Ministry for Primary Industries
Manatū Ahu Matua

10 January 2014

Project Officer Proposal P1017
Food Standards Australia New Zealand
PO Box 10559
The Terrace
WELLINGTON 6036

FS350-118-1017

Dear Sir/Madam

Proposal P1017 – Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods. 2nd call for Submissions

Thank you for the opportunity to comment on this proposal. The Ministry for Primary Industries (MPI) has the following comments to make on the draft Standard and supporting documents 1 and 2 (SD1 and SD2).

GENERAL COMMENTS

MPI strongly supports the revision of the microbiological limits for *L. monocytogenes* based on whether growth of *L. monocytogenes* will or will not occur in a ready-to-eat food. The approach is in line with that taken internationally including by the Codex Alimentarius Commission (Codex), and reflects the increased knowledge of *L. monocytogenes* and the foods of concern. Moving away from specified food categories recognises that two specified products may in fact have very different hazard profiles due to the properties of the food and the processes that have been applied to it.

Further, the proposed change provides food operators with the flexibility to reformulate products or treat the food so that *L. monocytogenes* cannot grow. To take advantage of the microbiological limit of up to 100 cfu/g of *L. monocytogenes,* food operators will need to consider the physical and chemical characteristics of the food throughout its shelf life. The accompanying guide (SD1) provides assistance in this respect; however MPI suggests that some of the detail should be replicated in the Standard itself in order for the Standard to be a standalone document and to ensure that the detail has legal effect. Examples of where further detail is suggested are provided in this submission.

While the proposed Standard as drafted meets the objective of updating the criteria for *L. monocytogenes* limits in ready-to-eat foods from specific named foods to the inclusion of broad horizontal categories, it does

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not fully take into account the science or the intent of the review of the microbiological limits. The proposed draft Standard 1.6.1 may be open to misinterpretation due to the lack of explanation about the food categories to which it applies. Further detail should be provided to remove potential inconsistencies in interpretation and to prevent inappropriate application.

To assist in the development of further detail, MPI proposes that a teleconference is held between FSANZ and the jurisdictions to progress the Standard. The main issue for discussion is that the proposed inclusion of a generic definition for a ready-to-eat food inadvertently captures a wide range of different ready-to-eat products where *L. monocytogenes* is not a known hazard, either due to the nature of the processing that has been applied (and the packaging) or where the food characteristics would ensure rapid inactivation if contamination occurs, or where testing would not be helpful. These foods should be excluded from the scope in Column 1 (Food) of the Schedule and include:

- those foods which have received heat treatment or other processing that is able to eliminate *L. monocytogenes*, and where recontamination is not possible after this treatment (e.g. products heat treated in their final package),
- products where, because of their characteristics, *L. monocytogenes* would not be able to survive including; bread, biscuits and similar products, sugar, honey and confectionery, including cocoa and chocolate products, bottled or packed waters, soft drinks, beer, cider, wine, spirits, fruit wine and similar products,
- fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds,
- live bivalve molluscs

The setting of limits for these foods listed above is not consistent with the Codex *Principles and guidelines for the establishment and application of microbiological criteria related to foods* (CAC/GL 21-1997 revised and updated 2013) as it is contrary to the principles (abridged) of establishing a criterion where appropriate to protect the health of the consumer, and practical, feasible and established only where necessary. It is noted that a similar approach has been adopted by the EU in the setting of criteria for *L. monocytogenes.* Testing of the products listed above for *L. monocytogenes* should be performed only when there has been a known or suspected process control failure or where the effectiveness of the process used during production is unknown. Testing thus would not be part of routine verification of the food safety objective.

MPI also recommends that further guidance should be provided to the regulatory authorities so that the microbiological limits can be consistently implemented and responded to by industry and regulatory authorities when *L. monocytogenes* is detected.

SPECIFIC COMMENTS

Attachment A – Draft variations to the Australia New Zealand Food Standards Code

Schedule

MPI suggests that where '<' or '>' are used in the Schedule that these are replaced with 'less than' or 'greater than' respectively to aid interpretation.

The numbers in square brackets below refer to the proposed draft variation provided in Attachment A.

[1.1] The variation to Standard 1.1.1 includes a new generic definition for a ready-to-eat food. The definition for ready-to-eat foods as drafted is too narrow in scope for application to the entire Food Standards Code (FSC) and too broad for the purposes of 1.6.1 and 1.3.3. The FSC currently includes several different definitions of ready-to-eat food tailored to specific circumstances. This is also the practice followed by Codex, and New Zealand food safety legislation and guidance documents.

