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

Part 1: *Listeria* Management

July 2011

Ministry of Agriculture and Forestry
Te Manatū Ahuwhenua, Ngāherehere

BIOSECURITY NEW ZEALAND

NEW ZEALAND FOOD SAFETY AUTHORITY

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Requests for further copies should be directed to:

MAF Information Bureau
PO Box 2526
WELLINGTON

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

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Prelims

Amendment 0

July 2011

Contents

Page

Review of Guide

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

Manager (Food Standards)
New Zealand Standards Group
MAF
PO Box 2526
Wellington

Telephone: 04 463 2500
Facsimile: 04 463 2643

1 Purpose

Amendment 0

July 2011

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

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

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

Food operations and food products not covered by this guide

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

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

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

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

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

Amendment 0

July 2011

2.1 WHAT IS COVERED BY THIS GUIDE

This document is Part 1 in the series and provides guidance on the general principles relating to the control *Listeria* in the production 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.

This document is intended to explain why control measures for *Listeria* should be put in place and how these should be applied. It also describes how the application of the control measures will depend on the particular type of RTE foods, the production process and environment. If the guidance is applied effectively it will reduce the incidence of *L. monocytogenes* in the processing environment and the potential contamination of RTE foods.

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* management programme appropriate to the risks associated with the RTE foods being produced.

3 Definitions

Amendment 0

July 2011

Biofilm is a population of microorganisms which are attached to each other and/or to a surface. The microorganisms, 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 sanitizers to penetrate into biofilm.

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

- Control the initial level of *Listeria monocytogenes* and other *Listeria* species.
- Prevent an unacceptable increase in *Listeria monocytogenes* and other *Listeria* species.
- Reduce or eliminate *Listeria monocytogenes* and other *Listeria* species.

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

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).

GOP - Good Operating Practice.

HACCP - Hazard Analysis and Critical Control Point.

***Listeria* event** is when *Listeria* species or *L. monocytogenes* is detected in a RTE-food or the product contact surfaces after a *Listeria* control step (i.e. hygiene area 4), e.g. during routine monitoring, surveys, illness investigation.

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

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

Niche (or harbourage site) is a localised site in which food debris and moisture can accumulate and provides an area for *Listeria* 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 the purpose of these guidance documents the shelf life refers specifically to the survival and growth of *L. monocytogenes*.

Water activity (a_w) is 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.

4 Why *Listeria* management is needed

Amendment 0

July 2011

4.1 THE *LISTERIA* GROUP OF BACTERIA

Listeria monocytogenes (*L. monocytogenes*) commonly referred to as *Listeria* is a bacterium that can be found widely in the environment in which food is grown and processed. *L. monocytogenes* is the most pathogenic (able to cause illness) member of the *Listeria* genus. Other members of the genus collectively referred to as *Listeria* species (spp.) are unlikely to cause illness but can often be found growing under the same conditions. Therefore finding any type of *Listeria* species e.g. L. innocua can be a warning that the pathogenic bacteria could also be present. *L. monocytogenes* causes the illness, listeriosis. About 90% of cases of listeriosis in New Zealand are associated with the consumption of food contaminated with *L. monocytogenes*.

Listeria is different from most other harmful foodborne bacteria such as *Salmonella* in that the bacteria can grow at low temperatures. So while refrigeration will slow down or prevent the growth of most food-poisoning bacteria, the *Listeria* bacteria may continue to grow, albeit more slowly at lower temperatures. Very little if any growth will occur if foods are dry (water activity under 0.90) or are acidified. *Listeria* bacteria may survive in frozen food, but they will not grow. However once the food is thawed, growth may occur if the conditions are right. *Listeria* is also able to continue to survive and grow in most types of packaging where the normal atmosphere has been changed or removed e.g. vacuum packaging.

4.2 WHAT CAN HAPPEN WHEN A FOOD IS CONTAMINATED WITH *LISTERIA*

While small numbers of *L. monocytogenes* (less than 100cfu /g) in food are unlikely to cause illness, as the numbers of bacteria increase, consumers will be at risk of becoming ill. If foods are contaminated with very large numbers (over 100,000cfu/g) of *L. monocytogenes* consumers may become ill with listeriosis. For most people the illness is likely to be mild, often people will experience flu-like symptoms or an illness similar to other types of ‘tummy bugs’. However for some people, even a lower number of bacteria (around 1,000) will result in a severe illness and may even lead to death.

People most vulnerable to severe infections are the very young, the elderly, people with lowered immunity (usually due to chronic diseases) and pregnant women. Pregnant women are especially vulnerable and an infection may lead to the death of the baby before or after birth. This group who is at risk from the severe form of listeriosis are typically referred to as ‘vulnerable consumers’ or YOPIs (the young, old, pregnant and immuno-compromised).

While severe cases of listeriosis are not very common in New Zealand (about 25 are reported annually) the outcome of a severe infection can be significant. Of the 25 cases, 4 may die (about 20-30% of cases).

The concern for food operators, public health agencies and regulators is what the outcome could be if a large volume of a *Listeria* contaminated RTE food entered the market. This could result in an outbreak of listeriosis with a great number of cases and with many deaths.

> An outbreak of listeriosis in Canada traced back to processed meats made by Maple Leaf Foods in 2008 resulted in 57 reported cases and 22 deaths. The people who died were mostly elderly and/or had underlying illnesses.
>
> The investigation of the outbreak is reported at -
>
> http://www.listeriosis-listeriose.investigation-enquete.gc.ca
>
> For more information on *Listeria* see Listeria monocytogenes Science Research.pdf (29KB PDF), http://www.foodsafety.govt.nz/industry/general/foodborne-illness/listeria/ and http://www.foodsmart.govt.nz/food-safety/foodborne-illnesses/listeria/

4.3 *LISTERIA* IS BECOMING 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 USA. The bacteria have always been present but food production has changed and with the greater 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 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.

4.4 WHICH RTE FOODS AND FOOD PROCESSING OPERATIONS HAVE BEEN ASSOCIATED WITH *LISTERIA* AND LISTERIOSIS?

There is a large range of RTE foods that may be associated with foodborne listeriosis and it is hard to provide a simple list of higher-risk foods. Nevertheless it is evident that these RTE foods tend to have some common features, such as that they support the growth of *Listeria* or there is the potential for contamination following a listericidal step and before final packaging.

