Guidance for the Control of *Listeria monocytogenes* in Ready-To-Eat Foods

Part 4: Corrective Actions

July 2011

Ministry of Agriculture and Forestry
Te Manatū Ahuwhenua, Ngāherehere

BIOSECURITY NEW ZEALAND

NEW ZEALAND FOOD SAFETY AUTHORITY

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Requests for further copies should be directed to:

MAF Information Bureau
PO Box 2526
WELLINGTON

Telephone: 0800 00 83 33
Facsimile: 04-894 0300

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Prelims

Amendment 0

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Review of Guide

This guide will be reviewed, as necessary, by the Ministry of Agriculture and Forestry. Suggestions for alterations, deletions or additions to this guide, should be sent, together with reasons for the change, any relevant data and contact details of the person making the suggestion, to:

Manager (Food Standards)
New Zealand Standards Group
MAF
PO Box 2526
Wellington
Telephone: 04 463 2500
Facsimile: 04 463 2643

1 Purpose

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The Ministry of Agriculture and Forestry (MAF) has developed a series of documents "Guidance for the control *Listeria monocytogenes* in ready-to-eat foods" that cover different areas of *L. monocytogenes* management in a food manufacturing or processing environment. The guidance documents are:

1. Part 1: *Listeria* management
2. Part 2: Good operating practices (GOP)
3. Part 3: Monitoring
4. Part 4: Corrective Actions

The Guidance material is intended to be used by operators who produce ready-to-eat (RTE) foods which are not intended to be consumed immediately and which will be stored refrigerated for more than 3 days prior to consumption.

Food operations and food products not covered by this guide

This Guidance does not apply to food operators who produce RTE foods that are:

- commercially sterile (e.g. canned food);
- cooked in their retail container/packaging (e.g. cook-chill pouched food);
- aseptically filled into sterile containers preventing the recontamination of the food;
- short shelf-life food intended to be consumed immediately or within 3 days of preparation.

Food operators not covered by this guidance may wish to establish an environmental and product monitoring programme for the purposes of verification of their HACCP. The primary consideration should be based on the monitoring and verification of the critical control points. As such this guide may be a useful reference document.

For operators for whom *Listeria* management requirements are described elsewhere, e.g. dairy and seafood industry requirements for pathogen control, this guidance may provide some useful information. This guidance will also assist food operators who are developing new operations and/or product lines or ranges.

The production of RTE foods intended for immediate consumption and very short shelf life RTE foods e.g. food service and catering, including food provided to at risk consumers in care situations, may also require the establishment of a *Listeria* management programme. The *Listeria* management programme would be defined according to the type of RTE food, the type of the process, the likelihood of contamination as well as the as the hygiene of the operation and previous history of contamination events.

Operators with specific queries may wish to seek the advice of their Food Act Officer or Territorial Authority.

2 Scope

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2.1 WHAT IS COVERED BY THIS GUIDE

This document is Part 4 in the series and provides guidance, and where appropriate the legal requirements for appropriate responses should *Listeria* species or *L. monocytogenes* be detected in a RTE food or on a product contact surface, i.e. a surface that if contaminated may contaminate (or recontaminate) exposed RTE food prior to final packaging.

For operators where there are specific legal requirements for the control of pathogens, dairy and RTE seafood, and whose corrective actions are described elsewhere, e.g. the Seafood Code of Practice and the dairy requirements for pathogen control, this document may provide some useful information. This document will also assist food operators who are developing new RTE operations and/or product lines or ranges.

2.2 WHAT YOU SHOULD GET FROM THIS GUIDE

After reading this document you should have a better understanding of how to respond when *Listeria* species or *L. monocytogenes* is detected in a RTE food or where the potential for post-processing contamination to occur has been identified due to a positive result for *Listeria* from a product contact surface.

Different microbiological limits for *L. monocytogenes* apply to RTE foods depending on the food and whether the food is capable of supporting its growth, the process and the associated history with cases or outbreaks of listeriosis.

When *L. monocytogenes* is detected in RTE foods for which microbiological criteria are specified in the Australia New Zealand Food Standards Code, Standard 1.6.1, the actions described in this Part should be implemented.

When *L. monocytogenes* is detected in RTE foods that have limits that have been defined by the operator or industry and:

- will support its growth, the actions described in this Part should be implemented;
- do not support its growth and the count is not known, the actions described in this Part should be implemented;[1]
- do not support its growth and the count is greater than 100cfu/g, the actions described in this Part should be implemented;[1]
- do not support its growth and the count is between 1 and 100cfu/g the actions described in this Part should be implemented with the exception of the decision to recall or release product from the premises. There should be an investigation of the contamination event and the risk that the counts may actually be higher in some of the product.

[1] Where the limit has been set at 100 cfu/g, this must not be exceeded during the shelf life of the food and so for a RTE food that has an extended shelf life and will support the growth of *Listeria*, this will usually mean that *Listeria* should not be detected at the end of processing. Otherwise the 100cfu/g limit is likely to be exceeded by the end of the shelf life.

3 Definitions

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At risk product or at risk means all batches of RTE product that are potentially contaminated with *L. monocytogenes* as a result of being processed around the same time as *L. monocytogenes* was detected on a product contact surface or product detection or due to some other commonality with the contaminated product.

Batch means a quantity of product of the same type produced under essentially the same conditions during a particular time interval, generally not exceeding 24 hours, e.g. all product of the same type and processed between major clean-downs, or product given an individual batch code to distinguish it from other product produced on the same day[2].

Contaminated product means product that testing has shown to be contaminated with *L. monocytogenes.*

Contamination event is when *Listeria* species and/or *L. monocytogenes* are detected on product contact surfaces (hygiene area 4) and/or in product during routine monitoring, surveys or an illness investigation.

Corrective actions are the sequence of actions taken to resolve an incident involving the detection of *Listeria* species or *L. monocytogenes* on a product contact surface (Area 4) or on product.

GHP means good hygienic practice.

***Listeria* Management Programme (LMP)** is a documented record of the activities that an operator has in place to minimise the potential for a RTE food to be contaminated with Listeria species including L. monocytogenes, such as environmental risk assessment, environmental controls, monitoring, training, GOP and process controls. Where L. monocytogenes has been identified as a specific biological hazard during HACCP analysis, the LMP should be integral to the FSP or RMP.).

Listericidal process is a process which is capable of reducing or eliminating counts of *L. monocytogenes* that could be present in product to levels that are safe and suitable.

Product means RTE food covered by the scope of this programme.

[2] The term 'lot' may be used instead of batch and is defined in the Food Standards Code as:
lot means a quantity of food which is prepared or packed under essentially the same conditions usually –
(a) from a particular preparation or packing unit; and
(b) during a particular time ordinarily not exceeding 24 hours.

Trend analysis is the recording, review and analysis of laboratory results and routine monitoring data (environment and process controls) on a regular basis, e.g. at least every six weeks, to identify trends, take appropriate corrective actions and to adjust the *Listeria* Monitoring Plan. See Part 3: Monitoring, for further information on how to conduct data management and trend analysis.

