Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Guidance for the Control of *Listeria monocytogenes* in Ready-to-eat Foods Part 1: *Listeria* Management and Glossary

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Title

Guidance Document: *Guidance for the Control of Listeria monocytogenes in Ready-to-eat Foods Part 1: Listeria Management and Glossary*

About this document

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

These guidelines are intended to assist food operators to develop, implement and review control measures for *Listeria monocytogenes* in the context of a Risk Management Programme (RMP) or a Food Control Programme (FCP). The guidelines do not replace any specific requirements for *L. monocytogenes* and/or other pathogen management as described in New Zealand legislation, such as the Animal Products Act 1999, for dairy and seafood.

Related Requirements

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

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

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

(3) Part 3: Monitoring Activities; and

(4) Part 4: Corrective Actions.

Document history

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1 Purpose

The documents "Guidance for the control of *Listeria monocytogenes* in ready-to-eat foods" are intended to provide guidance and information on the management, control and monitoring of the foodborne pathogen *L. monocytogenes* during the manufacture, processing or preparation of a ready-to-eat food.

The documents have been developed by the Ministry for Primary Industries (MPI). The guidance material is intended to be used by food operators who produce ready-to-eat foods that:

- are not intended to be consumed immediately; and
- will be stored refrigerated for more than five days before consumption.

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

The guidance documents are:

(1) Part 1: *Listeria* management and glossary; and

(2) Part 2: Good operating practices (GOPs); and

(3) Part 3: Monitoring activities; and

(4) Part 4: Corrective actions.

These guidance documents may be a useful source of information and reference for:

- food operators for whom *Listeria* management requirements are described elsewhere;
- food operators who are developing new operations and/or product lines or ranges;
- food operators who are producing ready-to-eat foods intended to be eaten by vulnerable consumers; or
- food operators who produce food that is predominantly consumed by vulnerable groups.

These guidance documents provide reference to HACCP applications, Critical Control Points (CCP) and critical limits (CL). However these documents do not provide specific applications of the HACCP principles to any ready-to-eat (RTE) food and process. This is intentional because HACCP applications should be tailored by the food operator for each food business. It is not possible for MPI to cover HACCP applications for all types of RTE foods mentioned above.

Food operators are advised to use MPI's guidance material on application of HACCP principles found at: http://www.foodsafety.govt.nz/industry/general/haccp/using-haccp.htm

Any HACCP application should become an integral part of the food operator's *Listeria* Management Programme (LMP) or other similar risk-based programme such as a:

- Risk Management Programme (RMP); or
- Food Control Plan (FCP).

Food operators with specific queries should seek the advice of their verifier, auditor or territorial authority.

2 Scope

2.1 What is covered by this Part?

This document is Part 1 in the series "Guidance for the control of *Listeria monocytogenes* in ready-to-eat foods" and provides the general principles relating to the control of *Listeria monocytogenes* in the production of ready-to-eat (RTE) foods. 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.

This document explains why control measures for *Listeria* should be put in place and how they should be applied. It also describes how the control measures applied depend on the particular type of RTE foods, the production process and the processing environment.

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

2.2 What you should get from this Part

After reading this guide, you should have a better understanding of how to develop and implement a *Listeria* Management Programme (LMP) appropriate to the risks associated with the RTE foods being produced.

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

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

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

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

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

Glossary

(1) In this document series "Guidance for the control of *Listeria monocytogenes* in ready-to-eat foods", unless the context otherwise requires:

aerosol means a substance enclosed under pressure and released as a fine spray by means of a propellent gas

ante-room means a predefined area that enables the segregation of the animal housing area from the exterior environment

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, for example, 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[1]

biofilm means a population of microorganisms that are attached to each other and/or to a surface. The micro-organisms, such as *Listeria*, are frequently surrounded by slimy material that helps them stick to the surface and makes it difficult to remove them by cleaning or for sanitisers to penetrate into the biofilm

critical control point (CCP) means a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level

colony forming unit (cfu) means a measure of the number of bacterial cells in a sample and is a measure of the level of contamination

contaminated product means a batch of product that testing has shown to be contaminated with *L. monocytogenes*

corrective actions mean the actions taken following the detection of *Listeria* species or *Listeria monocytogenes* in an environmental or product sample, to:

- restore control;
- identify any affected ingredient or food and ensure its safety and suitability;
- manage its disposal; or
- prevent recurrence of the loss of control

critical and/or high-care hygiene areas means those processing areas after a CCP for *Listeria monocytogenes* or final microbiological hurdle before the exposed ready-to-eat food is placed into the final packaging. This includes product contact and non-product contact surfaces. An example is the critical hygiene area, zones 3 and 4, in the *Listeria* testing programme for ready-to-eat seafood

critical limit means a criterion that separates a level of acceptability from unacceptability

double barrier entry system means a system where the external footwear is left on the outside of the first barrier, hands are washed and protective clothing donned, then the internal footwear are changed into on the other side of the second barrier

[1] 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".

environmental samples means material collected from a processing area or the external environment for the purpose of testing the surface or material for the presence of *Listeria*

exposed ready-to-eat food means the ready-to-eat food after a critical control point specific for *Listeria monocytogenes* or after the final microbiological hurdle before it has been packaging or wrapped which may be contaminated by any *Listeria* bacteria present

Food Control Plan (FCP) means a plan designed for a particular food business to identify, control, manage, and eliminate or minimise hazards or other relevant factors for the purpose of achieving safe and suitable food (Food Act 2014)

good operating practice (GOP) (including good agricultural practice, good hygienic practice and good manufacturing practice) means documented procedures relating to practices that:

- are required to ensure food is fit for intended purpose; and
- are appropriate to the operating circumstances

harbourage site/niche means a nook or cranny, a crack, a crevice, a scratch, a ledge etc. where *Listeria monocytogenes* can survive and grow. Harbourage sites or niches are often hard to clean and sanitise

hazard analysis and critical control point (HACCP) means a system that identifies, evaluates and controls hazards that are significant for food safety

indirect product contact surface means surfaces in the high care area which do not directly come into contact with exposed ready-to-eat product but have the potential to introduce contamination, for example internal surfaces of a slicer which may periodically introduce contamination

input means any food material or product, additive, processing aid, ingredient, packaging or other associated thing where that associated thing is contained within, attached to, enclosed with, or in contact with, the food material or product

***Listeria* control measure** means any action or activity that is applied to:

- control the initial level of *L. monocytogenes* and other *Listeria* species;
- prevent an unacceptable increase in *L. monocytogenes* and other *Listeria* species; and
- reduce or eliminate *L. monocytogenes* and other *Listeria* species

***Listeria* Management Programme** (LMP) means a documented programme that a food operator has in place to minimise the potential for an RTE food to be contaminated with *Listeria* species, including *L. monocytogenes*. The LMP may be included as part of a food business's Food Control Plan, Food Safety Programme or Risk Management Programme

listericidal process means a process that reduces *L. monocytogenes* microorganisms to a safe level. Listericidal processes may include treatments, such as a heat treatment, high-pressure processing, drying and/or acidification

MPI means the Ministry for Primary Industries

test means to conduct a planned sequence of observations or measurements of control parameters to assess whether a process, procedure or CCP is under control

niche (or **harbourage site**) means a localised site in which food debris and moisture can accumulate and that provides an area for *Listeria* to become established and persist

non-product contact surface means the surfaces in a high care area which an exposed ready-to-eat food does not touch prior to final packaging. This may include the floors, walls, doors, handles, switches, door jams, table legs, air-conditioning units, exposed wiring and pipes, drains, etc.

potentially contaminated means all batches of ready-to-eat product that are potentially contaminated with *L. monocytogenes* as a result of being processed around the time that product in which *L. monocytogenes* was detected was processed or there was a product contact surface detection or some other commonality with the contamination event

product contact surface means the surfaces in the high care area which exposed ready-to-eat food touches prior to entering the final packaging. This may include tables, racks, trays, boxes, conveyor belts, slicers, dicers, weighing scales, packaging machines, etc.

ready-to-eat food (RTE food) means food that is ordinarily consumed in the same state in which it is sold or distributed and will not be subject to a listericidal process before consumption; and **ready-to-eat** when used in this document has a corresponding meaning

recall means to isolate and remove unsafe or unsuitable food that is no longer under the manufacturer's direct control and has passed into the control of others in the storage, distribution, retail or consumer chain. (Note the definition of "**withdrawal**" for comparison)

red line means the hygiene barrier that is in place to prevent direct access from the outside environment into the processing area

Risk Management Programme (RMP) means 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

safe food means a food that does not cause illness or injury through the presence of something that is offensive or whose presence would be unexpected or unusual in product of that description

suitability means aspects of product integrity other than food safety such as aesthetic defects, composition, and labelling

