



FOOD STANDARDS CODE 1.6.1 – MICROBIOLOGICAL LIMITS FOR FOOD – *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS

September 2014

PURPOSE

This fact sheet provides general advice to processors of ready-to-eat (RTE) food in applying the microbiological limits for *Listeria monocytogenes* in RTE foods in accordance with the Australia New Zealand Food Standards Code (the Food Standards Code) Standard 1.6.1.

People can become sick if high numbers of the bacteria are eaten. Pregnant women, the very young the elderly, and immunocompromised persons are particularly susceptible to the effects of *L. monocytogenes*. There are also some RTE foods which are excluded from Standard 1.6.1.

AMENDMENT TO THE FOOD STANDARDS CODE

The microbiological criteria for *L. monocytogenes* have been revised in the [Food Standards Code 1.6.1 – Microbiological Limits for Food](#). The Schedule to Standard 1.6.1 – Microbiological Limits in Food specifies end point microbiological limits (i.e. measured at the end of a product's shelf life) for *L. monocytogenes* in all types of RTE foods based on whether growth of the microorganism can occur. There are also some RTE foods which are excluded from Standard 1.6.1.

This amendment takes effect on 18th September 2014 in New Zealand, which means that from this date processors of any RTE foods to which Standard 1.6.1 applies must comply.

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Food	Microorganism/test	n	c	m	M
Ready-to-eat food in which growth of <i>Listeria monocytogenes</i> will not occur	<i>Listeria monocytogenes</i>	5	0	100 cfu/g	
Ready-to-eat food in which the growth of <i>Listeria monocytogenes</i> can occur	<i>Listeria monocytogenes</i>	5	0	Not detected in 25g	

It is expected that most operators will continue to apply the limit of *L. monocytogenes* not detected in 25g when testing product regardless of the changes in Standard 1.6.1. This is because it can be difficult to confirm that growth will not occur and when testing product, finding any *L. monocytogenes* may indicate that the process or product controls have not been fully effective.

L. monocytogenes is able to grow at refrigeration temperatures but this can be minimised or prevented by the specific characteristics of the food; including the acidity, salt content, moisture content, preservatives, etc. and the storage conditions of the particular food.

RTE FOODS EXCLUDED FROM STANDARD 1.6.1.

In general terms the new limits for *L. monocytogenes* apply to all RTE foods, however there are some RTE foods where testing is unnecessary. Standard 1.6.1 specifically excludes certain categories of RTE foods:

- ready-to-eat food means a food that –
- (a) is ordinarily consumed in the same state as that in which it is sold; and
 - (b) will not be subject to a listericidal process before consumption; and
 - (c) is not one of the following –
 - (i) shelf stable foods;
 - (ii) whole raw fruits;



- (iii) whole raw vegetables;
- (iv) nuts in the shell;
- (v) live bivalve molluscs.

Shelf-stable foods are foods that have been processed so that they can be safely stored at ambient temperature. Such foods include canned or retorted food, cereals, biscuits, soft drink, certain sauces, confectionery, flour, sugar and dried foods.

Whole raw fruits, vegetables and nuts in the shell are generally not considered RTE foods as most are intended to be either washed, hulled or peeled by the consumer. An exception would be raw fruits and vegetables that are washed and peeled, cut, sliced or shredded prior to packaging and sold as RTE foods. Pre-packaged products that are intended to be further processed need to be provided with cooking instructions on the package.

Live bivalve molluscs not intended for further processing are products that remain alive immediately prior to consumption, e.g. oysters (the shellfish will close by themselves when tapped).

HOW TO DETERMINE WHETHER THE GROWTH OF *L. MONOCYTOGENES* CAN OR WILL NOT OCCUR

Knowing whether growth can or will not occur in RTE food is important because of the potential impact on consumers and of the different microbiological limits that apply.

In spite of the changes, however, most operators are expected to continue to apply a limit of absence of *L. monocytogenes* (i.e. not detected) in a 25g sample of the food.

If you are able to apply the limit of less than 100 cfu/g of *L. monocytogenes* to the RTE food, then the remainder of this factsheet explains what you need to do.

