Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Guidance for the Control of *Listeria monocytogenes* in Ready-to-eat Foods Part 4: Corrective Actions

13 February 2017

A guidance document issued by the Ministry for Primary Industries

New Zealand Government

Title

Guidance Document: Guidance for the Control of Listeria monocytogenes in Ready-to-eat Foods Part 4: Corrective Actions

About this document

The Ministry for Primary Industries (MPI) has developed a series of documents "Guidance for the control of *Listeria monocytogenes* in ready-to-eat foods" that address different areas of *L. monocytogenes* management in a food manufacturing or processing environment.

These guidelines are intended to assist food operators to develop, implement and review control measures for *Listeria monocytogenes* in the context of a Risk Management Programme (RMP) or Food Control Plan (FCP).

The guidance document are intended to support but do not replace any specific requirements for *L. monocytogenes* and/or other pathogen management as described in New Zealand legislation, such as the Animal Products Act 1999, for dairy and seafood, or under the Food Act 2014.

Related Requirements

The documents in the series Guidance for the control of *Listeria monocytogenes* in ready-to-eat foods are:

(1) Part 1: *Listeria* Management and Glossary; and

(2) Part 2: Good Operating Practices (GOPs); and

(3) Part 3: Monitoring Activities; and

(4) Part 4: Corrective Actions.

Document history

Previous Version Date	Current Version Date	Section Changed	Change(s) Description
December 2012	February 2017	Entire document	• Split Part 3: Microbiological testing for verification of the control of *Listeria monocytogenes* into two documents; • New format and branding; • New section numbering; • Updated text for improved clarity; • No technical content change.

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Disclaimer

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Contents

1 Purpose

The documents "Guidance for the control of *Listeria monocytogenes* in ready-to-eat foods" have been developed by the Ministry for Primary Industries (MPI). This guidance document is Part 4 in the series of guidance documents and provides information on how to act in response to the detection of *Listeria monocytogenes* in the processing area or in ready-to-eat products. This guidance document should be used in conjunction with the other documents in the series to provide an overall strategy for managing *Listeria monocytogenes* in a ready-to-eat (RTE) food operation.

2 Background

2.1 What is covered by this Part?

Part 4 describes how to act in the event that *Listeria* is found in a RTE food or in the processing area. The responses include both corrective and preventative actions.

This guidance may provide some useful information for food operators:

- developing new operations and/or product lines or ranges;
- reviewing existing policies and procedures for the control of *Listeria*; and
- for other food operators who may have *Listeria* control measures described elsewhere, e.g. dairy and seafood industries.

The key source of listeriosis cases is the consumption of foods contaminated with *L. monocytogenes*. In particular those that are ready-to-eat, support the growth of *Listeria,* are stored under refrigeration temperatures and have a long shelf life.

All *Listeria* species can be found in the same niches in a processing environment. Finding any *Listeria* identifies the need to implement or increase control measures. Therefore in this document the term '*Listeria'* is used to include all *Listeria spp*. except where the actions relate specifically to the major pathogenic species *Listeria monocytogenes*, in particular where it is found in a RTE food or on a product contact surface.

2.2 How does this Part relate to the other parts of the guidance for the control of *Listeria monocytogenes* in ready-to-eat foods

Part 1 provides a glossary of terms and information on the characteristics of *Listeria monocytogenes*, the sources, the consequences of food contamination and how it may enter the processing environment. It also provides information on a *Listeria* Management Programme (LMP).

Part 2 provides information on specific Good Operating Practices (GOP) that should assist in either preventing contamination of food with *L. monocytogenes* or managing the pathogen if present.

Part 3 provides information on monitoring activities for verification of the control of *Listeria monocytogenes* through microbiological testing.

Part 4 identifies how to act response to the detection of *Listeria* in the processing environment, ingredients, raw materials or product.

3 Definitions

Definitions used in this guidance document can be found in Part 1: *Listeria* Management and Glossary.

4 Notification that *Listeria* has been detected

The LMP should include a response plan that identities the actions that should be taken when notified that *Listeria* has been detected. Ideally the plan should have been tested and reviewed using a mock notification and response involving all relevant staff.

4.1 Where can notifications come from?

An operator may be notified that *Listeria monocytogenes* has been detected in a food, ingredient or raw material or in a sample from the processing environment by:

- a regulator conducting a survey, or
- a regulator following investigation of a food complaint, illness or other event, or
- a supplier of raw materials or ingredients, or
- the laboratory in response to the operator's own testing programme, or
- a customer.

Note: The detection of *Listeria* from the processing area is more likely to be reported as part of the operator's environmental testing programme.

When the notification is received it is important to have the full details of the sample tested e.g.:

- type of sample; and
- batch number; and
- what the laboratory has found.

4.2 Notification of a 'presumptive positive' test result

When the laboratory notifies a 'presumptive positive' test result, this indicates that there may be *Listeria* contamination of product (or a product contact surface). The laboratory will need several days to provide a confirmed test result. Most presumptive results will be confirmed to be *Listeria*. Whether it is *Listeria monocytogenes* or another *Listeria spp.* will usually not be evident until the confirmed result is available.

Refer to Part 3: Monitoring Activities, for more detail about working with a laboratory and understanding the results in the laboratory report.

Operators should begin to respond as soon as they receive notification of a presumptive result. Taking corrective action early has the potential to limit the financial cost and effort required in undertaking corrective actions, especially when product is involved.

4.3 Confirmation that *Listeria* is present

The scale of the response should be proportional to the likelihood that the RTE food could be contaminated with *Listeria*. The likelihood of *Listeria* being found in the product is low if the positive sample has come from the external areas (Zone 1) or the standard hygiene areas (Zone 2). The likelihood increases if *Listeria* was found in Zones 3 or 4 (high care area/critical hygiene area). See Part 3 for a description of Zones.

4.4 Initial actions

All responses and actions made to finding *Listeria* should be based on robust and adequate information. Once the relevant information has been gathered, the appropriate response can be made. Table 1 includes examples of the type of information and response required depending on where *Listeria* was found.

Table 1: Information required to respond to the detection of *Listeria*

Where was *Listeria* found?	**Information needed to help the response**	**Where to find "how to respond"**
RTE product sample*	• The date on which the food was produced, how much, where it is now • What else was produced about the same time and might also need to be included in an investigation	*Listeria spp*.in foods intended for vulnerable consumers – section 5.4 *L. monocytogenes* in RTE foods - section 6
Product contact surface or a site that could act as a source of contamination for exposed RTE product (high care area / Zone 4)	• If a single site sample (recommended), when was the site tested previously? What were the results? • What foods have been produced since that test which would have been in contact with this surface? • Where is that food now?	• *Listeria* species (not *L. monocytogenes*) – section 5.4 • *L. monocytogenes* – section 6
Non-product contact site in the high care area / Zone 3 environmental sample site	• If a single site sample, what is the site? • Was this a composited sample, if yes what were the sites sampled? • Are there any issues about the site to be aware of e.g. equipment that has been recently serviced or repaired? • Previous results?	Zone 3 – section 5.3
Zones 1 and 2 environmental sample sites	• Was this a composited sample, if yes what were the sites sampled? • When was the site(s) tested previously? What were the results?	• Zone 1 – section 5.1 • Zone 2 – section 5.2

* Also includes when *Listeria* detected in products through customer testing programmes, regulatory surveys or as a result of illness investigations.

5 Responding to a *Listeria* detection in Zones 1-3

5.1 Outside the processing area - Zone 1

The purpose of testing the environment outside the processing area(s) is to:

- determine possible sources of contamination so that they can be managed; and
- prevent the movement of *Listeria* into the processing area.

Note: Not all environmental testing programmes will include the sampling of Zone 1 (refer to Part 3). Suggested actions to take in response to the detection of *Listeria* in the Zone 1 environment are provided in Table 2.