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 the purpose of these guidance documents, the shelf life refers specifically to the survival and growth of *L. monocytogenes*

single barrier entry system means a system that may take the form of a changing room which is separate but may not directly connected to the processing areas where external footwear are removed, hands may be washed before putting on protective clothing and internal footwear. This may also be located immediately prior to entering the processing area

standard hygiene area means the processing area before the final critical control point specific for *Listeria monocytogenes* where the raw ingredients, materials and intermediary products are handled. This includes the production/manufacturing area, raw ingredient store rooms, packaging store rooms, chillers/refrigerators, etc. Note - the standard hygiene area is equivalent to zone 2 in the *Listeria* testing programme for ready-to-eat seafood and Pathogen Management Guidelines for Dairy Products

trend analysis means the recording, review and analysis of laboratory results and routine data (environment and process control data) on a regular basis, for example, preferably weekly but at least every six weeks, to identify trends, take appropriate corrective actions and to adjust the LMP

US FDA means United States Food and Drug Administration

water activity (a_w) means a measure of water available for the growth of microorganisms in food. Note that 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

withdrawal (also known as a **trade level recall**) means the removal of an unsafe food from the distribution chain but does not extend to food sold to the consumer (Note the definition of "**recall**" for comparison)

zone refers to the division or a processing area based on the likelihood that a ready-to-eat food may be contaminated with *L. monocytogenes*. The term zone may be used as an alternative to hygiene areas

(2) Any term or expression used in this document series that is defined in the Act or Regulations made under the Act and used, but not defined, in this document series has the same meaning as in the Act or Regulations.

3 Information about *Listeria monocytogenes*

3.1 Why *Listeria* must be managed

Food contaminated with *Listeria monocytogenes* has the potential to cause the illness listeriosis. This can be a severe illness leading to death in vulnerable consumers. While severe cases of listeriosis are not common in New Zealand (about 25 are reported annually), the outcome of a severe infection can be significant, and 20 to 30 percent of those who become ill may die.

It has been found from investigating outbreaks that the main cause of listeriosis is the consumption of ready-to-eat (RTE) food that are contaminated with large numbers of *L. monocytogenes*. These are typically RTE foods that:

- allow the growth of *L. monocytogenes*;
- are stored at refrigeration temperatures; and
- have a long shelf-life.

Listeria bacteria unlike most of the common causes of foodborne illness can grow at the temperatures used for chilled storage i.e. below 5˚C. It is important to minimise the potential for food to be contaminated with *L. monocytogenes* by*:*

- identifying the foods that are at risk from contamination; and
- establishing control measures;

especially for those foods that support the growth of *L. monocytogenes.*

There has been a diverse range of foods associated with food incidents or cases of listeriosis in New Zealand. These foods include:

- RTE seafood;
- hot-smoked mussels;
- RTE cooked meats;
- hummus and/or tahini; pâté;
- pre-packaged salads;
- cooked and/or smoked chicken;
- vegetable dips;
- sandwiches;
- yoghurt;
- smoked fish; and
- cheeses.

Listeriosis is an increasing problem. Human listeriosis is a relatively recent disease. *L. monocytogenes* came to international prominence as a foodborne pathogen in 1985, following a large outbreak in the United States of America. The bacteria have always been present, but food production has changed and, with the increased availability and range of chilled, long shelf-life RTE foods, the risk of illness from *L. monocytogenes* is increasing.

In addition, people are living longer through better social and working conditions and medical advances in the treatment of chronic diseases that are prolonging life expectancy. This means that, over time, there will be more vulnerable consumers. The trend for more cases of severe listeriosis in the older population is already being seen in some parts of the world.

All species of *Listeria* bacteria including *L. monocytogenes* are widespread in the environment. Small numbers of *Listeria* can often be found on unprocessed foods and in and around a food premises. While only *L. monocytogenes* is a significant pathogen, the presence of any of the species of *Listeria* indicates that there is potential for the pathogen to be present. For this reason, the guidelines use the general and more commonly used term *Listeria*.

***Listeria* can be introduced into a processing environment in a number of different ways.** This can be on people's shoes, clothing and body, in dust, on equipment, such as tools and vehicles, and on ingredients or in raw materials and packaging. Once in the processing environment, the bacteria will find suitable niches or harbourage sites, in particular damp spots, in which to reside and multiply. These include hidden surfaces in equipment and machinery. If the cleaning and sanitation procedures are not thorough, the bacteria may then form a biofilm which is more difficult to remove. These harbourage sites can be a major source of contamination during food processing. It is very important to understand how *Listeria* can enter the processing environment and to continually review this for any changes that occur, e.g. new entry points and contamination routes.

Post-processing contamination with *Listeria* is a major concern. If the food is contaminated with *Listeria* after a processing step (a listericidal step) that is designed to eliminate pathogens, for example, pasteurisation or cooking, any *Listeria* may grow particularly rapidly as other competing bacteria (as well as other spoilage microorganisms) will have been significantly reduced by that process.

3.2 Microbiological limits for *Listeria monocytogenes*

3.2.1 Must all food be *Listeria* free?

It is not realistic or necessary to require that all RTE foods should be free of *Listeria. Listeria* is widespread in the environment and small numbers are frequently found on unprocessed food at levels of less than 100 cfu/g *Listeria monocytogenes*. Where foods are associated with illness in healthy adults, *Listeria* levels are considerably in excess of this i.e. more than 10,000 cfu/g. However smaller numbers of *L. monocytogenes* may result in illness for vulnerable consumers.

MPI supports the principles adopted by the Codex Alimentarius Commission (Codex) in relation to *Listeria (*see Codex Alimentarius (2007) *Guidelines on the application of general principles to the control of Listeria monocytogenes in foods – CAC/GL 61 – 2007*). Regulatory criteria

Microbiological limits for *L. monocytogenes* currently applied in New Zealand for ready-to-eat foods are:

- *Food Standards Code* Standard 1.6.1: absence in 25 grams for five samples is required throughout the shelf-life for ready-to-eat foods in which *L. monocytogenes* can grow; and
- *Food Standards Code* Standard 1.6.1: less than 100cfu/g for five samples is required throughout the shelf life of ready-to-eat foods in which growth of *L. monocytogenes* will not occur.

For the purpose of the Standard 1.6.1, food characteristics that will apply to foods "in which growth will not occur" includes those with:

- a specified pH and water activity i.e. foods that are too dry or too acidic;
- a combination of pH and water activity that prevents *Listeria* from growing; or
- the way or time for which the food is stored would not allow growth i.e. frozen food or food with a shelf life of less than 5 days.

For any other ready-to-eat foods there will need to be evidence that growth will not occur i.e. "it can be validated that the level of *Listeria monocytogenes* will not increase by greater than 0.5 log cfu/g over the food's stated shelf life."

See the Appendix to this guide for more information on the growth and survival of *Listeria* in food.

3.2.2 References to other guidance material

The Food Standards Code (FSC), Standard 1.6.1 – Microbiological Limits for Food can be accessed from the Food Standards Australia New Zealand website:
http://www.foodstandards.govt.nz/code/userguide/pages/microbiologicallimit1410.aspx

Guidance on how to apply the microbiological limits can be found in the following documents:

- Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food: http://www.foodstandards.gov.au/publications/Documents/Guidance%20on%20the%20application%20of%20limits%20for%20Listeria%20monocytogenes%20FINAL.pdf
- Which microbiological limits do I use?: http://www.foodsafety.govt.nz/elibrary/industry/Which_Microbiological-Outlines_Four.htm

Fact sheets on the application of FSC 1.6.1:

- Application of Food Standards Code 1.6.1 – Microbiological Limits for Food – *Listeria monocytogenes* in Ready-to-eat Foods (fact sheet)
- Application of Food Standards Code 1.6.1 - Microbiological Limits for Food - *Listeria monocytogenes* in Ready-to-eat Foods: Fresh Leafy Salads, Fresh Fruit Salads, Sprouted Seeds And Smoked And Gravadlax Seafood (fact sheet)

For RTE animal products (not dairy):

- Requirements for food operators processing RTE animal products (not dairy) under the Animal Products Act 1999 are included in the latest version of the Animal Products Notice: Specifications For Products Intended For Human Consumption signed 1 March 2016: http://www.foodsafety.govt.nz/elibrary/industry/animal-products-specifications-asd/

For seafood:

- The Processing of Seafood Products – Code of Practice includes sections on the control of *Listeria monocytogenes* and is intended to assist processors and manufacturers of seafood to comply with the requirements of the Human Consumption Specification and to produce seafood that are safe and suitable for human consumption: http://foodsafety.govt.nz/elibrary/industry/code-practice-seafood/index.htm

For dairy products:

- All dairy products have a product safety limit (PSL) of absent in 25 grams at the end of manufacture processing: http://www.mpi.govt.nz/document-vault/10145

3.2.3 Food operator-defined limits

To ensure that product will be compliant with the FSC limits, operators may set microbiological limits at additional specific points in the production process e.g. incoming raw materials, ingredients, and prior to or after a CCP.