There have been a diverse range of foods associated with food incidents or cases of listeriosis in New Zealand. This is not an exhaustive list and represents only those that have been reported to the regulatory authority. These foods include: seafood, hot-smoked mussels, RTE cooked meats, hummus/tahini, pate, pre-packaged salads, cooked/smoked chicken, vegetable dips, sandwiches, yoghurt, mussels and smoked fish, and cheeses.

4.5 HOW IS *LISTERIA* INTRODUCED INTO THE PRODUCTION FACILITY AND FOOD?

L. monocytogenes is widespread in the environment. Small numbers of the bacteria can often be found on unprocessed foods, and in and around a processing facility. It can be introduced into a processing operation on people's shoes, clothing and body, in dust, on equipment such as tools and vehicles and on ingredients and packaging. Once in the processing plant, the bacteria will find suitable niches, in particular damp spots in which to reside and multiply, including hidden equipment surfaces. If the cleaning and sanitation procedures are not thorough the bacteria may then form a biofilm and become difficult to remove. These niches can be a major source of contamination during food processing.

If this contamination occurs after a processing step designed to eliminate pathogens e.g. pasteurisation or cooking, the bacteria may grow particularly rapidly as other competing bacteria will have been significantly reduced by the process.

4.6 HOW *LISTERIA* CONTAMINATION IS PREVENTED OR CONTROLLED

The controls that are needed will depend on a number of factors relating to what the food is and how it is processed. Each RTE food will have its own set of risk factors, each of which will need to be managed. Some of these controls will be provided by the GAP and GOP that is in place but there may also need to be controls that specifically target *Listeria*.

Where there are a number of controls specifically targeting *Listeria*, it is highly desirable to capture these in a *Listeria* management programme.

4.6.1 Raw materials and ingredients

Ensuring that the incoming raw materials and ingredients are not highly contaminated with *Listeria* is important. Occasionally unprocessed foods can be heavily contaminated e.g. raw milk from an infected animal or produce exposed to contamination during the growing period e.g. from contaminated water or rotting plant material including poorly fermented silage and soil.

This contamination can be transferred into the processing environment and contaminate other foods and equipment. If the contamination level is high, the processes in place may not be able to bring about the required reduction in *Listeria* numbers to ensure a safe product. For example the time/temperature processes used for some gentle cooking processes might not be effective, controls factors (hurdles) such as acidity and low moisture in a soft raw milk cheese will be unlikely to be sufficient to control *Listeria* if the raw milk was highly contaminated.

Where raw ingredients for minimally processed RTE foods may be contaminated with *Listeria* from the environment from which they were harvested e.g. salad greens, every effort must be made to keep the contamination level low. If possible the contamination should be removed during processing e.g. by the use of sanitising washes.

Requiring incoming ingredients to meet a *Listeria* limit may be adopted as a control measure.

4.6.2 When a listericidal process is used

When assurance of the safety of a RTE food is dependant on a listericidal process, it will be important that there is confidence in the effectiveness of the process. Usually this is achieved by a combination of time and temperature during cooking or pasteurisation.

4.6.3 Post-processing contamination can be a major problem

The risk of *Listeria* contamination of a RTE food will be very low (negligible) if the food in its final packaging is exposed to a listericidal process e.g. canned or retorted pouched product.

However if the food receives a listericidal process but is then exposed to further handling e.g. slicing of bulk meat for consumer packs, the opportunity will then exist for *Listeria* contamination to occur from the environment. In this case as well as making sure the listericidal process is effective, it will be essential that the opportunity for post-processing contamination to occur is kept to a minimum. Monitoring is of particular importance in such cases (see Part 3).

4.7 THE HIGHEST RISK IS FOODS THAT SUPPORT THE GROWTH OF *LISTERIA*

4.7.1 Factors that impact on growth of *Listeria* in a food

Given the right conditions, a small number of *Listeria* in a food can rapidly increase to unsafe numbers. Factors that influence whether *Listeria* will grow in a RTE food include:

a) The characteristics and composition of food, in particular the water activity, sugar levels, acidity/pH, the inclusion of preservatives, etc. Food can sometimes be reformulated to stop or decrease growth by altering one or several of these characteristics. It is important to realise that the reverse is also true. Changing the characteristics may allow growth, where growth was previously not occurring.
b) The storage temperature. *Listeria* can grow at refrigeration temperatures but this 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.

> The impact of temperature on the doubling time for *Listeria* in a processed meat e.g. sliced ham can be significant
>
> 4°C – 61 hours; 6°C – 34 hours; 10°C – 17 hours
>
> *Source: Tom Ross, University of Tasmania*
>
> http://www.foodauthority.nsw.gov.au/_Documents/listeria_summit_2010/Listeria_behaviour_in_foods_Dr_Tom_Ross.pdf

c) The type of packaging. Removal or change to the normal atmosphere within the packaging can slow down the growth of spoilage organisms but *Listeria* may continue to grow. Vacuum packaging is unlikely to prevent any *Listeria* present in a refrigerated consumer pack from growing, as the bacteria can grow when there is no oxygen present.
d) The shelf-life of a product i.e. how long is there for growth to occur? While *Listeria* grow 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 will be important therefore to take this into account when shelf life is assigned to a product. If a very

small number (say 10cfu/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?

The risk profiles for *Listeria* in specific foods on the MAF website may be useful sources of information: http://www.foodsafety.govt.nz/science/risk-profiles/.

4.7.2 Definitions of growth and no growth

Definitions are 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 when a challenge study is done to see if *Listeria* will grow in the RTE food. In a challenge study *Listeria* are added to a food which is then stored under the manufacturer's recommended storage conditions until the end of the shelf life.

For there to be 'no growth' the number of bacteria should then be no more than 0.5 log higher than the number put in. Note that the Codex definition states that there should be some allowance for less than ideal storage during the foods shelf life once it leaves the processor's control. Therefore the challenge study should take this into account. For example domestic refrigerators may not always be at 4°C so challenge studies at higher temperatures may be needed if a product will be stored for long periods by consumers.

4.7.3 When does growth not occur?

It can be assumed that foods with characteristics outside the normal growth range for *L. monocytogenes* will not support growth. That means:

- a pH below 4.4
- an aw< 0.92
- specific combinations of these factors e.g. pH < 5.0 with aw < 0.94.

Growth will decrease as these values are reached.