Table 2: Suggested actions to take in response to the detection of *Listeria* in Zone 1

Sampling	**Review of results and trend analysis**	***Listeria* controls review and corrective actions**
• If composite samples were analysed, take additional individual samples to pinpoint the source of the *Listeria.* • Repeat sampling after corrective actions taken to assess effectiveness.	• Review the trend analysis to determine patterns of contamination and potential sources.	• Review the state of environmental cleanliness outside the premises e.g.: – measures to improve pest management such as a bird scarer; – remove rubbish; – prevent puddles and water pooling; – establish concrete areas directly outside doors. • Check that the control measures for raw materials and ingredients, equipment and people that enter and leave the premises are operating correctly

5.2 Standard hygiene area - Zone 2

Note: If the operation separates the processing of raw and RTE products using separation by time, unless there are control measures such as a full clean down between handling raw or RTE products, the entire processing area should be considered as high care, i.e. Zone 3.

The purpose of testing Zone 2 is to see if *Listeria* is coming into the processing area. Table 3 provides suggested actions that can be taken in response to the detection of *Listeria* in the Zone 2 environment (standard hygiene area).

Table 3: Suggested actions to take in response to the detection of *Listeria* in Zone 2 (Standard Hygiene Area)

Sampling	Review of results and trend analysis	*Listeria* controls review and corrective actions
• If the samples were analysed as a composite sample, take and analyse individual samples from the same areas and surrounding areas to determine the source of the contamination. • Repeat sampling after corrective actions taken • Consider taking additional samples to determine whether the barriers between the standard and high care areas have been breached.	• Conduct/review the trend analysis to determine patterns of contamination and potential sources. • Review results from Zone 3. **Note:** If *L. monocytogenes* continues to be detected in Zone 2 it suggests persistent contamination which will require an increased level of vigilance. That is, if 3 consecutive sampling days of non-detections for *L. monocytogenes* cannot be achieved, or where the routine (e.g. 6-weekly) records review suggests that there is recurring contamination.	• Isolate and inspect the contaminated area and equipment. • Review the cleaning and sanitation programme. Reassess access/entry restrictions into the standard hygiene area. • Review the results (if available) from outside the processing environment to identify any areas that may require a reassessment of controls to prevent the entry of any contamination. • Take corrective actions as appropriate to remove the contamination source and to prevent reoccurrence in future.

5.3 Critical hygiene/high care area - Zone 3 (non-product contact surface)

Note: For dairy products processed under a dairy RMP, Zone 3 sites may be considered in the same way as a Zone 4 sites.

Immediate: Inform the designated person responsible for *Listeria* management.

The detection of *Listeria* in this zone could potentially make its way on to product contact surfaces (Zone 4) and then onto the RTE product. Table 4 provides examples of actions that can be taken in response to the detection of *Listeria* in Zone 3 (critical hygiene area/high care area – non-product contact surfaces).

Table 4: Suggested actions to take in response to the detection of *Listeria* in Zone 3

Suggested actions to take in response to the detection of *Listeria* in Zone 3	Review of results and trend analysis	*Listeria* controls review and corrective actions
• If the samples were analysed as a single composite sample (not recommended), take and analyse individual samples from the same areas and surrounding areas to determine the source of the contamination. • Commence investigative sampling e.g. sampling daily with a focus on finding and eliminating the source of the contamination.	• Conduct/review the trend analysis to determine patterns of contamination and potential sources. • Review the testing results from the standard hygiene area (Zone 2). • Consider taking additional samples from this area to determine whether the barriers between the standard	• Isolate and inspect the contaminated area and equipment. • Reassess processing and product handling procedures. • Carry out an aggressive cleaning and sanitising operation. • Take corrective actions as appropriate to remove the contamination source and to

• After increased cleaning resample clean areas before processing recommences. • Maintain intensified sampling during processing until at least 3 consecutive sample days are clear for *Listeria*.	hygiene and high care areas have been breached	prevent reoccurrence in future. • If corrective actions have not completely removed the source of the contamination and *Listeria* continues to be detected, food operators should be able to demonstrate that they are taking all reasonable steps to control the *Listeria* contamination and prevent the contamination of the high care area.

5.4 Finding *Listeria spp.* when processing RTE product intended for consumption by vulnerable populations

If a Zone 4 sample is positive for *Listeria* species but not positive for *L. monocytogenes*, this indicates that the control measures including GOP may not be effective.

Operators should consider taking appropriate actions in response to the detection of *Listeria spp*. in RTE products. Often more than one species of *Listeria* may be present in a food or a niche in the processing environment but only one is detected in the laboratory or in a particular food sample. Producers of RTE food for vulnerable consumers should be aware that high levels of *L. ivanovii or L. innocua* may be a potential cause of illness in vulnerable consumers.

Immediate action: Inform the designated person responsible for *Listeria* management.

Table 5 provides examples of actions that can be taken in response to the detection of *Listeria spp*. in Zone 4 (product contact surface) or RTE products that are intended for consumption by vulnerable populations.

Table 5: Suggested actions to take in response to the detection of *Listeria* spp. in Zone 4 or RTE products intended for consumption by vulnerable populations

Sampling	Review of results and trend analysis	*Listeria* controls review and corrective actions
• Increase the testing frequency for the environment, all hygiene areas and product. • Resample Zone 3 (non-product contact) and 4 (product contact) sites. • Maintain increased daily sampling until at least 3 consecutive processing days with clear results are achieved. • Review product sampling especially if producing foods for vulnerable consumers.	• Review the trend analysis to determine any patterns and potential sources of contamination.	• Clean and sanitise and sample to evaluate effectiveness • Review process records to identify whether anything has changed and to ensure that the process controls for *L. monocytogenes* are operating correctly. • Review cross-contamination potential and personnel movement and access. • Prevent potential future contamination from *L. monocytogenes* by reviewing and amending controls where necessary e.g. personnel training.

Sampling	**Review of results and trend analysis**	***Listeria* controls review and corrective actions**
		• Review the cleaning and sanitation that occurred prior to and at the time of the incident. • Investigate potential sources of the *Listeria* contamination e.g. entry points to the high care area from the standard hygiene and external areas, areas where there are suitable wet growth conditions and transfer mechanisms.

6 *L. monocytogenes* is found in Zone 4 (product contact surface) or product

6.1 Detection on product contact surface

If *L. monocytogenes* is found in a Zone 4 site, product may also be contaminated. The response should be the same as when *Listeria* is found in product to ensure that no RTE product has been contaminated (refer to section 6.2 and figure 1).

Immediate action: Inform the designated person responsible for *Listeria* management.

6.2 Detection *of L. monocytogenes* in RTE product

This section describes recommended actions in response to:

- the detection of *L. monocytogenes* in RTE product; or
- when *L. monocytogenes* is found in Zone 4 (product contact surfaces which come into contact with exposed product prior to packaging).

The contamination could have resulted from either contact with a contaminated surface or faulty processing. In the latter case, the contaminated process could then contaminate product contact surfaces. It is recommended that the recommended actions in Figure 1 are taken in addition to the initial actions listed in section 4.4.

If the food has received a listericidal process the presence of *Listeria* indicates that there has been a failure of process control or hygiene that has resulted in post-processing contamination. Operators should make an immediate response irrespective of the applicable microbiological limit for *L. monocytogenes* in the Food Standards Code 1.6.1 – Schedule 27.

Immediate action: Inform the designated person responsible for *Listeria* management.

See Part 1 for information on identifying the microbiological limits that apply or are appropriate for a RTE product.

Refer to Table 6 for suggested actions to take in response to the detection of *L. monocytogenes* in product but at levels permitted in Standard 1.6.1.

Refer to Figure 1 for a breakdown of the recommended actions when *Listeria* is detected in product. This figure summarises the actions detailed in sections 6, 7, 9 and 10.