When food (product) safety limits are not set in legislation, the food operator may define their own limits in their RMP or FSP/FCP. Procedures for compliance with these limits and the expected response in the event that the limits are not met would also need to be documented.

Food Safety can only be assured by the use of risk-based programmes based on the principles of Good Operating Practice (GOP) and Hazard Analysis and Critical Control Point (HACCP). Reliance on the use of

product testing to meet the microbiological limits alone is not sufficient. Microbiological sampling of end products is a means of verifying that the control systems in place are working. There is little point in sampling product if the *Listeria* control measures are not in place.

Food operators may need to consider applying microbiological limits for *Listeria* at two points – at the end of the manufacturing process and at the end of the food's shelf-life although in many cases these could be the same. See Table 1 for more information.

Where there are no microbiological limits defined in legislation (refer to **4.4.1 Staff training**), food operators still have a legal requirement to produce food that is safe and suitable for human consumption. Table 1 provides guidance on limits that could be adopted.

The presence of *L. monocytogenes* at levels above 100 cfu/g in any RTE food is unacceptable and requires immediate action by the food operator. The detection of levels of *L. monocytogenes* below 100 cfu/g, where permitted by the regulatory requirements would be considered on a case-by-case basis taking into account the:

- shelf-life;
- nature of the food;
- production process;
- *Listeria* control measures;
- intended consumer;
- storage conditions; and
- past history of the food operator and process.

If a food has been subjected to a process that is designed to eliminate *Listeria*, the process should have been validated as able to achieve this outcome. Finding *Listeria* in the food therefore indicates that either a processing failure or post-processing contamination has occurred.

Table 1: Microbiological levels for foods

Characteristics of the food or ingredient and processing	***L. monocytogenes* limits or targets (see note 3 below)**	
	Recommended/required levels at the end of processing	**During and at the end of shelf life**
RTE foods in which growth of *L. monocytogenes* can occur (during the stated shelf life)	Absent in 25 g (required) (Analytical units of 5 x 25 g)	Absent in 25 g (required) (Analytical units of 5 x 25 g)
RTE foods in which growth of *L. monocytogenes* will not occur, including RTE foods to be eaten frozen (see note 4)	Absent in 25 g but, if present, less than 10 cfu/g (recommended) (Analytical units of 5 x 25 g)	Not more than 100 cfu/g (required) (Analytical units of 5 x 25 g)
All RTE foods specifically intended for consumption by vulnerable consumer groups (see note 3)	Absent in 25 g (recommended) (Analytical units of at least 10 x 25 g)	Absent in 25 g (recommended) (Analytical units of at least 10 x 25 g)
Products/unprocessed ingredients where the occurrence and/or survival of *L. monocytogenes* is highly unlikely, for example, powdered products, dried	*L. monocytogenes* not a pathogen of concern unless the product is to be added as an	Testing for *L. monocytogenes* not usually required

Characteristics of the food or ingredient and processing	***L. monocytogenes* limits or targets (see note 3 below)**	
	Recommended/required levels at the end of processing	**During and at the end of shelf life**
herbs, nuts (a_w less than 0.92), foods preserved in acid (acidity less than 4.4), high percentage of sugar	ingredient to a RTE food after a CCP has been applied	Not more than 100 cfu/g (recommended) unless lower levels to meet process controls
Raw materials, unprocessed foods and ingredients where exposure to *L. monocytogenes* and its survival are likely e.g. raw meats, milk, fruits and vegetables, fish and seafood	Ensure that levels prior to processing are not in excess of the reduction that processing can achieve to meet the required limits at the end of processing	

Notes

(1) RTE = ready to eat; CCP = critical control point; cfu/g = colony forming units per gram; a_w = water activity.

(2) While most countries are in agreement with the principles provided by Codex Alimentarius, i.e. for some foods a level of less than 100 cfu/g may be allowed, some countries may still set zero levels for *L. monocytogenes* in all foods to achieve their public health goals.

(3) For RTE food specifically intended for consumption by vulnerable consumers, the target should always be absence of *L. monocytogenes,* regardless of whether or not levels of 100 cfu/g are permitted in Standard 1.6.1. RTE foods for which the absence of *L. monocytogenes* cannot be assured at all times, should either not be provided to these consumers or should be monitored to provide an assurance that *L. monocytogenes* is rarely present and if present does not exceed 10 cfu/g.

(4) "No growth" is defined in the FSC as being the situation where "it can be validated that the level of *Listeria monocytogenes* will not increase by greater than 0.5 log cfu/g over the food's stated shelf life".

(5) These limits relate to product testing only. Environmental testing is discussed in Part 3: Microbiological testing for verification of the control of *L. monocytogenes.*

3.3 How to manage the risk of *Listeria* contamination

From studying contamination events and outbreaks of listeriosis the key learnings to manage *Listeria* are to:

(1) ensure that the level of *Listeria* in or on raw materials is as low as possible;

(2) process the food to reduce, eliminate or control the number of *Listeria* present;

(3) prevent post-processing contamination with *Listeria*; and

(4) minimise the potential for *Listeria*, if present, to grow in the food.

3.3.1 Raw materials and ingredients as a source of contamination

Raw materials and ingredients may sometimes be a source of contamination. For example, raw materials may be contaminated while growing and during harvesting. This contamination can be transferred into the processing environment, which can then become a contamination source for other foods and equipment if appropriate control measures are not in place.

Unprocessed foods that can be significantly contaminated include raw milk from infected animals or fresh produce that is exposed to contamination during the growing period. For example:

- from contact with soil;
- from the use of contaminated water; or
- rotting plant material, including poorly fermented silage.

If the level of contamination is high, the intended processes may not achieve the required reduction in *Listeria* numbers to ensure a safe product. Examples include:

- the time and temperature requirements used for some gentle heating processes might not be effective; and
- control factors (hurdles) such as acidity (pH) and low moisture (high water activity (a_w)), in a soft raw-milk cheese will be unlikely to be sufficient to control *Listeria* if the raw milk was highly contaminated.

Ensuring that all incoming ingredients and raw materials are produced according to GOP, should, in most cases, be sufficient to meet food operator specifications. Levels of *Listeria* on some incoming material, e.g. fresh produce, should be as low as possible but should not exceed 100 cfu/g.

There will be some situations where requiring incoming ingredients to meet a *Listeria* (or other microbiological) limit may be essential as a *Listeria* control measure, e.g. for raw milk for the manufacture of raw-milk semi-hard cheese. This raw milk would need to meet a “not detected” limit because cheese production conditions allow *Listeria* to grow. Subsequent micro-hurdles applied in many cases may not bring about the sufficient reduction in numbers to ensure the safety of the cheese.

If limits are set for incoming raw materials and ingredients, they should reflect the processes applied prior to receipt and take into account what could happen to *Listeria* levels during further processing.

3.3.2 Processing to reduce *Listeria* levels

During processing, any *Listeria* present should be reduced to the lowest level practicable.

This can be achieved by:

- washing and cleaning of the raw ingredients for food that is to be minimally processed, for example, fresh salads or pesto-style products;
- applying a listericidal process, for example, pasteurisation that will give a measurable reduction in the number of *Listeria* that could be present; or
- putting in place a variety of micro-hurdles that together provide an acceptable reduction in the number, or may minimise the potential for growth of *Listeria* that could be present.

For fresh produce, where there are no listericidal control steps, using wash water that contains a sanitiser will help to reduce any *Listeria* present. However, there is the potential for some limited growth during the shelf life of the product.

Note that micro-hurdles may, in some cases, continue to exert an inhibitory effect post-processing during the shelf life of a food, for example, fermented high-acid foods.

When assurance of the safety of an RTE food is dependent on a listericidal process or on micro-hurdles, it will be important that there is confidence in the effectiveness of the process or micro-hurdles applied. If any of the

processing steps are essential for the safety of the product, i.e. they ensure that the acceptable level of *Listeria* is met, they will be CCPs[2] and the Critical Limits (CLs) for each CCP will require validation.

