation can be very beneficial in investigating contamination events. One such method of subtyping is whole genome sequencing (WGS). WGS is a powerful molecular sequencing laboratory tool that determines the order of all, or most, of the nucleotides in the genome. The genome, or genetic material, of an organism is made up of a unique deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) sequence. Each sequence is composed of chemical building blocks known as nucleotide bases. Determining the order of bases is called “genomic sequencing” or, simply, “sequencing” (Centers for Disease Control and Prevention, 2024).

The information encoded in the genomes of bacteria, viruses, and fungi provide researchers with unique genetic ‘fingerprints’. These ‘fingerprints’ can be compared with each other to determine whether strains of the same microorganism are genetically similar or different. WGS enables the precise identification and characterisation of microorganisms. This significantly reduces the uncertainty that can hinder the ability of food business operators and competent authorities to effectively and efficiently investigate microbiological food safety issues, such as outbreaks of foodborne illness. Another potential benefit of using WGS is that a food business operator can be excluded from further investigations in an outbreak scenario if WGS results and epidemiological data suggest that there is no link between the food business operator and the pathogenic strain known to be causing the outbreak of foodborne illness under investigation.

WGS is a fast and increasingly affordable way to obtain detailed sequencing information about pathogens such as *L. monocytogenes* that can be integrated into the FSMS. In the event of a persistent *L. monocytogenes* contamination event within the food business operation, further characterisation of the isolated *L. monocytogenes* strains through WGS can positively benefit the investigation process by providing insights into the possible sources of contamination (e.g. by cross-contamination from an environmental source), while effectively ruling out other possibilities (e.g. where multiple isolates of *L. monocytogenes* have been detected in the environment and in raw materials). Comparison of the WGS results for the *L. monocytogenes* strains isolated in the environment of the food business operation is useful to determine whether the same strain of *L. monocytogenes* is persistent throughout the factory, or if they are transient strains. The WGS analysis can also offer valuable insights into potential root causes of contamination.

For this reason, WGS is most powerful when the sequencing results are combined with metadata (i.e. precise information on where the isolates originated from) and trend analysis for the swabs

and food samples tested (Baert *et al.,* 2021). In order to be meaningful, such metadata should include at least the collection date, sample location, and sample type (e.g. raw material, environmental sample, food product). Good-quality metadata are crucial in order to make accurate conclusions on WGS results. Recommended metadata fields and values associated with sample collection, with the isolate and the sequences are described in the ISO/DIS 23418:2022.

If there is an ongoing persistent issue with *L. monocytogenes* contamination in a food business, WGS results combined with the relevant metadata, trend analysis data, and hot spot mapping can generate useful information on the diversity of *L. monocytogenes* strains circulating in the food business operation's environment. This helps the LEM team to track different sequence types throughout the food business operation to understand what *L. monocytogenes* strains/sequence types are being found where, their relationship to each other, and their potential to cross-contaminate ready-to-eat food and/or ingredients used to make that food. For example, WGS analysis of various environmental sources in the operation could show that the *L. monocytogenes* isolates from the nearby drain thought to be the main source of environmental cross-contamination to the food do not in fact have the same WGS profile as the *L. monocytogenes* isolates detected in the final food product and can be ruled out. This would indicate that the cross-contamination to the final food product is coming from a different source than the drain, and that the issue needs to be further investigated to find the real root cause (see Section 8 of this guidance note).

If *L. monocytogenes* is identified in the final food product(s), WGS can be employed to assess whether the strains/sequence types detected in the food and/or raw materials share a genetic similarity with those present in the environment of the food business operation. A genetic similarity between environmental isolates (such as those found on surfaces or equipment) and isolates from the final product may indicate that the sampled location within the environment is a potential source of cross-contamination, Furthermore, if *L. monocytogenes* has been isolated from raw materials used as ingredients, WGS analysis can also determine whether these strains are genetically similar to those found in the environment or the final product. Identifying consistent genetic profiles across these sources may suggest that the raw materials could be the initial source of contamination. Information Box 9 provides an example of how WGS data can be used during an investigation to identify the root cause of contamination.

In summary, WGS can provide a huge amount of valuable information on the diversity of *L. monocytogenes* strains/sequence types circulating within a food business operation. It is most powerful when combined with the corresponding information for the isolates that were sequenced (e.g. metadata and trend analysis). This in turn effectively aids the LEM team in managing a contamination event by assisting with the investigation process to identify the root cause. It also allows them to put effective procedures in place to prevent recurrence of the issue.

Information Box 9: An example of how WGS characterisation of *L. monocytogenes* strains from various sources within the food business operation can be used to determine the root cause of contamination

A food business operator purchases whole sides of cold-smoked salmon from two different suppliers (A and B) as a raw material. The food business operator subsequently processes the whole sides of cold-smoked salmon by slicing it and repackaging it into a smaller-sized finished product of 100 g prior to distribution to a retailer.

In this scenario, the food business operator identified the presence of *L. monocytogenes* in a batch of the finished product. Traceback investigations showed that the implicated batch of product was made using a batch of raw material that was purchased from supplier B only. During the investigation to determine the root cause of the contamination, the LEM team took five environmental swabs of the on-site slicing equipment at different time points during production. They also tested five samples each of raw material supplied to the food business operation by supplier A and supplier B.

L. monocytogenes was detected in two of five samples of cold-smoked salmon from supplier A. *L. monocytogenes* was not detected in any of the five samples tested from supplier B. *L. monocytogenes* was detected in two of five environmental swabs taken of the on-site slicing equipment, one of which was taken after 2 hours of slicing, and the second at the end of production. WGS analysis revealed that the same *L. monocytogenes* sequence type was present in the raw material purchased from supplier A, the slicing equipment, and the batch of final product which was made using raw material only purchased from supplier B.

