Infant Nutrition Council

Industry supporting both
Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

28 September 2017

Food Standards Australia New Zealand
PO Box 7189
CANBERRA BC ACT 2610
AUSTRALIA

Email: submissions@foodstandards.gov.au

Dear Sir/Madam

The Infant Nutrition Council (INC) appreciates the opportunity to make a submission on Consultation paper – Proposal P1028 Regulation of Infant formula – Infant formula products for special dietary use.

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:
- Aspen Nutritionals Australia Pty Ltd
- Fonterra Co-operative Group Ltd
- H. J. Heinz Company Australia Ltd & H. J. Heinz Company NZ Ltd
- Nestlé Australia Ltd & Nestlé New Zealand Ltd
- Danone Nutricia Pty Ltd
- The a2 Milk Company Pty Ltd
- Synlait Milk Ltd

Infant Nutrition Council Ltd ABN 23 135 154 406

Web: www.infantnutritioncouncil.com
Email: info@infantnutritioncouncil.com

OFFICES
AUSTRALIA
L2, 2-4 Brisbane Avenue, Barton, ACT, 2600, Australia
PO Box 7190, Yarralumla ACT 2600, Australia
Tel: +61 2 62738164

NEW ZEALAND
Datacraft House, 99-105 Customhouses Quay, Wellington, NZ
P O Box 25-420 Wellington, 6146, NZ
Tel: +64 9 354 3272

Associate Members:

- Abbott Nutrition Pty Ltd
- Australian Dairy Park Pty Ltd
- Bayer Ltd
- Bodco Dairy Ltd
- BUBS Australia Ltd
- Burra Foods Pty Ltd
- Cambricare New Zealand Ltd
- Cargill Australia Pty Ltd
- Dairy Goat Co-operative Ltd
- DSM Ltd
- Fresco Nutrition Ltd
- GMP Dairy Ltd
- GrainCorp Ltd
- Jamestrong 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
- Nu-Mega Ingredients Pty Ltd
- Snow Brand Australia Pty Ltd
- Tatura Milk Industries Pty Ltd
- Wattle Health Austalia Ltd
- Westland Co-operative Dairy Company Ltd
- Winston Nutritional New Zealand Ltd
- Yashili Dairy New Zealand Pty 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.

Yours sincerely

Jan Carey
Chief Executive Officer

INFANT NUTRITION COUNCIL SUBMISSION ON Consultation Paper – Proposal P1028 Regulation of Infant Formula – Infant Formula Products for Special Dietary Use

Introduction and Key Points

1. INC appreciates the expansion of the P1028 to include consideration of infant formula products for special dietary use (IFPSDU) concerning the most vulnerable of all population groups – infants with special dietary needs who are under medical supervision for their condition. We also appreciate the opportunity to submit on issues explored by FSANZ in the *Consultation Paper – Proposal P1028: Regulation of Infant Formula Products for Special Dietary Use* (the Consultation Paper).

2. INC **supports** FSANZ view that P1028 is aligned with international regulations where relevant. This is particularly relevant for the inclusion in P1028 of infant formula products for special dietary use, as these products are predominantly sourced and imported from Europe and the US into Australia and New Zealand.

3. The regulatory framework is of core concern to INC and while there are elements of all three options, INC considers a **modified proposal** whereby there are three subcategories: *Subcategory 1*: Products for prematurity or low birthweight infants, *Subcategory 2*: Products for less serious disorders, diseases or medical conditions and *Subcategory 3*: Products for serious disorders, diseases or medical conditions. The rationale for these three subcategories and a description can be found in the response to Q2.

4. INC **supports** a definition of IFPSDU in order to differentiate from infant formula products for healthy infants. INC supports the introduction of a definition for the sub-category of products for serious disorders, diseases or conditions in order to differentiate this sub-category from other sub-categories. The reasons are set out in the responses to Q3 and Q4.

5. INC **strongly opposes** a sub-categorisation based on an ingredient such as protein substitutes and lactose free or low lactose rather than nutritional purpose/condition based. The compositional parameters in the current status quo for protein substitutes are not necessary, which negates a need for this category.

6. INC believes it is **not necessary** to include specifics about age or weight in the definition in the food standard category for infants born prematurely or who are of low birth weight, as the choice of formula is decided by medical specialists.

7. **Composition**: INC **supports** the current status quo permitting deviation to nutritional general purpose norms, when scientifically substantiated for the condition. Further INC **strongly supports**, for those ingredients not relating to serious disorders, diseases and medical conditions, a permission to allow deviation to 3 credible regulatory jurisdictions – specifically Codex, EU and US – if FSANZ requirements prevents the sale of such products in the ANZ market. INC **strongly believes** that without these permissions, there could be a potential significant impact on supply and sale to Australia and New Zealand for IFPSDU. INC **supports** one harmonised compositional approach for all IFPSDU.

8. INC considers **no benefit** would result from the inclusion of a specific requirement relating to scientific data for safety and benefit of effectiveness since all products that are represented as an IFPSDU must be safe and must have compositional modifications that are based on acceptable scientific data and address the specific condition.

9. INC continues to **strongly support** expansion of the scope of P1024 (Revision of the Regulation of Nutritive Substances & Novel Foods) to include all standards in the Food Standards Code. INC supports the scope extension made thus far to P1024 such that it now includes all Standards except for Standard 2.9.1, but we note that a carve-out for Standard 2.9.1 still creates risks related to consistency, timing and approach. INC **strongly supports** mutual recognition of key jurisdictions EU and US in relation to new ingredients.

10. **Food Additives:** Food additives play a significant role in the manufacture of infant formula products and IFPSDU in particular. For this reason, and as set out in the following response to questions, INC proposes firstly, a more appropriate framework for food additives and secondly, inclusion of all the food additives listed for consideration in the consultation paper (see responses to Q19-Q23).

11. **Contaminants:** INC **supports** FSANZ's view on contaminants **with exception** of aluminium. We restate our view that Standard 2.9.1 should align with Codex and the EU which do not include limits on aluminium as a contaminant metal in infant formula. The rationale is set out in the heading following Q24 on Contaminant MLs.

12. **Labelling:** Throughout this submission we have repeatedly stated that the vast majority of IFPSDUs used in Australia and New Zealand are imported in small, specialist quantities for use under medical supervision. Supply of IFPSDU is especially critical for these vulnerable populations. In general, INC does not support prescribed names, prescribed warning statements and prescribed preparation. INC considers that to do so unnecessarily constrains compliance of a category of products that are almost all imported.INC **supports** however, regulating the intent.

Detailed Comments

International Arrangements and the Regulatory Framework

13. INC considered Codex, the EU and US arrangements for comparative purposes with proposals for Australia and New Zealand. These arrangements have contributed to our proposals.

Q1 Are any other overseas regulations relevant to IFPSDU?

14. INC members consider the international regulatory arrangements (Codex, EU and US) have been adequately canvassed by FSANZ.

Q2 What are the advantages and/or disadvantages of these options, in particular creating an 'infant formula product for special medical purposes' subcategory? If you support creation of a separate category for IFPSMP, should products developed for pre-term and low birthweight infants be included or retained as a separate subcategory? Please provide your rationale. Are any other overseas regulations relevant to IFPSDU?

15. The regulatory framework needs to consider the importance of accommodating products for conditions that are extremely variable, sometimes serious or life threatening, produced in small quantities and with often special distribution arrangements. The

variability and the pace of change and innovation in this area of science is likely to have been the key influencers of the Codex approach which was to avoid categorisation. While this is attractive, the need for greater clarity in national legislation is recognised.

16. As set out in the Policy Guidelines, the regulations should be consistent to the greatest extent possible with Codex standards and guidelines. As stated by FSANZ in the regulatory framework proposal, international requirements of the EU and US are particularly relevant given the extent of importation into ANZ of these highly specialised products.

17. INC does not believe any framework option presented by FSANZ is appropriate without modification and agrees with FSANZ that the final arrangements of sub-categorisation will depend upon the necessary variations in the specific requirements for composition, labelling and distribution and access.

18. INC strongly supports categorisation being based on the purpose of the products, and not ingredients used, in order to assist with reducing current uncertainty in regulations. Products are developed for specific serious disorders, diseases and medical conditions and should only be used under medical supervision. INC therefore opposes the current and proposed sub-categorisation of protein substitutes. The approach of having a subcategory of IFPSDU based on protein substitutes currently results in ambiguity (e.g. a hydrolysate could be used in a general formula or a formula for allergic individuals or a formula for preterm infants).

FSANZ proposed options (Figure 1 in the Consultation Paper)

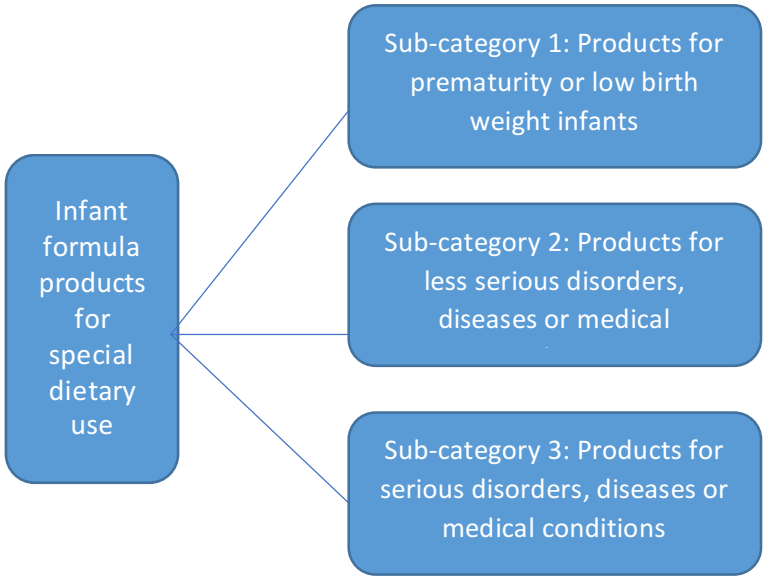
19. Option 1 is largely aligned with Codex and INC agrees that there should not be specific composition criteria for sub-categories. However, INC is concerned that this approach may not manage risks associated with the availability of highly specialised IFPSDU and is therefore not in support of Option 1.

20. Option 2 is similar to EU however INC does not support the 'transient' conditions being located with general purpose infant formula products. For protein hydrolysates, these are ingredients that could be used both for general purpose as well as IFPSDU.

21. Option 3 provides sub-categorisation reflective of the current status quo, which INC agrees may help minimise the concerns on differentiation and regulatory clarity associated with the availability of highly specialised IFPSDU to be managed by splitting the current category of infant formula products for metabolic, immunological, renal, hepatic and mal-absorptive conditions into two sub-categories. However, as previously stated, INC does not agree with retaining the current differentiation based on specific composition requirements for protein substitutes and not based on purpose.