3.3.3 Post-processing contamination

The risk of *Listeria* being present in an RTE food will be very low (negligible) if a listericidal process is applied to a food in its final packaging, e.g. retorted or pasteurised. However, if the food receives a listericidal process before it is packaged then there is the opportunity for *Listeria* contamination to occur from the environment. The risk of *Listeria* contamination is greater if the product is subjected to further handling before packaging, e.g. slicing of bulk meat for consumer packs. In this case, as well as making sure that the listericidal process is effective, it is essential that the opportunity for post-processing contamination to occur is kept to a minimum. The lack of competition from spoilage microorganisms will mean it is easy for *Listeria* to grow. Testing the environment for the presence of *Listeria* is of particular importance in this situation (see Part 3: Microbiological testing).

Water used during processing and cleaning will contribute to spreading the bacteria around the processing area. When the processing environment is dry, there is limited opportunity for *Listeria* to increase in numbers. Where there is a lot of moisture present, this will provide the opportunity for the bacteria to become established. For this reason, the use of high-pressure hoses for cleaning should be avoided.

The use of complex processing equipment will increase the opportunity for *Listeria* to find niches, and some equipment is inherently difficult to clean and sanitise adequately. Experience from different parts of the animal products industry has shown that, once *Listeria* has found a niche in a piece of complex machinery, it is very hard to eradicate. This may lead to a potentially dangerous situation that necessitates the eventual removal of the equipment.

3.3.4 Foods that support the growth of *Listeria*

Which foods are most likely to support growth?

Given the right conditions, a small number of *Listeria* in a food can rapidly increase to unsafe numbers. Foods that are moist and of neutral pH, low in salt and sugar and high in protein are likely to support the growth of *Listeria*. As the acidity is lowered and salt or sugar concentrations increased or food becomes drier, growth will slow down and eventually cease (see the Appendix for more detail). Many RTE foods that require refrigerated storage will support the growth of *Listeria* to some extent.

Some plant surfaces readily trap dirt and micro-organisms and these will not be completely removed during processing, for example:

- the crinkled surfaces of vegetables like broccoli; or
- the netted rind of fruit such as cantaloupe melons.

While fresh produce will not usually support the entry or growth of *Listeria*, any surface damage during harvesting, transport or washing may allow the bacteria to penetrate and growth may then occur.

The use of some preservatives may inhibit the growth of *Listeria* but cannot be expected to have an impact on the number present.

Food can be reformulated to stop or decrease the growth of *Listeria* by altering one or several of the food's characteristics, for example, through the use of humectants or increased acid. It is important to realise that the

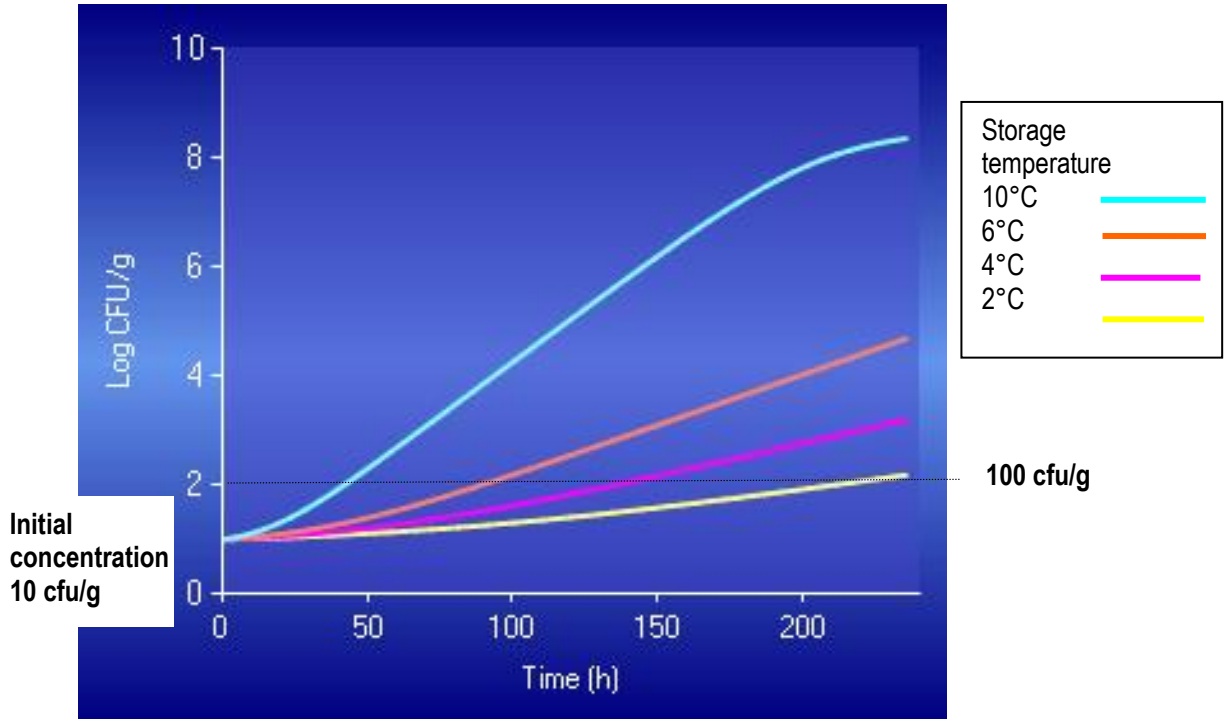
[2] See guidance on HACCP application

reverse is also true. Changing the characteristics of a food may allow growth of *Listeria*, where growth was previously not occurring. For example, through using reduced salt and softer and moister hams.

Impact of storage temperature

Listeria can grow at refrigeration temperatures but the rate will be slower than for a food held at room temperature. No growth will occur during frozen storage. When temperature abuse occurs, *Listeria* numbers may increase rapidly. Figure 1 also shows how even low numbers of *Listeria* (10 cfu/g) will increase to significant levels when a food that supports growth is stored at a range of different temperatures. Maintaining the integrity of the cold chain is very important. As counts of *Listeria* rise above 100 cfu/g (log_{10} 2 on the graph) there will be a potential for some consumers to become ill. As levels increase above 1000 cfu/g (log_{10} 3) all consumers are at risk of becoming ill and the food could be a potential source of a listeriosis outbreak.

Figure 1: Predicted growth using ComBase Predictor (www.combase.cc) of *Listeria monocytogenes* 2 degrees, 4 degrees, 6 degrees and 10 degrees Celsius over 240 hours (10 days)



Note: cfu/g = colony forming units per gram.

Type of packaging used

Removal of, or change to, the normal atmosphere within the packaging can slow down the growth of spoilage micro-organisms but *Listeria* may continue to grow. Vacuum packaging is unlikely to prevent any *Listeria* present in a refrigerated consumer pack from growing, because the bacteria can grow when there is no oxygen present. *Listeria* can grow in relatively high carbon dioxide concentrations (for example, 30 percent) but is inhibited under 100 percent carbon dioxide.

Shelf life of a product, that is, how long is there for growth to occur?

While *Listeria* grows only slowly during chilled storage, if the food is stored for an extended period, *Listeria* numbers may be able to increase to significant levels. It is important to take this into account when shelf-life is assigned to a product. If a very small number of *Listeria* (e.g. 10 cfu/g) are present at the end of processing, how many would there be at the end of the shelf-life under the expected storage conditions?

A guide is available on the MPI food safety website that provides information on the points that should be considered when determining the shelf-life of foods - Guidance Document: How to Determine the Shelf Life of Food: http://www.mpi.govt.nz/document-vault/12540

Risk profiles for specific food/hazard combinations are used across the food industry to help assess food safety risks, including *Listeria monocytogenes* in a variety of foods, e.g. ice cream, low-moisture cheeses, processed RTE meats, RTE salads and soft cheeses. The risk profiles are available from: http://foodsafety.govt.nz/science-risk/risk-assessment/risk-profiles/

If it is not known whether a product will support the growth of *Listeria*, undertaking a shelf-life study is recommended. Ideally, this will be in the form of a challenge trial study where the food is inoculated with expected levels of *Listeria* contamination. The counts of *Listeria* should be compared between the start and the end of a predetermined period. Predictive microbiological models may also be of assistance (see the Appendix for more details).

3.4 Hazard analysis of the products and processes

To help determine the appropriate control measures to apply, identify for each product or group of similar RTE foods:

- where and when *Listeria* could contaminate the product; and
- the effect of each processing steps on the number of *Listeria* present (increase, decrease and no effect).

This should be assessed from incoming ingredients and materials or harvesting to the end of shelf-life. It should include consideration of what may happen to the food after it leaves the premises for the remainder of its shelf life, that is, during distribution, repacking (and slicing), retail sale and storage by shops, restaurants and consumers.

A number of potential sources of *Listeria* contamination can be eliminated or kept to a minimum by the application of GOP and can limit the scope of any investigation in the event of the detection in food. These are described in Part 2: Good Operating Practices.

