Comments from the Departments of Health and Environment and Primary Industries, and Dairy Food Safety Victoria and PrimeSafe.

Due date of submission: 10 January 2014

The Victorian Departments of Health and Environment and Primary Industries, and Dairy Food Safety Victoria and PrimeSafe welcome the opportunity to provide comments on Proposal P1017 – Criteria for *Listeria monocytogenes* (Lm) – Microbiological Limits for Foods.

The proposed approach

We support the proposed change from prescriptive product based standards for Lm to an approach based on whether a ready to eat (RTE) food can support the growth of Lm.

Our initial response to FSANZ following the first call for public submissions (November 2012) identified the preferred option as option 1, which includes criteria for foods that will support the growth of Lm and those that will not. This represents a major change for all stakeholders and will require appropriate guidelines for successful implementation. The following comments outline some factors that we believe must be considered in adopting option 1.

Guidelines

The proposed approach will apply to all ready to eat foods (as defined) and represents a major change for stakeholders which will require appropriate guidelines for successful implementation. As such, we believe that this guidance should extend beyond the interpretation and application of the definition of RTE foods and the processes and criteria required to establish 'growth' or 'no growth', as detailed in the proposed guidelines (supporting document 1).

The case for review of the existing standard was based on several factors, including:

- the current disconnect between the prescriptive, product based standards for Lm in the Code, the current Lm recall guidelines, and the food safety requirements in Chapters 3 and 4 of the Code that support a preventative through-chain approach to managing food safety risks; and
- a lack of certainty for businesses and enforcement agencies around trigger points for action when Lm is present in foods not currently listed in Standard 1.6.1.

Therefore we believe that the guidelines should be broadened to also:

- explain the role of end product standards for Lm and how they are consistent with all through-chain risk management requirements described in Chapters 3 (Food Safety) and 4 (Primary Production and Processing) of the Code, or the New Zealand equivalents;
- reference existing sector-specific guidance; for example 'National Guidelines – Pathogen Management' (Dairy Industry), and 'Regulatory Guidelines for the Control of Listeria' (Meat industry). The current work of ISFR, led by the NSW Food Authority, is to address pathogen management knowledge and guidance gaps that exist for seafood (including cold-smoked fish) and horticulture. However, the proposed guidelines should also briefly outline the key elements required in **any** industry-specific guidance including the importance of environmental monitoring in-plant;
- reference national Lm recall guidelines;
- clarify that the selection of appropriate Lm testing methods for foods that support growth or those that do not (ie. detection or enumeration, respectively) is critical to the successful implementation of this proposal. When the full review of Standard 1.6.1 is completed, it is anticipated that this information may be

expanded and that the more general, non-pathogen specific, information would move into a more generic guidance document.

- address environmental monitoring. Achieving the Lm criteria proposed in the draft amendment requires food businesses to implement through-chain control measures and these can be verified by process controls and environmental monitoring. The importance of environmental monitoring was recognized by Codex when drafting the microbiological criteria for Lm (on which the proposed Option is based). Hence detailed guidance on environmental monitoring is included in the **Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria Monocytogenes in Foods** (CODEX CAC/GL 61 – 2007). It was included because environmental testing programs verify that a manufacturer has successfully identified and controlled niches and harbourage sites for Lm in a food plant and has verified that sanitation programs have been appropriately designed and implemented to control contamination by Lm, particularly for RTE foods that support the growth of Lm.

By broadening the scope of the guidelines, FSANZ will not overlap with the roles and responsibilities of other agencies or stakeholders but will provide an overview of the through-chain process and how the various elements align.

The draft standard

The definition of ready to eat food

As stated in the initial Victorian submission we support in principle the adoption of the Codex definition for RTE food, that is "any food which is normally eaten in its raw state or any food, handled, processed, mixed, cooked, or otherwise prepared into a form which is normally eaten without further listericidal steps", and the inclusion of this definition in the Standard. However, because of the potential for some foods that could be consumed in their raw state but would ordinarily be subject to further listericidal steps (for example, cheese supplied for pizza toppings), we recommend that the guidelines include advice on the interpretation of the definition of RTE foods.

The proposed P1017 definition includes: (a) does not require further processing (such as cooking), but may be defrosted, reheated or portioned before consumption; and (b) does not include nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer. Victoria suggests that, wherever possible, Codex definitions should be adopted in Australian standards. Therefore it is our view that it is more appropriate and effective for the additions (a) and (b) to be included as notes in the Standard and in the guidance document to make clear the scope of the definition.

Criteria for establishing growth or no growth

The departments considered that, at this stage, the inclusion of criteria for foods that will not support the growth of Lm in the standard as is proposed is important for implementation of the standard by industry and for enforcement. However, it is noted that innovative food processes and evolving research evidence may in future necessitate review and revision of the current ready to eat food parameters, and that at this time it may be more appropriate to include such criteria in the guidance documents. If the criteria are to be included in the standard, it is critical that the science and intent of the criteria are clearly translated into an effective legal instrument. We are concerned that the drafting of clause 6 sits somewhere between a guideline and a standard and lacks the required legal precision. The clarity of Clause 6 will need to be addressed as it will play an important part in enabling imported foods to be adequately assessed against the standard.

