CALL FOR SUBMISSIONS – PROPOSAL P1028 INFANT FORMULA

Submission from the Australia New Zealand Infant Nutrition Council

17 June 2022

Executive Summary

1. INC welcomes the opportunity to consider the issues and views proposed in this first Call for Submission – Proposal P1028 Infant Formula (the "**CFS**"), and to provide comment and information to Food Standards Australia New Zealand ("**FSANZ**") on the Regulation of Infant Formula.

2. INC believes that breast feeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breastmilk the only suitable and safe alternative is a scientifically developed infant formula.

3. To ensure the best possible nutrition for non-breastfed infants, policy and regulatory instruments must ensure a balance between restrictions on use and formulation in order to protect public health and provide flexibility and incentive for innovation for continuous improvement of infant formulas.

4. Our key concerns, relate to the following:

5. INC does not support the modified category. The few products identified for this category are in the main not in the market and the category would therefore be delivering very little for consumers or industry.

6. INC supports the Special Medical Purpose Products for Infants ("**SMPPi**") proposal but ONLY for infant formula products and not for any other partial products, especially highly specialised products from Standard 2.9.5 and bovine human milk fortifiers on the basis that:
   - partial products are NOT infant formula products in so far as they are not complete nor principal sources of nutrition for infants – infant formula products that are complete or principal sources of nutrition for infants are the building blocks for Standard 2.9.1
   - partial products do not comply with the Policy Guideline for infant formula products
   - some of these products are beyond the scope of P1028.

7. The SMPPi category as a component of P1028 was only introduced at this CFS1 stage and has not been subject to previous consideration. The risk of getting this wrong is too high a public health risk for those very few infants that might need the products.

8. INC believes these partial products must remain under Standard 2.9.5 and FSANZ should raise a separate proposal to allow for full and thorough consideration of impacts and consequences.

9. INC strongly opposes turning the clock back two decades in relation to L(+) lactic acid producing microorganisms and requiring all except those for acidification to have pre-market approval. This would take products off the shelf in Australia and New Zealand, could impact IF supply (potentially creating shortages similar to the current US situation) and impact New Zealand and Australian export markets since our customers offshore look to our domestic product/market for comfort on what they are putting on their shelves.

10. INC is not generally supporting prescribed permitted protein sources.

11. INC is supporting a more regularised Nutrition Information Statement ("**NIS**") but not the extent of prescription proposed for the NIS and labelling generally.

12. INC is broadly supportive of the majority of micronutrient and macronutrient proposals and where this is not the case has provided detailed reasons for other options.

13. INC identified major issues with the costs and benefits. Most significantly is the fluid basis for numbers of products and the belief that changes will always be one off for each of composition and labelling. Member companies are likely to provide further data for this section on a commercial-in-confidence as they have done in the past. INC also recommends FSANZ conducts an industry survey of SKUs separate to the CFS1.

14. Finally, transition will be a major factor in minimising cost as FSANZ has identified. INC recommends a 5 year transition plus a 2 year stock-in-trade period.

Introduction

1. INC welcomes the opportunity to consider the issues and proposed in this this first Call for Submission – Proposal P1028 Infant Formula and to provide comment and information to FSANZ on the Regulation of Infant Formula.

2. 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.

3. To ensure the best possible nutrition for non-breastfed infants, policy and regulatory instruments must ensure a balance between restrictions on use and formulation in order to protect public health, and providing flexibility and incentive for innovation for continuous improvement of infant formulas.

4. INC considers that the key elements in policies and regulations governing infant formula must allow for:

   - consistency with the policy objectives outlined in other food-related policy decisions
   - the provision of a safe and nutritious food
   - a scientific, evidence-based approach which does not unnecessarily restrict the use of ingredients considered to be safe for use in general foods in infant formula
   - flexible provisions in the food regulations, with minimal levels of prescription and complexity, to facilitate innovation and continuous improvement of infant formula to promote health and wellbeing of infants
   - sufficient information to support informed choice by consumers enabling them to select products which are suitable to the dietary needs of their non-breast-fed infant
   - clarity of requirements to facilitate compliance to and enforceability of the Standard,
   - ready access to infant formula products to avoid public health consequences caused by being either not available or difficult to source, and
   - cost effectiveness to minimise the potential burden on industry and enforcement agencies and minimise unnecessary cost impact on consumers.

5. INC recommends adherence to the principles of minimum effective regulation. Any proposed changes to regulation warrant a proper evaluation including risk analysis to quantify the evidence in terms of risk to infants to ensure restrictions are not applied that are out of proportion to diminishingly small probabilities of harm.

6. In responding to the CFS, we have located questions with the issues covered in the order they appear in the CFS.

Comments and Responses to questions

CFS1 Introduction

CFS1 1.6 The current regulatory environment

7. Industry applies great caution to improve infant formula as the body of scientific research consolidates. This is evidenced by the list of permissions in CFS1 Table 1.6: New permissions or changes to standards for infant formula products since 2002. This Table makes it clear that changes in composition are rare – 8 changes in two decades. Seven of the eight were the result of applications from industry.

CFS1 1.7 Risk assessment and consideration of evidence

8. INC notes the extensive risk assessment and consumer research that FSANZ has conducted in the last 5 years in particular.

CFS1 2 Regulatory framework

CFS1 2.4 Discussion

CFS1 2.4.1 Infant formula products

9. FSANZ proposes to maintain the regulatory framework for infant formula products intended for healthy infants. This includes products consumed as a sole source of nutrition by an infant up to 4 to 6 months and as part of a progressively diversified diet, from 6 to 12 months.

10. INC supports the maintenance of the current regulatory framework for healthy infants.

CFS1 2.4.2 Modified Infant formula products

11. FSANZ has proposed a new subcategory that deviates from baseline infant formula or follow-on formula composition by only having modified protein and/or lactose free/low lactose content.

12. FSANZ is not proposing to define the proposed subcategory for modified infant formula products but advises that the characteristics of these products include:
    - only modified protein and/or lactose content for the dietary management of infants with a transient gastrointestinal condition based on appropriate scientific evidence.
    - modified protein meaning partial hydrolysis of one or more of the proteins on which infant formula is normally based (i.e. current definition in Standard 2.9.1), not including extensively hydrolysed protein
    - intended to be used following advice from a health professional.
    - safe if consumed by healthy infants.

13. INC appreciates the effort of FSANZ to try to find a solution for the regulatory framework that works for all stakeholders. However, we do not believe that this resolves the concerns of stakeholders and thus there appears to be no benefit from an industry perspective in having the proposed Modified subcategory. We are therefore not supportive of its inclusion.

14. INC believes that this proposed subcategory creates confusion between products suitable for healthy infants and products for special conditions that should only be fed to

an infant under medical supervision. Infant formula for transient conditions should only be used under medical supervision and must communicate its purpose.

15. We comment on this further below and propose an alternative.

16. FSANZ plans to specify permitted protein sources for infant formula products such as cow's milk protein, goat's milk protein and protein hydrolysates of one or more proteins normally used in infant formula (but excluding extensively hydrolysed proteins – refer to *SD2* 2.1.2 Protein Source (page 16)). Similarly, it is proposed that carbohydrate sources used in infant formula products are not prescribed. Consequently, formulas with partially hydrolysed proteins and/or no/low lactose fulfil the requirements of infant formula products without modification. Categorising them as "modified" is therefore inappropriate and potentially confusing.

17. Further, this proposed sub-category does not include all formulas designed for dietary management of infants with functional gastro-intestinal problems based on appropriate scientific evidence and intended to be used under the advice of a health professional.

18. Identifying/restricting partially hydrolysed and/or low/no lactose products to this proposed modified formula category ignores their broader application in infant formula products and SMPPi. If infant formula products for conditions such as reflux and colic were to be included in this proposed sub-category of modified infant formula products, some additive permissions under SMPPi would likely be needed to ensure products can use efficacious ingredients that are backed by scientific evidence.

Purpose not labelled

19. The most serious concern for the products in this proposed "modified" category is labelling as health professionals and consumers could only be informed if infant formula products contained partially hydrolysed protein and/or low/no lactose. The problem is set out in SD3, section 5.2 that proposes restricting references to conditions such as anti-reflux and colic and asking stakeholders for views on how the label can inform carers of the nature of the modification. It is highly likely that, in not being able to accurately describe the purpose of these products, carers could be led to choose the wrong product for their babies with these conditions.

20. The dietary management of babies with these conditions (e.g. anti-reflux and colic) should be addressed in a timely way to ensure that this does not impact the health of the baby unnecessarily. As well, prolonged unwell babies could potentially affect carer's maternal mental health and these are unnecessary stresses which could be easily avoided with accurate description of the conditions the product is formulated for. It is too much to expect consumers to have the ability to interpret ingredient lists and nutrition information for the conditions their babies are suffering from.

Consumers likely to be frustrated

21. More importantly, consumers will likely be frustrated in their search for products recommended by their healthcare professional to provide nutrition for their babies and instead buy ordinary infant formula leaving the baby in discomfort and the carer anguished. This seems unreasonable when there are products on the market which are supported by scientific evidence for the dietary management of these gastrointestinal conditions. As mentioned above, maternal mental health is also an important consideration. These public health issues affecting both infants and their carers appear to have not been considered or given sufficient weight with the simplistic labelling proposed for this sub-category of products.

22. There needs to be a way(s) to convey to carers and parents the information necessary to select relevant products. Without this, the only way to differentiate such products would be by brand and healthcare professionals do not use brand names when suggesting formulas to carers for specific conditions.

No dairy-based lactose-free products on the market

23. In addition, there is the ongoing problem that powdered dairy-based infant formula products cannot be manufactured to meet). the current requirements to be labelled as lactose free. We are not aware of any powdered dairy-based infant formula products labelled as lactose-free in the market. Instead, products with very low lactose content are labelled as formula for babies with lactose intolerance.

Product labels must communicate adequate information to carers

24. Furthermore, it is important to consider how these products are currently recommended by healthcare professionals and the condition they describe to carers. If a wrong can is picked up by a carer due to lack of communications on pack, the babies with lactose intolerance conditions would further suffer from symptoms such as abdominal pain, acute and irritable diarrhoea, nausea, excessive wind and bloating. Hence without the dietary management of symptoms, this would put babies with symptoms at health risk. It is important to note that product labels must communicate adequate information to allow carers to identify correct products and not to put babies with conditions further at risk. This is not possible under the proposed framework for dairy-based virtually lactose free products if only lactose free or low lactose is permitted.

25. If this sub-category is pursued, then, as noted above, additive permissions under SMPPi may need to be considered (e.g. thickened formula) depending on the final scope of products included.

26. In summary, on the proposed modified infant formula category, we have concerns as set out in the following:

Public health concerns	• The proposed category of 'modified' will not be understood and instead will create unnecessary worry and concern at a time of high stress for carers • Infants with transient conditions may not receive the infant formula products that they need for the dietary management of symptoms – because these products cannot be identified simply and easily by consumers, healthcare professionals or regulators. This may put infants with these conditions at further health risk. • Carers (often desperately and on instruction from health professionals) will not be able to identify the products recommended by their healthcare professional for their babies with the result that infants and carers alike will consequently suffer and, potentially, affect health. ○ a clear description of the condition the product is intended to be used for is imperative in order to provide enough information to consumers and healthcare professionals to make an informed choice
Other	• Misrepresents the formulation (they comply with infant formula products requirements so are not 'modified') as well as the purpose of these products.

CFS1 2.4.3 Special Medical Purpose Products for infants (SMPPi)

27. FSANZ proposes to remove the category of Infant Formula Products for Special Dietary Use ("**IFPSDU**") within Standard 2.9.1 and the current specific sub-categories contained within Division 4. Instead, a new category for SMPPi is proposed covering any special medical product formulated for infants under 12 months. This includes specialised supplementary or modular products such as human milk fortifiers for pre-term infants and formula products which may not serve as the sole or principal source of nourishment. This will include all relevant products for infants currently included in Standard 2.9.5.

28. FSANZ also proposes a set of principles to apply to the SMPPi category:
    - SMPPi are specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition
    - SMPPi are for use under medical supervision
    - SMPPi must be safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data
    - For those SMPPi that may be the sole source of nutrition, the composition is to be based on infant formula and follow-on formula in order to take into account the specific nutritional requirements of infants, and modified as appropriate to satisfy the particular disease, disorder or medical condition
    - SMPPi may form the sole source of nutrition, or not.

29. INC does not support the new categorisation in its current form. The inclusion of other specialty foods for infants from Standard 2.9.5 presents as a whole new area that has not been raised in any previous consultation in the past 10 years. It is a proposal that needs thorough consideration to mitigate serious health concerns.

30. INC considers, in its current form, and without further consideration, it may seriously jeopardise the health and safety of infants with diagnosed diseases, disorders or conditions. INC raises a number of concerns throughout this submission: the lack of consideration of nutrient sources, additives or other refined ingredients; how the product is used; and the intended consumer group.

31. INC considers that the package of proposed principles for SMPPi are inconsistent with the category of "Infant formula products". The last two principles referring to products that may form the sole source of nutrition, or not, are particularly problematic and do not fit within the current scope of Standard 2.9.1, as understood and described. This would allow for the extension of the SMPPi category to other special medical infant products that do not meet the current definition of an infant formula product "...as the sole or principal liquid source of nourishment for infants."

32. INC believes that only special medical infant formula products that form the sole or principal liquid source of nourishment should be considered under Standard 2.9.1 at this time. The extension and impact to other infant products has not previously been fully considered and it could have unintended health and safety and trade restrictive consequences. INC recommends that all other special infant products that do not meet the definition of an infant formula product should otherwise remain under Standard 2.9.5. This includes human milk fortifiers, specialty modular products, feed thickeners and other products for highly specialised conditions (e.g. specialty cereals). This aligns with FSANZ's previous position in FSANZ CP3 2021, which INC supported. It also aligns with Codex where only Formula for Special Medical Purposes Intended for Infants is captured under Codex STAN 72-1981.

33. INC is concerned that there is no principle of international alignment for these highly specialised SMPPi, since most of these products are imported. It is neither commercially feasible nor necessary for industry to create specific labels and formulations for Australia and New Zealand. INC notes that FSANZ considered this as part of SD4 C, but it did not translate into any tangible assurances about the flexibility for specialised modular products, that are not sole or principle sources of nourishment.

34. INC recommends changes to the scope of products included within SMPPi for further discussion and consideration to:
    - Limit the scope SMPPi to special medical infant formula products that form the sole or principal liquid source of nourishment and specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition
    - Remove the proposed modified infant formula products subcategory and move all products intended for a special medical purpose from this proposed category to SMPPi, but do not apply a restriction on sale to these products (retain status quo for trade provisions)
    - That SMPPi that do not have a restriction on sale should have clear and consistent labelling. INC welcomes a discussion on an approach to labelling of these products that is in the best interest of the carer and infant. INC has set out some points for consideration in response to SD4. These points of consideration should address concerns raised by some stakeholders regarding potential misuse e.g by having additional labelling statements in a prominent place and including the mandatory provision of characteristics of such products
    - Ensure continued supply of other SMPPi, INC is aligned with the proposal to permit flexible labelling and is open to considerations on restrictions on sale of these products.
    - Minimise risks of product being held up at the border, the regulation should refer explicitly to the Codex, EU, and US Regulations that SMPPi can adhere to.

35. In summary on SMPPi, INC is concerned that:

Public health concerns	• the proposed incorporation of products for infants that comply with Standard 2.9.5 into Standard 2.9.1 has not been fully considered and could have unintended consequences. ○ the most serious being that specialty infant products for the very neediest infants may not be able to be imported at all • restriction on sale has not been thoroughly considered. A possible restriction of sale of some SMPPi is inequitable and unsafe for those in need, particularly due to limited access in rural and remote communities
International alignment	• there is no principle of 'international alignment for highly specialised SMPPi', this needs to be clearly laid out as most of these products are imported • the approach proposed for SMPPi is not aligned with Codex.
Other	• It extends the scope of the stated Proposal P1028 being "aims to revise and clarify standards relating to infant formula products in the Code"

CFS1 2.4.4 Human milk fortifiers and pre-term supplementary products

36. FSANZ is proposing to include modular products in the SMPPi category to enable permission and restrictions to products without the need for duplication in Standard 2.9.5.

37. INC does not support this proposal within the framework currently proposed. As previously noted , the majority of the products FSANZ intends to now be in scope are not based on infant formula which is the current building block for Standard 2.9.1.

38. CFS1 does not make it clear which aspects of Standard 2.9.5 will need to be duplicated in Standard 2.9.1.

39. We are concerned that the whole 'specials' framework in two critical standards, Standards 2.9.1 and 2.9.5, is being jeopardised to try to accommodate Human Milk Fortifiers.

CFS1 2.5 Preferred option

40. INC does not support the preferred option put forward by FSANZ in its current form. However, INC believes there is a workable solution: by removing the proposed 'Modified IF and FOF' sub-category and including any special medical purpose infant formula products under SMPPi and specifying requirements that accommodate the full range of these products e.g. splitting the restriction on sale and labelling requirements of this category.

41. These amendments would address (a) the significant and concerning public health issues that would otherwise exist and (b) the international trade concerns that would otherwise increase public health and safety risks.

CFS1 3 Definitions

CFS1 Definitions for infant formula products

CFS1 3.1.4 Preferred option

42. FSANZ proposes to retain definitions as were proposed in 2021 CP3 for infant formula and include the existing definition in the Food Standards Code for infant formula products and follow-on formula.

Infant formula product

43. As noted in 2021 by INC, 'infant formula products' is a term specific to the regulatory framework of Australia and New Zealand and is not used elsewhere in the world. It is the building block of Standard 2.9.1 and has defined the scope of the review for the past decade:

> **"Infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant."

44. Infant formula products is a collective term currently used for IF, FoF and IFPSDU. Under the proposed amended framework, the term 'Infant Formula Products' will only encompass IF and FoF (including modified formula sub-category if this is retained). SMPPi are proposed as a separate category.

45. INC notes that FSANZ proposes to change the title of the standard to “Infant formula products and special medical purpose products for infants”.

46. INC considers that the phrase “based on milk or other edible food constituents of animal or plant origin.” in the infant formula products definition is important. It needs to be retained with modification within Standard 2.9.1 for alignment with the Codex IF standard (Codex STAN 72-1981) and the part of the Codex Follow-up Formula Standard currently under revision covering Follow-up Formula for Older Infants (Codex draft Standard for FuFOI).

47. INC proposes the following definition which aligns more closely to wording used by Codex for consideration:

> “**Infant formula product** means a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have proven to be safe for infant feeding that ~~or other edible food constituents of animal or plant origin which~~ is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.”

Infant formula

48. FSANZ proposes to amend the definition for infant formula by making the changes shown in red below:

> “Infant formula means an infant formula product that:
> a) Is represented as a breast milk substitute for infants; and
> b) Satisfies by itself the nutritional requirements for infants under the age of 4 ~~to~~ 6 months.
>
> Infant means a person under the age of 12 months.”

49. INC opposes the reference to a specific age as in proposed definition (b) (*satisfies by itself the nutritional requirements of infants under the age of 6 months*). In our view this is unhelpful and potentially confusing.

50. The reference to a specific age is not aligned with the definitions of infant formula applied by the Ministerial Guideline, Codex STAN 72-1981 or EU Regulation 2016/127.

51. Setting an age limit at 6 months ignores the science developing rapidly around measures to address allergies from food. This science is considering the introduction of allergenic food from as young as 1 month (Sakihara T *et al*, 2021) through 4 months and beyond (Schroer B *et al* 2020; Comberiati P *et al* 2019; Heine RG 2018; Fewtrell M *et al* (ESPGHAN 2017).

52. In this respect the proposed amended definition does not future proof the Standard and sets the Standard up to potentially be at odds with updated evidence-based guidance issued by policy departments such as the Ministry of Health in New Zealand and the Department of Health in Australia. The proposals risk lack of alignment with policy guidelines which require FSANZ to consider “*The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding*.”

53. It would be more appropriate to refer to, “the first months of life up to the introduction of complementary food,” in relation to being a sole source of nutrition, with the role of the

product subsequently moving to the principal liquid source of nutrition. INC therefore recommends the following definition is applied:

> "Infant formula means an infant formula product that:
> a) Is represented as a breast milk substitute for infants; and
> b) Satisfies by itself the nutritional requirements for infants for the first months of life up to the introduction of complementary food. ~~under the age of 4 to 6 months~~."

54. Adoption of this definition will negate the need to add text regarding the definition of infant beside the definition as proposed by FSANZ.

Infant

55. FSANZ proposes to maintain the definition of infant as "means person under the age of 12 months"

56. INC supports maintaining this definition for infant.

Follow-on formula

57. FSANZ proposes to maintain the definition for follow-on formula.

> "Follow-on formula means an infant formula product that:
> a) is represented as either a breast milk substitute or replacement for infant formula; and
> b) is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months."

58. INC agrees with the proposed definition.

CFS1 3.2 Definition for SMPPi

CFS1 3.2.4 Preferred option

59. FSANZ proposes a new definition for SMPPi as follows:

> A Special Medical Purpose Product for infants means a food that is
> a) specially formulated for the dietary management of infants
> i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
> ii) whose dietary management cannot be completely achieved without the use of the food; and
> b) intended to be used under medical supervision; and
> c) represented as being
> i) a food for special medical purposes intended for infants; or
> ii) for the dietary management of a disease, disorder or medical condition in infants.

60. INC does not support the definition for SMPPi as proposed.

61. Previously, the consultation on Standard 2.9.1 has only considered infant formula products that form the sole or principal source of nutrition for infants. However, the proposed definition for SMPPi allows for the extension of the SMPPi category to other special medical infant products that do not meet the current overarching concept for

Standard 2.9.1: “form the sole or principal liquid source of nourishment” for infants. It also creates ambiguity around the applicable standard for some products currently regulated under Standard 2.9.5. This ambiguity has the potential to lead to delays at the border.

62. Without more thorough consideration, there is a high risk that the health and safety of infants in Australia and New Zealand could be compromised.

63. If it is FSANZ’s intention to bring products regulated under Standard 2.9.5 that are not the sole or principal liquid source of nutrition for infants into the scope of Standard 2.9.1, INC is strongly of the view that a further consultation is needed.

64. INC also believes that the proposed definition of SMPPi goes beyond the scope of Standard 2.9.1, P1028 and also the Australia and New Zealand Food Regulation Ministerial Council Policy Guideline on the Regulation of Infant Formula Products. The Policy Guideline is only intended to cover infant formula, follow-on formula and infant formula for special dietary uses for infants from 0 to 12 months of age.

International alignment

65. FSANZ has stated that Infants who are particularly vulnerable and depend on SMPPi will benefit from greater certainty of continued access to special formula through greater alignment with international regulations. However, the proposed definition does not align with Codex or the EU:
    - Codex Stan 72-1981 on formula for special medical purposes intended for infants states the products are substitutes for human milk or infant formula in meeting the special nutritional requirements arising from the disorder disease or medical condition for whose dietary management the product has been formulated.’
    - The EU regulated special purpose infant formulas as food for special medical purposes designed for infants (iFSMP). Food for special medical purposes is defined in Regulation (EU) 609/2013. Specific compositional and information requirements are set out in Commission Delegated Regulation 2016/128. This includes a requirement for the nutritional composition of iFSMP to be based on that of infant and follow-on formula, except where necessary for the intended purpose of the product.

66. Greater consideration needs to be taken with regard to the potential scope of SMPPi as it is currently defined. INC recommends that only products for infants that are the sole, or principal liquid source of nutrition, are in scope. For the purpose of this submission we have used the term SMPPi as proposed by FSANZ but note that the appropriateness of this term should be reviewed once the scope of products to be included is finalised. For example, the term, ‘Infant Formula for Special Dietary uses,” as currently used may be able to be retained.

CFS1 3.3 Definition for protein substitute

67. FSANZ proposes to remove the definition for ‘protein substitutes’.

68. INC supports the removal of the protein substitutes sub-category and therefore the removal of the definition of protein substitutes.

CFS1 3.4 Other Definitions

CFS1 3.4.1 Soy-based infant formula

69. FSANZ proposes to remove the definition of soy-based infant formula from Standard 2.9.1. The current definition is

> "Soy-based formula means an infant formula product in which soy protein isolate is the sole source of protein."

70. INC supports the removal of the definition of soy-based infant formula, as the product is self-explanatory and is not defined in Codex.

CFS1 3.4.2 Pre-term formula

71. FSANZ proposes to remove the definition of pre-term formula from Standard 2.9.1 due to the change in regulatory framework which removes the premature or low birthweight infant sub-category. The current definition is:

> "Pre-term formula means an infant formula product specially formulated to satisfy particular needs of infants born prematurely or of low birth weight.

72. INC agrees with the removal of the pre-term definition and the rationale provided including the removal of premature or low birthweight infant sub-category.

CFS1 3.4.3 Medium chain triglycerides (MCT)

73. FSANZ proposes to remove the definition of MCT from Standard 2.9.1. INC understands that this will result in the definition of MCT also being removed from Standard 1.1.2 but this needs to be confirmed. The current definition is:

74.

> "medium chain triglycerides means triacylglycerols that contain predominantly the saturated fatty acids designated by 8:0 and 10:0."

75. INC's strong preference is for the restriction on use of MCTs to be deleted from the standard for infant formula products (refer to our comments on MCT later in this submission under 6.1 Macronutrients). If the restriction is removed, then we agree that the definition of MCT can be removed.

76. However, if the restriction on the use of MCTs is retained, then a definition is needed. While MCT is a commonly used term, it has different definitions applied to it. The current definition for MCT refers to saturated fatty acids designated 8.0 and 10.0, yet in most peer reviewed papers MCFA and MCTs encompass saturated fatty acids designated 6.0. 8.0, 10.0 and 12.0. This term is also sometimes mistakenly used interchangeably with medium chain fatty acids (MCFA) (see examples provided in Attachment A). Consequently, the current definition does not achieve regulatory clarity and the removal of the definition increases ambiguity.

77. INC reiterates its previous recommendation to apply the restriction, if retained, to MCT oils and to provide a definition for these. The following wording is recommended:

> "**MCT oils** means oils commercially manufactured via fractionation and /or esterification to yield a high proportion of medium chain saturated fatty acids (designated by 8.0 or 10.0)."

78. The Standard could then be amended to restrict the use of 'MCT oils' as an ingredient other than for a fat-soluble vitamin as per Standard 2.9.1(1)(a)(ii):

> *" for a fat soluble vitamin that is specified in the table to section S29—9 – a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula".*

79. Implementation of these changes would provide improved regulatory clarity.

80. FSANZ has taken the view that changing the definitions is out of scope for P1028. However, FSANZ is proposing removal of a number of definitions and changes to others. It is also our understanding that P1028 does not preclude the addition of new definitions (for example as proposed for SMPPi). We therefore do not accept that a new definition for MCT oils can or should be ruled out of scope.

81. Two of the outcomes sought from this P1028 review are revised standards that are readily understood and able to be implemented by food manufacturers and enforceable by jurisdictions. Notifications of issues giving rise to a lack of clarity in the existing Food Standards Code, such as the restriction on the use of MCT in infant formula products as currently defined, need to be addressed to achieve these objectives.

CFS1 3.4.4 New Definitions

82. FSANZ is not proposing to introduce new definitions for terms such as gastrointestinal reflux, gastrointestinal disorders or impairment of the gastrointestinal tract, inborn errors of metabolism or related.

83. INC supports the FSANZ proposal that further definitions on the above terms are unlikely to add to regulatory clarity and that these terms are not defined under either Codex or EU regulations.

Guidance Upper Limits

84. INC strongly recommends that a definition for Guidance Upper Limits (GULs) be included in the Food Standards Code to provide regulatory clarity. This is because auditors, verifiers and regulators regularly demonstrate they do not understand what a Guidance Upper Level is. A definition in the Food Standards Code would make this clear.

85. As was covered in FSANZ CP2 2021 on Nutrient Composition, recommended maximum amounts as GULs are listed where the risk posed by the nutrient was "not of significance on the basis of current scientific knowledge" (ANZFA 1999a). These are not binding and serve as guidance for industry in deriving formulations.

86. Codex currently provides the below note on GULs but a note or definition in the Food Standards Code could be much simpler text:

> "*Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in infant formulas should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. When a product type or form has ordinarily contained*

lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs."

87. INC recommends Guidance Upper Limits be defined as:

"Guidance Upper Limits are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. The Guidance Upper Levels should usually not be exceeded unless *higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons.*"

CFS1 4 Novel foods and nutritive substances

CFS1 4.1 Pre-market assessment requirements

CFS1 4.1.1 Previous consideration

CFS1 4.1.2 Stakeholder views

88. INC notes that in response to a submitter commenting on past Advisory Committee on Novel Foods (ACNF) work, that FSANZ has stated that "The ACNF no longer considers questions about substances to be added to infant formula products as such substances are subject to pre-market assessment. INC was not aware that this change had occurred and to our knowledge this had not been explicitly stated. It had been suggested by FSANZ that ACNF had never reviewed substances in relation to infants but this in fact appears incorrect since considerations by the ACNF and the body that predated it include references to infants in relation, for example, to Beta palmitin vegetable oil, Docosahexaenoic acid (DHA) powder sourced from algae Crypthecodinium cohnii, and Perilla oil (derived from the seeds of Perilla frutescens).

