



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

Part 3: Monitoring

July 2011

DRAFT



Ministry of Agriculture and Forestry
Te Manatū Ahuwhenua, Ngāherehere



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Prelims

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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:

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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.

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* monitoring programme. The monitoring programme would be defined according to the type of RTE food, the type of the process, the likelihood of contamination as well 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 3 in the series and provides guidance on the development of a monitoring programme which if implemented effectively, will reduce the incidence of *L. monocytogenes* in the processing environment and the potential contamination of RTE foods. The key source of listeriosis cases is the consumption of RTE foods contaminated with *L. monocytogenes*. This guide should be used in conjunction with the other documents in the series to provide an overall strategy for managing *Listeria* in a RTE food operation.

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

A *Listeria* monitoring programme monitors the production areas and product for the presence of *L. monocytogenes*. As *L. monocytogenes* is the main *Listeria* species of concern, it is simply called *Listeria* in this guide. Where other species are referred to they will be named as appropriate e.g. *Listeria spp.* (any and all members of the group), *L. innocua*, etc.

2.2 WHAT YOU SHOULD GET FROM THIS GUIDE

After reading this guide you should have a better understanding of how to develop and implement a *Listeria* monitoring programme.

3 Definitions

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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.

Control measure is any action or activity that is applied to:

- control the initial level of *Listeria*
- prevent an unacceptable increase in *Listeria*
- reduce or eliminate *Listeria*.

Colony forming unit (cfu) is a measure of the number of bacterial cells in a sample and is an indicator of the level of *L. monocytogenes* contamination of the product or surface sampled.

An environmental sample is material that is collected from a processing area or the external environment for the purpose of testing the surface or material for the presence of *Listeria* species or *Listeria monocytogenes*.

Food Safety Plan (FSP) is a programme designed to identify and control food safety risk factors in order to establish and maintain food safety (Food Act 1981; amended 1996).

Hygiene Areas – refer to part 1

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

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 or *L. monocytogenes*, such as monitoring, training, GOP, HACCP and process controls.

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

Microbiological hurdles are discussed in Part 1.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process or procedure is under control (Codex).

Niche is a localised site in which food debris and moisture can accumulate and provides an area for *L. monocytogenes* to become established and persist.

Ready-to-eat food (RTE food) is a food which is ordinarily consumed in the same state in which it is sold or distributed.

Risk Management Programme (RMP) is a documented programme designed to identify and control hazards and other risk factors in relation to the production and processing of certain animal material and animal products, to ensure that the resulting animal product is fit for its intended purpose under the Animal Products Act 1999.

Shelf life means the period of time for which a product remains safe and meets its quality specifications as defined by the 'best before' or 'use by' date, when held under the conditions for use and storage printed on the label. For these guidance documents the shelf life will refer specifically to the survival and growth of *L. monocytogenes*.

Trend analysis includes a system to record, review and analyse laboratory results and routine monitoring data (environment and process controls) on a regular basis, e.g. every 6 weeks, to identify trends and appropriate corrective actions.

Water activity (a_w) is a measure of water available for the growth of microorganisms in food. Note that this moisture may not be available if there are substances dissolved in the water such as salt, sugar or acid or the water is bound into a gel.

Critical/high care hygiene areas are those areas in an operation after a *Listeria* control step where the food could be exposed to being recontaminated with *Listeria*

Normal/Standard hygiene areas are those areas in an operation before a *Listeria* control step occurs and which can act as a source of contamination for critical/high care areas

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4 The basics of monitoring

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4.1 WHAT IS MONITORING AND WHERE DOES IT FIT INTO *LISTERIA* CONTROL?

RTE foods that are contaminated with *L. monocytogenes* may cause cases of listeriosis. One way to manage this risk is by monitoring the product and the environment where the food is produced.

Monitoring is what an operator does to show that a process is under control. In this case it is to show that the controls used to prevent or minimise *Listeria* contamination of RTE food are being effective. These controls will be provided by effective use of Good Operating Practices (GOP) and include process controls that are applied both generally to maintain good hygiene and specifically to control *Listeria* (described in Part 2). Controls may thus include elements of GOP, e.g. cleaning and sanitation, specifications for raw materials and ingredients, etc or Critical Control Points (CCPs) which are listericidal e.g. cooking or pasteurisation or there may be a number of microhurdles e.g. washing, thermisation, acid pH and water activity reduction which act collectively to ensure *Listeria* levels are as low as practicable.

In a *Listeria* Management Programme (LMP) an operator should identify the actions which are critical for *Listeria* control and how they should be applied and monitored for effectiveness. LMPs are described in Part 1.

Tools used to monitor effectiveness of *Listeria* control may include:

1. Shelflife testing of product.
2. Ingredient and raw material testing.
3. Monitoring the CCPs, e.g. time and temperature of the cooking and pasteurisation step, or measuring the pH, water activity, etc.
4. Monitoring the effectiveness of cleaning and sanitation programmes by the use of indicator organisms, ATP, etc.
5. Monitoring of the process environment for the presence of *Listeria*.
6. Product testing.

For more information on the application of the first four of these tools see Part 2. The remaining sections of this guide will focus on developing and implementing an effective *Listeria* monitoring programme using the microbiological analysis of samples (environmental and product).

Environmental monitoring and product testing are not ‘silver bullets’ and are not a substitute for the application and monitoring of GOP (see Part 2) and the CCPs. Monitoring of the product and environmental are additional tools or weapons in the operator’s armoury to assist with the control of *Listeria*.

4.2 HOW ENVIRONMENTAL MONITORING CAN BE AN EFFECTIVE TOOL IN THE BATTLE

It is essential to manage the risk of listeriosis by ensuring that food does not become contaminated during processing. This typically occurs when the product is exposed to the environment prior to final packaging. *L. monocytogenes* is widely distributed in the environment and so the potential for the bacteria to be introduced into critical areas of the processing environment is constantly present. Food operators processing RTE foods need to be vigilant to minimise the potential for contamination to occur.

Environmental monitoring is the collection of data that can help to:

- provide an ongoing assurance that the controls being applied (process control, GOP including sanitation and cleaning) are appropriate and effective
- look for breaches of these controls
- provide assurances that new processes and procedures are effective at managing *Listeria* in the environment prior to final packaging
- provide an early warning system showing where and when there is a potential for contamination of product to occur.

4.3 WHERE DOES PRODUCT TESTING FIT INTO *LISTERIA* MANAGEMENT?

Testing product for *Listeria* in the absence of a LMP and a *Listeria* monitoring programme is of limited value in identifying whether *Listeria* controls are being effective. This is because testing product has a low probability of identifying contaminated product even when large numbers of a product are tested (see Table 1). However, product testing can be useful when linked to environmental monitoring in a *Listeria* monitoring programme and is essential when there is evidence that a product is or could be contaminated.

Table 1: Chances of finding contaminated product in relation to number of product samples

Sample number	Chance of missing contamination in a 'lot'		
	Rate of contamination in the lot		
	1%	5%	10%
1	99%	95%	90%
5	95%	77%	59%
10	90%	60%	35%
25	78%	28%	7%
50	60%	8%	0.50%

4.4 WHAT IS NEEDED FOR MONITORING TO BE BENEFICIAL?

The purpose of the monitoring programme is to find *Listeria*. This allows corrective action to be taken and to prevent the costly repercussions if *Listeria* is detected at high levels in a product at retail or is attributed as the source of an outbreak.

To be effective, monitoring requires some financial and time inputs. It is important that these costs deliver positive benefits to the operator. Achieving these benefits and running a successful monitoring programme will depend on:

- Trying to find *Listeria*; and
- Making the right response to finding *Listeria* species or *L. monocytogenes* during monitoring. The responses will depend on the product, the process and the point where *Listeria* was detected and the likelihood of further contamination.

Note that monitoring the environment or product for *Listeria* is not a substitute for GOP and process controls targeted at reducing the presence of *Listeria* in the processing environment and in the RTE food. This is because sampling will not be undertaken every day, will on each occasion only include a selection of sampling sites and only a small number of product samples will be tested. Any sampling and testing programme will only provide a snapshot of the operation.