These findings suggest that the raw material from supplier A was likely the primary source of contamination, which then cross-contaminated the slicer. The *L. monocytogenes* strain was not removed by cleaning and disinfection because the slicer had poor hygienic design and it was not routinely disassembled prior to implementing the hygiene programme. The location of the positive environmental swab for *L. monocytogenes* showed that the strain was surviving in a growth niche between the blade and the holder as it was a hard-to-reach part of the equipment to clean and disinfect.

Once the root cause was identified, corrective actions were implemented by the LEM team to prevent recurrence. They notified Supplier A and temporarily suspended their approval status pending verification of the safety of the supplied raw materials. The LEM team updated the procedure for cleaning and disinfection of the slicer to improve its efficacy. The new procedure included full disassembly of the equipment prior to cleaning and disinfection in order to improve access to hard-to-reach areas. The relevant staff were trained in the new procedure to ensure it was properly implemented.

To verify that the remedial actions implemented by the LEM team were successful in mitigating the issues identified by the root cause analysis, there was increased monitoring of raw materials, the slicer, and finished product for a period of 6 months, which was defined by the LEM team.

11. References

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12. Glossary

Term	Explanation
ATP measurement	ATP is an energy molecule found in all living organisms, including animals, plants, and microorganisms. ATP detection devices use bioluminescence to rapidly indicate the level of residual ATP present on swabbed surfaces. This value correlates to the level of organic debris and microorganisms present on a surface in order to assess the cleanliness of surface swabbed.
Barrier controls	Practices used to prevent or minimise the introduction and spread of microorganisms, including *L. monocytogenes,* within the food business operator's environment.
Biofilm	Microorganisms can aggregate together and form a thin but robust protected layer on a surface called biofilm. It provides protection to extreme environmental stress, increasing the potential for *L. monocytogenes* to survive and grow in harbourage sites. A biofilm can protect *L. monocytogenes* from being readily removed by surface cleaning and chemical disinfection treatments allowing it to persist for a long time in the environment of the food business operation.
CCP	A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system (Codex CXC 1-1969, Rev. 2022).
Cleaning	The process of physically removing soil, dirt, food debris, grease and other contaminants from surfaces by using a detergent and water. This helps to reduce the number of harmful bacteria present.
Cleaning instruction card	A short document that contains important information for the hygiene operative on how to properly clean and disinfect a particular area or piece of equipment (Campden BRI, 2020c).
Cold chain	The cold chain refers to controlling the temperature of food products from the point of origin, through the distribution chain, to the final consumer. Lower temperatures stop or slow the growth of bacteria on food, assisting both food safety by inhibiting illness-causing bacteria, and food quality by inhibiting spoilage organisms. Any break in the cold chain at any point along the whole supply chain (including the preparation, storage, distribution, and retail stages) can allow bacteria to grow to problematic

Term	Explanation
	levels. All food business operators play a role in ensuring the chain remains unbroken.
Collector samples	Collector samples maximise the detection of *L. monocytogenes* by swabbing locations that have high environmental surface contact (e.g. footwear, wheels, cleaning equipment). They could also be concentrated samples, such as from a floor drain, that draw in fluid from a large surface area, or food debris that builds up on a slicer blade (Holah, 2022).
Control	When used as a noun: the state wherein correct procedures are being followed and any established criteria are being met; and when used as a verb: to take all necessary actions to ensure and maintain compliance with established criteria and procedures (Codex CXC 1-1969, Rev. 2022).
Control measure	Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level (Codex CXC 1-1969, Rev. 2022).
Corrective action	Any action taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product, if any, and prevent or minimise reoccurrence of the deviation (Codex CXC 1-1969, Rev. 2022).
Consumer	The end user of the finished food product.
Disinfection	Reduction by means of biological or chemical agents and/or physical methods in the number of viable microorganisms on surfaces, in water or air to a level that does not compromise food safety and/or suitability (Codex CXC 1-1969, Rev. 2022).
Environment	Any item in contact with the food product, or likely to represent a contamination or recontamination source; for example, material, premises or operators (ISO 18593:2018).
Food business operator	The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control (Regulation (EC) No 178/2002, as amended, European Commission, 2002).
Food business operation environment	The built space in which the food product is processed and which may represent a source of contamination (e.g. building fabric, processing equipment, food handlers).
Food contact surface	Where the food touches food processing surfaces or equipment (e.g. food preparation table, conveyor belt, slicer blade).

Term	Explanation
FSMS	A combination of GHPs/PRPs and procedures based on the principles of HACCP to identify and control any hazards that could pose a danger to the production of safe food.
GHPs	Fundamental measures and conditions applied at any step within the food chain to provide safe and suitable food (Codex CXC 1-1969, Rev. 2022).
Growth niches	Harbourage sites which may allow microorganisms such as *L. monocytogenes,* if present, access to nutrients, temperature, oxygen, water or humidity, and lack of competition from other microorganisms, thus providing an ideal environment for growth.
Hazard	A biological, chemical or physical agent in food with the potential to cause an adverse health effect (Codex CXC 1-1969, Rev. 2022).
Hazard analysis	The process of collecting and evaluating information on hazards identified in raw materials and other ingredients, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards (Codex CXC 1-1969, Rev. 2022).
HACCP-based procedures	An own-check system which identifies, evaluates and controls hazards that are significant for food safety, consistent with the HACCP principles (European Commission, 2022).
Harbourage sites	Physical areas in which microorganisms such as *L. monocytogenes* can lodge and be protected from external forces, such as cleaning and disinfection actions. For example, drains, poor hygienic design features of equipment, or damaged areas of the food business operation's building structure (Holah, 2022).
Hygiene programme	A written protocol for the implementation of cleaning and disinfection procedures in the food business operation to control hazards and to ensure fitness for human consumption of a foodstuff. The hygiene programme requires the implementation of adequate procedures for both cleaning and disinfection because cleaning alone is not enough to kill all microorganisms, and disinfection alone is not enough to remove all dirt and debris.
LEM programme	A risk-based written procedure which details specific information on sampling locations, times and frequencies, swabbing protocols, interpretation of results and actions to take if *L. monocytogenes*