CFS1 4.1.3 Discussion

89. INC notes the rationale explored in earlier consultations on this topic for excluding consideration of novel foods and nutritive substances particularly that of the potential for creating regulatory ambiguity and inconsistencies. We concur with the position that novel foods and nutritive substances regulation and review is a much broader issue than for infant formula and it should not be included in the scope of P1028.

90. Nonetheless, the CFS proposes several changes that are commented on below.

CFS1 4.1.4 Preferred option

91. FSANZ's preferred option is to retain the proposed approach from FSANZ CP3 2021, that requirements for novel foods and nutritive substances in infant formula products are to be considered as part of the broader review of these substances for all food categories in P1024.

92. INC notes that FSANZ has pointed out that the regulatory approach for pre-market assessment has been clarified in the P1025 Code revision and in P1028. In particular, existing stringent regulations include:
    - a general prohibition unless pre-market assessment (Standard 1.1.2)
    - pre-market assessment of novel foods and nutritive substances for infant formula products must include application of the Ministerial Policy Guideline
    - application of the Ministerial Policy Guideline is enshrined in the Application Handbook Guidelines (which are statutory requirements)
    - a definition of protein sources (see SD2 section 2.1.2)

- changes in definitions in Standard 1.1.2 implemented through P1025 and proposed changes in this CFS1.

93. INC agrees with FSANZ's preferred option to review the regulatory framework for novel foods and nutritive substances in infant formula products with P1024 so that requirements for infant formula products are considered in parallel with other food categories. Assessment with P1024 will enable consideration of problems and solutions that apply to all food categories, will prevent inconsistency in the Code whilst still having regard to the Ministerial Policy Guideline.

94. Consideration of the future regulation of nutritive substances cannot effectively be conducted from the perspective of one of six Standards that apply the term. Consideration must be from the broader perspective.

95. INC notes that FSANZ is proposing an amendment to Standard 1.1.2—8 Definition of Novel Food so that a novel food is defined as a non-traditional food **for the intended consumer population**.

96. INC supports this change in principle but notes that there has been no consultation outside of P1028 on this proposed change which has the potential to impact on population groups other than infants. INC therefore suggests that if this amendment is progressed as part of P1028 rather than P1024, then it should be specific to the infant population and may better form a separate element. For example: "For infants, a novel food is defined as a non-traditional food for the intended infant consumer population".

97. INC appreciates that the term 'optional ingredients', as used in Codex, as a preferred term to use instead of 'may be used as a nutritive substance' may be considered as part of P1024.

98. INC recommends priority be provided to progressing P1024 to facilitate innovation within the food sector. INC would greatly appreciate FSANZ providing clarity on next steps for progressing P1024.

99. INC has responded to the proposal to define protein sources in Section 8 below.

CFS1 4.2 Novel Foods – Schedule 25

CFS1 4.2.4 Preferred option

100. FSANZ's preferred option is to amend Schedule 25 to include conditions for α-cyclodextrin, γ-cyclodextrin, diacylglycerol oil (DAG oil), isomaltulose, D-tagatose, and trehalose that restricts these substances from being used in infant formula products (i.e. infant formula and follow-on formula). The conditions will not be applied to formulated supplementary food for young children.

101. FSANZ will not amend conditions for dried marine micro-algae (Schizochytrium sp.) rich in docosahexanoic acid (DHA), oil derived from marine micro-algae (Schizochytrium sp.) rich in docosahexanoic acid (DHA) and oil derived from marine micro-algae (Ulkenia sp.) rich in docosahexanoic acid (DHA) as the risk assessments had included the use of these substances in infant formula products.

102. INC agrees that substances added to Schedule 25 that have not been assessed for suitability for infants should not be permitted to be added to infant formula products. Infants are a particularly vulnerable population and certain ingredients that are suitable for the general population may not be suitable for them.

103. INC agrees that constraints on the use of novel foods in formulated supplementary food for young children should not apply where risk assessments undertook dietary exposures for the population aged 2 years and older. Such constraints would otherwise effectively segment these products from the general food supply which does not make sense because young children are sharing family foods and, where novel foods might be used, they make up only a very small part of foods consumed.

CFS1 5 Safety and food technology (SD1)

CFS1 5.1 Food additives

SD1: 3 Food Additives

SD1: 3.2 Food Class System for food additive permissions

104. FSANZ's preferred option is that there a simplified structure for food classes for food additive permissions be applied to infant formula and related products in the table to section 5 of Schedule 15: 13.1.1 Infant formula products and 13.1.2 SMPPi. Under this option, condition statements are proposed to be used to differentiate or qualify specific food additive permissions.

105. INC supports the preferred option for two food categories in Schedule 15 of the Food Standards Code which is consistent with international approaches and aligned to INC's previous view (in FSANZ CP1 2021) supporting a simplified approach (IFPs and IFPSDU subclass). However, INC notes that for alignment with the Codex draft Standard for Follow-up Formula for Older Infants some additional additives should be added.

106. As noted at the outset, INC is concerned at the proposed inclusion of a sub-category of modified products within the category of infant formula products and for all foods for special medical purpose for infants to be included in SMPPi.

107. If the modified infant formula products proposed sub-category is retained, the additive permissions may need to be extended to include some currently sitting under SMPPi depending on the scope of products included.

108. If the category of IFPSDU in the current Standard is extended to include all foods for special medical purpose for infants in the SMPPi category, a further review of additives for these products would be required to ensure international alignment. In particular, this includes potential consideration of EU 1333/2008 category 13.1.5.2 Dietary foods for babies and young children for special medical purposes.

109. INC is concerned that alignment with international additive standards needs to be maintained. INC recommends that amendments to international additive standards could be proposed for adoption in Australia and New Zealand. For SMPPi, INC recommends addressing permissions by cross-reference to accepted overseas standards.

SD1: 3.3 Carry-over principle for food additives and infant formula products (page 15)

110. FSANZ's preferred option is that the carry-over of food additives should not be permitted unless a specific permission exists for that food additive in the final food.

111. INC reiterates its previous response with a very strong position for maintenance of the status quo. However, we would urge that in removing the carry-over principle for infant

formula, there needs to be new provisions for infant formula products added to the Food Standards Code to allow for the continuation of the use of certain substances that may be carried over into infant formula products that are currently used. These include permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes listed in Schedule 29—7.

112. Additionally, INC recommends that these new provisions be included in the second consultation so that the removal of the carry-over principle occurs concurrently with the addition of the necessary new additive permissions to enable a smooth transition for industry.

SD1: 3.5 Food additive permissions by type or substance (page 25)

113. FSANZ's preferred option is set out in INC's Table 2 below, Food Additive Proposals and Impacts.

114. INC found it hard identifying FSANZ's position for all food additives as FSANZ only provided a summary table for changed food additives and there were some inconsistencies. We cover these below.

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SD1 3.5.1 Acidity Regulators

115. INC reinforces previous views in which we strongly support the position that food additives that contribute essential nutrients do not have MLs specified for the Food Standards Code which are set above the maximum levels specified for the nutrients concerned within the compositional requirements
    - it is the level of the substance present that determines safe use not whether it is added as a nutrient or food additive.

116. Including MLs for food additives that are higher than compositional maxima just adds additional (but redundant) compliance checks that need to be undertaken by product formulators, auditors and regulators. Such checks are a waste of time and resources. If a condition of use is to be applied, it should simply state that the maximum level for the nutrient concerned is not to be exceeded. The proposed ML for use of calcium hydroxide as an acidity regulator falls into this category as do other examples provided below.

117. The Codex draft Standard for Follow-up Formula for Older Infants includes these additives at GMP levels which is consistent with the approach INC is recommending for all infant formula products under 13.1.1. This is also consistent with EU 1333/2008 category 13.1.5.1 which permits these additives at GMP levels.

SD1 3.5.2 General Considerations on thickeners, emulsifiers and stabilisers

118. INC recommends provision for INS 1422 Acetylated distarch adipate for use in follow-on formula to align with the Codex draft Standard for FuFOI, with limitations as below:
    0.5 g singly or in combination in soy-based products only;
    2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only

119. INC previously requested consideration of this additive for inclusion in 2012 however it was excluded from FSANZ previous considerations in 2016 and 2017 as Follow-on Formula was out of scope.

SD1 3.5.6 Pectins

120. FSANZ's preferred option is to prescribe the following two permissions for pectins within SMPPi:

    2000 mg/L MPL for hydrolysed protein liquid formulas
    5000 mg/L MPL for gastro-intestinal disorder formulas

121. INC supports these permissions to ensure that SMPPi permitted for sale in the EU or markets that adopt Codex Standards would be available to infants in Australia and New Zealand. This would mitigate any public health concern in restricting SMPPi to very vulnerable infants. INC is concerned that the misalignment with current EU/1333/2008 13.1.5.1 could inadvertently restrict the availability of products in this category.

122. Pectin (INS 440), is additionally permitted in the Codex draft Standard for FUFOI with an ML of 1g/100mL.

Antioxidants

123. INC notes that a number of additional antioxidants are permitted in the Codex draft Standard for FUFOI or permitted at levels that differ from Codex Stan 72-1981. INC recommends these as listed in Table 1 below are added:

Table 1: **Antioxidants permitted for Codex Follow-up Formula for Older Infants**

Antioxidants		
307b	Tocopherols concentrate, mixed	3 mg per 100mL singly or in combination
307	Tocopherol, d-alpha	
307c	Tocopherol, dl-alpha	
304	Ascorbyl palmitate	5 mg per 100mL singly or in combination, expressed as ascorbic acid (INS 300, 301,302,304) Within the limits for sodium.
300	Ascorbic acid, L	
301	Sodium ascorbate	
302	Calcium ascorbate	

124. INC recommends FSANZ further consider the ML for SMPPi for INS 304 ascorbyl palmitate as the proposed limit does not align with EU 1333/2008 category 13.5.1 which permits 100mg/kg. This could unintentionally create a barrier to import of SMPPi.

125. Also, there has not been any consideration of gamma-tocopherol E308 and delta-tocopherol E309 for SMPPi which are permitted for use in EU 1333/2008 category 13.5.1 with an ML of 10mg/L.

126. Additional comments on proposed MLs are set out in Table 2 below:

Table 2: Food Additive Proposals and Impacts

Food additive	FSANZ proposed MPL (mg/L)		INC Response
	Infant Formula Products	SMPPi	
Calcium carbonates (INS 170)	NP	GMP (aligns with EU) (13.1.5.1)	INC supports the proposal and reiterates our position in response to FSANZ CP1 2021, that calcium carbonate should be permitted for use in all IFP at GMP given there are also permitted forms of minerals in these products. INC also recognises that while a specific permission for calcium citrate has been provided as a nutrient carrier, the same is not true for calcium carbonate. These permissions should be considered to ensure consistency.
Calcium citrates (INS 333)	NP	GMP (aligns with EU) (13.1.5.1)	INC supports the proposal that calcium citrate should be permitted for use in all infant formula products at GMP given calcium citrates are also permitted forms of minerals in these products.
	Permit as carrier in nutrient preparations, consistent with EU MPL and with condition statement.		INC does not support. INC does not consider that the Food Standards Code needs to specify permission of 333 as a carrier since this is classed as a processing aid under the Food Standards Code. Introduction of this new terminology, which is currently not used, risks introducing ambiguity since this approach is not recommended for all additives which may be included within nutrient preparations.
Calcium hydroxide (INS 526)	2000 (aligns with Codex and EU), limits for sodium, potassium and calcium.		**Per CP1:** INC recommends calcium hydroxide is permitted at GMP or provided the maximum specified for calcium in S29---10 is not exceeded. Refer to comment regarding the redundancy of MLs set above maximum permitted nutrient levels. Also, both the CODEX draft Standard for FUFOI and EU 13.1.5.1 specify GMP. INC therefore supports a ML of GMP.

Table 2 (cont)

Food additive	FSANZ proposed MPL (mg/L)		INC Response
	Infant Formula Products	SMPPi	
Sodium carbonates (INS 500)	2000 (aligns with Codex) limits for sodium, potassium and calcium.		INC supports use of these substances as acidity regulators. As noted above, we consider the application of the ML proposed is redundant for sodium carbonates and sodium hydroxide given the maximum sodium level permitted in infant formula is lower than application of this ML. Also, both the Codex draft Standard for FUFOI and EU 1333/2008 category 13.1.5.1 specify GMP. INC therefore recommends a ML of GMP for sodium carbontes, sodium hydroxide, potassium carbonates and potassium hydroxide.
Sodium hydroxide (INS 524)	2000 (aligns with Codex), limits for sodium, potassium and calcium. Consequential addition also needed to Schedule 8.		
Potassium carbonates (INS 501)	2000 (align Codex) limits for potassium.		
Potassium hydroxide (INS 525)	2000 (aligns with Codex), limits for potassium. Consequential addition also needed to Schedule 8.		
Phosphoric acid (INS 338)	450 (as phosphorus), (aligns with EU). Additional condition statements on ions.	450 (as phosphorus), (aligns with EU). Only for pH adjustment.	INC supports this proposal for INS 338 and 450 but again considers that the application of the ML is redundant and unwarranted. INC does not consider that the Food Standards Code needs to specify permission of 341 as a carrier since this is classed as a processing aid under the Food Standards Code. Introduction of this new terminology, which is currently not used, risks introducing ambiguity since this approach is not recommended for all additives which may be included within nutrient preparations. It is not clear why FSANZ's position has changed from CP1 2021 which proposed to allow 341 in all IFP at 450mg/kg and which INC supported. A food additive permission is needed for SMPPi to align with EU 1333/2008 category 13.1.5.1. In FSANZ CP1 2021 it was noted that if sodium or potassium phosphates were used at the ML, the maximum levels of sodium or potassium permitted in IF could be exceeded. EU applies a ML of 1000mg/kg which is well in excess of the maximum permitted phosphorus levels in IF of approximately 670mg/kg.
Calcium phosphates (INS 341)	Consistent with EU: Specific permission for tricalcium phosphate (INS 341(iii)) in nutrient preparations added to products (MPL in nutrient preparation 70 mg/L as phosphate).		
Sodium phosphates (INS 339) Potassium phosphates (INS 340)	450 (as phosphorus), (aligns with Codex). Additional condition statements relating to calcium/phosphorous ratio.		
Citric and fatty acid esters of glycerol (CITREM) (INS 472c)	9000 for liquid products, and 7500 for powdered products, (aligns with Codex and EU).		INC supports the proposal.

Table 2 (cont)

Food additive	FSANZ proposed MPL (mg/L)		INC Response
	Infant Formula Products	SMPPi	
Starch sodium octenylsuccinate (INS 1450)	NP	20,000 for extensively hydrolysed protein formulas (aligns with Codex and EU), with condition statement.	INC supports the proposal.
Locust bean (carob bean) gum (INS 410)	1000, maintain current permission, align Codex.	5000 for gastro-oesophageal formulas (aligns with EU), with condition statement.	INC supports the proposal for IFPs. The EU currently permits 10,000mg/kg under category 13.1.5.1. As noted by FSANZ, EFSA is currently reconsidering further data on safety and suitability. INC supports aligning with the EFSA Opinion once finalised.
Pectins (INS 440)	NP	2000 for extensively hydrolysed protein liquid formulas (aligns with Codex), with condition statement.	INC supports 2000mg/L for extensively hydrolysed liquid formula for SMPPi. INC recommends review of MPL for pectins follow-on formula.
		5000 mg/L for gastro-intestinal disorder formulas, (aligns with EU) with condition statement.	INC notes the FSANZ table does not align with EU 1333/2008 13.1.5.1 which has a MPL of 10,000mg/kg (see above)
Xanthan gum (INS 415)	NP	1000 for extensively hydrolysed protein formulas (aligns with Codex), with condition statement	INC supports the proposal
		1200 for gastrointestinal, protein mal-adsorption, or inborn errors of metabolism formulas (align with EU), with condition statement.	INC supports the proposal

Table 2 (cont)

Food additive	FSANZ proposed MPL (mg/L)		INC Response
	Infant Formula Products	SMPPi	
Guar gum (INS 412)	1000 (aligns with the Code, Codex and EU), with condition statement	10,000 for extensively hydrolysed protein formulas (aligns with EU), with condition statement.	INC supports the proposal for IFPs and SMPPi
Sodium alginate (INS 401)	NP	1000 for metabolic disorders and for general tube-feeding (aligns EU) with condition statement.	INC supports the proposal
Sodium carboxymethyl-cellulose (INS 466)	Not proposing to permit use of sodium carboxymethylcellulose in any infant formula product. Seeking any information from stakeholders on current use and levels to inform a final decision		INC does not support the FSANZ proposal to not permit addition to SMPPi. As noted by FSANZ, this is not aligned with the EU which allows sodium carboxymethylcellulose for use from birth onwards in products for the dietary management of metabolic disorders with ML 10,000 mg/kg.
Sucrose esters of fatty acids (INS 473)	NP	120 for extensively hydrolysed protein formulas (aligns with EU) with condition statement.	INC supports the proposal
Diacyltartaric and fatty acid esters of glycerol (INS 472e)	Remove the permission in the Code (aligns Codex and EU).		INC recommends maintaining the permission for diacyltartaric and fatty acid esters of glycerol. This additive is authorised for general use in food, for example in the US under 21 CFR 184.1101 that allows its use in some infant products. There has not been any identified risk in relation to this additive and products containing it have been present in the market globally for decades. Any decision to remove this permission should be based on a risk assessment.

SD1: 3.6 Clarifications to the Code: Preferred option

127. FSANZ's preferred approach is:
    a) Hydroxypropyl starch – reduce the MPL for hydroxypropyl starch for soy-based infant formula to 5000 mg/L.
    b) Carrageenan – clarify permissions in the Code for carrageenan such that it is clear that it may be used in all liquid infant formula, including soy-based liquid infant formula.
    c) Starches (INS 1413, 1414 and 1440) – remove the condition statement 'Standard 1.3.1—6 applies' next to these three starches within food classes 13.1.1 and 13.1.3.

128. INC has previously supported all these clarifications and confirms that is still the case.

SD1: 3.7 Updates to nomenclature and INS numbers

129. FSANZ's preferred approach is to refrain from making changes to nomenclature and INS numbers as part of this proposal.

130. INC has previously supported this proposal and confirms that this is still the case.

5.3 Processing aids

SD1: 4.1 Processing aids

131. FSANZ's preferred approach is to make no changes to the Food Standards Code concerning processing aids.

132. INC supports the maintenance of existing processing aid permissions.

5.2 Contaminants

SD1: 5.2 Contaminants

133. FSANZ's preferred option for MLs is 'as consumed' form in mg/kg.

134. Proposed maximum permitted levels are described in CFS1 Table 5.2 (page 40). INC recommends MLs remain stated on a powder basis, however INC members accept FSANZ's preference for 'as consumed' if this is pursued. INC notes that there are inconsistent units used by FSANZ in the contaminants section as identified below. INC uses mg/L but further clarity is needed over the specific units FSANZ proposes.

135. INC supports the preferred approach for all contaminants except for Aluminium.

136. INC supports change to:
    - Lead (Lower ML from 0.02 mg/L to 0.01 mg/L in infant formula products applied to infant formula on a ready-to-feed basis)

137. INC supports no change to the MLs for the following:
    - Acrylonitrile (ML of 0.02 mg/L)
    - Tin & inorganic tin (ML of 250 mg/L.)
    - Vinyl chloride (ML of 0.01 mg/L)

138. INC supports FSANZ's proposal to not set MLs for the following:

- Arsenic (no ML for infant formula products. Monitor and review (for rice that may be used as an ingredient in infant formula)).
- Cadmium
- Melamine
- Aflatoxins B1 and M1
- Ochratoxin A
- Polycyclic aromatic hydrocarbons (PAH)
- Perchlorate
- Chloropropanol, glycidol and their esters

Aluminium

139. On aluminium, FSANZ proposes to move the ML from Standard 2.9.1 to Standard 1.4.1 and Schedule 19 and retain a single ML of 0.05 mg/100mL for aluminium for infant formula products including soy-based.

140. INC reaffirms its previous position and recommends alignment with Codex which **does not** set limits for aluminium in infant formula. This also aligns with both EU and US regulations.

141. INC also does not support the reduction in ML to 0.05mg/100mL for soy-based formulas. FSANZ is proposing this significant reduction in the ML from 0.1g/100mL and, due to levels in soy ingredients. this reduction is unlikely to be achievable. If this ML is to be retained for aluminium, it must remain at 0.1g/100mL.

142. Plants take up aluminium from the soil. For dairy products, the plant material is processed by the cow before coming out as milk, hence some levels of the contaminant are processed out by the cow's liver. For plant-based products, there is no processing by an animal, so contaminant levels are generally higher and reduction difficult. Therefore, the contaminant limits should not be the same for dairy and soy.

143. The toxicological understanding for this (provided in previous INC submissions e.g.to FSANZ CP1 2021) has evolved since JEFCA's 2011 assessment derived a Provisional Tolerable Weekly Intake (PTWI) of 2mg/kg-bodyweight. In 2017, the EU established a Tolerable Daily Intake (TDI) for aluminium of 0.3 mg/kg-bodyweight/day. It is not apparent how FSANZ has calculated the ML of 0.05 mg/100 mL from either the JECFA or EU health-based guidance value. Nor is it apparent that current dietary exposure to aluminium from infant formula comes close to any toxicologically based limits. INC had requested further information that would demonstrate what (if any) public health benefit this ML achieves and notes that none has been provided.

144. The ADS dietary information that was shared to support the ML suggests that older infants (9 months) receive most of their dietary exposure to aluminium from baked goods (muffins, scones, cakes, slices). INC considers it important to recognise that infant formula is for 0 to 6 months where formula is a sole source of nutrition, and that baked goods are irrelevant to the dietary intake of this age-group. Any assessment of risk should take this into consideration.

145. INC remains firmly of the 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).

CFS1 5.4 L(+) lactic acid producing microorganisms

CFS1 5.4 Preferred option – L(+) lactic acid producing microorganisms (page 42)

146. FSANZ's preferred approach is to retain the existing permission, however stating that L(+) lactic acid producing microorganisms may only be added for acidification purposes. FSANZ also proposes to clarify the permission that only non-pathogenic or nontoxigenic microorganisms may be used.

147. INC strongly recommends retaining the current permission for L(+) lactic acid producing microorganisms without the proposed clarifications regarding purpose. INC is surprised at the dramatic retrospective change proposed by FSANZ in this consultation which has not been covered in earlier consultations.

148. INC does not agree with the FSANZ proposal for retrospective change for the following reasons:

    (i) L(+) lactic acid producing microorganisms are generally considered as safe and traditional for infants. This is evidenced by their inclusion within regulations globally, scientific literature and the outcome of FSANZ's own risk assessment in 2021. The FSANZ proposal to change status quo does not appear to be based on risk analysis using the best available scientific evidence.

    (ii) L(+) lactic acid producing microorganisms have a demonstrated history of safe use in infant formula products within Australia and New Zealand as a result of current permissions for addition in conjunction with overarching requirements for ensuring foods are safe. There has been no evidence of harm to public health and safety.

    (iii) 22 years has passed since the Food Standards Code was written with no indication by guidance or enforcement that the intent was to limit addition of L(+) lactic acid producing microorganisms for acidification purposes only. The microbiological testing requirements at the time the Food Standards Code was written anticipate the presence of live microorganisms, this is inconsistent with an intent to have no viable microorganisms present.

    (iv) The proposal lacks international regulatory alignment and creates barriers for trade in an internationally competitive food industry.

    (v) The horizontal novel and GM standards are appropriate levels of regulation to manage exceptions that require FSANZ pre-market assessment prior to addition.

Non-alignment with Codex, EU etc

149. The FSANZ proposal to limit use of L(+) producing lactic acid bacteria for acidification purposes is not aligned with Codex, EU and many other overseas regulations and is counter to the goal of international alignment. The proposed approach will differ to Codex which expressly recognises L(+) lactic acid producing cultures as permitted ingredients.
    - Codex STAN 72-1981 provides "O*nly L(+)lactic acid producing cultures may be used*" as optional ingredients and also recognises use as an acidity regulator.

150. The use of lactic acid producing cultures as optional ingredients was discussed at the 38th meeting of the Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU) in relation to the essential composition of Follow-up Formula for Older Infants (6-12 months) as part of the review of the Follow-up Formula Standard **(**Codex STAN 156-1987). The text in Codex STAN 72-1981 was used as a starting point but it was recognised that the text regarding use of L(+) lactic acid producing bacteria as an

optional ingredient in the Codex Infant Formula Standard did not recognise the two distinctly different purposes for which these cultures may be added. The conclusion noted in paragraph 63 of the CCNFSDU38 report is as follows:

> "*In terms of the technological use of L(+) lactic acid producing cultures for the purpose of producing acidified follow-up formula, it was noted that the final formula should not contain significant amounts of viable L(+) lactic acid producing cultures. The safety and suitability of the addition of L(+) lactic acid producing cultures for particular beneficial physiological effects must be demonstrated by clinical evaluation and generally accepted scientific evidence for the particular strain used. The text was redrafted to reflect these issues."*

151. The Essential Composition of Follow-up Formula for Older Infants, now at step 7, permits the addition of L(+) lactic acid producing cultures for the purposes of acidification and for particular beneficial physiological effects as follows:

> ***"L (+) lactic producing cultures***
> *Only L (+) lactic producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final product should not contain significant amounts of viable L(+) lactic acid producing cultures, and residual amounts should not represent any health risk.*
>
> *The safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.*"

152. INC notes that while the Codex draft FUF Standard has included new text to support (L+) lactic acid producing culture addition, it is unnecessary and duplicative to repeat the safety, suitability and benefit clauses of Codex specifically for L(+) lactic acid producing cultures within the FSANZ context. This concept is covered more generally within the Food Standards Code and respective policy guidelines for optional formula ingredients.

EU

153. The proposed approach does not align with EU. EU 2016/127 which allows microorganisms/cultures used for purposes other than acidification, Article 3 allows optional ingredients such as L(+) lactic acid producing microorganisms to be added provided safety and suitability is demonstrated through appropriate studies. In practice this means that companies are required to hold safety and suitability substantiation for the specific L(+) lactic acid producing microorganisms strains used that are considered to be not-novel, and this does not require a regulatory pre-market assessment.

> ***Article 3 Suitability of ingredients***
> *1. Infant formula shall be manufactured from protein sources as set out in point 2 of Annex I and other food ingredients, as the case may be, whose suitability for infants from birth has been established by generally accepted scientific data.*
> *2. Follow-on formula shall be manufactured from protein sources as set out in point 2 of Annex II and other food ingredients, as the case may be, whose suitability for infants aged over six months has been established by generally accepted scientific data.*
> *3. The suitability referred to in paragraphs 1 and 2 shall be demonstrated by the food business operator through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary,*

appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

History of safe use

154. INC further points out that globally, L(+) lactic acid producing microorganisms have been added to infant formula products for over 30 years. While a minority of countries maintain a positive list e.g. China, the majority do not and rely on general permission statement for L(+) lactic acid producing microorganisms and requirements for safety and suitability (e.g. EU).

FSANZ Risk Assessment 2021

155. In FSANZ CP1 2021 and related SD2 papers, FSANZ assessed the risk to the health and safety of infants – healthy, as well as preterm, low birth weight and immunocompromised – from the addition to infant formula products of any L(+) lactic acid producing microorganisms. FSANZ made a number of conclusions:
    - for healthy full-term infants, infant formula supplemented with non-pathogenic and non-toxigenic L and DL lactic acid producing microorganisms does not present a risk to the public health and safety
    - there is insufficient data to support the safety of all L lactic acid producing microorganisms. For enterococci and bacillus spp., this would need to be established on a case by case basis
    - for infants with underlying clinical complications, there are some reports of, for example, sepsis with the dietary supplementation of non-pathogenic L and DL micro-organisms, however there is insufficient data to assess the level of risk
    - the use of non-toxigenic L(+) lactic acid producing microorganisms in the production of fermented infant formula – where no viable bacteria are present in the final product – does not present a risk to public health and safety.

156. INC recommends continued permission for non-pathogenic and non-toxigenic L(+) lactic acid producing microorganisms in infant formula products as these do not present a risk to the public health and safety for healthy full term infants.

Background to Australia and New Zealand permission

157. Australian and New Zealand manufacturers have been able to add L(+) lactic acid producing microorganisms over the past 22 years due to the permission in the Food Standards Code (refer to Proposal P93 – review of infant formula supplementary final assessment (Inquiry – s.24) report dated 13 March 2002 which confirms the wording currently in Standard 2.9.1—6 has not changed since the amendments in that report were implemented):

> "L(+) lactic acid producing microorganisms may be added to infant formula product."