INC preferred Regulatory Framework

22. INC proposes the following sub-categories considering aspects of Option 1 and Option 3. Amendments have been made to focus on product purpose related to serious disorders, diseases and medical conditions and excluding ingredients (e.g. non-intact protein which could be used across multiple categories including those in Division 3 and Division 4) and to ensure clear differentiation of high risk IFPSDU to enable management of access and distribution.



(The tagging of the categories in the INC-proposed framework as Sub-categories 1, 2 and 3 are arbitrary and for referencing purposes only)

23. Based on the framework proposed, INC has provided some examples as follows, to illustrate products that could be included in each of the three sub-categories above. Additionally, INC has proposed to support trade and distribution access to two sub-categories only (Categories 1 & 3) These examples are provided purely to supplement the framework, and not proposed for inclusion in regulation.

1. **Sub-category 1. Products for prematurity or low birthweight infants**
    a. These formulas should only be sold from or by:
        i. a medical practitioner or dietitian; or
        ii. a medical practice, pharmacy or responsible institution
        iii. a majority seller of that food
    b. Examples – Pre-term infant formula, Post-discharge pre-term infant formula products

2. **Sub-category 2. Products for less serious disorders, diseases or medical conditions**
    a. Infant formulas typically represented and labelled for use to provide dietary management for disorders, diseases or medical conditions that are not clinically serious or potentially life-threatening
    b. Examples – constipation, diarrhoea, lactose intolerance

3. **Sub-category 3. Products for serious disorders, diseases or medical conditions**
    a. Infant formulas typically represented and labelled solely to provide dietary management for specific disorders, diseases or medical conditions that are clinically serious or potentially life-threatening and are generally required to be used for prolonged periods of time. These formulas should only be sold from or by:

i. a medical practitioner or dietitian, or
ii. a medical practice, pharmacy or responsible institution, or
iii. a majority seller of that food

b. Example – Phenylketonuria (PKU)

24. The suggestion has been that sub-category 1 could be accommodated by sub-category 3. However, INC supports a separate category of preterm and low-birth weight infants for clear labelling identification of these products.

25. The proposed definition of the sub-category for serious disorders, disease or medical conditions is covered in Question 4

Q3 Do you support including a category definition for IFPSDU in the Code? Why or why not? Is the proposed definition of IFPSDU appropriate; if not, what should it say?

26. INC considers a category definition useful. INC supports the provisions described in the FSANZ definition in sub-clauses (a), (b) and (c) with the following modifications. FSANZ proposed: (INC strikeouts)

> Infant Formula Products for Special Dietary Use means an Infant Formula Product that is specifically formulated:
> (a) for an infant with a specific disorder, disease or medical condition;
> (b) to satisfy, either partially or fully, the ~~special~~ nutritional requirements of that infant; and
> (c) to be used under medical supervision.
>
> If FSANZ finds it appropriate to include human milk fortifiers within the scope of Standard 2.9.1, the definition proposed above would need to be re-drafted to account for products that are not considered Infant Formula Products -
>
> Products for Special Dietary Use means Product for infants that is specifically formulated:
> (a) for an infant with serious disorders, disease or medical conditions;
> (b) to satisfy, either partially or fully, the ~~special~~ nutritional requirements of that infant; and
> (c) to be used under medical supervision.

Q4 If you support including a subcategory definition for IFPSMP in the Code, is the proposed definition of IFPSMP appropriate; if not, what should it say?

Definition for proposed sub-category 3 (Products for serious disorders, diseases or medical conditions) is supported:

27. INC supports the introduction of a definition for the sub-category of products for serious disorders, diseases and medical conditions. FSANZ has described the reason for a categorisation for 'special medical purposes' as providing "*a clear differentiation for the highly specialised products including those that may pose a risk to healthy infants"*. INC considers that this description is better suited to the overarching category and definition for IFPSDU which are not suitable for healthy infants.

28. The purpose of a definition for the sub-category for 'serious disorders, diseases and medical conditions' is to differentiate this sub-category from the other sub-categories,

rather than differentiate the products it might cover from products for healthy infants. In INC's view, it is the purpose of the definition for the overarching category of IFPSDU to differentiate these from products intended for healthy infants.

29. INC considers that the definition proposed by FSANZ for the sub-category of products for special medical purposes is already covered by the definition for IFPSDU:
    - "*used under medical supervision*" is somewhat similar to "*medically determined nutrient requirements*" since all infants needing any IFPSDU will usually have a product recommended by a health care professional (HCP) who will need to have the appropriate nutrient requirement for the condition considered in recommending the appropriate product for use
    - "*limited or impaired capacity to take, digest, absorb, metabolise or excrete food*" can be satisfied by "*Product for infants that is specifically formulated: with a specific disorder, disease or medical condition*", since those infants with such disorders, disease or medical condition will necessarily have the *limited or impaired capacity to take, digest, absorb, metabolise or excrete*.

30. To recap, INC considers that if a definition for the sub-category of products for serious disorders, diseases and medical conditions is to be supported, rather than provide differentiation for products intended for healthy infants, this definition should instead provide differentiation to the other special dietary use product sub-categories. For example, the phrase *"limited or impaired capacity to take, digest, absorb, metabolise or excrete food*" applies to both sub-categories covering 'less serious' and 'more serious' conditions of a disease or disorder.

31. As such, a definition is required that can differentiate between the less serious conditions (where an infant could otherwise recover to a healthy state and can then subsequently switch to a general-purpose product for healthy infants) and the more serious (typically medically diagnosed by the HCP, but often accompanied by follow-up and recurring HCP consultations).

32. Products for the less serious conditions may require initial HCP advice/medical supervision and recommendation for the appropriate product, however, recurring HCP consultation is much less likely as compared to those for more serious conditions.

33. From the preceding discussion, INC considers there could be two factors reflected in a definition for products for serious disorders, diseases or medical conditions: that of a condition, disease or disorder that is [1] serious, and [2] could be potentially harmful if consumed by a healthy infant.

34. Such a definition could draw some elements from the US FMSP regulations (Title 21 of the Code of Federal Regulations 107 subpart C: Exempt Infant Formula), which refers to:
    "*specific diseases or conditions that are clinically* ***serious*** *or life-threatening and generally are required for prolonged periods of time*."

35. The proposed modification is as follows:
    ~~Infant formula~~ Products for serious disorders, disease, or medical conditions ~~special medical purposes~~ mean~~s an infant formula~~ product~~s~~ for special dietary use that are ~~is~~ specifically formulated for infants:
    a) who have
        ~~i) Medically determined nutrient requirements, or~~
        ~~ii) Limited or impaired capacity to take, digest, absorb, metabolise or excrete food including another type of infant formula product~~
        i) Specific disease or conditions that are clinically serious or potentially life-threatening, and

ii) A need for a specially formulated infant formula product not otherwise suitable for healthy infants

Q5 Are there any issues with the current definition for protein substitutes?

36. INC has no issues with the current definition for protein substitutes. Manufacturers are well aware these relate to non-intact protein and there is no failure in the market in terms of appropriate differentiation with the different types of protein hydrolysates or amino acid based formulas. As noted in the preceding commentary on the regulatory framework, however, INC strongly opposes a sub-categorisation based on an ingredient such as protein substitutes rather than nutritional purpose/condition based. In INC's view, the category is inconsistent with a condition/use/intent approach and should not proceed. INC notes that there are protein substitute products that can be used for any of the following:
    - as general-purpose infant formula products,
    - those for prematurity and low birth weight conditions, and
    - those for metabolic, immunological, renal, hepatic and mal-absorptive conditions otherwise to be proposed as products for special medical purposes or products for transient conditions.

37. INC therefore questions the validity of such a sub-category and the need for the related definition for products that could otherwise be relocated to other categories in Standard 2.9.1. Additionally, there is no regulatory precedence for such an approach and Codex, EU nor US have definitions for protein substitutes.

Q6 Is there a benefit to defining one or more of the following in the Code: – Hypo-allergenic formula – Partially hydrolysed formula – Extensively hydrolysed formula – Amino acid-based infant formula?

38. As noted in the response to Q5, INC opposes a categorisation based on form or ingredient of a formula. Such an approach is inconsistent with a condition/use/intent approach and should not proceed. INC notes there is controversy globally on attempts to define such products and clarity would be lost if these were used.

39. With the exception of amino acid based infant formula, INC believes it will be very difficult to define these terms. There is no generally accepted definition globally for hypoallergenic; partially hydrolysed; and extensively hydrolysed infant formula.

40. Hypoallergenic has vastly different meanings in different parts of the world, as discussed in a recent review by Vandenplas 2017:

    "The meaning and definition of a "hypo-allergenic formula" varies in different parts of the world. While in Europe a "hypo-allergenic formula" means a formula that contains hydrolyzed protein and thus a reduced allergenicity, the American Academy of Paediatrics defined it as a formula that is effective in the treatment of at least 90% of the children with CMA, with a 95% confidence interval".

41. As such, a 'partially hydrolysed' formula may be considered "hypoallergenic" in Europe but not, for example, in the US.

42. Partially and extensively hydrolysed infant formulas have been studied for many years and even though they have been discussion topics since the 1999 ESPACI position paper, yet still there is no generally accepted definition. The topic was discussed at length by Host & Halken in 2004, and again more recently by Vandenplas et al in 2015. Host & Halken (2004) stated:

    "Attempts have been made to classify products according to the degree of protein hydrolysis ['extensive' or 'high degree' (EHF) vs 'partial' or 'low degree' (PHF)], but there is no unanimous agreement on firm criteria on which to base such a classification".

43. More recently, Vandenplas et al (2015) commented that:

    "There is no general agreement on standards to define pHF and eHF specifically and protein/peptide size is generally used to identify each of them…The technique of hydrolysis and thus the end result, the partially hydrolysed protein, differ for each company".

44. To recap, INC opposes a categorisation based on form or ingredient used in a IFPSDU product. Such an approach is inconsistent with a condition/use/intent approach and should not proceed. In any case, there are no internationally agreed definitions of the terms proposed for sub-categorisation covered in this question.

Q7 Are there any issues with the current definition for pre-term products?

45. INC considers there are no issues with the current definition of pre-term products.

Q8 What, if any, are the benefits of including age and weight parameters in the regulatory definition for pre-term products?

46. Age and weight parameters are an arbitrary distinction in relation to the formula used for pre-term or low birth weight infants. INC understands that the objective of HCPs is for the infant to reach a healthy state so that they might be discharged from hospital. Parameters should remain the province of clinical decision-making. In any event, the clinician involved makes final decisions as to the needs of the infant and the appropriateness or adjustment of any particular formula proposed for the infant.

47. In line with the recommendation in the P93 Inquiry report, INC believes it is not necessary to include specifics about age or weight in the definition in the food standard category for infants born prematurely or who are of low birth weight, as the choice of formula is decided by medical specialists. Manufacturers would also be in the best position to state the most appropriate use for this type of formula.

Human Milk Fortifiers

Q9 What is the general composition of human milk fortifiers for premature or low birthweight infants? What are the uses of these products other than premature or low birthweight infants?

