Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

INC SUBMISSION ON PROPOSED AMENDMENTS TO THE *FSANZ APPLICATION HANDBOOK* RELATING TO INFANT FORMULA PRODUCTS

20 December 2012

INTRODUCTION

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 Infant Nutrition Council is a responsible body that voluntarily restricts its marketing practices to support government policies for the protection and promotion of breastfeeding.

Members:

- Abbott Nutrition;
- Bayer 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; and
- Pfizer Nutrition.

Associate Members:

- Biolife New Zealand Pty Ltd;
- Dairy Goat Co-operative (NZ) Ltd;
- Murray Goulburn Co-operative Co Ltd (Aust);
- Sutton Group (NZ);
- Synlait Milk Ltd (NZ);
- Westland Milk Products (NZ).

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 who do not receive breast milk.

We welcome the opportunity to provide written comment to Food Standards Australia New Zealand (FSANZ) in response to the *Call for Submissions – Draft Explanatory Statement: Amendments to the FSANZ Application Handbook.*

EXECUTIVE SUMMARY

INC recognises the need for the Food Standards Australia New Zealand (FSANZ) *Application Handbook* to keep abreast of policy and legal developments within the food regulation system. INC therefore supports amendment where appropriate for this purpose.

However, in relation to the amendments proposed relating to infant formula product applications, INC does not agree that the proposed amendments to Part 3 are of a low or negligible impact nor that the amendments generally will not add any additional requirements to potential applicants. This statement is made at the outset in the *Call for Submissions* document. The INC considers these statements underestimate the significance of impact that the proposed amendments will have on applications for amendment to the Standards related to Infant Formula Products.

The proposed amendments relating to infant formula products have been preceded by two other related and key developments:

- the issue in May 2011 of *Guidelines on the Regulation of Infant Formula Products* (the Policy Guidelines) by the Legislative and Governance Forum on Food Regulation and
- the recent consultation on the *Review of Infant Formula Regulation* (the Review) by FSANZ September-November 2012.

The latter development has resulted in the amendments to the *Application Handbook* appearing as pre-emptive of possible amendments to Standard 2.9.1 since they go beyond the current legislative framework for infant formula products. This has created confusion especially as the Policy Guidelines suggest a fundamental change in the approach to dealing with infant formula products in the Australia New Zealand Food Standards Code in the future that has yet to be translated into legislative requirements. The Review of Standard 2.9.1 is essential in order to determine the extent and appropriateness of change necessary, having regard to the Policy Guidelines.

INC recognises that implementing the requirement to "have regard to" guidelines that suggest fundamental changes might be needed to the law, creates a dilemma as to the extent of change possible and appropriate in the *Application Handbook*. INC appreciates that, once issued, FSANZ is required to "have regard to" guidelines. Our concern is that "have regard to" has been reflected in the *Application Handbook* as mandatory requirements that go beyond current regulatory requirements and potentially to the exclusion of other matters that FSANZ is required to also "have regard to". By mandating requirements in the *Application Handbook*, no applications can proceed without those requirements being met whether in law or not. This creates confusion, uncertainty and 'quasi-law'.

There is also confusion as to whether the provisions of section 3.6.2 on infant formula products will apply to non-nutritive substances that might be added to infant formula such as additives, processing aids and ingredients which must meet separate provisions in the *Application Handbook*. Requiring the provisions of both 3.6.2 and other sections of the *Application Handbook* specific to types of substances to apply concurrently creates conflicts and inconsistencies. Most importantly, however, it could severely limit the manufacture and import of infant formulas in Australia and New Zealand in the future including those for the most vulnerable infants with conditions requiring special dietary products simply because infant formula products would not be able to comply with such a restrictive regime.

Mandating clinical studies for every application associated with infant formula products will have a major impact on infant formula in the future. Clinical studies will not always be

appropriate nor available for non-nutritive substances. For example, and depending on the substance, pre-market assessment should not require a clinical study for ingredients added to play a technological role such as additives and processing aids. INC considers that it is more appropriate to require a review of the best available, relevant, scientific evidence, including international reviews/assessments. The American Academy of Pediatrics suggests that clinical studies are needed in some circumstances only in order to supplement laboratory studies. In terms of availability, while regulators might want clinical studies for all changes to composition, ethics committees are, correctly, very sparing of interventions involving infants and such studies will not always be available. Some flexibility must be built into the *Application Handbook* to accommodate such situations.