158. Prior to the amendments introduced by P1039, Standard 1.6.1 differentiated between powdered infant formula products with and without lactic acid producing cultures. Standard 1.6.1—2(2) indicates that there was recognition that live cultures could be present in the finished product:

> *"In the case of powdered infant formula with added lactic acid producing cultures, the Standard Plate Count (SPC) microbiological limit applies prior to the addition of the lactic acid cultures to the food."*

159. Live cultures added to the liquid infant formula during manufacture to ferment milk sugars are inactivated in the heat treatment and drying of powdered infant formula. It is

therefore INC's view that FSANZ had intended to allow for *lactic acid producing cultures* to be added for purposes beyond acidification.

160. INC recognises the responsibility to ensure these ingredients were safe and suitable has been conducted by manufacturers and there has been no evidence of harm or safety concerns associated with their use over this very extended period of time. This provides evidence for a history of safe use of existing L(+) lactic acid producing cultures in infant formula products.

161. This is also supported by FSANZ's own risk assessment which demonstrated:

> "*no public health and safety concerns, there is no scientific or technical basis to restrict addition of L(+) lactic acid producing microorganisms*" (FSANZ, CP1, 2021).

L(+) lactic acid producing microorganisms and pre-market assessment

162. In response to submitters comments to FSANZ CP1 2021, FSANZ outlines in CFS1 that L(+) lactic acid producing microorganisms require pre-market assessment and infer these are novel foods. INC does not agree that all L(+) lactic acid producing microorganisms are novel foods.

163. Currently, manufacturers have regard to various aspects of the Food Standards Code when developing new formulations and introducing new ingredients. As such, when L(+) lactic acid producing microorganisms are considered to be added to infant formula, manufacturers conduct reviews for safety and suitability while also considering the GM and novel food status (as horizontal standards) to determine if FSANZ pre-market assessment is required.

164. The science on the infant gut colonisation demonstrates that infants have high exposure to L(+) lactic acid producing microorganisms, including Lactobacillus or Bifidobacterium:

> "Species of both genera can be found in human breast milk, are common gut commensals in humans and other animals, and are commonly isolated from dairy and other foods. Lactobacilli are also considered ubiquitous in the environment. Thus, exposure of infants to lactic acid bacterial such as lactobacilli and bifidobacterial can be regarded as a natural event." (Dekker et al.).

165. This demonstrates that a number of L(+) lactic acid producing microorganisms, specifically of the Lactobacillus and Bifidobacterium genera may be considered not-novel in infants.

166. The EU operates a Qualified Presumption of Safety ("**QPS**") list to support food manufacturers in determining if a further pre-market safety assessment is required. To be granted QPS status, the taxonomic identity must be well defined, the available body of knowledge must be sufficient to establish its safety, a lack of pathogenic properties must be established and substantiated and its intended use must be clearly described. Many Lactobacilli and Bifidobacterium have EU QPS Status.

167. To summarise, L(+) lactic acid producing microorganisms are generally considered safe, traditional and common substances for infants (i.e. not novel); Lactobacilli and Bifidobacterium genera abundantly populate the infant gut, and can be found on the EU QPS list. The horizontal novel and GM standards are the appropriate level of regulation to manage exceptions that require FSANZ pre-market assessment prior to addition. FSANZ's own risk assessment found that non-pathogenic and/or non-toxigenic L(+) lactic acid producing microorganisms were safe for healthy infants and the proposed

update to restrict L(+) lactic acid producing microorganisms addition for acidification only purpose is not aligned with Codex and EU.

Public health and cost impacts of proposed change

168. It is not regulatory best practice – or even regulatory practice – to retrospectively change a permission that has been in place for in excess of two decades unless there is a public health risk.

169. The public health consequences of doing so would be severe:
    - extensive product withdrawal and removal from shelves undermining confidence in the regulatory system that had allowed such products to remain in market for that period of time without taking compliance action
    - creating stress for caregivers transitioning infants from their current formulation to another formulation.
    - creating panic buying and shortages of supply (as the US has recently experienced, resupply is difficult and takes time).

170. The cost to industry for such an exercise is incalculable but would include existing product withdrawnals, loss of export markets, and global headlines. Australia and New Zealand trade impacts would be significant.

If proposal proceeds

171. Notwithstanding proposing to wind the clock back 22 years to a position misaligned internationally, a position we very strongly oppose, if FSANZ proceeds with “clarifying” addition of L(+) lactic acid producing microorganisms for acidification only, consideration must be given to supporting industry in the continued use of existing L(+) lactic acid producing microorganisms used in existing products that are not novel and have a demonstrated history of safe use and no market failure.

172. Grandfathering of existing strains in use must be provided to avoid retrospective regulatory amendment without cause, undermining the demonstrated safety of cultures in use and the reputational damage that would ensue.

173. FSANZ needs to consider if the restriction to acidification is appropriate to follow--on formula since there is a history of safe consumption of L(+) lactic acid producing microorganisms in older infants through complementary foods such as cheese and yoghurt.

174. FSANZ also needs to consider that if the restriction to acidification is introduced, there will be a need for it to provide necessary extra resources to conduct assessments of an anticipated large number of applications for pre-market assessment to permit addition of L(+) lactic acid producing microorganisms to infant formula within the transition period. Additionally, there will be a substantial cost to industry in submitting such applications.

175. In summary the consequences of the proposed change to *L(+) lactic acid producing microorganisms* are:
    - severe public health consequences within and external to Australia and New Zealand
    - significant/catastrophic trade impacts
    - huge costs to industry
    - huge resource issues for FSANZ and all stakeholders to address the wave of applications that would be necessary.

SD1 7 Gene Technology

176. FSANZ proposes to maintain the status quo that all food produced using gene technology, or have an ingredient or component produced using gene technology requires assessment and express permission.

177. INC supports maintaining the status quo for gene technology applicable to Standard 2.9.1.

CFS1 6 Nutrient Composition (SD2)

General Comments

Units of Measure

178. In FSANZ 2021 CP2, FSANZ proposed to overcome technical calculation errors identified in the nutrient composition specified in Codex STAN 72-1981 by aligning with the minimum or maximum values in this Standard as stated in units per 100kJ.

179. INC agrees with FSANZ that from a public health perspective these differences are small and not nutritionally significant. However, FSANZ has not considered the practical and financial impact of aligning the limits on the basis of per 100kJ only. For example, product that meets the Codex limits per 100 kcal may not meet the limits per 100kJ and would be rejected. Further, for New Zealand manufacturers, exemptions would need to be requested for each difference. This adds cost for both manufacturers and MPI.

180. INC recommends again that instead, FSANZ aligns with the units stated per 100kcal multiplied by 4.18. This is because the limits in Codex STAN 72-1981 were set on a kcal basis and the limits per 100kJ listed within it were subsequently calculated from the kcal figures, in some cases incorrectly. This approach for the Food Standards Code will result in better alignment of the revised Standard 2.9.1 with Codex STAN 72-1981. INC notes that the Codex draft Standard for FUFOI has adopted this approach.

181. INC also recommends that limits on nutrient composition are consistently stated to 2 significant figures (with exceptions like energy, where more significant figures are warranted, stated to 3 significant figures).

182. INC has found it complex to consider kcal, kJ and conversions. We note that both Codex and the EU present levels used in relation to infant formula and follow up formula in both kcal and kJ. INC strongly recommends FSANZ adopts this approach in Standard 2.9.1 and the associated Schedules.

Guidance Upper Limits (GULs)

183. INC notes that GULs are referred to in the call for submissions. Currently guideline maximum amounts of vitamins and minerals in infant formula products are listed in Schedule S29—10. They are not referred to as GULs. To better align with Codex standards, INC recommends that the term ‘GUL’ is used within the Food Standards Code replacing the use of guideline maximum amounts.

184. INC also recommends that the Guidance Upper Limits are defined clearly in the Code as outlined in the definition Section 3.

Nitrogen Conversion Factor

185. FSANZ's preferred option is to adopt a single nitrogen conversion factor of 6.25 as it aligns with the EU 2016/127 and the Codex draft Standard for FuFOI. FSANZ considers this is valid for whey and soy-based infant formula.

186. INC supports FSANZ's preferred option to adopt a NCF of 6.25 for both dairy and soy-based formula to align with Codex STAN 72-1981 and the draft Codex FUF Standard. This will achieve harmonisation with international standards and have fewer issues to work through for implementation than Option 2, a choice of three NCFs (5.71, 6.25, 6.38), as was previously drafted.

187. We note, however, that Option 2 also had the potential to achieve harmonisation, and could have provided a valid, flexible approach with overlap with the existing use of NCFs in formula, however INC does not support mandating different NCF for whey-based vs other dairy formula as was previously proposed by FSANZ due to insufficient evidence to support this.

Milk Protein

188. FSANZ includes goat milk in its preferred option for permitted protein sources however the nutrient composition tables refer only to cow's milk.

189. INC recommends that in CFS 2, the nutrient composition requirements state 'milk protein'.

CFS1 6.1 Infant formula

SD2 Macronutrients (p20)

FSANZ's preferred option for IF macronutrient composition is set out in SD2 Table 2.1.3 Preferred macronutrient composition for infant formula reproduced below:

Table 2.1.3 Preferred macronutrient composition for infant formula

Nutrient	Unit	Change Proposed	Proposed Approach		Standard 2.9.1 (Schedule 29)		Codex CXS 72-1981		EU 2016/127	
		(Y/N)	Min	Max	Min	Max	Min	Max	Min	Max
Energy	kJ/L	Yes	2500	2950	2500	3150	2500	2950	2500	2930
Protein (cow)	g/100kJ	Yes	0.43	0.7	0.45	0.7	0.45	0.7	0.43	0.6
Protein (soy)	g/100kJ	Yes	0.54	0.7	NS	NS	0.5	0.7	0.54	0.67
Total fat	g/100kJ	Yes	1.05	1.4	1.05	1.5	1.05	1.4	1.1	1.4
LA	mg/100kJ	Yes	90	330*	90	371	70	330*	120	300
ALA	mg/100kJ	Yes	12	NS	11	57	12	NS	12	24
DHA	mg/100kJ	Yes	NS	7.2	NS	NS	NS	0.5^	4.8	12
PL	g/L	Yes	NS	2	NS	NS	NS	2	NS	2
TFA	% total FA	No	NS	4	NS	4	NS	3	NS	3
Myristic & Lauric acid	% total FA	No	NS	NS	NS	NS	NS	20	NS	NS
Erucic Acid	% total FA	No	NS	1	NS	1	NS	1	NS	0.4
AA	% total FA	No	NS	1	NS	1	≥ DHA	NS	NS	1
Carbohydrate	g/100kJ	o	NS	NS	NS	NS	2.2	3.3	2.2	3.3

* = GUL ^ = % total fatty acids

Retain restrictions on inulin-type fructans and galacto-oligosaccharides in Standard 2.9.1—7.

190. INC agrees with the FSANZ's preferred option for the following macronutrients with no further comments:
    a. Energy
    b. Protein quality
    c. Linoleic acid (LA)
    d. Linolenic acid (ALA
    e. LA:ALA ratio
    f. Trans fatty acids (TFA)
    g. Myristic & Lauric acid
    h. Erucic Acid
    i. Dietary Fibre
    j. Carbohydrate range

Protein Range (Milk Proteins)

191. INC agrees with the FSANZ proposal for a protein range of 0.43 – 0.72 g/100kJ (maximum corrected to two significant figures). However, INC opposes this range being applied only to cows' milk-based formulas. INC recommends this range is applied to mammalian milk-based infant formula products, which is consistent with Codex STAN 72-1981 and EU Regulation 2016/127.

Protein Range (Soy Protein)

192. INC is not aware of any indications that soy-based formulas, formulated to Standard 2.9.1, are unable to meet nutritional needs to support normal growth and development.

193. INC agrees with the FSANZ's proposal for a protein range of 0.54 – 0.72 g/100kJ (maximum corrected to two significant figures) with an NCF=6.25.

Protein Source

194. FSANZ's preferred approach is that the protein sources in infant formula be specified to be cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins normally used in infant formula and soy protein isolate. Any protein sources outside of those specified will need to undergo a premarket assessment through FSANZ.

195. Extensively hydrolysed proteins or proteins hydrolysed for other nutritive purposes permitted in Special Medical Purpose Products for infants (SMPPi) are covered in Section 8 of this submission.

196. INC agrees that all proteins sources used in the manufacture of infant formula need to be safe, suitable, and support normal growth and development of infants, while also not interfering with absorption of other essential nutrients.

197. Dietary protein is an essential component of the infant diet, supplying the body with nitrogen and amino acids. Protein occurs in all living cells and has both functional and structural properties (NHMRC, 2006). Proteins play a particularly important function in infancy, when growth and development are at their peak.

198. The amino acid profile of infant formulas is intended to mimic their profile in human milk with the intent that proteins provided in infant and follow-on formulas achieve similar functions (i.e. infant growth and development) to naturally-occurring proteins in human milk. In addition the ratio of whey to casein proteins are frequently adjusted in milk-based infant formula products to mimic the whey to casein ratio observed in human milk for most of the lactation period (Nagasawa et al., 1972; Nagra, 1989; Kunz and Lönnerdal, 1992; Montagne et al., 2000; Lönnerdal and Kelleher, 2009).

199. The Food Standards Code already controls the amount of protein and protein quality through the establishment of essential amino acid minimums. INC highlights that where a new protein source is added to meet the established requirements for normal growth and development of a healthy infant then pre-market assessment should not require to demonstrate benefit.

200. INC agrees with FSANZ that recent studies have re-affirmed that partially hydrolysed proteins are safe and appropriate for use in starter formulas and show no difference in growth or development when compared to infants who consume intact cow's milk protein formula (Vandenplas 2019, Gappa 2021).

201. INC understands that all members except one consider that a novel protein source for use in infant formula that has been concentrated, refined or synthesised to achieve a nutritional purpose would require pre-market approval (as per Standard 1.1.2—12). Also, that an enzyme used in the preparation of protein hydrolysates for infant formula needs to be approved within the Food Standards Code. INC notes that there is at least one product on the market using a concentrated, refined plant protein to achieve a nutritional purpose and that this will be the subject of separate submission.

202. FSANZ does not appear to provide any scientific justification to vary from Codex internationally in this area. Codex STAN 72-1981 and Codex draft FUFOI clearly allow milk of other animals as the following attests:

> *Codex draft FUFOI*
> *3.1.1. Follow-up formula for older infants is a product based on **milk of cows or other animals or a mixture thereof** and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.*
>
> *Codex STAN 72-1981*
> *3.1.1 Infant formula is a product based on **milk of cows or other animals or a mixture thereof** and/or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten-free.*

203. Currently, sheep milk-based infant formulas are made and for sale in New Zealand and exported to Australia and other international markets including China, Malaysia and Hong Kong. Sheep milk formula has been available for several years on the market without any issues raised by authorities in New Zealand or Australia.

204. Notably, the FSANZ proposal CP2 2021 and submitters to FSANZ CP2 2021 did not raise any issues specifically with sheep milk or other mammalian milk. In fact, the New Zealand Food Safety Authority submission did not support a restriction for mammalian milks. The main concerns for protein source raised under the proposal and by submitters in 2021 were in relation to plant-based proteins and the presence of anti-nutritive factors.

205. Although most products (including infant formulas) are based on cows' milk which accounts for 83% of global milk production, the use of other mammalian milks has increased in recent years. The contributions of buffalo (13%), goat (2.3%), sheep (1.4%) and camel (0.3%) milk are ever-increasing, and these milk alternatives have the potential to contribute to food security, nutrition and health (Verduci et al. 2019). Milk from Ovis aries (sheep), is currently available in New Zealand, China, Turkey, Greece.

Syria and Romania, amongst others (Maryniak et al. 2022). Sheep milk, like all mammalian milks, has a high nutritional content and quality protein even before modification in accordance with infant formula standards.

206. Although INC is opposed to a positive list for protein sources, at the request of FSANZ, data that would support the inclusion of sheep milk formula is included in this submission (see Attachment B).

207. A number of New Zealand government authorities already refer to sheep milk formula which demonstrates acceptance that sheep milk formula is accepted as complying with the current Food Standards Code and is a suitable protein source. This includes:

- the New Zealand Ministry of Health "…*when breast milk is not available, a dairy-based infant formula (made from cows', goats' or sheep milk) is the next best choice for most babies. Research suggests that no particular infant formula offers benefits over any other*"
- MPI in the New Zealand *Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children* states "…*dairy-based means the formula contains, as its predominant protein constituent, protein derived or processed from milk extracted from a milking animal such as a cow, goat or sheep*"

208. Individual INC members will provide further documentation demonstrating compliance of sheep milk-based infant formula with the protein requirements specified by Codex and the Food Standards Code.

Amino Acids

209. FSANZ's preferred option is to align the minimum amounts of all amino acids with Codex STAN 72-1981.

210. INC agrees with this approach and assumes that FSANZ will retain the current wording in Standard 2.9.1—10 of the Food Standards Code.

211. In addition, as INC requested in response to CP2 2021, INC recommends this include the option for clinical evaluation of the suitability for formula with methionine to cysteine ratios greater than 2 as is included in both the Codex STAN 72-1981 and EU Regulation 2016/127.

212. The additional note regarding clinical evaluation of suitability for formulas with methionine to cysteine ratios greater than 2 is important. INC refers to both the Codex and EU Footnotes on this matter (INC submission on FSANZ CP2 2021). This approach ensures regulations applied do not inadvertently lead to compliance issues for formulas that have been clinically demonstrated as suitable to support infant growth and development

Total Fat

213. INC agrees with the FSANZ approach and recommends that three significant figures be applied to support a rounding to 1.44 g/100kJ. This rounded level is slightly less of a reduction from the current 1.5 g/100kJ than 1.4 g/100kJ and is therefore of significance to industry. Also, the current minimum is provided to 3 significant figures and the maximum should be aligned to this rounding for consistency within this provision.

Long Chain Polyunsaturated Fatty Acids (LC-PUFA), Docosahexaenoic Acid (DHA), Eicosapentaenoic Acid (EPA), Arachidonic acid (AA) and their ratios

214. INC agrees with retaining the current voluntary permission for DHA, EPA and AA addition to infant formula.

215. INC supports replacing the current maximum for long chain omega-3 series fatty acids with a DHA GUL however remains opposed to the lower GUL preferred by FSANZ. A GUL of 12mg/100kJ is within the range reported in breast milk of 0.06-1.4% (Brenna et al. 2007). INC strongly supports a GUL of 12mg/100kJ.

216. The declared level of DHA in infant formula currently on the market in Australia and New Zealand exceeds the proposed maximum of 7.2 mg/100kJ. These products would have to be withdrawn from the market. It should be noted that whilst other declared levels may be below the new maximum, this does not take into consideration manufacturing and analytical tolerances. INC members have provided further commercial-in-confidence data on this area.

217. INC recommends aligning with Codex STAN 72-1981, which does not include an AA maximum but instead includes a ratio with DHA, rather than retaining the current limit of 1% fatty acids.

218. INC agrees with retaining the current ratio of EPA no more than DHA and replacing the minimum ratio of total n-6 to total n-3 LCPUFA with the requirement for AA to be no less than DHA to avoid metabolic imbalance. INC considers that there is an error in Table 2.4.3 and has provided further comment in that Section.

Fat Source

219. FSANZ's preferred option is to retain the current approach as it is similar to the approach taken in Codex STAN 72-1981.

220. INC agrees with FSANZ's preferred option which restricts specific fats and no further definition of fat source.

Medium Chain Triglycerides (MCT)

221. FSANZ's preferred option is to retain the current MCT restriction on the basis that the inclusion of MCT in infant formula does not provide any benefit to infant health, and that MCTs are not normally present in significant amounts in breast milk.

222. INC continues its strong opposition to this restriction, given that it is peculiar to Australia and New Zealand and not aligned with Codex or any other international jurisdiction.

223. In addition, the term 'MCT" is problematic. The current definition for MCT refers to saturated fatty acids designated 8.0 and 10.0, yet in most peer reviewed papers MCFA and MCTs encompass saturated fatty acids designated 6.0. 8.0, 10.0 and 12.0. This term is also sometimes mistakenly used interchangeably with medium chain fatty acids (MCFA) (see examples provided in Attachment A). Consequently, the current definition does not achieve regulatory clarity.

224. If the restriction is to be maintained, then INC recommends changes to remove the existing ambiguity. We reiterate our previous request to apply the restriction, if retained, to MCT oils and to provide a definition for these. The following wording is recommended:

> **"MCT oils** means oils commercially manufactured via fractionation and /or esterification to yield a high proportion of medium chain saturated fatty acids (designated by 8.0 or 10.0)."

225. The Standard could then be amended to restrict the use of 'MCT oils' as an ingredient other than for a fat-soluble vitamin as reflected in Standard 2.9.1(1)(a)(ii):

> *"for a fat soluble vitamin that is specified in the table to section S29—9—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula*".

226. Implementation of these changes would provide improved regulatory clarity making Standard 2.9.1 more readily understandable and implementable by food manufacturers and more readily enforceable by jurisdictions.

227. INC does not agree that the definition of medium chain triglycerides is out of scope. Although, FSANZ has advised that the nutrient definitions are out of scope, most nutrient definitions (e.g. trans-fatty acids) are used elsewhere in the Food Standards Code while the definition of medium chain triglycerides is only used under Standard 2.9.1 and therefore the definition is being considered by FSANZ under section 3.4.3. Please refer to our comments in relation to CFS1 section 3.4.3 as well as Attachment A for examples illustrating different applications of the term MCT in the literature.

Phospholipids (PL)

228. FSANZ proposes a maximum of 2 g/L. If this is based off the level of Codex STAN 72-1981 of 300 mg / 100 kcal the appropriate maximum would be 2.1 g/L based on a maximum energy of 70 kcal/100mL.

229. INC considers that there are no safety concerns, and recommends the limit be a GUL and not a maximum. INC prefers the GUL units for PL in mg/100kJ so 72 mg/100kJ (2.1 g/L) rather than g/L.

230. INC refers to its earlier comments made in both 2016 and 2021 (CP2) submissions that highlight a total PL limit is unnecessary in the absence of specific safety concerns, no evidence of adverse effects or any market failure with the current approach where no limit is set. Even so, FSANZ is continuing to pursue an upper limit. If this persists, INC would support the 72mg/100kJ (2.1g/L) which aligns with both EU and Codex. We recommend this is, instead, presented as a GUL rather than a maximum.

231. We consider a GUL is more appropriate to reflect the absence of adverse effects and low risk posed by PL intake in infancy. For example, older infants regularly consume significantly higher amounts of PL in usual complementary foods eg 3.5g of PL in a hen's egg (Koletzko et al 2012). Use of a GUL is in line with the general principles for the selection of GULs or maximum amounts for vitamin and mineral addition

232. As highlighted by FSANZ in Section 7.1 of CP2 in 2021, absolute maximum amounts are only prescribed for vitamins and minerals considered to pose a significant risk to infants if consumed in excess. GULs may instead be used for nutrients where the risk is "n*ot of significance on the basis of current scientific knowledge (ANZFA 1999a IN CP2*)".

233. INC has repeatedly stated that the maximum for lecithin when used as a food additive, should remain at 5000 mg/kg (approximately equivalent to 5 g/L). This maintains alignment to Codex of 0.5 g per 100 mL. As in our submission on FSANZ CP2 2021, we noted that lecithin was not addressed in CP1 which looked at food additives. Lecithin

has not been listed in Table 6.3 of the current CFS1 but inexplicably, a limit of 1g/L is proposed in SD2.

234. Lecithin is currently only permitted for use as a food additive, but the present approach appears to infer treatment as a nutritive substance. We wonder if there is an intention to add lecithin to the list of approved nutritive substances or to leave it as a food additive and the adjustment made in Schedule 15. INC considers that the current proposal in SD2 would introduce contradictions to the Food Standards Code. INC considers that the function of Lecithin in infant formula products is primarily as an additive.

235. Manufacturers generally add lecithin for technological purposes including instantising dry infant formula powders for easier dispersion in water or adding to the oil blend during the manufacture of infant formula to stabilise the oil droplets during emulsification of the oil blend with the proteins. This needs to be accommodated and there is concern the proposed revised and significantly reduced limit of 1g/L is unnecessarily restrictive and does not allow for sufficient flexibility during manufacture.

Carbohydrate source

236. FSANZ's preferred option is to adopt limits on sucrose and fructose that are aligned with Codex STAN 72-1981.

237. INC accepts the proposal is to adopt limits on sucrose and fructose that are aligned with the guidance in Codex STAN 72-1981 due to the safety concerns. INC notes, however, that Codex STAN 72-1981 provides the following guidelines which does not include specific limits:

> *"Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance."*

238. INC recommends that consideration is given to including the rationale from the Codex documents for guidance to avoid the use of sucrose and fructose. Also, there should be no inference that no sucrose or fructose is permissible in these products as these sugars can be present in low levels in other ingredients, for example fructo-oligosaccharides.

239. INC suggests text along the following lines for consideration:

> *"The use of sucrose, except where needed, and fructose, as direct ingredients should be avoided in infant formula products. This is to address potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance, limit sugars other than lactose and manage sweetness".*

SD2 2.2 Micronutrients

240. FSANZ's preferred option is set out in SD2 Table 2.2.3 Preferred micronutrient composition for infant formula reproduced below.

Table 2.2.3 Preferred micronutrient composition for infant formula

Nutrient	Unit	Change Proposed	Proposed Approach		Standard 2.9.1 (Schedule 29)		Codex CXS 72-1981		EU 2016/127	
		(Y/N)	Min	Max	Min	Max	Min	Max	Min	Max
Vitamin A	µg RE/100 kJ	No	14	43	14	43	14	43	16.7	27.2
Vitamin D	µg /100kJ	No	0.25	0.63	0.25	0.63	0.25	0.6	0.48	0.6

Vitamin E	mgα-TE/100kJ	Yes	0.12	1.2*	0.11	1.1	0.12	1.2*	0.14	1.2
Vitamin K	µg /100kJ	Yes	0.24	6.5*	1	5.0*	1	6.5*	0.24	6
Thiamin	µg /100kJ	Yes	10	72*	10	48*	14	72*	9.6	72
Riboflavin	µg /100kJ	Yes	14.3	119*	14	86*	19	119*	14.3	95.6
Niacin	µg /100kJ	Yes	70	360*	130	480*	70	360*	100	360
Vitamin B6	µg /100kJ	Yes	8.5	45*	9	36	8.5	45*	4.8	41.8
Vitamin B12	µg /100kJ	Yes	0.025	0.36*	0.025	0.17*	0.025	0.36*	0.02	0.12
Pantothenic acid	µg /100kJ	Yes	96	478*	70	360*	96	478*	100	480
Folic acid	µg /100kJ	Yes	2.5	12*	2	8	2.5	12*	3.6	11.4
Vitamin C	mg/100kJ	Yes	1.7	17*	1.7	5.4*	2.5	17*	0.96	7.2
Biotin	µg /100kJ	Yes	0.24	2.4*	0.36	2.7	0.4	2.4*	0.24	1.8
Iron	mg/100kJ	No	0.2	0.5	0.2	0.5	0.1	NS	0.07	0.31
Calcium	mg/100kJ	Yes	12	35*	12	33*	12	35*	12	33.5
Phosphorus	mg/100kJ	Yes	6	24*	6	25	6	24*	6	21.5
Magnesium	mg/100kJ	Yes	1.2	3.6*	1.2	4.0	1.2	3.6*	1.2	3.6
Sodium	mg/100kJ	Yes	5	14	5	15	5	14	6	14.3
Chloride	mg/100kJ	Yes	12	38	12	35	12	38	14.3	38.2
Potassium	mg/100kJ	Yes	14	43	20	50	14	43	19.1	38.2
Manganese	µg /100kJ	Yes	0.25	24*	0.24	24	0.25	24*	0.24	24
Iodine	µg /100kJ	Yes	2.5	14*	1.2	10	2.5	14*	3.6	6.9
Selenium	µg /100kJ	Yes	0.48	2.2*	0.25	1.19	0.24	2.2*	0.72	2
Copper	µg /100kJ	Yes	8.5	29*	14	43	8.5	29*	14.3	24
Zinc	mg/100kJ	Yes	0.12	0.36*	0.12	0.43	0.12	0.36*	0.12	0.24

* = GUL NS = not specified

241. INC agrees with FSANZ's preferred option for micronutrients, except as noted below, however refers again to comments in the paragraphs on Units of Measure. The current approach of aligning only the kJ values creates unnecessary complexity for manufacturers.

Vitamin E

242. INC recommends alignment of the Vitamin E minimum to the EU and setting a slightly higher minimum of 0.14 mg/100kJ (0.60 mg/100kcal) with no additional vitamin E PUFA requirement, provided that SMPPi are able to be aligned to Codex. This would result in the removal of the existing conditions around vitamin E PUFA which would be easier to set and check from a compliance perspective.