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

4.7.4 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 (e.g. heating, refrigerated storage) removing moisture (e.g. drying, adding salt/sugar), acidity (e.g. pickling), redox potential (e.g. fermentation) and preservatives (e.g. 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 convenient foods that are minimally processed. An example of a RTE food preserved by hurdle technology is a pre-packaged, sliced, cooked ham. This product is preserved using a combination of curing, cooking, chilling and modified atmosphere packaging (MAP).

Processors of RTE foods however, need to realise that managing a series of hurdles is more complex than applying fewer process controls e.g. a single listericidal cooking step, 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 hurdles to control growth than in the past.

The following table describes how to use hurdles effectively

What:	Record the hurdles that contribute to a safe product and the corresponding operating parameters
Why:	RTE foods must be formulated so as to reduce, ideally prevent *Listeria* survival and growth. The failure of one hurdle may lead to unsafe product
How:	• Identify intrinsic characteristics of the food which inhibit growth e.g. pH, moisture, salt, inhibitors • Identify processes that inhibit growth or reduce *Listeria* numbers e.g. heating, chilling, freezing, aging of cheeses, use of acidulants, acid increase, salt addition • Set performance criteria or operating parameters for each e.g. amount added, time taken, acceptable range of values • Identify how each will be recorded and monitored to ensure that it is effective • Identify how to respond when parameters are exceeded. • Validate the combination of control measures

4.7.5 Shelf life and growth studies

It may be necessary to be confident that *L. monocytogenes* does not grow in a RTE food during its shelf life. This may be done by:

- Establishing that the food will not support growth because of its composition and characteristics.
- Evaluating historical data for the RTE food processed under validated conditions where risks of *Listeria* contamination have been controlled.
- Conducting durability studies. For foods that are sometimes naturally contaminated with *Listeria*, tests at the end of the shelf life could demonstrate if growth occurs during storage. However, this would not occur with many foods.
- Conducting challenge tests. This will need to be performed in a specialist laboratory. The food will be inoculated with a known number of *Listeria* and this number compared with the number present at the end of the shelf life.

There are a number of resources that have information on growth of *L. monocytogenes* and shelf life studies that could be of use:

- Conducting scientific evaluation of the product characteristics. There are various publications and models for RTE foods that could predict the potential for the food to support growth. Refer to A Guide to Calculating the Shelf Life of Foods (NZFSA, 2005) for further information on conducting shelf-life studies:
- http://www.foodsafety.govt.nz/elibrary/industry/Guide_Calculating-Contains_Background.pdf.
- Shelf life of ready to eat food in relation to *L. monocytogenes* – Guidance for food business operators 2010 www.chilledfood.org.

4.8 RISK OF CONTAMINATION FROM THE PROCESSING ENVIRONMENT

The processing environment is most often the source of *Listeria* contamination. Complex operations with a number of different ingredients and processes provide more opportunities for contamination.

When the processing environment is dry there is limited opportunity for *Listeria* to increase in numbers, but where there is a lot of moisture present this will provide the opportunity for the bacteria to become established. Water used during processing and cleaning, in particular high pressure hoses will contribute to spreading the bacteria around the processing area.

Complex processing equipment will increase the opportunity for *Listeria* to find niches and some equipment is inherently very difficult to clean and sanitise adequately. Experience in the dairy, seafood and meat industry has shown that once complex large machinery has been colonised it is almost impossible to eradicate. This may lead to a potentially dangerous situation that necessitates the eventual removal of the equipment which is likely to be a costly exercise.

> Quote from the investigation of a listeriosis outbreak
>
> *Maple Leaf Foods International Expert Panel concluded that the most likely origin (root source) of the contamination of deli meat products was deep inside a commercial meat slicer. The company has reported that to disassemble the meat slicing machines, thoroughly sanitize and then reassemble them, necessitated shutting down the plant for three days.* http://www.listeriosis-listeriose.investigation-enquete.gc.ca/index

4.9 FROZEN RTE 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 prior to freezing e.g. if an ingredient is added after pasteurisation and before container filling this could make a frozen food a higher risk than if filled immediately after pasteurisation.

If a food is frozen and then thawed before consumption or sale it will be important to take into consideration the potential chilled shelf life of the food. This will help to determine whether *Listeria*, if present, will be able to grow to non-compliant levels before it is consumed.

4.10 REDUCING THE RISK

The potential impact of risk factors may be reduced by changes to the processing environment or the characteristics of the product or the packaging e.g. a dry not wet processing

environment; remove environmental exposure after a listericidal processing step, reformulate to limit *Listeria* growth.

4.11 CAN *LISTERIA* BE CONTROLLED?

Listeria can be controlled but it is a constant ongoing process where any failure to ensure that the controls are being implemented can have major consequences. The most important control measure for a food operator is to prevent *Listeria* from entering the production and manufacturing premises. Where prevention is not possible, then minimising the impact of those that are present is essential. Control measures are described in 6.3 and in Part 2.

5 Microbiological limits for *Listeria*

Amendment 0

July 2011

5.1 WHAT ARE MICROBIOLOGICAL CRITERIA?

Microbiological limits, specifications or criteria for *Listeria* in foods are concentrations (numbers) that should not be exceeded. The limits are either quantitative i.e. number of bacteria in a set amount of food or qualitative i.e. zero, absent or 'not detected' in a set amount of food.

Criteria will usually also have a requirement to test more than one sample of the food from the same batch to increase the chance of finding contamination if present. The lowest number of samples taken is usually 5. When a higher level of food safety assurance is needed, the number of samples should be increased according to statistical tables that show the probability of correctly identifying whether the limits have been exceeded according to the numbers of samples taken. In Part 4 there is more information on the numbers of samples needed in these situations.

Microbiological limits will include:

1. The type of food.
2. The microorganism (or toxin) – in this case *Listeria monocytogenes.*
3. Where the limit applies e.g. at the end of processing or throughout the duration of the shelf-life.
4. A sampling plan, including:
    - the number of samples, given as n
    - The number of non-conforming sample units that will result in the failure of the analysis, given as c
    - The micro limit, defined as m (for presence/absence testing) and as m and M for qualitative testing.
5. The sample size to which the criteria apply e.g. 25g, per g, per 100g.

5.2 WHO SETS THE LIMITS?

Microbiological limits or criteria may be set by regulators or by industry.

When food (product) safety limits are set in regulation they must be complied with and if the food exceeds the limits it may be considered unsafe to consume. Where the limits are set by the operator (operator defined limits) or have been adopted by industry, then compliance and the response to failure to meet them will be described in the FSP or RMP.

