Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

20 November 2015

Food Standards Australia New Zealand
PO Box 7189
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Email: submissions@foodstandards.gov.au

Dear Food Standards Australia New Zealand

The Infant Nutrition Council (INC) appreciates the opportunity to make a submission on ***Proposal P1039 Microbiological Criteria for Infant Formula***

INC is the association for the infant formula industry in Australia and New Zealand and represents manufacturers, marketers and brand owners who between them are responsible for more than 95% of the volume of infant formula manufactured, sold and exported 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 Austrlia
- Fonterra Co-operative Group Ltd
- H. J. Heinz Company Australia Ltd & H. J. Heinz Company NZ Ltd
- Nestlé Australia Ltd & Nestlé New Zealand Limited
- Danone Nutricia Pty Ltd
- Synlait Ltd

Associate Members:

- A2 Infant Nutrition Ltd
- Australian Dairy Park Pty Ltd
- Bayer Ltd
- Bodco Dairy Ltd
- Burra Foods Pty Ltd
- Cambricare New Zealand Ltd
- Cargill Australia Pty Ltd
- Dairy Goat Co-operative Ltd
- Fresco Nutrition Ltd
- GMP Dairy Ltd
- GrainCorp LtdJamestrong Packaging Pty Ltd
- Murray Goulburn Co-operative Co Ltd
- Peerless Foods Pty Ltd
- New Image Group Pty Ltd
- New Zealand New Milk Ltd
- Nuchev Food Pty Ltd
- Tatura Milk Industries Pty Ltd
- The Infant Food Co. Ltd
- Unitech Industries Ltd
- Westland Co-operative Dairy Company Ltd
- Yashili Dairy New Zealand Pty Ltd

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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.

Yours sincerely

Jan Carey
Chief Executive

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INC Submission on Call for Submissions – Proposal P1039 – Microbiological Criteria for Infant Formula

20 November 2015

SUMMARY

FSANZ has prepared a draft variation to the Code to reflect an assessment and update of the microbiological limits in the current *Australia New Zealand Food Standards Code* (the Food Standards Code) and in associated guidelines, both of which were developed before 2000. The draft variation, which renames the Standard to better indicate its scope (Standard 1.6.1 Food Safety Microbiological Criteria), reflects the evolution over the past 15-20 years of a preventative through-chain approach to food safety. INC concurs with the overall approach taken by FSANZ in its review.

INC particularly supports the efforts that have been undertaken to harmonise as far as possible with international standards and with Codex Alimentarius and with the creation of two distinct categories of products to which microbiological limits are now applied: powdered infant formula and follow-on formula. The categorisation not only aligns with Codex and the EU, but also with epidemiological evidence and risk profiling in relation to pathogens in particular, which differ between products targeted for consumption by the two age groups.

INC agrees with the draft variation that replaces the existing microbiological limits for: 1) powdered infant formula with food safety criteria for *Salmonella* and *Cronobacter*; and 2) powdered follow-on formula with food safety criteria for *Salmonella*. INC recognises that, in the rare cases when present, *Salmonella* and *Cronobacter* are severe hazards for infants and supports stringent sampling plans for these pathogens in the Standard to provide an appropriate level of assurance that, if tested, a contaminated batch of powdered formula will be detected.

International experts consider that low levels (<100 cfu/g) of *B. cereus* and *S. aureus* do not represent a direct threat to the health of infants and INC therefore agrees that microbiological limits for *B. cereus* and *S. aureus* are not necessary.

INC agrees that only food safety microbiological criteria be included in the Food Standards Code and supports the removal of process hygiene criteria from the Standard to the guidance document, *Compendium of Microbiological Criteria for Food*. INC recognises that testing of infant formula products, both end product and during processing, for mesophilic aerobic bacteria (MAB) and Enterobacteriaceae (replacing coliforms), are useful to manufacturers to assess the effectiveness their hygiene programmes and that these should not be used as regulatory limits.

Introduction

FSANZ has prepared a draft variation to the Code to reflect an assessment and update of the microbiological limits in the current *Australia New Zealand Food Standards Code* (the Food Standards Code) and in associated guidelines, both of which were developed before 2000. Since then, as FSANZ notes, a preventative through-chain approach to food safety has evolved and work has progressed internationally on pathogen management in the food chain, including the management of 'emerging' pathogens. The variation FSANZ proposes reflects this development.

Comment

INC concurs with the overall approach taken by FSANZ in its review and with the renaming of the Standard to better reflect its scope (Standard 1.6.1 Food Safety Microbiological Criteria).

INC recognises that the current infant formula limits in Schedule 27 do not reflect recent scientific knowledge and approaches to food safety (i.e. they are not fit for purpose) because the limits are:

- out of step with more recent international risk assessment work and microbiological criteria developed by Codex for powdered infant formula for the pathogens *Cronobacter* species and *Salmonella*
- included for indicator tests that are not appropriate as pass/fail criteria for a lot of food
- included for pathogens which do not represent a direct threat to the health of infants.

INC supports the efforts that have been undertaken to harmonise as far as appropriate with international standards and with Codex Alimentarius in particular. Such harmonisation assists in reducing the complexity of microbiological environmental and release plans especially for those manufacturers that supply infant formula products to many markets globally.