"The greatest risk to the (Canadian) food safety system is the multitude of (Canadian) plants which do not find positive test results simply because they don't test adequately. If you test, you will find and you can eradicate with the proper protocols. If you don't test, you won't find but there will be no eradication which is the real food safety risk in this country" Michael H. McCain, President. Maple Leaf Foods Inc. (2009)

4.5 WHO NEEDS A *LISTERIA* MONITORING PROGRAMME?

It is recommended that Part 1 should be read first to provide background information on *Listeria* and *Listeria* management. Operators who process RTE foods which are at risk of contamination prior to final packaging (see Part 1) should undertake *Listeria* monitoring. Operators who process RTE foods in the low risk category or foods which are not at risk of contamination prior to final packaging should determine through the application of HACCP (which is applied during the development of a RMP or FSP) whether there is the need to set up a *Listeria* monitoring programme. While for these foods sufficient control should be provided by the GOP and other process controls in place, operators should be alert to the potential for these controls to be compromised so that *Listeria* control is no longer assured.

The extent and intensity of the monitoring programme will depend upon:

1. the characteristics of the RTE food i.e. does *L. monocytogenes* grow or not grow,
2. the type of processing (is there a listericidal step (CCP)?), and
3. the likelihood of contamination (exposed to the environment or not).

The more risk factors are present, the more emphasis should be placed on *Listeria* monitoring. The flow chart in Section 11.1 provides guidance on who needs a monitoring programme and how monitoring fits into other aspects of *Listeria* management.

4.6 SETTING UP A MONITORING PROGRAMME

A *Listeria* monitoring programme is unique to each processing facility and the foods produced. The types of foods and the processing environment and processes used will therefore influence how the monitoring programme is set up.

Factors that define the nature and complexity of the programme include:

1. Risk categorisation based on the type of product and process; the opportunity for post-processing contamination to occur i.e. is the product exposed prior to final packaging.
2. The way in which separation of the hygiene areas is achieved.
3. Process flow and the potential for cross-contamination to occur – in general, the more linear the flow the less opportunity for post-processing contamination.
4. The effectiveness of processing to reduce *Listeria* present to safe levels i.e. the validation of relevant processing methods and CCPs.
5. Controls for ingredients e.g. supplier assurance programmes and specifications.

4.7 WHAT TO TEST FOR - *L. MONOCYTOGENES*, *L. INNOCUA* AND *LISTERIA* SPECIES?

L. monocytogenes is the most important type of *Listeria* as it causes the illness listeriosis. Other *Listeria* species, such as *L. innocua* can be found in the environment and are associated with food and the processing environment in the same way as *L. monocytogenes*. Therefore finding any *Listeria* species in the processing environment or food indicates that there is the potential for *L. monocytogenes* to be present as well. It is therefore good practice to consider finding any *Listeria* species during environmental monitoring as of equal significance in relation to process control.

In the laboratory the first step in testing for the presence of *L. monocytogenes* is to see if any *Listeria* is present i.e. *Listeria sp* and then which specie it is (i.e. confirm whether or not it is *L. monocytogenes*). Thus tests for *Listeria sp* only, will provide faster results and will cost less than tests for *L. monocytogenes*.

However when testing product it is important to know which *Listeria* species and often how many *Listeria* there are i.e. count per gram of food. Counting the number of bacteria such as *Listeria* in a food is called enumeration. Counts are expressed as colony-forming-units (cfu) per g of food. The food will be considered unsafe for most consumers if *L. monocytogenes* is present at unacceptable levels, usually greater than 100cfu/g. However it should be remembered that for RTE foods where there is a *Listeria* control step finding any *Listeria* species will indicate that there has been a control failure or recontamination has occurred and *L. monocytogenes* may be present. Note that for vulnerable consumers it is possible that high levels of *Listeria* species other than *L. monocytogenes* could be the cause of illness.

5 A monitoring programme

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5.1 COMPONENTS

To be effective, the programme will need to be documented and will include the following activities and information:

- a) Responsibilities i.e. the name and/or designation of personnel responsible for the programme and a description of their responsibilities (see section 5.2).
- b) Training of samplers (see section 5.3).
- c) A sampling plan to show for each hygiene area, from where and when environmental samples are to be collected; product sampling if required. (see section 5.4).
- d) Procedures for collecting environmental and product samples and situations where increased sampling is needed (see section 5.5).
- e) The laboratory – arrangements for sending samples and receiving results (see section 6.0).
- f) Record keeping– for recording and reporting laboratory results and trend analysis (see section 7.0).
- g) Responding to finding *Listeria* i.e. an action plan for when *Listeria* is found (see section 8).
- h) Monitoring programme review (see section 9.0).

5.2 RESPONSIBILITIES

5.2.1 Role of senior management

It is important that senior management in the business understand the importance of *Listeria* control and its impact on food safety and that there is an agreed system for alerting management to positive findings. Management must understand that positive results can be expected to occur from time to time in the processing environment and what is important is how this is responded to. The failure of staff to report positive results and of the management to respond appropriately has contributed to listeriosis outbreaks and product recalls (this may be some time later) and loss of reputation for the company and expense. Early detection of problems may prevent a costly recall along with the associated loss of reputation and the potential for cases of illness.

5.2.2 Designated person to be in charge

Responsibility for the implementation and ongoing activities of the *Listeria* monitoring programme should be assigned to a specific individual. This person may also have responsibility for the overall *Listeria* Management Programme (see Part 1). The responsibilities of the designated person and their deputy when they are absent must be clearly identified, in particular the way the outcome of testing is communicated and acted on.

Review of listeriosis outbreaks and incidents invariably identifies poor communication as contributing factors to both the size and duration of an outbreak.

At all times a designated person must be available to initiate a response process in the event of there being:

- a positive notification from the laboratory
- an event that would require additional sampling to be undertaken.

Scenario setting, using fictional laboratory results for contaminated samples can be used to see if the communication plans are workable, that everyone along the production line knows and agrees with their roles and responsibilities and ensures that nothing has been missed.

5.2.3 Checklist of responsibilities

- Negotiate a contract with a laboratory – includes costing for tests, frequency and types of tests, arrangement for getting samples to the laboratory e.g. couriers and transport containers, how results will be notified.
- Design sampling plans and schedules. Make sure that sampling gets carried out according to the schedules.
- Ensure that all the materials needed to take and transport samples are available and not out of date when sampling is to be undertaken. Materials include sterile swabs, sterile sample containers, gloves, forceps and sterile liquids to moisten swabs.
- Document the sampling procedure. Ensure that samplers are trained, competent and that there is a consistency in sampling technique, including knowledge of samples sites, sample coding and recording.
- Determine requirements for increased sampling, response to positive findings, trend analysis and at least an annual review of the monitoring programme.

5.3 TRAINING OF SAMPLERS

Samplers should be trained to ensure that they are competent to take samples and identify relevant sample sites. Training records should be kept and only competent samplers used to collect samples. It is important that samplers understand why and how samples must be collected aseptically.

All aspects of the sampling process should be written down. Detail that could be included would be:

- where to find the documents with the sampling requirements i.e. where and when to sample
- sampling materials e.g. swabs, diluents, forceps, transport containers
- how to sample e.g. hygiene and gloves, area and equipment to be swabbed, sequence for taking samples
- labelling samples and storage prior to dispatch
- documentation and transport arrangements.

5.4 THE SAMPLING PLAN

5.4.1 What is a sampling plan?

A sampling plan will identify:

- the locations in the operation environment from which samples will be collected
- the number of samples and the frequency at which each site is sampled
- the type of sample, e.g. gauze or sponge swabs of surfaces or materials such as scrap, sweepings or liquids.

A sampling plan will be unique to the particular operation depending on the RTE food, the process, the likelihood of contamination prior to final packaging and the past history of *Listeria* detections.

Product may also be sampled at the same time as the environment. This may help to build a complete picture of what is happening in the operation. The sampling plan will identify the product batch, how much is sampled, the sample frequency and how the sample is taken.

