



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

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PURPOSE

This fact sheet provides general advice to processors of certain ready-to-eat (RTE) food (e.g. fresh leafy salads, fresh fruit salads, sprouted seeds and smoked and gravadlax seafood) 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.

AMENDMENT TO THE FOOD STANDARDS CODE

The revised Schedule to the Standard 1.6.1 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.

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. People can become sick if high numbers of the bacteria are eaten.

The amendment removes the specific 100cfu/g *L. monocytogenes* limit for processed finfish. Processed finfish will need to comply with the microbiological limit of *L. monocytogenes* not detected in 25g unless further information can be provided.

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

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 a **listericidal process** which Standard 1.6.1 states 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, under intended conditions of distribution, storage, retail and use, that the food would remain safe and suitable.

WHAT IS THE CONCERN?

Some foods do not receive a validated listericidal process during manufacture. In this case product safety relies on either:

- minimising or reducing contamination during primary production;
- minimising contamination during processing;
- limiting growth by maintaining the cold chain; or
- restricting the shelf life.

Occasional low level contamination of such products by *L. monocytogenes* may be unavoidable but may not present a risk provided that growth cannot occur and there is less than 100 cfu/g within 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.

Where evidence of limited growth **cannot** be provided the default limit of absence of *L. monocytogenes* in 25g will continue to apply to any RTE food that is intended for sale or on sale during the shelf life of the food.

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

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* then you should have documented evidence available that clearly shows for each RTE food that *L. monocytogenes* will not grow or that the counts will not exceed 100 cfu/g in a RTE food during the shelf life may be based upon:

- Information about the particular parameters and characteristics of the 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;
 - 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 the 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.

This information may be requested by a verifier, auditor or Food Act Officer.

DEMONSTRATION OF COMPLIANCE WITH STANDARD 1.6.1

5 samples should be analysed for the purposes of demonstrating compliance:

- For RTE food in which the growth of *L. monocytogenes* will not occur the limit of 100 cfu/g must not be exceeded in any of the samples analysed.
- For RTE foods in which the growth of *L. monocytogenes* can occur, *L. monocytogenes* must not be detected in 25g for any of the samples analysed.

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>)