The proposed requirements include reference to mature breast milk from Australia and New Zealand mother. There is very little information available on the composition of breast milk in Australia or New Zealand., In addition, the composition of breast milk changes rapidly and frequently, depending on the infants' needs. INC suggests that flexibility is needed to address the absence of data on the composition of breast milk in Australia or New Zealand as well as the variability of breast milk.

Finally, the terminology used in the proposed new section 3.6.2 in the *Application Handbook* is confusing. Terms that would benefit from further description and the inclusion of examples is identified in the details below. Descriptions along the lines of the Note to section 3.5.2 B1 in the *Application Handbook* would be very helpful.

COMMENTS

General

This submission is limited to comments on those amendments of the *Application Handbook* focussed on Infant Formula Products, that is "Proposed Amendments to Part 3 (Mandatory Requirements) *6.1 Infant formula products …*". While other amendments may impact on applications related to infant formula products, the core changes are proposed in the new section on infant formula products.

Context

The proposed amendments to the *Application Handbook* have been preceded by two other key developments relating to infant formula: the issue in May 2011 of *Guidelines on the Regulation of Infant Formula Products* (the Policy Guidelines) by the Legislative and Governance Forum on Food Regulation and the recent consultation on the *Review of Infant Formula Regulation* (the Review) by FSANZ September-November 2012.

Overarching Comment

The INC has found the timing of the amendments to the *Application Handbook* frustrating and somewhat confusing, coming as it does when initial consultations on the Review have recently closed but over a year and a half since the Policy Guidelines were issued to FSANZ. The reason for this confusion is that the Policy Guidelines suggest a fundamental change in the approach to dealing with infant formula products in the Australia New Zealand Food Standards Code in the future that has yet to be translated into legislative requirements. The Review of Standard 2.9.1 is therefore essential in order to determine the extent and appropriateness of change necessary, having regard to the Policy Guidelines. So on the one hand, the proposed amendments to the *Application Handbook* might be considered pre-emptive of the outcome of the Review of Standard 2.9.1. On the other hand, if as has been suggested, the amendments are to satisfy FSANZ's obligations to "have regard to" the Policy Guidelines, the proposed amendments are much delayed given the Policy Guidelines were issued some time ago. In either case the amendments must not go beyond the current regulatory requirements until such time as Standard 2.9.1 is amended.

In addition, implementing the requirement to "have regard to" guidelines that suggest that fundamental changes might be needed to the law, creates a dilemma as to the extent of change possible in the *Application Handbook*. As noted above, INC appreciates that, once issued, FSANZ is required to "have regard to" guidelines. The concern is that "have regard to" has been reflected in the *Application Handbook* as mandatory requirements potentially to the exclusion of other matters that FSANZ is required to also "have regard to". It is also difficult to reconcile the requirements in the *Handbook* with the legislative requirements when there is a disjunct of some significance.

Section 18 of the FSANZ Act '*Objectives of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures***'** sets out the matters that FSANZ is required to "have regard to" is as follows:

> "18(2) In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:
> (a) the need for standards to be based on risk analysis using the best available scientific evidence;
> (b) the promotion of consistency between domestic and international food standards;
> (c) the desirability of an efficient and internationally competitive food industry;
> (d) the promotion of fair trading in food;

(e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority."

Section 18(6) then states:

"18(6) A policy guideline formulated by the Council for the purposes of paragraph (2)(e) is not a legislative instrument."

However, the proposed amendments to the *Application Handbook* appear to have had regard only to the Policy Guidelines to the exclusion of other matters and to present these as requirements as though they have the force of law. By mandating requirements in the *Application Handbook*, no applications can proceed without those requirements being met whether in law or not. This creates the confusion and the uncertainty and 'quasi-law'.

It is this situation: the considerable disjunct between the Policy Guidelines and the current provisions of Standard 2.9.1 and the attempt by the *Application Handbook* to bridge that gap, that has created confusion and uncertainty for industry.

Specific comments

The Draft Explanatory Statement (the Statement) states at the outset, that "The proposed amendments to Part 3 are of a low or negligible impact."[1] and further that "The amendments generally do not add any additional requirements to potential applicants"[2]. The INC considers these statements underestimate the significance of impact that the proposed amendments will have on applications for amendment to the Standards related to Infant Formula Products. This is alluded to a couple of paragraphs later in the description of the proposed amendments to Infant Formula Product applications: that they will, in future require "information on breast milk composition, as well as evidence of physiological equivalence from consumption of the substance in infant formula with that of breast milk and evidence of potential beneficial health outcome." These are all substantial and complex requirements.