Recommended actions when *L. monocytogenes* is found in product but at levels permitted in Standard 1.6.1

If counts up to 100cfu/g are permitted **but** the food has received a listericidal process, the presence of *Listeria* indicates a failure of process control or that post-processing contamination has occurred. Operators should consider an immediate response as for products where there is an 'absent in 25g' limit.

The product should be either:

- withdrawn from sale; or
- placed on hold until the extent of contamination is known and appropriate disposition is agreed.

If counts up to 100cfu/g are permitted but the food is minimally processed e.g. salads, non-shelf stable pesto, processed fin-fish, low levels of *Listeria* may sometimes be present. Corrective actions should be taken, the range of actions may depend on the level of *L. monocytogenes* detected and whether the operator has validated that only limited if any growth will occur during the products shelf life (i.e. will not exceed 100cfu/g at the end of its shelf life).

Table 6: Suggested actions to take in response to the detection of *L. monocytogenes* in product but at levels permitted in Standard 1.6.1

Sampling	**Review of results and trend analysis**	***Listeria* controls review and corrective actions**
• Increase the frequency and numbers of product samples taken during future production in a long shelf life product, especially if contamination has not been found previously. • Collect product samples from all product batches made since the product batch in which *Listeria* was found. This will help to determine if *Listeria* is present in other batches.	• Review environmental sampling results for possible contamination sources.	• Review the processing and incoming raw material to see if any changes or one off events could have contributed to *Listeria* being present e.g. damaged produce, heavy soil load depleting sanitiser activity. • Review processing, cleaning and sanitation and/or suppliers if occurrence becomes too frequent or counts near the permitted limits.

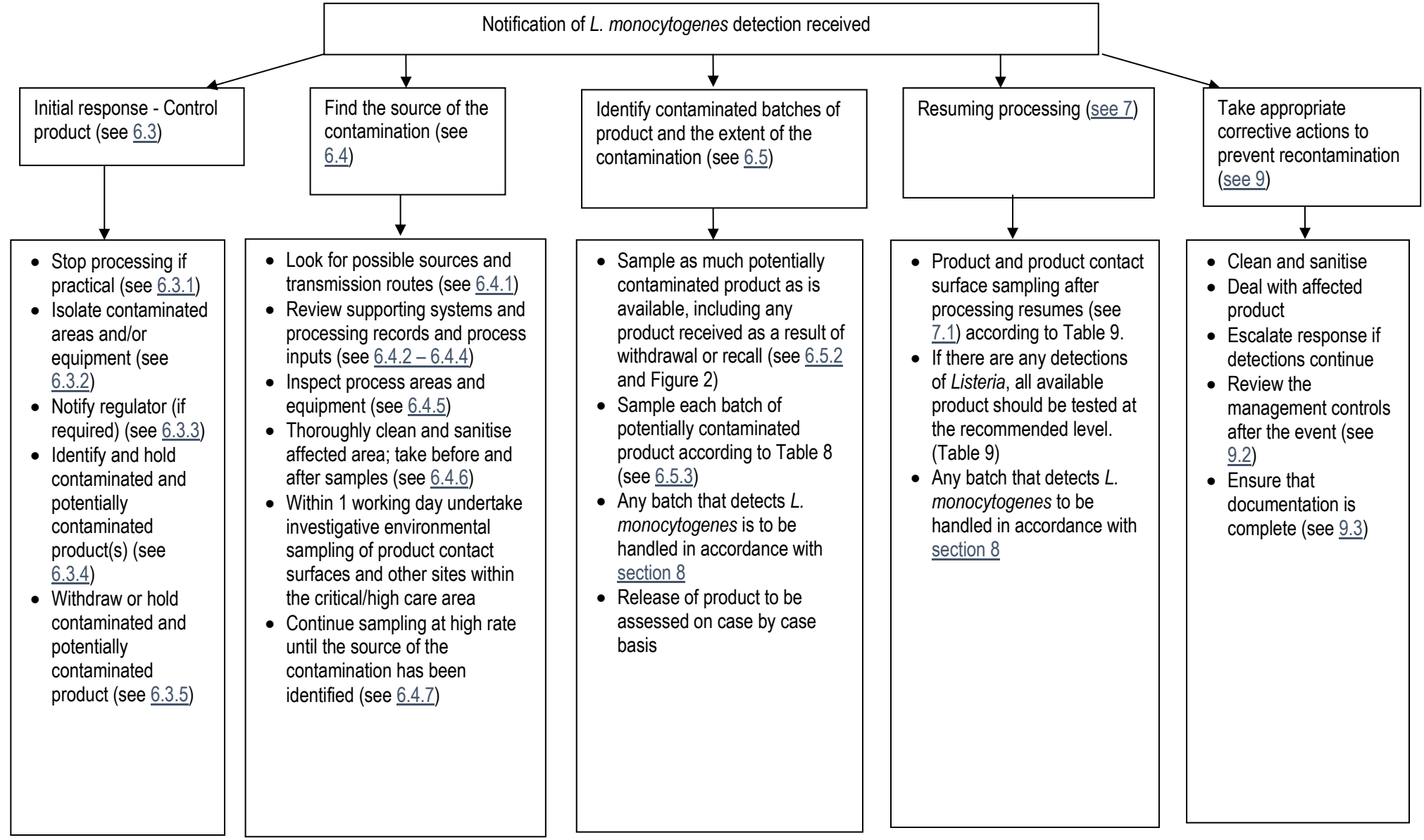


Figure 1: Actions to be taken when *L. monocytogenes* is detected in product

6.3 Control product

6.3.1 Stop processing

For some processes (e.g. continuous operations) it may not be possible to stop processing. If processing continues, all resulting product from the affected lines should be considered as potentially contaminated.

Product contaminated because of inadequate process control may act as a source of contamination for subsequent production, either by direct contact with other product or indirectly by contaminating product contact surfaces.

6.3.2 Isolate contaminated equipment and area(s)

If processing has been halted then isolate the following areas:

- the processing areas (including equipment) that have processed contaminated product after a listericidal step; or
- all processing areas that have processed contaminated product where there is no listericidal step; or
- high care areas from which a product contact surface has tested positive for *L. monocytogenes*.

All high care areas may be contaminated. It is possible that standard hygiene areas contain the source and that routine testing has not been effective at identifying that source.

Consider restricting access to and from these areas to essential staff members only. Access can be restricted by:

- keeping the door shut into a separate room; or
- taping off areas; or
- using personnel control (e.g. foot baths, clothing exchange, appropriate signage etc.).

6.3.3 Notify the regulatory authority (where appropriate)

Dairy and seafood operators under the Animals Product Act 1999 (APA), are required to notify their verifier within 24 hours of receiving confirmation of the detection of *L. monocytogenes* in product or, depending upon the programme, on product contact surfaces[1].

All other food operators under the APA and the Food Act regime are expected to notify the relevant regulatory authority (verifier, Food Compliance Officer or MPI) if affected product has left their control such that a recall (trade or consumer level) of the product is required.

For dairy operators under the APA the requirement is specified in regulation 5 of the Animal Products (Dairy) Regulations 2005, section 5 of the Animal Products Notice: Dairy Processing Specifications and section 7 of DPC 1: Animal Products (Dairy): Approved Criteria for General Dairy Processing. For RTE seafood processors under the Animal Products Act the requirement is specified in the Animal Products (Risk Management Programme Specifications) Notice 2008 clause 13(3)(a) and expanded upon in the Processing of Seafood Code of Practice section 18.9.2.

[1] The management of contamination events for dairy processors under the Animal Products Act will remain with MPI. MPI will continue to make any disposition rulings for that sector.

6.3.4 Identify and hold contaminated and potentially contaminated product(s)

Potentially contaminated product includes:

- product processed on a line where *Listeria* has been detected on a product contact surface, and/or
- on a line used to process product in which *Listeria* was detected.