In assessing the operation, the food operator should also consider external factors, for example:

- the effect of adverse weather on the carriage of *Listeria* on fresh produce; or
- consumer behaviour such as whether a RTE food in which *Listeria* can grow is likely to be taken in and out of refrigerated storage.

These are factors that may need to be taken into consideration to ensure that they do not undermine the effectiveness of *Listeria* control measures. If any of these could be an issue, the need for modifications should be considered. Actions could include:

- reducing the product shelf life;
- enhanced product testing; or
- stricter microbiological limits.

3.4.1 Distribution and cold-chain integrity

Failure to maintain the cold chain can be a potential contributor to allowing the growth of *Listeria* in food. Distributors should be able to effectively maintain and track their refrigeration temperatures. *Listeria* may be present at levels undetectable in the product at the end of processing (depending on the nature of the processing that has been applied). However, if those foods are subjected to temperature abuse, *Listeria* may rise to unsafe levels in a short time.

3.4.2 Consumer of product

Vulnerable consumers, especially pregnant women, are advised to avoid certain foods because of the potential for *Listeria* contamination. However, it is harder to reach other vulnerable consumer groups, for example the carers of infants and the frail elderly, with risk communication messages.

RTE foods may be produced for and marketed directly to a particular vulnerable group, for example:

- powdered infant formula, baby foods, foods for infants and children; or
- they may be commonly and frequently eaten (daily or several times a week) by these at-risk groups, e.g., ice-cream, sliced RTE meats, sandwiches and so on.

It is important that all food operators across the food chain work together, from harvesting, food processing, food retail and food service to carers of vulnerable people so that informed food choices can be made. For RTE foods intended to be consumed by vulnerable people, the *Listeria* control measures in place should be strict and rigorously applied. This should also be reflected in the microbiological limits, sample size and frequency of the testing applied to the product and process.

3.4.3 Ready-to-eat versus ready-to-cook food

Consumers may not prepare or consume a food product in the way that a producer intends. They may not read the instructions on the label or they may ignore them. For example, foods intended as ready-to-cook or ready-to-reheat may be perceived by the consumer as RTE, e.g., chicken nuggets, frozen toasted sandwiches, frankfurters and so on. In these situations, the food operator should consider these products as RTE.

3.4.4 Frozen ready-to-eat food and food frozen then thawed

Listeria will not grow but can survive in frozen food. The risk categorisation of foods eaten in the frozen state will depend on the potential for contamination to have occurred before freezing. For example, if an ingredient is added after pasteurisation and before container filling this could make a frozen food a higher risk than if an ingredient was added before pasteurisation.

If a food is frozen and then thawed before sale or consumption, it will be important to consider whether any *Listeria* present could grow to levels exceeding 100 cfu/g during the potential chilled shelf life of the food.

3.5 Which *Listeria* control measures should you focus on for *Listeria* management?

There are a number of different *Listeria* control measures that can be applied. The extent to which each is applied will depend on the food including its characteristics, the production processes and the processing environment. The greater potential there is for an RTE food to be contaminated with *Listeria,* and for growth to occur in the food during its shelf life, the greater the emphasis there should be on the application of specific control measures within an overarching *Listeria* management programme.

Listeria control measures will include any activities relating to:

- GOP (refer to Part 2), in particular:
  - i) preventing the introduction of *Listeria* into the processing environment, for example, on incoming materials (ingredients or on packaging) or by people or equipment and by air and water;
  - ii) reducing the opportunity for *Listeria* to become established in the processing environment, for example, by using good process design and appropriate building materials;

iii) ensuring effective cleaning and sanitising of all processing and environmental surfaces to eliminate any build-up of *Listeria*;

- process controls, ensuring product formulations and processing steps as appropriate, for example, pasteurisation, achieve the expected effects in killing or preventing the growth of *Listeria*;
- environmental testing to identify the potential for post-processing contamination with *Listeria* (see Part 3);
- product testing to verify compliance with a CCP, or regulator or food operator-defined limit, (see Part 3);
- the corrective actions to be undertaken when GOP is not met, critical limits or other process control limits are exceeded, or when the results from product and environmental testing exceed pre-determined limits (see Part 3); and
- the type of packaging used and the storage conditions.

This document categorises foods according to the potential for:

- *Listeria* to be present; and
- the food to support the growth of *Listeria.*

Foods will be identified as having a "high", "medium" and "low" potential to be contaminated. The decision tree in Figure 2 will provide an indication of the particular *Listeria* control measure(s) that a food operator should focus on relative to a food's categorisation.

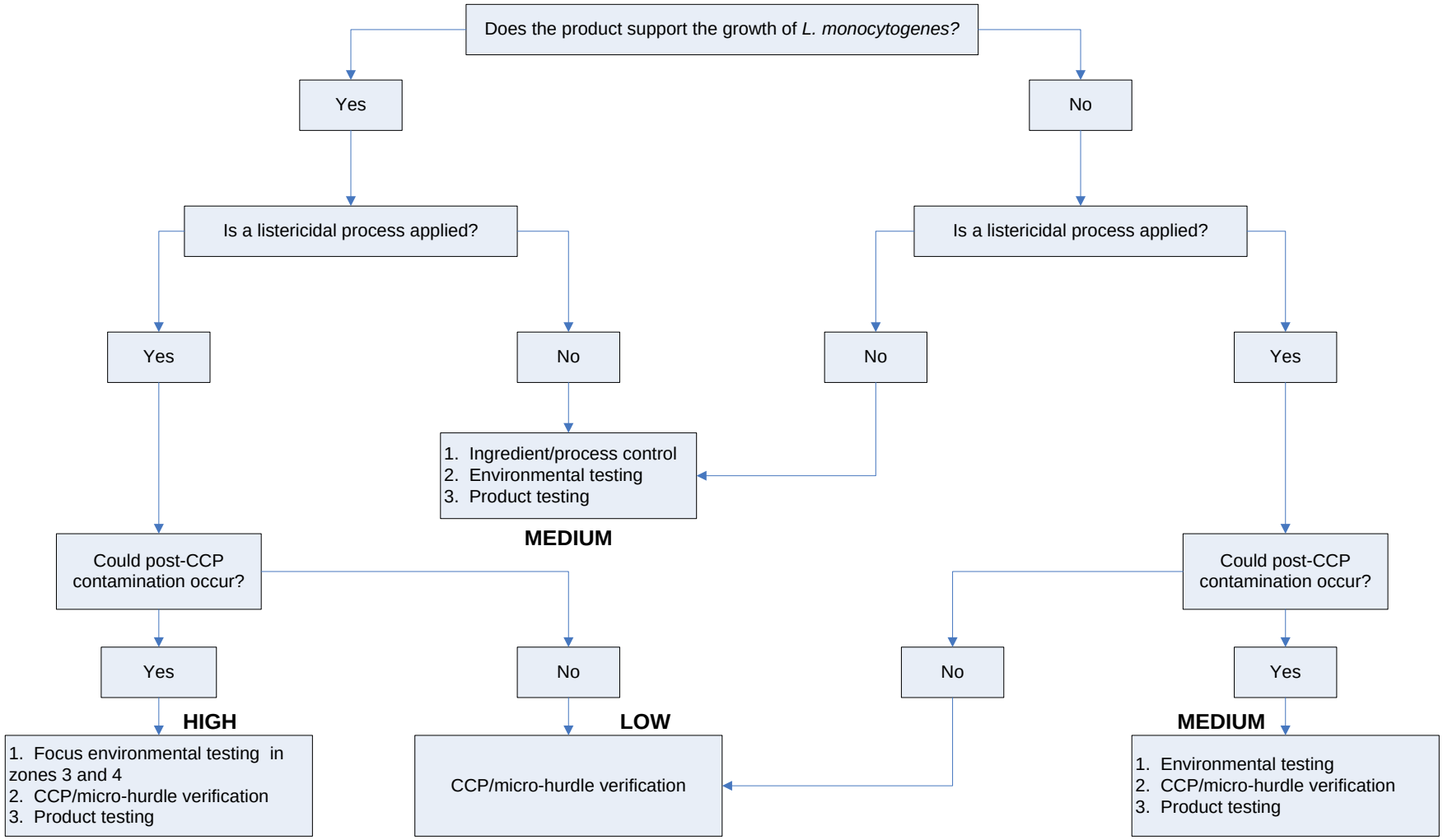
It is important to select the *Listeria* control measures that are appropriate to the food and process and then to apply these effectively.

Examples:

(1) For a food that is exposed to the environment after a listericidal processing step, it will be important to demonstrate that the potential for post-processing contamination is minimised, such as testing that the post-processing environment to which the food is exposed for *Listeria*.