5.3 WHEN DO THE LIMITS APPLY TO RTE FOODS?

The points in the life of the RTE food that the microbiological limits usually apply are:

1. at the end of processing, or
2. throughout the designated shelf life of a food, i.e. whilst the food is available in the retail and distribution chain until the end of the shelf-life.

Microbiological limits may also be set by operators in specifications for incoming ingredients where ingredient contamination with *L. monocytogenes* has been identified from a HACCP analysis as important.

5.4 WHAT ARE THE LIMITS FOR *L. MONOCYTOGENES*?

Microbiological limits for bacteria in food are set either as absent (zero or not detected) or as a maximum number. For *L. monocytogenes* both types of limits are applicable. It is agreed by international experts (see Codex Alimentarius) that where the levels are below 100cfu/g, the risk of infection is low for most consumers. Therefore where there are no regulatory limits on *L. monocytogenes*, counts up to 100cfu/g may be acceptable at the time of consumption.

However as the 100 cfu/g limit must not be exceeded during the shelf life of the food for a RTE food that has an extended shelf life and will support the growth of *Listeria*, this will usually mean that *Listeria* should not be detected at the end of processing. Otherwise the 100cfu/g limit is likely to be exceeded by the end of the shelf life, especially in foods stored refrigerated.

5.4.1 Regulatory limits for New Zealand

Standard 1.6.1 Microbiological Limits for Foods of the Australia New Zealand Food Standards Code (FSC) applies to all food produced in Australia and New Zealand. Foods specified in the FSC Standard 1.6.1 must meet the listed microbiological limits in at the end of its shelf life. The microbiological standard for *L. monocytogenes* is in most cases absence in 5 x 25g for a number of high risk foods. The only exception is smoked fish where one of five samples may have up to 100cfu/g. The list of foods in Standard 1.6.1 includes certain dairy, meat and fish products, especially RTE foods that have been previously linked to listeriosis

http://www.foodstandards.govt.nz/foodstandards/foodstandardscode.

Product safety limits of absence in 25g for dairy products are in the Approved Criteria for General Dairy Processing (http://foodsafety.govt.nz/elibrary/industry/1_Animal-Sets_Additional.pdf).

5.4.2 Operator defined limits

Where there are no regulatory limits, food operators may set their own limits based on HACCP (Animal Products Act 1999) (http://www.legislation.govt.nz/act/public/1999/0093/latest/DLM33502.html?search=ts_act_animal+products+act_resel&p=1&sr=1).

5.4.3 Microbiological targets for a *Listeria* management strategy

Operators may need to consider limits for two points - at the end of the manufacturing process and at the end of the foods shelf life although in many cases they will be the same. Note that 'absent in 25g' is equivalent to <0.4cfu/g. Note also that these are indicative and need to be aligned with any regulatory requirements.

Table 1 Microbiological Targets

Product risk group	**Characteristics of the food and processing**	***L. monocytogenes* level targets (see also notes below)**	
		At the end of processing	**At the end of shelf life**
High	Processed RTE foods in which growth of *L. monocytogenes* can occur (during storage in the final packaging) and the food is stored refrigerated for > 3 days	Absent in 25g	Absent in 25g
Medium	Processed RTE foods in which growth of *L. monocytogenes* will not occur	Absent in 25g (see note 2).	Not more than 100cfu/g
Low	Products where the occurrence and/or survival of *L. monocytogenes* is highly unlikely	*L. monocytogenes* not a pathogen of concern	Testing for *L. monocytogenes* not usually required. Not more than 100cfu/g

Notes

While accepting that low levels of *L. monocytogenes* in some foods may not make them unsafe for most consumers, the following must be taken into consideration:

1. Limits may be specified for some foods in regulations.
2. For the medium risk foods where there is not a listericidal process, occasional contamination with *L. monocytogenes* may be found in some foods at the end of processing. This should be considered when developing the *Listeria* Monitoring Programme (see Part 3.)
3. While most countries are in agreement with the Codex recommendations, some may set zero levels for *L. monocytogenes* in all foods to achieve their public health objectives. If the food is intended for export it will be necessary to comply with the requirements of the importing country.
4. It may be necessary to take into account any specifications that the retail sector or other assurance schemes puts in place for the products they sell.
5. These results relate only to product testing. Environmental monitoring is discussed in Part 3.
6. *Listeria* spp other than *L. monocytogenes* may be found in food. These are unlikely to be pathogenic unless present at very high levels (>100,000cfu/g) when they could be pathogenic for at risk consumers. However finding high levels of these *Listeria* spp. indicates that *Listeria* control measures have failed or have not been applied.

6 *Listeria* management programmes

Amendment 0

July 2011

6.1 WHY HAVE A *LISTERIA* MANAGEMENT PROGRAMME (LMP)?

Reducing the level of *L. monocytogenes* in RTE food requires all food operators to be proactive in managing the risk. So while in New Zealand it may not be mandatory to have a *Listeria* management programme (LMP), if *Listeria* is identified as a hazard from a HACCP assessment or the foods being processed have a number of risk factors, it is expected that food operators will be able to demonstrate that there are appropriate controls in place. This will be most easily demonstrated by having a documented LMP. For some of the RTE food production and manufacturing sectors, dairy and seafood, there are already specified regulatory *Listeria* management requirements.

6.2 WHAT IS A LMP?

A *Listeria* management programme is intended to identify the control measures that a food operation has in place to prevent *Listeria* contamination. The documented plan should be a living document subject to constant review and responsive to events that could alter the control requirements. It will be unique to each food operation. In general LMPs are likely to cover procedures that specifically target the control of *Listeria* through the application of good operating practice (GOP) which enables the production of safe and suitable food. GOP is a system made up of a collection of procedures that set out how you operate your business to produce safe and suitable food. GOP is fundamental to a risk-based programme, such as a food safety programme (FSP) or a risk management programme (RMP).http://foodsafety.govt.nz/industry/general/gop/.

Note that a LMP is a Pathogen Management Plan with a specific focus on *L. monocytogenes*. For guidance material on Pathogen Management Plans see http://www.foodsafety.govt.nz/elibrary/industry/Pathogen_Management-Sets_Requirements.pdf

6.3 DEVELOPING A LMP FOR A FOOD OPERATION

Food operators should begin by reviewing their operation in terms of the potential for the RTE foods produced and/or packaged to be contaminated with *L. monocytogenes*.