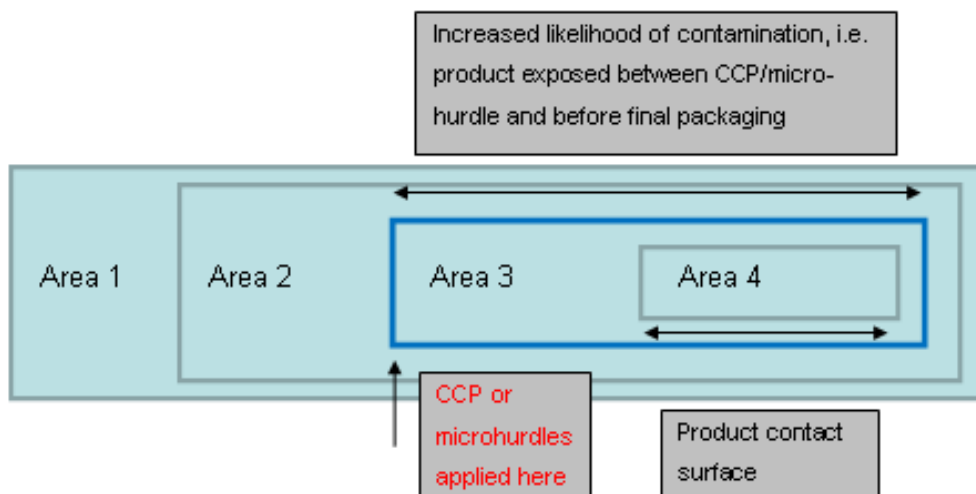
5.4.2 Documenting the sampling plan

The sampling plan will describe in words and/or using diagrams:

- The hygiene areas specific to the food operation (see Part 1 for assistance with how to define hygiene areas in an operation and Diagram 1 below).
- The sampling sites (niches and possible contamination routes) in each hygiene area and when they are to be sampled (see section 5.4.4).
- Instructions to look for sites that are new or changed especially where the unpackaged product is handled, i.e. hygiene areas 3 and 4.
- Requirements for product to be sampled, usually in conjunction with the environmental monitoring.

A good sampling plan is critical to the success of a monitoring programme, so it is important to make sure that the plan is well designed. If there is no expertise in *Listeria* monitoring programmes within the operation, it is advisable to seek input from an external expert familiar with the food sector.

Diagram 1: Hygiene Areas and risk to the product from *Listeria* contamination



5.4.3 Sampling sites

Mark the sampling sites on floor plans in each hygiene area. Describe sites accurately and in detail to avoid confusion. Codes are usually assigned to each for ease of sample labelling. Anything and everything in a hygiene area should be considered for sampling and may include parts of buildings, access ways, equipment, fork lifts, knives, gloves and door handles.

Past experience provides the following guidance on how to select sites:

- For processing equipment focus on hard to clean areas, old and damaged equipment or surfaces, moving parts, valves, wheels on conveyor belts, seals (and areas behind and beneath seals), safety covers, cracks, ducts and on and in hoses and spray nozzles. Particular attention should be given to high use equipment, hard to clean equipment and surfaces, including porous or damaged areas and sites where *Listeria* has been found previously.
- Product contact surfaces are very important. These are any surfaces on equipment that exposed product may come into contact with and which may be a possible route of contamination. This is especially important in the level 3 hygiene areas, if product has been subject to a listericidal process (CCP designed to control pathogens or microhurdles) and is exposed to the processing environment prior to final packaging. Examples of product contact surfaces include work tops, conveyor belts, trays, knives, slicers and dicers e.g. equipment used to slice a cooked product.
- Surfaces and hidden away areas which may not be cleaned properly and could drop contaminants onto the product. These are identified as area 4 on the diagram and present a high risk should they be contaminated.
- It is important that the sites are chosen to give the best chance of finding any *Listeria* that may be present - be aggressive in finding contamination sites. This means taking lots of samples. It is not unexpected to find *Listeria* on occasion, especially in external areas remote from the high care area. Cracks and crannies that are potential niches should be looked for. Tracking down such sites is also helpful in identifying areas where maintenance could eliminate a potential niche.

5.4.4 Looking for niches and transmission routes

Niches are sites where *Listeria* is harboured and which can potentially contaminate the product or from where it can be transmitted to other parts of the processing plant.

For survival *Listeria* needs moisture, a temperature within its growth range and food. Food for bacteria means any organic material. So an ideal niche will be somewhere that provides these essentials and is difficult to clean or infrequently cleaned. Once *Listeria* is on a surface where growth is possible it may form a biofilm. Biofilms are difficult to remove and resistant to chemicals.

Typical niches are:

- floors, especially if damaged or repaired
- drains, especially when pooling occurs
- areas where there is condensate which could drip onto product or equipment
- chillers and refrigeration units, often difficult to clean
- tools and handles, seals and pull cords
- any damaged or porous contact surfaces e.g. on trolleys or conveyor belts
- pierced or hollow components where liquid or product can accumulate
- areas with poor drainage

- seams and small gaps in equipment that is difficult or unable to be taken apart
- any difficult to clean surfaces.

Equipment such as dicers, slicers and conveyors will often be very complex and difficult to take apart and to clean. Their design may allow material to become trapped internally in the housing, rollers etc.

Once a niche is identified, consider the potential for it to be transmitted to other areas, especially critical areas. Focus on these when developing a sampling plan.

If new equipment or new products are introduced they must immediately be assessed for addition to the plan. The plan should also be adjusted in light of positive laboratory results to focus on sites where *Listeria* is isolated.

Appendix 11.2 provides some assistance for small operations on how to identify sampling sites.

5.4.5 Sampling frequency

The sampling frequency will vary between sampling plans and between different hygiene areas.

The higher the risk to the product from contamination during processing, the more need there is for the area to be sampled more frequently, i.e. sample sites in hygiene area 4 will be sampled more often than in hygiene area 1. This is identified in Table 2 which explains the reasons for sampling each area.

Table 2: Monitoring strategies and sampling frequency

Hygiene area description ¹	Risk to product if <i>Listeria</i> present	Why monitor?	Sampling strategy for high and medium risk foods
<p>Area 1- Outside the processing areas</p> <p>May be outside the premises. Areas through which people and equipment pass e.g. loading bays, waste bins, storage areas, especially those used for packaging.</p>	Low	Finds <i>Listeria</i> lurking outside which could easily be brought into the processing area on feet, equipment etc.	Identify sites which people, materials or equipment may come into contact with before entering processing areas. Consider prioritising some for regular testing, other sites sampled at least annually according to a written sampling plan.
<p>Area 2 - Standard care hygiene area</p> <p>Initial preparation and processing area e.g. cutting, dicing, washing including the equipment.</p>	Low if there is a CCP designed to control pathogens later and medium/high if no CCP. Risk will depend on whether food supports growth of <i>Listeria</i> and shelf life	Shows if <i>Listeria</i> is coming into the processing area and monitors the effectiveness of cleaning and sanitation. Find it here before it moves into high care areas. Will be important area to monitor if there is no CCP for <i>Listeria</i> .	Identify sites from which <i>Listeria</i> could be transmitted to the food e.g. drains, condensate, hoses, conveyor belts, walls, floors, processing equipment. Consider prioritising some for regular testing, other sites less frequently.

Listericidal process, e.g. CCP, or a micro-hurdle or product exposed prior to packaging			
<p>Areas 3 and 4 High care areas and product contact surfaces</p> <p>Main processing and post-processing areas where further handling occurs e.g. slicing and packaging.</p>	High	Food that has been subjected to a listericidal process is very vulnerable to recontamination. Lack of competitive bacteria allows <i>Listeria</i> to grow. Damp areas act as a reservoir for contamination as can product contact surfaces and equipment in contact with the food. <i>Listeria</i> can be introduced from standard care areas.	Include all sites every sampling cycle

¹ Areas are ideally separated by physical barriers such as walls but in small operations this may be ‘virtual’ and indicated only by markings e.g. red line on the floor, change in floor colour or be separated by time (see Part 2).

Sampling plans are usually based on a yearly cycle with samples being collected at regular intervals during the year. The interval between these routine sampling rounds may vary from a week to months. Some sites, especially product contact surfaces may be sampled every time but other sites less frequently. All sites should be sampled at least annually. An example of a sampling site spread sheet is shown in 11.3.

Hint: Use a calendar format to schedule sampling rounds and a spreadsheet with colour coding to show when a site is to be sampled.

How often and how many samples are taken will depend on:

- the risk category that the foods being processed fall into and
- the size and complexity of the operation..

