Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

2 March 2015

The Infant Nutrition Council (INC) appreciates the opportunity to make a submission on ***RESPONSE TO CALL FOR SUBMISSIONS – FSANZ CONSULTATION PAPER ON COMPLETING THE REVIEW OF MICROBIOLOGICAL CRITERIA***

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 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

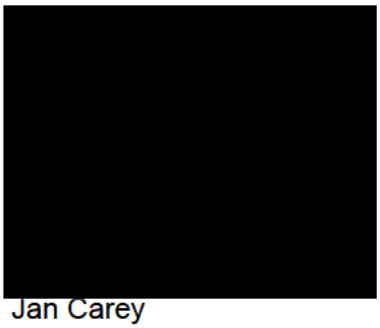
Associate Members:

- A2 Infant Nutrition Ltd
- Ardagh Group NZ Ltd
- Australian Dairy Park
- Bayer Ltd
- Best Health Products NZ
- Biolife New Zealand Ltd
- Burra Foods
- Cambricare New Zealand Ltd
- Cargill Australia
- Dairy Goat Co-operative Ltd
- Fresco Nutrition Ltd
- GMP Dairy Ltd

- GrainCorp Ltd
- Murray Goulburn Co-operative Co Ltd
- Peerless Foods
- New Image Group
- New Zealand GoldMax Health Limited
- New Zealand New Milk Ltd
- Tatura Milk Industries
- The Infant Food Co.
- Unitech Industries Ltd
- Westland Co-operative Dairy Company Limited
- Yashili Dairy New Zealand

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

Infant Nutrition Council
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RESPONSE TO CALL FOR SUBMISSIONS – FSANZ CONSULTATION PAPER ON COMPLETING THE REVIEW OF MICROBIOLOGICAL CRITERIA

The initial FSANZ work in this area focussed on the review of microbiological limits for *Listeria monocytogenes* in ready-to-eat foods. The current *Call for Submissions* is the start of a broader review of Standard 1.6.1 that is to consider the role and purpose of microbiological criteria.

Executive Summary of INC position

Infant formula product manufacturers undertake a range of microbiological testing in order to meet internal food safety and process controls, regulatory requirements, market requirements and customer requirements. As a result there can be overlap, duplication and redundancy within the overall testing regime in many manufacturing operations. The challenge is to establish an efficient and effective testing regime that ensures all needs are met. The greatest difficulty for INC members is meeting the differing testing requirements of regulators, markets and customers.

INC favours the flexibility to use any of a range of internationally recognised test methods appropriate to the product/requirement matrix and does not support the prescription of specific methods for particular products in regulation. INC does not support use of Australian or New Zealand [Micro Methodology] Standards and considers that in a global market, internationally recognised standards are more acceptable.

INC supports differentiation of food safety requirements and process hygiene requirements (monitoring). The two criteria perform very different purposes for both the manufacturer and regulator. The CODEX hygiene criteria are intended to be used by the manufacturer to assess the effectiveness of the manufacturer's hygiene programs. They are not intended to be used as a regulatory measure by the competent authority. For this reason, while INC supports separation of the food safety and process hygiene criteria, INC does not support the inclusion in Standard 1.6.1 of process hygiene criteria. Ideally, process hygiene criteria should be contained in food processing guidelines to provide flexibility for the manufacturer to select the criteria that best satisfy the multiple needs of the requirements to be met.

INC does not support regulation requiring a specified and 'prescribed' corrective action on the basis that this removes other possible solutions that could better meet the particular situation or address identified issues.

INC supports the consideration of infant formula products first in this broader review of microbiological criteria on the basis that the target consumer group is one of the most vulnerable groups in the population. INC suggests it would be more helpful to prioritise

consideration of dairy foods next to or concurrently with infant formula products as alignment and consistency of approach with similar products is vital.

In relation to resources to assist in the application of microbiological criteria, INC is aware of the several guidelines (international and national) and internationally recognised standards (test methodologies) that are available. INC would also be prepared to nominate industry experts for an expert advisory group to assist with the review of criteria for infant formula products.

Detailed Comments

1. **What microbiological testing is currently undertaken by industry and government and why**

Those INC member companies submitting on this review are expected to set out in general terms the microbiological testing that is undertaken in industry. Suffice to say this comprises a range of such testing in order to meet internal food safety and process controls, market requirements, regulatory requirements customer requirements. As a result there is overlap, duplication and redundancy within the overall testing regime in any manufacturing operation. The challenge is rationalisation to ensure all needs are met through the most efficient, effective and streamlined testing regime.

2. **How existing microbiological limits are used and any difficulties in their application**

The existing microbiological limits in Standard 1.6.1 for infant formula are food safety limits for end product. This is consistent with the purpose of the Standard: “This Standard specifies the microbiological food safety criteria which determine the acceptability of a lot or consignment of food for sale or intended for sale.”

The greatest difficulty for INC members is meeting the differing testing requirements of regulators, markets and customers. This is exacerbated when a particular test method is locked into regulation since this excludes the prospect of some tests satisfying a range of test requirements.