It is important to note that the limit of less than 100 cfu/g of *L. monocytogenes* applies to a RTE food throughout its stated shelf life. The characteristics of the food or the storage conditions determine whether or not growth of *L. monocytogenes* will occur in a RTE food. Standard 1.6.1 defines food in which the growth of *L. monocytogenes* will not occur:

6 Food in which the growth of *Listeria monocytogenes* will not occur

- (1) For the purposes of the Schedule, the growth of *Listeria monocytogenes* will not occur in a ready-to-eat food if –
 - (a) the food has a pH less than 4.4 regardless of water activity; or
 - (b) the food has a water activity less than 0.92 regardless of pH; or
 - (c) the food has a pH less than 5.0 in combination with a water activity of less than 0.94; or
 - (d) the food has a refrigerated shelf life of no greater than 5 days; or
 - (e) the food is frozen (including foods consumed frozen and those intended to be thawed immediately before consumption); or
 - (f) the level of *Listeria monocytogenes* will not increase by greater than 0.5 log cfu/g for at least the expected shelf life.
- (2) A ready-to-eat food that does not receive a listericidal process during manufacture is considered as a food in which the growth of *Listeria monocytogenes* will not occur if the level of *Listeria monocytogenes* will not exceed 100 cfu/g within the expected shelf life.

Clause 6(2) refers to products that do not receive a listericidal process. Standard 1.6.1 states that a **listericidal process** means a validated process that reduces *L. monocytogenes* to a safe level. This may include treatments, such as a heat treatment, high-pressure processing, drying and/or acidification.

The **expected shelf life** is the time established by the food business that, under the intended conditions of distribution, storage, retail and use, the food will remain safe and suitable.



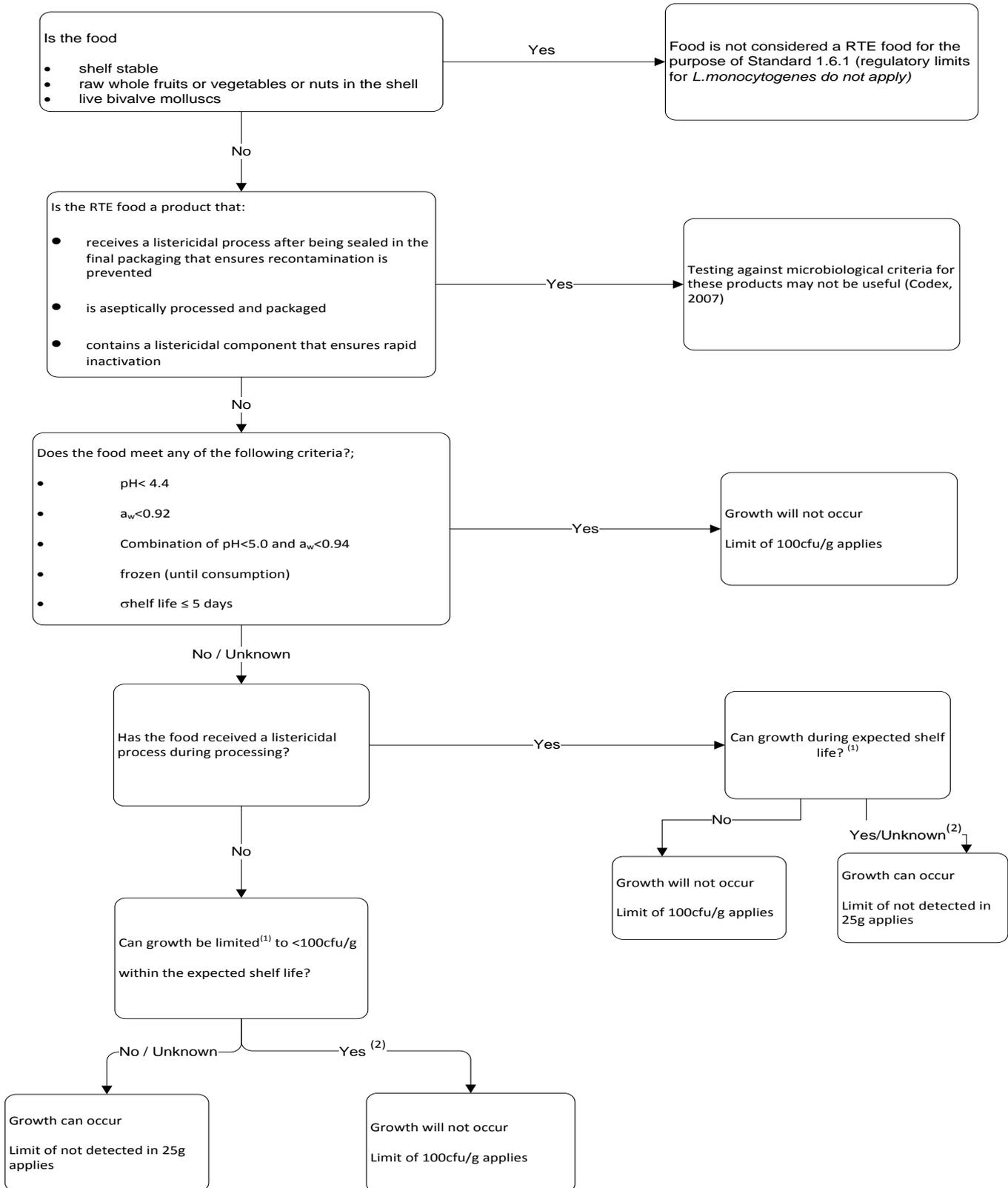
Clause 6 (2) takes into account that some foods do not receive a validated listericidal process during manufacture and product safety relies on:

- reducing opportunities for contamination during production, processing and distribution;
- limiting growth by maintaining the cold chain; and
- restricting the shelf life.

Examples of these foods include smoked and gravadlax seafood and fresh-cut salads (sprouted seeds, leafy and fruit salads). Occasional low level contamination of such products by *L. monocytogenes* may be unavoidable but this may not present a risk provided that growth cannot occur and there is less than 100 cfu/g throughout the stated shelf life.

If evidence can be provided that the level of *L. monocytogenes* would be less than 100 cfu/g throughout the stated shelf life, then a limit of 100 cfu/g applies for the purpose of Standard 1.6.1.

FSANZ has developed a decision framework that can be used to help determine which microbiological limit should apply to a RTE food. This has been included here:



(1) Whether growth occurs or is limited may depend upon product characteristics, use of inhibitory substances, production/ packaging practices, and /or the shelf life to be specified. In the absences of evidence to the contrary, growth should be assumed.

(2) Evidence for this decision provided through validation.

Figure 2: Recommended framework for applying limits for *L. monocytogenes* in RTE foods for the purpose of Standard 1.6.1 and where validation is required.



VALIDATION THAT GROWTH WILL NOT OCCUR OR THAT COUNTS WILL NOT EXCEED 100 CFU/G

If you wish to apply the limit of less than 100 cfu/g *L. monocytogenes* to your RTE food then you should have documented evidence available that clearly shows for each RTE food that *L. monocytogenes* will not grow or that the counts would not exceed 100 cfu/g in the RTE food during its shelf life. Evidence may include:

- Information about the particular parameters and characteristics of your food and process that affect the growth of *L. monocytogenes*:
 - pH, water activity, salt content, concentration of preservatives, antibacterial agents, etc;
 - washing, smoking or preserving conditions, packaging, packaging atmosphere and storage conditions, etc; and
 - control measures that ensure product and process parameters are met and verified.
- Historical information, such as that gathered during operator verification;
- Information gathered from the scientific literature and risk assessments (note for this to be valid the parameters must accurately represent your product);
- Challenge studies where the food is inoculated with a cocktail of several strains of the pathogen (or surrogate microorganisms) and then tested at intervals to see how the bacteria respond (increase in numbers or are inactivated);
- Predictive microbiological modelling where the characteristics of your food are entered into a computer model to predict whether growth or inactivation will occur and, to provide a growth or inactivation curve (note for this to be valid the model parameters must accurately represent the product); or
- A combination of these approaches.

Validation documentation should provide objective evidence that shows that:

- the product does not support the growth of *L. monocytogenes*; or
- any growth is limited (level remains less than 100 cfu/g throughout the stated shelf life) under reasonably foreseeable conditions of distribution, storage, retail and use; or
- the process controls ensure that the level remains less than 100cfu/g throughout the stated shelf life.

The validation documentation should include how this evidence was generated, i.e. the conditions under which the process or product parameters have been validated.

Until evidence of validation is available, the limit of *L. monocytogenes* not detected in 25g should continue to be used when determining compliance with Standard 1.6.1.

Information about how a product meets Standard 1.6.1 may be requested by a verifier, auditor or Food Act Officer.

ADDITIONAL INFORMATION

FSANZ has published a document 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>) that provides useful guidance.

MPI has also published a guidance document How to determine the shelf life of food which will also assist (<http://www.foodsafety.govt.nz/elibrary/industry/determine-shelf-life-of-food/index.htm>)