4 Overview of actions to be taken when *Listeria* is detected

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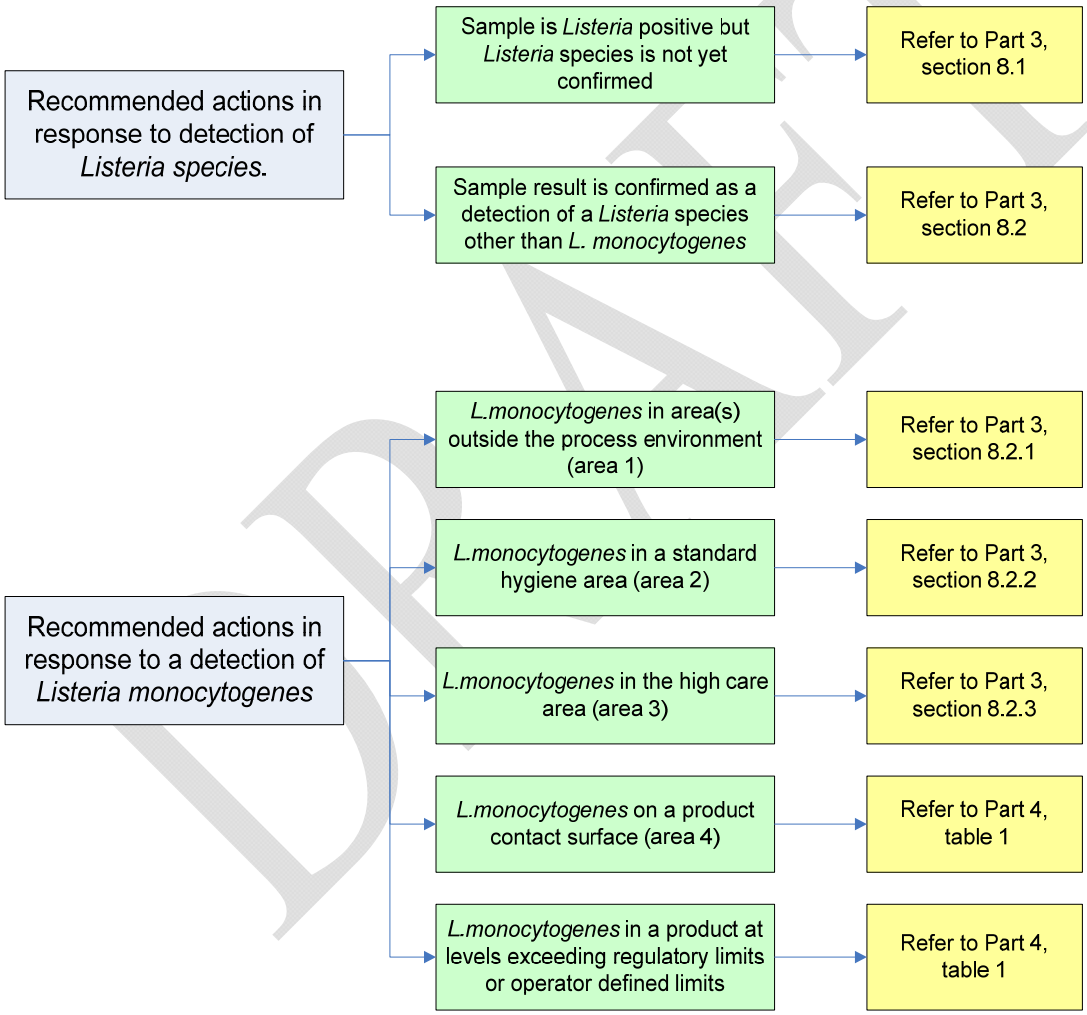
The response needed if *Listeria* species or *L. monocytogenes* is detected during routine monitoring will depend upon the source and nature of an environmental sample and for product, the microbiological limits for *L. monocytogenes* that apply. The diagram below identifies for each type of *Listeria* detection where to find information relating to the response that should be made. In some cases the information will be found in Part 3, Monitoring.

Figure 1:



Listeria detection in products may be also notified by way of customer sampling and testing programmes, regulatory surveys or as a result of illness investigations. The appropriate response as indicated in Figure 1 should be followed but some of the actions may be affected by the increased time delay between the receipt of the notification and when the product was produced.

5 Recommended actions when *L. monocytogenes* is detected

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The recommended corrective actions following the detection of *L. monocytogenes* will depend on the RTE product, the process and in the case of a product contact surface contamination, the likelihood of contaminating the product. This Part focuses on the recommended actions for detections that result in the greatest risk of product contamination, i.e. the product and product contact surfaces which come into contact with exposed product prior to packaging.

Table 1 summarises the recommended corrective actions that would be expected. The actions are not necessarily in chronological order and some of the activities will occur concurrently. It is not an exhaustive list and the appropriate corrective actions should be taken on a case-by-case basis. Each *Listeria* event is different and there will also be differing levels of response depending on past history of events, the product type, process set-up, processing environment and industry sector, with the most at risk product requiring the most intensive response.

It is strongly recommended that expert assistance be obtained to review the corrective actions if a contamination event occurs. If expertise is not available in-house, this should be sought externally e.g. from an individual or organisation with known expertise in this area.

Table 1: Recommended corrective actions in response to the detection of *L. monocytogenes*

Actions to be taken when *Listeria monocytogenes* is detected	Sample source		Guidance section to refer to:
	Product at levels exceeding regulatory or operator defined limits[3]	Product contact surface	
Halt processing on the contaminated process line(s)	Recommended[4]	Recommended[4]	5.1
Isolate contaminated equipment and area(s)	Recommended[4]	Recommended[4]	5.2
Notify verifier, Food Act Officer or MAF	√	√	5.3
Retrieve or recall contaminated and at risk product	√[5]	√[5]	5.4
Identify and hold contaminated and at risk product(s)	√	√	5.5
Investigate cause of contamination	√	√	5.6
Clean and sanitise	√	√	5.7
Intensive microbiological sampling	√	√	5.8
Intensive microbiological verification	√	√	5.9
Dispose of contaminated and at risk product	√	√	5.10
Actions specified in this document if *L. monocytogenes* continues to be detected	√	√	5.11
Prevention of recurrence	√	√	5.12
Review of *L. monocytogenes* management controls after the event	√	√	5.13
Documentation, records and reporting	√	√	5.14

Each of these actions is discussed in succeeding sections. In addition to these actions, you should be familiar with any specific requirements for your industry sector (see Part 1).

[3] Refer to Part 1, section 5 more information about regulatory and operator defined limits.
[4] This action would be expected unless impractical due to processing constraints.
[5] Whether at risk products need to be recalled would depend on information available about the cause of the contamination and the product itself.

5.1 HALT PROCESSING ON THE CONTAMINATED PROCESS LINE(S)

If *L. monocytogenes* is detected in product or on product contact surfaces, processing on the affected lines should cease. For some processes (e.g. continuous operations) this may not be possible or appropriate. If processing continues, all resulting product from the affected lines should be considered at risk, isolated, readily identifiable and placed on hold to prevent it from being used, sold or further distributed until the appropriate testing and checks have been completed.

5.2 ISOLATE CONTAMINATED EQUIPMENT AND AREA(S)

If processing has been halted then:

- the processing areas (including equipment) which have processed contaminated product after a listericidal step; or
- all processing areas which 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*;

should be isolated from other processing areas.

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

Access to and from these areas should be restricted to essential personnel only. The means by which isolation can be achieved will depend on the equipment and type of separation used but may include such actions as keeping the door shut into a segregated room, taping off areas and personnel control (e.g. foot baths, clothing exchange, appropriate signage etc).

5.3 NOTIFY YOUR VERIFIER, FOOD ACT OFFICER AND MAF

It is mandatory for processors of dairy and RTE seafood products produced under the Animals Product Act 1999 to notify their verifier within 24 hours of receiving confirmation of the detection of *L. monocytogenes* in product or on product contact surfaces[6].

All other RTE food operators operating under the Animal Products Act or Food Act should notify their verifier, Food Act Officer or MAF within one working day, and follow this up in writing as soon as possible on receipt of confirmation of the detection of *L. monocytogenes* in product or on product contact surfaces.

It is the operator's responsibility to ensure that the contamination event is managed in accordance with the procedures documented in the *Listeria* Management Programme, with involvement from the verifier, Food Act Officer or MAF.