Thiamin

243. As we have previously submitted, INC supports FSANZ's rationale to retain the current minimum for thiamin in Standard 2.9.1 of 10 µg/100kJ and to not align thiamin with the Codex minimum of 14 µg/100kJ. As the EU 2016/127 minimum is slightly lower at 9.6 µg/100kJ, INC would also support lowering to the EU minimum rather than maintaining the current level in the Food Standards Code.

Iron

244. While INC understands FSANZ's rationale for iron levels we do not support the levels as these are not aligned internationally.

Equivalents, conversion factors and units of expression

245. FSANZ's preferred option is set out in SD2 Table 2.4.3 Preferred equivalents, conversion factors and units of expression for infant formula reproduced below.

Table 2.4.3 Preferred equivalents, conversion factors and units of expression for infant formula

Nutrient	Change Proposed	Proposed Approach	Standard 2.9.1 (Schedule 29)
	(Yes/No)	Equivalents	Equivalents
		Conversion Factors	Conversion Factors
		Units of Expression	Units of Expression
Vitamin A	No	Retinol, retinyl acetate, retinyl palmitate, retinyl propionate, β-carotene	Retinol, retinyl acetate, retinyl palmitate, retinyl propionate, β-carotene
	Yes	exclude β-carotene from the vitamin A calculation	NS
	No	µg RE/100kJ	µg RE/100 kJ
Folic Acid	No	Folic acid	Folic acid
	Yes	Naturally occurring folate will not be included in the permitted range	NS
	No	µg / 100kJ	µg / 100kJ
Vitamin E	No	dl-α-tocopherol, d-α-tocopherol concentrate, tocopherols concentrate mixed, d-α-tocopheryl acetate, dl-α-tocopheryl acetate, d-α-tocopheryl acid succinate, dl-α-tocopheryl succinate	dl-α-tocopherol, d-α-tocopherol concentrate, tocopherols concentrate mixed, d-α-tocopheryl acetate, dl-α-tocopheryl acetate, d-α-tocopheryl acid succinate, dl-α-tocopheryl succinate
	No	NS	NS
	Yes	α-TE / 100kJ	mg/100kJ
Niacin	No	Niacinamide	Niacinamide
	No	Add niacin and any niacin provided from the conversion of the amino acid tryptophan, using the conversion factor 1:60.	Add niacin and any niacin provided from the conversion of the amino acid tryptophan, using the conversion factor 1:60.
	No	µg / 100kJ	µg / 100kJ
Fatty Acids (LA, ALA, DHA)	No	NA	NA
	No	NA	NA
	Yes	mg/100kJ	% total fatty acids

NA = Not Applicable

246. INC agrees with the FSANZ preferred options for equivalents, conversion factors and units of expression, which are aligned with Codex STAN 72-1981, with the following exceptions and additional comments.

Vitamin A

247. INC agrees with FSANZ's option to retain the permission for β-carotene as a permitted form of vitamin A in Schedule S29–7. INC notes that there are no safety concerns and to remove the existing permission, which is aligned to Codex STAN 72-1981 and other international regulations would create an unnecessary barrier to trade.

Niacin

248. SD2 Table 2.4.3 Preferred equivalents, conversion factors and units of expression for infant formula states that in Standard 2.9.1 (Schedule 29) there is a niacin conversion factor and that there will be no change:

> "*For niacin, add niacin and any niacin provided from the conversion of the amino acid tryptophan, using the conversion factor 1:60"*

249. INC believes that this may have been erroneously copied from Note 2 for S29—21 Amounts of nutrients for food for special medical purposes represented as a sole source of nutrition. INC does not agree with the insertion of this new requirement.

Ratios

250. FSANZ's preferred option is set out in the Table (un-numbered) Preferred ratios for Infant Formula from SD2 reproduced below.

Table (un-numbered) Preferred ratios for infant formula

Nutrient	Change Proposed (Y/N)	Proposed Approach		Standard 2.9.1 (Schedule 29)		Codex CXS 72-1981		EU 2016/127	
		Min	Max	Min	Max	Min	Max	Min	Max
Zn : Cu	Yes	NS	NS	NS	15 : 1	NS	NS	NS	NS
LA : ALA	No	5 : 1	15 : 1	5 : 1	15 : 1	5 : 1	15 : 1	NS	NS
Ca: P	Yes	1 : 1	2 : 1	1.2 : 1	2 : 1	1: 1	2 : 1	1: 1	2 : 1
Vitamin E : fatty acids	No	0.5mg : 1g	NS	0.5mg : 1g	NS	0.5mg : 1g	NS	NS	NS
EPA	No	NS	≤ DHA	NS	≤ DHA	NS	≤ DHA	NS	≤ DHA

NS = not specified

Ratio of total long chain omega 6 series fatty acids (C>=20) to total long chain omega 3 series fatty acids (C>=20) that is not less than 1.

251. INC agrees with the FSANZ preferred option for ratios in the Table above, except that INC recommends the removal of the Vitamin E ratio altogether. In any case, it should be noted that the ratio of Vitamin E: fatty acids should be the ratio of Vitamin E: **polyunsaturated fatty** acids.

252. INC considers that there is an error in the footnote of the Table. FSANZ has consistently proposed to replace the current minimum ratio of total n-6 and total n-3 fatty acids with a minimum ration of AA: DHA (2016, 2021). In the current consultation, FSANZ states that its preferred option is unchanged from 2016 consultation paper. INC does not support a minimum ratio of total long chain n-6 to n-3 fatty acid but rather a minimum ratio where AA ≥ DHA.

Other nutritive substances

253. FSANZ's preferred options are set out in SD2 Table 2.5.3 Other nutritive substances for infant formula reproduced below:

Table 2.5.3 Other nutritive substances for infant formula

Nutrient	Change Proposed (Y/N)	Units	Proposed Approach			Standard 2.9.1 (Schedule 29)		
			Vol/Man	Min	Max	Vol/Man	Min	Max
Choline	Yes	mg / 100kJ	Man	1.7	12	Vol	1.7	7.1
L-Carnitine	Yes	mg / 100kJ	Man	0.3	0.8*	Vol	0.21	0.8
Inositol	Yes	mg / 100kJ	Man	1.0	9.5*	Vol	1.0	9.5
Chromium	Yes	µg /100kJ	NS	NS	NS	Vol	NS	2.0*
Molybdenum	Yes	µg /100kJ	NS	NS	NS	Vol	NS	3.0*
Taurine	No	mg/100kJ	Vol	0.8	3	Vol	0.8	3.0
Lutein	No	µg/100kJ	Vol	1.5	5.0	Vol	1.5	5.0
2′-O-fucosyllactose ^	No	mg/100kJ	Vol	NS	96	Vol	NS	96

Nucleotides								
Adenosine-5′-monophosphate	Yes	mg / 100kJ	Vol	NS	0.38	Vol	0.14	0.38
Cytidine-5′-monophosphate	Yes	mg / 100kJ	Vol	NS	0.6	Vol	0.22	0.6
Guanosine-5′-monophosphate	Yes	mg / 100kJ	Vol	NS	0.12	Vol	0.04	0.12
Inosine-5′-monophosphate	Yes	mg / 100kJ	Vol	NS	0.24	Vol	0.08	0.24
Uridine-5′-monophosphate	Yes	mg / 100kJ	Vol	NS	0.42	Vol	0.13	0.42
Total free nucleotide 5'-monophosphates	Yes	mg / 100kJ	Vol	NS	3.8	Vol	≤ 3.8	NS

NS = not specified * = GUL Vol = Voluntary addition, Man = Mandatory Addition

^A combination of 2′-O-fucosyllactose and lacto-N-neotetraose may reach a maximum of 96 mg/100kJ, which contains not more than 24 mg of lacto-N-neotetraose

254. INC has the following comments in regard to FSANZ's preferred options for other nutritive substances for infant formula.

L-Carnitine

255. INC agrees that the presence of L-carnitine should be mandatory in infant formula to align with international regulations (EU, CODEX, GB) and scientific literature (SCF 2003, EFSA 2014, Koletzko 2005). INC supports the proposed minimum, however, we note the content conversion should be corrected to 0.29 mg/100kJ (1.2 mg/100kcal).

256. INC maintains that there should be no maximum or GUL for infant formula. FSANZ's proposed approach is not aligned with international regulations (EU, CODEX, GB) or expert scientific opinions (SCF 2003, EFSA 2014, Koletzko 2005), which do not recommend any maximum or GUL.

257. We note the Life Sciences Research Organisation ("**LSRO**") paper from 1998 suggests a maximum L-Carnitine level in infant formula, based on the upper end of the usual breast milk content (LSRO 1998). However, the LSRO paper was subsequently considered within the recommendations of the ESPHGAN international expert group paper on the global standard for infant formula and no maximum was set (Koletzko 2005). Further, the ESPHGAN paper outlines that using only minimum and maximum human milk content to inform levels in infant formula can be limited, and that other factors such as the source of nutrients, absence of adverse effects and an established history of safe use should also be taken into account (Koletzko 2005).

258. Therefore, INC would emphasise previous evidence provided (May 2016, September 2021) which demonstrates that dairy-based infant formula products typically contain higher levels of L-Carnitine than the GUL currently proposed, due to the natural and variable content of L-Carnitine in dairy ingredients and that there are no indications of any untoward effects of higher intakes of L-Carnitine in infants (Koletzko 2005), highlighting that no upper limit is required.

259. Whilst INC strongly supports no maximum or GUL for infant formula as outlined, if FSANZ persists with proposing a GUL level in infant formula, there must be a clear GUL definition to ensure consistency of interpretation and which acknowledges technical issues and nutrient source, as outlined in section 3.4.4.

260. Consideration should also be given to the natural L-Carnitine content in infant formula products when setting a GUL level, particularly given L-Carnitine is predominantly found in the whey portion of dairy and most infant formulas are whey dominant.

Nucleotides

261. INC fully supports FSANZ proposal to amend the maximum for total limit of nucleotides in Standards 2.9.1 to limit for total *free* nucleotides. This clarification is very much appreciated.

262. INC agrees with the FSANZ option to retain the current permissions in Schedule 29 for individual 5'monophosphate nucleotides with one key exception. INC recommends that the upper limit specified for Guanosine-5′-monophosphate (GMP) is amended from a maximum to a GUL or to a higher maximum which accommodates the natural levels in goat milk based infant formula. This issue was raised in submissions made to FSANZ CP2 2021 which provided evidence-based rationale for this change. Refer to data provided in Attachment C.

263. Assuming that infant formula has an energy content of 65kcal/100mL (270kJ/100mL the mean level of GMP is 0.31mg/100kJ with levels as high as 0.4mg/100kJ possible. It is our understanding that the intent of the upper limits applied for individual 5'monophosphate nucleotides are intended to constrain nucleotide supplementation of formulas, not the nucleotide levels naturally present. There is ambiguity on this and the current maximum is proving to be a recurring issue with regard to compliance verification for goat milk-based formulas. This P1028 review of Standard 2.9.1 provides an opportunity for this issue, which we regard as an unintended consequence, to be addressed.

264. FSANZ's rationale for not making this requested amendment was that the current maximum is aligned with the EU regulations. The evidence presented was published since the last review of the EU regulations and INC strongly recommends that FSANZ uses this P1028 review to update the Food Standards Code provisions, in accordance with the most recent scientific evidence. Without this amendment the compliance of goat milk infant formula with the Food Standards Code will continue to be called into question despite the rigorous safety assessments undertaken on goat milk-based formulas and the international recognition of the suitability of goat milk as a base for the manufacture of infant formula products.

265. Regulations are updated in different jurisdictions at different times and it is of paramount importance that any reviews conducted take into account the most recent scientific information and do not simply rely on limits set in other jurisdictions at reviews undertaken some years prior.

Taurine

266. INC supports the preferred option to retain the voluntary permission for taurine and the maximum within Standard 2.9.1 which is aligned with Codex and the EU regulation. INC recommends no minimum for taurine is defined which would be more consistent with international regulations.

267. INC recognises the need to monitor the evolution of science however it is important to understand that this does not follow a fixed time schedule. Only when new science emerges would it be appropriate to review specific nutrients.

Lutein

268. INC supports retaining the voluntary permission for lutein and the maximum within Standard 2.9.1 which has previously been assessed by FSANZ as part of *Application A594 - Lutein as a nutritive substance in infant formula*. For consistency with permissions for other optional ingredients, INC recommends that the minimum for lutein is removed.

269. Codex STAN 72-1981 includes permissions for optional ingredients that can be added in order to provide substances ordinarily found in breast milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies.

270. EU Regulation 2016/127 includes permission for other food "…ingredients, as the case may be, whose suitability for infants from birth has been established by generally accepted scientific data."

2′-O-fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT)

271. INC supports the preferred option to retain the current voluntary permissions.

Proposed composition once reconstituted

Fluoride

272. FSANZ's preferred option is to set a compositional limit for fluoride of 24 µg/100kJ when prepared ready for consumption and to remove the labelling statements relating to dental fluorosis in paragraph 2.9.1—23(1)(b). This limit would then be addressed within paragraph 2.9.1—23(2)(a).

273. INC supports the increase to 24 µg/100kJ of fluoride in alignment with Codex and removal of the labelling requirements on dental fluorosis but recommends this is additionally specified on a product 'as sold' basis.

274. Water is the main contributor to the fluoride content of infant formula as consumed. Only specifying the maximum of 24 µg/100kJ when reconstituted and prepared ready for consumption, is ambiguous to interpret and enforce. It is not clear whether regulators and manufacturers should assume no fluoride content, average amount of fluoride content or a high level of fluoride content in water when calculating levels to determine compliance. The manufacturer might attempt to make provision for this but does not have control over it. Since fluoridation varies by region across Australia and New Zealand and almost certainly in export destinations, this is an impossible task.

6.2 Follow-on formula

SD2 3.2 Macronutrients

275. FSANZ preferred option is set out in Table 3.2.3 Preferred macronutrient composition for follow-on formula of CFS 1 SD2 below.

Table 3.2.3 Preferred macronutrient composition for follow-on formula

Nutrient	Unit	P1028 follow-on formula	P1028 infant formula	Standard 2.9.1 (follow-on formula)	Codex CXS 72-1981	Codex Draft Standard for FuFOI	EU 2016/127 ANNEX I	EU 2016/127 ANNEX II
Energy	kJ/L	2500 - 2950	2500 - 2950	2500 - 3550	2500 - 2950	2510 - 2930	2500 – 2930	2500 - 2930
Protein (cow)	g/100kJ	0.43 – 0.7	0.43 – 0.7	0.38 – 1.3	0.45 – 0.7	0.43 – 0.72	0.43 – 0.6	0.38 – 0.6
Protein (soy)	g/100kJ	0.54 – 0.7	0.54 – 0.7	0.45 – 1.3	0.5 – 0.7	0.54 – 0.72	0.54 – 0.67	0.54 – 0.67
Carbohydrate	g/100kJ	NS	NS	NS	2.2 – 3.3	2.2 – 3.3	2.2 – 3.3	2.2 – 3.3
Total fat	g/100kJ	1.05 – 1.4	1.05 – 1.4	1.05 – 1.5	1.05 – 1.4	1.1 – 1.4	1.1 – 1.4	1.1 – 1.4
ALA	mg/100kJ	12 – NS	12 – NS	1.1 – 4%^	12 – NS	12 – NS	12 – 24	12 – 24

LA	mg/100kJ	90 – 330*	90 – 330*	9 – 26%^	70 – 330*	72 – 335*	120 – 300	120 - 300
DHA	mg/100kJ	NS - 7.2	NS - 7.2	NS	NS - 0.5%^	NS – 7*	4.8 – 12	4.8 – 12
AA	% total FA	NS – 1	NS – 1	NS – 1	≥ DHA	≥ DHA	NS – 1	NS – 1
TFA	% total FA	NS - 4	NS - 4	NS - 4	NS – 3	NS - 3	NS – 3	NS – 3
Lauric & Myristic acid	% total FA	NS	NS	NS	NS - 20	NS - 20	NS	NS
Erucic Acid	% total FA	NS - 1	NS – 1	NS – 1	NS – 1	NS – 1	NS – 0.4	NS – 0.4
PL	g/L	NS – 2	NS – 2	NS	NS – 2	NS – 2	NS – 2	NS – 2

* = GUL NS = not specified ^ = % total fatty acids
Retain restrictions on inulin-type fructans and galacto-oligosaccharides in Standard 2.9.1—7.

276. INC agrees with the FSANZ preferred options for the following macronutrients and has no further comments other than those already stated in Section 2 Infant Formula:
    - Energy
    - Protein Range (Soy)
    - Carbohydrate Range
    - Total Fat
    - Linoleic Acid (LA)
    - Linolenic Acid (ALA)
    - LA:ALA ratio
    - Fat Source
    - Trans Fatty Acids (TFA)
    - Myristic, Lauric and Erucic Acids
    - Dietary Fibre.

Protein Range (Milk Proteins)

277. FSANZ's preferred option is to prescribe a permitted protein range of 0.43 – 0.7 g/100kJ for cow's milk-based infant formula.

Minimum

278. INC does not support the proposed protein minimum of 0.43 g/100kJ for milk-based follow--on formula. INC notes that FSANZ did not take into consideration *A1173 – Minimum protein in follow-on formula* in this first CFS.

279. The outcome of A1173 was gazetted in December 2019, whilst Follow-on Formula was not being considered as part of P1028. INC recommends FSANZ adopts the outcomes of A1173:
    - *for a milk-based follow-on formula—a protein content of no less than 0.38 g/100kJ.*

280. The minimum protein requirements for soy-based follow-on formula and SMPPI are discussed elsewhere in this Submission.

281. INC recommends that this minimum be applied to all milk-based follow-on formula products.

Maximum

282. INC supports FSANZ's proposed protein maximum for follow-on formula however recommends this be updated to 2 significant figures to align with the recently revised draft Codex follow-on formula Standard i.e. 0.72g/100kJ and recommends further consideration based on the following.

283. INC notes the revised protein maximum is a significant reduction, nearly half that of the existing maximum of 1.3g/100kJ. INC recommends, along with both the Australian and New Zealand government positions in earlier Codex follow-on formula deliberations, allowing a slightly higher maximum (3.5g/100kcal 0.8g/100kJ) for follow-on formula as this would provide a 'cross-over' with the existing protein levels of the current Codex FUF Standard (3-5.5g/100kcal; 0.7 - 1.3 /100kJ). This level would also align with China's revised Follow-on Formula Standard.

Protein Source

284. INC refers to the comments made in relation to infant formula above.

Protein quality

285. FSANZ states that the nutrient composition for follow-on formula should only deviate from infant formula when there is substantiated science to support the differences in needs between the age groups.

286. INC assumes that FSANZ intends to retain the current requirements for protein quality in follow-on formula 6 to 12 months by mandating minimum amino acid amounts comparable to breastmilk levels. INC supports and recommends this approach.

Amino Acids

287. FSANZ states that the nutrient composition for follow-on formula should only deviate from infant formula when there is substantiated science to support the differences in needs between the age groups.

288. INC assumes that FSANZ intends to adopt the amino acid minimums set out in Codex STAN 72-1981 for follow-on formula 6 to 12 months. INC supports and recommends this approach.

289. In addition, as INC requested in response to FSANZ CP2 2021, INC recommends this include the option for clinical evaluation of the suitability for formula with methionine to cysteine ratios greater than 2 as is included in the Codex STAN 72-1981, Codex draft Standard FUFOI and EU Regulation 2016/127. The additional note regarding clinical evaluation of suitability for formulas with methionine to cysteine ratios greater than 2 is important. INC refers to both the Codex and EU Footnotes on this matter (as included in INC's submission to FSANZ CP2 2021 Attachment A). This approach ensures provisions applied do not inadvertently lead to compliance issues for formulas that have been clinically demonstrated as suitable to support infant growth and development.

Potential renal solute load (PRSL)

290. FSANZ's preferred option is to remove the maximum PRSL from Standard 2.9.1 based on the below rationale and international alignment.

291. FSANZ considers there is minimal risk associated with removal of the maximum PRSL. This is evidenced from a recent study that concluded healthy infants consuming a predominantly liquid diet have sufficient renal concentrating ability to maintain water balance even if the diet would provide a PRSL comparable to cow's milk (46 mOsm/100 kcal or 11 mOsm/100kJ) and WHO states that from the age of 4 months infants have a matured renal function and metabolic interconversion system which can manage a higher dietary protein content (Fomon 2020, Michaelsen 2000).

292. INC supports FSANZ's preferred option and concurs with the rationale.

Carbohydrate source

293. FSANZ states that the nutrient composition for follow-on formula should only deviate from infant formula when there is substantiated science to support the differences in needs between the age groups.

294. INC recommends that consideration is given to including the rationale for guidance to avoid the use of sucrose and fructose from the draft Codex Standard FuF for Older Infants:

> *"Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate."*

295. INC also notes that it is important that there is no inference that no sucrose or fructose is permissible in these products as these sugars can be present in low levels in other ingredients, for example fructo-oligosaccharides.

296. This reflects the international drive to reduce the amounts of sugars (excluding lactose in this case) in products and to manage sweetness.

297. INC recommends text along the following lines for inclusion:

> *"The use of sucrose, except where needed, and fructose, as direct ingredients should be avoided in infant formula products. This is to address potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance, limit sugars other than lactose and manage sweetness".*

Long Chain Polyunsaturated Fatty Acids (LC-PUFA), Docosahexaenoic Acid (DHA), Eicosapentaenoic Acid (EPA), Arachidonic acid (AA) and their ratios

298. INC refers to comments made in the Infant Formula Section of this submission.

Phospholipids (PL)

299. INC refers to comments made in the Infant Formula Section of this submission.

Micronutrients

300. FSANZ's preferred option is set out in SD2 Table 3.3.3 Preferred micronutrient composition for follow-on formula reproduced below:

Table 3.3.3 Preferred micronutrient composition for follow-on formula

Nutrient	Unit	P1028 follow-on formula	P1028 infant formula	Standard 2.9.1 (follow-on formula)	Codex CXS 72-1981	Codex Draft Standard for FuFOI	EU 2016/127 ANNEX I	EU 2016/127 ANNEX II
Vitamin A	µg RE/100 kJ	14 – 43	14 – 43	14 – 43	14 – 43	18 – 43	16.7 – 27.2	16.7 – 27.2
Niacin	µg /100kJ	70 – 360*	70 – 360*	130 - NS	70 – 360*	72 – 359*	100 – 360	100 – 360
Vitamin B6	µg /100kJ	8.5 – 45*	8.5 – 45*	9 – 36	8.5 – 45*	8 – 42*	4.8 – 41.8	4.8 – 41.8
Vitamin B12	µg /100kJ	0.025– 0.36*	0.025– 0.36*	0.025 – NS	0.025– 0.36*	0.02 - 0.36*	0.02 – 0.12	0.02– 0.12
Vitamin C	mg/100kJ	1.7 – 17*	1.7 – 17*	1.7 – NS	2.5 – 17*	2.4 – 17*	0.96 – 7.2	0.96 – 7.2
Vitamin D	µg /100kJ	0.25 – 0.63	0.25 – 0.63	0.25 – 0.63	0.25 - 6	0.24 – 0.72	0.48 – 0.6	0.48 – 0.72
Vitamin E	mgα-TE/100kJ	0.12 – 1.2*	0.12 – 1.2*	0.11 – 1.1	0.12 – 1.2*	0.12 – 1.2*	0.14 – 1.2	0.14 – 1.2
Vitamin K	µg /100kJ	0.24 – 6.5*	0.24 – 6.5*	1 – NS	1 – 6.5*	0.96 – 6*	0.24 – 6	0.24 – 6

Zinc	mg/100kJ	0.12 – 0.36*	0.12 – 0.36*	0.12 – 43	0.12 – 0.36*	0.12 – 0.36*	0.12 – 0.24	0.12 – 0.24
Thiamin	µg /100kJ	10 – 72*	10 – 72*	10 – NS	14 – 72*	14 – 72*	9.6 – 72	9.6 – 72
Biotin	µg /100kJ	0.24 – 2.4*	0.24 – 2.4*	0.36 – NS	0.4 – 2.4*	0.36 – 2.4*	0.24 – 1.8	0.24 – 1.8
Copper	µg /100kJ	8.5 – 29*	8.5 – 29*	14 – 43	8.5 – 29*	8 – 29*	14.3 – 24	14.3 - 24
Phosphorus	mg/100kJ	6 – 24*	6 – 24*	6 – 25	6 – 24*	6 – 24*	6 – 21.5	6 – 21.5
Magnesium	mg/100kJ	1.2 – 3.6*	1.2 – 3.6*	1.2 – 4.0	1.2 – 3.6*	1.2 – 3.6*	1.2 – 3.6	1.2 – 3.6
Folic acid	µg /100kJ	2.5 – 12*	2.5 – 12*	2 – NS	2.5 – 12*	2.4 – 12*	3.6 – 11.4	3.6 – 11.4
Sodium	mg/100kJ	5 – 14	5 – 14	5 – 15	5 – 14	4.8 – 14	6 – 14.3	6 – 14.3
Chloride	mg/100kJ	12 – 38	12 – 38	12 – 35	12 – 38	12 – 38	14.3 – 38.2	14.3 – 38.2
Potassium	mg/100kJ	14 – 43	14 – 43	20 – 50	14 – 43	14 – 43	19.1 – 38.2	19.1 – 38.2
Pantothenic acid	µg /100kJ	96 – 478*	96 – 478*	70 – NS	96 – 478*	96 – 478*	100 – 480	100 – 480
Manganese	µg /100kJ	0.25 – 24*	0.25 – 24*	0.24 – 24*	0.25 – 24*	0.24 – 24*	0.24 – 24	0.24 – 24
Riboflavin	µg /100kJ	14.3 – 119*	14.3 – 119*	14 – NS	19 – 119*	19 – 120*	14.3 – 95.6	14.3 – 95.6
Iron	mg/100kJ	0.2 – 0.5	0.2 – 0.5	0.2 – 0.5	0.1 – ~	0.24 – 0.48	0.07 – 0.31	0.14 – 0.48
Calcium	mg/100kJ	12 – 43*	12 – 35*	12 – NS	12 – 35*	12 – 43*	12 – 33.5	12 – 33.5
Iodine	µg /100kJ	2.5 – 14*	2.5 – 14*	1.2 – 10	2.5 – 14*	2.4 – 14*	3.6 – 6.9	3.6 – 6.9
Selenium	µg /100kJ	0.48 – 2.2*	0.48 – 2.2*	0.25 – 1.19	0.24 – 2.2*	0.48 – 2.2*	0.72 – 2	0.72 – 2

* = GUL NS = not specified ~ = levels may be determined by national authorities

301. INC agrees with the FSANZ preferred options for most micronutrients as these are closely aligned to Codex Draft Standard for FuFOI. The exceptions and rationale are set out below.

Vitamin D

302. INC does not support the level proposed for vitamin D. We note that the maximum for follow-on formula in the more recent EU regulation and in the draft revised Codex Standard for FUF is 0.72 µg/100kJ.

303. INC strongly recommends reviewing the maximum level of vitamin D for older infants and increasing it in line with these international standards. The rationale for this recommendation covering two key aspects is summarised below and each is expanded below the bullet points:

- **A:** the adequate intake set for infants by National Health Medical Research Council ("**NHMRC**") is not based on local or more recent evidence, is out of step internationally and should not form the basis for the level. The NHMRC was directed in 2018 to continue its review of nutrients including all adequate NRVs for infants however, this work has not yet been reported on since the phased approach in 2019 commenced with sodium and iodine (https://www.nrv.gov.au/). As yet, there does not appear to have been an infant working group membership established. Therefore, to future proof the standard it is appropriate to consider internationally accepted levels for infants.

- **B**: the contribution of vitamin D from foods would be very limited as FSANZ does not permit fortification in infant foods and the EU does allow fortification has no safety concerns for older infants.

A: *NHMRC adequate intake basis outdated*

304. There is a lack of data on the vitamin D status of Australian and New Zealand infants. The vitamin D Adequate Intake level set by NHMRC is based on outdated studies, which are 2-3 decades old (1982-1995) as set out in Table 3 below. These studies have a small sample of infants in countries other than in Australia and New Zealand. Therefore, the suggestion that Australian and New Zealand infants require less vitamin D is not based on any local data.