From a legal drafting perspective, it appears that the proposed definition of ready-to-eat food is not included with a view to set a standard, but rather to define the types of food to which a standard applies. This tends to indicate that its appropriate placement is within the specific standards rather than being Code-wide. As a result, MPI considers that a generic definition for ready-to-eat foods should not apply Code-wide but should be tailored for the specific Standard, for example to Standards1.6.1, 1.3.3 Processing Aids (the application of the P100 bacteriophage to solid ready-to-eat foods), and Standard 3.2.2. Food Safety Practices and General Requirements.

MPI would like to propose the following 4 options for consideration by FSANZ:

Option 1: MPI's preferred approach is not to include a generic definition for a ready-to-eat food in Standard 1.1.1, but to provide a specific and tailored definition where required for different purposes, e.g. for Standards 1.6.1 and 1.3.3. In these Standards, the definition of a ready-to-eat food can be more specific to apply to those ready-to-eat foods where *L. monocytogenes* has been identified as a hazard of concern. This has the advantage of excluding shelf-stable products, live bivalve molluscs, whole or unprocessed fruits and vegetables and ready-to-eat foods where *L. monocytogenes* is not normally a concern. The drafting intent of the specific definition is as follows:

> "Ready-to-eat food of concern for *Listeria monocytogenes* means any food which is normally consumed in the same state as that in which it is sold and is not subject to any further listericidal treatment."

Additionally -

"For the purpose of this Standard ready-to-eat foods that are excluded are:

- those which have received heat treatment or other processing that is able to eliminate *L. monocytogenes*, and when recontamination is not possible after this treatment (e.g. products heat treated in their final package),
- products that because of their characteristics *L. monocytogenes* would not survive including; bread, biscuits and similar products, sugar, honey and confectionery, including cocoa and chocolate products, bottled or packed waters, soft drinks, beer, cider, wine, spirits, fruit wine and similar products,
- fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds,
- live bivalve molluscs"

Option 2: To provide a revised generic definition for a ready-to-eat food and a specific definition for ready-to-eat foods of concern for *Listeria monocytogenes*

> "Ready to eat food ~~in relation to food~~ means a food that is ordinarily consumed in the same state as that in which it is sold, and — ~~(a)~~ does not require further processing (such as cooking) to eliminate or

reduce the micro-organism of concern to an acceptable level. ~~but may be defrosted, reheated or portioned before consumption; and~~

(b) ~~does not include nuts I the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer~~."

And

"Ready-to-eat food of concern for *Listeria monocytogenes* – means any food which is normally consumed in the same state as that in which it is sold and is not subject to any further listericidal treatment."

With -

"For the purpose of this Standard ready-to-eat foods that are excluded are:

- those which have received heat treatment or other processing that is able to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (e.g. products heat treated in their final package),
- products that because of their characteristics *L. monocytogenes* would not survive including; bread, biscuits and similar products, sugar, honey and confectionery, including cocoa and chocolate products, bottled or packed waters, soft drinks, beer, cider, wine, spirits, fruit wine and similar products,
- fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds,
- live bivalve molluscs"

Option 3: To revise the proposed draft definition for a ready-to-eat food.

"Ready to eat food ~~in relation to food~~ means a food that is ordinarily consumed in the same state as that in which it is sold, and — ~~(a)~~ does not require further processing (such as cooking) to eliminate or reduce the micro-organism of concern to an acceptable level ~~but may be defrosted, reheated or portioned before consumption; and~~

(b) ~~does not include nuts I the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer~~."

Option 4: To not include any definition for a ready-to-eat food in the Food Standards Code.

[2.2] MPI supports the inclusion of a *Purpose* to the Standard section as it establishes the intent of the Standard, and highlights the consequences of what happens if a food does not conform to the limits, i.e. 'Foods that fail to meet these limits may pose a risk to human health and must not be offered for sale.' This addresses the concerns raised by MPI in Proposal P1025 Code Revision.

[2.3] MPI suggests that definitions of 'Growth' of *L. monocytogenes* should be incorporated from SD1, as well as a 'Lot', to aid interpretation.

[2.4] Suggest that the definition for microorganism is revised to read:

"microorganism means a microbiological agent, test or toxin as listed in Column 2 of the Schedule."