Terminology

1. The terms; 'shelf life', 'stated shelf life' and 'refrigerated' are not defined in the proposed Standard or elsewhere in the Code.

Where terms are not defined in the standard, other definitions may be applied. The Macquarie dictionary defines 'shelf life' as; 'the period of time in which a product may remain on the shelf before being purchased and still be marketable', and 'refrigerate' as; 'to make or keep cool'. We question the applicability of these definitions, and suggest that these terms be defined in the Standard.

A definition of "stated shelf life" is found in Supporting document 1 – Guidance on the application of microbiological criteria for Lm, where it is described as:

> 'The period of time, established under intended conditions of distribution, storage, retail and use, that the food would remain safe and suitable".

This definition is in a guideline which has no legal status, and is incomplete in that it does not address 'established by whom' or 'intended by whom'. It may be argued that the wording is ambiguous and prevents the intended application of the standard. That is, as soon as a food was deemed to be unsafe or unsuitable it would, by definition, be outside its stated shelf life regardless of whether or not it was prior to any date marking (Use by date).

There is a difference between 'shelf life', which is the actual time the product remains safe, suitable and marketable, and a business's stated expectation of shelf life which is expressed through date marking. Date marking is generally conservative because of the likelihood that the 'intended conditions of distribution, storage, retail and use' may not be met.

We recommend that FSANZ consider amending:

- Clause 6(d) - to refer to foods which have a refrigerated (not more than 5^{o}C which aligns with Standard 3.2.2) Use by Date of not more than five days from production (intended for sale).
- Clause 6(f) and (g) – to remove the references to 'throughout the food's stated shelf life' and replace them with 'up to the food's stated Use by date'.

The rationale for the use of 'Use by date' in this amendment is that FSANZ's decision tree for determining whether a food should have a Best before or a Use by Date would direct that these foods should have a Use by Date.

2. Further clarification of Clause 6
Clause 6 of the proposed Standard also states:

> 'Food not supporting the growth of *Listeria monocytogenes*
>
> For the purposes of the Schedule, the growth of *Listeria monocytogenes* will not occur in a ready to eat food if'

Subclauses; (d),(f) and (g) technically cover foods that will, or may, support the growth of Lm but under conditions where growth will be limited and should remain at a level of not exceeding 100 cfu/g. For accuracy and clarity we recommend that the wording be amended to (or similar):

> 'Food not supporting the growth of Lm and food to be treated as such
>
> For the purposes of the Schedule to this Standard, the growth of Lm will not occur in a ready to eat food, or the ready to eat food will be treated as if growth of Lm will not occur if'

3. Purpose statement
The 'Purpose' statement in the proposed Standard includes; '…the limits that a lot or consignment of food must comply with when sampled'.

We recommended that the words 'when sampled' are removed. The *Food Act* makes it an offence to sell food that does not comply with any requirement of the Code. This makes it clear that any offence will be committed when the food is for sale or intended for sale. The use of 'when sampled' is redundant and potentially confusing.

We have made similar comments in response to the Code revision proposal, stating the view that the Act provides sufficient clarity on where in the supply chain the Code requirements apply.

4. Clause 3 Sampling of food for microbiological analysis.
A recent event in Victoria highlighted that more clarity could be provided around the requirement that each sample unit (the minimum number of sample units required to be taken is listed in column 3 to the table in standard 1.6.1) *must be of the minimum weight or volume* to enable the analyst to perform all of the tests specified in column 2 for each of the sample units of that food.

This could be achieved via a note in the Standard.

As raised in Victoria's previous submission on this proposal, it is important that laboratories and their clients are made aware of their obligations to conduct the appropriate tests that meet the standard. Given the changes to permit RTE foods to contain LM under defined conditions, guidance material will need to be detailed to ensure that laboratories and their clients understand exactly what tests will be required to meet the standard ie that the food falls within the standard's definition of RTE and that the levels of Lm are not exceeded.

Other matters

FSANZ's call for submissions report refers to the level of Lm as < 100 cfu/g in a number of places, where the Standard itself requires; 'must not exceed 100 cfu/g'. For consistency the latter should be used throughout.

In our initial submission we commented on the inappropriateness of the prescribed sampling plan for assembled mixed foods, and recommended that there be some discretion around sampling plans built into any new Lm standard and that guidance material be provided. These comments do not appear to have been addressed in the proposed standard. We reiterate our previous statement that Clause 3.3 of 1.6.1 provides flexibility in sampling plans for both complaints and food poisoning incidents, and a similar approach should be taken for assembled mixed foods.

We note FSANZ response in relation to advice to vulnerable populations regarding consumption of RTE foods that have a risk of containing LM. Victoria supports action on improving communication to the community on this and is happy to participate in any review of existing strategies.

We look forward to working with FSANZ to address the issues raised above.

Please contact [redacted], Department of Health, if you require any clarification or further information.