Information such as details about the contaminated product (shelf-life, batch number(s) or other identification, microbiological results if available, current location, distribution and

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

volume of affected product) and the at risk product will need to be made available to the verifier, Food Act Officer or MAF. They will also need to see routine monitoring results and trend analyses of environmental results. It is useful to make this information available as soon as practicable, but no longer than 72 hours after notification. See Appendix 4 for an example of a Event Notification Form.

The verifier, Food Act Officer or MAF will also be involved in the review of any sampling plans and in decisions on product disposition.

5.4 RETRIEVE OR RECALL CONTAMINATED AND AT RISK PRODUCT

If contaminated product has left the processing premises but remains within the company's control it should be retrieved from the distribution chain. If contaminated product has left the company's control it is likely that a recall will be required. The verifier, Food Act Officer and/or MAF will need to be informed of the location of contaminated and at risk product and of any recall.

Product retrieval or recall should also be considered for at risk product.

The decision to recall product should take into account:

- Whether the product is still within its 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 whether it remains within the company's control.

Under section 40 of the Food Act 1981, the Minister may issue an order directing the recall of any food for the purpose of protecting public health. 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.

For further details on product recall refer to the "Recall Guidance Material", including Appendix 3: Recall Criteria Guide: Microbiological Contamination.

An operator with a registered RMP or approved FSP should follow the recall procedure documented in their programme.

5.5 IDENTIFY AND HOLD CONTAMINATED AND AT RISK PRODUCT(S)

Any contaminated or at risk product should be identified, isolated (where possible) or segregated and held to prevent it being used, sold or distributed, including any product received as a result of retrieval or recall. This also allows time to undertake an investigation of the level and extent of *L. monocytogenes* contamination and to make appropriate decisions about product disposition.

Contaminated or at risk product(s) should be held in a manner that prevents direct contact or cross-contamination with other product(s), raw materials, packaging, equipment and surfaces. Physically isolating the product is of particular importance if it is not packaged.

Product(s) should be clearly identified 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.

> Problems have occurred where there has been reliance on electronic inventory systems to prevent the release of contaminated or at risk product. Using electronic systems as the sole method of control is not recommended unless you have a high level of confidence in your system.

5.6 INVESTIGATE CAUSE OF CONTAMINATION

It is unlikely that *Listeria* will have miraculously appeared inside the processing area. It is likely that there has been a breach of pathogen control measures by something or someone. A review of access controls for people, raw materials, equipment, packaging and any other material should occur.

Building integrity including the possibility of unsealed doors or windows, roof leaks, unflashed pipes and untrapped drains should be assessed.

A good starting point when undertaking an investigation is to systematically review the floor plans and process flows through the premises to identify anything that may be a cause for concern and that should be targeted during the investigation.

5.6.1 Inspect contaminated process area(s) and equipment

The equipment and process area(s) should be inspected in an attempt to identify equipment and area(s) that may be the source and/or harbourage point of *L. monocytogenes*. If the positive result is 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.

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 in order 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).

To investigate the contamination source and rule out those areas that are not, microbiological samples should be taken. (See section 5.6.2. Investigative sampling)

Once the inspection and investigative sampling has been completed affected areas should be thoroughly cleaned and sanitised to ensure that any harbourage sites that may have been disturbed by the inspection do not contaminate the processing area or product.

5.6.2 Investigative sampling to identify environmental contamination source

Investigative environmental sampling can be a costly and time consuming exercise. A large number of samples (for example n=50) are taken from the processing environment in accordance with a thorough and systematic sampling plan to 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. Sampling may be targeted where there is clear evidence to support this. Getting positive results is good as this means that the sampling programme is effective and specific corrective actions can then be taken.

Ideally sampling would occur both before and after a thorough cleaning and sanitation but due to cost constraints this may not always be possible. The benefits of sampling after cleaning is that processing may spread contamination around the processing area, whereas *L. monocytogenes* detected after cleaning are more likely to be at or near the contamination source. However, sampling afterwards may make the task of finding the contamination source more difficult.

The number of samples to be taken will depend on the complexity of the process and equipment involved. However where a reasonable number of samples is not taken, evidence to justify this decision may be required by the regulatory authority.

Discussion with an expert in *Listeria* management is recommended.

- Review the floor plan and process flow to identify areas that present the most likely sources of contamination and cross contamination.
- In the case of a product contact surface positive:
  - Determine the site, date and time when the positive swab(s) was taken. If the swabs were analysed as a composite sample it is important to identify which sample sites were included in the composite.
  - Review the environmental monitoring results from past testing activity to determine those sites that tested "not-detected" for *Listeria* species and those sites with a greatest likelihood of being a source of contamination.
- In the case of a product positive:
  - 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 at risk 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.
- Environmental swabs should not be composited for microbiological analysis during the investigative sampling, as 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.
- Sampling methodology may differ when undertaking an investigation, for example the sample area may increase in size in an attempt to reach greater surface areas or nooks within a piece of equipment. See Part 3: Monitoring for further information on sample taking during an investigation.
- Investigative sampling should commence no more than one working day after receiving notification of a positive result for *L. monocytogenes*.
- It is extremely important to explore **all** possible areas of contamination rather than concentrating effort on small parts of the process, as this can delay detection of the source
- Revisit the environmental monitoring results from other areas to identify any areas that may require a reassessment of the controls (see Part 3: Monitoring).
- Wherever possible, this level of sampling should continue until the source of the contamination has been identified.
- Thoroughly clean and sanitise the affected areas after investigative sampling to ensure that any harbourage sites that may have been disturbed do not contaminate the processing areas or product.

5.6.3 Review supporting systems

A review of supporting systems (GHP) can assist in identifying the cause of the contamination (e.g. cleaning/sanitation program, access restrictions, GHP & operational procedures, staff training).

Aim to check the records that date back to the last not-detected result for *Listeria* species to identify any unusual or atypical information.

For example:

- Did anything different or unusual occur?
- Were the cleaning and sanitation procedures being 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)?
- Did any modifications or repairs to or near the line(s) take place such as replacing flooring or repairing a refrigeration unit?
- Are there ongoing problems that could be linked to the sanitary 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?

5.6.4 Review processing records

A review of processing records is useful to establish the extent of possible contamination and which product lines could be considered at risk. This review should assist in determining whether the process was under control, and that procedures were being followed.

The processing records, especially records of those steps that are used to control *Listeria* (e.g. heat treatment steps) should be reviewed. Aim to check the records that date back to the last not-detected result for *Listeria* species. For example:

- Was there a loss of process control, e.g. at a listericidal step? Do records show that the critical limits or processing parameters were met?
- How many product batches may be contaminated or at risk? E.g. batches produced in common facilities on the same day as the contaminated product and product produced on previous and subsequent processing days.
- Is more than one product line suspected of being contaminated?
- 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.
- Were processing and handling procedures being followed correctly?
- Were there frequent changes in the speed of the process line(s), stoppages or several changes in packaging films/containers?

5.6.5 Sample raw and in-process materials

Listeria may be introduced into the processing environment and products through contaminated raw materials (i.e. ingredients, additives, processing aids and packaging materials). To assist in the identification of the source of the contamination, the raw materials used should be reviewed. Samples of raw materials and any available in-process materials (also known as intermediaries) that could be a source of *Listeria* and whose safety cannot be confirmed by other means, e.g. through supplier guarantees or test results, should be sampled and tested.

In particular any materials that could be a source of contamination and that may be added to the product after a listericidal step, or any materials used in products that are not subject to a listericidal step should be identified, and placed on hold. This will prevent inadvertent use until it is possible to confirm whether they are a source of contamination.