[2.5] clause 4 Reference methods of analysis

The Codex document *Principles and guidelines for the establishment and application of microbiological criteria related to foods (*CAC/GL 21-1997 revised and updated 2013*)* states that a microbiological criterion is made up of a number of components including the analytical method and their performance criteria. Standard 1.6.1 provides the Australian Standards 5013 food microbiology series as the reference methods of analysis that must be used to determine conformance, however it is essential that the reference methods are applicable and relevant to both Australia and New Zealand.

MPI's preferred approach is that the reference method of analysis shall be the current ISO method, or any method that has been appropriately validated for the matrix tested as achieving an equivalent or better outcome to the ISO method. As the Australian Standard methods are adapted ISO methods they would therefore be acceptable.

In addition to the reference to AS/NZS 4659 series *Guide to determining the equivalence of food microbiology test methods* MPI suggests that an alternative reference to ISO 16140:2003 *Protocol for the validation of alternative methods* is provided in line with MPI's preferred approach for referencing international methods.

[2.5] clause 5 Microbiological limits in foods

Under (1) MPI proposes that the sentence is rewritten to read:

> "A '**lot' of a** food that is listed in Column 1 of the Schedule in this standard must comply with this Standard, including the microbiological limits set in relation to that food in the Schedule."

[2.5] clause 6 Food not supporting the growth of *Listeria monocytogenes*

MPI would prefer that this section covered food that supports the growth of *L. monocytogenes* as opposed to the foods not supporting the growth. The list can then address the exclusions; i.e. foods with characteristics such that growth will not occur.

Alternatively, it is suggested for consistency that the heading for this clause uses the same wording as in the criteria and the text below i.e. food in which the growth of *Listeria monocytogenes* will not occur

MPI proposes that cfu/g is inserted after $\log_{10}$ to clarify the units of increase. Therefore;

> "(f) it can be validated that the level of *Listeria monocytogenes* will not increase by > 0.5 $\log_{10}$ **cfu/g** over the food's stated shelf life, or"

As currently worded, further explanation is required following the list of inclusions in the Standard or SD1 to articulate why foods are assigned to this category, e.g. the short shelf-life foods and foods that support limited growth. In particular, clauses (f) and (g) require further explanation to prevent them from being misused. MPI suggests that FSANZ clarifies that clause (g) is intended for horticultural produce and cold smoked ready-to-eat products, otherwise it may be unintentionally applied to other products, for example by providing an exception in the Schedule for these categories of food.

[2.5] clause 7 Powdered infant formula products

The text included under this point differs from the text and meaning in the current Code. The proposed text states that the limit for Standard Plate Count (SPC) in infant formula does not apply to powdered infant formula products that contain lactic acid producing microorganisms. In other words, there is no SPC specified for infant formula prior to the addition of the lactic acid producing microorganisms. This is in contrast to the current Code (clause 2 (2) of standard 1.6.1), which states that the SPC limit applies prior to the addition of lactic acid producing microorganisms.

Further to this comment, under 6.2 (item 2) of Attachment B (Draft Explanatory Statement) states there is an explanation of the new clause 7, which appears to be incorrect. It refers to a duplication of limits, when in fact it appears that in the new clause 7, the meaning has changed (by removing the limit for SPC prior to the addition of lactic acid producing microorganisms, in powdered infant formula that contains this addition).

[2.6] SCHEDULE Microbiological Limits in Food

MPI agrees that standard 1.6.1 should continue to apply to food for sale or intended for sale. The Codex document *Principles and guidelines for the establishment and application of microbiological criteria related to foods (*CAC/GL 21-1997 revised and updated 2013*)* states that there should be a specific point in the food chain where the microbiological criterion should apply. *Listeria* is capable of continuing to grow in some chilled ready-to-eat foods throughout the shelf-life; therefore it is important that processors aim for the absence of *L. monocytogenes* in their products at the end of processing. MPI asks whether guidance should be provided to processors and enforcement agencies to state the microbiological limit that applies at the end of manufacture, and also to consider the effect that further handling by wholesale, retail and consumers may have on the product and levels of *L. monocytogenes*?