The following specific comments follow the order and headings of the Draft Explanatory Statement and of the proposed amendments.

Standards Related to the Composition and Labelling of Food Products
3.6.2 Special Purpose Foods – Infant Formula Products

The opening sentence is the same for any specific section of the *Application Handbook*, that an application is required to vary the requirements in the Standard 2.9.1. The next sentence states that this "includes addition of a food additive, processing aid, novel food or novel substance or nutritive substance to infant formula products."[3] This is confusing as some substances, under current arrangements, are automatically permitted to be added to infant formula products once they are approved for the general food supply under the Food Standards Code. Since there is a review of Standard 2.9.1 underway and the prospect of Standard 2.9.1 being amended, the sentence that reads "…includes addition of a food additive, processing aid, novel food or novel substance or nutritive substance to infant formula products" proposed for the *Application Handbook* may well be applicable after Standard 2.9.1 is amended. The sentence could otherwise be interpreted broadly to mean that any substance added to infant formula, whether in Standard 2.9.1 or not, must meet the application requirements of section 3.6.2 or it could be interpreted more narrowly to mean

1 p3 *Call for Submissions – Draft Explanatory Statement: Amendments to the FSANZ Application Handbook*, FSANZ 8 November 2012
2 p3 Ibid
3 p25 Ibid

that only those aspects actually in Standard 2.9.1 must meet the application requirements of section 3.6.2.

The broader interpretation is particularly problematic because many processing aids (and some additives) will not be identified in breast milk making application for change impossible.

The broader interpretation appears confirmed by the third paragraph in section 3.6.2 which states that "There may also be additional information requirements in other parts of this *Application Handbook* if an application relates to the addition of a food additive, processing aid, novel food or novel substance or nutritive substance …"[4].

The problem is that this is a 'plus plus approach such that an application for a processing aid in infant formula products requires not only the requirements of section 3.3.2 in the *Application Handbook* to be met but also the requirements proposed in section 3.6.2 to be met even though processing aids may never be found in breast milk. Some additives and other substances that occur naturally in breast milk have synthetic equivalents (e.g. Taurine) that are not naturally occurring substances in breast milk and the proposed amendments to the *Application Handbook* would prevent their addition. There may also be substances particularly required to treat pre-term infants or infants with special dietary needs for which applications could not be made. This particular conflict reflects a very narrow interpretation of the Policy Guidelines that is expected to emerge in the process of the Review of the Regulation of Infant Formula Products.

The Policy Guidelines, under the heading "Specific Policy Principles – Composition", provides in paragraph (h) that:

"The composition of breastmilk should be used as a primary reference for determining the composition of infant formula and follow-on formula." (INC underline).

"A primary reference" is not the exclusive reference or the only reference or sole reference but rather a first point of reference amongst others. If the interpretation of the Policy Guidelines was that it be the first point of reference, this would accommodate variations to the Australia New Zealand Food Standards Code (the Food Standards Code) relating to processing aids or other substances intended to be added to infant formula but which are not necessarily evident in breast milk.

At the time of consultation on the Policy Guidelines, INC stated that it supported in principle the clause that breast milk be the primary reference but it also noted that "as prominently described in clause (d) and (e) of the Policy Guidelines, the safety and normal growth and development in healthy term infants is a critical consideration for determining the composition of infant formula products. Ingredients, therefore, should not be limited to those components solely found in breast milk." This position remains applicable.

A. Information related to compositional requirements

INC notes that the web link to the CONSRT statement is incorrect and a hyphen is required between 'consort' and 'statement'..
We note that the work of the American Academy of Pediatrics task force, as per the link, has now been accepted by the US Food and Drug Administration. We suggest FSANZ provide that a link to the FDA confirmed document in place of the discussion paper.

[4] p26 *Call for Submissions – Draft Explanatory Statement: Amendments to the FSANZ Application Handbook*, FSANZ 8 November 2012

A1. Information on the purpose of the compositional change

INC suggests that some clarification of the terms "potential health benefit" and "beneficial health outcome" in section 3.6.2 would be useful. Neither term is described or contrasted in order to assist the applicant distinguish 'health benefit' and 'beneficial health outcome'. It would be helpful to describe the terms in order to be able to distinguish between them and for their use to be assessed as appropriate or not.