Categorisation

In its submission to FSANZ on these issues in 2012, INC favoured the creation of two distinct categories of products to which microbiological limits were applied – infant formula and follow-on formula. We suggested that this would not only align with Codex and the EU, but also with epidemiological evidence and risk profiling in relation to pathogens in particular, which differ between infant formula and follow-on formula products. INC is therefore pleased to see a separation of the criteria in the draft variation between the powdered infant formula and powdered follow-on formula.

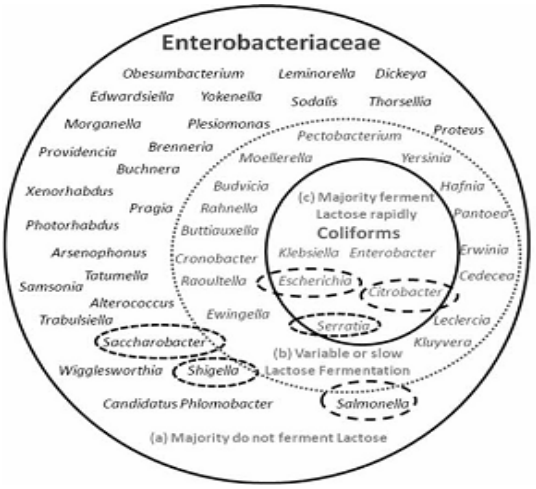
Differentiation between Process Hygiene vs Food Safety criteria and lot testing

INC has consistently favoured a division between food safety criteria (pathogen testing) and process hygiene indicators**.** Such a division of the sampling plan into pathogen testing for food safety and testing for hygiene indicators in order to verify hygiene programmes, harmonises with the approach used in Codex.

INC agrees with the draft variation that replaces the existing microbiological limits for: 1) powdered infant formula with food safety criteria for *Salmonella* and *Cronobacter*; and 2) powdered follow-on formula with food safety criteria for Salmonella. International experts consider that low levels (<100 cfu/g) of *B. cereus* and *S. aureus* do not represent a direct threat to the health of infants. There is, nonetheless, still a need to eliminate products with high levels of *B. cereus* and *S. aureus*, but since high levels of these bacteria will lead to total plate counts out of specification, INC - agrees that microbiological limits for *B. cereus* and *S. aureus* are not necessary and agrees with the removal of limits for these microorganisms.

In relation to process hygiene criteria, INC agrees that testing of infant formula products, both end product and during processing, for mesophilic aerobic bacteria (MAB) and Enterobacteriaceae, are useful to the manufacturer to assess the effectiveness their hygiene programmes and that these should not be used as regulatory limits. This is consistent with developments in microbiological food safety management which has moved from a reactive approach based on inspection and compliance with end product testing to a preventative approach where control measures are implemented by industry throughout the food chain.

INC therefore supports the inclusion of process hygiene criteria for MAB and Enterobacteriaceae in powdered infant formula in a guidance document that is intended to be available on the FSANZ website (the *Compendium of Microbiological Criteria for Food*). We are particularly pleased to see Enterobacteriaceae replace coliforms as the criteria on the basis that, as the diagram shows, Enterobacteriaceae have a broader scope which is inclusive of coliforms.



(Source ILSI, 2011)

Sampling plans

INC recognises that, in the rare cases when present, *Salmonella* and *Cronobacter* are severe hazards for infants. As such, INC supports stringent sampling plans for these pathogens in powdered infant formula to provide an appropriate level of assurance that, if tested, a contaminated batch of powdered infant formula would be detected.

We note that FSANZ presents the example of a case 15 sampling plan (where n=60 and c=0) which provides a 95% probability that a *Salmonella* contaminated lot will be detected if the mean concentration of the pathogen is at least 1.9 cfu per 1000g (1 cfu in 526g). We also note that FSANZ proposes a case 14 sampling plan for *Cronobacter*, (where n=30 and c=0). In this situation, case 14 provides a 95% probability that a mean concentration of *Cronobacter* of 1 cfu in 340g will be detected. INC supports both these sampling plan proposals.

The Codex *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66 – 2008) provides guidance on the hygienic manufacture of powdered infant formula and on the hygienic preparation, handling and use of

reconstituted formula products. The sampling plans proposed by FSANZ for regulatory application for *Salmonella* and *Cronobacter* are consistent with the Codex guideline.

Sampling plans for process hygiene criteria for MAB and Enterobacteriaceae verify that the hygiene measures in place within a manufacturing facility are working as intended. As FSANZ notes (in SD2 Process hygiene criteria in powdered infant formula products – Proposal P1039 Microbiological Criteria for Infant Formula), failure to consistently meet criteria for Enterobacteriacea may be a trigger to examine environmental and process hygiene controls and to evaluate product safety through increased sampling of final product for *Cronobacter* and *Salmonella.*

Conclusion

As noted at the outset, INC is supportive of stringent sampling plans in regulation for *Salmonella* and *Cronobacter* on the basis that, in the rare cases when present, these pathogens are severe hazards for infants. The separation of plans for powdered infant formula and powdered follow-on formula recognises that the epidemiological evidence and risk profiling in relation to pathogens in particular, differ between these products.

INC supports the provision of a *Compendium of Microbiological Criteria for Food* containing process hygiene indicators and associated sampling plans for MAB and Enterobacteriaceae so that manufacturers might verify that the hygiene measures in place within a manufacturing facility are working as intended.