The Schedule or the Microbiological Limits in Food should clarify whether there are any ready-to-eat foods where the microbiological limits for ready-to-eat foods do not apply, e.g. shelf-stable foods, live bivalve molluscs, alcoholic drinks, vinegar, biscuits, cakes, bread, chocolate and confectionery. By not specifically excluding these foods from the scope of the criteria, they will still be required to be tested to demonstrate that they conform to the limits. Such testing is both unhelpful with regards to reducing the amount of contaminated food in the marketplace and is a waste of resources that could be more usefully deployed.

Vulnerable people
MPI has previously proposed a separate criterion for ready-to-eat products of concern for *L. monocytogenes* that are intended to be consumed by vulnerable population groups, e.g. in residential care homes and hospitals. MPI believes that there is a role for a more stringent microbiological limit to be part of the Schedule, and asks that FSANZ gives further consideration to the inclusion of limit for *L. monocytogenes* in foods intended for consumption by vulnerable populations (n=10, c=0, m= absence in 25g).

Supporting document 1 – Guidance on the application of microbiological criteria for *Listeria monocytogenes* in ready-to-eat food

Page 3 – add that shelf-stable products, e.g. sauces and other products that are hot filled may also not be subjected to testing for *L. monocytogenes.*

Page 4 - Replace 'Pre-packed raw vegetables and salad mixes' with 'fresh-cut raw vegetables and salad mixes'. Although there is the later clarification that whole fruit and vegetables are excluded, it is becoming more common for some whole fruits and vegetables to be sold in consumer-ready packages.

Page 5 – Foods not supporting the growth of *L. monocytogenes*
The list includes those foods where the level of *L. monocytogenes* will not increase by >0.5 log10 cfu/g. Does this mean that growth is characterised by foods where the level of *L. monocytogenes* will increase by ≥ 0.5 log10 cfu/g over the food's stated shelf life?

Second paragraph under the heading 'Stated shelf life' - insert the word 'growth' after 'for when'.

Page 6 – Under the heading:

1. Has the ready-to-eat food received a listericidal treatment? –

   MPI suggests this is amended to also include a consideration of the storage conditions i.e. '….specified shelf life and storage conditions.'

Page 7 - Figure 1
MPI welcomes the inclusion of the first decision box that highlights that testing for some foods is not useful or appropriate. MPI asks that this is included in the schedule of the Standard and is expanded to include live bivalve molluscs.

Page 8 – MPI suggests that the following text, given its importance, is also included at a more prominent place in the guidance document (such as an upfront statement):

> "In the absence of any other information, a limit of 'not detected' in 25g would apply to these RTE foods throughout their shelf life. This is the default criterion should a business not have specific information available about their RTE food (e.g. are unable to validate whether growth of *L. monocytogenes* can occur or not during the stated shelf life)."

Further wording to the effect that Processors and manufacturers should aim for 'absence' at the end of manufacture' irrespective of the limit that applies to their product' should be included within the guidance document SD1.

FURTHER COMMENTS

Following the completion of the FSANZ proposal P1017 Criteria for *L. monocytogenes* – Microbiological Limits for Foods, MPI asks that FSANZ reviews the remaining microbiological limits in the Standard following the establishment of the principles for the development and application of microbiological limits (criteria). One of the key principles should be to adopt the principles established by the Codex document *Principles and guidelines for the establishment and application of microbiological criteria related to foods (*CAC/GL 21-1997 revised and updated 2013*).* The microbiological limits should be periodically reviewed for their continued applicability and relevance to current foods, food production systems, emerging hazards, etc. A number of limits in the current Standard 1.6.1 do not reflect food safety concerns, for example; coliforms, SPC,

coagualse positive staphylococci and (generic) *E. coli* which are related to the function of the food production and processing systems.

A review of the Standard should harmonise the limits and focus on those that are food safety concerns based on scientific evidence. The microbiological limits should be used by food operators in the context of their HACCP-based food safety programmes, and therefore should include the point where any microbiological limit applies.

MPI notes that the separate consultation on Proposal P1022 – Primary Production and Processing Requirements for Raw Milk Products includes a proposal to establish microbiological limits for a single food category 'Raw Milk Products' for *Salmonella* and Staphylococcal enterotoxin. A review of the *E. coli* limit in cheeses will be included as part of a wider review of the role of indicator and index microorganisms in the Standard.

MPI asks that there is a wider review and discussion about the use of indicator and index bacteria outside of the commodity specific standards to ensure that the approach taken is consistent and harmonised throughout the different food industries.

Yours sincerely

[redacted]
Manager Food Science and Risk Assessment