Term	Explanation
	contamination is detected in the environment of a ready-to-eat food business operation.
LEM team	A multidisciplinary team responsible for designing, implementing and monitoring the LEM programme. It should include representatives with useful knowledge of the day-to-day operations within the food business. In smaller food business operations, the team may consist of one to two people, as the same person may cover a number of roles such as quality, hygiene, etc.
Listeriosis	Listeriosis is an infection caused by *L. monocytogenes* which is usually acquired by eating food contaminated with this bacterium. It can cause mild flu-like symptoms, or gastrointestinal symptoms such as nausea, vomiting and diarrhoea. In rare cases, the infection can be more severe, causing serious complications. Some people are more vulnerable to listeriosis, including pregnant women and their unborn children, babies, older adults and people with weakened immune systems.
Metadata	Data that describe the origin of a bacterial isolate (e.g. the collection date, sample location, sample type).
Minimally processed foods	Under the NOVA food classification system, minimally processed foods are natural foods altered by processes such as removal of inedible or unwanted parts, drying, crushing, grinding, fractioning, filtering, roasting, boiling, pasteurisation, refrigeration, freezing, placing in containers, vacuum packaging, or non-alcoholic fermentation. None of these processes add substances such as salt, sugar, oils or fats to the original food (Monteiro *et al.,* 2016). The minimally processed food usually retains most of its inherent physical, chemical, sensory and nutritional properties (e.g. pre-cut fruit and vegetables, bagged salad leaves, frozen fruit and vegetables).
Non-food contact surface	Any food processing equipment or the environment in the food production area that is not in direct contact with the food. For example, this can be the outside of the food contact equipment, underneath the equipment, the framework of the conveyor, drains, door handles, light switches.
Non-ready-to-eat area	An area where the processing or handling of foods presents minimum risk of product contamination or growth of microorganisms, or where the subsequent processing or preparation of the product by the consumer will

Term	Explanation
	ensure product safety (Brand Reputation Compliance Global Standards 2022a).
Placing on the market	The holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves (Regulation (EC) No 178/2002, as amended, European Commission, 2002).
PRP	Programmes including good hygiene practices, good agricultural practices and good manufacturing practices, as well as other practices and procedures such as training and traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of a HACCP system (Codex CXC 1-1969, Rev. 2022).
Processing	Any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes (Regulation (EC) No 852/2004, as amended, European Commission, 2004).
Production risk areas	A production risk area is a designated space where the level of risk associated with a specific foodstuff determines the extent of the necessary food safety controls. For example, certain products are handled within high-risk or high-care environments (Brand Reputation Compliance Global Standards, 2022a; 2022b).
Ready-to-eat by default food products	Foods that are intended to be reheated for palatability purposes but may not reach a core temperature of 70 °C after reheating, or food products where there is evidence suggesting that consumers may choose to consume them without fully following the recommended cooking instructions, even when such instructions are provided (Food Safety Authority of Ireland, 2014).
Ready-to-eat food	Food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate, or reduce to an acceptable level, microorganisms of concern (Commission Regulation (EC) No 2073/2005, as amended, European Commission, 2005).
Ready-to-eat area	A physically segregated area designed to a high standard of hygiene, where practices relating to personnel, ingredients, equipment, packaging

Term	Explanation
	and environment aim to prevent product contamination by pathogenic microorganisms (Brand Reputation Compliance Global Standards, 2022a).
Transfer point	Surfaces frequently handled by staff that may serve as points of contact, enabling the transfer of *L. monocytogenes* between surfaces by a vector such as a gloved hand (e.g. control panels, light switches, door handles).
Vector	Routes (e.g. personnel, waste), activities (e.g. hygiene, maintenance) or items (e.g. footwear, wheels), which may facilitate the transfer of *L. monocytogenes* contamination from a point source to a transfer point or from a transfer point to a ready-to-eat food and/or food contact surfaces.
Vector swabbing	Aims to assess the extent of *L. monocytogenes* contamination within the environment of the food business operation, track potential pathways of spread, and to assist in identifying the root cause of the contamination.
WGS	Whole genome sequencing is the process of determining the DNA sequence of an organism's genome using total genomic DNA as input (ISO 23418:2022).