Table 3 **Studies relied on by NHMRC for vitamin D Adequate Intake level**

Study	**Population**	**Year Published**
Greer FR, Searcy J, Levin R, Steichen J, Steichn-Asche PS, Tsang RC. Bone mineral content and serum 25-hydroxyvitamin D concentrations in breast fed infants with and without supplementation; one-year follow-up. *J Paediatr* 1982;100:919-22.	18 healthy term infants, exclusively breastfed, in USA	1982
Leung S, Lui S, Swaminathan R. Vitamin D status of Hong Kong Chinese infants. *Acta Paediatr Scand* 1989;78:303-6.	150 bottle-fed infants in Hong Kong	1989
Markestad T, Elzouki AY. Vitamin-D deficiency rickets in northern Europe and Libya. In: Glorieux FH, ed. Rickets: *Nestle nutrition workshop series*, vol 21. New York, NY: Raven Press, 1991.	22 infants with rickets in Libya; 17 children with rickets in Europe	1991
Koo W, Tsang R. Calcium, magnesium, phosphorus and vitamin D. In: *Nutrition during infancy*, 2nd edition. Cincinatti: Digital Education, 1995. Pp 175-89.	"Formula-fed infants"	1995

305. The reference values for Australian and New Zealand infants are not aligned internationally where levels have been more recently set. As the current NHMRC guidelines are based on older international data, the levels therefore appear to be set too low as shown in Table 4 Australian and New Zealand vitamin D guidelines for infants compared with those from around the world below:

Table 4: **Australian vitamin D guidelines for infants compared with those from around the world:**

Country	**Recommended Dietary Reference Value for Vitamin D**	**Recommended Upper Limit of Vitamin D**	**Year Published**
Australia & New Zealand (NHMRC)	5 µg per day (0-12 months)	25 µg per day (7-12 months)	2006
USA (Institute of Medicine (IOM))	400 IU or 10 µg per day (for 0-12 months)	38 µg per day (7-12 months)	2010
Europe (EFSA)	10 µg (for 7-11 months)	25 µg per day (0-12 months)	2016
Canada (IOM)	400 IU or 10 µg per day (for 0-12 months)	38 µg per day (7-12 months)	2010

306. As noted by the NHMRC, the vitamin D status of the infants is further compromised by restricted exposure to sunlight, and reduced ability to synthesise 25(OH)D due to skin pigmentation. The amount of sunlight across Australia and New Zealand varies significantly depending on latitude and time of year, with some parts of the New Zealand's lower South Island getting very limited sunlight in winter. And, although there may be a lot of sunlight at times outside, carers are advised to restrict sunlight exposure of infants.

307. The Australian College of Dermatologists and Cancer Council Australia recommend that babies under 12 months are kept out of direct sunlight when the UV Index is three or higher, and the UV levels in Australia are more often than not above 3 (Cancer Council, 2020).

308. The Ministry of Health in New Zealand "*recommends that infants are not left in direct sunlight*", considering guidelines around the world and research that infant's skin barrier remains immature throughout the first two years of life. In fact, Plunket in New Zealand, while recognising the role of sunlight in vitamin D production, notes this is only 10-15 minutes a day and suggests it is best to keep your child out of strong sunlight.

309. Australian vitamin D deficiency rates are similar to those around the world, suggesting that infants in Australia and New Zealand do not face a unique challenge:
    - Australian population (2-71+ years): more than 95% of people had inadequate vitamin D intakes (compared to 10µg) (Dunlop, et al. 2022) and 23% of the population is deficient (25(OH)D levels <50 nmol/L) (Australian Bureau of Statistics 2013). Furthermore, 20% of young Australian children were recently found to be vitamin D deficient (25(OH)D <50 nmol/L) (Zhou et al 2015).
    - US population: 25% deficient (25(OH)D levels <50 nmol/L) (Amrein, et al. 2020)
    - European population: ~40% of Europeans are vitamin D deficient (25(OH)D levels <50 nmol/L) (Amrein, et al. 2020)
    - Canadian population: 37% were vitamin D deficient (Amrein, et al. 2020).

B: *Limited contribution of vitamin D from foods*

310. As FSANZ does not permit vitamin D fortification in infant foods, the vitamin D contribution from other foods would be limited and should not be of concern. The EU does allow the fortification of infant foods and permits 0.72µg/100kJ in follow-on formula. EFSA stated (2018):

> "*For infants aged 4–12 months, the 95th percentile of vitamin D intake (high consumers) estimated from formulae and foods fortified or not with vitamin D does not exceed the ULs, without considering vitamin D supplemental intake*."

311. Therefore, the EU assessment with the same Upper Limit of 25 µg/day determined there was no safety concerns for older infants even after considering fortification with food.

312. Also note that due to variance, a product would also need to target a level lower than the maximum to always comply. There is analytical variance in just testing of +/- 15% without consideration of manufacturing variance (e.g. dosing variance, ingredient variance) and shelf-life degradation. The current level allows for +/-43% variance from the midpoint, this is technically achievable but relatively tight compared to the ranges for other nutrients and therefore can be an issue at times for manufacturers.

Thiamin

313. INC supports FSANZ's rationale to retain the current minimum for thiamin in Standard 2.9.1 of 10 µg/100kJ and to not align thiamin with the Codex minimum of 14 µg/100kJ. As EU 2016/127 minimum is slightly lower at 9.6 µg/100kJ, INC would also support lowering to the EU minimum rather than maintaining the current level in the Code.

Ratios

314. FSANZ's preferred option is set out in SD2 Table 3.4.3 Preferred ratios for follow-on formula reproduced below.

Table 3.4.3 Preferred ratios for follow-on formula

Nutrient	Unit	P1028 follow-on formula	P1028 infant formula	Standard 2.9.1 Schedule 29	Codex CXS 72-1981	Codex Draft Standard for FuFOI	EU 2016/127 ANNEX I	EU 2016/127 ANNEX II
LA:ALA	ratio	5:1 - 15:1	5:1 - 15:1	5:1 - 15:1	5:1 - 15:1	5:1 - 15:1	NS	NS
Ca:P	ratio	1:1 – 2:1	1:1 – 2:1	1:1 – 2:1	1:1 – 2:1	1:1 – 2:1	1:1 – 2:1	1:1 – 2:1
Vitamin E : fatty acids	ratio	0.5mg : 1g - NS	0.5mg : 1g - NS	0.5mg : 1g - NS	0.5mg : 1g - NS	0.5mg : 1g - NS	NS	NS

315. INC agrees with the FSANZ preferred option for ratios, noting that the INC recommends removal of the Vitamin E ratio. Also, that the ratio of Vitamin E: fatty acids should be the ratio of Vitamin E: polyunsaturated fatty acids.

Other nutritive substances

316. FSANZ preferred option is set out in SD2 Table 3.5.3 Other nutritive substances for follow-on formula reproduced below.

Table 3.5.3 Other nutritive substances for follow-on formula

Nutrient	Unit		P1028 follow-on formula	P1028 infant formula	Standard 2.9.1 (Schedule 29)	Codex CXS 72-1981	Codex Draft Standard for FuFOI	EU 2016/127 ANNEX I	EU 2016/127 ANNEX II
Choline	mg/100kJ		NS – 12*	1.7 – 12*	1.7 – 7.1	1.7 – 12*	NS – 12*	6 – 12	NS
Myo-inositol	mg/100kJ		NS – 9.5*	1.0 – 9.5*	1.0 – 9.5	1.0 – 9.5*	NS – 10*	0.96 – 9.6	NS
L-Carnitine	mg/100kJ		0.3 - NS	0.3 – 0.8	0.21 – 0.8	0.3 – NS	~	0.3 - NS	NS
Taurine	mg/100kJ		0.8 – 3	0.8 – 3	0.8 – 3	NS - 3	NS – 2.9	NS – 2.9	NS – 2.9
Lutein	µg/100kJ		NS	NS	1.5 - 5	NS	NS	NS	NS
2′-O-fucosyllactose ^	mg/100kJ		NS - 96	NS - 96	NS - 96	NS	NS	NS	NS
	Nuceltodies								
Adenosine-5′-monophosphate	mg/10 kJ		NS - 0.38	NS - 0.38	0.14 – 0.38	~	~	NS – 0.36	NS – 0.36
Cytidine-5′-monophosphate	mg/100kJ		NS - 0.6	NS - 0.6	0.22 – 0.6	~	~	NS – 0.60	NS – 0.60
Guanosine-5′-monophosphate	mg/100kJ		NS - 0.12	NS - 0.12	0.04 – 0.12	~	~	NS – 0.12	NS – 0.12
Inosine-5′-monophosphate	mg/100kJ		NS - 0.24	NS - 0.24	0.08 – 0.24	~	g~	NS – 0.24	NS – 0.24
Uridine-5′-monophosphate	mg/100kJ		NS - 0.42	NS - 0.42	0.13 – 0.42	~	~	NS – 0.42	NS – 0.42
Total free nucleotide 5'-monophosphates	mg/100kJ		NS - 3.8	NS - 3.8	NS - 3.8	~	~	NS - 1.2	NS - 1.2

NS = Not specified * = GUL ~ = Levels may need to be determined by national authorities.
^ A combination of 2′-O-fucosyllactose and lacto-N-neotetraose may reach a maximum of 96 mg/100kJ, which contains not more than 24 mg of lacto-N-neotetraose

317. INC largely agrees with the FSANZ preferred options for other nutritive substances for follow--on formula except for GMP where the same comments made for infant formula apply. INC also suggests consistency in not specifying a minimum. Additional comments are set out beow.

Taurine

318. INC supports the preferred option to retain the voluntary permission for taurine and the maximum within Standard 2.9.1 which is aligned with Codex draft FUFOI and the EU regulation. INC recommends no minimum for taurine be defined which would be more consistent with international regulations.

Choline

319. INC supports the preferred option to retain the voluntary permission and GUL for choline as it aligns with the Codex Draft Standard for FUFOI. Although choline is not mandatory in EU Regulation 127/2016 for follow-on formula, it is permitted and frequently present in products on the market in Europe.

Myo-inositol

320. INC supports the preferred option to retain the voluntary permission and GUL as it aligns with the Codex Draft Standard for FUFOI. Although myo-inositol is not mandatory in EU Regulation 127/2016 for follow-on formula, it is permitted and frequently present in products on the market in Europe.

L-carnitine

321. INC supports the preferred option to retain the voluntary addition of L-carnitine to follow-on formula and not specifying an upper limit. INC recommends that no minimum be defined which would be more consistent with international regulations.

Nucleotides

322. INC agrees with the preferred option except for the retention of the maximum for guanosine 5'monophosphate nucleotide. INC recommends this is stated as a GUL rather than a maximum. Please refer to comments made under infant formula composition section and to data provided in Attachment C. Also, as previously stated, INC appreciates the clarification proposed by FSANZ that the total nucleotide maximum applies to total *free* nucleotides.

Lutein

323. INC supports the option to retain the voluntary permission for lutein and the minimum and maximum within Standard 2.9.1 which have previously been assessed by FSANZ as part of *Application A594 – Lutein as a nutritive substance in infant formula*.

324. Codex draft Standard FUFOI includes permissions for optional ingredients, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.

325. Similarly, EU Regulation 2016/127 also includes permission for other food:

> "…*ingredients, as the case may be, whose suitability for infants from birth has been established by generally accepted scientific data*."

2′-O-fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT)

326. INC supports the preferred option to retain the current voluntary permission for 2'-FL alone or in combination with LNnT which was permitted in Schedule S29—5.

Proposed composition once reconstituted

Fluoride

327. INC refers to the comparable section in infant formula.

6.3 Infant formula products

Permitted Forms for Infant Formula Products

328. FSANZ's preferred option is set out in Table 4.1.3 Preferred permitted forms for infant formula products of CFS 1 SD2 below.

Table 4.1.3 Preferred permitted forms for infant formula products

Nutrient	Change Proposed (Y/N)	Proposed Approach	Standard 2.9.1 (Schedule 29)
Pantothenic Acid	Yes	D-panthenol, calcium D-pantothenate, sodium D-pantothenate as new forms in addition to existing permissions	Calcium pantothenate, dexpanthenol
Vitamin D	No	Vitamin D_2, vitamin D_3 and vitamin D (cholecalciferol-cholesterol)	Vitamin D_2, vitamin D_3 and vitamin D (cholecalciferol-cholesterol)
Niacin	No	Niacinamide (nicotinamide)	Niacinamide (nicotinamide)
Copper	Yes	Cupric carbonate as a new form in addition to existing permissions	Copper gluconate, cupric sulphate, cupric citrate
Magnesium	Yes	Magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric acid as new forms in addition to existing permissions	Magnesium carbonate, magnesium gluconate, magnesium oxide, magnesium phosphate dibasic, magnesium phosphate tribasic, magnesium sulphate
Potassium	Yes	Potassium L-lactate as a new form in addition to existing permissions	Potassium bicarbonate, potassium carbonate, potassium chloride, potassium citrate, potassium glycerophosphate, potassium gluconate, potassium hydroxide, potassium phosphate, dibasic, potassium phosphate, monobasic, potassium phosphate, tribasic
Zinc	Yes	Zinc lactate and zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate) as new forms in addition to existing permissions	Zinc acetate, zinc chloride, zinc gluconate, zinc oxide, zinc sulphate

Iron	Yes	Ferric citrate, ferrous bisglycinate and ferrous sulphate as new forms in addition to existing permissions	Ferric ammonium citrate, ferric pyrophosphate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous succinate, ferrous sulphate
Choline	Yes	Choline, choline citrate and choline hydrogen tartrate as new forms in addition to existing permissions	Choline chloride and choline bitarate
L-Carnitine	Yes	L-carnitine hydrochloride and -carnitine tartrate as new forms in addition to existing permission	Does not permit other forms of L-carnitine
Inositol	Yes	Refer to inositol as myo-inositol	Inositol

329. INC agrees with the amendments to permitted forms proposed by FSANZ, noting FSANZ's rationale.

330. INC recommends there be regulatory clarity on the permitted forms allowed for SMPPi (L-methyl folate) and FSANZ should consider this further. This is covered in further detail in Section 8 of this submission.

Vitamin and Mineral Supplementation

331. FSANZ proposes to remove the guideline on advice regarding additional vitamin and mineral supplementation (Schedule S29—10(2)). This is based on the lack of evidence that this is a problem for Australian and New Zealand formula fed infants, combined with the lack of voluntary use of the statement on labels.

332. INC points out that the voluntary statement is in use however can agree with the FSANZ proposal to remove it from use.

Measuring scoop

333. FSANZ's preferred option is to not standardise the scoop size or dilution ratio, and instead maintain existing requirement that a package of infant formula product in a powdered form must contain a scoop to enable the use of the infant formula product in accordance with the directions contained in the label on the package.

334. INC strongly supports the option preferred by FSANZ which is in line with international requirements. A standardised measuring scoop would be costly and difficult to achieve. In addition, there are a range of requirements including provision of a scoop and labelling requirements which ensure consumer safety.

Modified Formula

335. FSANZ has proposed to include products which have been compositionally modified to be either low lactose/lactose free or contain partially hydrolysed protein as infant formula products.

336. INC does not agree with the Framework proposed by FSANZ as discussed in Section 2 of this submission. Modified Formula for the dietary management of a particular disease or conditions should only be consumed under a medical supervision and should be considered a SMPPi.

CFS1 7 Labelling

7.1 Safety and technology (SD1)

SD1: Labelling

SD1 8.2 Directions for preparation and use (page 61)

337. FSANZ's preferred option is to:
maintain without change the mandatory requirement for directions:
to prepare bottles individually (paragraph 2.9.1—19(3)(a)), and
    a. instructing that if a bottle of made-up formula is to be stored before use, it must be refrigerated and used within 24 hours (paragraph 2.9.1—19(3)(b)).
    b. instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used (paragraph 2.9.1—19(3)(d)).

revise the directions:
    c. for water used to reconstitute powdered formula to include the word 'cooled' (paragraph 2.9.1—19(3)(c)).
    d. instructing to discard unfinished formula to include the text 'within 2 hours' (paragraph 2.9.1—19(3)(e)).

not apply the following directions to ready-to-drink formula:
    e. that each bottle to be prepared individually (paragraph 2.9.1—19(3)(a))
    f. to refrigerate formula and use within 24 hours if it is made up and stored prior to use (paragraph 2.9.1—19(3)(b))
    g. to use potable, previously boiled water (paragraph 2.9.1—19(3)(c)).
    h. to not apply the direction to only use the enclosed scoop to concentrated and ready-to drink formula.

338. INC supports the revisions to the directions for preparation and use, noting the clarification that synonyms for 'cooled' may be used to indicate that boiling water should not be used directly (e.g. lukewarm). This is important as manufacturers will also be considering other important aspects for a particular formula, for example the impact of water temperature on specific, heat sensitive ingredients and the solubility of the powder.

339. INC supports the revisions to include 'within 2 hours', noting the clarification that similar terms that do not contradict this maximum (2 hours) as determined appropriate by the manufacturers could be used (e.g. within one hour or immediately after a feed).

340. INC supports the maintenance of the other mandatory requirements for directions and the exclusions relevant to certain directions for ready-to-drink formulas as they are not relevant.

SD1 8.3 Standardised wording or pictures for directions for preparations and use (page 67)

341. FSANZ's preferred option is to maintain the current approach not to prescribe the exact wording or pictures to be used for the required directions for preparation and use on infant formula products.

342. INC continues to support the current approach not to prescribe the exact wording or pictures of directions for preparation and use of infant formula products. Maintaining the current flexibility in the application of words, terms or phrases proposed would continue to be permitted so long as these are non-contradictory. This is important for manufacturers, reflecting the range of matters taken into account when developing directions.

343. However, INC recommends yet again the need for clarification under Standard 2.9.1—19(3) to ensure it is clear to enforcement agencies that the exact wording is not prescribed. This is particularly due to some statements including the word 'must', which can create confusion that the exact wording must be followed. Wording similar to that used in Standard 2.9.1—19(4) "statements are ones indicating that" along with removal of the word "must" within this paragraph would provide greater clarity.

SD1 8.2 Date marking (page 67)

344. FSANZ's preferred option is to maintain existing date marking requirements for infant formula products.

345. INC continues to support maintenance of status quo.

SD1 8.5 Storage instructions (page 67)

346. FSANZ's preferred option is to maintain:
- existing generic requirements for storage instructions
- the specific requirement for infant formula products, to cover the period after the package is opened.

347. INC supports maintenance of existing approach.

SD1 8.6 Legibility requirements for warning statements (page 68)

348. FSANZ's preferred option is to maintain existing legibility requirements for generic or specific warning statements on infant formula product labels.

349. INC supports maintenance of existing legibility requirements.

SD1 8.7 Warning statements about following instructions exactly (page 69)

350. FSANZ's preferred option is to require a new direction for the preparation and use of infant formula products:
   i. for powdered and concentrated formula - not to change proportions of [powder/concentrate] or add other food except on medical advice
   ii. for ready-to-drink formula - not to dilute or add anything except on medical advice.

351. FSANZ is also proposing to consolidate the warning statements for powdered, concentrated and ready-to-drink infant formula products into a single prescribed warning statement applicable to all product types that states:
   i. Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.

352. INC supports the proposed approach for infant formula products only, to consolidate the warning statement and to relocate important information on dilution and not to add anything else to the product to the directions for preparation and use of infant formula products.

SD1 8.8 'Breast milk is best for babies' warning statement (page 71)

353. FSANZ's preferred option is to retain the existing 'breastmilk is best for babies' warning statement as currently required by paragraph 2.9.1—19(1)(d).

354. INC continues to support the approach to maintain the existing ‘breast is best’ warning statement.

SD1 8.9 Prescribed name (page 73)

355. FSANZ’s preferred option is to maintain the requirement for ‘Infant formula’ and Follow-on formula’ as prescribed names for these products.

356. INC supports FSANZ’s preference to maintain current prescribed names.

SD1 8.10 Statement that infant formula product may be used from birth (page 74)

357. FSANZ’s preferred option is to maintain the requirement for the statement indicating that the infant formula product may be used from birth as currently required by paragraph 2.9.1— 19(4)(a).

358. INC supports maintaining status quo of a statement indicating infant formula may be used from birth. It should however be noted that this requirement is for “infant formula” only and not “infant formula product”.

359. Attachment 1 of SD3 outlines research carried out that states ‘overall ‘age information’ was considered the most useful/important piece of information’ by caregivers. Most manufacturers know that carers find this information useful and important and already voluntarily provide age indications on the front of label. This also is consistent with the Codex STAN 72-1981 requirement 9.6.5 “products shall be labelled in such a way as to avoid risk of confusion between infant formula, follow-on formula”

SD1 8.11 Statement that FOF should not be used for infants aged under 6 months (page 75)

360. FSANZ’s preferred option is to maintain the requirement for a statement on follow-on formula labels indicating that follow-on formula should not be used for infants aged under the age of 6 months as currently required by paragraph 2.9.1—19(4)(b).

361. INC supports continued use of the statement which is aligned to both Australian and New Zealand infant feeding guidelines.

362. Again, most manufacturers want to clearly indicate the product is only suitable from 6 months and additionally include age indication information on the front of label.

SD1 8.12 Statement about age to offer food in addition to formula (page 75)

363. FSANZ’s preferred option is to maintain, as it is currently worded, the statement indicating that infants from the age of 6 months should be offered foods in addition to the infant formula product in paragraph 2.9.1—19(4)(c)).

364. INC reiterates its position from 2021 and continues to recommend use of the term ‘around’ to align with both New Zealand and Australian dietary guidelines for infants and toddlers and the Australian Infant Feeding and Allergy Prevention guidelines (ASCIA, 2020). This change would also support the specific policy principle that the regulation of infant formula products should not be inconsistent with national nutrition guidelines.

365. We recognise the timing of introduction to offered foods is subject to growth and development as noted by FSANZ and while we respect that the Food Standards Code

does not serve the same purpose as feeding guidelines, the Food Standards Code directly impacts information provided to parents on the label. Infant formula labels are a key source of information for carers of infants. It is therefore important that there is consistency for parents by ensuring no contradictory information is provided. This is therefore a public health issue.

366. Continued use of "from the age of 6 months" risks being out of step with the evolving scientific literature (as noted in our submission on FSANZ CP1 2021). Furthermore, this term contradicts the Australian Infant Feeding and Allergy Prevention guidelines (ASCIA, 2020), which states: *"*around six months, but not before four months". This is a consistent message being communicated by healthcare professionals to parents. If FSANZ does not amend this statement, parents may be confused by different messages being shared.

SD1 8.13 Statement on protein source (page 77)

367. FSANZ's preferred option is to clarify that the 'source' of protein in Standard 2.9.1—23 refers to the origin of the protein (e.g. cow's milk) and not the protein fractions (e.g. whey or casein protein).

368. INC does not support this clarification. As FSANZ notes, the original intent of the statement was to provide clarity for consumers to enable informed decisions. Further limiting the statement will in some cases limit the information and clarity that can be provided to consumers. There is currently no evidence of consumer confusion or issues with the status quo and there is anecdotal evidence that this information is sought out through consumer queries.

369. FSANZ further states that this was introduced for consistency with Codex STAN 72-1981. The proposal to not allow the protein fractions does not align with Codex. Codex does not prescribe what cannot be included in the statement.

370. Describing the true, complete and accurate description of products is required under Consumer Law and manufacturers consider fully how to do this clearly for each product label both on front and on back of pack. Clarifying that additional information on protein fractions cannot be used could be interpreted as limiting other useful and necessary information to enable consumers to make informed choices on protein including clarifications for partially hydrolysed and A2 beta casein. This information on protein is relevant and important for both consumers and healthcare professionals.

371. INC recommends that information about relevant protein fractions and processing methods should be maintained within the protein source statement. This is important for continuing caregiver familiarity with the placement of this information.

372. INC is confused by the following statement made by FSANZ that the protein source statement, 'would clarify the intent for enforcement purposes, provide information for caregivers of infants with allergies and intolerances'.

373. The intent of this statement is not to indicate the allergens to caregivers. It is not appropriate as allergen information and suggesting this to caregivers poses a food safety risk. There is a full allergen statement that caregivers should be guided towards which is discussed under Allergen Declarations in SD3. Furthermore, a caregiver should always be seeking diagnosis and guidance from a healthcare professional for an infant with allergies.

374. INC supports Division 3 of Standard 1.2.3 applying to infant formula products, as we believe this provides appropriate information on the allergens present in the product to help protect public health and safety. The food industry has worked tirelessly to ensure that allergen labelling is as clear and useful as possible.

SD1 8.14 Co-location of protein source statement with name of food (page 78)

375. FSANZ's preferred option is to maintain the requirement for the co-location of the protein source statement with the name of the food and clarify that the co-located **protein source statement and name of the food** needs to appear in a prominent position just once on the label.

376. INC does not support the inclusion of 'prominent' in relation to the position of the protein source statement. There is currently no requirement for the name of the food to be located in a prominent position on product packaging and no evidence of consumer confusion as to the type of product being purchased. Requiring the protein source statement and name of the food to be in a prominent position for the reason of allergen management is not appropriate, as this statement does not provide full and complete allergen declaration. Further, appropriate allergen declaration is not required to be prominent according to Division 3 of Standard 1.2.3.

377. INC recommends protein source statement not be given prominence over the allergen statement as this may inadvertently risk public health and safety.

378. INC recommends the proposal for 'prominent' positioning of protein source information be removed to allow manufacturers enough flexibility to ensure consumers take note of both protein source and allergen information within a similar field of view. Further, general legibility requirements in FSANZ Standard 1.2.1-24 already contains a requirement for wording to be:

> "*prominent so as to contrast distinctly with the background of the label*"

379. Any use of 'prominent' within the Food Standards Code should be used with the same intent.

380. INC notes that the justification for this proposed change appears to be due to the belief that 'it would alert caregivers to the appropriate formula choice for infant age, it could reduce the safety risks for those infants with allergies, and Codex STAN 1-1985 specifies the name of the food appears in a prominent position'.

381. INC has covered in detail the inappropriateness of considering the protein statement equivalent to allergen declaration above.

382. Reference to Codex STAN 1-1985 is related to the name of the product being in a prominent position. INC supports Codex's position on the position of the name of the product, however, this does not relate to the protein statement. Codex STAN 72-1981 states 'the sources of protein in the product shall be clearly shown on the label'.

383. The only aspect of this proposed change that INC supports is the requirement for co-location of the protein source statement with the name of the food, and the clarification that this only needs to appear once on the label.

384. INC supports the protein source statement not applying to SMPPi.

7.2 Provision of information

SD3

Labelling of Ingredients

Statement of Ingredients

385. FSANZ's preferred option is
    a. that generic labelling requirements should continue to apply for infant forma products and
    b. to permit the optional grouping of added vitamins and minerals under the subheadings 'vitamins' and 'minerals' and within these groups the vitamins and minerals need not be listed in the descending order of ingoing weight

386. INC supports FSANZ's preferred option.

Allergen Declarations

387. FSANZ's preferred option is for the generic allergen declaration requirements in Division 3 of Standard 1.2.3 to continue to apply to infant formula products.

388. INC supports FSANZ's preferred option. INC points out that this is separate from the protein source statement. Clarification is required that when caregivers are looking for allergen information, they should be taken to the allergen declaration statement, NOT the protein source statement. The CFS appears to suggest that both these statements provide appropriate allergen information.

Labelling as 'genetically modified'

389. FSANZ's preferred option is to continue to apply existing labelling requirements in Standard 1.5.2—4 for GM foods to infant formula products.

390. INC supports FSANZ's preferred option.

Declaration of Nutrition Information

391. FSANZ's preferred option is to:
    - prescribe the format of the nutrition information statement (NIS) in accordance with the recommended format in the existing guideline in Schedule 29 of the Food Standards Code with additional subheadings 'Vitamins', 'Minerals' to group the micronutrients and the subheading 'Additional' to group optional substances
    - only permit the base unit of expression (per 100 mL as reconstituted) in the NIS for average energy:
        - require nutrition information (excepting energy) to be expressed as the 'average quantity' in the NIS
        - clarify that the calculation method for average quantity in paragraph 1.1.1—6(3)(c) will not apply to infant formula products
    - maintain the requirements for the weight of one scoop to be declared (if a powdered product), and the proportion of powder or concentrate required to reconstitute the formula according to directions to be declared (if a powdered or concentrated form of infant formula) (paragraph 2.9.1—21(1)(b)) and clarify this nutrition information must not be located in the NIS.

Q1 Do you agree with FSANZ's preferred option to prescribe the format of the NIS as shown in Figure 1? Please provide the reasons for your views.

392. INC **supports some formatting of the NIS** aligned with general food and international food standards. The aspects that INC supports prescribing include:

- use of subheadings ‘Vitamins’, ‘Minerals’ to group the micronutrients and the subheading ‘Additional’ to group optional substances
- base unit of expression of per 100mL (but no prohibition on per 100g)
- use of average quantity
- a tabular format that aligns with the general legibility requirements in Standard 1.2.1--24
- the title ‘Nutrition information’
- the macronutrient order, names and required units.

393. INC **does not support the highly prescribed NIS format** in SD3 Figure 1 for the following reasons:
    - does not allow provision of adequate information
    - lacks any scientific evidence that there is an issue with the current NIS and the effectiveness of the proposed NIS
    - is not consistent with international food standards; and
    - does not allow for an efficient and competitive food industry or for fair trading.