48. Preterm or low birthweight infants have increased nutritional requirements. Breast milk alone may be nutritionally inadequate for preterm or low birthweight infants. A human

milk fortifier (HMF) is designed to increase the nutritional content of breast milk to help preterm infants achieve an optimal growth rate.

49. The general composition of human milk fortifiers:
    - provide additional energy from protein, carbohydrates and fat, and
    - contain vitamins, minerals and trace elements to supplement breast milk.

50. In principle, a preterm infant is an infant who is born before term (before the start of the 37th week of gestation (<37 weeks)).

51. The primary positioning of HMF is for infants who are both preterm **and** below 1800g (low birth weight) when following ESPGHAN guidelines. It is up to the discretion of the HCP to prescribe the HMF for infants who are term and low birth weight according to their individual nutritional requirements. The use of HMF for other indications is not supported by INC, including failure-to-thrive or other medical conditions which require provision of additional protein, energy and micronutrients.

52. A HMF is only designed for use within the hospital setting for breastfed infants who require the product for the condition of prematurity or low birth weight. They are used only to fortify human milk.

Points to consider with regard to inclusion of human milk fortifiers within the scope of Standard 2.9.1

53. HMF are not currently regulated under Standard 2.9.1 as they do not fit the definition of an infant formula product. There are particular labelling requirements, warning statements and directions that are listed under Standard 2.9.1 that would not be applicable to human milk fortifiers and this would need to be taken into account. Specifically, labelling requirements covered by 2.9.1—19 are not appropriate for such products.

54. Due to the specialised nature of HMF, there is a very small market for these products within Australia and New Zealand. The products on the market in Australia and New Zealand are manufactured overseas and this needs to be taken into account as prescribing particular warning statements and mandatory labelling requirements may create a trade barrier and a gap in the market for such highly specialised products designed for the most vulnerable infants. There is a critical need for such products especially in neonatal intensive care units and a very small number of manufacturers are supplying in this area at the moment.

55. HMF products are very specific and are developed for use in premature or low birthweight infants. For this reason, the trade and distribution access for these products should be restricted in the same manner as Food for Special Medical Purposes under Standard 2.9.5—5.

56. INC would like to note that throughout our submission we refer to IFPSDU. If, however, HMF were to be considered within the scope of Standard 2.9.1, then (possibly through a review of the definitions) the use of IFPSDU would need to be substituted with “Products for Special Dietary Use (PSDU)”, if the current definition for infant formula products was not expanded to include products providing partial nutrition. For the purposes of this submission however, we will continue to use the acronym ‘IFPSDU’.

Q10 Is there a need to prescribe a name for IFPSDU – what are the implications for

subcategories?

Q11 Is there a need to prescribe names for any the IFPSDU subcategories? If yes, what benefit would this provide

57. INC does not support any prescription of names. Prescribing a name for infant formula products for special dietary use unnecessarily constrains compliance of a category of products that are almost all imported. Internationally while such products are described, names are not prescribed.

58. Wherever possible, INC supports harmonising with international regulations to reduce costs and the burden on the industry and to increase availability of these products to the Australian and New Zealand market. Although the majority of IFPSDU in Australia and New Zealand are imported, the current Code labelling requirements do not allow flexibility. Hence, most manufacturers of IFPSDU customise labelling information for the ANZ market. This adds cost to the consumer and has implication for potential threats to supply.

59. Due to the nature of these products, typically only small volumes of these products are needed for the Australian and New Zealand market and inflexible labelling requirements could therefore potentially lessen product availability. Codex Stan 72-1981 states:

    "the name of the product shall be "Formula for Special Medical Purposes Intended for Infants" or any appropriate designation indicating the true nature of the product, in accordance with national usage".

    INC supports a similar approach for Standard 2.9.1 for IFPSDU.

Q12 Are any specific compositional requirements (energy/macronutrient etc.) needed in the Code for formula intended for premature or low birthweight infants, or for those suffering metabolic etc. conditions? If so, what are they?

Q14 Are any specific compositional requirements (energy/macronutrient etc.) needed in the Code if a new subcategory of formula for special medical purposes were created? If so, what are they?

60. INC recommends nutrient parameters not be introduced for any sub-categories. The consultation paper states: "*The EU regulations acknowledge the need to ensure adequate flexibility to develop innovative products, and state that it is not appropriate to lay down detailed compositional rules for such food products*. "

    INC supports this approach.

Q13 Are any specific compositional changes needed in the Code for protein substitutes? If so, what are they and what is your justification for them?

61. INC considers that the current specific requirements for chromium, molybdenum, protein maximum, fat minimum, renal solute load and permission for medium chain triglycerides (MCT) that differs from general purpose infant formula products are not necessary and as such redundant. This then supports removal of a sub-category for protein substitutes. The rationale for chromium and molybdenum is provided in detail in the responses to Q17 and Q18.

62. **For protein maximum**: Protein maximum for protein substitutes is currently 1.4g/100kJ. This differs from the general purpose infant formula section where protein maximum for an infant formula is 0.7g/100kJ and for a follow-on formula 1.3g/100kJ. As such, a non-intact protein starter infant formula for special dietary use would be using the range for a general-purpose follow-on formula, albeit a slightly higher maximum.

63. INC considers that the protein levels for all infant formula products, including those for IFPSDU should be based on breast milk levels unless the condition dictates otherwise. The latest science, as recently evaluated by the Codex Follow-up Formula Standard revision for 6-12 months, is that a protein maximum of 3.0g/100kcal (0.72g/100kJ) is appropriate, and already well above breast milk levels.

64. For IFPSDU, and depending on the condition for which the product is formulated for, INC considers that higher levels of protein may be warranted for catch up growth (for example in situations where infants have compromised gastrointestinal function who may require a higher protein content due to a mal-absorptive condition). Even so, irrespective of whether there is an intact, or non-intact protein base, these levels would be nowhere close to the current 1.4g/100kJ maximum in the Food Standards Code. This is supported by a review of current infant formula products on the market. Through a survey conducted by INC (September 2017) of INC members, it was confirmed that no company currently formulates for non-intact protein formulas, to the protein maximum of 1.4g/100kJ.

65. The rationale for protein from Proposal 93 appears to be as follows (INC underlining):

> "Protein content: The protein content recommended for standard formula is 1.26-1.97 g/100ml but in protein hydrolysate formulae on the Australian market, protein content ranges to 2.5 g/100ml, (Alfare). This is within the Codex regulations (1.2-2.7 g/100ml) and the R7 regulation for follow on formula (<2.8g/100ml). Considering the limited data suggesting a fall in plasma protein if fed whey protein hydrolysed formula with a protein content of 1.6 g/100ml (Riga et al 1994), and the possibility of protein losing enteropathy in some conditions for which a protein hydrolysed formula may be prescribed, it seems appropriate to increase the upper limit for protein allowable in these formula."

66. The rationale from P93 is over 15 years old and, specific to this point, is largely out-dated. Alfare (an extensively-hydrolysed protein formula which historically was used for chronic diarrhoea) is referenced as having a declared protein content of 2.5g/100ml. Alfare still exists on the Australian market, however it is now prescribed primarily for the dietary management of cows' milk protein allergy (much rarer in the early 2000s) and currently has a declared protein level of 2.0g/100ml.

67. Another product on the Australian and New Zealand markets is Neocate (prescribed for the dietary management of cows' milk protein allergy) which has a declared protein level of 1.9g/100ml which is also within the protein max for general infant formula. Protein losing enteropathy, mentioned in P93, is rare in children and even rarer in infants (Braamskamp, 2010). Additionally, one possible cause of infectious diarrhoea, from rotavirus, has declined sharply since the introduction of the rotavirus vaccine in Australia in 2007, with a 71% decrease in rotavirus-related admissions (Dey, 2012).

68. It should be noted that the current protein level of products such as Alfare (2.0g/100ml) and Neocate (1.9/100ml) are still ~ 50% higher than the current protein minimum for

infant formula. Such products have been specifically formulated to meet the needs of infants with cows' milk protein allergy, where it is possible that these infants require more protein than a general-purpose infant formula due to their compromised gastrointestinal function upon diagnosis (Nowak-Wegrzyn, 2015). However, as already mentioned, no IFPSDU currently exist on the Australian or New Zealand markets with protein levels up near the protein maximum level.

69. If extra protein was required in a specific instance, this protein could be supplemented modularly (using protein supplements) as is done on occasion by neonatal/paediatric dietitians and suitably trained medical staff. Alternatively, use can be made of the harmonised compositional approach where deviation to general purpose norms is permitted if scientifically substantiated for the disorder, disease or medical condition. Any conditions where higher protein may be needed is able to follow this compositional approach. As such, INC considers there should be no issues to remove this parameter of 1.4g/100kJ for protein and apply the compositional approach for IFPSDU, if higher protein in certain situations is required.

70. **Fat minimum:** Fat minimum for protein substitutes at 0.93g/100kJ differs to general purpose infant formula products at 1.05g/100kJ. INC is unsure as to the full rationale for this minimum fat level, but assumes that it was regulated to compensate for the higher protein maximum whilst maintaining equivalent energy requirements to a general-purpose infant formula. If, however, the higher protein parameter of 1.4g/100kJ is not necessary, and instead defaults to general purpose norms but with permission to deviate for the disorder, disease or medical condition when scientifically substantiated, then we consider the lower fat parameter of 0.93g/100kJ becomes redundant.

71. In trying to better understand the legacy of this lower fat minimum of 0.93g/100kJ, the rationale from Proposal 93 was reviewed which appears to be as follows (INC underlining):

    "The lipid content of one protein hydrolysate formula on the Australian market (Nutramigen) is lower than that recommended for standard formula. However, the carbohydrate content is relatively high, achieving a nutritional profile which may be desirable in infants with fat malabsorption. Therefore, it is probably not unreasonable to reduce the minimal requirement to embrace this formula (2.60 – 3.93 g/100ml). The sources of lipid currently used in commonly used formula for children with special needs are listed in Table 3."

72. To the best of INC's knowledge, Nutramigen has not been on the market since 2001. No current manufacturer formulates to fat minimum levels that fall below the permitted levels for general purpose infant formula products. As such INC does not see the need for a lower fat minimum for protein substitute formulas.

73. Lastly, through a survey conducted by INC (September 2017) of INC members, it was confirmed that no company currently formulates for non-intact protein formulas, to the fat minimum of 0.93/100kJ.

74. **Potential renal solute load (PRSL):** The PRSL is the sum of dietary nitrogen, sodium, potassium, chloride, and phosphorus. Its relevance for protein substitutes was due to a permitted higher maximum for protein. If the protein parameters are adjusted to follow the same compositional approach as all other products for special dietary use, then PRSL is not required for a starter IFPSDU as the protein maximum defaults to the

general-purpose norm of 0.7g/100kJ, and if a follow-on specialty product, then a PRSL is required anyway if as this is the requirement currently also for general purpose follow-on formula for healthy infants. Ziegler & Fomon (1989) in their review of this topic stated that decreasing the protein of the infant formula will decrease the PRSL, which is clear given that the nitrogen (protein) is a major contributor to the PRSL.