Sampling and testing of packaging materials (e.g. inner and outer packaging, and pallet wrapping) should also be considered since this may also be a source of the 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 raw and/or in-process materials it will be important to check the validation records to ensure that the validated 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 validated 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 raw material supply.

5.7 CLEANING AND SANITATION

It is important to clean and sanitise any areas(s), equipment and utensils associated with the contaminated product or surfaces, paying particular attention to suspect areas. The cleaning and sanitation programme should be reviewed to ensure that it is effective for the operation.

It is essential that cleaning and sanitation takes place in a planned manner which:

- utilises suitable and effective chemicals and cleaning materials and follows the suppliers instructions for their effective use; and
- effectively reduces level of contaminants to below detectable levels; and
- ensures that the cleaning process and personnel do not spread the contamination to other areas and equipment (e.g. by the use of compressed air or high pressure to clean lines or equipment, or by poor practices).

Prior to recommencing processing the cleaned and sanitised area(s) and equipment should be inspected to confirm that they are visually clean.

> In a high proportion of incidents where *Listeria* contamination occurs there have been problems with the cleaning and sanitising systems. A person with the appropriate level of expertise should be involved in any review of the cleaning and sanitation programme.

See Part 2 for further guidance on cleaning and sanitation.

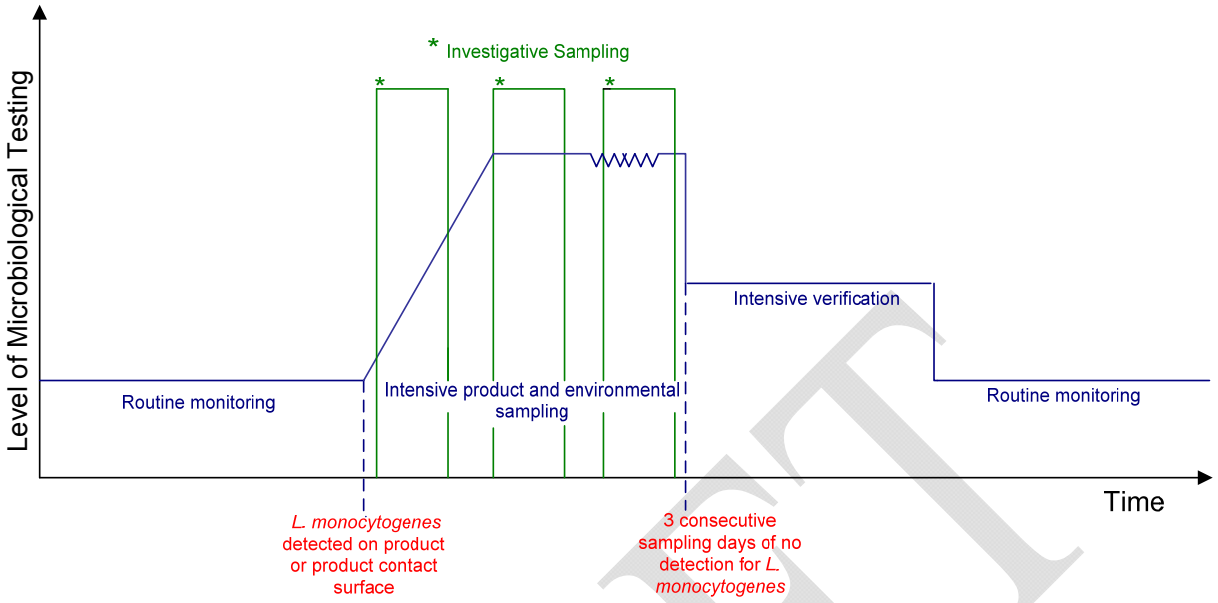
5.8 INTENSIVE MICROBIOLOGICAL SAMPLING PROGRAMME

The intensive sampling programme is an ongoing programme that requires product and product contact surface samples to be taken at a higher frequency from that which occurs during routine microbiological monitoring.

It is intended to identify any product that may have been contaminated around the time of the detection of *L. monocytogenes* and to test product and product contact surfaces on the resumption of processing.

The following diagram provides a simplified time-line in relation to the level of microbiological sampling that would be expected following a *L. monocytogenes* detection.

Figure 2: Time line of microbiological testing following a contamination event



The following sections provide an example of the recommended sample sizes for product and product contact surfaces. As the number of samples 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. For example, at a sampling frequency of n = 60 per batch you would have 95% confidence of detecting *L. monocytogenes* in at least one product where 5% of the product is contaminated. If the sample size is reduced to n=30 per batch, you would have 95% confidence of detecting *L. monocytogenes* in at least one product where 10% of the product is contaminated.

For product that will not support the growth of *Listeria* and that has a limit of 100 cfu/g, having the laboratory enumerate the *Listeria* present should be considered. This result can then be used to assist in determining product disposition (see section 5.10). When *Listeria* are enumerated product samples cannot be composited.

It is possible to further differentiate any *L. monocytogenes* detected to help to determine whether the same or a new type of *L. monocytogenes* is contaminating product contact surfaces and/or the product. Serotyping will differentiate the bacteria into groups 1, 2, 1/2, 3 and 4, the serotypes associated with human cases of listeriosis are 1/2 and 4. Whilst useful, serotyping is limited; the use of Pulse Field Gel Electrophoresis (PFGE) will provide a specific DNA fingerprint. It is then possible to compare the different DNA patterns and see if there is a recurring 'house' *L. monocytogenes* which will have established itself in a niche or harbourage site that is protected from cleaning chemicals. If there are different DNA fingerprints of *L. monocytogenes* appearing, this suggests that the contamination is being introduced, e.g. from the external environment, ingredients and intermediaries, equipment, personnel or packaging, etc. The further typing of *L. monocytogenes* is useful when there is a *recurring L. monocytogenes* detection but it can also be useful to type each sporadic detection as this will build up a history and baseline from which corrective management decisions can be made.

There are two aspects to product sampling that need to be addressed if *L. monocytogenes* is detected on product or a product contact surface. These are given in the following table.

Table 2: Aspects of product sampling

Time frame	Product Sampling	Section to refer to
At the time of the contamination event	Sampling of at risk product processed around the time that the positive result occurred to identify contaminated product	5.8.1.1 for product contact surface detection 5.8.2.1 for product detection
On resumption of processing	Sampling of product that is subsequently processed until sufficient clear tests are achieved	5.8.1.2 for product contact surface detection 5.8.2.2 for product detection

5.8.1 Intensive sampling following detection of *L. monocytogenes* on a product contact surface

Detection of *L. monocytogenes* on a product contact surface should be taken seriously. There is every likelihood that product will also be affected.

5.8.1.1 At risk product sampling

To determine which (if any) products are contaminated, at risk product that was processed around the time of the product contact surface detection for *L. monocytogenes* and that is held in store, retrieved or recalled should be sampled and tested[7].

To assist in identifying which product is at risk, the results from past testing activity and the investigations conducted so far, such as the review of the process control and supporting system records should be used to narrow down the range of product to be sampled and tested. See Appendix 1 for an example of which product could be considered at risk. At risk product will vary depending on the cause of the contamination but could potentially include all product processed (involving exposure to the processing environment):

- since the last not-detected result for *Listeria* species;
- on the same processing line or equipment as the positive result;
- on the same day as the positive result;
- on the day before the positive result;
- between the taking of the positive sample and notification of the *L. monocytogenes* detection
- on processing lines that were in close proximity to the contaminated line
- in the same room or subsequent rooms as the positive result.