(2) If the food is processed in its final packaging, the emphasis should be on ensuring that the process is working effectively and able to reduce any *Listeria* present to low levels. The focus will be on the quality and source of ingredients (and other incoming materials) and process control. In this case, environmental testing will be less important.

Figure 2: Where to focus *Listeria* control measures depending on potential for contamination with and/or growth of *Listeria*



Note: CCP = critical control point.

4 *Listeria* Management Programmes (LMP)

4.1 General

One of the most effective ways for a food operator to be confident, and able to demonstrate, that they have the appropriate *Listeria* control measures in place is to have documented these within a *Listeria* Management Programme (LMP).

A LMP should describe how a food operator will reduce or minimise the presence of *Listeria* during processing, monitor and verify that the control measures are effective and determine what should occur if something went wrong with these control measures.

By documenting the LMP this should ensure that all aspects of effective control have been considered and the *Listeria* control measures identified. The implemented LMP should provide an ongoing assurance that *Listeria* control measures are in place and are effective. Documentation will need to be updated when changes to systems and products happen. If contamination occurs or if there is a failure of a process control, the LMP should provide details of the response to swiftly and effectively resolve the event and return to normal operation with the least possible disruption.

A LMP is optional. However, if *Listeria* is identified as a hazard from a hazard analysis, food operators producing RTE foods should be able to demonstrate to customers and regulatory authorities that they are:

- aware of; and
- effectively managing;

this bacteria by putting appropriate *Listeria* control measures in place.

This is greatly assisted by having a documented LMP or by similar means such as adding some *Listeria*-specific points to a pathogen management plan or risk based programme such as a RMP or FCP.

The amount of documentation in a LMP should be directly related to the likelihood that the food could be the source of *L. monocytogenes*. Food operators who already have a:

- LMP;
- pathogen management plan; or
- risk-based programme such as a FCP or RMP;

should review their documents against this guide and check that they are covering all aspects of *Listeria* control relevant to their business

Where the information is not held in a single document, it is recommended that a record be kept of where any relevant information can be found. This will help to identify any gaps and simplify auditing and review.

The production of RTE foods intended for immediate consumption or very short shelf life, for example, food service and catering for at-risk consumers in care situations, may require the establishment of a LMP. The scope of the LMP would be defined according to the type of RTE food, the process, the likelihood of contamination as well as the hygiene of the operation and previous history of contamination events.

4.2 Components of a *Listeria* Management Programme

Table 2 provides a list of components that should be covered within the LMP. This table can be used as a checklist to make sure that all aspects of the programme have been considered and to reference where information is to be found if there is not a stand-alone LMP.

Table 2: Suggested components of a *Listeria* Management Programme (LMP)

Component	Why is this needed?	Where to find guidance
Roles and responsibilities – the name or position of the staff responsible for the various aspects of the LMP, including education and training	So that the people responsible for LMP are identified and have the appropriate authority, as well as the competency and knowledge	Part 1, Section 4.4
Identification of where Listeria could occur Analyse the product(s), the constituent ingredients and raw materials; determine the effectiveness of each processing step, and the processing environment to identify where *Listeria* may be introduced and where there is a listericidal process. Include a plan of the operation showing access points to the process environment, the process flow and hygiene areas (showing the areas where ingredients and raw materials are handled as well as the RTE food)	It should provide the food operator with a greater knowledge of the food and process and ensures that the potential sources of *Listeria* are identified and allows control measures to be put in place to minimise potential contamination. Part of HACCP application	Part 2 (Good Operating Practice) HACCP - to be documented by the food operator
Microbiological limits Identify regulatory-defined limits and/or food operator-defined limits. Programmes for sampling, testing, recording and responding to laboratory results	Ensures that the appropriate regulator or food operator-defined limits are adopted and applied so that the food can meet the appropriate microbiological limits. Ensures that a measurement, including any laboratory testing is appropriate; and can be correctly interpreted and responded to	Part 1, Section 3.2 and Part 3
Listeria control measures to be applied at any stage in the processing, including product packaging and labelling. Includes process controls such as time/temperatures and characteristics of the food e.g. pH, a_w	Ensures that appropriate control measures are identified.	Part 2
Identify any critical control points (CCPs)[3]	Part of HACCP application	To be documented by the food operator as necessary

[3] Regulatory or operator-defined limits will be used to determine any CCP and will influence selection of critical limits

Component	Why is this needed?	Where to find guidance
Identify any critical limits (CLs)	Part of HACCP application	To be documented by the food operator as necessary
Monitoring of GOP and CCPs applicable for the control of Listeria	GOP – part of GOP requirements CCP – part of HACCP application	GOP documentation – Part 2 HACCP - to be documented for each CCP by the food operator if any CCPs determined as part of HACCP application
Determine corrective actions when regulator or food operator-defined limits and critical limits (for CCP) are exceeded	Ensures that failures can be identified promptly and acted on appropriately CCP corrective actions	Part 2 HACCP - to be done by the food operator if any CCPs determined as part of HACCP application
The *corrective actions* that will be taken when responding to *Listeria* process control failures and *Listeria* events	Ensures that the potential exposure of consumers to contaminated food is reduced and minimises the potential impact (financial and reputation) on the business	Part 3
Review of the *Listeria* Management Programme	Ensures that the LMP is up to date and covers any changes in the operation and, if required, improves the programme's effectiveness. This also would cover HACCP application	Part 1, Section 4.6.2

4.3 Ensuring that the *Listeria* Management Programme has the right focus

When *Listeria* has been identified as a hazard to be managed in a food, food operators should review their operation to determine which RTE foods produced and/or packaged have the potential to be contaminated with *L. monocytogenes*. Refer to Part 2: Good operating practices for guidance on how to reduce the potential for *Listeria* contamination to occur. Remember to take into account unique *Listeria* characteristics including biofilm formation, persistence in damp processing environments and ability to grow at low temperatures.

The first step is to identify:

- everything that enters the processing area and could introduce *Listeria*;
- the *Listeria* control measures that are in place;
- the monitoring activities – how you know that the *Listeria* control measures are working and what corrective action would be taken if they were not; and
- testing to verify the *Listeria* control measures.

The next step is to review the information and identify any gaps, changes that could be made to improve the work flow, equipment placements, repairs and remedial work, educational material that is needed, restrictions to the movement of people and equipment, processing records and so on.

If the product will support the growth of *Listeria*, it will be especially important to identify if *Listeria* could be controlled during the shelf-life of the product. For example, post-packaging pasteurisation, frozen storage, modified atmosphere packaging and so on.

4.4 Roles and responsibilities

Poor communication within an organisation is often noted when the response to a *Listeria* contamination event is reviewed. In particular, the lack of clear roles and responsibilities with the lack of the appropriate authority for components of the LMP is usually seen.

In a small operation, all the activities may be undertaken by the same individual. In larger companies, it is important that the person with overall responsibility is relatively senior or is able to report directly to senior management. This is to ensure that, when an event occurs, senior management is immediately alerted and participates in the response process.

The plan should include the name or position of the person responsible for:

- overall responsibility for the LMP;
- documenting the LMP;
- maintaining specified *Listeria* control measures;
- *Listeria* testing for GOP and CCPs, etc;
- responding to the detection of *Listeria* and identifying problems in association with GOP and/or HACCP application including CCP or CL failures;
- staff training and education; and
- HACCP application review.

4.4.1 Staff training

The person with overall responsibility for the LMP should have at least a basic knowledge of *L. monocytogenes*:

- what it is;
- the illness it causes;
- measures to prevent contamination; and
- actions to take in the event of its detection.

Listeria is included in a number of the unit standards relating to food safety http://www.nzqa.govt.nz/

It is important for all other staff to receive training and education on the risks to the operation and consumers from *Listeria* contamination and their role in minimising the potential for contamination to occur. Staff involved directly with the production and handling of RTE food should have appropriate training in the following:

- the risks to consumers from contamination of product;
- the nature of *L. monocytogenes* and how it may be carried into processing areas;
- common harbourage sites;
- control measures that apply during processing, distribution, marketing, use and storage; and
- means for verifying effectiveness of pathogen management programmes (including the LMP).

In large operations, it may be useful to develop in-house training programmes or to use external providers for training.

4.4.2 Training and competency

The training of staff involved with the processing of RTE foods helps to reinforce the food safety and hygiene messages and to develop a food safety culture.