INC favours the provision that permits any of a range of internationally recognised test methods appropriate to the product/requirement matrix. Specific methods for particular products could be described in guidance. INC does not support use of Australian or New Zealand Standards and considers that in a global market, internationally recognised standards are more appropriate.

Another difficulty with the application of the limits in Standard 1.6.1 is inconsistency in classification of products. This is particularly the case with dairy products of which

"powdered infant formula products" is one category. Other products are omitted entirely. A systematic approach to classifying types of products for the purpose of end product testing would improve the standard.

3. **Comment on the proposed approach to include food safety criteria and process hygiene criteria in the Code noting that each will have different corrective actions (i.e. response to not conforming to the criteria)**

a) Proposed approach to include food safety criteria and process hygiene criteria

INC **supports** differentiation of food safety requirements and process hygiene requirements (monitoring). The two criteria perform very different purposes for the manufacturer and regulator.

Pathogen testing for food safety requirements are a direct indicator of any potential presence of pathogens in the product. Testing for hygiene indicator purposes is undertaken in order to verify hygiene programs applied by the manufacturer. This is consistent with the approach used in some CODEX Codes of Hygienic Practice. The hygiene criteria are intended to be used by the manufacturer to assess the effectiveness of their hygiene programs.

Microbiological requirements for food safety, using Infant formula as an example, would include absence for pathogens such as *Salmonella spp.* and *Cronobacter* species for starter infant formula, and *Salmonella spp.* for follow-on infant formula.

As stated in CODEX (CAC/RCP 66 – 2008 *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children*), the proposed criteria applied for the sampling plan should also allow flexibility by the manufacturer to determine, based on an internal risk assessment, a demonstration of equivalence to obtain the same outcome.

CODEX (2008) states: "*The criteria above are applied with the underlying assumption that the history of the lot is unknown, and the criteria are being used on a lot-by-lot basis. In those instances where the history of the product is known (e.g., the product is produced under a fully documented HACCP system), alternate sampling criteria involving between-lot process control testing may be feasible (FAO/WHO, 2006)*."

For hygiene requirements with respect to mesophilic aerobic bacteria (MAB) and Enterobacteriaceae, the CODEX hygiene criteria are intended to be used by the manufacturer to assess the effectiveness of their hygiene programs. They are not intended to be used as a regulatory measure by the competent authority. This is confirmed by CODEX stating: "*The following additional* [MAB and EB] *microbiological criteria are intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs, and not by the competent authority. As such these criteria are not intended to be*

used for assessing the safety of a specific lot of product, but instead are intended to be used for verification of the hygiene programs".

For this reason, while INC supports separation of the food safety and process hygiene criteria, INC does not support the inclusion in Standard 1.6.1 of process hygiene criteria. Ideally, process hygiene criteria should be contained in guidelines to provide flexibility for the manufacturer to select the criteria that best satisfy the multiple needs of the requirements to be met.

b) Corrective actions with Failure of Process Hygiene Criteria

INC does not support regulation requiring a specified and 'prescribed' corrective action.

The example provided in the Consultation paper for infant formula is described as "Actions when limits are not met: failure to meet the above [process hygiene] criteria should result in investigation to determine and correct the root cause of the failure. Continued failures should be accompanied by increased sampling of the product for *E. sakazakii* and *Salmonella*."

In the example, increased pathogen testing for *E. sakazakii* and *Salmonella* is prescribed after repeated failure of hygiene criteria. INC does not consider testing to be a corrective action but rather an investigative measure supporting (the corrective action. INC does not support mixing the requirements for hygiene indicators with the requirements for end products. Finished product requirements are clearly defined, and should not be subject to interpretation.

INC does not support the inclusion in regulation of the "obligation of means" (i.e. prescribed corrective actions) on the basis that this removes other possible solutions that could better meet the particular situation or address identified issues.

INC would support a general requirement (not prescriptive) for increased monitoring of the relevant processing environment and/or production lines, using the most appropriate microbial indicators, in the case of repeated failure of hygiene indicators.

4. **FSANZ seeks input for prioritising the work. Information that may assist includes:**

   a) **whether the proposed order is appropriate**

   b) **issues related to specific commodities/commodity groups that should be considered under this review and the rationale**

   c) **resources available to assist in the application of microbiological criteria.**

a) Whether the proposed order is appropriate

The order proposed by FSANZ is: infant formula products, seafood, dairy foods, meat and poultry products, low moisture foods, packaged water and 'other'.

INC supports the consideration of infant formula products first on the basis that the target consumer group is one of the most vulnerable groups in the population. INC suggests it would be more helpful to prioritise consideration of dairy foods next or concurrently as alignment and consistency of approach with similar products is vital.

b) Issues related to specific commodities/commodity groups that should be considered under this review and the rationale

As noted in the foregoing, there are classification issues that need addressing particularly in the dairy area.

c) Resources available to assist in the application of microbiological criteria

INC is aware of the several guidelines (international and national) and internationally recognised standards (test methodologies) that are available to assist in the application of microbiological criteria. INC would also be prepared to nominate industry experts for an expert advisory group to assist with the review of criteria for infant formula products.