Actions include:

- isolate the product (where possible) and hold to prevent it being used, sold or distributed, including any product received as a result of withdrawal or recall;
- prevent direct contact or cross-contamination with other product(s), raw materials, packaging, equipment or surfaces;
- clearly identify product to indicate status. For example, each carton or pallet could be marked with 'hold' labels, or it could be held using an electronic inventory control system to ensure product is not released;
- prepare a full product inventory. Determine which products, where and how much is affected.

Other products may be contaminated as a result of being processed:

- on the same line; or
- in the same processing room around the time of a contamination; or
- may be subsequently contaminated once processing resumes.

It is important that all resources available are used to help narrow down the range of potentially contaminated product so that the response and testing can be targeted. This can be achieved by reviewing the results from routine testing and investigative sampling, as well as reviewing the process control and supporting system records.

To help visualise what should be considered when determining which product may be contaminated and what testing may be required, refer to Figure 2.

- Figure 2, day zero represents the day that the sample was taken that tested positive for *L. monocytogenes* and may be the first evidence of a contamination event. In this example, the result is notified on day 5.
- The days that pass between the last clear test and when the positive sample was taken are represented by Xs. The number of "X days" will be determined by the frequency at which routine testing samples are taken. If routine testing samples are tested more frequently, this will be a shorter timeframe and fewer products may be affected provided a robust testing programme has been used. Contamination notified on day 5 could have been occurring since the last clear test (or longer). At this stage, the food operator does not know when the process hygiene failed.
- Product processed on days indicated by Xs, if available, should be identified and held so that testing can be carried out. This will assist in the identification of the onset of the hygiene failure.
- The days numbered 1 to 5 represent product that was produced between taking the positive sample and notification of the detection. Potentially contaminated batches should be held so that testing can be carried out.

6.3.5 Withdraw or recall contaminated product

If contaminated product has left the processing premises but remains within the company's control consider whether it should be withdrawn from the distribution chain. If contaminated product has left the company's control it is likely that a recall (trade or consumer level) will be required.

Any contaminated or potentially contaminated product that remains under control of the operator should be placed on hold.

- Under section 284 of the Food Act 2014, the Chief Executive may issue an order directing the recall food or a food related accessory that is not safe or suitable or whose safety or suitability is in doubt. Under section 85 of the Animal Products Act 1999, the Director-General may issue a notice directing the recall of any animal product that is not fit for intended purpose or whose fitness is in doubt.
- The decision to recall product should take into account:
  - whether the product is still within shelf life;
  - whether the positive result was in product or on a product contact surface;
  - the level of contamination in the product and the risk presented by it;
  - the intended consumer;
  - where the product is in the distribution chain and/or whether it remains within the company's control.

If a recall is required then the regulatory body is likely to require the following information:

- details about the contaminated and potentially contaminated product (shelf life, batch number(s) or other identification); and
- current location, distribution and volume of affected product; and
- routine testing sampling plans, results and trend analysis of environmental results; and
- any decisions about the disposition of the food product.

The MPI Recall Guidance Material provides guidance for the food and beverage industry and sets out the procedures for identifying and removing unsafe food from the food chain. This can also be found by using the search terms "recall guidance material" in the search field of the MPI website.

6.4 Find the source of the contamination

6.4.1 Look for possible sources and transmission routes

Finding the source or cause of the *Listeria* contamination can help to minimise any future reoccurrence by allowing the food operator to tighten or put in place control measures (refer to Table 7).

Table 7: Actions to help identify possible sources of *Listeria* contamination

Action	Rationale
Review the access controls for people, raw materials, equipment, packaging and any other materials and previous testing results upon notification of the detection of *Listeria*.	The detection of *Listeria* suggests that one of the control measures (GOP or process controls) that are in place to prevent pathogen contamination has not been effective
Systematically review the floor plans and process flows through the premises.	Identifies anything that may be a cause for concern and that should be targeted during the investigation.
Assess the integrity of the building.	Possibility of unsealed doors or windows, roof leaks, unflashed pipes and untrapped drains causing problems.

6.4.2 Review supporting systems

Reviewing the supporting systems (GOP) helps to identify the cause of the contamination (e.g. cleaning and sanitation programme, access restrictions, GOP, staff training).

Aim to check any records for the period around the date of detection, and if possible back to the last non-detected result, to identify whether anything unusual or unexpected occurred.

Checklist for reviewing the support systems

- Were the cleaning and sanitation procedures followed correctly, including chemical concentrations and contact times?
- Was there an equipment breakdown or maintenance work being carried out on or near the process line(s)?
- Was there a large order processed or a new product?
- Did any modifications or repairs take place at or near the line(s) such as replacing flooring or repairing a refrigeration unit?
- Are there ongoing problems that could be linked to the hygienic design of the equipment or facilities?
- Were there new or inexperienced personnel on the process line(s)?
- Were the access/entry restrictions into high care areas being followed correctly, including any movement of equipment between areas?
- Was there a breach of the hygiene requirements?
- Was there potential for cross-contamination between the high care area, product contact surfaces and/or product?

6.4.3 Review processing records

Reviewing the processing records helps to establish:

- the extent of possible contamination; and
- which product lines could potentially be contaminated.

This review should assist in determining whether the process was under control and that procedures were being followed.

Aim to check the records that date back to the last non-detected result for *Listeria* species and see if the process is operating as intended.

Checklist for reviewing the processing records

- Check CCPs specific to the control of *Listeria* (e.g. heat treatment steps).
- Do records show that the critical limits were being met?
- Was the equipment used for critical measurements calibrated (e.g. thermometers, pH probes, pressure gauges etc.)?
  - Are the readings accurate?
  - Where necessary, recalibrate the equipment.
- Check the competency and training of workers responsible for supervising CCPs. Observe them performing their tasks and assess their competency by questioning the actions that would be taken given certain scenarios.
- Was there a loss of process control at any particular step?
- Were the processing parameters met (time or temperature of freezer, refrigeration, heat shock, etc.)?
- Were there changes to product formulation, ingredient substitutions or were ingredients from a different supplier used?
  - Review ingredient records and the traceability of those ingredients to the process (refer to section 6.4.4).
- Were the process and handling procedures followed correctly?
- Were there frequent changes to the process line(s)? For example, the speed, stoppages or several changes to lots of ingredients and materials used.
- How many product lines or product batches are possibly contaminated?
  - For example batches produced in common facilities as the contaminated product between major clean downs, and product produced on previous and subsequent processing days.

- Section 6.5.2 provides further guidance on how to determine what and the volume of product affected.

All these activities should be occurring as part of a standard operation. It can be useful to for people who have not previously been involved to provide a fresh set of eyes.

In practice, it is useful to set up a system that allows the data from checks and testing undertaken to be visualised and updated, e.g. charts on the event manager's wall.

6.4.4 Sampling process inputs

Listeria can enter the processing area and into the food product via inputs, ingredients and raw materials, such as additives, processing aids and packaging materials, etc.

To assist in the identification of the source of the contamination, the inputs used should be reviewed. Test samples of any available inputs whose microbiological status cannot be confirmed by other means, e.g. through verified supplier guarantees, etc., to determine if they are a source of contamination. For example, using appropriate sampling plans, test:

- ingredients;
- packaging (including inner and outer packaging, pallets and wrapping, etc.);
- in-process materials (also known as intermediaries).

Identify and hold ingredients added to the product after a listericidal step, or that are not subject to a listericidal step should be identified. This will prevent accidental use until it is possible to confirm whether they are a source of contamination.

Processes with a listericidal step will be designed to eliminate or reduce *L. monocytogenes* to acceptable levels in the final product. If *L. monocytogenes* is detected in the ingredients or raw material and/or in-process materials it will be important to check the validation records to ensure that the controls are adequate to reduce the pathogen to acceptable levels. If this is not the case, the process will need to be revalidated or an alternative supply of raw material sought. The correct implementation of the controls should also be checked. Where there is no listericidal step, the raw material supply will need to be reassessed.