Training of staff working in high-care areas, including process staff, cleaners and engineers should be tailored to the work performed and should provide an understanding of:

- general process controls and why they are in place;
- *Listeria* and any unique characteristics;
- specific control measures that should reduce the risk of *Listeria* during processing, distribution, marketing, use and storage of a RTE food;
- verification of the effectiveness of specific control programmes, including sampling and analytical techniques;
- specific procedures needed by the food operator for each control measure;
- specific documentation and record keeping including any measurements taken, training records, version control etc.; and
- specific roles and responsibilities in relation to a LMP.

HACCP training and competency should be essential for staff who develop, implement and review a LMP for a RTE food processing operation.

Training may be provided internally or externally. The training programme records should include:

- frequency of training and retraining;
- ongoing review, peer review and visual observation, and mentoring of new staff (induction process); and
- the name and date when each staff member attended so that refresher courses can be scheduled and, that staff who have received appropriate training are selected for specific tasks, for example:
  - i) undertaking corrective actions;
  - ii) interpreting laboratory reports; and
  - iii) training samplers.

Training records should be kept and every effort made to familiarise new staff with the risks posed by *Listeria* at the earliest opportunity so that the LMP is not compromised by a lack of awareness.

4.5 Microbiological Testing for verification of the control of *Listeria*

Refer to Part 3: Microbiological testing for verification of the control of *L. monocytogenes*.

4.6 Implementing and reviewing a *Listeria* Management Programme

4.6.1 How does a *Listeria* Management Programme get put into action?

Once the LMP has been documented, either as a stand-alone document or a list providing links to the appropriate sections within other documentation, it needs to be put into action. During the initial implementation phase there are a number of specific activities that may need to be undertaken that provide a focus on *Listeria* control, such as:

- developing training material;
- training staff in cleaning;
- access control;

- safe handling;
- *Listeria* awareness;
- sampling;
- recording of findings; and
- undertaking any particular corrective actions.

At the end of the implementation phase, it is important to review the LMP with all staff involved to ensure that any issues with the LMP can be considered and addressed. It is important that all staff understand the importance of the LMP, their role in it and that it is being implemented correctly.

4.6.2 Review of the *Listeria* Management Programme

The LMP should be periodically reviewed. It is recommended that this occurs annually, as a minimum. It is recommended that this review take the form of an internal audit. Updates may also be needed if changes have occurred, for example:

- changes in management structure and responsibilities;
- building renovations; and
- new or amended/updated products, processes and equipment.

Records for specific *Listeria* control measures should be reviewed periodically to see if there are any recurring failures that can be removed, for example:

- following a change to an ingredient supplier;
- replacing equipment; or
- a review of control parameters.

5 Resources

5.1 General information on *Listeria* in food and control

- MPI *Listeria* – project reports: http://www.foodsafety.govt.nz/science-risk/project-reports/biological-hazards/listeria.htm
- MPI. Risk Profile: *Listeria monocytogenes* in Ice Cream: http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profile_Listeria_Monocytogenes-Science_Research.pdf
- MPI. Risk Profile: *Listeria monocytogenes* in Low Moisture Cheeses: http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profile_Listeria_Monocytogenes-Science_Research.pdf
- MPI. Risk Profile: *Listeria monocytogenes* in Processed Ready-to-eat Meats: http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profile_Listeria_Monocytogenes_Processed-Science_Research.pdf
- MPI. Risk Profile: *Listeria monocytogenes* in Ready-to-eat Salads: http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profile_Listeria_Monocytogenes_Ready-Science_Research.pdf
- MPI. Risk Profile: *Listeria monocytogenes* in Soft Cheeses: http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profile_Listeria_Monocytogenes_Soft-Science_Research.pdf
- MPI. Risk profile (update): *Listeria monocytogenes* in Cheese: http://www.foodsafety.govt.nz/elibrary/industry/listeria-monocytogenes-cheese.pdf
- Government of Canada (27 July 2009) Report of the Independent Investigator into the 2008 Listeriosis Outbreak. http://publications.gc.ca/collection_2009/agr/A22-508-2009E.pdf . Accessed 15 January 2016.
- Tompkins, R B (2002) Control of *Listeria monocytogenes* in the food-processing environment. Journal of Food Protection 65(4): 709–725.
- ILSI Research Foundation (2005) Achieving continuous improvement in reductions in foodborne listeriosis – a risk-based approach. Journal of Food Protection 68(9): 1932–1994.
- University of California, Division of Agriculture and Natural Resources (2000) Guidelines for controlling *Listeria monocytogenes* in small- to medium-scale packing and fresh-cut operations: http://anrcatalog.ucdavis.edu/Postharvest/8015.aspx. Accessed 15 May 2012.
- Codex Alimentarius Commission (2007) Guidelines on the application of general principles to the control of *Listeria monocytogenes* in foods – CAC/GL 61 – 2007: http://www.codexalimentarius.net/download/standards/10740/CXG_061e.pdf. Accessed 15 May 2012.
- Scientific Opinion of the Panel on Biological Hazards (2007) Request for updating the former SCVPH opinion on *Listeria monocytogenes* risk related to ready-to-eat foods and scientific advice on different levels of *Listeria monocytogenes* in ready-to-eat foods and the related risk for human illness. The EFSA Journal 599, 1–42. http://www.efsa.europa.eu/en/efsajournal/pub/599. Accessed 15 January 2016.
- Food Safety Authority of Ireland (2005) The Control and Management of *Listeria monocytogenes* Contamination of Food: http://hdl.handle.net/10147/44799. Accessed 15 January 2016

5.2 For industry sector requirements and food safety documentation

- Risk Management Programmes: http://www.foodsafety.govt.nz/industry/general/rmp/
- Food Safety Programmes: http://foodsafety.govt.nz/industry/general/fsp/
- Codes of Practice: http://www.foodsafety.govt.nz/industry/general/cops/
- Food Control Plan: http://mpi.govt.nz/food-safety/food-act-2014/food-control-plans/

- National Programmes: http://mpi.govt.nz/food-safety/food-act-2014/national-programmes/
- MPI Dairy Pathogen Management Plan Guidance Material (Draft): http://www.foodsafety.govt.nz/elibrary/industry/Pathogen_Management-Sets_Requirements.pdf
- MPI. Processing of Seafood Products – Code of Practice. Part 2: Good Operating Practice: http://www.foodsafety.govt.nz/elibrary/industry/code-practice-seafood/part-2.pdf
- MPI. Managing *Listeria* in the care sector: http://www.foodsafety.govt.nz/elibrary/industry/managing-listeria-in-the-care-sector.pdf

5.3 How to determine the shelf life of a food

- Guidance document: How to determine the shelf life of food: http://www.mpi.govt.nz/document-vault/12540
- Chilled Food Association: www.chilledfood.org
- CFA/BRC/FSA Shelf life of ready to eat food in relation to *L. monocytogenes* – Guidance for food business operators: http://www.chilledfood.org/wp-content/uploads/2015/08/Shelf-life-of-RTE-foods-in-relation-to-Lm-FINAL-v1.1.1-23-3-10-with-worked-examples.pdf
- Request for updating the former SCVPH opinion on *Listeria monocytogenes* risk related to ready-to-eat foods and scientific advice on different levels of *Listeria monocytogenes* in ready-to-eat foods and the related risk for human illness - Scientific Opinion of the Panel on Biological Hazards: http://www.efsa.europa.eu/en/efsajournal/pub/599
- Food Safety Authority of Ireland, Guidance Note No. 18: Validation of Product Shelf-Life (Revision 2): https://www.fsai.ie/publications_GN18_shelf-life/
- New South Wales Food Authority. Shelf life testing 'Use by' dates for food safety: http://www.foodauthority.nsw.gov.au/_Documents/scienceandtechnical/shelf_life_testing.pdf
- EU (2008) Guidance Document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs: https://www.fsai.ie/uploadedFiles/Food_Businesses/Microbiological_Criteria/EU_Guidance_listeria_monocytogenes2008.pdf
- EU (2014) Technical guidance document for conducting shelf-life studies on *Listeria monocytogenes* in ready-to-eat foods: http://ec.europa.eu/food/food/biosafety/salmonella/docs/technical_guidance_listeria_en.pdf

5.4 For information on how to undertake challenge studies

- *Listeria monocytogenes* Challenge Testing of Refrigerated Ready-to-Eat Foods**:** http://www.hc-sc.gc.ca/fn-an/legislation/pol/listeria_monocytogenes-test-eng.php
- Challenge Testing of Microbiological Safety of Raw Milk Cheeses: The Challenge Trial Toolkit http://www.foodsafety.govt.nz/elibrary/industry/challenge-trial-toolkit/index.htm

6 Appendix: Growth and survival of *Listeria monocytogenes* in food

6.1 How growth is defined

Growth of bacteria means an increase in number. This can be determined by testing a sample of food and comparing the bacteria count before and after storage, for example, comparing counts at the end of processing with the count at the end of the shelf-life. Counting bacteria is not an exact science as the bacteria will not be evenly distributed in food. Each sample of a food will give a result that indicates a representative count for a food rather than an exact count.