If there is a high degree of separation e.g. physical barrier and boot and clothing changes, between the low hygiene areas 1 and 2 and the high care areas 3 and 4, sampling may focus on the latter areas.

Each processing facility and each type of food will present a unique set of issues. Testing is expensive and so it is important that the plan decided on gives good value for money. However, if a high risk RTE food is being produced it is important to take into account the impact that a failure will have on the business and the community.

Small businesses that find the level and cost of testing too burdensome should look at whether they should continue to make a high risk product or drop that product line or look at whether the risk categorisation could be reduced e.g. by applying a heat treatment to packed product or reformulation so that *Listeria* will be less likely to grow in the food.

5.4.6 Product sampling

Monitoring programmes usually include product sampling and testing for *Listeria*. This testing will assist to validate the process, verify CCPs and microhurdles identified by HACCP that are being applied to control *Listeria* and provide for due diligence.

Keep in mind that if product becomes contaminated with *Listeria*, not all units in the batch may be contaminated, especially when the contamination level is low. Also even if a unit selected is contaminated, only a 25g portion of the unit will be tested in the laboratory. Thus retesting a sample or a batch and getting a negative result does not mean that the first result was incorrect. This is a true and valid result and must be treated as real, the batch can not be retested and the original result discounted.

5.4.7 Sampling frequency

Table 3 provides suggested frequencies for testing. These assume that GOP, HACCP and process controls are also being monitored. These may be reduced when there is sufficient evidence to justify a reduced sampling frequency.

Table 3: Suggested Minimum Testing Frequency

Food Risk Category (See Part 1 for definitions)	High care area		Product (n=5)
	Each general site should be sampled	Product contact surfaces	
High	At least monthly	Weekly	Weekly
Medium	At least quarterly	Group 1 - fortnightly Group 2 – monthly	Fortnightly or monthly (no less than once every 10 batches)
Low	Annually if monitoring undertaken	Quarterly if monitoring undertaken	Quarterly

The number of samples collected each time will vary according to the size and complexity of the operation and the risk category. The recommended minimum sampling regime for small operations or where low risks RTE foods are being processed is no less than 5 environmental samples plus 5 product samples. (In Section 5.5.1 below, information is given on what constitutes a sample.) However it is important that the sampling plan is appropriate and gives assurance that the risk is being managed.

For small facilities with relatively small product volumes the temptation will be to keep the sampling to the absolute minimum, however if the sampling is very infrequent, failures of the control programme could go undetected for some time with costly consequences. It is therefore recommended that sampling occurs as frequently as is economically viable, taking into account the cost if there was a failure to control *Listeria* adequately. Appendix 11.3 provides guidance for a sampling plan for a small operation.

5.5 PROCEDURES FOR COLLECTING ENVIRONMENTAL AND PRODUCT SAMPLES

5.5.1 How many food samples and what to sample?

No less than 5 product samples should be sampled each time. Tests performed on single samples of product provide no information on the effectiveness of the *Listeria* control programme, unless the result is positive. When there is a failure to control *Listeria*, the level

of contamination in product at the end of processing is usually fairly low (but if the bacteria can grow in the food this may become a large number by the end of the food's shelflife) and therefore the chances of detecting contaminated food is not highly likely.

The 5 samples may be from a single batch of product or may be a combined sample from a product line over a period of time e.g. one week. A disadvantage of the latter type of sampling is that if the samples have been composited, in the event of a positive result it will need to be assumed that the contamination occurred on the earliest day of the production run. For continuous processes, grab samples may be more appropriate. Grab sampling may be performed on liquids and powders. Small samples are taken manually or automatically by a sampling device over a specified time period. By the end of the sampling period the required sample volume or weight for submission to the laboratory will have been collected.

When product contact surfaces are sampled, product (i.e. final packaged product that can be linked to the site and time of sampling) could be collected. In the event of either being found positive for *Listeria*, the task of working out the appropriate response will be made easier when product and product contact samples are connected in space and time.

Where there are a number of different products and lines, it may not be practical to test all of them each sampling round. Instead decide which foods are sampled and when. It may be preferable to focus on the RTE foods with the higher risk, foods which have been a concern previously or are most open to post-processing contamination. Make sure that each sampling cycle includes foods that have been processed on each of the processing lines from which product contact surface swabs have been taken.

5.5.2 Amount of food needed in each sample

The laboratory will usually require that each sample is at least 100g. Ideally the products should be submitted in their final packaging. If samples are needed to be taken from bulk product, this needs to be done aseptically immediately prior to the final packing step into individual sterile containers. Where final product is in units of less than 100g, multiple samples will need to be submitted to the laboratory.

Note that if it is required to show compliance with the Australia New Zealand Food Standards Code, Standard 1.6.1 or another Product Safety Limit, usually no fewer than 5 samples from the same batch of product need to be sampled. Each sample must be in excess of 25g where compliance is absence in 25g and n=5. The 5 samples can usually be composited, and this may lower testing costs. However the laboratory must be able to demonstrate that compositing does not lose the required sensitivity of the test method through pooling the samples.

5.5.3 Compositing samples

Testing costs may be able to be reduced by compositing samples i.e. testing a set of samples as a single sample. The laboratory needs to know when samples are to be or have been composited. Usually 5 samples are composited. The samples should all be from the same hygiene area or if product from the same batch or production line. When very large numbers of foods need to be tested e.g. when a contamination event has occurred it may be possible to composite more than 5 samples. However this may not always be practical and must be discussed in advance with the laboratory.

The disadvantage of compositing environmental swabs is that if the results come back positive all the sampling sites will need to be investigated further. Caution should be taken in compositing samples from product contact surfaces and any other critical sites.

Compositing of environmental samples may be undertaken by the sampler e.g. 5 swabs placed in one sterile container. However products samples will usually need to be composited by the laboratory.

5.5.4 Situations where sampling should be increased

There are a number of situations where enhanced sampling is required or advisable because the *Listeria* controls may have been compromised or have failed. Sampling rates may be returned to normal once the situation has ceased to have an impact. It is however important to continue increased sampling for sufficient time to have confidence that the system is under control. For example at least 3 sets of negative results at the increased rates after a change to a cleaning and sanitation programme.

Table 4: When to increase sampling

Situation	Response
Start up of new facility or processing line	<ul style="list-style-type: none"> Decreased time between sampling e.g. weekly instead of monthly Increase number of samples from high care areas and product contact surfaces More frequent product samples e.g. every batch rather than weekly or monthly
New product formulation, packaging or process	<ul style="list-style-type: none"> Increased product samples i.e. more samples each time or more frequent sampling for the first month
Changes to cleaning procedures, chemicals and equipment	<ul style="list-style-type: none"> Increased samples from affected hygiene areas and affected downstream processing areas
Building or equipment repairs, maintenance, alterations – scheduled or unscheduled	<ul style="list-style-type: none"> Increased samples from affected hygiene areas and affected downstream processing areas Extra samples from affected equipment
Environmental disruption e.g. flood, roof damage	<ul style="list-style-type: none"> Increased samples from affected hygiene areas and downstream processing areas Sample more frequently until evidence that no impact or impact remedied Extra samples from any affected equipment
Increased production for a defined period e.g. longer work days, more work days (bigger product volumes and altered cleaning schedules)	<ul style="list-style-type: none"> Increase product samples Increased monitoring of cleaning and sanitation and cleaning especially if schedules are changed or potentially compromised by production demands
<i>Listeria</i> has been found in product or product contact surface	See Part 4 Corrective actions

5.5.5 When to sample

Sampling should be scheduled according to activity. While equipment or lines are not in use they should still be sampled but at a reduced frequency.

Samples are usually taken during processing to show if *Listeria* is being introduced or if normal processing is disturbing *Listeria* niches which could contaminate the product. It is recommended that there is at least 2 hours operation before samples are taken. This gives time for bacteria that were trapped to work out onto surfaces, especially important for product contact surfaces.

When *Listeria* has been found and a traceback is being undertaken, sampling may also be done just prior to the start-up of processing to assess the effectiveness of cleaning and sanitation procedures and whether this has been sustained during shut down. A lot can happen after the cleaning crew have gone home. For example, refrigeration units have a defrost cycle and, if there has been any icing on the fins, aerosols can splatter on the tables and equipment below them, or air movement from the dispatch area may introduce contamination.