394. Manufacturers require the flexibility to present information in the best manner to allow for informed choice. Prescribing the following does not allow for adequate information to be communicated:
    - **Only** permitting per 100mL base unit of expression. The ability to voluntarily include per 100g should be permitted
    - **Only** permitting kJ unit of Energy. The ability to voluntarily include kcal should be permitted
    - Not requiring information on the powder in the NIS including weight of one scoop and the proportion of powder or concentrate required to reconstitute the formula. Companies should have the ability to provide this information when deemed appropriate
    - Current order of vitamins and minerals. These should be listed in an order that makes sense to consumers and healthcare professionals
    - Restricting ability to use common terms, acronyms/abbreviations and additional information which are understood by consumers
    - **Only** allowing prescribed nutrient names and sub-groups to be listed

Rationale for Industry response to Q1

Base unit of expression

395. FSANZ’s preferred option is to permit the base unit of expression (per 100mL) in the NIS. INC supports this however, also considers it is important for manufacturers to have the ability to voluntarily include the base units for per 100g as this:

    - would be particularly useful for those markets that have adopted the Codex provision of using ‘per 100g’, allowing for harmonisation with those requirements on an as needs basis.
    - is known to be helpful in healthcare situations (e.g. hospital formula rooms) when formula is prepared in large bulk quantities by healthcare professionals. INC members are advised that healthcare professionals are using the current voluntary provision for including base units per 100g.

Proportion of powder or concentrate weight of one scoop of powder

396. INC agrees with maintaining the requirement to declare the weight of one scoop and clarification that this does not need to be included in the NIS but this restriction should not include powder weight per 100mL. This would be consistent with Standard 1.2.8 requirements for dehydrated or concentrated food. INC believes that this should be an

option for manufacturers to include if deemed appropriate to provide adequate information.

Macronutrients, vitamins and minerals order and units of expression

397. INC is aligned with the proposal to order macronutrients, micronutrients and specify units of expression.

398. Healthcare professionals can also benefit from Energy being presented in calories as well as kilojoules. INC believes it is important for manufacturers to be able to voluntarily present Energy in calories.

399. INC recommends that the order and units of vitamins and minerals in the NIS should align with the NHMRC Nutrient Reference Values (NRVs). This would make it easier for healthcare professionals to use the NIS. INC believes the order of vitamins and minerals provided in the NRVs make more logical sense and that it would generally be expected that B vitamins be presented together. INC proposes the following to align with the NRVs:
    - Reorder of Vitamins and Minerals
    - Change units of Vitamin A to µg-RE
    - Change units of Vitamin E to mg α-TE
    - Change units of Pantothenic acid to mg

Also, to align with SD2 change of folate to folic acid to reflect accurately what the value includes and not mislead that the value includes all folate.

Restrictions on use of common terms, acronyms/abbreviations *and additional information*

400. There is no evidence of issues with the current flexibility in the NIS. Restrictions on further information, such as use of common terms, acronyms/abbreviations and additional information does not allow manufacturers to provide information to consumers in accordance with the FSANZ Act objective to allow for adequate information and not mislead consumers.

401. This also does not align with international food standards. Although Codex *Guidelines on Nutrition Labelling CXS 2-1985* recommends nutrients are declared in a specific order and should be consistent across food, it does not limit additional information or prescribe the nutrient names. INC supports a specific order of nutrients, however, we do not support explicitly permitting or limiting additional information that may be provided within that prescribed order.

402. FSANZ has said that 'permitted optional nutrients and substance the naming of these will not be prescribed', however, other subheadings with common terms would not be allowed by virtue of the prescribed format and wording. These statements do not align with one another and do not consider the best way to present information to caregivers/consumers in a way that they understand.

403. Restricting the use of other common terms and subheadings does not provide the flexibility for industry to use more consumer-friendly language and commonly understood terminology (which is permitted in other food categories and may already be familiar to consumers). An example of this is the term 'nucleotides'. This heading is often used in the NIS with the specific types of nucleotides listed underneath. This is done as these have scientific names. Caregivers are not comfortable with scientific names, and therefore providing additional information can provide more context. Flexibility also allows for inclusion of common terms or acronyms/abbreviations which healthcare

professionals might commonly use with their patients. For instance, suggesting they look for a formula that contains DHA.

404. Companies often use common acronyms/abbreviations to help with the legibility of the NIS. Requiring lengthy scientific names can make it difficult for consumers to accurately determine the corresponding values with ease.

405. Within CFS1 and associated documents , FSANZ acknowledges the need for flexibility in the ingredients list:

> "FSANZ considers any further standardization of the statement of ingredients beyond the current requirements would reduce labelling flexibility and be a barrier to trade, noting international and overseas regulations contain no such provisions."

406. INC recommends that a similar approach be taken with the NIS.

407. The NIS serves many purposes. Although caregivers use the NIS to differentiate between products, the research presented by FSANZ shows that further contextual information is needed for them to determine which product is best for their infant. Caregivers were looking at the presence or absence of nutrients only. Further restrictions could prevent allowing for adequate information to be presented.

408. The current NIS proposal limits the ability of companies to communicate differences between formulas which in turn will disincentivise innovation. The flexibility of the current NIS allows for manufacturers to label for naturally present and additional nutrients in an appropriate location within the NIS (e.g. listed with similar nutrients) and with appropriate contextual information (e.g. subheadings, common terms, acronyms/abbreviations) to assist both caregivers and healthcare professionals. The high level of prescription proposed by FSANZ would lead to an uncompetitive food category both domestically and internationally as consumers will not be able to differentiate between products.

409. In addition, allowing for flexibility in the NIS can help future proof the Standard as this may help reduce the frequency of regulatory changes in the prescribed NIS as a result of changing science and nutrients of interest, or due to new ingredient applications where it may be more appropriate to list the nutrient(s) provided alongside similar nutrients (e.g. subcomponents of macronutrients).

Q2 How should the subheadings for 'Vitamins', 'Minerals' and 'Additional' be separated from other text (e.g. using lines, bolding)?

410. INC strongly opposes this level of prescription of the formatting as it is not aligned with Codex and not harmonised with other international jurisdictions. Companies are already required to meet the legibility provisions under Standard 1.2.1 Division 6, and these general provisions of food labelling should be sufficient as they are for all other foods. Manufacturers are also well placed to determine whether lines, bolding and other formatting tools are needed to provide for clear contrast and legibility in accordance with other considerations of the label (e.g. colours used, space constraints etc.). As noted by FSANZ there is a need for some flexibility.

Macronutrient sub-group nutrients in the NIS (SD3 p16)

411. FSANZ's preferred option is to permit with prescribe[d] wording and format the voluntary listing in the NIS of:
    - 'Whey' and 'Casein', indented under the macronutrient 'Protein'

- ‘Docosahexaenoic acid’, ‘Eicosapentaenoic acid’ and ‘Arachidonic acid’, indented under the sub-group nutrient heading ‘Long chain polyunsaturated fatty acids’, which is indented under the macronutrient ‘Fat’.

412. INC **supports** generally permitting **voluntary declaration** of macronutrient sub-groups in the NIS to ensure adequate information is provided.

413. INC **does not support** an explicit list, prescription of wording and format of the voluntary declaration of macronutrient sub-groups for the following reasons, each of which is expanded on below:
    - It does not allow provision of adequate information
    - It could result in misleading consumers
    - Further restrictions could be harmful to competition and public health
    - There is a lack of scientific evidence that there is an issue with the current voluntary listing of macronutrient sub-groups
    - It is not consistent with international food standards; and
    - It does not allow for an efficient and competitive food industry or fair trading.

Adequate information

414. Companies already voluntarily provide relevant macronutrient sub-group information to inform carers and there is no evidence of issues with the status quo. Not all infant formula products are the same and **prescribing a list may limit relevant information for carers to be informed and compare products.** Therefore, it is counter to the FSANZ Act objective of provision of adequate information.

415. INC notes FSANZ acknowledged the importance of macronutrient sub-groups in the 2016 Consultation Paper. INC further agrees with the FSANZ summary, that the addition of these sub-groups is of particular importance to enable informed choice, provide information for healthcare professionals and allow for product differentiation. INC therefore considers allowing for voluntary declaration of macronutrient sub-groups is of vital importance.

416. INC notes that submissions in 2016 from healthcare professionals stated that macronutrient sub-groups should be mandatory in the NIS in order to provide accurate information to consumers. Companies are already required to provide accurate information and have processes such as testing to ensure the levels declared in the NIS are correct. INC agrees that providing information on macronutrient sub-groups where relevant is important to healthcare professionals. However, mandating this will not enable companies to vary macro-nutrient sub-groups in accordance with different products into the future and change based on healthcare professionals’ opinion on the relevant information they need on products.

417. INC believes that while at present the proposed sub-group nutrients are of particular interest to consumers and healthcare professionals, consideration also needs to be given to what information may be of relevance in the future. The fact that it is difficult to predict which sub-groups may be of interest to future consumers and healthcare professionals highlights the importance of providing flexibility.
    - Whey dominant formula was introduced in Australia in 1964 and it took over 30 years for LCPs to be introduced in 1998. Hence, the present consumers are very familiar with these sub-groups but these may not be their interests in the future as science evolves over time.
    - A standard review takes a very long time in Australia and New Zealand. This current review started in 2012 and it is still under review. INC therefore considers that listing

sub-groups should be allowed without prescribing a permitted list in order to help future proof this Standard.

- It seems that an infant formula standard review takes place around every 20 years including the review time which seems to take more than 10 years for each review. Prescribing a permitted list only creates a burden to industry without any public health benefits.

Further restrictions could be harmful to competition and therefore harmful to public

418. Voluntary declaration of macronutrient sub-groups in the NIS is important to support consumers making informed choices and ensuring fair competition between brands is encouraged, and that consumer choices are not distorted. This is the only section of the label which allows consumers to directly compare one product to another based on facts in a consistent manner and also represents the only place on the label that industry can communicate differences to consumers. The additional flexibility to voluntarily label macronutrient sub-groups means that industry is encouraged to improve its products, making a better choice when selecting an ingredient and continuously innovating to ensure formula-fed babies are less disadvantaged.

Lack of evidence of issue with status quo

419. FSANZ provides no evidence of issues with allowing voluntary declaration of macronutrient sub-groups in the NIS other than some consumers in a small focus group in 2018.

420. The rationale provided in the proposal that sub-groups should be limited is to ensure companies do not provide “too much information” which could “hinder caregivers” is simply not supported by evidence. The research provided by FSANZ on the standardised NIS does not appear to have considered caregivers view on limiting macronutrient sub-group nutrients. Attachment 1 to SD3 only provides anecdotal evidence on the length of the NIS and there is no clear evidence that this is what caregivers want or need.

421. Companies only include information in the current NIS that they understand is important and useful for both carers and healthcare professionals to be able to make informed choices. All nutrition information must be accurate and relevant.

International food standards

422. A prescribed listing of macronutrient sub-groups does not align with Codex or the EU.

423. As noted by FSANZ, EU 2016/127 outlines requirements similar to the Food Standards Code. However, it also allows for the voluntary declaration of components of protein, carbohydrate or fat, the whey/casein ratio, and the amount of substances whose suitability has been established by generally accepted scientific data. Codex STAN 72-1981 does not prescribe macronutrient sub-groups and is silent on voluntary declaration. INC supports a similar approach to the EU labelling that allows more generally for the voluntary declaration of macronutrient components.

Not supporting an efficient and internationally competitive food industry or fair trading

424. A prescribed list will limit companies’ ability to include relevant information to consumers and healthcare professionals and in effect limit manufacturers ability to be able to differentiate between product nutrition composition.

425. Most companies will determine that it is overly burdensome in terms of time and resources to go through a FSANZ application process to change an explicit list of macronutrient sub-groups in the Code. INC is strongly of the view that consumers should

be provided with adequate information to show how products differ to be able to make informed choices on what is best for their infant.

Lactose

426. The contribution of lactose in an infant formula product provides important information to caregivers and healthcare professionals. The inclusion of lactose and galactose as a sub-group of carbohydrate should always be able to be included as a voluntary listing in the NIS when deemed necessary. Especially, when a product is formulated for a management of lactose related condition or disease, lactose and galactose levels should be provided. If a lactose free or low lactose declaration is made, then this should be mandatory. The current regulatory requirement of Standard 2.9.1—14(4) and Standard 2.9.1—14(6) do not allow the industry to manufacture ”lactose-free” powdered infant formula products with milk protein as protein source.

Inter-relationship between declarations in the nutrition information statements and the statement of ingredients

Ingredient and nutrient names

427. FSANZ’s preferred option is to maintain the status quo and not align the declaration of ingredient names in the statement of ingredients and nutrient names in the NIS.

428. INC supports FSANZ’s preferred approach. This acknowledges that complex ingredient names are often present in the ingredients list, together with the common term (e.g. sodium ascorbate (vitamin C)). Within the nutrition information statement common terms are used.

429. INC also points out that ingredients and nutrients are not the same. Although most ingredients contain nutrients, many ingredients contain several different types of nutrients and it would be misleading to refer to them as containing just one type of nutrient. This section appears to suggest they can be used interchangeably which is not correct and is very important when considering how to describe a product.

Modified infant formula products

Lactose free and low lactose formula

430. FSANZ’s preferred option is to maintain existing specific labelling requirements for ‘lactose free’ and ‘low lactose’ infant formula products.

431. INC maintains its position outlined in its submission on FSANZ CP3 2021. In this, INC acknowledges the ACCC requirements with regard to ‘free’ to mean ‘no detectable presence’. As a result, industry does not use the term ‘free’ and nor is the term ‘low lactose’ generally used as mentioned above INC therefore does not support the continuation of the use of ‘low lactose’ and ‘lactose free’ being part of the name for these products. This inhibits a manufacturer’s ability to convey the lactose content of some products as part of the nutritional modifications which may be inherent to the product or have been made to products. It also creates confusion from a consumer perspective, as some products may have more than one condition for which it has been formulated.

432. INC does, however, continue to support the continuation of requirements for the lactose level and galactose content currently contained in Standard 2.9.1—14 for infant formula products as mentioned above.

Partially hydrolysed formula

Q.3 Without referencing specific conditions, how should partially hydrolysed formula be labelled to inform caregivers of the nature of the modification from other infant formula products?

433. INC does not agree with the Framework proposed by FSANZ as discussed in Section 2. As noted in the CFS SD2, recent studies have re-affirmed that partially hydrolysed proteins are safe and appropriate for use in starter formulas and show no difference in growth or development when compared to infants who consume intact cow's milk protein formula (Vandenplas 2019, Gappa 2021).

434. INC recommends that partially hydrolysed protein should be labelled in the ingredient list and in the protein source statement.

Representations

6.1 Prohibited representations

435. FSANZ is proposing to maintain the following prohibitions:
Standard 2.9.1—24(1)(a) to (e) state the label on a package of infant formula products must not contain:
(a) a picture of an infant, or
(b) a picture that idealises the use of infant formula products, or
(c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect, or
(ca) the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect, or
(cb) abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect, or
(d) words claiming that the formula is suitable for infants, or
(e) information relating to the nutritional content of human milk.

436. INC has responded on the prohibitions in previous INC submissions.

6.2 Nutrition content and health claim prohibition

437. FSANZ preferred option is not to consider further the existing prohibition on nutrition content and health claims and maintain the following:
- Division 3 of Standard 1.2.7 (Standard 1.2.7—4(1)) which states that a nutrition content or health claim must not be made about an infant formula product.
- Paragraph 24(1)(f) of Standard 2.9.1 prohibits a reference to the presence of a nutrient or nutritive substance except where it relates to the name of a 'low lactose' or 'lactose free' IFPSDU, or is in the ingredient list or the NIS.
- Standard 2.9.1—24(2) prohibits a reference to inulin type fructans (ITF) or galacto-oligosaccharides (GOS) except for a reference in the statement of ingredients or the NIS.
- Mandatory nutrition information requirements, such as the declaration of nutrition information (Standard 2.9.1—21), and the statement of ingredients (Standard 1.2.1—8(1)(e) and Standard 1.2.4—2)) do not constitute nutrition content claims.

438. INC recognises that some infants are not breastfed, for a variety of medical, practical or personal reasons. Information provided on the label does not trigger the initiation of formula feeding, and caregivers will usually only look for this information ***after*** the decision has been made to initiate formula feeding.

439. INC raises the following concerns in relation to this existing prohibition, each of which is expanded on below:
    - does not allow provision of adequate information
    - does not allow for product comparison
    - evidence of benefit to caregiver understanding; and
    - does not support scientifically research formulas

Adequate information

440. INC believes that it is very important that the needs of formula-fed infants are supported. Often caregivers are struggling to find adequate information on formula feeding. Ideally, caregivers should seek infant formula information from a healthcare professional before starting the use of a formula, but this will not always be the case. Labelling information is a very important source of information for caregivers to improve the prospect of being able to make an informed choice. Equally, it is important that, for infant health and safety, infant formula representatives can provide scientific and factual information on products to healthcare professionals.

441. Once a decision to use formula is made in consultation with their healthcare professional, caregivers should be able to make informed choices about the infant formula they buy. When compared to all other foods, which infant formula to purchase is possibly the most important purchasing decision because it may be the sole source of nutrition for infants in the first 6 months of life.

442. INC considers there to be a serious gap in information available to consumers to make informed choices about the formula that is most suitable for their infants. The restrictions proposed to the label will further limit the ability to provide consumers with information that is required to make an informed choice.

Product comparison

443. It is essential to recognise and acknowledge that no infant formula product is competing with breast milk. Breast milk will always be better than any infant formula product and every can states this. As stated above, the complexity of breastmilk, and the social and several other implications can never be met through an infant formula product. INC therefore recommends that FSANZ consider labelling requirements which facilitate further comparisons between different infant formula products. The label should provide caregivers with sufficient information to differentiate between infant formula products and make an informed choice on the most suitable product for their infant.

444. Although INC understands that the proposed restrictions on nutrition content and health claims are intended to align the Food Standards Code to with the WHO and Codex, outcomes of research conducted in this market regarding caregivers' preferences when it comes to communication about infant formula products must be acknowledged.

Caregiver understanding

445. The research commissioned by FSANZ indicates that most caregivers do not understand the purpose of nutrients present in infant formula products. This highlights the need to provide caregivers with contextual information in order for them to truly understand nutrients in a formulation. Little consideration has been given to this research and how it can be translated for the caregivers benefit.

446. Further, the restrictions placed on manufacturers compel caregivers to seek guidance from other sources to make informed choices. Although it is preferred that this guidance comes from a healthcare professional, FSANZ research has shown that healthcare

professionals are often unwilling or unable to discuss formula options with caregivers. INC believes that more must be done to support caregivers in being able to access adequate information in order for them to make informed choices. Government must acknowledge the significant role it plays in supporting caregivers in this instance and implement measures that facilitate the dissemination of information which fosters informed choice.

Scientifically researched formulas

447. A lack of differentiation between brands is a significant disincentive to innovation, which is not in the best interest of a formula-fed infant. Whether or not the caregiver has the choice to formula-feed their infant, the infant never has that choice. Infants who receive formula must not be disadvantaged more than they already are by not being breast-fed by disincentivising innovation and the substantial clinical research that goes into improving infant formula products, the Government is discriminating against caregivers and penalising the infant.

448. More concerning still is the possibility that caregivers who formula-feed their infants and are not given adequate information on infant formula product labels will be unable to differentiate between a scientifically researched infant formula product and other potentially dangerous nutrient sources. For example, caregivers faced with home-made infant formula recipe such as Paleo baby formula promoted by celebrity chef Peter Evans, may be more easily misled about the quality and effectiveness of the home-made recipe if it cannot be easily compared and discredited in favour of an infant formula product manufactured by a recognised and regulated infant formula company.

SD3 6.3 Claims about ingredients (p25)

449. FSANZ's preferred option is to only permit information about ingredients in the statement of ingredients (except for ingredients (e.g. nutritive substances) that are required to be declared in the NIS).

450. INC strongly opposes the proposed further restriction on ingredient claims for the following reasons expanded on below, that it:
- does not allow provision of adequate information
- could result in misleading consumers
- is not supported by evidence on the risk and issues with ingredient claims notably the concept of ingredient-based claims is poorly defined and not clear.
- is not consistent with international food standards
- does not allow for an efficient and competitive food industry or fair trading; and
- is not aligned to the policy guideline which does not include ingredient claims.

451. The fact that the term 'ingredient' is not defined in the Food Standards Code makes this proposal very confusing. To be able to enforce this concept, a definition of 'ingredient' would need to be created. From CFS SD3, it is evident that submitters are confused about the scope of the term and FSANZ suggests that ingredients are distinct from nutrition content or health claims. However, submitters do not have the same view:
- one Government submitter noted that 'claims made about ingredients added for a nutritional reason or a health effect are effectively nutrition content or health claims.'

452. INC interprets that a statement which includes a nutrient or health effect would be considered a nutrition content or health claim and not permitted. The Food Standards Code defines health claim as *"a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect*". General information about ingredients is not the same as the nutrition content and health claims as defined by FSANZ. Inferring that nutrition and health claims identified by FSANZ as examples are

not already restricted and that therefore further restrictions on ingredient claims are required is misleading.

453. There is a suggestion that ingredient claims could influence comparisons to breast milk. INC reiterates that infant formula products are not competing with breast milk. Furthermore, breast milk does not contain ingredients, the complexity of breast milk extends far beyond what is present in infant formula products. FSANZ should not further restrict fair competition of infant formula products resulting from further prohibitions which provide no public benefit.

Does not allow adequate information, which could result in misleading and deceptive conduct

454. INC notes that ingredient claims are not considered in any category except infant formula products. General information about ingredients outside of the ingredients list is common, because it allows food to be correctly described. This proposal could set a precedent that could restrict the ability to ensure manufacturers do not mislead consumers.

455. Restrictions on ingredient information must also be considered in the context of consumer law. A failure to provide clear information on what the product is could be perceived as misleading through omission.

456. The proposed restriction creates many major issues in the ability of companies to describe products accurately. INC does not believe that the issue with ingredient-based claims could be resolved by explicitly permitting certain types of ingredient claims, as it is not possible to consider all situations currently and into the future.

Lack of evidence

457. FSANZ includes the following examples of ingredient claims, “unique ingredients to help promote comfortable digestion” and “fish oil to help support brain and eye development”, these clearly meet the definition of a “health claim” and are already restricted on infant formula products.

458. We note that FSANZ’s research references both nutrient and ingredient claims. However, most of this research refers to nutrient claims. Little evidence is provided on ‘ingredient claims’. This is most likely due to the lack of clarity regarding what constitutes an ‘ingredient claim’. The influence that ingredient claims have over caregivers is uncertain, and the potential negative implications of restricting ‘ingredient claims’ are severe. The difference between what might be considered a ‘nutrition or health claim’ and what is ‘general information’ should also be considered should any further research be undertaken.

Not consistent with international food standards

459. The proposed restriction on ingredient claims is not internationally aligned with Codex, the WHO Code, the EU or the US:
    - Codex STAN CXS 72-1981 only restricts nutrition and health claims for foods for infants except where specifically provided for in relevant Codex Standards or national legislation
    - WHA58.32 resolutions adopted subsequent to the WHO Code also only references restrictions on nutrition and health claims for breastmilk substitutes, unless national/ regional legislation allows. If ingredient-based claims were an issue, then this restriction would be explicitly included in Codex and the WHO Code which it is not
    - In the EU which is so often used as a reference point, EU 2016/127 restricts nutrition and health claims on infant formula, but allows them on follow-on formula.

- The US FDA, also used as a reference point, allows nutrition and health claims to be displayed on infant formula products that are specifically provided for under the Code of Federal Regulations.

460. The Food Standards Code already restricts nutrition and health claims for infant formula products which should be sufficient to allow enforcement. FSANZ proposal to restrict ingredient 'claims' is not internationally aligned and unprecedented.

Does not allow for an efficient and competitive food industry or fair trading

461. Placing restriction on general ingredient information through an unnecessary restriction on undefined 'ingredient claims' does not allow for clear differentiation between products. This creates a significant disincentive to innovation, which is not in the best interest of the formula-fed infant. Formula feeding is sometimes not a choice – and infants that receive formula need to benefit from the substantial clinical research and innovation that goes into improving infant formula products and is in the best interest of the infant.

Not in accordance with the Ministerial Policy Guideline

462. The Ministerial Policy Guideline specifically states "prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products". This does not state "all claims", defined by the Code. As noted by FSANZ the Code defines claim as *"an express or implied statement, representation, design or information in relation to a food or a property of food which is not mandatory in this Code."* This includes anything that is voluntary, including pictures and branding.

463. The Ministerial Policy Guideline is **clear and unambiguous** on the types of claims that should be restricted, indicating that consideration of the types of claims has been carefully given.

464. There has been stakeholder feedback on equity. The Ministerial Policy Guideline does not refer to distortion of choice.

Line marketing and proxy advertising

SD3 Q4 What evidence can you provide of caregivers' understanding of stage labelling on infant formula products?

465. Labelling of infant formula products currently has multiple references to age-appropriate text, numbers and symbols to provide multiple visual cues. Numbers are simple and easily-recalled label features and a useful tool for primary and secondary caregivers. They help reduce consumer confusion and minimise the likelihood of purchasing an incorrect product for the age of an infant. Numbers and symbols (in addition to text) can benefit tired primary and secondary caregivers making hurried subsequent purchases and are also likely to benefit those with low proficiency in English.

466. Many labels also contain information about the range of products intended to be used in sequence as a formula-fed infant grows. It relates to a sequence of products in the range suitable as a formula-fed infant grows, not "add on" products. Caregivers of formula-fed infants from 6 months will either continue using infant formula or decide to substitute it with follow-on formula, not both.

467. In this sense, staging information on labels provides a factual, age-appropriate guide to carers and should not be seen as "promoting" additional products for purchase by infant formula users. Notably staging is used on a range of products for infants including, for example, nappies.

SD3 Q5 What evidence can you provide about caregivers' understanding and behaviours associated with proxy advertising appearing on the labels of infant formula or follow-on formula?

468. INC notes that SD3 Attachment 1 frequently references toddler milks which are out of scope of P1028. The MAIF Agreement and the INC CoP in New Zealand do not permit advertising of infant or follow -on formula. Therefore, it is not possible to research caregivers' understanding and behaviours in this category because these products are not advertised.

469. FSANZ did not conduct or commission any research in the findings section, 2 Advertising of later stage formulas (12 months +) on infant or follow-on formula (page 13 – 16) of SD3 Attachment 1, which considers this question. The research provided is limited and, in many instances, irrelevant as it refers to toddler milk advertising. The additional literature search findings presented in this section outline 3 studies conducted by Berry and colleagues, these are all at least 10 years old, and two have very small sample sizes (for example – a sample size of 15 people). INC is disappointed that FSANZ considered the oldest of these with the smallest sample size to be a 'high quality study'. INC does not believe that this is a high-quality study and should not be relied on to support any argument on proxy advertising behaviours.

470. Further, the research papers looked at print advertising only. This clearly shows the age of the research. The industry has since gone to greater lengths to differentiate between infant formula products and toddler milk drinks through the MAIF Agreement and the INC CoP in New Zealand, working with both Health departments of the Australian and New Zealand governments.

Notification of product reformulation

471. FSANZ's preferred option for the notification of changes in product formulations is to maintain the current non-regulatory approach. That is, manufacturers would continue to decide how best to inform caregivers and healthcare professionals about formulation changes as appropriate.

472. INC supports maintaining the current non-regulatory approach. INC supports the approach taken in the MAIF Complaints Committee Guidance related to Clause 5(a), changes and updates to infant formula section. We believe this is in the best interest of the caregiver and infant and would lessen anxiety and ambiguity.

473. The lack of specific communication results in an increase in consumer contacts with symptoms including vomiting, diarrhoea, rash, stomach cramps, refusal, and constipation as infants' transition. Most complaints are found in young infants who are most vulnerable. Caregivers want to understand what the differences are and express concern about formulation changes as their infant struggles to adjust.

Trade marks and online advertising

474. FSANZ does not intend to consider the issues of trademarks or online advertising further as part of Proposal P1028.

475. INC supports the removal of consideration of trademarks and online advertising from the P1028 proposal.

8. Special Medical Purpose Products for infants

Supporting Document 4 – Special Medical Purpose Formula for infants (composition and labelling)

476. INC acknowledges FSANZ for its consideration of specialised infant formula products and the new proposed framework for Special Medical Purpose Products for infants (SMPPi). The intended approach from FSANZ is for SMPPi to better align with international regulation to provide a more consistent composition and labelling approach. Hence, reducing restrictions on trade and significantly reducing costs associated with compliance regarding import of products classified as SMPPi. It will further allow continued and sustainable access of these products for infants with specific nutritional feeding conditions.

477. INC supports an approach whereby it is important to set principles and requirements specific to SMPPi, to ensure that they are safe, beneficial and effective for the infants for whom they are intended, based on generally accepted scientific data.

478. The introduction of a defined category for SMPPi provides more flexibility to accommodate additional variation in labelling and distribution for very specialised products imported into Australia and New Zealand and used under medical supervision. In theory, this should reduce the trade barriers and compliance costs that could potentially restrict access to these products and ensure the relevant population gets access to the best possible products.

479. However, INC does not agree with FSANZ preferred framework and definition for SMPPi. A broad range of product types would be captured by this definition including many unrelated to the composition of infant formula products and which are not intended to be used as a substitute for an infant formula product. We also have concerns related to meeting compositional criteria and the proposed labelling requirements. Our concerns in regard to the SMPPi framework and definition are detailed in our response to Section 2.4.3 and Section 3.2.4 of this submission.