See Part 2 for guidance on process controls and the supply of raw materials (Part 2, sections 7 and 8 for information on Incoming Materials and Identification and Traceability).

6.4.5 Inspect process area(s) and equipment

Review the floor plan and process flow to identify areas that are the most likely sources of contamination.

Carefully inspect the equipment and process area(s) to identify equipment and area(s) that may be the source and/or harbourage point of *L. monocytogenes*. Assess the state of equipment used, including the repairs and maintenance records to determine whether there are any hidden surfaces that may trap food and allow it to build up.

The inspection is likely to involve dismantling some equipment and may require assistance from maintenance personnel. Isolation measures around the area and equipment should be maintained to minimise the spread of any contamination throughout the area. Refer to Part 2 for tips on the maintenance of equipment and possible sources of contamination and Part 3, Appendix 3: Examples of potential niches.

If *Listeria* is detected from a product contact surface and a composite sample was originally analysed, or the result is from a product, then the particular equipment may not be identifiable. If so, review:

- the equipment together with the environmental testing results, the process records (refer to section 6.4.4); and
- the supporting system records (GOP) (refer to section 6.4.3).

6.4.6 Clean and sanitise the affected area and equipment

If the affected area and equipment are known, swab then thoroughly clean and sanitise and resample to determine whether corrective actions have been successful.

6.4.7 Conduct investigative environmental sampling to find the source of the contamination

Review environmental testing results

Review the environmental testing results for the standard hygiene and high care areas to indicate where to focus investigative environmental sampling.

- Investigative environmental sampling will help to identify the contamination source(s) and rule out those areas that are not the source of contamination.
- Any investigative environmental sampling should commence as soon as possible, ideally within one working day after receiving the laboratory notification.

Investigate environmental sampling can be a costly and time consuming exercise and requires collecting a greater number of samples than those collected for routine testing from the processing environment. Apply a thorough and systematic sampling plan to help identify the source of the contamination (where possible). It is important that the investigation is thoroughly planned from the start and that sufficient samples are taken from well considered sample sites. Every effort should be taken to ensure that sampling does not need to be repeated due to mistakes or gaps in the initial sampling plan. The number of samples to be taken will depend on the complexity of the process and equipment, but generally the more samples that are taken from well considered sites, the better the chances of resolving the problem. Sampling may be targeted where there is clear evidence to support this.

During the investigation sampling immediately after cleaning is useful because any *L. monocytogenes* detected is more likely to be at or near the contamination source.

A person with expertise in *Listeria* management should be involved.

Getting positive results is good as this means that the sampling programme is effective and specific corrective actions can then be taken.

In the case of a product contact surface positive:

- determine the site, date and time from where the positive swab(s) was taken. If the swabs were analysed as a composite sample, identify which sample sites were included in the composite;
- review the environmental testing results from past testing to determine those sites that tested "not-detected" for *Listeria* species and those sites with the greatest likelihood of being a source of contamination (see Table 4 in Part 3 for an example of how results may be recorded for easy review).

In the case of the detection of *L. monocytogenes* in product:

- determine the processing line, date and time when the product that tested positive for *L. monocytogenes* was processed;
- determine the sample date of the last clear test for *L. monocytogenes* to help establish the time frame when potentially contaminated product may have been processed;
- use any further product results to assist in expanding or reducing the scope of the search;
- sample any likely product contact surface site(s) that have tested positive in the past;

- select other product contact surfaces and other sites in the high care area, particularly in hard to clean areas;
- consider sampling indirect contact surfaces. These are sites that are not in direct contact with the product but may be an important source of contamination. For example overhead surfaces from which condensate may drip on to the product or product contact surfaces.

Taking environmental samples

When taking investigative environmental samples:

- include items such as waste from the floor or hidden ledges, product scraps, cleaning equipment when selecting samples;
- Do not composite environmental swabs for microbiological analysis. The use of composite samples may delay identifying the source of contamination. The exception to this would be if all swabs in the composite come from the same piece of equipment or same surface;
- the sampling method may differ during investigative sampling, for example the area swabbed may be larger in an attempt to reach greater surface areas or nooks within a piece of equipment;
- consider including pieces of equipment, etc. that move between the standard hygiene and high care areas, including the wheels;
- during the investigation swabs from the same piece of equipment can be composited for analysis. Swabs from different pieces of equipment or surfaces should not;
- explore **all** areas of possible contamination and not just on a limited / small part of the process as this can delay detecting the source and returning to full production. See Part 3, Appendix 3 for photos of some potential pathogen niche and harbourage sites.

Where appropriate, intensive sampling should continue until the source of the contamination has been identified. Intensive sampling may not always find the source of contamination;

After sampling thoroughly clean and sanitise the affected areas to ensure that any harbourage sites that may have been disturbed do not contaminate the processing areas or product.

6.5 Sampling and testing of product on hold

6.5.1 Intensive microbiological sampling requirements

If an operator intends to investigate the possibility of some of the product on hold being released, this product will need to be tested intensively to determine extent and level of contamination between each batches. Intensive microbiological sampling differs from routine testing. Routine testing programmes are designed as an additional 'check' that a food safety control system is working properly over time rather a pass/fail for each batch of product.

Intensive sampling programmes are undertaken because a problem has been identified and there is an increased likelihood that product is contaminated. It cannot be assumed that the system is working as intended and therefore information on individual batches is required. Only a portion of each batch is likely to be affected because microbial contamination, unlike some other forms of contamination, tends to be unevenly distributed. As a result, higher sample numbers per batch are required so they can provide information on the acceptability of an individual batch. Product to be tested is identified in section 6.5.2 using Figure 2.

6.5.2 Identify product to be tested

Each batch of product on hold may need to be sampled. Testing will help to:

- determine which product produced prior to, during and after the contamination event is or is not contaminated; and

- allow decisions about the release or disposition of product to be made.

The level of testing should be intensive with samples taken at a higher frequency than during routine microbiological testing.