A2. Information demonstrating the safety of the proposed compositional change

Mandating clinical studies for every application associated with infant formula products will have a major impact on infant formula in the future because clinical studies will not always be appropriate nor available because of ethical concerns. For example and depending on the substance, pre-market assessment should not require a clinical study for ingredients added to play a technological role such as additives and processing aids. These should instead require review of available relevant scientific evidence, including international reviews/assessments. The American Academy of Pediatrics report for FDA noted early on that "Clinical studies are needed in some instances to supplement laboratory studies…"[5] (INC underlining). In terms of availability, while regulators might want clinical studies for all changes to composition, ethics committees are, correctly, very sparing of interventions involving infants and such studies will not always be available. Some flexibility must be built into the *Application Handbook* to accommodate such situations.

A2(a) refers to "Clinical studies in infants which assess adverse effects…" This assumes that there are adverse effects for all compositional changes when this might not be the case. The phrase should refer to 'potential adverse events' since the potential might be studied but the study might determine there are none.

This part of section 3.6.2 also introduces more terminology that would benefit from further examples to assist with their understanding. Further examples to describe the following would be helpful:

- 'physiological, biochemical or functional effects'
- 'development.'

The term 'development' appears to be defined by relevance: "where it directly relates to the purpose of addition of the proposed substance". Further explanation of the intent of this term would be helpful.

Paragraph A2(a)(i) states that "for infant formula intended as the sole source of nutrition (i. e. from birth) measures of growth should be over a period of at least four months"[6]. It is unclear whether the period of comparison should be over at least 4 months or whether just the 'measures of growth' must be continued over at least a 4 month period that includes the period of any trial. Rather than set the period of measures of growth at 'over a period of at least 4 months' it would be more helpful to state a minimum of 3 months. This is based on the recommendations of the American Academy of Pediatrics[7] "The Task Force recommends, that weight gain be determined over an interval of 3 to 4 months".

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[5] p2 Clinical testing of infant formulas with respect to nutritional suitability for term infants, USFDA , June 1988
[6] p27 *Call for Submissions – Draft Explanatory Statement: Amendments to the FSANZ Application Handbook*, FSANZ 8 November 2012
[7] Task Force on Clinical Testing of Infant Formulas, American Academy of Pediatrics "Clinical Testing of Infant Formulas with Respect to Nutritional Suitability for Term Infants" Report prepared under FDA contract 223-86-2117, June 1988

Paragraph A2(a)(ii) states that "for infant formula intended for use from 6 months, measures of growth should be over a period of 2 months."[8] If the compositional change applies to a product that is suitable from birth to 12 months, then INC believes that the data provided for the younger, more vulnerable population group should be sufficient to support the safety in the older infant. When compositional changes are extended from an infant formula product to a follow-on formula (from 6 months), the INC does not support the need for additional clinical data and/or clinical studies. INC believes the clinical data in the 0-6 month population continues to support the safety of use for infants beyond 6 months. If FSANZ does not consider this to be the case, INC suggests that the rationale be included in the *Application Handbook* that would justify and support the need for additional data/clinical studies in order to extend a compositional change from infant formula for infants aged 0-6 months into follow-on formula for infants from 6 months.

Paragraph A2(b) introduces the concept of "nutrient imbalances". It is not clear what FSANZ intends should be indicators for 'nutrient imbalances 'and why this is included. 'Nutrient imbalance' does not appear in the Policy Guidelines. If this requirement is to remain, INC queries whether 'marker' minerals or vitamins are intended to be indicators of 'nutrient imbalances' such as calcium levels. If this is the intention, then some examples or specific minerals or vitamins should be suggested. In any event, the rationale for requiring 'nutrient imbalances' should be included.

A3. Information on comparable substances in breast milk

The paragraphs in the *Application Handbook* reflect an interpretation of the Policy Guidelines that every substance in infant formula must be found in breast milk and must have an equivalence from consumption when the Policy Guidelines refer to breast milk as a *primary*' reference but not the only, exclusive or sole reference and do not refer to any equivalence of consumption. This requirement needs amending to reflect the intention that the reference to breast milk is non-exclusive.

Paragraph A3(a) states that information "should include reference to mature breast milk from Australia and New Zealand mother"[9]. There is very little information extant on the composition of breast milk in Australia or New Zealand. It is generally understood from overseas studies that the composition of breast milk changes rapidly and frequently, depending on the infants' needs. The European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) stated in 2009[10] that "Human milk is not a uniform body fluid but a secretion of the mammary gland of changing composition. Foremilk differs from hindmilk, and colostrum is strikingly different from transitional and mature milk. Milk changes with time of day and during the course of lactation." In light of the variability of breast milk and the absence of data on the composition of breast milk in Australia or New Zealand, this requirement needs to be reconsidered.