480. The inclusion of products from Standard 2.9.5 presents as a whole new area that has not been raised in any previous consultation as part of P1028. It is a proposal that needs much more thorough consideration to mitigate serious health concerns. Please see member's submissions for specific examples.

481. Only products that are nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants should be considered under Standard 2.9.1. All other special infant products that do not meet the definition of an infant formula product should otherwise remain under Standard 2.9.5. They are out of scope and could be subject to a separate proposal in due course.

482. INC supports a solution for regulating products specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition that meets the needs of the infant and carer.

483. INC recognises that highly specialised products are already restricted due to extremely small number of infants that require them. It is reasonable that any product labelled in accordance with international regulation should not be available in the grocery channel. In fact, due to the limited demand of these products, no grocery retailers would be interested in listing these in their stores.

484. However, infant formula has a highly prescribed nutritional composition under both the Code and international regulations. Restrictions on sale were put in place under Standard 2.9.5 as part of the overall risk management strategy due to the minimal prescribed composition and lack of advertising restrictions. In Section 2.4.3, INC has put forward a proposal to remove the proposed modified subcategory and move all products intended for a special medical purpose to SMPPi. However, INC believes that products in the proposed modified subcategory should not be under the same requirements to meet restrictions on sale.

485. In the *Policy Guideline on the Intent of Part 2.9 - Special Purpose Foods* it states that: consideration, where appropriate, should be given to the application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.

486. Products that would have been categorised under the modified subcategory are primarily based on the baseline composition of Standard 2.9.1. These products have been on the market for a significant period of time, with no known specific risk to public health due to their intended use. The risk of inappropriate use of these specialised products is very low and there is no evidence of market failure for these products. Furthermore, these products are often located on top or bottom shelves away from eye level. Hence, unless a consumer is searching for it, it is highly unlikely these products would be inappropriately chosen over a general infant formula product.

487. Additionally, accessibility of infant formula is a public health issue. INC is concerned that access to a reliable and sustainable availability of supply is a critical issue for parents and caregivers and restricting access adds to the stress and anxiety of these groups. This has been exemplified with the current infant formula shortage in the US.

488. Restricting access may result in less shelf space for these products which could lessen competition and have consequences for consumers.

489. For this reason and for the purpose of this submission, INC recommends the following as its preference for the proposal on the scope of SMPPi and restriction on sale.

Access: SMPPi that do not have a restriction on sale	**Access: SMPPi that have a restriction on sale**
• An SMPPi that may be described in CFS1 as modified infant formula products and that is specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition	• A product that is specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition **and** nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants • A product formulated and/or labelled in accordance with Codex, EU and US Regulations and Standards.

490. For the balance of this submission, 'SMPPi' will refer to only products within the scope of the table above, unless stated otherwise.

491. SMPPi that do not have restrictions on sale, should have clear and consistent labelling. INC welcomes further consideration on an approach to labelling of such products. We have laid out some points for consideration below to address key concerns raised by stakeholders.

Where SMPPi do not have a restriction on sale

INC proposal for additional requirements	Rationale
• The product has properties and/or characteristics specific to the disease, disorder or medical condition for the dietary management of which the product is intended • Any product must include this information on the label	• Product composition is based on scientific evidence • For protection of public health and safety • Provision of adequate information to help consumers and HCPs make informed choices
• Carry an important notice in a prominent place, such as "use under medical supervision" to stop carers from self-diagnosing and to allow easy enforcement by regulators	• For protection of public health and safety • Provision of adequate information to help consumers and HCPs make informed choices
• Carry a statement in a prominent place that states 'for the dietary management of…' These products are for recognized diseases, disorders or conditions with broadly accepted diagnostic criteria	• For protection of public health and safety • Provision of adequate information to help consumers and HCPs make informed choices
• Carry the breastmilk is best statement	• For protection of public health and safety • Provision of adequate information to help consumers and HCPs make informed choices • INC is supportive of the approach of mandating the 'breast is best' warning statement on these products.

492. We note in other international markets e.g. the EU some 'iFSMP' carry similar statements and, although not a pan-EU arrangement, can be available in the grocery channel.

493. **Other provisions in Standard 2.9.1 should apply as necessary for SMPPi that do not have a restriction on sale**. INC welcomes further consideration of additional provisions for these products. Indication of INC's position on labelling of products that are currently under Division 4 of Standard 2.9.1 was submitted as part of the INC submission on CP3 2021.

494. INC considerations specific to composition and labelling of SMPPi that have a restriction on sale are detailed in the sections below. These comments refer specifically to those products intended to be used as the sole or principal source of nutrition for infants with special dietary needs who are under medical supervision for their condition. Our concerns and position on the scope of SMPPi must be considered throughout our response on composition and labelling of SMPPi.

SD4 2. Composition (p7)

495. FSANZ has proposed that SMPPi composition should meet the composition prescribed for infant formula products, except where deviation is required to address the specific disease, disorder or medical condition the product is intended for, and in doing so any deviation meets international regulations, such as the Codex, EU or US.

SD4 2.1 General nutrient composition

496. In the CFS FSANZ is proposing that the compositional requirements for SMPPi are flexible enough to ensure undisrupted access to these special medical purpose products, as the wellbeing and sustenance of infants rely on their availability. FSANZ notes that composition for SMPPi will be flexible to allow:
(1) deviation from baseline composition, prescribed in Standard 2.9.1, to address the special medical purpose
(2) alignment with international standards and regulations (i.e Codex, EU, and USA).

497. As many SMPPi are primarily imported from the EU and US, it is pertinent that the products are able to be imported into Australia and New Zealand. FSANZ proposes there will be no unintentional restrictions for import and supply from international manufacturers. This approach will enable this subpopulation of infants to have timely access to the best possible product for their nutritional needs and dietary management of specific disease, disorder or medical conditions.

498. FSANZ has recognised that because of the wide diversity of SMPPi and the rapidly evolving scientific knowledge on which products in this category are based, and the need to ensure adequate flexibility to develop innovative products, it is not appropriate to set detailed compositional rules specific to Australia and New Zealand for such food products.

499. The addition of optional substances to SMPPi is proposed to require pre-market approval, unless the addition is made for the products special medical purpose. Any deviation from the baseline infant formula products composition must be based on scientific evidence. Further to this, FSMP regulations that apply to SMPPi, should be flexible enough to accommodate new ingredients or future innovation for the specific disease, disorder or medical condition for which the food is formulated.

500. INC supports the approach to allow composition of SMPPi to be flexible enough to ensure undisrupted access and with that ensure no unintentional international restrictions on supply and import from of such products.

501. The composition of SMPPi may differ substantially depending on: (a) the specific disease, disorder or medical condition of which the product is intended; (b) the age of the patients and the place in which they receive nutritional support; and (c) the product's intended use.

502. As infant formula and follow-on formula are intended for healthy infants, SMPPi should derogate from the composition of infant formula and follow-on formula in order to satisfy the intended use of the product and nutritional requirements of the respective infant. This derogation may be a derogation from baseline compositional requirements under Standard 2.9.1 specific to the disease, disorder or medical condition for which the product is intended or where composition meets international regulation, namely Codex, EU or the US, for highly specialised products. INC recommends that the specific international regulations and standards that SMPPi products are permitted to adhere to are set out clearly in the Standard.

503. There should be provision to deviate from protein sources for products intended for healthy infants where it is necessary, i.e. extensively hydrolysed proteins or proteins hydrolysed for other nutritive purposes should be permitted in SMPPi for the dietary management of the medical condition, if it is safe and suitable.

504. INC believes that rationale on derogations from the composition of infant formula products should not only be based on the purpose of each ingredient, specifically for highly specialised products, but also consider the following:
    a. There are limitations on providing medical rationale for each nutrient that derogates from the baseline composition requirements under Standard 2.9.1
    b. It is sometimes necessary for the variations from 'infant formula product baseline composition' to be broader than those required to address the special purpose of the product. For example, the Code has a different requirement for levels of particular nutrients (e.g. minimum iron) compared to international regulation e.g. (EU) 2016/128.
    c. Although a manufacturer of an SMPPi will have medical rationale of how the product meets the dietary management for a specific disease, disorder or condition, this may not be the case for the specific nutrient forms or additives used within the formulation. A specific nutrient form or additive may be used, simply because it is permitted internationally; not because there is medical rationale for why it is needed for a specific disease, disorder or condition.

505. To fully align internationally, FSANZ should include a provision that if a substance is explicitly permitted under Codex, EU or US requirements and is in an imported product, it is permitted.

506. Given that these international regulations are updated, providing medical rationale for each nutrient that derogates from standard infant formula could prevent undisrupted access to these products in Australia and New Zealand. , . Additionally, due to the limited population that uses some SMPPi across Australia and New Zealand, the low volumes required by Australia and New Zealand do not economically, justify unique, local development and manufacture. Additionally, it may not be economically feasible to have country specific labels for these products, that differ from EU, US or Codex labels. There is a risk that these products may then not be made available for the vulnerable populations of infants that require them in Australia and New Zealand in the future.

507. INC supports the approach that optional substances in SMPPi will not require pre-market approval, if the addition is made for the product's special medical purpose. However, the proposed flexibility does not go far enough as there are other optional substances not for the product's special medical purpose that should also not require pre-market assessment as they are clearly permitted internationally, having undergone required scrutiny and assessment.

508. Notably, Standard 2.9.5 provides flexibility to allow for international alignment by including an explicit exception from nutritive substances and novel foods which needs to be included for SMPPi to allow international alignment.

509. Permitting this flexibility from 'infant formula product baseline composition' will also enable SMPPi to be shared with and imported from other markets, such as EU and US. This will allow vulnerable infants, with specific dietary requirements, timely access to the best possible food product for the dietary management of their condition.

2.9.5—3 Application of other standards

510. The following provisions do not apply to food for special medical purposes:
    (a) paragraphs 1.1.1—10(6)(b) (foods used as nutritive substances) and 1.1.1—10(6)(f) (novel foods);

511. Even if this exemption is implemented, further regulatory clarity is needed on permitted ingredients. INC strongly recommends that the Code explicitly states that if an ingredient is permitted under Codex, EU or US requirements that it would be permitted for SMPPi. This flexibility must also include vitamins and trace minerals where requirements of CAC/GL 10/1979 or EU Regulations may not align precisely with those set out in the Food Standards Code. Australia and New Zealand cannot operate in a vacuum for such highly specialised products and must therefore have enough flexibility to allow full international alignment which does not result in overburdensome preapproval for substances.

512. There is already an example of the New Zealand Ministry for Primary Industries (MPI) interpreting that ingredients that could be considered as nutritive, used in Food for Special Medical Purposes (FSMP) were not compliant and therefore preventing product being imported which was required by vulnerable patients. An Urgent Proposal P1046 was requested by MPI to allow L-arginine acetate explicitly as part of the Food Standards Code. Including permitted forms allowed in international standards for SMPPi provides regulatory clarity and reduces the likelihood of compliance issues with product that is required by vulnerable infants with rare disease, disorders or conditions.

513. Many, if not all, of the products imported from other international markets have required pre-market authority. It is vital that FSMP regulations, including SMPPi remain flexible enough to accommodate new ingredients or future innovations for the specific disease, disorder, or medical condition for which the formula has been formulated. Without these permissions, there is the potential that patients would be restricted from accessing the most up to-date and efficacious products for their infant's specific condition.

SD4 2.2 Composition for premature or low birthweight infants

514. FSANZ prefers not to propose any specific nutrient composition requirements for premature or low birthweight infants.

515. INC agrees with FSANZ's proposal that no additional mandatory compositional requirements are necessary for products for premature or low birthweight infants.

SD4 2.3 Composition for metabolic, immunological, renal, hepatic and malabsorptive conditions

SD4 2.3.1 Manganese guideline maximum for infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

516. FSANZ's preferred option is to remove the guideline maximum for manganese (7.2 µg) from S29—10, which is specific for infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

517. INC agrees with FSANZ's preferred option to remove the guideline maximum for manganese from S29—10, specific to infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions. For SMPPi, there must be permission for products to have compositional variations from

'infant formula product baseline composition', where they comply to credible international regulations, including Codex, EU and USA

SD4 2.4 Composition for specific dietary use based on a protein substitute

518. FSANZ considers the compositional requirements noted in Standard 2.9.1—15 are no longer required.

519. INC agrees that the compositional requirements noted in Standard 2.9.1—15 are no longer required. A category of products for special dietary use based on a protein substitute and any specific compositional requirements are not required.

SD4 2.5 Composition Medium Chain Triglycerides

520. FSANZ's preferred option is to include a permission for the addition of MCT to SMPPi to address the product's medical purpose.

521. INC supports FSANZ's preferred option to include a voluntary permission for the addition of MCT to SMPPi where it helps to support the product's medical purpose. Although, optional substances for the medical purpose of a SMPPi should not need to be explicitly listed as voluntary, it does provide regulatory clarity. INC also supports the proposal to not have specific compositional limits. SMPPi products that contain additional MCTs (i.e. other than those products that contain MCTs that are naturally present), are highly specialized and should be used under medical supervision. The addition of MCT oils to these products is considered a nutrition modification.

522. MCTs have been expressively permitted and safely added to Infant Formula Products for Special Dietary Use for many years. Therefore, the addition of MCT oils should be considered as safe for addition to SMPPi where it helps to address the products medical purpose.

523. The levels of MCT oils used in a product for a specific condition would need to be based on scientific data as safe and suitable. No other jurisdiction has restricted or set limits for MCT oils and therefore setting limits could create an inability to import some of these highly specialised products.

SD4 2.6 Composition for molybdenum and chromium

524. FSANZ's preferred option is to allow the voluntary addition of molybdenum and chromium in SMPPi where required to address the specific disease, disorder or medical condition.

525. INC supports FSANZ's preferred option to allow for the voluntary addition of molybdenum and chromium to SMPPi where it helps to support the product's purpose. INC also supports the proposal to not have specific compositional limits.

526. INC opposes FSANZ's proposal to not permit other forms of molybdenum and chromium in the Food Standards Code. As outlined above, INC recommends, for clarity, the inclusion of a provision that ingredients that are explicitly permitted under Codex, EU and US for SMPPi are permitted.

527. Notably, both chromium chloride and ammonium molybdenum are permitted for FSMP in the Food Standards Code, Schedule S29—20; Codex for Formula for Special Medical Purpose Intended for Infants; and the EU for Infant Food for Special Medical Purposes.

SD4 2.7 Measuring scoop for SMPPi

528. FSANZ's preferred option is to not standardise the scoop size or dilution ratio, and instead maintain the existing provision for a direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used.

529. INC agrees with FSANZ's proposal not to standardise the scoop requirement, size or dilution ratio for SMPPi. These products are used under medical supervision and for some highly specialised SMPPi, the powder weight is advised by the health care professional. Therefore, standardising the scoop size or dilution ratio, is not appropriate**.** This should not prevent manufacturers from placing a scoop in the product if they deem it reasonable for the intended product.

SD4 2.8 Food additives

530. As stated in section 5.1 on Food Additives in this submission, INC supports the preferred option for two food categories in Schedule 15 of the Food Standards Code. This is consistent with international approaches and INC's previous view (in 2021 Consultation Paper 1) supporting a simplified approach (infant formula products and IFPSDU subclass). If the category of IFPSDU is extended to include all foods for special medical purpose for infants in the SMPPi category, a further review of additives for these products would be required to ensure international alignment.

531. Please refer to section 5.1 on Food Additives for INC's full position on food additives for SMPPi.

SD4 3 Labelling

532. FSANZ is proposing to apply the following labelling requirements to SMPPi:
- the requirement to label food as 'genetically modified' in Standard 1.5.2—4
- inner packages in Standard 2.9.5—8(3)
- transportation outers in Standard 2.9.5—8(4)
- mandatory labelling information in Standard 2.9.5—9
- mandatory statements and declarations in Standard 2.9.5—10
- nutrition information requirements in Standard 2.9.5—13(b)(i) and (ii)
- a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

533. Labelling requirements that would not apply to SMPPi, or where SMPPi are exempt are:
- name of business address in Standard 1.2.2—4
- characterising ingredients and components in Standard 1.2.10
- prescribed names 'Infant formula' and 'Follow-on formula' in Standard 2.9.1—17
- a prescribed name for SMPPi
- warning statements for infant formula products in Standard 2.9.1—19(1)
- directions for preparation and use for infant formula products in Standard 2.9.1—19(3)
- age-related statements for infant formula products in Standard 2.9.1—19(4)
- a protein source statement in Standard 2.9.1—23(1)(a)
- prohibited representations for infant formula products in Sandard 2.9.1—24
- nutrition information requirements in Standard 2.9.5—13(b)(iii) or (iv)

- requirements for claims in relation to lactose and gluten content in Standard 2.9.5—14 and 15 and the existing conditions for 'lactose free' and 'low lactose' for infant formula products (see section 5.1 of SD3).

SD4 3.2 Application of Standard 2.9.5 labelling requirements

534. FSANZ considers this approach is also suitable for SMPPi and is proposing the mandatory labelling information as required by Standard 2.9.5—9 would apply to SMPPi:
    - name or description sufficient to indicate the true nature of the food (see further discussion in section 3.3.1 below)
    - lot identification
    - information relating to irradiated food
    - required advisory statements, warning statements, other statements and other declarations (see discussion in section 3.2.1 below)
    - information relating to ingredients
    - date marking, including allowing flexibility to use 'Expiry Date' or similar words
    - directions for the use or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons, (see discussion in section 3.3.3 below) and
    - legibility requirements (i.e. Division 6 of Standard 1.2.1).

535. INC supports, within reason, FSANZ's proposal to adopt a labelling approach consistent with Standard 2.9.5—9 for SMPPi that have a restriction on sale. However, there are not tangible assurances that all labelling provisions under Standard 2.9.5 will be carried across into Standard 2.9.1 for SMPPi. It is assumed that FSANZ will also carry forward the provisions under Standard 2.9.5—11 and Standard 2.9.5—12 which was indicated in FSANZ CP3 2021, but not explicitly stated in this CFS. This also allows for flexibility in labelling as well as international alignment of labels.

536. However, INC has proposed the removal of the FSANZ proposed modified subcategory and to move all products intended for a special medical purpose to SMPPi, where these products would not be subject to restrictions on sale. INC supports further consideration by FSANZ to ensure there is a clear and consistent approach to labelling of these products. A summary of the labelling changes proposed in CP3, together with the INC position, was provided in our response to FSANZ CP3 2021 in Annex A of our submission. Please refer to this document and member comments.

537. It is critical that the label of an SMPPi includes a description of the properties and/or characteristics that make the product useful in relation to the disease, disorder or medical condition for the dietary management of which the product is intended. This information is necessary for healthcare professionals to easily compare products and recommend use to carers and users.

538. FSANZ is also proposing the labelling requirements for inner packages and transportation outers in Standard 2.9.5—8(3) and (4) would apply to SMPPi.

539. INC supports FSANZ's proposal to adopt labelling requirements consistent with Standard 2.9.5-8(3) and (4). This also allows for flexibility in labelling as well as international alignment of labels.

540. Similar to FSMP, the remaining generic labelling requirements from Part 1.2 that are proposed not to apply to SMPPi are:
    - name of business address (Standard 1.2.2—4)
    - characterising ingredients and components (Standard 1.2.10).

541. INC supports FSANZ's proposal for generic labelling requirements of name of business address (under Standard 1.2.2—4) and characterising ingredients and components (under Standard 1.2.10) to not apply to SMPPi.

542. However, there needs to be further consideration of flexibility from labelling under Part 1.2. Standard 2.9.5 states that "the following provisions do not apply to food for special medical purposes unless contrary intention appears, Part 1.2 of Chapter 1". FSANZ has only listed Standard 1.2.2 and Standard 1.2.10 which implies all other Standards under 1.2 would apply. This would create significant issues in terms of international alignment and create duplication between aspects from Standard 2.9.5—9. SMPPi should be similarly exempt from all Standards under 1.2. unless contrary intention appears. This also allows for flexibility in labelling as well as international alignment of labels.

543. FSANZ has considered the application of other generic labelling requirements more broadly in Chapter 1 of the Code. Specifically, the requirement for food to be labelled as 'genetically modified' in accordance with Standard 1.5.2—4. FSANZ notes this existing labelling requirement applies to all food for sale, including FSMP and SMPPi. As noted in section 2.3 of SD3, FSANZ's preferred option is to maintain this labelling requirement for infant formula products, and considers the same approach is appropriate for SMPPi.

544. INC supports FSANZ's preferred option on the requirement for food to be labelled as 'genetically modified' in accordance with Standard 1.5.2-4.

SD4 3.2.1 Mandatory statements and declarations

545. FSANZ is proposing to apply the required advisory statements, warning statements, other statements and declarations (Standard 2.9.5—9(1)(d)) to SMPPi. The specific mandatory statements applying to FSMPs are provided in Standard 2.9.5—10(1) and these are proposed to apply to SMPPi.
- A statement to the effect that the food must be used under medical supervision
- A statement indicating, if applicable, any precautions and contraindications associated with consumption of the food
- A statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated
- A statement describing the properties or characteristics which make the food appropriate for the medical purpose
- If the food has been formulated for a specific age group- a statement to the effect that the food is intended for persons within the specified age group
- A statement indicating whether or not the food is suitable for use as a sole source of nutrition
- For products represented as the sole source of nutrition, the statement to the effect that the food is not for parental use, and additional statements about the nutritional modifications made to the product.

546. The provision in Standard 2.9.5—10(1)(g) also requires additional statements to apply to SMPPi when the product has been modified to vary from the baseline composition requirements for infant formula products in Standard 2.9.1 and Schedule 29 indicating:
- The nutrient or nutrients which have been modified, and
- Unless provided in other documentation about the food- whether each modified nutrient has been increased, decreased, or eliminated from the food, as appropriate.

547. Generic requirements as indicated in Standard 2.9.5—10(2) and Standard 2.9.5—10(3) relating to advisory or warning statements about the presence of bee pollen, propolis,

guarana and aspartame and the declaration of allergens are also proposed to apply to SMPPi.

548. FSANZ's proposal is to apply the required advisory statements, warning statements, other statements and declarations (Standard 2.9.5—9(1)(d)) and Standard 2.9.5—10(1), inclusive of Standard 2.9.5—10(1)(g) to SMPPi.

549. INC does not support Standard 2.9.5—10(1)(g) applying to SMPPi due to this creating misalignment of labelling requirements internationally. Under Standard 2.9.5, this requirement is only for products represented as a sole source of nutrition, not all Food for Special Medical Purpose. The key issue is that the baseline composition for infant formula varies from Codex, EU and US. Therefore, mandating the provisions in Standard 2.9.5—10(1)(g) will lead to misalignment with international labels. For example, the iron level of an SMPPi may be 0.1mg/100kJ which will vary from the composition criteria in Standard 2.9.1 and Schedule 29, however, this level is within the composition criteria of credible international regulations and standards, specifically, the EU and Codex.

550. If FSANZ believes such information is important for SMPPi, an alternative approach would be for companies to provide such information on SMPPi represented as sole source of nutrition directly to Healthcare Professionals upon request.

551. INC is aligned that 2.9.5—10(2) and (3) relating to advisory or warning statements about the presence of bee pollen, propolis, guarana and aspartame and the declaration of allergens should apply to SMPPi.

SD4 3.2.2 Nutrition information

552. Standard 2.9.5—13(a) and Standard 2.9.5—13(b)(i) require nutrition information expressed per given amount of food in relation to the minimum or average energy content; and the minimum amount or average quantity of protein, fat and carbohydrate; and any vitamin, mineral or electrolyte that has been used as a nutritive substance in the food.

553. FSANZ is proposing these requirements apply to SMPPi without the specific format requirements for nutrition information as proposed for infant formula product labels (see section 3.3 of SD3). FSANZ considers this approach provides flexibility to accommodate the differing overseas nutrition information requirements on imported products.

554. INC put forward a proposal to remove the proposed modified subcategory and move all products intended for a special medical purpose to SMPPi. For SMPPi that do not have a restriction on sale, INC supports further consideration by FSANZ to establish a workable solution for formatting of the nutrition information for such products, as proposed for infant formula product label.

555. INC supports FSANZ's proposal for requirements in Standard 2.9.5—13(a) and Standard 2.9.5—13(b)(i) to apply to SMPPi, without the specific format requirements for nutrition information as proposed for Infant Formula Product labels. It is important to allow for flexibility to enable access to imported products which will meet different nutrition information requirements. This allows for alignment with international labels.

556. Standard 2.9.5—13(b)(iii) and (iv) require the declaration of any substance used as a nutritive substance listed in the table to S29—20, as well as declaring the amount of any other substance in respect of which a nutrition content claim has been made. However, FSANZ has determined these requirements should not apply because the table to

S29---20 is specific to FSMP composition, and nutrition content claims are prohibited on infant formula products, including SMPPi. FSANZ is proposing a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose (see Section 2.1.2 general nutrient composition).

557. Composition of SMPPi should be flexible enough to ensure undisrupted import access and ensure no unintentional international restrictions on supply and import from of such products.

558. INC strongly recommends that international alignment is considered when setting requirements to declare the amount of any other nutritive substance that is added to the product, for its intended medical purpose. Nutritive substances should be permitted to be declared if they are added to the product for its intended medical purpose or are present in the product due to permissions applicable to SMPPi in credible international regulations and standards, namely Codex, EU and US.

SD4 3.2.3 Nutrition content and health claims

559. FSANZ notes that if an SMPPi is formulated for a specific disease, disorder or medical condition, and lactose or gluten content is a feature of that formulation, the information would be provided in the statement describing the properties or characteristics which make the food appropriate for the medical purpose.

560. INC supports FSANZ's approach that any SMPPi formulated for a specific disease, disorder or medical condition whereby its gluten or lactose content is a feature of the formulation, should be able to include the information on the label. Whilst INC is aligned that Standard 2.9.5—14 and Standard 2.9.5—15 should not apply to SMPPi, this should not prevent SMPPi from including information on gluten or lactose content, where applicable consistent with this.

561. It is important that manufacturers can provide all information that is necessary to ensure the appropriate use of SMPPi. This should include the ability to provide information on the properties and characteristics in relation to, among others, the special processing and formulation, nutritional composition and rationale on what makes the product useful for its specific intended purpose. Such information should not be considered as nutrition and health claims under Standard 1.2.7 and if there is a risk it is, then an exemption should be explicit.

562. The ability to provide information on the product should take into account the intended use of the product and without prejudice to the need to provide food information to patients and healthcare professionals, to ensure its appropriate use.

563. Given that SMPPi are intended to be used under medical supervision, those restrictions should not make it more difficult for food business operators to communicate with healthcare professionals and should allow healthcare professionals to easily and effectively assess the suitability of different products for their intended use.

SD4 3.3 Application of Standard 2.9.1 labelling requirements

SD4 3.3.1 Prescribed name

564. FSANZ maintains Standard 2.9.1—17 should not apply to SMPPi and that a prescribed name is not required. Other labelling risk management measures proposed for SMPPi will ensure these products can be distinguished from standard formula (e.g. restriction on the sale, the statement 'use under medical supervision', a statement indicating the

medical purpose of the food, a statement on the properties that make the product suitable for the medical condition, and (if relevant) a statement to the effect that the food is intended for persons within the specified age group).

565. INC agrees that a prescribed name is not required and should not apply to SMPPi. Generic provisions in Standard 1.2.2—2(1)(b) would apply to SMPPi. Notably, prescribing a name would result in international misalignment with labelling and a trade barrier.

566. Currently, IFPSDU regulated under Standard 2.9.1 include a prescribed name. Provision on the exemption of Standard 2.9.1-17 applying to SMPPi, should not prevent manufacturers placing this information on the product if they deem it reasonable for the intended product.

567. FSANZ's proposed risk management measures for labelling of SMPPi, must take into consideration adjustments to labelling that take into account: clear identification of the intended use of the product, without prejudice to the need to provide food information to patients and health care professionals, to ensure the product's appropriate use. It must also consider flexibility in labelling requirements to allow for international alignment of labels.

SD4 3.3.2 Warning statements

568. FSANZ considers these warning statements should not apply to SMPPi because they are not specified by Codex and not required by EU regulations. Prescribed wording would therefore present a trade barrier. FSANZ is instead proposing to apply Standard 2.9.5—9(1)(g) for directions for the use or the storage of the food. FSANZ also notes SMPPi are also intended for use under medical supervision, and so the risks that this statement manages are addressed. Standard 2.9.1—19(1)(d) requires infant formula product labels to include a heading that states 'Important Notice' (or words to that effect), with under it the warning statement —'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'.

569. FSANZ's preliminary view in the FSANZ 2021 CP3 was that it was appropriate for SMPPi to be exempt from this statement. There was general submitter agreement. Exempting SMPPi from the breastfeeding statement is consistent with EU and US regulations. FSANZ also notes SMPPi are intended for use under medical supervision. Healthcare professionals to be best placed to advise when to breastfeed infants with medical conditions, rather than relying on SMPPi labels for this information.