An example of how to select samples using a random sampling system is given in Appendix 2. Suggested sample sizes are given in Table 3; alternative sample sizes may be used based on

[7] If you choose to fully reprocess at risk product using a validated listericidal process or dispose of it by some other means (see Section 5.10) testing of that product is not required. You will still need to conduct a thorough investigation of the cause of the contamination to ensure that subsequent product is not contaminated.

the particular *Listeria* event. Product samples may be composited unless enumeration is required.

Table 3: *L. monocytogenes* detected on product contact surface: Suggested intensive product sampling

Sample type	Low risk product[8]	Medium risk product	High risk product
Product	n=5	n=5	n=5

Five samples of at risk product should be selected from each batch processed on each suspect line.

> For a greater degree of certainty that contaminated product will be detected, a larger sample size would be needed. For example, 60 samples could be taken from each batch of at risk product and these could be composited into 5 samples for testing. This would reduce the likelihood that contaminated product could be released for trade.
>
> There may be situations where it is appropriate to take fewer samples for analysis, this will depend on the particular circumstances and practices, processes and product types as every *Listeria* event is different.

If any sample returns a positive result for *Listeria* species the batch must be disposed of in accordance with section 5.10.

Discuss the release of product with your verifier, Food Act Officer or MAF prior to its release.

> Whether all at risk product should be held until the results from testing have been received or could be released on a batch by batch basis will need to be individually assessed. Issues such as the product shelf life, where *L. monocytogenes* was detected, availability of storage space etc would need to be considered. Any decision to release product prior to the receipt of all results would be a commercial risk. It is likely that product with a longer shelf life would be held pending the outcome of all results.

5.8.1.2 Product and product contact surface sampling after processing resumes

When processing resumes in an area after a positive result for *L. monocytogenes* has been received on a product contact surface, the product should be sampled and tested to check if the corrective actions have resolved the problem. The results of the investigation into the source of the environmental contamination may limit the range of product that is considered at risk.

Samples should be taken, for example, during processing based on random times or hourly. As an alternative, the first and last products of the batch may be sampled and then further samples taken at 3 hourly intervals in the intervening period[9]. Product and product contact surface samples should taken at the same time, as this will make the task of determining the

[8] Refer to Part 1 for an explanation of product risk categorisation.
[9] For product with a short shelf life, sampling and testing may need to occur using trial batches rather than sampling from full scale production. Discuss this with your verifier, Food Act Officer or MAF.

appropriate response from any positive result easier if samples are connected by location and time.

Table 4 gives the suggested minimum sample numbers for product and product contact surfaces that are expected to be taken on each processing day following a *L. monocytogenes* detection on a product contact surface. Product samples may be composited unless enumeration is required but product contact surface samples should be individually tested.

Table 4: *L. monocytogenes* detected on product contact surface: Suggested intensive sampling

Sample type	Low risk product[10]	Medium risk product	High risk product
Product	n=5	n=5	n=5
Product contact surface	n=5	n=5	n=5

Five samples of at risk product should be selected from each batch processed on each suspect line. Product contact surface samples should include any sites that have tested positive for *L. monocytogenes* and other suspect areas.

> If the source of a product contact surface detection for *L. monocytogenes* has not yet been identified, sampling at a rate of n=5 is unlikely to be sufficient. Investigative sampling of product contact surfaces should continue as described in Section 5.6.2.

It is suggested that all product should be held until samples from at least three consecutive[11] processing days are "not detected" for *Listeria* species.

Discuss the release of product with your verifier, Food Act Officer or MAF prior to its release.

If any product or product contact surface sample returns a positive result for *Listeria* species at the sample size given in Table 4, the sample size should be increased according to Table 5. Sampling at an increased rate should occur on all available product batches produced since the last clear test for *L. monocytogenes* and all future batches. This includes any product batches that have already been tested and given not-detected when sampled in accordance with Table 4.

> This will require additional samples to be taken from some previously tested batches. Product should be held until the results of the subsequent testing are available to determine product disposition. The results from the original testing using a sample size of n=5 can be used to make up the sample numbers for the batches to be retested at the higher rate.
>
> Retesting of short shelf life product may not be practical and these products may need to be disposed of.

[10] Refer to Part 1 for an explanation of product risk categorisation.

[11] Throughout this Part for intermittent operations, the requirement to have a "not detected" result from three consecutive days of testing would mean consecutive days when processing occurs.

Sampling product and product contact surfaces according to Table 5 should be considered from the outset, to avoid additional delays in the event of a positive result at the sampling rate given in Table 4.

Table 5: *L. monocytogenes* detected on product contact surface: Suggested increased intensive sampling

Sample type	Low risk product[12]	Medium risk product	High risk product
Product	n=15	n=30	n=60
Product contact surface	n=5	n=5	n=5

An escalated response would be expected to identify the cause of the positive result and to prevent recurrence. As a minimum thorough cleaning and sanitation would be expected before processing continues.

The sampling given in Table 5 should continue until at least three consecutive processing days of "not-detected" for *Listeria* species is achieved. Any product batches that test positive for *L. monocytogenes* should be disposed of in accordance with section 5.10.

There may be situations where it is appropriate to follow an alternative sampling plan, this will depend on the particular circumstances and practices, processes and product types as every *Listeria* event should be treated on a case-by-case basis.

Discuss the release of product with your verifier, Food Act Officer or MAF prior to its release.

If *Listeria* species continues to be detected on product or product contact surfaces after nine days of intensive testing, further assistance should be sought to identify the contamination source and to take appropriate corrective actions. It will be necessary to notify your verifier or Food Act Officer and MAF (see section 5.11).

Nine days will allow time to obtain results from three 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.

5.8.2 Intensive sampling following detection of *L. monocytogenes* in product

In the event that *L. monocytogenes* is detected in product, all product in that batch should be disposed of in accordance with section 5.10. If contaminated product has left the control of the operator a recall must be considered in consultation with your verifier, Food Act Officer or MAF (also see Section 5.4).

[12] Refer to Part 1 for an explanation of product risk categorisation.

5.8.2.1 At risk product sampling

To determine if any other product is contaminated, at risk product that was processed around the time of the contamination event and that is held in store or recalled should be sampled and tested[13]. The results from past testing activity and investigations conducted to date, such as the review of the process control and supporting system records should be used to narrow down the range of product to be sampled. Which products are considered at risk product will vary depending on the cause of the contamination but could potentially include all products processed:

- since the last not-detected result for *Listeria* species;
- on the same processing line or equipment as the positive result;
- on the same day as the positive result;
- on the day before the positive result;
- between the taking of the positive sample and notification of the *L. monocytogenes* detection;
- on processing lines that were in close proximity to the contaminated line;
- in other high care areas that had been fed by the same standard hygiene area or processed using common materials;
- under abnormal processing conditions or whilst there has been a failure or uncertainty of control methods such as a failure at a CCP, cleaning procedures in high care areas or building integrity that could affect high care areas.

An example of how to select samples using a random sampling system is given in Appendix 2. An example of the suggested sample sizes is given in Table 6. Product samples may be composited unless enumeration is required.

Table 6: *L. monocytogenes* detected on product: Suggested intensive product sampling

Sample type	Low risk product	Medium risk product	High risk product
Product[1]	n=15	n=30	n=60

Samples of at risk product should be selected from each batch processed on each suspect line. If any sample returns a positive result for *Listeria* species the batch must be disposed of in accordance with section 5.10.

Discuss the release of product with your verifier, Food Act Officer or MAF prior to its release.

> Whether all at risk product should be held until the results from testing have been received or could be released on a batch by batch basis will need to be individually assessed. Issues such as the product shelf life, where *L. monocytogenes* was detected, availability of storage space etc would need to be considered. Any decision to release product prior to the receipt of all results would be at commercial risk. It is likely that product with a longer shelf life would be held pending the outcome of all results.