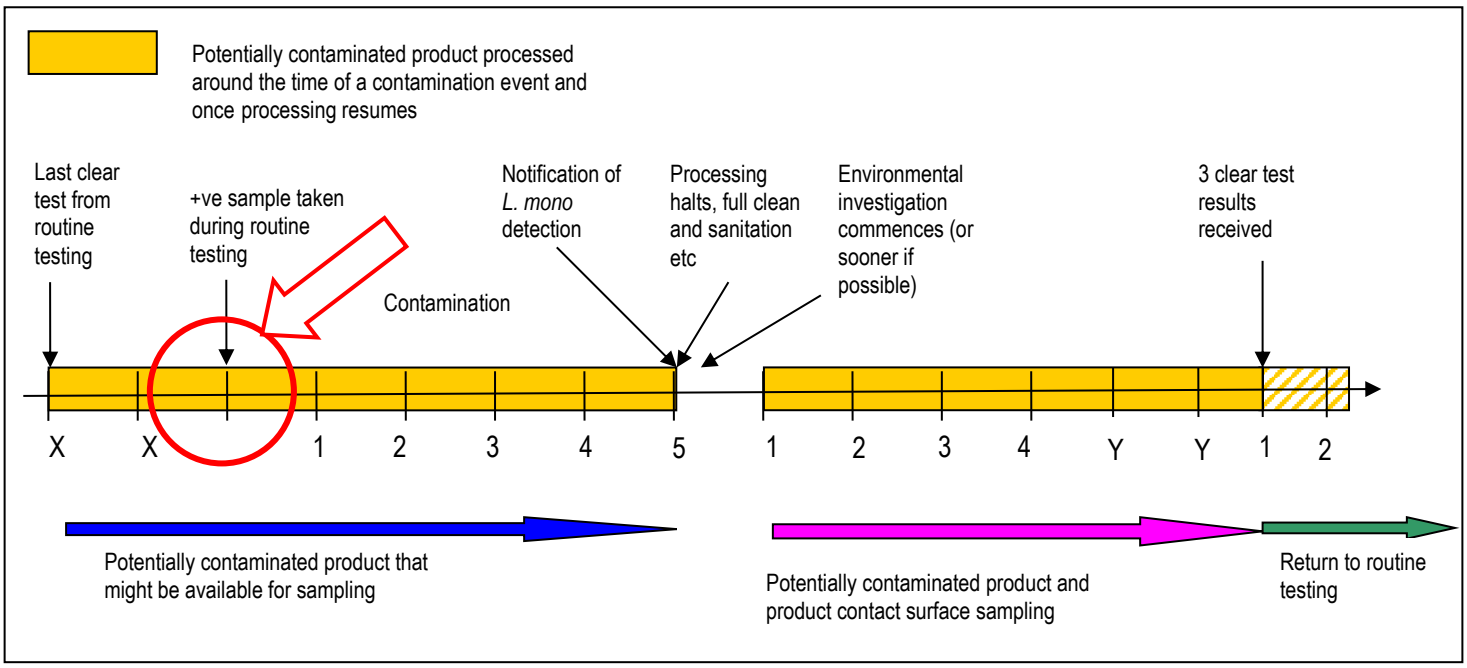


Figure 2: Which product may be contaminated?

6.5.3 Sampling plans

When conducting intensive microbiological sampling, it is recommended that sampling plans that give 95 percent confidence of detection are used.

When undertaking an intensive sampling programme the food operator should note that:

- As the number of samples taken decrease, the chance of accepting an unacceptable product batch increases. The costs involved in sampling and testing need to be weighed against the impact of making an incorrect decision.
- Sampling using a sample size of 60, i.e. n = 60, per batch provides 95% confidence of detecting *L. monocytogenes* in at least one product where 5% of the product is contaminated. If the sample size was reduced to n= 5 the batch would need to be 45% contaminated for a *L. monocytogenes* detection.

For product that will not support the growth of *Listeria* and that has a limit of 100cfu/g, having the laboratory enumerate the *Listeria* present should be considered. This result can then be used to assist in determining product disposition (refer to section 8). **When *Listeria* will be enumerated the product samples cannot be composited.**

Suggested minimum and recommended sample sizes are presented in Table 8. Samples should be selected from each batch processed on each suspect line. A maximum of 15 product samples may be composited unless enumeration is required. The whole sample should be analysed and not a subsample of the composite. An example of how to select samples from product held in store using a random sampling system is given in Appendix 2 Sampling selection for testing product.

Table 8: Suggested intensive sampling of product processed prior to or at the time of the contamination event (see Figure 2)

Original source of positive result: Product contact surface	**Sample numbers**	**Potential contamination likelihood for product**	
		Medium	**High**
Sample type: product (25g samples)	Minimum	n=5	n=5
	Recommended	n=30	n=60
Original source of positive result: Product	**Sample numbers**	**Medium**	**High**
Sample type: product (25g samples)	Recommended	n=30	n=60

Alternative sampling frequency and number of samples analysed can be proposed.

The minimum suggested sample size is n=5 in the event that the original positive sample was taken from a product contact surface. A larger sample size would be needed if product is likely to be contaminated or for a greater degree of assurance is needed. 60 samples could be taken from each batch of potentially contaminated product and these could be composited into 5 samples of 300g each for testing. This would reduce the likelihood of the release of contaminated product to trade.

Further detections would provide evidence that action should be taken to locate and where necessary recall potentially contaminated product that has left the control of the operator.

6.5.4 Release of product

Potentially contaminated product can be released:

- after all the results from all the testing has been received; or
- on a case-by-case basis; or
- to operator if intended for cooking (using a thermal treatment sufficient to eliminate *Listeria*); or
- for another valid disposition method agreed by the verifier.

The particular approach taken to release product depends on:

- the particular contamination event; and
- the results from additional analysis of different batches or production days; and
- the respective product shelf life etc.

Releasing product prior to the receipt of all results would be a commercial risk unless the release of on-hold product is approved by the regulator. Product with a longer shelf life should be held pending the outcome of all results. Batches that are clear from a single day of testing should not be released solely on the basis of that result (i.e. a series of results to build up a picture of the event should be used).

7 Resuming processing of RTE foods

The processing of RTE foods might cease whilst corrective and preventative actions are occurring. In order to restart processing:

- these actions should be completed in discussion with the verifier; and
- there should be evidence that the *L. monocytogenes* contamination is under control.

Evidence may include microbiological testing results from the processing areas, trial production runs with associated testing, validated control measures, etc.

Once there is agreement to restart production there should be an intensive sampling programme for the processing area and the product. This will help to demonstrate that the process controls and other measures are limiting the presence and contamination with *L. monocytogenes*.

7.1 Managing product once processing resumes

There may be a break of days to weeks before processing resumes, as corrective actions such as investigations, cleaning and repairs and maintenance occur.

Once processing resumes, product and product contact surface samples should be taken to allow determination of whether the corrective actions have been successful and the contamination source has been identified and addressed. Testing should continue until there are 3 consecutive processing days of clear results (see section 7.1.1).

7.1.1 Sampling of product and product contact surfaces when processing resumes

When processing resumes it is important to determine that product processed is not contaminated and that the corrective actions have been effective. Complementary environmental samples from product contact surfaces should also be collected and tested.

It is recommended that product should be kept on hold until there have been at least 3 consecutive days of product and product contact surfaces having acceptable results.

(1) Product samples should be taken during processing, ideally selected based on random times or hourly. As an alternative, the first and last products of the batch may be sampled and then further samples can be taken at 3 hour intervals in the intervening period[2].

Collecting samples of the first product processed will only provide an indication of the effectiveness of the cleaning and sanitation procedures and will not show how well the process is operating.

(2) Product samples should be selected from each batch processed on each suspect line and may be composited[3] by the laboratory unless enumeration is required.

[2] For product with a short shelf life, sampling and testing may need to occur using trial batches rather than sampling from full scale production.

[3] While compositing of product samples is recommended when sampling product produced around the time of the contamination event it is not recommended for testing once processing resumes as it does not allow assessment of the frequency of contamination to be made.

(3) Product contact surface samples should be individually tested by the laboratory until the event is resolved. Product contact surface samples should include any sites that have tested positive for *L. monocytogenes* and might include other suspect areas.

(4) Product and product contact surface samples should be taken at the same time, as this will make the task of determining the appropriate response from any positive result easier if samples are connected by location and time.

(5) Any product batches that test positive for *L. monocytogenes* should be handled in accordance with section 8. Where there are intermittent detections of *Listeria*, it is recommended that batches of product that are clear for *Listeria* not be released for trade. The product may be contaminated but that the testing regime has not detected it.

Table 9 provides the suggested and the minimum sample numbers for product and product contact surfaces for each batch processed on each suspect line in relation to product or each processing day for product contact surfaces.

Table 9: Suggested intensive sampling of product and product contact surfaces once processing resumes

Original Source of positive result: product or product contact surface	Sample numbers	Potential contamination likelihood for product	
		Medium	High
Sample type: Product (25g samples)	Minimum	n=5	n=5
	Recommended	n=30	n=60
Sample type: Product contact surface	Minimum	n=5	n=5
	Recommended	n=30	n=60

Alternative sampling frequency and number of samples analysed can be proposed.

7.1.2 If *Listeria* is detected on product contact surfaces and product once processing resumes

If *Listeria* is detected once processing restarts on product contact surfaces or in the product then the operator should take further corrective actions. Sampling at the increased frequency should occur on all available product batches produced since the last clear test for *L. monocytogenes* and on all future batches produced. This should include any product batches that were cleared using a n=5 sampling plan. This but does not include product batches that have had a detection for *L. monocytogenes*, as these should be disposed of in accordance with section 8.
If there are further detections after processing is resumed, the response should escalate to increase the likelihood of identifying the source of contamination and to take additional corrective actions.