5.5.6 How to collect environmental samples

The aim of sampling a surface is to extract as many bacteria as possible. The techniques used should be written down to ensure that there is some consistency in sampling.

For sampling surfaces:

- Swabs of different types are available commercially. The sampling plan must identify which to use at each site. Gauze swabs and forceps are most effective at picking up *Listeria* from surfaces. Swab sticks however may be useful for getting into cracks and crevices and for complex equipment.
- The aim of swabbing is to find *Listeria* if it is present. Swab as much of the identified area as possible. Gauze swabs are usually the most effective means of achieving this.
- Samples need to be collected aseptically. Make sure that bacteria from hands/ other sources do not enter the sample and cause a false result. Sampling equipment must be sanitised prior to and after sampling and stored in a *Listeria*-free area.
- Instructions should be written down e.g. using tongs or gloves; whether the swabs are to be used dry or pre-moistened in sterile liquid, and the liquid to be used; what to do with the samples once collected i.e. labelling and preparation for transport to the laboratory.
- Sampling should commence in the highest risk areas and move progressively to the lower risk areas.

Environmental samples may also include materials such as sweepings, scrapings, rubbish, samples from puddles, pooled water and product scrap material.

5.5.7 Sample identification

Each set of samples sent to the laboratory must be very clearly identified so that anyone receiving the laboratory reports can clearly see from where and when the sample was taken. The coding of samples will be taken from the sampling plan. Care should be taken when extra samples are taken from other sites that the site is clearly noted so there is no confusion when the test results are received.

5.5.8 Sample handling

Samples must be handled carefully to ensure that test results are reliable. All samples should be stored under refrigeration prior to despatch to the laboratory. Seal samples in plastic bags and pack clean chilly bins with freezer packs to ensure that the sample reaches the laboratory in the same state as it was collected or that a low temperature (<6°C) is maintained during transit. Complete a sample submission form with each despatch identifying samples, sample date(s), company details, tests to be performed and contact details for the person receiving the results. Try to ensure that the samples reach the laboratory within 24 hours of collection.

6 The laboratory

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6.1 ESSENTIALS

It is essential to have a contract with a testing laboratory so that costs, reporting and sample transport and delivery arrangements are clearly understood and agreed. Laboratories will not appreciate receiving samples without notice as there is often a limit on how long there can be between samples being collected and the tests commencing, and not all laboratories operate 7 days a week.

The laboratory should be competent to do the test that is required i.e. IANZ accredited. That means that they are approved to test the type of sample or food that is to be tested using an appropriate test. It is important to inform them if a different type of food or sample from usual is to be tested as they may not be approved for this or have a suitable test method.

The laboratory will be able to advise on most aspects of sampling and testing.

It is important that the samples reach the laboratory as soon as possible after collection and that they are transported under the appropriate conditions.

6.2 KEEPING IN CONTACT WITH THE LABORATORY

It is important to know how and who to contact at the laboratory so that testing can be arranged at short notice should a crisis arise. This information should be easily located within the documentation by any member of the company including management, who could be called upon at short notice to respond to a *Listeria* problem.

The laboratory must also be able to make contact with the designated person responsible for the *Listeria* monitoring programme or the LMP or an alternative at all times.

It is also important to discuss with the laboratory at which stage in the testing process the company should be alerted as to the possibility of *Listeria* being present. The process of finding and identifying the *Listeria* takes several days and the laboratory will be able to notify the operator when they suspect they have found *Listeria*. This is called a presumptive test. As the laboratory process continues they will be able to provide an update each day or every second day on progress. However it is necessary to discuss the reporting process with the laboratory and make suitable arrangements. The sooner operators are aware of the possibility that *Listeria* has been found, the sooner the response can be started. This may have significant benefits in allowing any problems to be more quickly resolved and can minimise the amount of at risk product produced.

6.3 TEST METHODS

6.3.1 How long does it take to get a result?

Traditional culture methods are slow as they need several days for the bacteria to grow and to perform confirmation tests to identify which species is present. However there are more rapid tests becoming available but they may be more expensive. It is recommended that the timeline is confirmed with the laboratory.

Diagram 2: Approximate timeline for traditional *Listeria* testing

Day 1 – sample submitted and test set up
Day 3 – Presumptive <i>Listeria</i> (i.e. laboratory suspects <i>Listeria</i> present)
Day 4 – Confirmed that a <i>Listeria</i> species present but don't know if it is <i>L. monocytogenes</i>
Day 5 – Confirmed that the <i>Listeria</i> is <i>L. monocytogenes</i> or another <i>Listeria</i> e.g. <i>innocua</i>

6.3.2 *Listeria* counts (enumeration)

When *Listeria* is found in a food, it may be useful and in some cases highly desirable to have additional tests done to find out how many are present. The laboratory will need to be informed that a count may be required so that they maintain the appropriate media. It will take several days before the laboratory have a count available. Responding to the count will depend on the nature of the RTE food and will need to take into account the type of processing that it has been subjected to and the ability of the food to support growth during its intended shelf life as well as any regulatory limits that apply.

Part 1 discusses *Listeria* limits for RTE foods. Foods with *L. monocytogenes* counts >100cfu/g are never acceptable. Counts between 1 and 100cfu/g must be responded to (see Part 4) and the response will depend on the nature of the food. A spectrum of responses exists. At one end, with minimally processed produce occasional low contamination rates may be expected. At the other end, with foods that support growth and which have been subjected to a listericidal process *Listeria* should never be detected. In this case finding *Listeria* means that there has been a significant failure of a CCP or a contamination event has occurred.

6.3.3 Keeping *Listeria* isolates

Laboratories will usually keep *L. monocytogenes* isolates for later follow up work, but it may be necessary to ensure that this does happen i.e. specified in the contract with the laboratory.

When there have been several isolations over a period of time from a processing area, it may be helpful to have all the isolates typed e.g. by the pulse-field gel electrophoresis (PFGE) procedure to see if they are all the same type or different. While this may be costly, it will help to determine if there is a resident strain in the environment that keeps popping up or if the bacteria are transient i.e. appear briefly and then disappear, which may mean that new strains are constantly being introduced rather than being a resident strain hidden away in a niche somewhere. This information will help to focus on what needs to be done to reduce future isolations e.g. find the niche or identify how the transient strains are being introduced into the premises. Typing isolates will also be useful in assessing whether or not they can be linked to an outbreak in the event of their being cases of listeriosis.

7 Record keeping

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A vital element of the *Listeria* monitoring programme is having a system in place to record, review and evaluate the data received from the laboratory, and to verify CCPs and process controls. The data should be reviewed and should form the basis for the revision and adjustment of the *Listeria* monitoring programme. The review of the data through trend analysis may show untackled low level and intermittent contamination which can be addressed.

7.1 WHAT TO DO WITH THE LABORATORY REPORTS

Laboratory reports should not just be filed when they are received. The results should be transferred on to a spreadsheet or sampling site plan so that the data can be organised and reviewed. The data should be recorded in such a way as to make it easy to see where hot-spots are and to see patterns and trends in the presence or absence of *Listeria*. On Table 5 the positive examples have been highlighted. Another way would be to mark where detections occur on a site plan to help identify any patterns or process control or GOP failures.

7.2 LOOKING FOR TRENDS

Reviewing the results from the previous 4 to 8 samplings provides a moving window that can help to detect patterns and trends. This will help to identify sites where biofilms may be forming and not responding to the cleaning regime and niches where *Listeria* is evading cleaning. Periodically the results for a longer period e.g. quarterly should be reviewed to see if the same site is reappearing. These sites should then be investigated to find a remedy e.g. repairs, replacement, intensive cleaning.

"It was a failure to analyze test data that we weren't even obligated to collect - a failure on our part to analyze that data and look for root-cause analysis, investigate and follow-up on individual trends, to look for patterns so that we could find the bacteria that we couldn't see inside these facilities, and end up with a different result.

It was more a failure to analyze those findings for a root cause, and a failure of those protocols, than it was a failure of inspection, per se."