Appendix 1 List of useful learning resources

Reading materials:

- British Frozen Food Federation (2015). Guide to the Management of *Listeria* in food processing. Available at: https://bfff.co.uk/wp-content/uploads/2015/11/Listeria-Guidance.pdf
- Bulletin of the International Dairy Federation (2019). Ecology of *Listeria* spp. and *Listeria monocytogenes*: Significance in Dairy Production. Available at: https://shop.fil-idf.org/products/bulletin-of-the-idf-n-502-2019-ecology-of-listeria-spp-and-listeria-monocytogenes-significance-in-dairy-production
- Campden BRI (2019). *Guideline 78 Sampling for food safety – a practical guide*. Available at: https://www.campdenbri.co.uk/publications/publication.php?publicationId=1af6361b-86be-e911-819f-0050569719df
- Campden BRI (2022). G79 Practical control of *Listeria* in food production. Available at: https://www.campdenbri.co.uk/publications/publication.php?publicationId=8634f128-fc88-ec11-93b0-002248006e03
- European Commission (2025) GUIDANCE DOCUMENT on *Listeria monocytogenes* monitoring and shelf-life studies for ready-to-eat foods under Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. Available at: https://food.ec.europa.eu/document/download/44257174-bf8c-4214-a60d-6790a7ca4109_en?filename=biosafety_fh_mc_guidance_document_lysteria.pdf
- Food Safety Authority of Ireland (2005). The Control and Management of *Listeria monocytogenes* Contamination of Food. Available at: https://www.fsai.ie/getmedia/b89e141f-e1b5-4d1f-a63b-2eb00d110e84/listeria_report.pdf?ext=.pdf
- Food Safety Authority of Ireland (2011). *Listeria monocytogenes*. Microbial factsheet series. Issue 1. Available at: https://www.fsai.ie/getmedia/dd505649-488d-4860-b2a5-815553aa5dca/listeria-monocytogenes-factsheet-final.pdf?ext=.pdf
- Food Safety Authority of Ireland (2016). *Guide to Food Law for Artisan and Small Food Producers Starting a New Business*. Available at: https://www.fsai.ie/publications/guide-to-food-law-for-artisan-small-food-producers
- Food Safety Authority of Ireland (2022). Infographic – Reducing the risk of listeriosis to vulnerable groups. Available at: https://www.fsai.ie/getmedia/f3e3abd9-9fc7-4540-bc86-505bd2759569/listeriosis-infographic.pdf

- Food Safety Authority of Ireland (2024). *Resources Booklet for Small Food Businesses*. Available at: https://www.fsai.ie/publications/resources-booklet-for-small-food-businesses
- Food Safety Authority of Ireland (2025). *Guidance Note 44 Food Safety Culture.* Available at: https://www.fsai.ie/publications/guidance-note-44-food-safety-culture
- Safefood (2022). Lab testing explained. Available at: https://www.safefood.net/Professional/Food-Safety/Food-testing/Lab-Testing-Explained
- Safefood (2024). *Listeria.* Available at: https://www.safefood.net/Food-Safety/Food-poisoning/Listeria
- British Sandwich & Food to Go Association (2024). Controlling *Listeria* in the supply chain. Available at: https://www.sandwich.org.uk/advice/microbiology/720-controlling-listeria-in-the-supply-chain-october-2019-update
- The New South Wales Food Authority, Australia (2019). Controlling *Listeria monocytogenes* in the food processing environment. Available at: https://www.foodauthority.nsw.gov.au/sites/default/files/2020-01/controlling_listeria_monocytogenes_food_processing.pdf
- World Health Organization and Food and Agriculture Organization of the United Nations (WHO/FAO) (2022). *Listeria monocytogenes* in ready-to-eat (RTE) food: attribution, characterization and monitoring. Available at: https://www.who.int/publications/i/item/9789240034969

Videos/webinars:

- Campden BRI (2020a). Cleaning and disinfection of food factories – Cleaning a drain. Available at: https://www.campdenbri.co.uk/videos/drain-cleaning.php
- Campden BRI (2020b). Cleaning and disinfection of food factories – Producing a Cleaning Instruction Card. Available at: https://www.campdenbri.co.uk/videos/cleaning-instructions.php
- European Food Safety Authority (2014). Listeria infections in humans. Available at: https://www.youtube.com/watch?v=fVfmHtvMAZs
- Food Standards Agency United Kingdom (2019). FSA explains Listeria. Available at: https://youtu.be/mOXU7Yuhsds
- EURL *Lm* (2023). Tutorials for the implementation of sampling techniques. Available at: https://sitesv2.anses.fr/en/minisite/listeria-monocytogenes/tutorials-implementation-sampling-techniques

- Safefood (2022). Microbiological testing: what food businesses need to know. Available at: https://www.safefood.net/events/microbiology-webinar
- International Commission on Microbiological Specification for Foods (2020). Playlist "Useful testing in food safety management". Available at: https://www.youtube.com/playlist?list=PLEsli45q1rXQhTlxZy1opM0nSeXWerun_

E-learning/training courses:

- An Bord Iascaigh Mhara (BIM) Two Day Seafood HACCP Workshops. For information see: https://bim.ie/seafood-processing/training/two-day-seafood-haccp-workshop/
- Food Safety Authority of Ireland (2024). Learning Portal. Available at: https://learningportal.fsai.ie/
- Food Standards Agency (2024) An introduction to Root Cause Analysis Course. Available at: https://rcatraining.food.gov.uk/#home
- Ministry for Primary Industries, New Zealand (2017). *Listeria* in ready-to-eat foods: A training resource for businesses. Available at: https://www.mpi.govt.nz/dmsdocument/42913-Listeria-in-Ready-to-eat-foods
- Safefood for business online training programme in basic food safety. Available at: https://www.safefood.net/professional/food-safety/safefood-for-business
- Teagasc Food industry training courses. For information see: https://www.teagasc.ie/food/food-industry-development/food-industry-training/
- University College Cork Food Industry Training Unit. For more information see: https://www.ucc.ie/en/fitu/foodlineucc/