Listeria control measures will include any activities relating to:

- the introduction of *Listeria* into the processing environment e.g. in ingredients or on packaging or by people or equipment and by air and water
- reducing the opportunity for *Listeria* to become established in the processing environment e.g. by using good process design, appropriate building materials
- ensuring effective cleaning and sanitising of all processing and environmental surfaces to eliminate any build up of *Listeria*

- ensuring product formulations and processing steps e.g. pasteurisation achieve the expected effects in killing or preventing the growth of *Listeria*.

Tools that can be used to achieve these controls could include:

- restricting the movement of people, equipment, air, water and materials and product within the processing environment
- educating staff on what could happen if contaminated food is produced and how this can be prevented
- cleaning and sanitation programmes and monitoring
- environmental and product monitoring programmes
- building and equipment design and workflow
- clothing /footwear /personal hygiene policies and protocols
- microbiological limits or customer specifications for *L. monocytogenes* in ingredients and products.

A number of these tools are discussed in Part 2.

6.4 KEY FACTORS IN A RISK BASED APPROACH TO *LISTERIA* MANAGEMENT

Analysis of cases and outbreaks of listeriosis, incidents of *Listeria* contaminated foods and scientific studies have identified the risk factors for a particular food product being contaminated with *Listeria* and for the growth of *Listeria* to numbers that could cause illness. The more risk factors the higher the potential risk for the food to be the source of an outbreak of listeriosis unless these risks factors are carefully managed. This provides the basis for the MAF *Listeria* Risk Management Strategy.

> The MAF *Listeria* Risk Management Strategy 2008-2013 can be found at –
>
> http://www.foodsafety.govt.nz/industry/general/foodborne-illness/listeria/strategy.htm

The key risk factors are:

1. the characteristics of the RTE food, i.e. whether or not *L. monocytogenes* is able to grow
2. the potential for *Listeria* to be present in the ingredients
3. the type of processing (e.g. is there a listericidal step)
4. the likelihood of contamination (exposed to the environment or not) before final packaging, and
5. who is intended to eat the food, i.e. the general population or a specific sub-set, e.g. infants.

Operators who process RTE foods in the low risk category (see Table 1) 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 LMP. 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.

6.5 DOCUMENTING A LMP

The amount of documentation that would be expected in a LMP will be directly related to the level of risk that the food could be the source of listeriosis. Operators who already have a pathogen management plan or LMP in place as part of their FSP or RMP should review their documents against this guide and add to their current documentation if necessary to ensure it is covering all aspects of *Listeria* control. Where the information is not held in a single document, it is recommended that a record of where the relevant information is to be found and any additional material that needs to be documented. This will help to identify any gaps in the LMP and simplify auditing.

Table II – LMP Checklist

Topic	Why is this needed	Where to find information
Responsibilities – the names or positions of staff responsible for the various aspects of the plan, including education	Lack of clarity as to who is responsible and what needs to be done can result in loss of control and failure to understand issues	6.5.1
Risk assessment of the operation. A premises plan of the operation showing access points, process flow and hygiene areas	Identifies potential sources of contamination and strategies to minimise and control each source	6.5.3 and 6.5.5
Control strategies	Identifies strategies to minimise and control each potential source	Part 2
Microbiological limits for *L. monocytogenes*	Identifies appropriate microbiological limits and at which point they apply. Ensures that laboratory testing is appropriate and correctly interpreted and responded to	5
Control limits and corrective actions	Ensures that failures will be identified promptly and acted on appropriately	6.5.4 and Part 2
Listeria monitoring	Reduces the potential for the food to become contaminated during processing	Part 3
Responding to *Listeria* process control failures and *Listeria* events	Reduces the potential exposure of consumers to contaminated food Minimises the potential impact (financial and reputation) on the business of a contamination event	Part 4

6.5.1 Responsibilities

Poor communication within an organisation are often noted when the response to a contamination is reviewed. In particular the lack of clear roles and responsibilities 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 are immediately alerted and participate in the response process.

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

1. Overall responsibility for the *Listeria* management programme
2. Documenting the LMP.
3. *Listeria* monitoring
4. Responding to the detection of *Listeria*, identified problems with the LMP application or GOP/HACCP control failures.
5. Staff training and education of the *Listeria* control measures.

6.5.2 Staff Training

Whoever is responsible for applying 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 the detection. *Listeria* is included in a number of the Unit Standards relating to Food Safety http://www.nzqa.govt.nz/framework/index.html.
Presentations on *Listeria* may also be given at food safety and food sector conferences and workshops.

It is also important for 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 with the production and handling of ready-to-eat food should have appropriate training in the following:

- 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
- the means for verifying effectiveness of control programmes, including the LMP

In large operations it may be useful to develop in-house training programmes or to use external providers. Suppliers of cleaning chemicals, materials and equipment may be able to provide suitable training or training material that operators can use.

> 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.

6.5.3 Risk assessment of the operation

6.5.3.1 Step One - Foods that support the growth of *Listeria*

The most important risk factor is whether *Listeria* can grow in the food. Given the right conditions, a small number of *Listeria* in a food can rapidly increase to unsafe numbers.

Factors that influence whether *Listeria* could be present and then able to grow in a RTE food include:

1. Whether a food received a listericidal process (e.g. heat treatment) in the final packaging.
2. The storage temperature, *Listeria* can grow at refrigeration temperatures but this will be considerably slower than for a food held at room temperature.
3. The characteristics and composition of food, this is usually based around the water (moisture) content, acid levels, the inclusion of preservatives, etc. Food can sometimes be reformulated to stop or decrease growth.
4. The type of packaging, the removal or change to the normal atmosphere within the packaging can slow down the growth of spoilage organisms and pathogens, like *Listeria*. Foods that spoil easily due to bacterial (not fungal) growth will also allow *Listeria* to grow.
5. The shelf-life of a product is also important, as well as being set to ensure that consumers eat good quality foods it should also take into consideration the potential for growth of *Listeria*.

The potential for a RTE food to allow *Listeria* growth (see 4.7) can be determined by analysis of characteristics that reduce or prevent growth e.g. pH and water activity or by doing challenge study where *Listeria* is added to the food to see if and how fast it can grow.

If a LMP includes monitoring product for the presence of *Listeria* at the end of production, it is important to remember that for all medium and high risk foods, not detecting *Listeria* in a food does not necessarily mean that it is not present, only that it was not in the sample of product tested or that the level was too low to be detected by the method used in the laboratory.

6.5.3.2 Step two - Site maps and work flow

In order to have a clear picture of where contamination events could occur in a processing area and where controls are possible it is good practice to have a diagram or site map that clearly shows key features of the facility and the processing. On this diagram the work flow should be identified.