75. With changes to lower protein content in most infant formulas in recent years, and to more closely align to breast milk levels, the PRSL has become less important clinically, as high solute loads are not being provided. An example here would be with the extensively hydrolysed protein formula Alfare, mentioned in P93 as having a declared protein of 2.5g/100ml in the early 2000s, decreased now to 2.0g/100ml in 2017, significantly reducing its PRSL and making regulation in this area redundant.

76. **Medium chain triglycerides (MCT):** Unless innately present, MCT are currently prohibited for addition unless added for a specific dietary use relating to the disorder, disease, or medical condition, or expressly permitted for protein substitutes. INC considers that if MCT are warranted for any particular condition (such as chronic diarrhoea with inflammation, or preterm infants), then the compositional approach should address this. INC is not sure why MCT is a nutritional parameter to differentiate an intact, from a non-intact protein based formula. INC believes this was more historic reasoning in that some protein hydrolysate formulas had a dual purpose for immunological/allergic conditions, and mal-absorptive conditions - as MCT have been shown to have good absorption even in the presence of low intraluminal bile salts and pancreatic lipases (Koletzko et al, 2014).

77. For preterm infant formula products, MCT have been used for absorption purposes plus to increase the coefficient of fat absorption and to spare other substrates (glucose; essential fatty acids) from oxidation (Koletzko et al, 2014). ESPGHAN (2010) state that, if added to preterm infant formulas, the MCT content "should be in the range of up to 40% of the total fat content". There should also be no questions doubting safety. MCT have been safely added to special use infant formulas for many years, with Klein's (2001) review of preterm infant requirements stating;

    "MCTs account for 40-50% of the total fat content of currently available preterm infant formulas, and these formulas have not been associated with adverse effects related to their content of MCTs".

Q15 What benefit, if any, would the inclusion of a specific requirement for any IFPSDU to be demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of intended infant subpopulation?

78. All products that are represented as an IFPSDU must be safe in order to satisfy overarching jurisdictional food act requirements concerning the provision of safe food. All IFPSDU must have compositional modifications that are based on acceptable scientific data and address the specific condition. This specific requirement is already referenced under Standard 2.9.1—-14. These products are developed using a standard infant formula composition as a base, with specific nutrient adaptations/deviations from the standard formula composition allowed, based on disease, disorder or medical condition resolution or specific feeding requirements. All deviations are based on scientifically substantiated evidence that have to justify a benefit of the specific nutrient in the final product. INC has reservations around the use of the two terms, beneficial and effective, as both contribute to a single outcome. Manufacturers are required to hold the scientific

evidence that substantiates the nutritional suitability for the disease, disorder or medical condition.

79. There is no evidence of market failure of IFPSDU product available in Australia and New Zealand to date. There is evidence that products available are formulated based on sound scientific and medical evidence.

Q16 Are there issues with the current requirements for micronutrients and nutritive substances in IFPSDU products?

Composition

80. For all ingredients (macronutrients, micronutrients, nutritive substances and new ingredients) not relating to the disorder, disease or medical condition, INC considers there **are issues,** when permission is not granted for deviation.

81. INC's position on compositional approach for IFPSDU is to maintain the status quo allowing for the products to be developed with nutrient adapted/deviations for the specific medical condition, disorder or disease that are scientifically substantiated. Other nutrients in the product, not related to the disorder, disease or medical condition, are defaulted back to the general purpose or standard formula compositional requirements as set out in Standard 2.9.1. IFPSDU products are developed using a standard infant formula composition as a basis, with specific nutrient adaptations/deviations from standard formula composition allowed, based on disease, disorder or medical condition resolution or specific, feeding requirements. All deviations are based on scientifically substantiated evidence.

82. Additionally, due to the highly specialised nature of these products and to enable access and international alignment, a provision that permits a default to the general formulation requirements of a credible regulatory jurisdiction – Codex, EU, US only – should be allowed in situations where IFPSDU are imported from countries that are governed by these overseas jurisdictions and the importation and sale of such products into ANZ is otherwise prevented if such a default was not allowed. This is needed as a prevention of sale would lead to a significant feeding gap for these very vulnerable infant populations and significantly higher costs to make the product available.

83. The following is an example of where a nutrient is not related to a disorder, disease or medical condition and which has varying compositional permissions across Codex, EU regulations and the ANZ Food Standards Code (FSC). This demonstrates the issues faced by manufacturers who are attempting to comply with varying requirements across markets with a single product.

84. **Vitamin D:** The compositional requirements across the FSC, Codex and the EU is as follows:

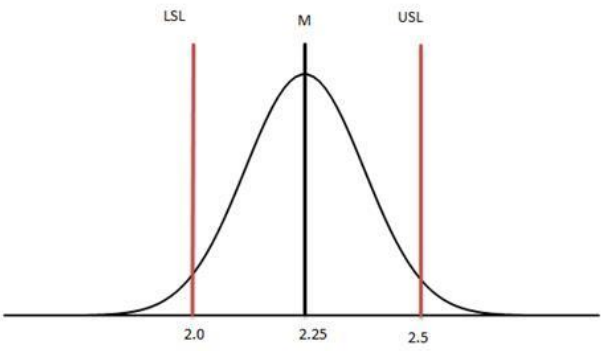
Regulatory requirement	Minimum per 100kcal)	Maximum (per 100kcal)
FSC Standard 2.9.1	1.045mcg	2.6334mcg
Codex STAN 72-1981	1mcg	2.5mcg
EU delegated regulation 2016/128	2mcg	3mcg

85. Manufacturers cannot achieve a narrow nutrient range as there is a variation allowance of for analytical purposes of +/- 15% for declared vitamin D nutrient. As can be seen, the Vitamin D ranges for IFPSDU in the FSC and Codex are incompatible with the EU vitamin D compositional range since the overlap between the FSC/Codex and the EU is only 2mcg – 2.5mcg/100kcal, too narrow to achieve compositional accuracy. This is concerning as currently most IFPSDU products are sourced from Europe. The dilemma faced by manufacturers is further described in the following.

86. For any vitamins or minerals, a range for minimum and maximum levels that is achievable for the manufacturer needs to consider the manufacturer's ability to control the sum of three variabilities:
    - the raw material variables
    - processing/manufacturing variables, and
    - analytical variables.

AOAC SMPR 2011.004

87. Considering only the analytical variability for Vitamin D, according to the Standard Method Performance Requirements for Vitamin D in Infant Formula and Adult/Paediatric Nutritional Formula (AOAC SMPR 2001.004), the relative Standard Deviation of Reproducibility (RSD_R) is around 15% (see opposite). This means the probability for a range of 2-2.5 mcg/100 kcal based on a standard deviation of 15% is 48.7% without considering variability from processing methods.



Mean	M	2.25
Standard deviation	SD	0.36
Lower specification limit	LSL	2.0
Upper specification limit	USL	2.5
Frequency upper violation	F_u	24.37%
Frequency lower violation	F_l	24.37%
Total refquency of non-conformity	F	48.74%

88. The manufacturer then needs to factor in raw material and processing/manufacturing variability, and each time the target range reduces again and again until it becomes an impossibility. Thus, for vitamin D, the <u>total</u> variability across a range of 2 – 2.5 mcg/100kcal cannot be achieved.

89. This is an example of compositional dis-harmonisation, highlighting the need for compositional flexibility to align with credible regulatory jurisdictions for general infant formula compositional requirements, where to do otherwise by Australia and New Zealand would effectively prevent the supply and sale of these products.

90. Under the currently proposed regime for P1024, the term 'nutritive substances' would be deleted. This term is used in Standard 2.9.1. If P1024 proceeds ahead of P1028, then this will become an orphan term in Standard 2.9.1 with no definition or regulatory context.

91. For these reasons, INC continues to submit that Standard 2.9.1 should be included within the scope of P1024.

Q17 Do you have any information to support including a minimum and maximum amount of chromium in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?

92. INC does not support the inclusion of a minimum and maximum amount of chromium in IFPSDU, and proposes these regulatory requirements are removed.

93. **Minimum amount:** Although Codex Standard 72-1981 specifies a minimum amount for chromium in section 3.1.4, it is mentioned only in situations '*where appropriate*'. INC considers in this respect that chromium is optional for addition and 'if added', then the minimum limit applies. In the more recent EU regulations, neither the Community Directive 1999/21/EC and the incoming Community Delegated Regulation (EU) 2016/128 on FSMP set a minimum amount, and chromium is therefore not proven as essential for normal growth and development outcomes.

94. In EFSA's 2014 opinion (section 6.12), because there was unproven essentiality of chromium and no specific physiological function that could be ascribed to chromium, the EFSA panel considered that there was no necessity to add chromium to infant formula or follow up formula.

95. INC concludes that there is no strong evidence that justifies chromium as essential and therefore, a minimum amount is not necessary.

96. **Maximum amount:** Codex STAN 72-1981 does not specify a maximum amount, only a GUL amount for chromium in section 3.1.4, again only in situations '*where appropriate*'. INC considers that chromium is optional for addition and if chromium is added *where appropriate*, the sum of added and inherent (naturally occurring) chromium must not be more than the GUL. Although the EU regulations, both Commission Directive 1999/21/EC on FSMP and the incoming Commission Delegated Regulation (EU) 2016/128 on FSMP, set a maximum for chromium in IFSMP, INC still considers that chromium is not being treated as a mandatory addition. However, in situations where it is added, it must not exceed the maximum value. If not added, however, and if the minimum regulatory criteria is not necessary, then it is highly unlikely that inherent chromium will ever come close to the maximum.

97. The NHMRC and New Zealand Ministry of Health (2006) noted that ULs for chromium are unknown as there are insufficient data to establish these values. It was also noted that no adverse side effects were reported in a number of supplementation trials in which subjects received up to 1 mg chromium/day for several months (Flodin 1990, Hathcock 1997).

98. INC concludes that, since both Codex and EU regulations present chromium as a non-mandatory addition, and with no ULs and adverse effects established for chromium, there is no evidence to support the inclusion of a maximum amount of chromium for any infant formula product including those based on protein substitutes/ non-intact protein.

Q18 Do you have any information to support including a minimum and maximum amount of molybdenum in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?

99. INC does not support inclusion of a minimum and maximum amount of molybdenum in IFPSDU.

100. **Minimum amount:** Although Codex STAN 72-1981 specifies a minimum for molybdenum in section 3.1.4, it mentions '*where appropriate*', INC therefore considers that if added, then the minimum applies. The more recent EU regulations, neither the Community Directive 1999/21/EC on FSMP nor the incoming Community Delegated Regulation (EU) 2016/128 on FSMP set a minimum amount for molybdenum. INC considers this as meaning that it is not mandatory to add molybdenum and therefore not proven as an essential ingredient for normal growth and development outcomes.

101. In the EFSA 2014 opinion (section 6.13), the EFSA Panel noted that molybdenum deficiency has never been observed in healthy humans. Only one human case of possible dietary molybdenum deficiency has been reported in an adult patient on total parenteral nutrition (TPN) because of short-bowel syndrome (Abumrad 1981 reported in EFSA 2014).