The following definition is provided in the Codex document *Guidelines on the application of general principles of food hygiene to the control of Listeria* monocytogenes *in foods – CAC/GL 61 – 2007*.

For practical purposes, a food in which growth of *L. monocytogenes* will not occur will not have an observable increase in *L. monocytogenes* levels greater than (on average) 0.5 log CFU/g for at least the expected shelf-life as labelled by the manufacturer under reasonably foreseeable conditions of distribution, storage and use, including a safety margin.

The 0.5 log increase allowed is to take into account the measurement errors associated with microbiological testing methods and variation between samples.

6.2 Growth and survival limits

Growth and survival limits for *L. monocytogenes* are shown in Table 3 (adapted from the Food Safety Authority of Ireland (2005) *The Control and Management of Listeria monocytogenes Contamination of Food).*

Table 3: Growth and survival limits for *Listeria monocytogenes*

Parameter	Minimum	Maximum [d]	Optimal	Can survive (but no growth)[e]
Temperature (°C)	-1.5 to +3	45	30 to 37	-18
pH [a]	4.2 to 4.3	9.4 to 9.5	7.0	3.3 to 4.2
Water activity (a_w)[b]	0.90 to 0.93	> 0.99	0.97	< 0.90
Salt (%) [c]	< 0.5	12 to 16	N/A	≥ 20

Notes:

a Hydrochloric acid as acidulant (inhibition is dependent on type of acid present).

b Sodium chloride as the humectant.

c Percent sodium chloride, water phase.

d When growth rate is highest.

e Survival period will vary depending on nature of food and other factors.

N/A = Not applicable.

The principal factors that influence the survival and growth of *L. monocytogenes* in food are temperature, acidity and water activity (a_w). As with other bacteria, the tolerance of *L. monocytogenes* to particular environmental constraints (processing and/or storage conditions) is greatest when all other conditions are optimal for growth.

Growth will not take place while a food is frozen or stored under high carbon dioxide conditions, that is, greater than 30 percent. There are also preservatives and other inhibitors that can be added. More detailed information can be found in the scientific literature and risk assessments.

6.3 Hurdles to eliminate or control the growth of *Listeria*

Hurdle technology refers to the concept of achieving control of pathogens by combining, in series, a number of measures that would not individually be adequate for control. Each individual control measure is considered a hurdle to the survival and growth of pathogens.

A hurdle may be based on:

- temperature (for example, heating, refrigerated storage);
- removing moisture (for example, drying, adding salt and/or sugar);
- acidity (for example, pickling);
- redox potential (for example, fermentation); and
- preservatives (for example, adding salt).

Using hurdle technology allows food businesses to control pathogens through the application of a series of milder preservation steps while at the same time meeting consumer demands for foods that are minimally processed and for those produced using traditional (artisan) methods of food preservation.

Processors of RTE foods, however, need to realise that managing a series of hurdles is more complex than applying fewer process controls. For example, a single listericidal cooking step or traditional high-salt curing or drying. The risks of listeriosis associated with modern RTE foods are due in part to a greater use of multiple mild (micro) hurdles to control growth than in the past.

Table 4: How to use hurdles effectively

What:	Record the hurdles that contribute to a safe product and the corresponding operating parameters.
Why:	Ready-to-eat foods must be formulated and processed so as to reduce, or ideally prevent, *Listeria* survival and growth. The failure of one hurdle may lead to unsafe product.
How:	• identify intrinsic characteristics of the food that inhibit growth, for example, acidity, moisture, salt, inhibitors; • identify processes that inhibit growth or reduce *Listeria* numbers, for example, heating, chilling, freezing, aging of cheeses, use of acidulants, acid increase, salt addition; • set performance criteria or operating parameters for each process, for example, amount added, time at a certain temperature or pressure, acceptable range of values; • identify how the characteristics, processes and performance criteria will be monitored to ensure that they are effective; • identify how to respond when parameters are exceeded; and • validate the combination of *Listeria* control measures.

6.4 Growth studies

6.4.1 How to determine the fate of *Listeria monocytogenes* in a food

Determining the growth, survival or inactivation of pathogens in food requires:

(1) Knowledge of the intrinsic and extrinsic properties of the product, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life.

(2) Consultation of available scientific literature and research data regarding the survival, growth and inactivation of micro-organisms of concern.

(3) Where necessary, on the basis of these studies, food operators should also conduct additional studies, which may include:

a) laboratory-based microbiological sampling and analysis;
b) predictive microbiological modelling; and
c) challenge trial tests to investigate the ability of micro-organisms of concern to grow or survive in the food product under reasonably foreseeable conditions of distribution and storage.

6.4.2 Predictive microbiological modelling

Predictive microbiology is a description of the responses of micro-organisms to particular environmental conditions such as temperature, acidity and water activity. Predictive microbiology uses mathematical models (built with data or validated by laboratory testing, including challenge trials) and computer software to graphically describe these responses.

Predictive microbiological models do not replace laboratory analysis or the training and judgement of an experienced food microbiologist. The models must be used with great caution and only by trained, experienced personnel with an understanding of the limitations of use.

In all predictive microbiology, a prediction must only be used as a guide to the response of micro-organism(s) to a particular set of environmental conditions. Consultation with a competent body is strongly recommended before their use. Food businesses should never rely solely on any predictive microbiological model to determine the safety of foods and/or processing systems.

In product development, a predictive microbiological model may allow a food business to evaluate the safety and stability of new formulations and identify those that may give a desired shelf-life. They are also useful when the shelf-life has been determined but the product is then subjected to a minor process or formulation change (either planned or unplanned through loss of process control) to establish if the change might have any effect on the safety and shelf-life of the product.

Predictive microbiological models allow product developers to pinpoint the combinations of hurdles that may achieve a desired shelf-life. These specific conditions can then be tested by experiment, if necessary, thus reducing the cost of challenge studies.

Predictive microbiological models are normally developed assuming that microbial responses are consistent. Predictive models can provide a cost-effective means to minimise microbiological testing in determining shelf-life. However, there may be occasions when the model's predictions may not be accurate, due to inconsistent microbial responses and variations in the growth media. Research has indicated that this is often why some predictive microbiological models fail to accurately predict the survival, growth or inactivation of pathogens in food products. Furthermore, predictive microbiological models must undergo validation before they are used to aid in food-safety decisions. Validation involves comparing model predictions to experimental observations not used in model development.

Initiatives to develop microbiological modelling programmes have been ongoing in the United States of America, the United Kingdom, Denmark, France, Australia and other countries for a number of years. These programmes have resulted in the development of a wide range of microbiological modelling software packages that are becoming available on the internet for download. Some of the more commonly used models are listed below:

(1) ComBase: http://www.combase.cc/index.php/en/

(2) Pathogen Modeling Program: http://www.ars.usda.gov/services/docs.htm?docid=6786

(3) Growth Predictor & Perfringens Predictor: http://www.ifr.ac.uk/Safety/GrowthPredictor/;

(4) Food Safety and Spoilage Predictor Software, Danish Institute for Fisheries Research: http://fssp.food.dtu.dk/

(5) Sym'Previus: http://www.symprevius.net/index.php?rub=why_use_sym_previus

6.4.3 Challenge tests

Challenge testing involves:

- adding a known quantity of bacteria, in this case *L. monocytogenes*, to a food at some point during its production; and
- then retesting the food at the end of its shelf-life to see what has happened to the numbers of bacteria during this time.

Such studies can produce very valuable information but are difficult to undertake. Ideally, the studies should be conducted under normal manufacturing conditions but the ability to do this will be constrained by the need to work with live and potentially pathogenic organisms.

While a well-planned and executed challenge study will contribute a great deal of information, it needs to:

- be conducted by experts;
- take into account the variability of processing and the food being processed; and
- take into account the diversity of strains of *L. monocytogenes* that exist.

It is important that the test is performed in the food as it will be available to the consumer, that is, final formulation and taking into account the consumer packaging. Because of the cost of such studies, they are most appropriate where large quantities of a product are being produced. Sources of information on conducting challenge tests can be found in the Guidance Document: How to Determine the Shelf Life of Food http://www.mpi.govt.nz/document-vault/12540

The report: *Challenge Testing of Microbiological Safety of Raw Milk Cheeses: The Challenge Trial Toolkit* presents detailed information about the conduct of challenge trials to assess the microbiological safety of raw milk cheeses, and is applicable to other food products: http://foodsafety.govt.nz/elibrary/industry/challenge-trial-toolkit/index.htm.