Listeria may be carried into a processing environment. Identify everything that is moved, carried, piped, pumped or otherwise transferred in the processing building e.g. people, raw materials, other ingredients, equipment, cleaning materials, air, water, ice, packing, pallets, forklifts, etc. Identify all controls needed to manage these risks.

6.5.3.3 Step Three – Review of site maps and process flow

Review the process flow, taking note of the routes that a food takes from raw ingredients to finished product. There should be a linear process flow so that the food is not at risk from being cross contaminated as it progresses through the facility. Ideally the process steps should be in separate rooms but this may not always be possible. As the risk from contamination at the end of processing is the greatest danger, this area must be the most protected from inadvertent reintroduction of contamination.

Where the process flows have a potential to be a source of contamination, make changes if possible.

6.5.3.4 Step Four – Hygiene areas

Once the site plan and process flow are finalised, identify the hygiene areas. Hygiene requirements to control *Listeria* will increase along the process flow. The progression from

low care hygiene to high care (critical) hygiene requirements is achieved by dividing the process flow into areas. Each area is separated from the area on either side by the hygiene requirements. Ideally the separation between each area should be a wall and door.

The demarcation of areas will depend on the complexity of the operation and the configuration of the processing areas. The areas with the highest risk will be where product could be exposed to post-processing contamination (before packaging) and will be named appropriately i.e. critical hygiene or high care. See Diagram 1 below for relative risks associated with each area.

In the diagram, area 1 is an external area, area 2 is an inside area which is a non critical or standard hygiene environment and area 3 will a critical environment. Note that area 4 (within area 3) is where there are equipment surfaces i.e. product contact surfaces which may be a source of product contamination.

Separation of hygiene areas may be achieved by various means e.g. physical barriers, floor marking, etc. For a description of these options, see Part 2.

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

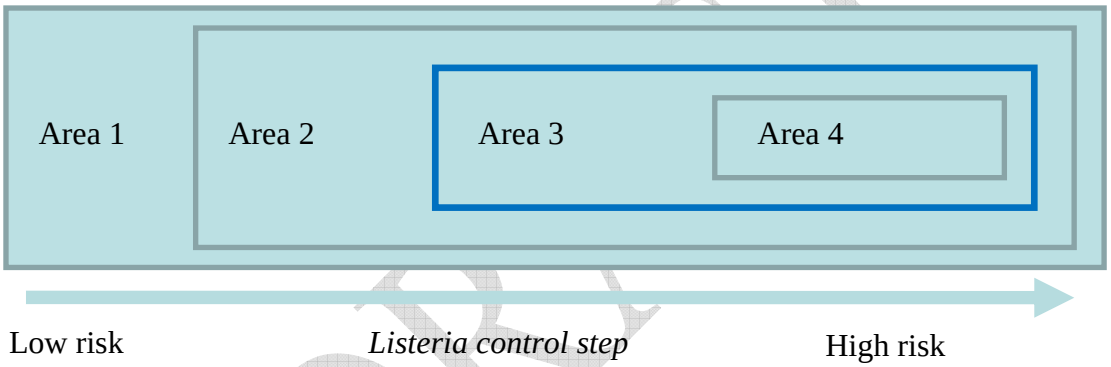
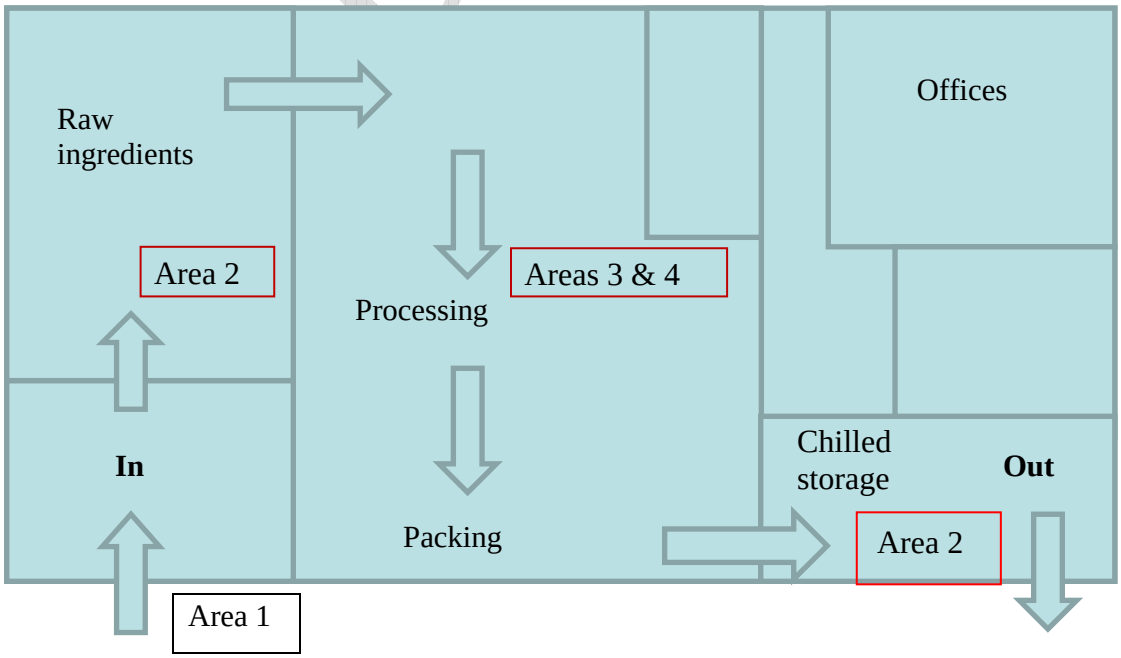


Diagram 2: Schematic operation



Hygiene areas and process flows are closely linked and should always be considered together. By drawing the flow on a floor plan as shown above, it is possible to see where separation is needed to prevent or at least reduce the potential for contamination and to identify the hygiene areas and their risk level. It will also be possible to see from the floor plan where movement should be restricted e.g. no entrance to refrigerated storage from offices; no movement from processing to raw ingredients unless specific control point such as boots and clothing exchange.