102. INC concludes that there is no strong evidence that justifies molybdenum as essential and therefore, a minimum is not necessary.

103. **Maximum amount:** The Codex Standard 72-1981 does not specify a maximum, only a GUL amount for molybdenum in section 3.1.4, again in situations '*where appropriate*'. INC considers that if molybdenum is added, it shall not be more than the GUL. Although the EU regulations, both Community Directive 1999/21/EC on FSMP and the incoming Community Delegated Regulation (EU) 2016/128 on FSMP do set a maximum for molybdenum in iFSMP, INC considers this as being not mandatory to add molybdenum, and that only if added, it shall not exceed the maximum value.

104. In addition, NHMRC noted that there is insufficient information to establish an estimate for UL in infants. There are limited toxicity data in humans which may relate in part to the rapid excretion of molybdenum in urine, particularly at higher intake levels.

105. INC concludes that since both Codex and EU regulations presented that molybdenum is not a mandatory addition, with no ULs and toxicity data available for molybdenum, INC does not support the inclusion of a maximum amount of molybdenum for any infant formula product including those based on protein substitutes/non-intact protein.

Food Additives

106. Food additives play a significant role in the manufacture of infant formula products generally and including IFPSDU. For this reason, and as set out in the following response to questions, INC proposes first, a more appropriate framework for food additives and second, inclusion of all the new food additives listed for consideration in the consultation paper.

Q19 Could one category of IFPSDU be used for all additional food additives, or should additional or modified subcategories be devised (noting the possible four subcategories in section 2.2).

107. INC welcomes the FSANZ proposal to extend the current list of permissible food additives for infant formula products to enable harmonisation. This is particularly in light of the reliance of IFPSDU on harmonisation opportunities to ensure supply to the Australian and New Zealand markets.

108. INC considers that the most appropriate framework is to have **one food additive category for infant formula products**, instead of the proposed special category for IFPSDU for all additional food additives, or devised according to the sub-categories.

109. Additionally, we do not consider the status quo Standard 1.3.1, Schedule 15 is optimal. INC is proposing a change to current arrangements which will still achieve the intent and purpose, but will also facilitate innovation and harmonisation.

General comments on food additives

110. It is critical to emphasise that the use of food additives in the manufacture of formulas for infants is indispensable and unavoidable; they are essential for preserving the nutritional quality, stability and/or aiding in the manufacturing or storage of these products until the end of shelf life.

111. There are 2 main elements to regulation of food additives:
    (1) safety for the target population of infants;
    (2) technological justification
    As safety is not the issue of discussion here, INC has focussed on technological justification.

Issues with the current food additives framework

112. The framework within Schedule 15 is to limit the use of food additives depending on the food matrix (e.g. liquid vs powder) and ingredients (e.g. soy vs other plant or animal based protein, and non-intact vs intact protein). Whereas food additives are chosen for use by the manufacturer based on *a <u>combination of</u>* technical elements not necessarily limited to only the food matrix and ingredients.

113. Regulatory clarity:
    Example 1: Carrageenan is permitted for both liquid infant formula products and IFPSDU based on a protein substitute, but at a different level. It may be unclear as to which ML to apply to a liquid IFPSDU based on a protein substitute.
    Example 2: Locust bean (carob bean) gum is permitted for use in all infant formula products however a higher amount would be necessary for the proposed purpose of a thickener in an anti-regurgitation IFPSDU which may also be based on a hydrolysed protein.

Issues with FSANZ proposed revised categories / sub-categories

114. INC is unsure how it is possible that a food additive framework can align to a product categorisation framework based upon a nutritional purpose relevant to a disorder, disease or medical condition (e.g. prematurity or LBW), when the principles relating to food additive use are technological (e.g. manufacturing process, ingredients, stability, food matrix, nutrient delivery). The framework for additive permissions varies internationally, although they are based upon the common principles of safety and technological justification. The use of differing sub-categories that do not exist in other jurisdictions could limit the access of this population to appropriate nutrition.

INC proposed regulatory approach for Schedule 15

115. INC considers that the most appropriate framework for Schedule 15 would be to have **<u>one category for all infant formula products</u>**. While INC is proposing to remove the sub-categorisation that is either matrix or ingredient dependant, from Schedule 15

Category 13.1 (See Appendix A), it fully endorses the principle that the use of food additives in infant formula products should be limited to the lowest possible levels necessary to achieve the technological purpose. In addition, that appropriate optimal choice on the selection of a food additive or combinations of additives, to achieve the technological purpose, is made by the manufacturer. There has been no evidence of market failure in both these respects.

Proposed benefits to this regulatory approach

116. The proposed approach achieves the current intent of appropriate selection of a food additive at lowest possible levels to achieve the technological purpose.

117. This approach would facilitate innovation and access to overseas products whilst continuing to ensure safety. The manufacturer is well placed to determine appropriate additive selection based upon the specific combination of technological constraints. Additives with a similar technological purpose support continued innovation within the product category as new ingredients are introduced and/or other improvements are made to these products e.g. through manufacturing. Specific additives can be more effective under different product conditions.

118. The amended framework would minimise restricting access to products from other markets e.g. EU, US where the sub-categories are inconsistent with those in the FSC whilst remaining aligned to the intent.

Q20 Do you support the proposed amendments listed in Table 7 for IFPSDU at the amounts shown?

119. INC supports the proposed amendments listed in Table 7 which align to the permissions in Codex and, more particularly, to permissions in the EU. Highly specialised IFPSDU products are mostly imported and continued supply of these specialised products are essential to manage the dietary needs of this small sub-population of infants who have specific medical conditions.

120. **Acetylated distarch adipate (INS 1422)**: In 2012, INC sought permission for Acetylated distarch adipate (INS 1422) to be included in the FSC. Acetylated distarch adipate is approved internationally for use in hydrolysed protein and/or amino acid based products. INC repeats its support for alignment with Codex for inclusion of this additive in the FSC on the basis that a history of safe use has been established. Parameters are 2.5g/100ml (singly or in combination in hydrolysed protein and/or amino acid-based liquid products) as follow-up formula.

121. **Gellan gum (INS 418)**: INC requests that FSANZ consider the addition of gellan gum (INS 418) to the list of substances that may be used as a food additive in infant formula products made with partially or extensively hydrolysed protein and/or elemental amino acids (Schedule 15 Category 13.1).

122. The amount of gellan gum necessary to produce the desired technical effect in these products is up to 0.005 g/100 mL in prepared-as-directed, ready-to-consume formula.

123. Gellan gum provides technological purposes corresponding with the functional class of thickener (increases the viscosity of a food) and stabiliser (maintains the homogeneous dispersion of two or more immiscible substances in a food), as set out in Schedule 14.

International safety assessment

124. INC requests that FSANZ support the prioritisation of the re-evaluation of gellan gum by JECFA. In addition, EFSA is currently re-evaluating this food additive and an opinion is due before 30 June 2018.

Technological justification

125. Gellan gum acts as a thickener/stabiliser in ready-to-feed infant formula, or concentrated liquid products to improve physical stability through mechanisms such as maintaining homogeneity or minimising ingredient sedimentation. Gellan gum acts as a thickening or gelling agent through formation of a fluid gel. The fluid gel can aid with the sedimentation of dense components such as insoluble calcium and phosphorus salts. The gelation also provides a secondary benefit of thickening the solution viscosity, slowing the upward migration of fat, which is less dense. Gellan gum stabilises the emulsion of protein, fat and water created in the infant formula manufacturing process, minimising phase separation during storage, display and feeding. Without an ingredient added for stabilisation, infant formula would be more likely to produce insoluble sediments or creaming (separation of fat). This technical effect is particularly important to ensure infant formula is homogenous and delivers the appropriate level of all essential nutrients. Use of product that is not properly stabilised will result in suboptimal delivery of nutrients to an infant, and long-term use could result in nutrient deficiency. Infant formula products can uniquely benefit from these multifunctional properties of gellan gum.

126. Gellan gum is cold or hot water-soluble, which allows for advantageous flexibility of addition for manufacturing applications. It also has good thermal and acid stability. Full hydration of the gum occurs during thermal processing temperatures used in infant formula ensuring desired effectivity of the stabiliser. The elasticity of the gel obtained from gellan gum is adjustable based on presence of ions, pH, or temperature. Therefore, gellan gum can be adapted to improve the physical stability of a variety of nutritionally complete, low viscosity formulas. Another benefit of gellan gum is that it does not influence the efficacy of the other components, particularly the vitamins and minerals in the formulation. Thus, gellan gum is compatible with formulation processing, allowing the minimum undesirable impact on the ingredients and during subsequent storage.

Q21 Can you provide information on suitable international safety assessment, a demonstrated history of safe use in the context of IFPSDU, and a technological justification for:

a) Calcium carbonates
b) Calcium citrates
c) Phosphoric acid
d) Sodium alginate
e) Xanthan gum
f) Locust bean (carob bean) gum
g) Pectins
h) Sodium carboxymethylcellulose
i) Sucrose esters of fatty acids
j) Starch sodium octenylsuccinate

127. ***Calcium carbonates***: INC considers that calcium carbonates could be used as either a food additive (technological purpose of acidity regulators) as in the EU or as permitted forms of calcium in the manufacture of foods including infant formula as currently permitted by Schedule 29.

International safety assessment

128. Calcium carbonates are permitted calcium forms in Standard 2.9.1 when used for nutritional purposes. This is also the case with international regulations including EU and Codex. Calcium carbonates are a permitted form for nutritional purposes in the *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* (CAC/GL 10-1979). As such this evidences safety for the target population of infants.

Technological justification

129. There could be several functions for this food additive in infant formula products. In acidic condition, it will solubilise and increase the pH. In the case of slightly acidic products or during particular processing steps with pH 6 and lower, this compound will begin to slowly solubilize (dissociate) – the lower the pH, the higher the dissociation, and these dissociated carbonate ions will contribute to the chemical equilibrium by increasing the pH and provide some buffer capacity to the final product. In such conditions calcium carbonate can be classified as an acidity regulator. It will therefore act as buffering agent in this situation. It can also be used as anticaking agent in some raw materials. Calcium carbonates (as insoluble salts) may also function to provide calcium in an insoluble way that it cannot interact with milk proteins and induce protein flocculation during the heat treatments.

130. ***Calcium citrates***: INC considers that calcium citrates could be used as either a food additive (technological purpose of acidity regulators) as in the EU or as permitted forms of calcium in the manufacture of foods including infant formula as currently permitted by Schedule 29.

International safety assessment

131. Calcium citrates are permitted calcium forms in FSC 2.9.1 when used for nutritional purposes. This is also the case with international regulations including EU and Codex. Calcium citrates are permitted forms for nutritional purposes in the *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* (CAC/GL 10-1979). As such this evidences safety for the target population of infants.