[13] If you choose to fully reprocess at risk product using a validated listericidal process or dispose of it by some other means (see Section 5.10) testing of that product is not required. You will still need to conduct a thorough investigation of the cause of the contamination to ensure that subsequent product is not contaminated.

5.8.2.2 Product and product contact surface sampling after processing resumes

When processing resumes in an area after a positive result for *L. monocytogenes* in product has been received, product that is considered at risk should be sampled and tested to check if the corrective actions have resolved the problem. The results of the investigation into the source of the contamination may limit the range of product that is considered at risk.

Samples should be taken, for example, during processing based on random times or hourly. As an alternative, the first and last products of the batch may be sampled and then further samples taken at 3 hourly intervals in the intervening period[14]. Product and product contact surface samples should 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.

Table 7 gives the suggested minimum sample numbers for product and product contact surfaces that are expected to be taken on each processing day following a *L. monocytogenes* detection in product. Product samples may be composited unless enumeration is required but product contact surface samples should be individually tested.

Table 7: *L. monocytogenes* detected on product: Suggested intensive sampling

Sample type	Low risk product[15]	Medium risk product	High risk product
Product[1]	n=15	n=30	n=60
Product contact surface[2]	n=5	n=5	n=5

Samples should be selected from each batch processed on each suspect line. Product contact surface samples should be taken from any sites that have tested positive for *L. monocytogenes* and other suspect areas.

> If it is suspected that the source of the contamination is environmental, sampling at a rate of n=5 is unlikely to be sufficient. Investigative sampling of product contact surfaces should continue as described in Section 5.6.2.

It is suggested that all product should be held until samples from at least three consecutive processing days are "not-detected" for *Listeria* species. Any product batches that test positive for *L. monocytogenes* should be disposed of in accordance with section 5.10.

Discuss the release of product with your verifier, Food Act Officer or MAF prior to its release.

If *Listeria* species continues to be detected on product or product contact surfaces after nine days of intensive testing, further assistance should be sought to identify the contamination source and to take appropriate corrective actions. It will be necessary to notify your verifier or Food Act Officer and MAF (see section 5.10).

[14] For product with a short shelf life, sampling and testing may need to occur using trial batches rather than sampling from full scale production. Discuss this with your verifier, Food Act Officer or MAF

[15] Refer to Part 1 for an explanation of product risk categorisation

5.9 INTENSIVE MICROBIOLOGICAL VERIFICATION

After three days of "not-detected" for *Listeria* species have been achieved during the intensive sampling phase (see sections 5.8.1.2 and 5.8.2.2) intensive verification sampling should commence. Intensive verification sampling of product and product contact surfaces should continue for four days to give confidence that *Listeria* has been controlled and that the microbiological limits are being met.

Suggested minimum sample numbers are given in Table 8. Product samples may be composited but product contact surface samples should be individually tested. There may be situations where it is appropriate to take fewer samples for analysis, this will depend on the particular circumstances and practices, processes and product types as every *Listeria* event should be treated on a case-by-case basis.

Table 8: *L. monocytogenes* detected on product or product contact surface: Suggested intensive verification sampling

Sample type	Low risk product[16]	Medium risk product	High risk product
Product	n=5	n=5	n=5
Product contact surface	n=5	n=5	n=5

It is suggested that as a minimum that five samples of at risk product should be selected from each batch processed on each suspect line.

If at any stage a positive result is returned, intensive sampling should resume. Further assistance should be sought to identify the contamination source and to take appropriate corrective actions. It will be necessary to notify your verifier or Food Act Officer and MAF (see section 5.11).

If all results are "not-detected" for *Listeria* species routine monitoring can resume. Discuss the release of product with your verifier, Food Act Officer or MAF prior to its release.

5.10 DISPOSITION OF CONTAMINATED OR AT RISK

The disposition of contaminated or at risk product does not always mean the product should be destroyed. In some cases, it may undergo alternative disposal 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 at risk product is to be reprocessed by another food processor, the documents accompanying the product should clearly indicate the requirement for a

[16] Refer to Part 1 for an explanation of product risk categorisation

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 three consecutive processing days. Otherwise product will need to be retained and tested at the intensive sample size (see Table 4).

Approval from the verifier, Food Act Officer or MAF is needed once appropriate product disposition has been decided.

When determining product disposition consideration should be given to:

- 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);
- The quantity, identification and labelling information of the contaminated product(s);
- 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 location of contaminated product and the disposition premises/area;
- The date and time the proposed disposition would occur;
- The risk associated with the proposed disposition option and how these risks will be managed;
- Conditions and controls for the method of disposition;
- The requirements or constraints of other legislation e.g. the Resource Management Act 1991.

See Appendix 5 for a form that can be completed as part of this disposition assessment.

5.11 ACTIONS IF *L. MONOCYTOGENES* CONTINUES TO BE DETECTED

Where *L. monocytogenes* continues to be detected in product or on product contact surfaces (i.e. three consecutive days of not-detected results for *Listeria* species cannot be achieved after nine days of sampling) the response will need to be escalated. Repeated detection of *L. monocytogenes* suggests that there are bigger, more persistent problems within the premises. The actions described in the previous sections continue to apply. In addition:

- processing on the contaminated line, contaminated process area or of the products producing positive results should be halted until the cause has been identified and eliminated;
- an external expert should be engaged to review actions to date and assist in the resolution of the problem;
- where processing continues, all resulting product should be considered at risk and sampled at the intensive sample size (Table 4);
- consideration should be given to whether the recall should be expanded, particularly in relation to longer shelf life product that may still be available for consumption. Any further product received as a result of an expanded recall should be sampled and tested;
- environmental sampling in accordance with section 5.6.2 should continue to identify the contamination source;
- cleaning and sanitation procedures should be intensified;

- design and construction should be reviewed and any problems addressed;
- an in-depth review of application of HACCP, systems and procedures, wherever possible using people not previously involved in the event, should be conducted.

Where there are ongoing problems, there will be greater involvement from the verifier, Food Act Officer and/or MAF.

5.12 ACTIONS TO PREVENT RECURRENCE

If and when the cause of the contamination is identified, actions should be implemented to minimise the chances of recurrence. For example if:

- the cause of contamination was ineffective cleaning, then the cleaning and sanitation programme should be modified and trialled to validate its efficacy;
- the problem was staff related such as a failure at a CCP, or controls around separation or the movement of equipment in and out of high care areas, the procedures should be reviewed and affected staff trained to ensure that they have a good knowledge of their responsibilities;
- the problem was due to a fault in the processing equipment, then the equipment should be repaired or replaced, where necessary validated and then monitored to ensure that the process is under control;
- the cause of contamination was traced to contaminated ingredients, then the validated process should be reviewed or acceptance testing should be instituted and/or supplier contracts should be reviewed;
- the cause of contamination was linked to product formulation or contamination after the listericidal step, product reformulation or a post lethality step could be added;
- a harbourage site has been found inside equipment or facilities the site should be eliminated. This may be done by dismantling 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.

5.13 REVIEW OF *L. MONOCYTOGENES* MANAGEMENT CONTROLS AFTER THE EVENT

It is strongly recommended that routine *Listeria* management procedures are reviewed following a *L. monocytogenes* event. The event should be formally closed out and relevant staff debriefed. The review would normally include reassessment of 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 of the facilities and equipment;
- effectiveness of monitoring 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.

5.14 DOCUMENTATION, RECORDS AND REPORTING

Records, actions, reports and other relevant information should be kept for all aspects of the contamination event e.g. results, affected product, actions taken, product disposition, reports from external experts, communications with the verifier, Food Act Officer or MAF, decisions and meeting minutes etc.