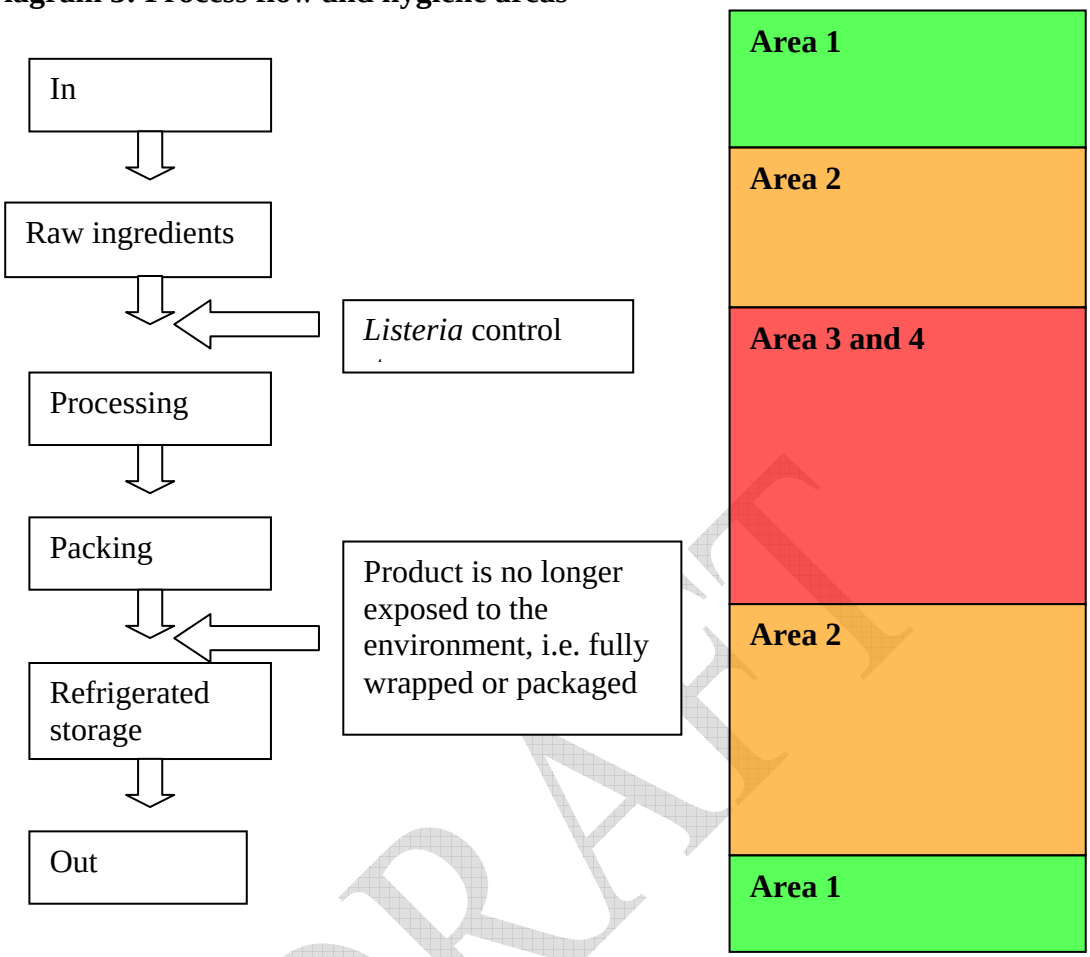
> It is important that the process flow accurately shows what really happens and not what is supposed to happen. Observation while processing is taking place may identify routine or occasional practices that compromise the process flow.

In the diagram above, area 1 is the outside environment, including access ways, rubbish areas and amenities and is a low risk areas Area 2 will include storage areas and raw product receivable areas and acts as a buffer between the outside environment and critical hygiene areas. Storage areas for packaged product will also be an Area 2. Area 3 will be the area where the processing takes place and will be a moderate or high care hygiene area depending on the nature of the processing and whether or not there is a CCP. Once the processing is finished there is often a transition to a critical high care area because of the risk of contamination occurring prior to or during the packing operation. Area 4 is within Area 3 and consists of the surfaces which product may come into contact with and which may be a source of post-processing contamination. These surfaces are of particular importance if they occur after a listericidal processing step.

> Note: there are a variety of conventions for identifying and naming hygiene areas, usually as a zone with numbers or letters and describing what each includes. This can be very confusing especially when a system used by one industry sector is the reverse to what is used in another sector. So when referring to an area in a plan make sure that everyone understands exactly what the area refers to.

6.5.3.5 Step 5 - Making the link between process flow and hygiene areas

Diagram 3: Process flow and hygiene areas



6.5.4 Control measures

6.5.4.1 Scope of a LMP

For each product or group of similar RTE foods, it will be necessary to know where and when *Listeria* could contaminate the product and what steps in the process could result in increases or decreases in the number of *Listeria* present. This should be assessed from incoming ingredients 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 i.e. during distribution, repacking (and slicing), retail sale, storage by consumers, shops and restaurants etc.

In developing a LMP, you should also consider some external factors that may need to be taken into consideration to ensure that they do not undermine effectiveness of the LMP. If any of these could be an issue, the need to modify the plan accordingly should be considered. Actions to mitigate these risks could include reducing the product shelf life, enhanced product testing and monitoring or stricter microbiological limits.

6.5.4.2 Distribution and cold-chain integrity

Failure to maintain the cold-chain can be a potential contributor to allowing the growth of *Listeria* in food. It is preferable that distributors operate their own RMPs and FSPs and effectively maintain and track their refrigeration temperatures. Smaller distributors may have poorer temperature control and this should be taken into account. While *Listeria* may be at levels undetectable in the product (depending on the nature of the processing that has been applied) it may still be present in some foods and if subjected to temperature abuse, rise to unsafe levels in a short time.

6.5.4.3 Consumers

Vulnerable consumers, especially pregnant women, are advised to avoid certain foods because of the potential for *Listeria* contamination. However it is more difficult to target messages at other vulnerable consumer groups and their carers such as infants and the frail elderly. Therefore RTE foods that are commonly and frequently eaten (daily or several times a week) by these at risk consumers may need to be targeted for *Listeria* control. These foods have a higher risk potential to be the source of illness if contaminated than would RTE foods infrequently eaten by these vulnerable groups.

6.5.4.4 RTE versus ready-to-cook

Consumers may not prepare or consume a food product in the way that the producer intended. They may not read the label instructions 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, etc. In these situations the food operator should consider including these products within their *Listeria* management programme.