Appendix 2 Example series of corresponding LEM site floor maps

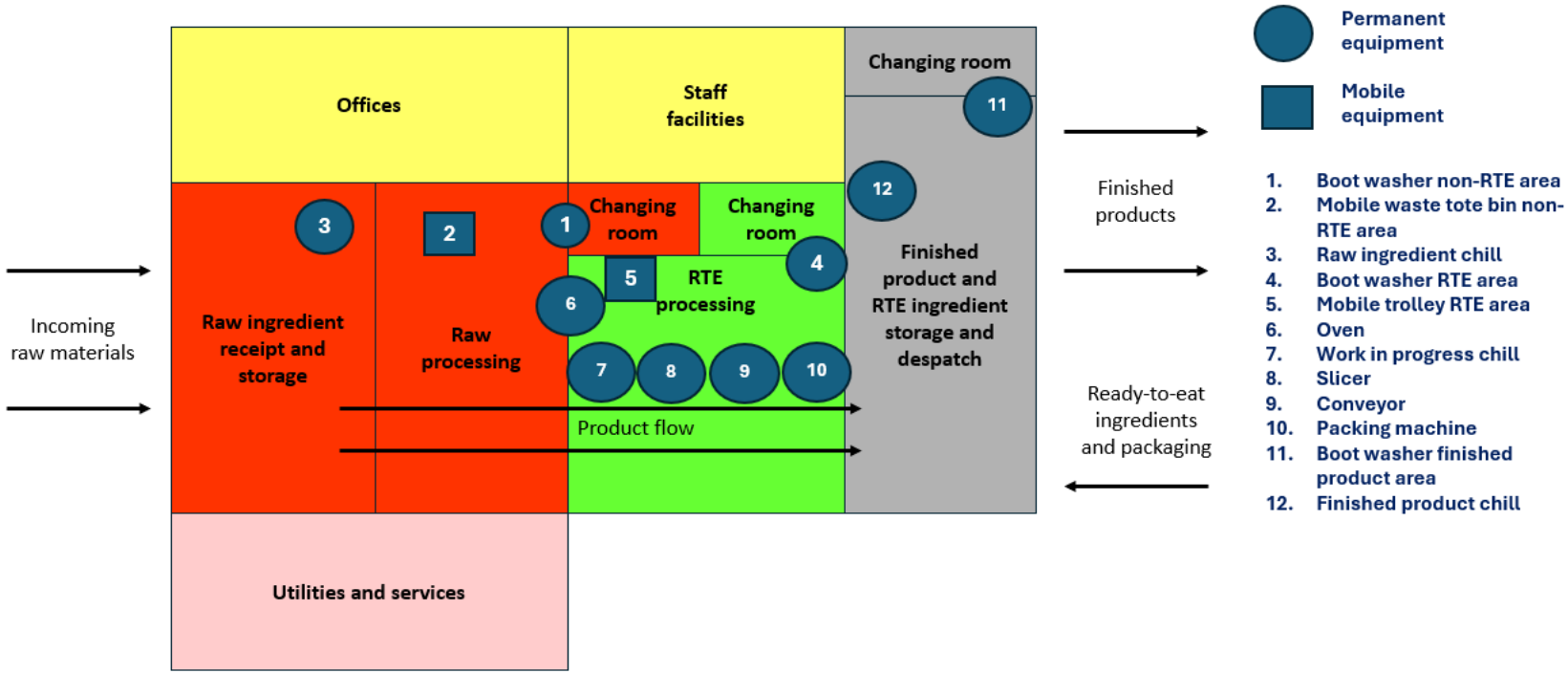


Figure 5 Map showing the ready-to-eat (RTE) and non-ready-to-eat (non-RTE) areas and the location of fixed and mobile equipment on the site map