All records should be made available on request from the verifier, Food Act Officer or MAF and kept for at least four years.

Appendix 1: Sampling days in relation to *L. monocytogenes* detection

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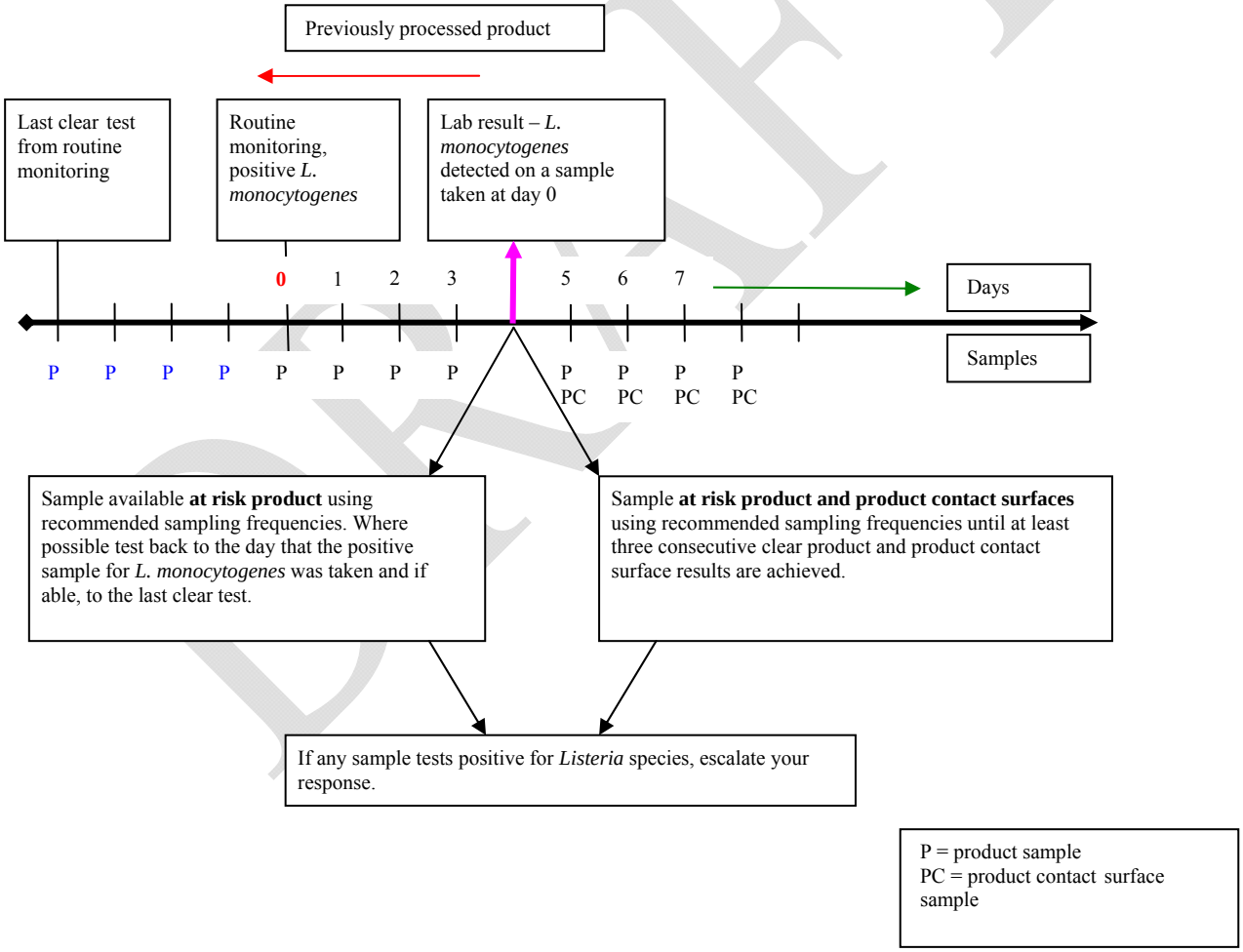
The following diagram illustrates the important days in relation to a detection for *L. monocytogenes* on a product or product contact surface. It also illustrates when product and product contact surface samples should be taken following the detection. Day zero represents the day that the sample was taken that has tested positive for *L. monocytogenes*. The result is notified on day 4. The arrow to the left indicates processing days since the last not detected result for *Listeria* and could be any length of time. P indicates product samples to be taken on any available product since the last clear test and on product once processing resumes. PC is product contact surface samples taken once processing resumes.



Appendix 2: Sample selection for testing product

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The following is an example of how samples of product in store or that have been held or recalled by the 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 incidence 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[17] for the purposes of microbiological analysis (provided enumeration is not required) thus absence of *L. monocytogenes* in 125g where n=12, c=0 and m=0.

Compositing of samples

- All compositing should be done by the laboratory
- 60 samples may form 12 composite samples made up of five individual samples for the purposes of laboratory analysis. Laboratory results should report presence or absence of *L. monocytogenes* in a 125g sample.
- When the composite sampling of on hold or recalled product is required, 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 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, e.g. 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. 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.

[17] The compositing of samples may not be applicable for certain products, e.g. non-instantised milk powders. Further information is available on the MAF 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)].

- 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.

Sample Labelling

Samples must be clearly labelled and sufficient information recorded to ensure easy trace back to the batch in question.

The following diagram shows how investigative samples (that can include waste RTE food product taken from the floor or hidden ledges) should be labelled. The diagram shows the label "Food Safety Mussel Processors" with the label where the type of sample is identified together with the sample number; this sample number then refers directly to the recorded sample sheet. In the event of *L. monocytogenes* being detected it would be possible to trace the contamination back to the points where the samples were collected and to facilitate corrective action.

Food Safety Mussel Processors

Product / Enviro
Product Sample ID: 32 / 325
LM / Salmonella / Staph / E. coli
Sample date: 18/05/2010

Listeria Sampling Results		32
Sampling Site	**Zone**	
Bulk Bag	2	
Bulk Bag Pallet	2	
Chiller Door Handle	2	
Chiller Floor	2	
Chiller Coving	2	
Chiller Drain Cover	2	
Chiller Drain (inside)	2	
Chiller Wall	2	
Chiller Hose	2	
Forks of Forklift	2	
Grading Room Door Handle	2	
Grading Room Floor	2	
Grading Room Coving	2	
Grading Room Drain Cover	2	
Grading Room Drain (inside)	2	
Grading Room Wall	2	
Grading Room Hose	2	
Grader Framework	2	
Grader Belt	2	
Grader Belt Rollers	2	
Shellstock Bin	2	
Grader Room Floor Mat	2	
Grading Staff Glove	2	
Grading Staff Apron	2	
Entry over Belt into HS Room	2	
HS Room Floor	3	