(1) As a minimum, a deep clean and sanitation would be expected before processing continues.

(2) Consider whether structural repairs may be needed required to the processing area, additional repairs and maintenance and stricter access controls.

(3) Re-evaluating possible sources of environmental and equipment contamination should occur and, where appropriate, intensify environmental sampling.

After further detections of *Listeria* it is recommended that intensive sampling of product and product contact surfaces is conducted at n=30 or n=60 sampling numbers rather than at the minimum to ensure that the issue has been resolved (refer to Table 9).

If *Listeria* species continues to be detected on product or product contact surfaces after nine days of intensive testing, seek further assistance to:

- identify the contamination source; and
- take appropriate corrective actions.

Nine days should allow time to obtain results from 3 consecutive testing days for *Listeria* species from the date that notification of *L. monocytogenes* was initially received, provided testing is well managed and laboratory facilities are available as required.

7.2 If *L. monocytogenes* continues to be detected

7.2.1 How to respond

The continued detection of *L. monocytogenes* in product or on product contact surfaces (i.e. 3 consecutive days of not-detected results for *Listeria* cannot be achieved after nine days of sampling) should result in an escalated response. The continued detection of *L. monocytogenes* suggests that there is a bigger, more persistent problem within the premises.

There may be greater involvement from the verifier, Food Compliance Officer and/or MPI in the event of the ongoing detection of *Listeria*.

The actions described in the section 6 continue to apply.

Checklist: Suggested actions in the event of further detections of *L. monocytogenes*

Consider:

- Stopping any processing on the implicated line, contaminated processing area or of the products producing positive results. This will provide the opportunity to conduct and obtain the results from additional investigations. Processing should not recommence unless:
  - the cause has either been identified and eliminated; or
  - an effective post-pack anti-*Listeria* treatment can be implemented; or
  - the product will be sold to a food processor or food service food operator for further processing using a valid listericidal process.
- Observe food processing, the movement of the food intermediaries and product, equipment and staff within the premises. Whilst doing this consider:
  - whether office staff, maintenance workers and the truck drivers walk through the processing area on the way to and from office, staff room etc;
  - whether external doors and windows are left open;
  - whether equipment and the food intermediaries travel back and forth across the processing area, is there clear separation between the raw and finished RTE product?
  - how staff behave around food, do they understand the importance of not crossing a ‘red line’ between raw and RTE product?
  - how separation between the raw and RTE product is managed;
  - whether there are areas where water pools on the floor
  - whether the equipment and premises is visibly clean. Is there a build-up of waste product on conveyor belts, fans, etc?

- Engaging an external expert to review the actions to date and assist in the resolution of the event. A fresh set of eyes can often spot potential sources of cross-contamination or practices that may result in the contamination of the food product that those closer to the issue may not see.
- If processing continues in the affected area, all of the resulting product should be considered potentially contaminated and sampled using the intensive sample plan (section 6.5.3, Table 8).
- Serotyping or DNA fingering printing (PFGE) if this is not already occurring.
- Whether a recall should be expanded to other batches, particularly in relation to long shelf life products. Any further product received as a result of an expanded recall may be sampled and tested.
- Continued environmental sampling in accordance with section 7.1.1 to identify any contamination source(s).
- Intensive cleaning and sanitation procedures, including dismantling equipment and deep cleaning.
- Reviewing design and construction issues and addressing any problems.
- An in-depth review of application of HACCP, systems and procedures, wherever possible using people not previously involved in the event.

8 Disposition of contaminated or potentially contaminated product

The disposition of contaminated or potentially contaminated product does not always mean the product should be destroyed. In some cases, the product may undergo alternative disposal or decontamination options such as reprocessing or use in non-food applications.

If product is reprocessed then this should be done using a process that has been validated as capable of destroying *L. monocytogenes*. There should be documented evidence of the process validation. If contaminated or potentially contaminated product is to be reprocessed, the documents accompanying the product should clearly indicate the requirement for a listericidal treatment. The further processor should have documented evidence that the process will eliminate *L. monocytogenes*.

If reprocessing of exposed product is to take place on the same process line where *L. monocytogenes* was detected, then this should not occur until results indicate that *L. monocytogenes* is not detected on product contact surfaces on 3 consecutive processing days. Otherwise, all reprocessed product will need to be retained and tested at the intensive sample size (see Table 9).

When determining product disposition options consider:

- the quantity, identification and labelling information of the contaminated product(s);
- the microbiological limits for *L. monocytogenes* that apply to the product;
- the level of *L. monocytogenes* in the contaminated product(s), if known;
- the intended consumer (e.g. general population, vulnerable population);
- disposition options (e.g. animal feed, destruction (burial, burning), reprocessing (heat treatment, filtration), alternative storage conditions (such as freezing and use under specified conditions) etc;
- the risk associated with the proposed disposition option and how these risks will be managed;
- the location of contaminated product and the disposition premises/area;
- the date and time the proposed disposition would occur;
- conditions and controls for the method of disposition;
- the requirements or constraints of other legislation e.g. the Resource Management Act 1991.

Refer to Appendix 3 for an example of a form that can be completed as part of this disposition assessment. The completed form can be held on file and made available to the verifier, Food Compliance Officer or MPI on request.

9 Prevention of future contamination

9.1 Actions to prevent reoccurrence

Implement actions to minimise the chances of the recurrence of *L. monocytogenes* contamination. Refer to Table 10.

Table 10: Possible preventative actions to take to minimise contamination

Possible causes of contamination	Possible action
Ineffective cleaning	Modify and validate the cleaning and sanitation programme
Failure at a CCP, or controls around separation or the movement of equipment in and out of high care areas	Review the procedures and train staff to ensure that they have a good knowledge of their responsibilities
Fault in the processing equipment	Repair or replace the equipment, where necessary revalidate and test to ensure that the process is under control
Found a harbourage site inside equipment or facilities	Eliminate the site. Dismantle the equipment and/or subjecting it to a process that will kill the bacteria; or by adding a new step to the routine cleaning and sanitation procedure such as steam treatment or heating the equipment in a moist oven overnight. If a niche remains where the bacteria can persist even after intensive cleaning, the equipment and/or facilities should be modified, replaced or renovated to eliminate the niche
Contaminated ingredients	Review the validated process or acceptance testing or supplier contracts
The product formulation permits the growth of *L. monocytogenes*	Reformulate the product
The product is contaminated after the listericidal step	Add an additional lethality step or review and improve process hygiene

9.2 Review of *L. monocytogenes* management controls after the event

It is strongly recommended to review the procedures for the *Listeria* control measures after a *L. monocytogenes* contamination event. The event should be formally closed out and relevant staff debriefed.

As part of a review consider the:

- access/entry restrictions between areas, including compliance with personnel hygiene requirements and the movement of equipment between areas;
- cross-contamination potential between the process areas and product contact surfaces;
- cleaning and sanitation programme, including the chemical concentrations and contact times;
- processing and product handling procedures;
- validated controls (where identified as a cause of the contamination);
- sanitary design and condition of the facilities and equipment;
- effectiveness of testing programmes (environmental and product);
- *Listeria* management programme to confirm that it is appropriate and complete;
- procedures around the management of the contamination event, including the recall procedures; where used.

9.3 Documentation, records and reporting

Keep records and document the actions taken during the contamination event.

Maintaining records is an important way of demonstrating that you took the appropriate action, will assist to review of response plan, and can be provided as a record of your actions by a customer or regulatory body.

All records should be made available on request from the:

- verifier;
- Food Safety Officer;
- Food Compliance Officer or MPI.