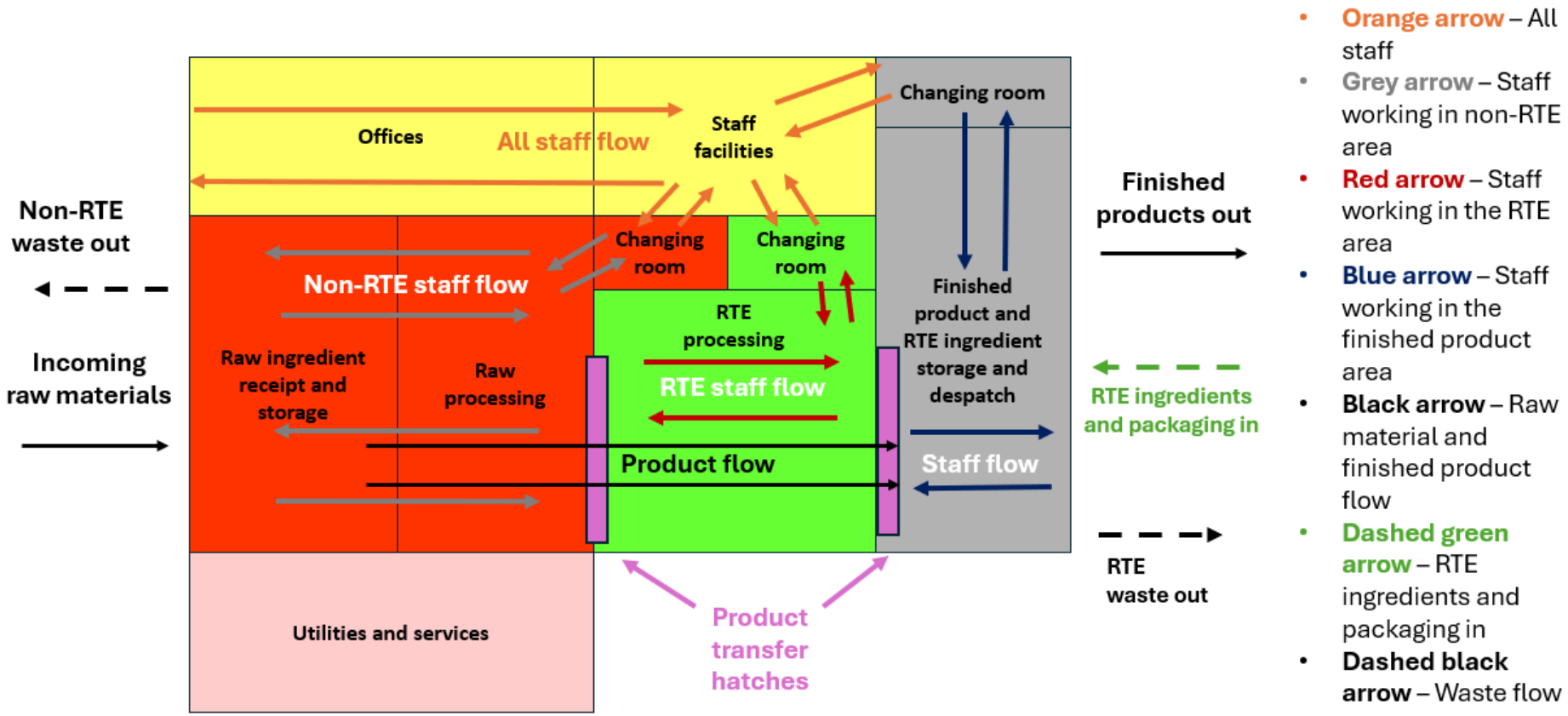


Figure 6 Map showing the product, people, packaging and waste flows in the food business operation