Technological justification

132. There could be several functions for this food additive in infant formula products. In acidic condition, it will solubilise and increase the pH. In the case of slightly acidic products or during particular processing steps with pH 6 and lower, this compound will begin to slowly solubilise (dissociate) – the lower the pH, the higher the dissociation, and these dissociated citrate ions will contribute to the chemical equilibrium by increasing the pH and provide some buffer capacity to the final product. In such conditions calcium citrate can be classified as an acidity regulator. It will therefore act as buffering agent in this situation. Calcium citrates (as low soluble salts) may also function to provide calcium

in an insoluble way that it cannot interact with milk proteins and induce protein flocculation during the heat treatments.

133. ***Phosphoric acid***: INC supports the continued availability of phosphoric acid for infant formula products.

International safety assessment

134. Phosphoric acid (E 338; INS 338) is approved for use in the EU in infant formulas and in FSMP as an acidity regulator. Phosphoric acid is already permitted under Standard 1.3.3 "Processing aids" for all foods, which includes infant formula products. The level of Phosphorus is well controlled as there is a maximum value in Standard 2.9.1 for Phosphorus and the Ca:P ratio is also regulated.

Technological justification

135. Phosphoric acid is a pH adjuster typically used during the course of manufacturing. One example of use, is that Phosphoric acid is used to acidify at low pH solutions containing milk protein ingredients before the heat treatment in order to prevent the aggregation and coagulation of milk proteins during the heat treatment (Bernal and Jelen 1985). No phosphoric acid remains in the final product because it is quantitatively transformed in phosphate salts due to the final pH of products and the presence in all of them of important concentrations of several reactive cations (Ca, Mg, Na, K, Na, K, Fe, etc.).

136. ***Sodium alginate:*** INC supports inclusion of sodium alginate for infant formula products.

International safety assessment

137. The EC Scientific Committee for Food (SCF) considers that the use of sodium alginate is acceptable up to a level of 1g/l in FSMP used from 4 months of age onwards. The SCF has already recommended sodium alginate is acceptable as an additive in weaning foods for infants and young children in good health, for use in desserts and puddings at levels up to 0.5g/kg. It is permitted for these uses under Annex VI of Directive 95/2/EC.

138. Sodium alginate is permitted in the FSC as a food additive in liquid milk to which phytosterols, phytostanols and their esters have been added.

Technological justification

139. Sodium alginate is the sodium salt of alginic acid. Sodium alginate is extracted from the cell walls of brown algae. It is used as a food additive for its thickening, stabilising and emulsifying properties.

140. ***Xanthan gum***: INC requests that FSANZ consider the addition of xanthan gum (INS 415) to the list of substances that may be used as a food additive in infant formula products. This food additive is typically used for partially or extensively hydrolysed protein and/or elemental amino acids.

141. The amount of xanthan gum required to produce the desired technical effect in these products is up to 0.1 g/100 mL in prepared-as-directed, ready-to-consume formula.

142. Xanthan gum provides technological purposes corresponding with the functional classes thickener (increases the viscosity of a food), and stabiliser (maintains the homogeneous dispersion of two or more immiscible substances in a food), as set out in Schedule 14.

International safety assessment

143. At JECFA 82 in June 2016, the JECFA assessment of xanthan gum, which included a review of safety for infants between 0-12 weeks of age, concluded that the intake of xanthan gum in infant formula or formula for special medical purposes intended for infants is of no safety concern at the maximum proposed use level of 1000 mg/L (0.1 g/100 mL) ready to consume formula. The JECFA review process included a comprehensive assessment of technological data for xanthan gum in the Chemical and Technical Assessment (CTA).

Technological justification

144. Xanthan gum is a food additive for use as a thickener/stabiliser in formulas made with partially or extensively hydrolysed protein, or free amino acids. Use of a thickening agent in these types of powder formulas increases viscosity once reconstituted. Protein hydrolysis often yields a reduction in viscosity, and in infant formulas made with hydrolysed proteins, thickener and stabiliser ingredients are used to improve product quality. Xanthan gum builds viscosity in the reconstituted formula matrix and helps to stabilize the emulsion of hydrolysed protein or free amino acids, fat and water. Minimizing phase separation is particularly important to ensure infant formula is uniform and delivers the appropriate level of all essential nutrients. Use of product that is not properly stabilised will result in suboptimal delivery of nutrients to an infant, and long-term use could result in nutrient deficiency.

145. Additionally, similar to the beneficial effect on infant tolerance by feeding a formula thickened with starch, non-intact protein-based formulas thickened with xanthan gum can help to reduce spit-up and regurgitation after ingestion of the formula.

146. Xanthan gum can be used at relatively low levels to achieve significant viscosity without gelling. Xanthan gum is easily hydrated with relatively low temperature water, which makes it ideal for use in infant formula powders that are typically reconstituted with room temperature, previously boiled water. Xanthan gum also is suitable for use in dry-blended infant formulations. As xanthan gum is carbohydrate-based and is derived from a source that is typically not associated with allergenicity, inclusion of xanthan gum in non-intact protein based formulae as a thickening agent presents minimal risk of allergenicity or sensitization potential.

147. ***Locust bean (carob bean) gum***: INC requests that FSANZ consider the increase of MPL to 10,000 mg/kg relating to locust bean (carob bean) gum (INS 410) currently permitted as a food additive for infant formula products in Schedule 15.

International safety assessment

148. Locust bean gum is permitted in the FSC as a food additive in infant formula products and infant foods. As such it is safe for the target population of infants. Such products containing locust bean gum have been on the market since the 1990s with no safety concerns. EFSA further endorsed the conclusions of the Scientific Committee on Food

(from 2003) (European Commission Health and Consumer Protection Directorate General, Directorate C) which accepted that there is a need for use of locust bean gum in dietary foods for special medical purposes for therapeutic use in a small number of infants with gastro-oesophageal reflux disease under medical supervision.

149. Locust bean gum is currently permitted in the EU in the following Foods for Special Groups:

	Category name	Maximum limit (mg/kg)	Remarks
13.1.2	Follow-on formulae as defined by Directive 2006/141/EC	1 000	If more than one of the substances E 407, E 410 and E 412 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	10 000	only processed cereal based foods and baby foods
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	20 000	only gluten-free cereal-based foods
13.1.4	Other foods for young children	10 000	E 410, E 412, E 414, E 415 and E 440 are authorised individually or in combination
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants (infant FSMP)	10 000	From birth onwards in products for reduction of gastro-oesophageal reflux
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	10 000	From birth onwards in products for reduction of gastro-oesophageal reflux

Technological justification

150. Locust bean gum (INS 410) can be used as a thickener, stabiliser, emulsifier and gelling agent. In the EU, locust bean gum is permitted at up to 10,000 mg/kg for infant formula products relating to reduction of gastro-oesophageal reflux. Locust bean gum is used in infant formula at higher levels of 5–10 g/L as a thickening agent in FSMPs for bottle

feeding to provide clinically effective dietary management of gastroesophageal reflux (GER). These levels provide acceptable thickening properties for bottle feeding and clinical efficacy through dietary management. In general, thickening agents act upon contact with the acidity (i.e. of the stomach) by thickening and increasing the viscosity of the alimentary bolus, thus making it possible to avoid the refluxes by gravitational effect (Balabaud and Loones, 1995).

151. The main advantages of locust bean gum are that it has the capacity to form viscous solutions in relatively low concentrations, which are almost unaffected by pH, or temperature, making it particularly suitable in the context of infant formula applications. Locust bean gum used in infant formula products also does not alter the taste of the product and considering it is made up of non-digestible polysaccharides it does not add additional energy to the overall infant formula product. Locust bean gum is demonstrated in applications for use in infant formula products to give adequate thickening properties between 0.3-1% in liquid infant milk formula (i.e. 3-10 g/l) (Balabaud and Loones, 1995). Below 0.3% (3 g/l) in reconstituted liquid preparations, the thickening effect is insufficient, while above 1% (10 g/l) a more gelled product is obtained which is less adapted for consumption through the teat hole in bottle-fed infants.

152. ***Pectins***: INC requests that FSANZ consider the addition of pectin (INS 440) to the list of substances that may be used as a food additive in infant formula products with a non-intact protein base.

153. The amount of pectin required to produce the desired technical effect in these products is up to 0.2 g/100 mL in prepared-as-directed, ready-to-consume formula.

154. Pectin provides technological purposes corresponding with the functional classes thickener (increases the viscosity of a food), and stabiliser (maintains the homogeneous dispersion of two or more immiscible substances in a food), as set out in Schedule 14.

International safety assessment

155. At JECFA 82 in June 2016, JECFA's assessment of pectin, which included a review of safety for infants between 0-12 weeks of age, concluded that the intake of pectin in infant formula or formula for special medical purposes intended for infants is of no safety concern at the maximum proposed use level of 0.2% (0.2 g/100 mL) ready to consume in formula. The JECFA review process includes a comprehensive assessment of technological data for pectin in the section Chemical and Technical Assessment.

Technological justification

156. Pectin is a food additive for use as a thickener and stabiliser in formulas for infants. Infant formula manufacturing may be influenced by factors such as heat treatment, acidity, product form (liquid or powder) and compositional factors (e.g. whey proteins and other constituents). Manufacturing conditions can affect protein denaturation, aggregation, and sedimentation. In typical processing operations, for example, heating will result in formation of sedimentable protein aggregates composed of both denatured and non-denatured proteins. Pectin addition minimises protein agglomeration and sedimentation during thermal processing, and over the shelf life. Thermal processes can also substantially impact the stability of emulsions.

157. With the addition of pectin, whey protein-pectin complexes are adsorbed to the emulsion interface, leading to the formation of stable emulsions (stabiliser) which help maintain product homogeneity during shelf life. Finally, pectin also provides increased viscosity (thickener) in the formula matrix, which serves to minimise product separation and maintain homogeneity during shelf life. The level selected to use in product is the minimum required to achieve the desired physical properties throughout shelf life.

158. ***Sodium carboxymethylcellulose***: INC requests that FSANZ consider the addition of sodium carboxymethylcellulose (E466) to the list of substances that may be used as a food additive in infant formula products with a non-intact protein base.

International safety assessment

159. As described in the 35th report of JECFA, safety studies conducted with sodium carboxymethylcellulose (INS 466) showed no evidence of mutagenicity, carcinogenicity, or developmental effects. These long-term studies showed that sodium carboxymethylcellulose (and other modified celluloses) are of low toxicity in general, and thus, based on available data, an Acceptable Daily Intake "not specified" was assigned to these compounds. The ingredient has low bioavailability and the lack of any effects in developmental toxicity studies, and a lack of adverse outcomes in general with its use has been demonstrated in older populations. An EFSA re-evaluation of sodium carboxymethylcellulose is in progress and is due to be completed by the end of 2017. This evaluation should include the <12 weeks age-group as sodium carboxymethylcellulose is permitted for FSMP for infants.

Technological Justification

160. Development of physically stable nutritional products is challenging when high levels of insoluble ingredients, like mineral salts, are incorporated. These characteristics can result in mineral fallout (resulting in sedimentation) and defects in emulsion stability (with results such as phase separation and foaming). These issues in turn can result in significant challenges to both manufacturing of these products and the optimal delivery of nutrition for infants consuming these products. Sodium carboxymethylcellulose functions as a thickener and an emulsification stabiliser to prevent these negative characteristics in these products.