Michael McCain, CEO of Maple Leaf Foods Inc., appearing before the Agriculture Subcommittee on Food Safety, April 20, 2009

7.3 RECORD RESPONSES

Records of corrective actions should be kept. The more detail that there is the more useful they will be in reviewing a contamination episode within the company or with an external agency. Make notes of all observations and decisions constantly while an event is occurring.

Table 5: Example of a record sheet for recording results of sampling

Listeria Sampling Results	Zone	0 = Negative Result			1 = LM Positive Results						
		13th Jan	20th Jan	27th Jan	3rd Feb	10th Feb	17th Feb	24th Feb	3rd March	10th Mar	17th Mar
Bulk Bag	2	0					0				
Bulk Bag Pallet	2	0					0				
Chiller Door Handle	2	0					0				
Chiller Floor	2	0					0				
Chiller Coving	2	0					0				
Chiller Drain Cover	2		0					0			
Chiller Drain (inside)	2		0					0			
Chiller Wall	2		0					0			
Chiller Hose	2		0					0			
Forks of Forklift	2		0					0			
Grading Room Door Handle	2			0					0		
Grading Room Floor	2			0					1	0	
Grading Room Coving	2			0					1	0	
Grading Room Drain Cover	2			0					0		
Grading Room Drain (inside)	2			0					0		
Grading Room Wall	2				0						0
Grading Room Hose	2				0						0
Grader Framework	2				0						0
Grader Belt	2				0						0
Grader Belt Rollers	2				0						0
Shellstock Bin	2					0					0
Grader Room Floor Mat	2					0					0
Grading Staff Glove	2					0					0
Grading Staff Apron	2					0					0
Entry over Belt into HS Room	2					0					
HS Room Floor	3	0					0				
HS Room Coving	3	0						0			
HS Room Drain Cover	3	0						0			
HS Room Drain (inside)	3	0						0			
HS Room Wall	3	1	0					1			
HS Room Hose	3		0					0			
HS Cooker Framework	3		0						0		
HS Cooker Belt	3		0						0		
HS Cooker Belt Rollers	3		0						0		
HS Cooker Exit Rollers	3			0					0		
Entry over Belt into Open Room	3			0					0		
Opening Room Floor	3			0							0
Opening Room Coving	3			1	0						0
Opening Room Drain Cover	3			0							0

8 Responding to finding *Listeria*

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The response will differ depending on the type of sample and/or the likelihood that the product may be contaminated.

8.1 RESPONDING TO AN ALERT THAT *LISTERIA* MAY BE PRESENT

How to respond to being informed that there may be or that there is *Listeria* in an environmental sample or a food produced by the operation will depend on:

1. What is being reported i.e. is it an alert from the laboratory that *Listeria* may be present (a presumptive result) or has the presence of *L. monocytogenes* been confirmed?
2. What was the sample i.e. an environmental sample, a product contact surface sample or a product?

It is important to correctly identify the sample and identify information relevant to the sample before starting to respond. Before making a response (see section 8.2) it is essential to be clear about the following:

- For a product - the date on which the RTE 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.
- For a product contact surface – when was the site tested previously? What foods have been produced since that would have been in contact with this surface? Where are they now?
- For an environmental sample from areas 1 and 2 – if this was a composited sample, what were the sites sampled?
- For an environmental sample from an area 3 site - if this was a composited sample, what were the sites sampled? If a single site sample, what is the site and are there any issues about the site to be aware of e.g. equipment that has been recently serviced or repaired.

8.2 *LISTERIA* HAS BEEN CONFIRMED

Once the laboratory has confirmed that *Listeria* is present then the response that needs to be made will depend on where the sample came from or if it is product and whether for product and product contact surfaces and high care areas the *Listeria* is found to be *L. monocytogenes*.

A positive *Listeria* is a ‘non-conformance’ and requires an operator to undertake a corrective action that will remove the problem. The impact on final product safety is low if the positive sample has come from the external areas (area 1) and increases in significance if found in high care areas or product. In this case the response will need to be intensified in proportion to the risk level.

There should be a documented response plan so there can be an immediate and automatic response. Table 6 shows where in these guidelines information can be found with regards to

the recommended response. Note that when *L. monocytogenes* is found in product or on product contact surfaces this may become a ‘*Listeria* Event’ and must be responded to accordingly. Part 4 outlines the required responses.

Table 6: Responding to a *Listeria* detection

Sample	<i>Listeria</i> species present – could be <i>monocytogenes</i>	<i>Listeria</i> species present – not <i>monocytogenes</i>	<i>Listeria monocytogenes</i> confirmed
External – Area 1	See section 8.2.1	See section 8.2.1	See section 8.2.1
Area 2	See section 8.2.2	See section 8.2.2	See section 8.2.2
High care process area (Area 3)	See section 8.2.3	See section 8.2.3	See section 8.2.3
Product contact surfaces (Area 4)	See section 8.2.4	See section 8.2.4	See Part 4
Product	See section 8.2.5 and Part 4	See section 8.2.5 and Part 4	See section 8.2.5 and Part 4

8.2.1 When *Listeria* species or *L. monocytogenes* is found outside the processing area (area 1) The purpose of monitoring the environment outside the processing area(s) is to determine possible sources of contamination so that they can be managed and do not become a source of *Listeria* for more sensitive areas.

- If composite samples were analysed, consider taking and analysing additional individual samples to pinpoint the source of *L. monocytogenes*.
- Review access restrictions into the standard hygiene area from outside the processing environment.
- Conduct/review the trend analysis, to determine patterns or contamination and potential sources.
- Review the state of environmental cleanliness outside the premises, e.g. measures to improve pest management such as bird scarers, remove rubbish or concrete areas directly outside doors.
- Inspect the contaminated area and remove contamination sources (if possible).

8.2.2 When *Listeria* species or *L. monocytogenes* is found in a standard hygiene area (area 2)

Note: If the operation uses separation by time (unless there is a full clean down between operations) or by distance to separate raw and RTE foods, a positive result in a standard hygiene area should be treated as though the result was for a high care area.

- If the samples were analysed as a single composite sample, take and analyse individual samples from the same areas and surrounding areas to determine the source of the contamination.
- Isolate and inspect the contaminated area and equipment.
- Review the monitoring results from the high care area. Consider taking additional samples from the high care area to determine whether the barriers between the standard and high care areas have been breached.
- Reassess access/entry restrictions into the standard hygiene area from the outside.

- Review the results from outside the processing environment to identify any areas that may require a reassessment of controls to prevent the entry of any contamination.
- Review the cleaning and sanitation programme.
- Reassess processing and product handling procedures.
- Take corrective actions as appropriate to remove the contamination source and to prevent reoccurrence in future.
- If corrective actions have not completely removed the source of the contamination and *L. monocytogenes* continues to be detected, operators must be able to demonstrate that they are taking all reasonable steps to control the *L. monocytogenes* contamination and prevent the contamination of the high care area.

Note: If *L. monocytogenes* continues to be detected in the standard hygiene area but remains undetected in the high care area and on product contact surfaces, this is suggestive of persistent contamination which will require an increased level of vigilance. That is, if three consecutive sampling days of non-detections for *L. monocytogenes* cannot be achieved, or where the routine (e.g. 6-weekly) review of records suggests that there is recurring contamination.

8.2.3 When *Listeria* species or *L. monocytogenes* is found in a high care, critical hygiene area (area 3) i.e. after a listericidal CCP or a final microhurdle has been applied

- Alert senior management.
- Commence investigative sampling.
- If the samples were analysed as a single composite sample, take and analyse individual samples from the same areas and surrounding areas to determine the source of the contamination.
- Isolate and inspect the contaminated area and equipment.
- Carry out an aggressive cleaning and sanitising operation in an attempt to remove any residual contamination.
- Re-sample clean areas before processing re-commences. This is important as it is likely that the contamination has already resisted routine cleaning. Dismantle as necessary to get at hard to reach places. This type of investigative sampling is more likely to find the source than sampling during processing.
- Maintain intensified daily sampling until at least 5 clear consecutive samples.
- Review the monitoring results from the standard care area, and consider taking additional samples from the standard care area to determine whether the barriers between the standard and high care areas have been breached.
- Reassess access/entry restrictions into the area.
- Review the cleaning and sanitation programme.
- Reassess processing and product handling procedures.
- Take corrective actions as appropriate to remove the contamination source and to prevent reoccurrence in future.