Appendix 3: Flow Chart for Sampling

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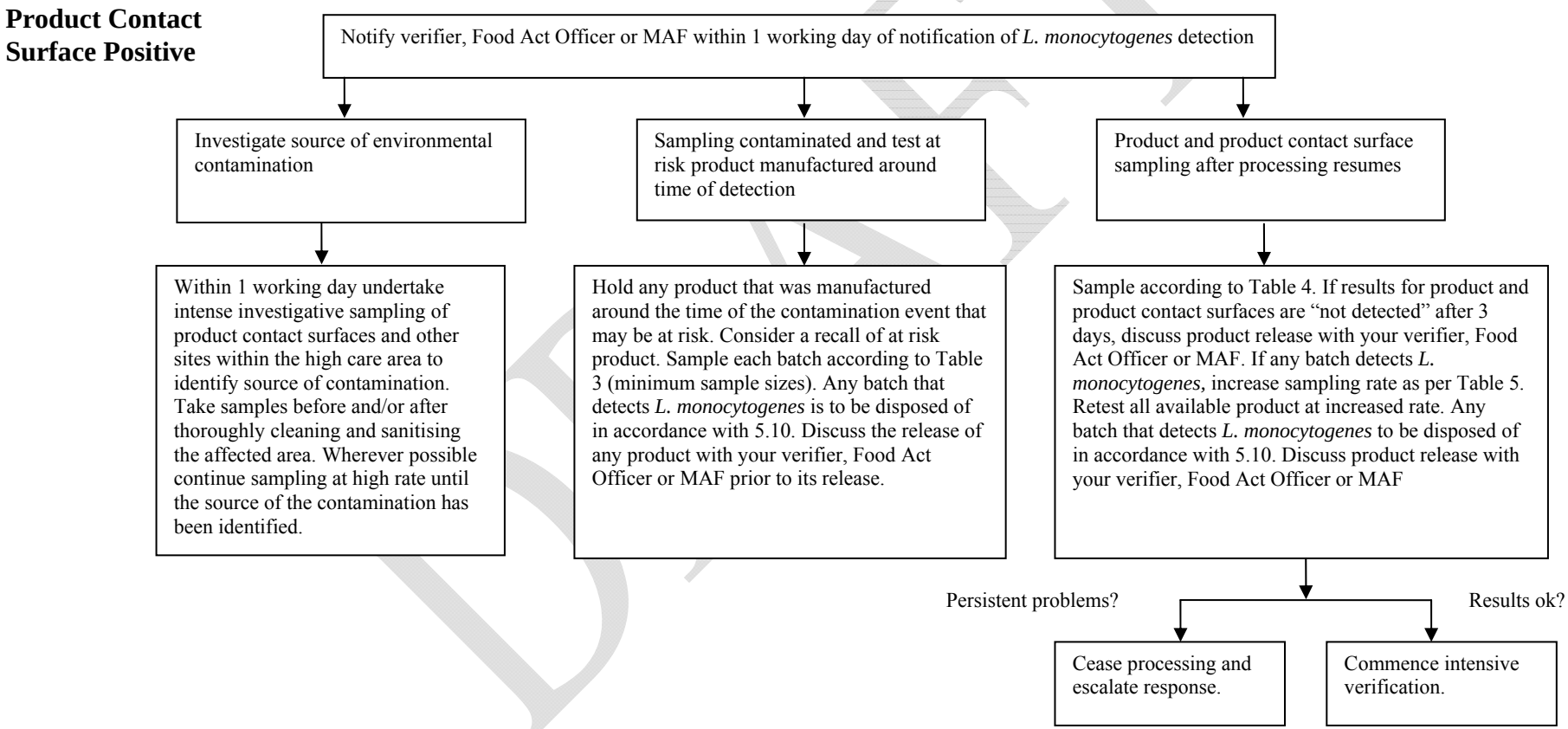
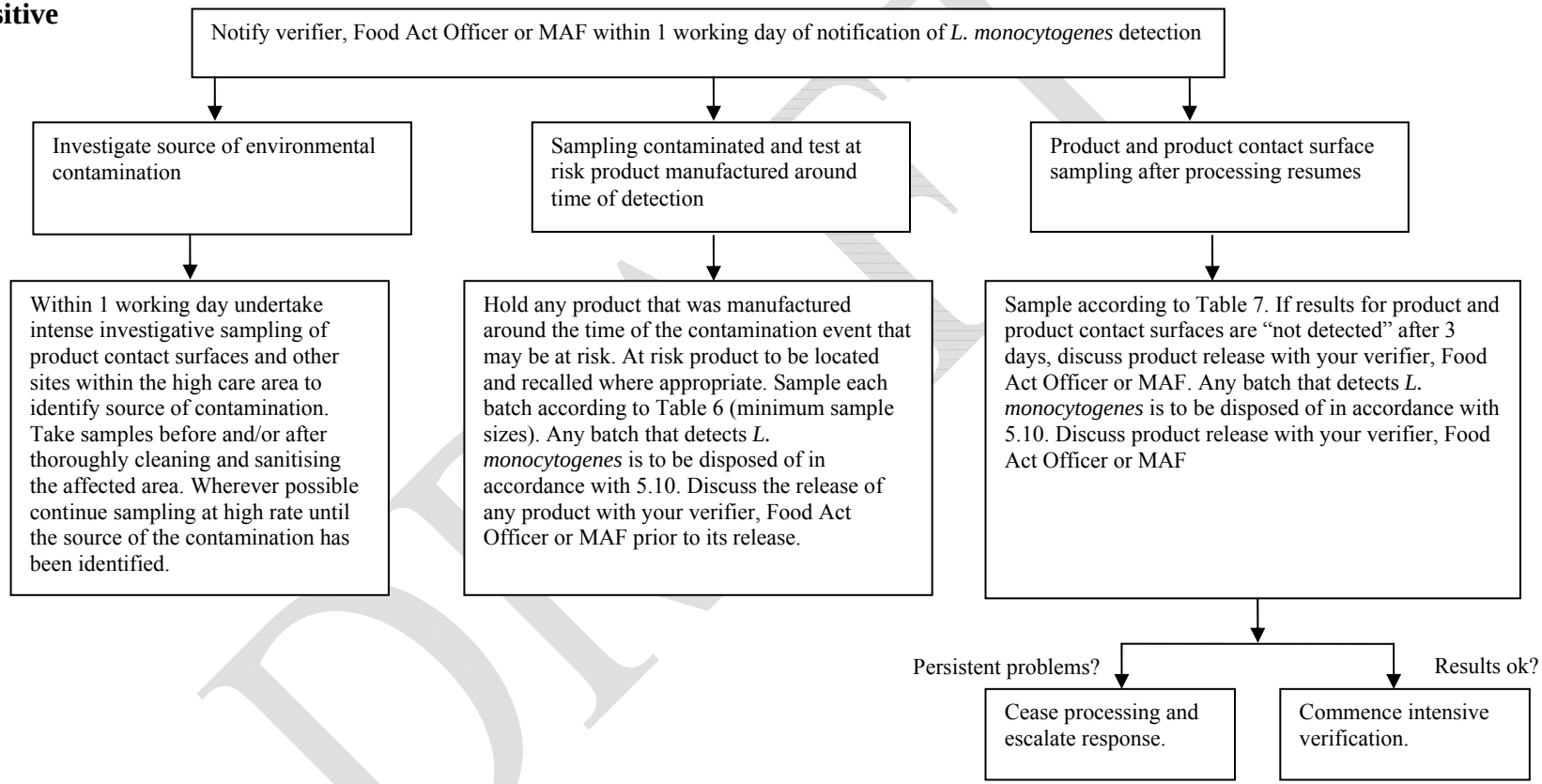


Product Positive



Appendix 4: Event Notification Form

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Operator: **Registration/Approval Number:** **Date:**					
Contact Person:					
Phone			Mobile:		
Fax			Email:		
Microbiological 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 at risk 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 at risk products:					
Details of Distributors, Retailers, and Manufacturers to whom this product has been distributed:					
Results of routine monitoring available?		Yes ☐	No ☐		
Trend analysis completed?		Yes ☐	No ☐		
Any Additional Information – (For example, where the problem is isolated to an ingredient, other supply chain members identified)					

Appendix 5: Product Disposition Form

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Operator: **Registration/Approval number:** **Date:**				
Contact Person:				
Phone			Mobile:	
Fax			Email:	
Details of contaminated or at risk 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 at risk products:

Method being used to hold the contaminated products (if any):
Physical ☐ Labelling ☐ Segregation ☐ Electronic ☐ Other ☐

Microbiological 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 ☐