161. ***Sucrose esters of fatty acids***: INC requests that FSANZ consider the addition of sucrose esters of fatty acids to the list of substances that may be used as a food additive in infant formula products.

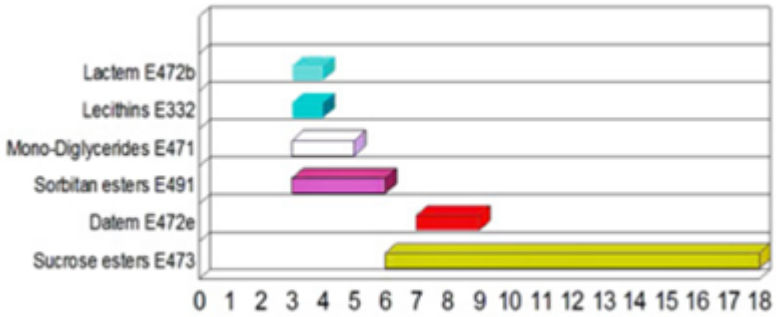
International safety assessment

As described in the 49th report of JECFA, safety studies conducted with sodium sucrose esters of fatty acids (INS 474) showed no evidence of toxicity. This long-term study supported previous studies showing sucrose esters of fatty acids are of low toxicity in general. JECFA also considered data from tolerance studies in humans, and despite limitations of those studies (single dose evaluated, low number of subjects), JECFA used concerns about possible laxative effects as a basis for determining an Acceptable Daily Intake (ADI) of 30 mg/kg body weight for sucrose esters of fatty acids.

Technological justification

162. Sucrose esters of fatty acids are emulsifiers with special properties. Emulsifiers are characterised by their hydrophilic-lipophilic balance (HLB). An emulsifier with a low HLB

is oil soluble and an emulsifier with a high HLB is water soluble. The following chart provides an overview of commercially available emulsifiers, their e-numbers and their HLBs:



Source: *https://www.newfoodmagazine.com/news/20581/sucrose-esters-specialty-emulsifiers/*

163. Infant formula products have a low viscosity, and as with other low viscosity beverages, emulsion stability is important for creating homogenous products which in turn is important for both the manufacturing of these products and the stability of these products. Emulsion stability is dependent on the size of oil droplets and the properties and power of the emulsifier. Sucrose esters of fatty acids have the ability to emulsify oil in low viscous liquids. Their applications in infant formula products include emulsification of long chain polyunsaturated fatty acids and stabilisation of products made from non-milk protein sources. Lack of homogeneity of infant formula products (either during production or finished product stability) can result in inaccurate delivery of nutrition to infants, which rely on these products as a sole source of nutrition. Sucrose esters of fatty acids are a unique category of high quality, non-ionic emulsifiers, which provide an important function to certain formulations. In addition to emulsification, sucrose esters of fatty acids have additional functions such as starch interaction, protein interaction, sugar crystallization and aeration.

I

164. ***Starch sodium octenylsuccinate***: INC supports the inclusion of Octenyl succinic acid (OSA)–modified starch (starch sodium octenyl succinate) (INS 1450) for infant formula products as it is now included in Codex STAN 72-1981 following the agreement at CCNFSDU36 (November 2014) and confirmed by CAC38 (July 2015).

International safety assessment

165. JECFA79 concluded that the consumption of OSA modified starch in infant formula or formula for special medical purposes intended for infants is not of concern at concentrations up to 20 g/l.

Technological justification

166. OSA-modified starch is used in infant formula products for its emulsification properties both during processing and after reconstitution, and its function in reducing free fat formation and oxidation. It is uniquely effective with extensively hydrolysed protein and free amino acid formulas, and does not contain allergenic protein.

Q22 Are there any technologically justified concerns with changing the permissions for citric and fatty acid esters of glycerol (472c) to:

a) MPL of 9000 mg/L for liquid products
b) MPL of 7500 mg/L for powdered products?

167. INC supports the proposed change to the MPL for citric and fatty acid esters of glycerol (472c) for liquid products. While aligned to Codex, we would query the units used for the MPL for powdered products of 'mg/L' suggesting that the MPLs apply to the powdered products as prepared for consumption. It then makes no sense to have an MPL for one liquid product and a different MPL for an equivalent liquid product when reconstituted. INC queries if the units of measure is mg/L, that both should be consistent as 9000 mg/L.

Q23 What is the technological justification for the use of diacyltartaric and fatty acid esters of glycerol (472e) in IFPSDU? Are there any technologically justified concerns with the removal of this permission?

168. INC does not support removal of this permission. **Diacyltartaric and fatty acid esters of glycerol** (472e) use in IFPSDU is based on protein substitute and may be added to help aid emulsification when formulas based on a protein substitute are reconstituted. INC supports continued permission for this food additive for infant formula products, as the manufacturer should have access to the most appropriate food additive for the infant formula product.

Safety
Potential Renal Solute Load

Q24 Do you support retaining the current maximum PRSL for any IFPSDU? Please provide your rationale

169. INC continues to oppose retention of the current provisions relating to PRSL for any infant formula product and for any IFPSDU. As noted earlier in this submission, the PRSL is the sum of dietary nitrogen, sodium, potassium, chloride, and phosphorus. Its relevance for protein substitutes was due to a permitted higher maximum for protein. If the protein parameters are adjusted to follow the same compositional approach as all other products for special dietary use, then PRSL is not required for a starter specialty product as the protein maximum defaults to the general-purpose norm of 0.7g/100kJ. Similarly, as protein maximum levels will be reduced in the revised Codex follow-up Standard, INC considers that PRSL will not be required for follow-up formula specials.

170. INC has stated in the past that it is not aware of any evidence to support the inclusion of the PRSL with regard to minimising dehydration illness in Australia or New Zealand. As stated before, there is very limited published evidence in the international literature in the past 20 years concerning PRSL. This suggests that there has been no issue globally on this point. There is no provision for PRSL for follow-up formula in Codex.

171. In the absence of evidence of use, and taking a range of other factors into account as described below, INC considers the PRSL should be removed.

172. Protein is the major contributor to PRSL (Ziegler & Fomon 1989). Currently the maximum permitted levels for protein in follow-on formula are aligned between Standard 2.9.1 and Codex at 1.3g per 100kJ. Therefore, little or no variation in PRSLs would be expected in formulas that have been formulated to Codex and Standard 2.9.1. Other factors that can affect the PRSL include sodium, chloride, and potassium. The maximum permitted level for sodium in Codex is higher (21mg per 100kJ) than in the FSC (15mg per 100kJ).

Codex does not include maximum values for either chloride or potassium with regards to follow-on formula. Therefore, a Codex formulation is more likely to be higher in PRSL than a formula made to Standard 2.9.1 based on these compositional parameters. This supports the removal of the PRSL as an unnecessary restriction, from Standard 2.9.1.

173. With the trend in recent years for the protein content of infant formula products to be lowered to more closely align to protein levels in breast milk, the PRSL has become less important clinically, as high solute loads are not being provided. An example here would be with the extensively hydrolysed protein infant formula Alfare, mentioned in P93 as having a declared protein of 2.5g/100ml in the early 2000s, decreased now to 2.0g/100ml in 2017, significantly reducing its PRSL and making regulation in this area redundant.

Contaminant MLs

174. ***Arsenic:*** INC agrees with FSANZ that there is no evidence of a public health and safety issues for arsenic levels in hydrolysed rice protein-based infant formulas in the Australia and New Zealand market. We agree with the conclusion that there is no need to amend the Code to include a limit for arsenic in IFPSDU. Should there be a need to consider an ML for inorganic arsenic (for rice that may be used as an ingredient in infant formula) we would support a separate Proposal at a later time if sufficient scientific basis for an ML exists.

175. ***Mycotoxins:*** INC agrees with the FSANZ conclusions for aflatoxins and ochratoxin A, that introducing new MLs for aflatoxin in infant formula is not necessary and ochratoxin A has not been detected in Australia, is generally found only at low levels overseas and there is no scientific basis for an ML.

176. ***Polycyclic aromatic hydrocarbons***: INC notes that there is no data on levels of PAH in IFPSDU or infant formula more generally in Australia or New Zealand and that there is therefore no scientific basis for an ML.

177. ***Cadmium***: INC agrees with FSANZ that new MLs for cadmium are not justified.

178. ***Aluminium:*** In 2012, INC was strongly of the view that any new contaminant limit should be based upon risk. We noted that aluminium could occur in infant formula as a result of its natural occurrence in ingredients (from the environment), or leaching from food contact materials but we also noted that aluminium had been re-evaluated by JECFA in 2012. While JECFA revised the Provisional Tolerable Weekly Intake (PTWI) for aluminium upwards to 2 mg/kg-bodyweight (JECFA 2012), we also noted that a Cochrane review of the safety of soya-based infant formulas concluded that whilst aluminium levels may be higher in soy-based infant formula, there was no published evidence of a negative health effect of aluminium in full-term infants fed modern soy-based infant formula (Vandenplas *et al* 2014).

179. INC noted that there were three typical packaging materials that contain aluminium:
    - aluminium foil (by itself or as a layer of a laminate)
    - metalised (aluminium deposited on a substrate)
    - aluminium oxide (in high barrier packaging)

180. Of the three typical packaging materials that contain aluminium (aluminium foil, metalised aluminium and aluminium oxide), the only infant formula packaging material in contact with infant formula was foil and the aluminium in foil was in a fixed state such that aluminium molecules **would not transfer to the infant formula**.

181. We note that FSANZ reported that some submitters were concerned that if the aluminium ML may be removed, this would present risks to premature infants who have reduced renal function. No evidence has been provided that this risk exists and INC has failed to identify any evidence that would justify disharmony with the rest of the world in this area.

182. INC restates its view that Standard 2.9.1 should align with Codex which does not include limits on aluminium as a contaminant metal in infant formula (Codex STAN 193-1995). The EU does not list aluminium as a contaminant metal in infant formula (nor any foods) (Commission Regulation (EC) No 1881/2006). In the US, limits for aluminium as a contaminant metal in infant formula are also not included (CFR, Chap 21, parts 106 & 107).

Labelling

183. Throughout this submission we have repeatedly stated that the vast majority of IFPSDUs used in Australia and New Zealand are imported in small, specialist quantities for use under medical supervision. Supply of IFPSDU is especially critical for these vulnerable populations. For this reason, more flexibility is sought in relation to labelling that recognises use by specialists or under HCP advice and for most use in the hospital environment. This position is expanded on response to questions Q25-Q30. In general, INC does not support prescribed names, prescribed warning statements and prescribed preparation. We support however regulating the intent. INC does not support prescribing a name for IFPSDU nor for sub-categories of product. INC considers that to do so would unnecessarily constrain compliance of a category of products that are almost all imported. Internationally, while such products are described, names are not prescribed and neither should they be for Australia or New Zealand This is expanded on in these last questions.