8.2.4 When a *Listeria* species other than *L. monocytogenes* is found on product contact surfaces (area 4)

If a product contact surface is positive for *Listeria* species but not positive for *L. monocytogenes*, this indicates a breakdown of controls and this would allow the growth or survival of *L. monocytogenes*. It is therefore recommended, especially in the case of high risk RTE foods producers that there is an immediate response. Note that as high levels of *Listeria* species other than *L. monocytogenes* e.g. *L. ivanovii* are a potential cause of illness in

vulnerable consumers, producers of food for vulnerable consumers should respond accordingly.

- Alert management.
- Increase the monitoring frequency of the environment, all hygiene areas and product. Note that if a positive has not also been identified in an area 3 sample this means that area 3 sample selection is probably inadequate as contamination has entered the processing area and ‘jumped’ directly on to a product contact surface.
- Resample area 3 and 4 sites.
- Carry out a major cleaning and sanitising operation and re-sample to evaluate effectiveness.
- Investigate the source of the *Listeria* contamination (e.g. entry points to the high care area from the standard hygiene and external areas, potential sources, areas where there are suitable wet growth conditions and transfer mechanisms).
- 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.
- Review the cleaning and sanitation that occurred prior to and at the time of the incident.
- Conduct/review the trend analysis, to determine patterns of contamination and potential sources.
- Prevent potential future contamination from *L. monocytogenes* by reviewing and amending controls where necessary e.g. personnel training.
- Maintain increased sampling until at least 5 consecutive negative results.

8.2.5 When *L. monocytogenes* is found on product contact surfaces (area 4)

If *L. monocytogenes* is found on a product contact surface, product may have been contaminated i.e. at risk. It is therefore recommended that the response be the same as for when *Listeria* is found in product (see section 8.2.6 and Part 4).

8.2.6 When *L. monocytogenes* is found in the product

In Part 1, guidance is given on identifying the *L. monocytogenes* limit appropriate for each RTE food. In some cases there may be a regulatory limit e.g. Food Standards Code Standard 1.6.1 or a product safety limit may be set elsewhere. If there are no set limits, the operator will need to have set their own limits.

Table I in Part 1 identifies microbiological targets that should be considered for different types of RTE foods. When these targets are exceeded the food should be considered unsuitable for consumption. The response that should occur is outlined in Part 4.

If *L. monocytogenes* is found but the targets are not exceeded, it is important to respond. This could be the tip of an iceberg or the beginning of a serious contamination event. The response will depend on the nature of the food and how it has been processed.

When *L. monocytogenes* is found in a high risk food at the end of processing, the food will usually be considered unsafe (see Part 4).

When *L. monocytogenes* is found in a medium or low risk food at the end of processing, operators may:

- Decide to take action as if it was a high risk food (i.e. remove the food from the market) see Part 4.

- Undertake more intensive sampling and testing to get a count of the number of *L. monocytogenes* present (if possible hold product back from the market while this is established) to ensure that the level is not >100cfu/g or unlikely to exceed that limit by the end of the shelflife.
- If the count exceeds 100 cfu/g or could exceed 100cfu/g by the end of the shelflife, the product should be considered unsuitable for consumption.
- If the counts do not exceed 100cfu/g, the results should be recorded for trend analysis and corrective actions implemented.
- Finding *L. monocytogenes* in a RTE food at the end of processing should always be responded to, even if the counts are acceptable from a product safety perspective because it will usually mean that the *Listeria* controls are not working adequately.
- For minimally processed foods where occasional contamination of the incoming food ingredients may be difficult to remove, record the results and watch for any increase in frequency. Review processing, cleaning and sanitation and/or suppliers if occurrence becomes too frequent.
- For processed foods, it is important to find the cause of the contamination and rectify. That will mean checking all CCPs and microhurdles for effectiveness, increased product, environmental and/or incoming material sampling to trace the source and to determine the extent of the contamination.

8.2.7 When *Listeria* species other than *L. monocytogenes* is found in the product

Listeria species all have common habitats and characteristics. Often more than one species 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. It is recommended that the response is the same as for *L. monocytogenes*.

9 Monitoring programme review

Amendment 0

July 2011

The elements of a *Listeria* monitoring programme should be reviewed, revised and adjusted as appropriate:

- Annually.
- After a *Listeria* contamination event.
- At the time of a significant change in the processing area or the introduction of new equipment.
- Following an unexpected event that could compromise the existing monitoring programme e.g. major building repair, equipment failure, flooding.
- Before major new product and process lines are introduced or significant reformulation or new packaging technology is adopted.

9.1 ANNUAL REVIEW

When conducting the annual review of the monitoring programme, look at the data collected of laboratory results for the past year:

- Identify sites that could be removed, added or sampled more or less frequently.
- Compare product sampling rates with production volumes and product risk categories and make adjustments if needed.
- Review sampling frequency – should it be increased, decreased or remain unchanged?
- Identify whether new products, equipment, processes etc have been incorporated into the programme appropriately.
- Consider whether amendments should be made to the cleaning and sanitation programmes.
- Assess whether maintenance events such as replacement of product contact surfaces, machinery dismantling etc are happening often enough?

With regard to the operation of the *Listeria* monitoring programme, consider the following:

- Are there enough trained samplers?
- Is there evidence that practices or people are compromising the control programme?
- Are the contract and general arrangements with the laboratory working?
- Are channels for communicating test results to those who need to know in the company working well?
- Has the data been analysed in a timely manner and acted upon appropriately?

10 Information sources

Amendment 0

July 2011

- R. B. Tompkin (2002) Control of *Listeria monocytogenes* in the food-processing environment Journal of Food Protection Vol. 65, pages 709-725.
- Guideline for controlling *Listeria monocytogenes* in small- to medium-scale packing and fresh-cut operations. University of California. <http://anrcatalog.ucdavis.edu> (publication 8015).
- Meat and Livestock Australia (2008) How to comply with Regulatory guidelines for the control of *Listeria* by meat retailers: advice on how to set up a testing program.
- Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes* in foods. Codex CAC/GL 61 – 2007.
- USFDA Workshop: Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products http://origin-www.fsis.usda.gov/Science/Workshop_SmallPlants_Lm/index.asp.
- Compliance guidelines to control *Listeria monocytogenes* in post-lethality exposed ready-to-eat meat and poultry products. Can be found on the following website <http://origin-www.fsis.usda.gov/>.

11 Appendix

11.1 HOW USEFUL WILL MONITORING BE FOR AN OPERATION?

Questions:

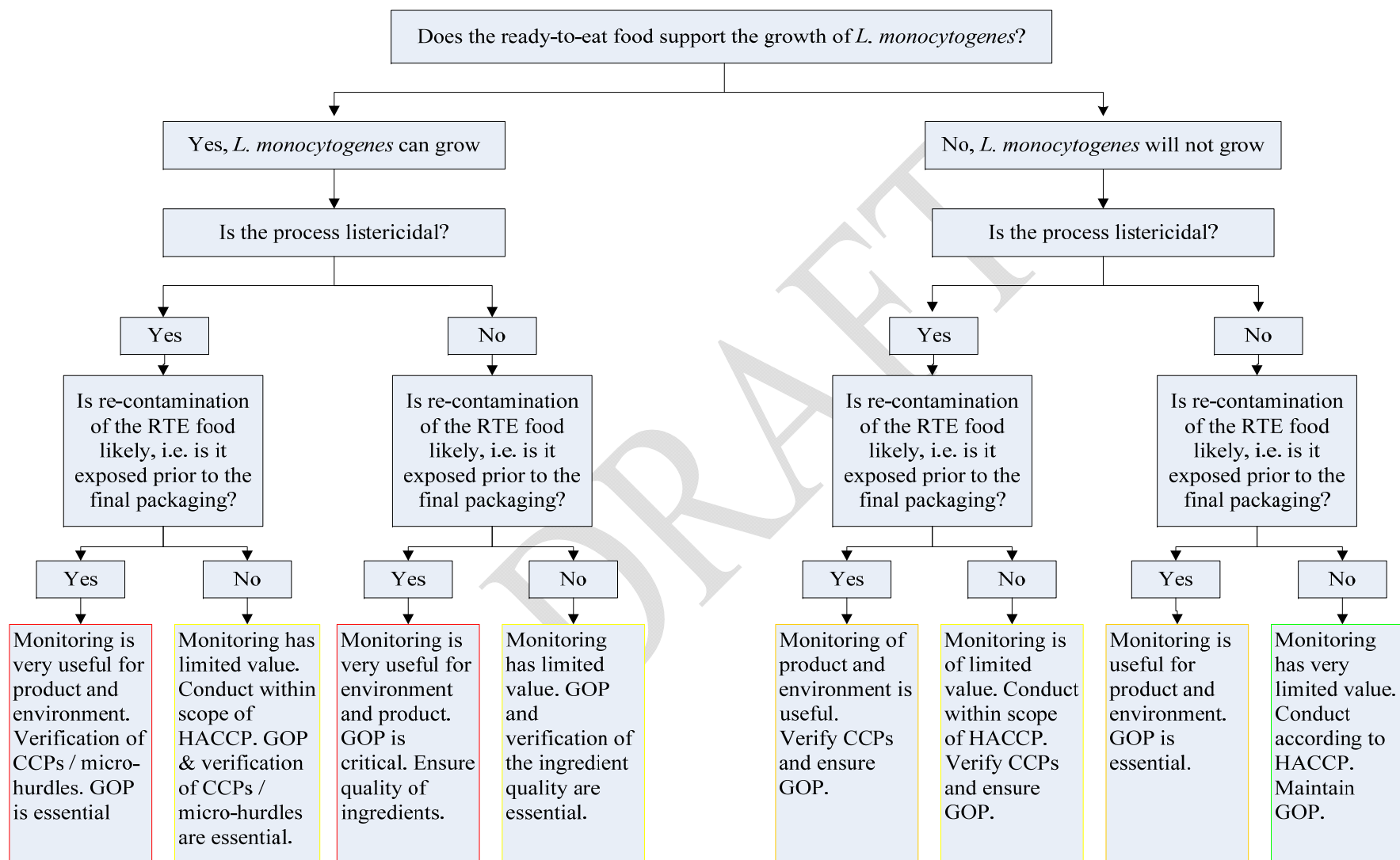
1. Will the ready-to-eat food support the growth of *Listeria monocytogenes*?
2. Is the process listericidal, i.e. does the process have a critical control point identified in your HACCP plan or series of micro-hurdles?
3. Is there potential for contamination of the ready-to-eat food likely prior to packaging, i.e. is the product exposed to the processing environment prior to packing? Note: Products that are not likely to be contaminated are those that are subject to post-packaging pasteurisation or aseptically hot filled into the packaging.

Other factors to consider when determining the type and frequency of your *Listeria* monitoring programme include:

- a) the general hygiene and condition of your premises
- b) whether there has been a history of *Listeria* detections in the process environment or product
- c) adherence to GOP and robust application of HACCP.

Figure 1 provides a decision tree to help an operation determine how useful monitoring would be together with the relative importance of GOP and HACCP.

Figure 1: How useful will monitoring be for an RTE food operation



11.2 IDENTIFYING SAMPLE SITES FOR A SMALL OPERATION

For a small operation, it may be most appropriate, to focus sampling on the niches and to concentrate on the critical area. If this is the case, then it is important to take lots of samples initially to determine where the niches and transmission pathways are. Niches are likely to be those where *Listeria* is detected following cleaning whereas transmission pathways may be found once processing has been in operation for a few hours. Examples of the different sites are in Table 7.

Table 7: Examples of niches and transmission pathways

Niche(s)	Transmission Pathway(s)
Drains	Access ways
Cracks	Equipment
Ducts	Fork lifts
Hoses and spray nozzles	Knives
Walls and other parts of the building	Gloves
Seals on doors and equipment	Door handles
Inside rollers of conveyor belts	Moving parts
Hard to clean areas inside equipment	Valves
Old and damaged equipment and surfaces	Seals (and areas behind seals)
	Safety covers
	Ingredients and raw material

Alternative, identify everything that enters the critical hygiene area and then identify the controls. Where there is no control then these should be included in the sample plan.

What enters the critical hygiene area?	What control(s) are in place	Include in sample plan?
RTE food	CCP – cooking step. Microhurdles	Yes
Racks	Equipment washed	Yes
Trolley	Equipment including wheels are washed	Yes, there are hard to clean areas
Hose	None	Yes, include the area inside the hose
Arnie, Bruce and Demi	Personal hygiene – hand-wash and sanitise, PPE provided. Dedicated staff that do not enter raw (before the <i>Listeria</i> step) area	Yes, at lower frequency
Personal Protective Equipment (PPE)	PPE cleaned professionally and available fresh each day. Laundry bags emptied in an ante-room	No
Packaging	Stored in dedicated area. Purchased from a recognised supplier. External packaging removed prior to entry	Yes, at lower frequency
Ingredients added to the product after CCP, e.g. spices or fruit puree	Supplier assurance, e.g. micro testing	Yes, include in sample plan
Air	No doors open to the immediate outside. All windows are sealed. Air conditioning units	Include the door handles especially the back of these, and door seals Check and clean the filter (not when processing is occurring). Sample any condensate from the AC unit and the top.
Water	Potable water used for clean down operations	No

Conveyor belt(s)	Included in major clean down however may be contaminated by people, raw materials or from persistent contamination	Include in sample plan. Concentrate on cracks, hard to clean surfaces especially where there is a build up of food residues
Knives	Washed in dedicated area	Include knives and all equipment used in the critical hygiene area
Maintenance and cleaning staff	Clothing change prior to entry, hand washing and the use of dedicated equipment	No
Wiring and pipes	No control	Include any exposed wiring and pipes in the sample plan especially if a high pressure hose is used to clean the area.

11.3 SAMPLING PLAN FOR A SMALL OPERATION

For these small operations, the hygiene areas are likely to be red line or time separated by distance or by time rather than by physical barriers. Because of the small scale of the operation only 2 hygiene areas have been identified.

In this example each site is sampled quarterly, and each monthly sampling cycle has 5 sites. In the table, **I** means the sample is taken while the item is in use and **B** means before use i.e. after cleaning and sanitation. Some sites will feature more frequently than others in the plan because they are the most important or the hardest to keep clean or the most used.

Table 8: Example of a six monthly sampling plan for a small operation

Site	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Food Product Contact Surfaces¹						
Container	I			I		
Bench		I			I	
Cutting Board	B		I	B		I
Knives		I			I	
Slicer	B		I	B		I
Non food contact surfaces						
Fridge door handle	I			I		
Vacuum-packaging machine	I			I		
Tap/sink		I			I	
Waste bin		B			B	
Drain		B			B	
Air Conditioner unit			B			B
Overhead structures (rails)			I			I
Plastic curtains			I			I

Product testing would be conducted fortnightly (i.e. one product is sampled, which means 5 subsamples of at least 25g of that product) for the first 3 months of a programme plan, with every product type being tested during the first 3 months of the *Listeria* monitoring programme. The frequency may then be lowered i.e. quarterly. However it is recommended that product is sampled every time food contact surface sampling is done.

¹ All product contact surfaces should be those that contact RTE product rather than those that contact raw or intermediate (in-process) materials only

11.4 ENVIRONMENTAL SAMPLING IN A MEDIUM TO LARGE OPERATION

The spreadsheet below is part of an annual sampling plan.

In the plan:

- Sites are code numbered to show hygiene level (first number) and site number (second and third numbers). The descriptions of each site are written down and can also be indicated on a site map/floor plan.
- Where there are sites grouped e.g. 202-205 these sites are composited during routine testing. Sites 402-404 are swabs from different places on a single piece of equipment, typically a conveyor belt. Do not composite samples from levels 3 and 4 that are from very different sites.
- In this plan, sampling occurs every week but sites are sampled only on the weeks indicated i.e. blue coloured infill.
- The sites with green or red infill are sampled only when certain activities are occurring.

A sampling site spreadsheet

		WEEKS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
HYGIENE AREA	SITE																									
1	101																									
1	102																									
2	201																									
2	202																									
	203																									
	204																									
	205																									
2	206																									
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