Paragraph A3(b) refers to "physiological control" a term that is not explained. As with other terms, a description and examples of 'physiological control' would assist in determining what is intended by the term.

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8 p27 *Call for Submissions – Draft Explanatory Statement: Amendments to the FSANZ Application Handbook*, FSANZ 8 November 2012

9 p27 Ibid

10 p113 Agostoni C, et al "Breast-feeding: A Commentary by the ESPGHAN Committee on Nutrition*"* ESPGHAN Committee on Nutrition in *Journal of Pediatric Gastroenterology and Nutrition*, 49:112–125

A4. Information related to the potential beneficial health outcome of the proposed compositional change

Paragraph 4(a) refers to the terms "physiological, biochemical or functional effects" and paragraph 4(b) to "beneficial health outcome" and "clinical condition". While, examples are given for beneficial effects for each of physiological, biochemical, functional, and beneficial health outcome, further examples would greatly enhance the understanding of what these terms are intended to mean.

Paragraph 4(c) refers to clinical studies and, as noted above, the term 'clinical studies' needs to embrace the range of studies available. Section 4 also contains two sets of 4(a) and 4(b). These need renumbering to avoid confusion.

The second 4(b) suggests that follow-up studies in older infants or children that were fed the infant formula products containing the proposed compositional change when they were younger should be included. Such longitudinal studies are particularly costly and difficult to achieve because of family mobility etc.

A5. Information related to internationally recognised standards, codes of practice and recommendations

The note to this section provides examples of relevant codes of practice and recommendations/ guidelines. 'Standards' should be added to this list for completeness since the first two examples are Codex Standards. The examples include the WHO Infant and Young Child Nutrition Global Strategy on Infant and Young Children Feeding. The INC supports the Global Strategy but it is difficult to see its relevance for the preparation of applications for compositional changes to infant formula products and particularly in this part on 'Information relating to Compositional Change'.

B. Information related to the dietary intake or dietary exposure

B1. Data to enable dietary exposure of the target population to be estimated

The INC has no comment on this explanatory statement.

B2. Data on the recommended level of formula consumption for the target population of the proposed changes to the currently permitted levels

At the end of this section it is stated that "The application should also contain information or references on levels of the substance in other foods." Infant formula products cover products for infants from 0-12 months. The products for infants from 6-12 months are limited and rather than request information on the 'substance in other foods', it would be more focussed to request information on the 'substance in other infant foods'.

B3. Information relating to the use of the nutritive substance in other countries

The title of this section refers to 'nutritive' substance which is only one kind of substance that an application in this part of the *Application Handbook* might involve. The heading might better read "Information relating to the use of the substance in other countries".

C. Information related to labelling requirements under Part 2.9 of the Code

The introductory statement provides that the "The application must contain the following information …" yet C2 relating to "Information to demonstrate that the proposed labelling change will be understood and will assist consumers" is to be included "if applicable". The introductory statement is therefore inconsistent in its current form with subsequent requirements. INC suggests it should therefore be amended to read "The application must contain the following information where applicable …"

C1. Information related to safety or nutritional impact of the proposed labelling change

The INC has no comment on this explanatory statement.

C2. Information to demonstrate that the proposed labelling change will be understood and will assist consumers, if applicable

The INC has no comment on this explanatory statement.

C3. Information related to internationally recognised codes of practice and guidelines on labelling

The WHO International Code of Marketing of Breast-milk Substitutes has been adopted in Australia and New Zealand through local interpretations: the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement 1992 and The Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand. It would therefore be more accurate for the Note in this section to state:

> "*The WHO International Code of Marketing of Breast-milk Substitutes* as interpreted for Australia by the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement 1992 at* http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-publicat-document-brfeed-maif_agreement.htm and for New Zealand by *The Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand* at http://infantnutritioncouncil.com/wp-content/uploads/2012/11/48511-INC-A5-booklet_FA-web.pdf."

Finally, amendment [13.3] proposes a new *Checklist for Standards Related to the Composition and Labelling of Food Products*. In line with above comments, INC suggests that under the checklist for Special Purpose Foods – Infant Formula Products (3.6.2) A3 should read "Comparable substances in breast milk if applicable", A5 should read "Internationally recognised standards, codes of practice and recommendations/guidelines on composition" and B3 should read "Information relating to the use of substance in other countries"

References

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