Q25 To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?

184. In Australia, there are two categories of preterm infant formula available, those designed primarily for use in hospital (preterm formula) and those designed for use post-discharge (post-discharge pre-term formulas) which differ in their macronutrient and micronutrient composition, as well as total energy. Generally, the preterm infant formula energy is ~ 24kcal strength per 30ml, with the post-discharge pre-term formula being ~ 22kcal and term infant formula ~ 20kcal, reflecting the different energy needs of the consuming population.

185. In Australia, post-discharge pre-term formulas are available via a home delivery service requiring healthcare professional registration of patients or at selected pharmacies (responsible institutions). Post-discharge pre-term formula is not currently available as a pharmaceutical benefits scheme prescription in Australia, however, in New Zealand, the Pharmac schedule permits subsidy of post-discharge pre-term formulas if the infant meets certain criteria.

186. Currently, preterm formula products in Australia and New Zealand are sold to hospitals and there is no subsidy provided for use after hospital discharge. There is also no general sale currently for these products, via either manufacturers or pharmacies. It is conceivable that the ongoing push towards earlier hospital discharge could lead to a situation where preterm infant formula may be required in the community under medical supervision. If that was to occur, then accessibility via responsible institutions could take place as it does for post-discharge pre-term formulas currently.

Q26 Would you support the requirement for a statement that the product must be used under medical supervision, where the wording is not prescribed (an approach which harmonises with the overseas and international requirements)? Please describe your reasons why you do/do not support?

187. INC supports a requirement that the product should be used under medical supervision so long as the wording is not prescribed to support harmonisation.

Q27 Are there any specific FSMP labelling requirements that you consider applicable to a particular type of IFPSDU?

188. INC would like a harmonised labelling approach between all sub-categories, with a few exceptions. INC supports the current status quo excluding the warning statement "Breast milk is best for babies" (Standard 2.9.1, 19 (1) d) relating to the sub-categories for products for less serious and products for serious disease, disorder or medical condition. INC considers however that this warning statement is still applicable for products for prematurity or low birth weight infants. Additionally, whilst INC supports regulating the status quo in relation to the breastfeeding notice, for products that fall under the prematurity or low birth weight sub-category, the wording should be un-prescribed.

Q28 Are there any specific FSMP labelling requirements that should apply to all IFPSDU?

189. In general, INC considers quite a number of FSMP elements are duplicated already in Standard 2.9.1. While the labelling elements from Standard 2.9.5 are not 'duplicated' *exactly*, we consider 'duplication' has respected the labelling intent of that Standard.

    For example - IFPSDU for preterm and low birthweight infants and products for metabolic, immunological, renal, hepatic and mal-absorptive conditions are already required to label that the products must be used under medical supervision. In addition, the labelling of products for metabolic, immunological, renal, hepatic and mal-absorptive conditions already require a statement that indicates that the formula is suitable for a particular condition and what that condition, disease or disorder is, along with a statement indicating the nutritional modifications made to the product. INC supports maintaining these labelling provisions.

190. In terms of any specific FSMP labelling requirements from Standard 2.9.5 not currently 'duplicated' or captured by Standard 2.9.1 –

    INC **supports** introduction of the following from Standard 2.9.5 to apply to IFPSDU for infants regulated by Standard 2.9.1:

    - *(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (*However optional application, not mandated.)
    - *the words 'Expiry Date', or similar words, may be used on the label.*

    INC is **not opposed to**:

    - *(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food*

    INC **DOES NOT support**:

    - *a statement to the effect that the food is not for parenteral use;*

- *a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the food, as appropriate.*

191. **In addition to** the consideration of applicable Standard 2.9.5 labelling requirements – INC supports **removing the prescription of wording that applies to IFPSDU**. Whilst INC agrees with the intent of the prescribed wording relating to medical supervision, the use of such prescription could restrict trade due to products being imported from overseas that have met international labelling provisions. INC also has concerns in relation to the additional prescribed wording under 2.9.1—19. INC agrees with the intent of the warning statements and directions listed, however INC supports removing the requirement for prescribed wording to be used to allow for flexibility and to remove, where possible, duplication of labels for products coming from overseas, especially in the context of Australia and New Zealand being seen as a very small market for such specialised products.

    Note that INC does not support retaining the prescribed requirement to label "pre-term" as part of the name of the food for products relating to prematurity or low birth weight as we consider the proposed expansion of the regulatory requirement to label for the disorder, disease, or medical condition to all sub-categories already addresses this. In the example of preterm, for another market the product may be labelled "for Premature Infants" which follows the same intent of the requirements under Standard 2.9.1, however would not be compliant for the Australian or New Zealand markets.

Q29 What specific labelling requirements for the safe preparation and use of IFPSDUs are being used that contradict the general requirements set out in subsection 2.9.1—19(3) of Standard 2.9.1?

192. INC considers that the existing Standard 2.9.1, 19 (3) is compatible for both infant formula products for healthy infants, and IFPSDU current products relating to those for sole or principle sources of nutrition. As such we consider there is no contradictions for safe preparation and use as the current requirements are broad enough to accommodate both categories.

Q30 What evidence can you provide to support concerns regarding inappropriate access to any IFPSDU?

193. INC is not aware of any evidence to support concerns regarding inappropriate access to any IFPSDU. At the same time, INC is open to support trade and distribution restrictions consistent to that of Standard 2.9.5 for 2 sub-categories **only** (sub-category 1 – Products for prematurity and LBW infants, and sub-category 3 – Products for serious disorders, diseases and medical conditions).

References

Bernal V, Jelen P. (1985). Thermal Stability of Whey Proteins – A Calorimetric Study. *Journal of Dairy Science*. 68:2847–2852. DOI:10.3168/jds.S0022-0302(85)81177-2

Braamskamp MJ, Dolman KM, Tabbers MM (2010) Clinical practice: Protein-losing enteropathy in children. Europe Journal of Paediatrics, 2010 Oct 169(10): 1179-85. doi:10.1007/s00431-010-1235-2

Corvaglia, L., Aceti, A., Mariani, E., De Giorgi, M., Capretti, M. G. and Faldella, G. (2011), The efficacy of sodium alginate (Gaviscon) for the treatment of gastro-oesophageal reflux in preterm infants. Alimentary Pharmacology & Therapeutics, 33: 466–470. doi:10.1111/j.1365-2036.2010.04545.x

Dey A, Wang H, Menzies R, Macartney K. (2012) Changes in hospitalisations for acute gastroenteritis in Australia after the national rotovirus vaccination program. *Medical Journal of Australia* 2012; 197(8):453-57.

Flodin NW (1990) Micronutrient supplements: Toxicity and drug interactions. *Progress in Food & Nutrition Science* 14:277–331.

Forum on Food Regulation. *Policy Guideline on Infant Formula Products*.

Hathcock JN (1997) Vitamins and minerals: Efficacy and safety. *American Journal of Clinical Nutrition* 66:427–437.

Høst A, Halken S. (2004) Hypoallergenic formulas--when, to whom and how long: after more than 15 years we know the right indication! *Allergy* 2004 Aug;59 Suppl 78:45-52.

Kolezko B, Baker S, Cleghorn G, Neto UF, Goplan S, Hernell O, Hock QS, Jirapinyo P, Lõnnerdal B, Penchaz P, Pzyrembel H, Ramirez-Mayans J, Shamir R, Turck D, Yamashiro Y, Zong-Yi D. (2005) Global Standard for the Composition of Infant Formula: Recommendations of an ESPGHAN Coordinated International Expert Group. *Journal of Pediatric Gastroenterology and Nutrition*, Vol. 41(5): 41:584–599.

Vandenplas Y, Marchand J, Meyns L. (2015) Symptoms, Diagnosis, and Treatment of Cow's Milk Allergy. Current paediatric Review 2015;11(4):293-7

Vandenplas Y. (2017) Prevention and Management of Cow's Milk Allergy in Non-Exclusively Breastfed Infants. *Nutrients* 2017 Jul 10;9(7). pii: E731. doi: 10.3390/nu9070731.

Ziegler EE and SJ Fomon “Potential renal solute load of infant formulas” in Journal of Nutrition Dec 1989, (12 Suppl) 119:1785-88.

APPENDIX A

AMENDED SCHEDULE 15 AS PROPOSED BY INC FRAMEWORK FOR FOOD ADDITIVES

[1] Amend Schedule 15 to remove categorisation approach and duplications of food additives, retain less restrictive MPL based on safety

PROPOSED AMENDMENTS to Schedule 15

Permissions for food additives			
INS (if any)	*Description*	*MPL*	*Conditions*
13	**Special purpose foods**		
13.1	***Infant formula products***		
270	Lactic acid	GMP	
304	Ascorbyl palmitate	10 mg/L	
307b	Tocopherols concentrate, mixed	10 mg/L	
322	Lecithin	5 000 mg/L	
330	Citric acid	GMP	
331	Sodium citrate	GMP	
332	Potassium citrate	GMP	
410	Locust bean (carob bean) gum	1 000 mg/L	
412	Guar gum	1 000 mg/L	
471	Mono- and diglycerides of fatty acids	4 000 mg/L	
526	Calcium hydroxide	GMP	
~~13.1.1~~	~~Soy-based infant formula~~		
~~1412~~	~~Distarch phosphate~~	~~5 000 mg/L~~	
~~1413~~	~~Phosphated distarch phosphate~~	~~5 000 mg/L~~	~~Section 1.3.1—6 applies~~
~~1414~~	~~Acetylated distarch phosphate~~	~~5 000 mg/L~~	~~Section 1.3.1—6 applies~~
~~1440~~	~~Hydroxypropyl starch~~	~~25 000 mg/L~~	~~Section 1.3.1—6 applies~~
~~13.1.2~~	~~Liquid infant formula products~~		
~~407~~	~~Carrageenan~~	~~300~~	
~~13.1.3~~	~~Infant formula products for specific dietary use based on a protein substitute~~		
407	Carrageenan	1 000 mg/L	
471	Mono- and diglycerides of fatty acids	5 000 mg/L	
472c	Citric and fatty acid esters of glycerol	9 000 mg/L	
472e	Diacetyltartaric and fatty acid esters of glycerol	400 mg/L	
1412	Distarch phosphate	25 000 mg/L	
1413	Phosphated distarch phosphate	25 000 mg/L	Section 1.3.1—6 applies
1414	Acetylated distarch phosphate	25 000 mg/L	Section 1.3.1—6 applies
1440	Hydroxypropyl starch	25 000 mg/L	Section 1.3.1—6 applies
xxx	*Add new proposed additives here*	..... mg/L	

[2] In terms of food additive levels and optimal choice and selection of a food additive appropriate for use – INC fully endorses the principle that the use of food additives in infant formula products should be limited to the levels necessary to achieve the technological purpose. In addition, that appropriate optimal choice on the selection of a food additive, or combinations of additives, to achieve the technological purpose, is made by the manufacturer. There has been no evidence of market failure in both these respects.