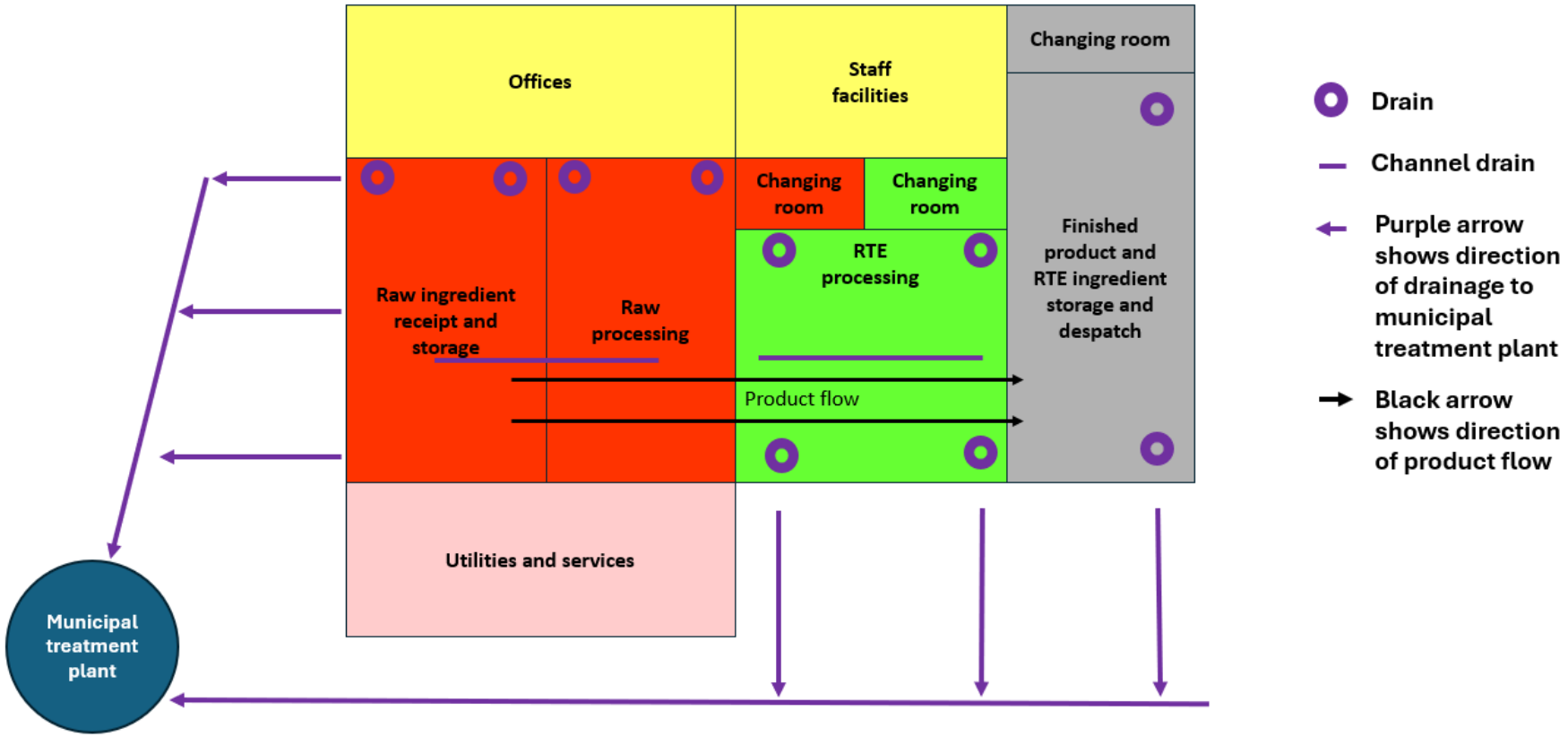


Figure 7 Map showing locations of drains and direction of flow on the site map

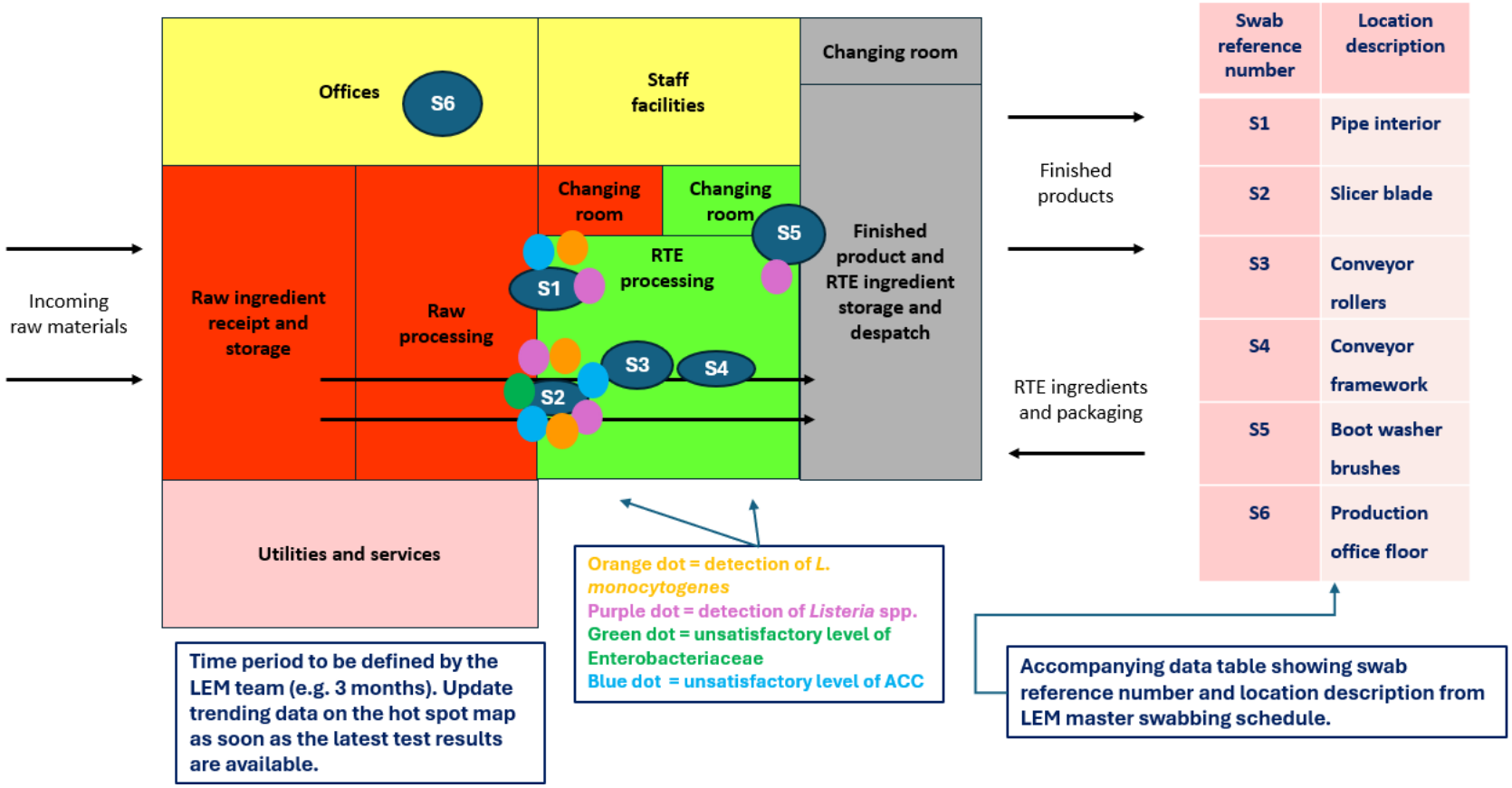
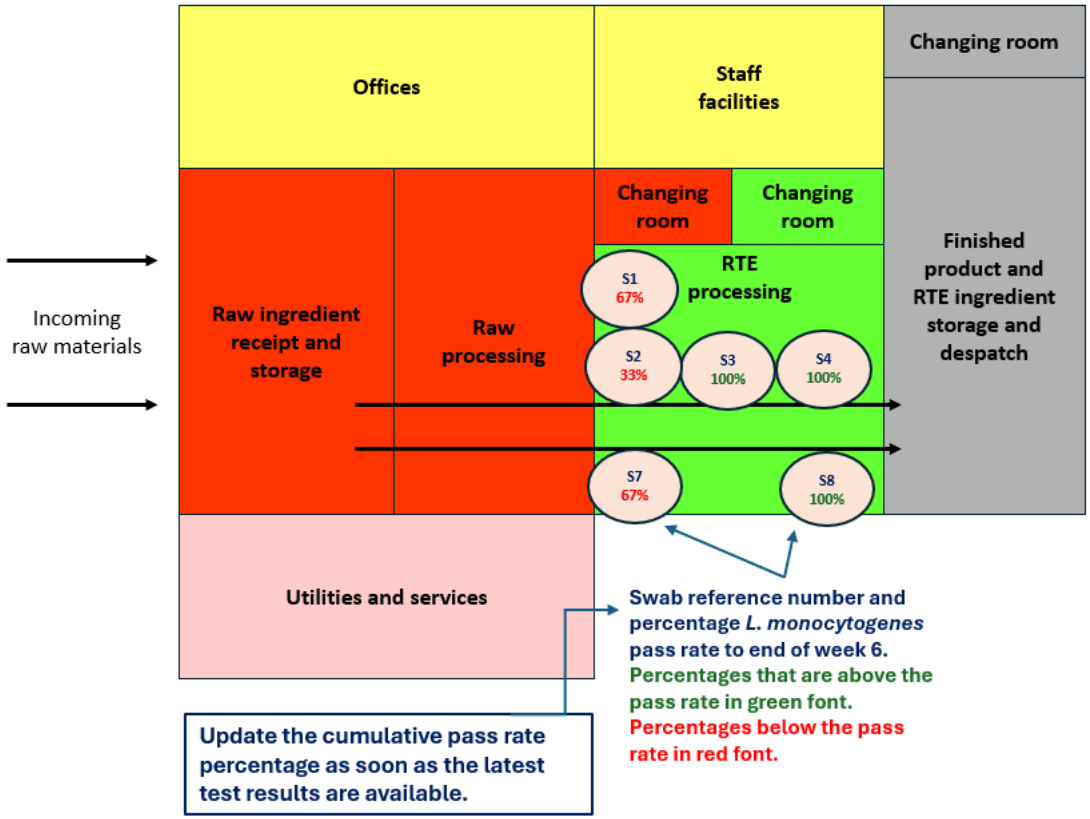


