# Proposal P1017
# Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods

**Major Procedure**

## Summary

NSW continues to support Option 1 to include microbiological criteria in Standard 1.6.1 for *Listeria monocytogenes* on the basis of whether the food is ready-to-eat and can or cannot support its growth.

NSW believes that an approach to allow levels of *L. monocytogenes* up to 100 cfu/g in foods where the organism will not grow provides the correct balance between the protection of public health and achievable limits for the food industry to consistently comply with. The primary benefit to the food industry is that this change will provide clarity to the food industry on the appropriate risk management for foods containing very low levels of *L. monocytogenes*, and minimise the chance of unnecessary product recalls.

NSW is of the view that fundamental to the successful implementation of the revised standard will be how clear the guidance material developed to support the standard will be for both industry and food safety regulators. The guidance material must be informative, but importantly must also provide advice on the level of validation evidence that will be considered acceptable. This is an imperative so that businesses can be proactive in collecting validation data and that food safety regulators are in the position to provide prompt, consistent and transparent interpretation of requirements.

## Specific Issues

### *Guidance document*

The aim of this document needs to be very clear, given that it will be used by both industry and food regulators to implement the proposed changes to the microbiological limit of *L. monocytogenes*. The technical capability of the food industry varies considerably across small, medium and large enterprises, and as such the document needs to be very clear and written in language that can be clearly understood. NSW believes there needs to be improvements in the language used in the document to make it more specific in order to minimise the chance of mis-interpretation.

Examples within the document include:

- “when evidence (validation) may be necessary for its application” (Purpose on pg 3)
- “it may be prudent” (pg 6)

- a statement on page 6 on final use of frozen products does not really provide guidance and just leaves a conclusion hanging. “Final use of the frozen product must be considered, for example, is the product intended to be thawed for retail sale at which stage it would not be a frozen product”. Rather than clarify the point, it is potentially confusing as does this mean that a different limit applies once the product is thawed for sale?

The position of regulators has always been that the onus will be on a food business to demonstrate whether their food products support the growth of *L. monocytogenes* or not. If a business does not have the information (evidence) to show that their product does not support the growth of *L. monocytogenes* then the default position is that the limit of ‘not detected in 25g” will apply. NSW does not believe that this position is clearly reflected by some of the vague wording throughout the guidance document, and it needs more consistency.

Rather than a guidance document which provides generic information, NSW believes that what may be more valuable for the implementation of the standards is a how-to guide on what evidence is needed to place a food product into one category or another, and therefore make a determination of which microbiological limit applies. More clarity is required about the validation evidence, choice of analytical methodology and risk management decision making, especially if the intention of FSANZ is that this guidance document will replace the *Listeria recall guidelines for packaged ready-to-eat foods*. As it is currently written, NSW does not think that the guidance document could effectively replace the recall guidelines for assessing risk management options.

Figure 1 of the guidance document needs to more clearly articulate the type of evidence required to support each decision in the framework (eg a validated listericidal treatment). At the moment there is only one step where it says that evidence is required. A business would also need evidence to show that their product has a pH/water activity below the critical value. Also the framework needs to reflect the choice of methodology (detection / enumeration) once a food is categorised into supporting the growth of *L. monocytogenes* or not.

The document does not deal with how a business can provide evidence on process variability, especially for products that might be near a growth/no growth boundary for *L. monocytogenes* and where small changes in product characteristics may affect whether the organism can grow or not.

It is suggested that, rather than the document “reflecting the views of FSANZ”, that input is gathered from the state regulators who will be enforcing the revised limit, through the Implementation Sub-committee for Food Regulation (ISFR), similar to what has happened with other industry guidelines, for example the National Dairy Industry Pathogen Manual.

***Definition of RTE food***

NSW supports the inclusion of the proposed definition of ready-to-eat in Standard 1.1.1.

***Reference methods of analysis***

NSW supports the inclusion of updated Australian standard methods to reflect the move from AS/NZS 1766 to AS 5013. However, currently the Standards Australia FT-035 Food Microbiology committee is looking to review the equivalence series AS/NZS 4659 and unless advised otherwise by Standards New Zealand, the revised

standards will be rebadged as AS 4659. Any future changes will need to be reflected in the Code.

### *Definition of listericidal treatment*

The proposed definition of listericidal treatment "means a process that can eliminate *Listeria monocytogenes"*. The use of the word "eliminate" in this definition – as opposed to words such as "reduces levels of" or "destroys" - is potentially problematic from a microbiological perspective for companies to provide the necessary validation data for any proposed listericidal treatment.

NSW urges FSANZ to consider other definitions of listericidal that may be more practical to implement, such as:

NZ MPI[1] defines "listericidal process means a process capable of reducing counts of *L. monocytogenes* by a defined amount". Within their guidance NZ MPI says that listericidal process should be validated so that "Listericidal steps should be designed and validated to eliminate or reduce *L. monocytogenes* to acceptable levels in the final product, e.g. a 6D reduction".

The Codex[2] definition of listericidal process is "any appropriate treatment that kills listeria".

The US FDA[3] defines "listericidal control measure means a control measure that will consistently destroy viable cells of *L. monocytogenes* and consistently lead to a finished food that contains less than 0.04 cfu of *L. monocytogenes* per gram (g) of food".

NSW notes that the *Listeria* phage P100 is listed in the Code as a listericidal treatment despite the fact that it may not fully eliminate the organism from foods.

### *Definition of growth*

NSW supports the definition of growth for *L. monocytogenes* that aligns with the Codex approach.

## ENDS

**The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.**

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1 NZ MPI (2013). Guidance for the control of *Listeria monocytogenes* in ready-to-eat foods. Part 1: *Listeria* management and glossary.

2 CAC/GL (2007). Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes in foods*

3 US FDA (2008). Guidance for Industry: Control of *Listeria monocytogenes in refrigerated or frozen ready-to-eat foods: Draft guidance*