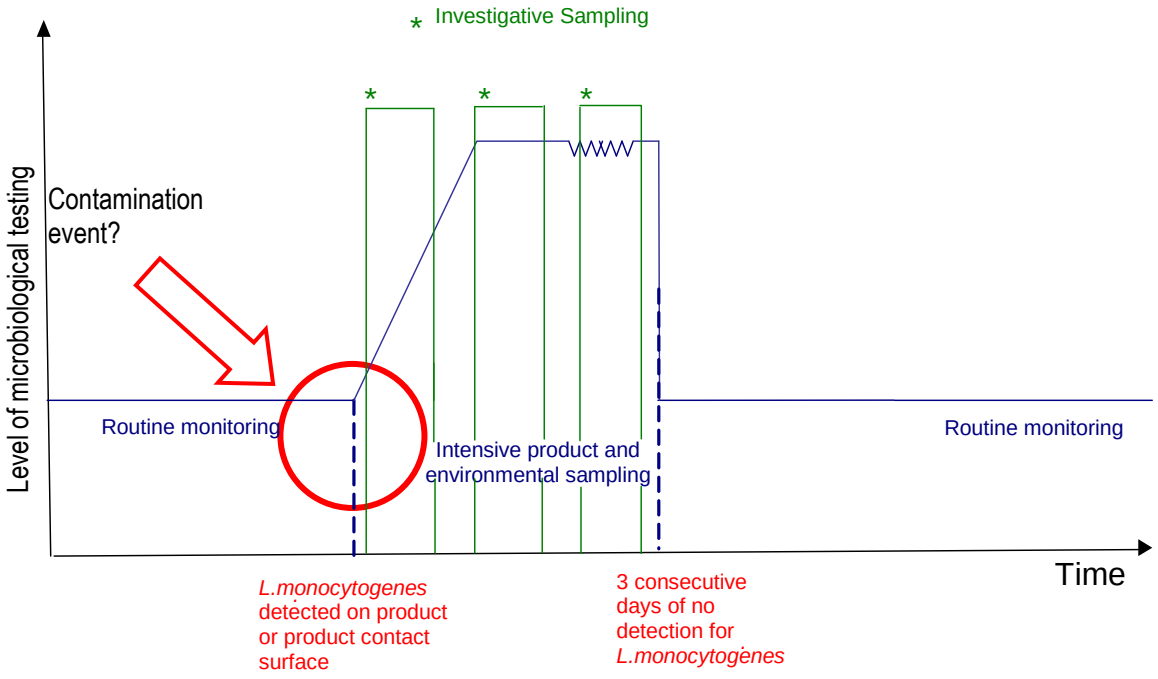
For RMP operators the records should be kept for at least four years.

Appendix 1: Sample taking and testing during a contamination event

Figure 3 provides a simplified time line in relation to the level of microbiological sampling that would be expected following a *L. monocytogenes* detection. The blue line represents the level of sampling that is undertaken when the process is under control and how this increases if there is a contamination event.

After a number of clear results are received the sampling then reverts to routine testing levels after the event. The green line represents an intensive level of environmental sampling to try to identify a contamination source. This high level of sampling may be continuous until the source is found or may be undertaken in bursts, with an opportunity for the results to be analysed in between.

Figure 3: Time line of microbiological testing following a contamination event



Appendix 2: Sample selection for testing product

The following is an example of how samples of product in store or that have been held or recalled by the food operator should be sampled for testing. The example is given for n=60, but the same principles would apply where a lesser number of samples are to be taken e.g. n=30 or n=15.

Sampling each batch of product using the following sampling plan provides 95% confidence of detecting at least one case where the contamination level in the batch is 5%. Absence of *L. monocytogenes* in 25g where, n=60, c=0 and m=0.

Product samples may be composited[4] for the purposes of microbiological analysis (provided enumeration is not required). A maximum of 15 25g samples may be composited and the whole composite sample should be enriched.

Compositing of samples

- All compositing should be done by the laboratory.
- 60 samples may form 12 composite samples made up of five individual samples (or 5 composite samples of 12 individual samples) for the purposes of laboratory analysis. Laboratory results should report presence or absence of *L. monocytogenes* in a 125g or 300g sample. It is important to confirm with the laboratory that they are able to test composites, especially the larger volumes.
- When the composite sampling of on hold or recalled product is required, only unopened packages of product should be submitted to the laboratory.
- Alternatively where there are large cartons of product, individual samples could be taken aseptically by the food operator at the premises. Care should be taken to ensure that the equipment and packaging material used does not contaminate the product.

Sample selection

Samples should be selected using a random sampling system. For example, the total number of cartons in each batch should be known prior to computing the sampling plan. Each carton in the batch is then issued with a sequential number and the required numbered cartons randomly generated[5]. For example:

- Take as a batch, all product processed and packaged on the same line on a particular working-day.
- Determine where this product is held and the total number of cartons.
- Assign each carton in the batch a sequential number.
- Using random number tables (or other means), generate 60 random numbers.
- A sample should be taken from each of the 60 cartons corresponding to the random numbers.
- Any carton which fits the parameters of the batch but which was not included in the batch at the time of sampling should not be considered as part of that batch (i.e. as a late entry) for the purposes of release.
- Use of results from retesting product previously found to contain *L. monocytogenes* (i.e. contaminated product) is **not permitted** other than for the purpose of providing trace back information.

[4] The compositing of samples may not be applicable for certain products, e.g. non-instantised milk powders. Further information is available on the MPI website (www.foodsafety.govt.nz) [Guide for the compositing of seafood samples for microbiological analysis (http://www.foodsafety.govt.nz/elibrary/industry/Guidance_Compositing-.pdf)].

[5] A simplified approach to sample selection is as follows:
Establish the number of pallets or cartons produced (if it was less than one pallet)
Ensure that samples are taken from all pallets or (if there are more pallets than the required number of samples) ensure that sampling is evenly distributed over all of the production).
Where multiple samples are taken from the same pallet then they should be taken from different levels to ensure an even distribution

Appendix 3: Product Disposition Form

Food operator: Registration/Approval Number: Date:					
Contact Person:			Contact person signature:		
Phone			Mobile:		
Fax			Email:		
L monocytogenes limit that applies to the product(s):					
Level of *L. monocytogenes* in the product(s) (if known):					
Illness details (symptoms, number of consumers affected) (where applicable and known)					
Details of contaminated or potentially contaminated product(s) (attach more pages if needed):					
Product Name/Brand	Identification details e.g. Batch codes	Dates of manufacture	Use-by / Best before dates	Shelf life	Quantity
Location(s) of contaminated or potentially contaminated products:					
Details of Distributors, Retailers, and Manufacturers to whom this product has been distributed:					
Results of routine testing available?		Yes □	No □		
Trend analysis completed?		Yes □	No □		
Any Additional Information – (For example, where the problem is isolated to an ient, other supply chain members identified)					

This record should be held on file and provided to MPI, the Food Compliance Officer or verifier on request.

Food operator:			Registration/Approval number:	
Date:				
Contact Person:			Signature of contact person:	
Phone			Mobile:	
Fax			Email:	
Details of contaminated or potentially contaminated product(s)				
Product Name/Brand	Identification details e.g. Batch codes	Dates of manufacture	Use-by / Best before dates	Quantity

Location(s) of contaminated or potentially contaminated products:

Method being used to hold the contaminated products (if any):

Physical □ Labelling □ Segregation □ Electronic □ Other □

L monocytogenes limit that applies to the product(s):

Level of *L. monocytogenes* in the product(s) (if known):

Intended disposal option

Destruction	□	Reprocessing for human consumption	□
Animal consumption with or without reprocessing	□	Non-food or non-animal feed	□

Other
(state):_____

(state method, transportation and final location details of destroyed products or final product type and intended market):

Justification to support disposal options:

(attach data to support disposal option, e.g.; investigative findings, laboratory test results, trace back findings, corrective actions, other relevant documents).

Records of disposal (including traceability of reprocessed product): Attached □