Figure 8 Map showing an example of a hot spot map displaying unsatisfactory test results for *L. monocytogenes, Listeria* spp., Enterobacteriaceae, and ACC



Swab reference number	Location description	Cumulative pass rate to end week 6
S1	Pipe interior	67%
S2	Slicer blade	33%
S3	Conveyor roller	100%
S4	Conveyor framework	100%
S7	Blade holder	67%
S8	Tote bin wheel	100%

Accompanying data table showing swab location information with *L. monocytogenes* pass rate. Additional data from other environmental monitoring test parameters (e.g. ACC, Enterobacteriaceae, ATP) may be incorporated into the hot spot map, should it be deemed beneficial by the LEM team.

Figure 9 Map showing an example of a hot spot map displaying the cumulative pass rate (%) for *L. monocytogenes* investigative swabs

Appendix 3. Supporting documentation: Example master swabbing schedule template

An Excel file template is provided in the publications section of the FSAI website as a supporting document to accompany this guidance note. It contains:

- An example of a completed master swabbing schedule template (tab 1).
- A master swabbing schedule blank template. Food business operators may modify and edit this template as required to best suit the needs of their own food business operation (tab 2).
- An example of how routine LEM data can be trended using the details in the master swabbing schedule (tab 3).
- A blank template to trend routine LEM data. Food business operators may modify and edit this template as required to best suit the needs of their own food business operation (tab 4).
- An example of how investigative LEM data can be trended (tab 5).
- A blank template to trend investigative LEM data. Food business operators may modify and edit this template as required to best suit the needs of their own food business operation (tab 6).

Appendix 4. Microbiological criteria for hygiene indicators on surfaces

There are no legal microbiological criteria published to determine an acceptable level of contamination with hygiene indicators such as total viable counts (TVCs), also known as aerobic colony counts (ACCs), Enterobacteriaceae, coliforms, *E. coli* or adenosine triphosphate (ATP) on food or non-food contact surfaces. As factors will vary among food business operations and the types of equipment used for the manufacturing of food, it is difficult to set standard microbiological criteria for the environmental monitoring of hygiene indicators or ATP on surfaces after cleaning and disinfection has been carried out. It is recommended that food business operators set their own internal standards for hygiene indicators or ATP to assess whether the levels remaining on a surface after cleaning and disinfection are satisfactory.

To do this, the food business operator should assess the levels of hygiene indicators or ATP present on a surface after 10 carefully controlled cleaning and disinfection sessions. This means sessions where the disinfection schedule is followed exactly, sanitiser and detergent are correctly diluted and used according to the manufacturer's instructions, contact times are strictly adhered to, etc. (Campden BRI, 2020c; 1999). The mean result will provide an achievable standard for hygiene indicators or ATP which can be immediately implemented by the food business operator.

The food business operator can use this information to set three limits for 'satisfactory', 'borderline' and 'unsatisfactory', and then detail corresponding corrective actions necessary for borderline or unsatisfactory test results. For example, a traffic light system could be used when representing the testing data using trend analysis (e.g. green for <100 cfu/cm^2 ACC, orange for 100–1000 cfu/cm^2 ACC, red for >1000 cfu/cm^2). The food business operators own hygiene standard limits can be reviewed and altered as necessary when subsequent data points are obtained from future testing and trend analysis. A review of the internal standards set by the food business operator would be required if either the food product, the process or the hygiene programme are changed.

The graphical representation of the test results per parameter tested over time could also be used as a visual aid to help operatives responsible for the hygiene programme to judge how the operatives or their hygiene team are performing. There is some guidance on how to trend microbiological test data and analyse the results in *Guidance Note No. 27* (Food Safety Authority of Ireland, 2014).

Action to take when the hygiene programme is not effective

If the test results breach the internal microbiological criteria the food business operator has set to assess the effectiveness of its hygiene programme, this should trigger corrective actions as set out under the FSMS.

This could include (non-exhaustive list):

- Perform surface re-cleaning and disinfection, followed by retesting to ensure compliance with the hygiene program after implementation
- Investigating the root cause of the unsatisfactory result
- Reviewing hygiene procedures to ensure they are effective
- Reviewing staff training to ensure that staff are appropriately trained
- Implementing cleaning instruction cards.

The food business operator must review the trends in the test results for environmental monitoring carried out for both hygiene indicators and *L. monocytogenes* to understand if the hygiene programme is working properly and to identify any problem areas or harbourage sites that need extra attention. When they observe a trend towards unsatisfactory results, they must take appropriate actions without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks.

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