6.5.4.5 Frozen RTE 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 prior to 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 filled immediately after pasteurisation.
If a food is frozen and then thawed before consumption or sale it will be important to take into consideration the potential chilled shelf life of the food. This will help to determine whether *Listeria*, if present, will be able to grow to non-compliant levels before it is consumed.

6.5.5 Using process flow to identify control points and measures

On a process flow chart for the food, using a HACCP approach locate the points where *Listeria* could be introduced or reduced. Identify how the increase or the decrease will be managed i.e. a potential increase minimised, opportunity for *Listeria* growth eliminated or reduced. *Listeria* controls may be achieved through the application of GOP or more specific control measures such as:

- Keeping contamination out of the premises by controlling access of people, equipment, raw materials, packaging.
- Controlling the movement of people and equipment between hygiene areas.
- Increased hand washing.

- A heat processing step (CCP) capable of reducing the potential number of *Listeria* present to a safe level i.e. a listericidal process such as cooking, canning, pasteurisation.
- Incoming ingredient specifications.
- Effective cleaning and sanitation programme specifically aimed at *Listeria* e.g. choice of sanitiser, cleaning protocols restricting the use of high pressure hoses.
- Process flows to prevent cross contamination from raw to cooked product.
- Monitoring each hurdle that contributes to the safety of the food to ensure they are within the required range (see 4.7.4 for information on the use of hurdles).
- Adding a preservative that inhibits the growth of *Listeria*.
- Using equipment that is designed to minimise the potential for contamination, especially in high care areas e.g. conveyor belts.

6.5.6 Control measures and corrective actions

For each control it is necessary to set performance criteria e.g. specification for an ingredient, time and temperature for a heating step, preservative concentration and to identify what the response will be if the limits are exceeded i.e. failure of a *Listeria* control. The response needs to be carefully planned so that it is appropriate to the severity of the failure and is realistic. For example, the action taken in response to an ingredient failing to meet specific requirements (e.g. microbiological limits) will be different depending on whether there is a specific *Listeria* control step in the process compared to a high risk food that will receive no further processing.

In the LMP identify the control measures and steps will have been identified and the operating limits for each. When these limits are exceeded, an appropriate corrective action will be needed. Failures and the corrective actions should be recorded. Additional comments and observations that could help with problem solving should also be recorded for future reference and review (see 7.3).

7 Implementing the LMP

Amendment 0

July 2011

7.1 HOW DOES IT GET PUT INTO ACTION?

Once the LMP has been documented, 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 such as developing training material, training staff in sampling, recording of control measures and undertaking monitoring activities.

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

7.2 *LISTERIA* MONITORING PROGRAMME

How do you check that the LMP is working properly? The usual way is through a monitoring programme. In Part 3, the requirements for monitoring a LMP, including environmental monitoring are outlined and the appropriate responses described. More details on the responses needed when the *Listeria* is found in food or critical hygiene areas can be found in Part 4.

7.3 RESPONDING TO CONTROL FAILURES

Failure records for specific *Listeria* controls should be reviewed periodically to see if the cause of a recurring failure can be removed e.g. change an ingredient supplier, replace equipment; review control parameters (are they unnecessarily strict?).

7.4 REVIEW OF THE LMP

The LMP should be periodically reviewed (ideally annually) to update as needed. Updates may also be needed if changes have occurred in -

- Management structure and responsibilities.
- Building renovation.
- New products, processes and equipment.

The *Listeria* monitoring programme is integral part of the LMP and care should be taken to ensure that the two remain in agreement.

8 Information sources

Amendment 0

July 2011

8.1 FOR GENERAL INFORMATION ON *LISTERIA*, *LISTERIA* CONTROL AND OUTBREAKS AND THE MAF *LISTERIA* RISK MANAGEMENT STRATEGY

- MAF website http://www.maf.govt.nz/
- Listeriosis Investigative Review http://www.listeriosis-listeriose.investigation-enquete.gc.ca/index_e.php?s1=rpt&page=summ
- R.B.Tompkins (2002) Control of *Listeria monocytogenes* in the food-processing environment. Journal of Food Protection 65, 709-725.
- ILSI Research Foundation (2005) Achieving continuous improvement in reductions in foodborne listeriosis – a risk-based approach Journal of Food Protection 68, 1932-1994.
- Guidelines for controlling *Listeria monocytogenes* in small- to medium-scale packing and fresh-cut operations http://anrcatalog.ucdavis.edu/Postharvest/8015.aspx
- Codex Alimentarius (2007) Guidelines on the application of general principles to the control of *Listeria monocytogenes* in foods CAC/GL 61 – 2007.
- Scientific Opinion of the Panel on Biological Hazards http://www.efsa.europa.eu/en/efsajournal/pub/599.htm

8.2 FOR INDUSTRY SECTOR REQUIREMENTS AND FOOD SAFETY DOCUMENTATION (RMPS AND FSPS)

- http://www.foodsafety.govt.nz/industry/general/rmp/
- http://www.foodsafety.govt.nz/industry/general/cops/

8.3 FOR INFORMATION ON HOW TO DETERMINE THE SHELF LIFE OF A RTE FOOD -

- http://www.foodsafety.govt.nz/industry/general/fsp/documents.htm
- www.chilledfood.org
- http://www.efsa.europa.eu/en/efsajournal/pub/599.htm

9 *Listeria* Management Programme Record

Amendment 0

July 2011

1.0	Responsibilities	Record position or name of person responsible
1.1	Overall responsibility for the LMP	
1.2	Documentation of the LMP	
1.3	*Listeria* monitoring	
1.4	Responding to *Listeria* control failures	
1.5	Education of staff	
2.0	**Risk categorisation of the RTE foods**	Action: Risk levels needs to be assigned to the food or groups of foods
	Products (list)	
	Products (list)	
	Products (list)	
3.0	**Risk assessment of the operation**	Action: Attach diagram/s or identify where can be found
	Premises plan	
	Process flow	
	Hygiene areas	
4.0	**Control strategies**	Identify on a flow chart, HACCP chart or other document key *Listeria* control points; how each is managed and monitored
5.0	**Microbiological limits**	Sample sizes, numbers, frequency and target microbiological limits
6.0	**Control limits and corrective actions**	Corrective actions including communication of failures to management, authorities, consumers etc
7.0	***Listeria* monitoring Programme**	Attach a copy or identify where can be found
8.0	**Responding to failures**	Attach a procedure or identify where can be found
8.1	Process control measure failures	
8.2	Environmental monitoring	
8.3	Events i.e. *Listeria* in a food or from a product contact surface	