Infant Nutrition Council
Industry supporting both Breastfeeding & Infant Formula
AUSTRALIA & NEW ZEALAND

PROPOSAL P1017: CRITERIA FOR *LISTERIA MONNOCYTOGENES* – *MICROBIOLOGICAL LIMITS FOR FOOD*

20 December 2013

OVERVIEW OF THE INC

This submission has been prepared by the Infant Nutrition Council (INC). The INC represents the majority of companies marketing infant formula and companies who manufacture infant formula in Australia and New Zealand.

INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula industry in Australia and New Zealand.

The INC is a responsible body that voluntarily restricts its marketing practices to support government policies for the protection and promotion of breastfeeding. The companies represented by INC are:

Members:

- Abbott Nutrition
- Aspen Nutritionals
- Bayer Australia Ltd
- Fonterra Co-operative Group Ltd
- H. J. Heinz Company Australia Ltd & H. J. Heinz Company NZ Ltd
- Nestlé Australia Ltd & Nestlé New Zealand Limited
- Nutricia Pty Ltd

Associate Members:

- A2 Infant Nutrition Ltd
- Ardagh Group NZ Ltd
- Biolife New Zealand Pty Ltd
- Cambricare New Zealand Ltd
- Dairy Goat Co-operative (NZ) Ltd
- Douglas Nutrition Ltd
- Fresco Nutrition Ltd
- GMP Pharmaceuticals Pty Ltd
- Milk World Natural Dairy

- Murray Goulburn Co-operative Co Ltd (Aust)
- New Image International Ltd
- New Zealand Dairy Products Ltd
- New Zealand Goldmax Health Pty Ltd
- New Zealand New Milk Ltd
- Nutricare Group Ltd
- Silver Fern Branding Ltd
- Sutton Group (NZ)
- Synlait Milk Ltd (NZ)
- Tatura Milk Industries
- Unitech Industries Ltd
- Westland Cooperative Dairy Co Ltd

The INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition for around the first 6 months. It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants that are unable to have the benefit of breast milk.

EXECUTIVE SUMMARY

INC made no submission in the first consultation round of this Proposal for several reasons:

- infant formula is generally not a ready-to-eat product
- infant formula is generally understood to not support the growth of *L.monocytogenes*
- there was no indication in the first consultation round that P1017 might also include general amendments along the lines of those being undertaken by P1025 to improve overall clarity of Standard 1.6.1.

While INC supports the general approach taken in P1017 concerning the setting of limits for *L.monocytogenes*, INC neither expected nor supports the proposed amendments to provisions relating to Infant Formula. The amendment of concern would mandate the "MPN" (Most Probable Number) test for coliforms in infant formula.

The scope of P1017, besides considering limits for *L.monocytogenes,* is described as reviewing unclear elements such as methods of analysis. Had this been confined to updating clause 4, INC would not have submitted. However, mandating a single method of analysis goes beyond a clarification or update. In the absence of any discussion of the rationale for the proposed amendment or its potential impact, INC does not support the proposed amendment to add "MPN" as the method of analysis for 'coliforms' in infant formula products. Some discussion of 'enumeration technology', the comparative merits of other analytical tests and their effectiveness and costs on industry and consumers would have been expected. An impact analysis might have explored current methodologies and the impact of removing the flexibility to take advantage of emerging and rapid test methodologies.

The legal effect of the amendment to add "MPN" the method of analysis for coliforms in infant formula is to create an internal conflict in Standard 1.6.1 between clause 4 which permits certain methods or equivalent methods to be used and the Schedule which effectively mandates a single analytical method. INC considers that validation of an alternate method would not permit its legal use so long as "MPN" was the specified method in the Schedule.

It has been made clear in earlier documents that microbiological limits for infant formula are intended to be considered as a group in the third stage of the review of Standard 1.6.1. At that time, the full range of issues and the close inter-relationships of many of those issues can be dealt with and addressed in full.

INC therefore recommends that there be no changes to the provisions relating to infant formula in Standard 1.6.1 until the limits for infant formula are considered as a group.

COMMENTS ON PROPOSAL P1017

Scope of P1017
The scope of P1017 in the first round of consultation was not described as including a review of elements that are out-dated or unclear nor the presentation of the Schedule.

In this consultation, we are advised that, besides changing the approach to setting limits for *L.monocytogenes* in ready-to-eat products, P1017 has also been prepared to "Review elements of Standard 1.6.1 that are out-dated or unclear such as reference methods of analysis, the purpose of Standard 1.6.1 and the presentation of information within the Schedule to the standard."

In general, these would appear to be laudatory objectives to maintain the currency of the Standard and improve its application and compliance. In this instance, however, nothing has prepared or been signalled to the non-ready-to-eat sectors, that changes have been made that may impact them.

Absence of assessment or discussion of proposed changes unrelated to *L.monocytogenes*
The assessment of the proposed changes unrelated to *L.monocytogenes*, is minimal to non-existent. The introduction provides, in three bullet points, the three areas of amendment unrelated to *L.monocytogenes* as:

- "updating reference methods of analysis
- including analytical units within the Schedule to the Standard
- rewording the "Purpose" to Standard 1.6.1 ..."

The risk assessment is limited to *L.monocytogenes,* as is the entire balance of the consultation document. Nowhere is there a discussion of the rationale for changes made to the Standard that are unrelated to *L.monocytogenes* or the potential impact on industry. This means that even by the standards of a 'minor amendment' the consultation document has failed to provide even the most minimal of explanation. Compare, for example, many of the Omnibus amendments and the related consultation papers and the expectation that a "minor procedure" generally concerns the correction of a typographical errors or minor editorial changes although not limited to them. Some discussion of 'enumeration technology' and the merits of other analytical tests might have been expected.

Any rationale is limited to the Explanatory Memorandum which, in the case of the amendment to the infant formula entry for coliforms and presumably to the other products similarly amended, the explanation is "MPN is included in relation to limits based on this methodology." This provides no indication of rationale or process for selecting the MPN method and is insufficient to justify amendment.

Infant formula not generally a ready-to-eat product
INC would not have expected to make a submission on *L.monocytogenes* in ready-to-eat products because infant formula is not generally a ready-to-eat product. The thoroughness and tenacity of an INC member's examination of the consultation document identified the issue which otherwise would have gone undetected.

Infant formula is generally known to not support the growth of *L.monocytogenes*
L.monocytogenes is not generally associated with infant formula as it is generally known not to support its growth. It is not mentioned, for example, in WHO/FAO microbiological risk

assessment series volumes 4 or 5[1]. Again, for this reason, INC would not have expected to make a submission on *L.monocytogenes* in ready-to-eat products.

Legal effect of amendment creates internal conflict in Standard
Standard 1.6.1, in clause 4, provides that methods of analysis in several standards may apply. By adding "MPN" as the method for several entries in the Schedule to Standard 1.6.1, including for coliforms in infant formula, the effect is to mandate the MPN method over all others thus creating a conflict with the approach reflected in clause 4. It also effectively removes choice and removes the prospect of utilising highly effective methods that might emerge over time and be acceptable under clause 4 in the future.

Changes to limits for Infant Formula to be considered in Stage 3 of P1017
It has been made clear in earlier documents that microbiological limits for infant formula are intended to be considered as a group in the third stage of the review of Standard 1.6.1. At that time, the full range of issues and the close inter-relationships of many of those issues can be dealt with and addressed in full. This might be expected to include an assessment of analytical tests and their comparative effectiveness and potential equivalence. This has not been attempted in the current Proposal.

INC therefore recommends that there be no changes to the provisions relating to infant formula in Standard 1.6.1 until the limits for infant formula are considered as a group. There are a number of issues that have overlap in the area and rather than deal with them in a piecemeal fashion, the expectation was that they would be considered as a package. Any mandating of MPN as a method should be deferred and considered as part of this broader work.

A full consideration of the limits for infant formula in Standard 1.6.1 would also be expected to assess the impact of change on the industry, consumers and government. No such assessment of the change to the entry for 'coliforms' for infant formula has been undertaken. For example, the impact of mandating "MPN" for coliforms in infant formula potentially also has significant cost and innovation effects (such as restricting innovation in the industry in terms of testing time turnaround and impact on product for lengthier "test and release", use of as effective, more rapid tests). As noted above, no comparative effectiveness nor equivalence assessments have been made.

Conclusion
In summary, INC does not support the proposed amendment to the entry for coliforms for infant formula products. There has been no indication to industries of non-ready-to-eat products that other changes affecting them were being made, there is no rationale or discussion of the non-*L. Monocytogenes* related amendments, there is no consideration of the impact of these changes and no indication that a change mandating analytical methods where this had not existed before was part of P1017 until now.

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[1] Risk assessment of *Listeria monocytogene*s in ready-to-eat foods: interpretative summary (Microbiological risk assessment series ; no. 4. WHO, FAO 2004)
Risk assessment of *Listeria monocytogene*s in ready-to-eat foods: technical report (Microbiological risk assessment series ; no. 5. WHO, FAO 2004)