570. INC agrees with FSANZ's proposed approach that Standard 2.9.5—10(1) will apply to SMPPi. This will cover the requirements for warning statements such as 'suitable only for pre-term infants under specialist medical supervision'. Aligning with Standard 2.9.5—10(1) allows for less prescriptive wording and therefore enables flexibility and ease of access to imported products.

571. For SMPPi it is not necessary to mandate the use of warning statements on Infant Formula Products that instruct caregivers to follow instructions exactly when preparing either a powdered, concentrated or ready-to-drink Infant Formula Product for use. This is in alignment with international regulations and standards. As FSANZ mentions in SD4, these statements are not required by EU regulations or specified by Codex. Hence, enforcing this prescribed wording would introduce a trade barrier.

572. Provision on the exemption of SMPPi from including the ‘breast milk is best’ statement on the label, should not prevent manufacturers placing this statement on the product if they deem it reasonable for the intended product.

SD4 3.3.3 Directions for preparation and use

573. FSANZ notes concerns and now considers that Standard 2.9.5—9(1)(g) regarding directions for preparation and use should apply to SMPPi as part of the overall approach to adopt FSMP labelling.

574. INC agrees that no additional, specific directions should be mandated for SMPPi and is aligned with FSANZ’s view that Standard 2.9.5—9(1)(g) on directions for the use or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons, should apply. Aligning with Standard 2.9.5—9(1)(g) allows for less prescriptive wording and therefore enables imported products to meet international requirements. However, this should not prevent manufacturers from using wording similar to that stated inStandard 2.9.1—19(3) if they deem it reasonable for the intended product.

SD4 3.3.4 Age-related statements

575. FSANZ is proposing FSMP statements in Standard 2.9.5 apply to SMPPi. Age--related statements in Standard 2.9.1—19(4)(a) and (b) are addressed by the FSMP requirement for a statement that the food is intended for persons within a specified age group.

576. FSANZ considers applying the statement about offering additional food to be inappropriate because the provision of additional foods may be contra-indicated and supervising healthcare professionals are best placed to advise caregivers on introducing a varied diet to an infant specific to their individual dietary management. Further, this requirement is inconsistent with Codex, EU and US labelling of SMPPi.

577. The statement under Standard 2.9.5—10(e) on a statement to the effect that the food is intended for persons within the specified age group is sufficient to cover requirements for an age-related statement on SMPPi. Given the specialised nature of these products, information on introduction of additional foods should be placed with the healthcare professional first and foremost. Therefore, INC agrees that a specific statement on offering additional food is inappropriate for SMPPi and is inconsistent with Codex, EU and US labelling of similar products.

SD4 3.3.5 Protein source statement

578. FSANZ considers the requirement for a protein source statement in accordance with Standard 2.9.1—23(1)(a) will not apply to SMPPi.

579. INC agrees with FSANZ that a statement regarding the specific source, or sources of protein in the product, immediately adjacent to the name of the product, should not apply to SMPPi. Accommodating the differing requirements on imported products is vital to ensure the affected individuals in Australia and New Zealand have timely and sustainable access to these products.

SD4 3.3.6 Prohibited representations

580. FSANZ considers prohibited representations on infant formula products should not apply to SMPPi because these are highly specialised products for use under medical supervision and which are not marketed to caregivers of healthy infants.

581. INC agrees with FSANZ's proposal that all the prohibitions on labels of infant formula products should not apply to SMPPi except when sold in supermarkets. Nevertheless, when sold in supermarkets, a representation that the food is suitable for a particular condition, disease or disorder must be permitted to protect babies that require a special dietary management.

582. SMPPi are highly specialised and it is intended that they are used under the supervision of a healthcare professional. It is critical that SMPPi must retain flexibility in permissions on labelling, to allow for imported products to meet credible international regulations and prevent any potential trade barriers. This will ensure the relevant population in Australia and New Zealand has timely access to these specialised products.

Accessibility

583. As noted above, accessibility of all infant formula is a public health issue.

584. Trade restrictions were put in place under Standard 2.9.5 as part of the overall risk management strategy due to the minimal prescribed composition and lack of advertising restrictions. As noted by FSANZ in SD3, there are controls in advertising restrictions in place for infant formula products due to voluntary government marketing codes which incorporate the principles of the WHO *International Code of Marketing of Breast-milk Substitutes*. Also, sole or predominant source nutrition product for infants is based on the prescribed composition requirements and are only varied for the purpose of the product. The composition requirements of these products are based on requirements set either by the Food Standards Code or by international regulations and are highly prescribed.

585. INC recognises that there are already restrictions on access to highly specialised products intended for use for clinically serious or potentially life-threatening disorders, diseases and medical conditions, given the small number of vulnerable infants who require these products. However, restricting sale of all products that are specifically developed for a disease, disorder or condition could make accessibility of these products problematic and difficult and potentially force carers to feed their babies alternatives, that may not be suitable and could potentially be harmful. This could add to poorer public health outcomes.

586. A general restriction on sale of SMPPi will have an impact on three major areas:
- a negative effect on some health outcomes for infants who require these products
- less accessibility and availability to of these products for parents and carers, and
- supply chain logistics.

Negative effect on some health outcomes for infants who require these products and their carers

587. The effects include carers potentially feeding their babies alternatives that may not be suitable and could potentially be harmful. Restricted sale and lack of ability to properly communicate on the purpose or intended use of the product, could potentially force carers to feed their babies alternatives that may not be suitable and could potentially be harmful.

Less accessibility and availability to of these products for parents and carers

588. The level of occurrence of functional gastrointestinal disorders is common worldwide and covers a wide range of disorders attributable to the gastrointestinal tract that cannot be explained by structural or biochemical abnormalities. Reported international prevalence rates of functional gastrointestinal disorders in neonates and toddlers vary between 27.1% and 38.0%, with the most prevalent disorders being infant regurgitation and functional constipation (1-25.9% and 1-31%, respectively) (Zeevenhooven et al 2017).

589. With occurrence at the levels stated above, products for these conditions require greater access than can be provided in the pharmacy setting due to the limited shelf space provided for infant formula products. In addition, pharmacies do not normally provide the same hours of access to products due to their limited opening hours or at home delivery. This is particularly apparent in rural communities.

Supply chain logistics

590. Once specialised products are recommended or prescribed under prescription by a healthcare professional, on-line direct home delivery is often the most reliable and convenient way to source these highly specialised products since they are not often readily found in local stores.

591. There have recently been significant global supply issues with the availability of specialised products which has resulted in many shortages of these critical products. Further limiting a brand owner's company ability to provide direct to customers further adds to issues in the supply of these products. Access to reliable and sustainable availability of supply is a critical issue for parents and caregivers and restricting access adds to the stress and anxiety of these groups.

9 FSANZ Act assessment requirements

9.1 Section 59

9.1.1 Consideration of costs and benefits

592. INC notes that the Office of Best Practice Regulation (OBPR) granted FSANZ an exemption from the requirement to develop a Consultation Regulation Impact Statement (CRIS) for this proposal on the basis that a separate CRIS process was not expected to yield new information on costs and benefits. The OBPR noted the extensive consultation that had already taken place and the two legislated six-week consultations planned for 2022. What was presumably not alerted to the OBPR was that a new approach to a significant part of the Standard was being proposed by FSANZ (SMPPi) that was introducing non-infant formula products to the Standard. Neither was this alerted to Industry.

9.1.2 Costs and benefits

Consumers

593. FSANZ states that "Overall, infants that are fed infant formula products may benefit from improved composition according to current science. The major compositional changes, including to food additives, contaminants and purity of fat sources will likely further ensure that infant formula products remain safe and suitable for infants into the foreseeable future. It is not possible to quantify safety outcomes. INC argues that improved compositional standards and innovations based on robust scientific research will also benefit public health outcomes for infants and in later life.

594. INC states categorically that current products are already safe and suitable, however INC supports updating composition and additives to align internationally with more recent science. It is possible to quantify safety outcomes if FSANZ has specific safety issues in mind. OBPR has guidance e.g. Value of statistical life, and other healthcare data for such calculations.

595. FSANZ proposes that improved product labelling will help parents and caregivers to select appropriate products for their infants. INC rejects this. Some ordering of the NIS will be a step in this direction but many of the proposed changes could have a negative impact on the ability to provide adequate information.

596. Consumers are negatively impacted by any label changes. We know this through experience that changing any element on cans creates high concern and uncertainty for consumers. The extent of changes proposed will strongly and potentially negatively impact consumers but we agree that costing this is difficult. We suggest Government actions that will be needed to address this below.

597. FSANZ proposes that in the short-run, some (mainly domestic) product manufacturers may pass-on some of the increased costs of meeting new domestic standards to parents and caregivers through higher prices of infant formula products. We agree this is highly likely.

598. FSANZ goes on to state that in the longer-run, greater alignment with international regulations will likely reduce production costs and consumers may then benefit from price reductions. Whilst this is the likely outcome should complete alignment with international standards be permitted, INC argues that the reductions above may not be achieved if there is not full international alignment. There may be some benefit of greater alignment however, not all composition requirements proposed are internationally aligned (e.g. iron minimum) and this means that formulations will likely still need to be specific to Australia and New Zealand.

599. Any such benefits will likely be out-stripped by other cost increases impacting production. Ingredient costs are rising, transport costs are rising, packaging materials eg tinplate costs are rising (see for eg www.stats.govt.nz/news/increasing-costs-of-imports-helps-push-up-food-prices/)

600. It is not correct to state that costs for consumers will reduce.

9.1.2 Costs and benefits

Industry

601. FSANZ identifies three key factors affecting costs:
- one-off product reformulation to meet new domestic standards
- processes to further reduce contaminant levels, including relevant carry-overs in fats
- one-off product label changes to meet new standards.

602. INC members provided significant additional information concerning costs during 2021 that should be used. We point in particular to the two sources of costs FSANZ has referred to for changing product labels – the cost of changing alcohol labels for alcoholic beverages (2021) and PWC Cost schedule for Food Labelling Changes – steel cans of general foods and beverages (2014). This is highly inappropriate given that alcoholic beverage labels have no mandated nutrition information and do not require such detailed information as is required of infant formula products. Costings from 2014 are irrelevant due to their age and timeliness particularly in an ongoing pandemic environment

characterised by packaging shortages and cost escalations in all areas of production and manufacture.

603. Furthermore, there are a lot more proposed labelling changes under P1028 and companies are likely to need to go through a full design review which is more costly than a simple text update.

604. Due to the extent of composition and labelling changes, most companies will not be able to do 'one-off' changes. As there are reformulation changes companies will need to do a "hard change" which will result in packaging write-off. Reformulated product cannot be packed into old packaging with incorrect ingredients listed and an incorrect NIS. It is simply not possible to schedule exactly the run-out of the old packaging with the production of new formulation. There are also:
    - GS1 requirements relating to barcoding and what constitutes the need for a barcode change; and
    - supermarket requirements are that when a barcode changes on a SKU then all old products are withdrawn and disposed of and the new product is displayed. This is because the supermarket cannot have two ostensibly 'same' products on sale at once with different barcodes.

605. FSANZ proposes two mechanisms to minimise costs:
    - An adequate transition period, and
    - Provision for carry over subject to "a formal risk- assessment as being safe".

Transition Period

606. Every infant formula product SKU will change as FSANZ has observed, given the extensive number of compositional and labelling changes required. INC is of the view that 5 years transition period plus 2 years for stock-in-trade (7 years) is required to give effect to the extensive changes proposed. Each company will need to develop its change programme.
    - such change programmes will require the coordination of multiple, complex and interconnected projects that take a significant time and resources
    - these are likely to be iterative in order to accommodate the extent of changes necessary
    - this will be significantly more complex than the Plain English Allergen Labelling change
    - research and development activities will include, as relevant: raw material qualification, specification set-up, production trials, quality testing, shelf-life testing programs, setting scoop size (depends on specific gravity or individual powders), implementation documentation, internal processes
    - complex inter-relationships may exist between product components rather than treating each SKU separately
    - redevelopment of base powder recipes, premixes and individual product recipes will be required
    - preparation, review, and receipt of new/changed artwork & packaging materials
    - consideration that not every recipe can be redeveloped simultaneously, may need staggering of project work
    - integration with other planned changes such as those in progress or required to: raw material ingredients, production facilities, packaging suppliers and sources
    - reformulation and label updates of each product will take approximate 36 months, noting (as stated above) that companies cannot start to commence implementation until after gazettal and companies do not have the resources to implement changes on all products at the same time. The 36 months omits consumer studies and full shelf-life studies

- where relevant, assessment of impact on export only products – reformulation, relabelling re-registration, costs.

Provision for carry over subject to "a formal risk- assessment as being safe"

607. Provision of existing carry-over food additives arrangements will be of assistance but since these have been safely in place for at least 20 years, quite probably for 30-40 years, then requiring 'formal risk assessments' is of very limited advantage and significant disadvantage and high cost. It is also not clear how these would be approached and who would do these, whether these have been done in the past and where the documentation is held. There are, as we know, currently only two means of making changes to the Food Standards Code (applications and proposals) and either of those routes is years in the making and a significant cost.

608. INC has considered the estimate of 100 SKUs of infant formula products including special products in the market, provided in SD5 and believes it is significantly under-estimated.

609. The estimate of 100 SKUs is taken from a now outdated 2018, time-limited online survey of supermarket information only, that was subsequently doubled to account for unknowns. The estimate would have had to encompass all the SMPPi products proposed. We are disappointed FSANZ has not updated this online survey for the past 3-4 years and did not conduct a parallel survey of industry participants to truth test its estimate and consider this work should have preceded the first CFS. INC estimates its members are likely to supply at least 200 SKUs. INC strongly recommends that FSANZ surveys industry separately to the submission process to determine with greater accuracy the number of SKUs and export products affected.

610. FSANZ has assumed that highly specialised formula products for highly specialised conditions (SMPPi) will not require any label changes under the Proposal. Industry is yet to confirm this analysis. Note that many current FSMP products can be used by infants, children and adults and it is unclear whether they will need to fit this new Standard or the current Standard 2.9.5. INC therefore does not support inclusion of FSMP products that currently are covered by Standard 2.9.5.

611. There will be products unable to adapt to the proposed new Standard that would have to be withdrawn. Clinical trials and FSANZ applications are a barrier to entry into the market. Yet many of these products are considered safe and suitable in countries around the world.

612. The current pre-market assessment process requires demonstrable efficacy whereas Codex requires safety and suitability. There will be reduced competition for innovative and beneficial products as these become expensive to research, produce evidence and any benefit or differentiator will be unable to be communicated on labels. This is not aligned with the *Policy Guideline Regulation of Infant Formula Products* to ensure that the composition of breastmilk should be used as a primary reference for determining the composition of infant formula and follow-on formula.

613. In summary, INC does not agree with the industry costing data provided by FSANZ, which is inappropriately based, seriously outdated and under-estimated.

614. The implementation will be a multi-million dollar exercise for industry. Individual companies will provide further data on reformulation costs and packaging costs.

615. Trade costs if products cannot be reformulated pending applications, then the need to run two or more production lines – one for export where exemptions from domestic labelling and composition might be available – at a cost and time (lost markets) and another to meet some of the most restrictive standards in the world for addition optional ingredients.

9.1.2 Costs and benefits

Government

616. FSANZ suggests that improved infant health outcomes will result from “reduced safety incidents”. FSANZ does not elaborate on what the improved health outcomes are likely to be. It is not clear what safety incidents attributable to labelling and composition is referred to by FSANZ that provides evidence that there will be “reduced safety incomes”. The safety record of products currently on the Australia and New Zealand market is exemplary. Data published by FSANZ between 2012 and 2021 show no recall of infant formula products manufactured in Australia and New Zealand, due to composition or labelling issues. In 2022, microbial contamination, not composition or labelling issues, saw the recall of product imported from the US.

617. The purported reduction in “burdens on health-care" should be quantifiable if FSANZ is aware of such safety incidents. Healthcare costs are readily available eg Health expenditure - Australian Institute of Health and Welfare (aihw.gov.au)

618. This will not change in the future as companies maintain stringent food safety controls and take a cautious and measured approach to changes in order to maintain its exemplary food safety record and minimise disruption in the market over time.

Unquantified Benefits

619. FSANZ should quantify any proposed benefits eg using Office of Best Practice Regulation Cost–benefit analysis procedures as validation for the proposed changes, even when full quantification is not possible.

620. The changes proposed do not always result in positive outcomes for Food Security. If significant amount of products are required to be reformulated and labelling changed this can create uncertainty in the market as “old” product is withdrawn, replaced by new. An appropriate transition will go someway to address this.

FSANZ Conclusions about Benefits versus Costs

621. FSANZ suggests that the proposed changes will further ensure that infant formula products and SMPPi remain safe and suitable into the foreseeable future for almost 3 million infants a decade.

622. The current products are safe and suitable already. INC agrees that infants would benefit from updated composition and additives that align internationally with Codex and more recent science. Industry anticipates that there will be long-term cost benefits with international standards alignment. However, INC does not agree with all composition changes proposed as outlined in our submission. Industry anticipates where there is a lack of alignment internationally, this will continue to restrict harmonised ingredients and formulations, which will therefore result in ongoing costs in Australia and New Zealand with no justified benefits.

623. FSANZ is also proposing additional highly restrictive labelling requirements that are not aligned internationally and could be to the detriment of parents and carers and their infants

624. A lack of differentiation between brands is a significant disincentive to innovation, which is not in the best interest of a formula-fed infant and ongoing public health outcomes. Whether or not the caregiver has the choice to formula-feed their infant, the infant never has that choice. Infants who receive formula must not be disadvantaged more than they already are by not being breast-fed by disincentivising innovation and the substantial clinical research that goes into improving infant formula products, the Government is discriminating against caregivers and penalising the infant.

625. FSANZ suggests the changes regulatory clarity for producers and enforcement agencies. INC also believes that there should also be clarity for consumers and this should be prioritised.

626. INC has highlighted where it does not agree that regulatory clarity is being provided (e.g. MCT oil, SMPPi).

Questions

Q1. To what extent do you agree with FSANZ's conclusion on benefits outweighing the costs?

627. INC does not consider that the benefits and costs have been fully considered. FSANZ has taken a very broad approach to assessing costs and benefits which does not consider the impact of specific proposals, particularly ones which are not internationally aligned.

628. The proposals in their current form as presented in the CFS and SDs will affect a significantly greater number of products/SKUs than estimated at significantly greater cost.

Q2. Do you agree with FSANZ's summary of industry costs and that the main costs will be:

a) one-off product reformulation to meet domestic standards
b) processes
c) one-off product label

629. INC absolutely does not agree. Industry cannot make all reformulation and labels in parallel as a 'one-off' event, due to the extent of changes needed and the sheer number of SKUs to be changed. Additionally, some products may require more than one reformulation. The changes must be phased to accommodate the necessary research, development, sustainable provision of ingredients/packaging in the supply chain, commercialisation and testing to deliver continued product safety and suitability and product integrity.

Q3. Do you agree with FSANZ's current estimates of relabelling costs in SD5?

630. INC absolutely does not agree with current estimates of relabelling costs.

631. Labelling cost must consider packaging write-off which will happen when updating labels for reformulated product. Also, due to the extent of labelling changes companies will likely need to do a full design rather than a simple text update.

Q4. Do you agree with FSANZ's current estimates of reformulation costs in SD5?

632. INC absolutely does not agree with current estimates of reformulation costs. The extent of changes can not physically occur in a single event at a point in time. Resourcing

requirements, safety and integrity will require several changes for some products over 5 years to give full effect to the proposed changes.

633. FSANZ needs to be aware that label and reformulation changes may require manufacturers to make amendments for other markets. This could include formulation, labels and re-registration.

Q5. Do you agree that reformulation costs would be lower for multinational companies than for domestic companies, if there is an adequate transition period?

634. No, there will be different costs.

635. Multinational companies could be sharing product formulation with other countries, the implementation could result in significant costs in updating labels, formulations and registrations in other markets.

Q6. Do you have any further information on estimated number of products that:
- **a. sell in Australia and New Zealand**
- **b. would need to reformulate?**

636. INC suggests there may be around 200 SKUs affected by the proposed changes and recommends FSANZ undertake a formal industry survey to confirm the number of products in each category. FSANZ should take an industry survey separate to the consultation.

Q7. Do you have any further information on the numbers of companies…?

637. Individual member companies will provide response.

Q8. Do you have any other comments…?

638. No further comments

9.1.3 Other measures
9.1.4 Any relevant New Zealand standards

639. Exported products from NZ that do not comply with FSANZ regulations require an S347 exemption for export. Due to proposed changes in the compositional requirements for infant formula products, exported products that have an existing compositional exemption under this process need to be reviewed. Industry will need to work with MPI on how best to manage this process.

9.2 Subsection 18(1)
9.2.1 Protection of public health and safety

640. INC strongly supports the protection of public health and safety. In several areas we identify that the current proposals will jeopardise public health and that FSANZ should reassess the relevant proposals to address these areas.

9.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Consumers

641. INC strongly supports the provision of adequate information to enable consumers to make informed choices. INC is concerned that the extent of prescription proposed for labelling will make this region one of the most constrained in the world, limiting choice and potentially impacting public health.

642. We are concerned at the heavy reliance placed by FSANZ on limited consumer research, especially that relating to small-sized focus groups. The research is indicative and should not underpin the extent of changes proposed.

9.2.3 The prevention of misleading or deceptive conduct

643. A number of the preferred options in labelling have the potential to be misleading primarily due to the absence of information that has been included to date and which is currently used by consumers.

9.3 Subsection 18(2) considerations

- **the need for standards to be based on risk analysis using the best available scientific evidence**

644. INC has identified some areas where the best available science has not been used eg vitamin D levels.

645. There seems to be a reluctance to use industry based/funded scientific research.

- **the promotion of consistency between domestic and international food standards**

646. INC appreciates the extent to which changes have accommodated consistency with international standards to which the vast majority of changes proposed in composition and additives. However, it should be noted that not all changes are internationally aligned (e.g. iron) and that this will mean that Australia and New Zealand may continue to require specific formulations from other countries into the future.

647. Also, FSANZ should consider how to maintain international consistency for the future particularly for SMPPi in relation to food additives and permitted forms. INC recommends addressing permissions by cross-reference to accepted overseas standards. Consistency also assists with reducing trade restrictions and keeping compliance costs down.

- **the desirability of an efficient and internationally competitive food industry**

648. Where changes proposed will have a negative impact on a competitive food industry, INC has made this clear. One of the most concerning is in relation to restrictions around the labelling. As pointed out, it is important to encourage competition between companies so that consumer choices are not distorted and correctly justified. Further restrictions could result in some reduction in competition, including reduced incentives to innovate and to improve product quality.

- **the promotion of fair trading in food**

649. Restricting trade to pharmacies of infant formula products that have been sold in supermarkets for decades could result in less competition, less choice and potential public health impacts all of which are described in the preceding sections of this submission.

- **Any written policy guidelines formulated by the Forum on Food Regulation [SD6]**

650. INC have identified where changes are not consistent with the policy guidelines (e.g. ingredient based claim restriction).

10 Risk communication

10.1 Consultation

651. INC considers that Standard 2.9.1 and the scope of P1028 should only include infant formula products. Any other special medical purpose products for infants that are not infant formula products and currently under Standard 2.9.5 would require a separate consultation.

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Attachment A

Examples of MCT mistakenly used - Medium chain saturated fatty acids (MCFA), Medium chain triglycerols (MCT's) and MCT oils

The purpose of this attachment is to demonstrate that while these terms are commonly used, differing meanings are attributed to them by different expert groups. The use of any of these terms in the Food Standards Code without a definition would consequently give rise to ambiguity and lead to different interpretations of their meaning.

Reference: EFSA, 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760

Excerpt:

> Human milk contains only small amounts of short-chain SFAs (SCFAs, with a carbon chain length < 6), but usually contains 8-10 FA % as medium-chain SFAs (MCFAs, usually defined as fatty acids with a carbon length of 6-10) (EFSA NDA Panel, 2010c)). TAGs containing SCFAs, MCFAs and to some extent also lauric acid, with 12 carbon atoms, are more rapidly hydrolysed by gastrointestinal lipases and the hydrolysis products are more easily absorbed and are taken to the liver directly via the portal vein (Novak and Innis, 2011). The ingestion of these fatty acids, therefore, could provide some benefit under conditions where fat absorption is a limiting factor. The MCFA content of human milk varies and is increased by a high carbohydrate and low fat intake of the mother (Koletzko et al., 1992; Sauerwald et al., 2001; Novak and Innis, 2011).

This reference states that MCFAs are usually defined as saturated fatty acids with chain length of 6 to 10 carbons. It also focuses on the ingestion of these fatty acids rather than the triglycerols of which they are a part (neither of the terms MCT or MCT oil is used).

Reference: FAO, 2010. Fats and fatty acids in human nutrition. Report on and expert consultation. FAO Food and Nutrition paper 91 published in 2010. RECOMMENDATIONS

Excerpt:

> FOR NOMENCLATURE
>
> The following definitions for the sub-classes of saturated fatty acids are recommended: …
>
> • Medium chain fatty acids: These are fatty acids with carbon atoms from eight to thirteen.

This reference recommends that the term MCFAs should be applied to saturated fatty acids with chain length of 8 to 13 carbons.

Reference: McKenzie, K.M. et al, 2021. Medium-Chain Triglyceride Oil and Blood Lipids: A Systematic Review and Meta-Analysis of Randomized Trials *The Journal of Nutrition*, Volume 151, Issue 10, October 2021, Pages 2949–2956, https://doi.org/10.1093/jn/nxab220

Excerpt

> We conducted a systematic review to determine the effects of medium chain triglyceride (MCT) oil, consisting almost exclusively of medium-chain fatty acids (C6-C10), on blood lipids.

This reference defines MCFAs as saturated fatty acids with chain length of 6 to 10 carbons and describes MCT oil as containing almost exclusively MCFA.

Reference: Wikipedia

Excerpts:

> Medium-chain triglycerides (MCTs) are triglycerides with two or three fatty acids having an aliphatic tail of 6–12 carbon atoms, i.e. medium-chain fatty acids (MCFAs). Rich food sources for commercial extraction of MCTs include palm kernel oil and coconut oil.

> MCTs are found in palm kernel oil and coconut oil and can be separated by fractionation. They can also be produced by interesterification.

This reference considers that fatty acids with chain length of 6 to 12 carbon atoms are of 'medium' length and that MCT's are triglycerides with two or three of the three fatty acids attached to the glycerol back bone are MCFAs.

Reference: Clegg, M. E. (2010, November). Medium-chain triglycerides are advantageous in promoting weight loss although not beneficial to exercise performance. *International Journal of Food Science and Nutrition*, *61*(7), 653–679 https://www.ncbi.nlm.nih.gov/pubmed/20367215

> Excerpt:
> Medium-chain triglycerides (MCT) are triglycerides with a fatty acid chain length varying between 6 and 10 carbon atoms. MCT differ from long-chain triglycerides as they are relatively soluble in water and, hence, rapidly hydrolysed and absorbed. MCT are transported in the blood through the portal system, consequently they bypass adipose tissue that makes them less susceptible to hormone-sensitive lipase and deposition into adipose tissue stores.

This reference considers that fatty acids with chain length of 6 to 10 carbon atoms are of 'medium' length.

Reference: Burgess L, 2017. What are the possible benefits of MCT oil? https://www.medicalnewstoday.com/articles/320251

> Excerpt:
> Fats are made up of chains of carbon atoms, and most of the fats in a person's diet are made up of 13 to 21 of these atoms. These are called long-chain fatty acids.
> In contrast, short-chain fatty acids are made up of 6 or fewer carbon atoms.
> MCTs refers to medium-chain triglycerides that sit in the middle of the other two types. They are of medium length and made up of 6 to 12 carbon atoms.
> MCTs are found in coconut oil and are processed by the body in a different way to long-chain fatty acids. Unlike other fats, they go straight from the gut to the liver. From here, they are used as a source of energy or turned into ketones.

In this peer reviewed article for medical practitioners the term MCTs is used instead of MCFAs. It is the MCFAs that are made of 6-12 carbon atoms, not MCTs.

Attachment B

Sheep Milk Data to Support Inclusion of Sheep Milk Formula

Protein and Amino Acid Content of Different Species of milk (adapted from Claeys, 2014)

Nutrient	**Sheep**		**Goat**		**Cow**	
Total Protein Content (g/100g milk)	4.5-7.0	5.75	3.0-5.2	4.1	3.0-3.9	3.45
Amino Acid	**(mg/100g milk)**	**(mg/g protein)**	**(mg/100 g milk)**	**(mg/g protein)**	**(mg/100 g milk)**	**(mg/g protein)**
Histidine	167	29	98	24	100	29
Isoleucine	338	59	207	50	140	41
Leucine	587	102	314	77	290	84
Lysine	513	89	290	71	270	78
Threonine	268	47	240	59	150	43
Tryptophan	84	15	44	11	50	14
Valine	448	78	240	59	160	46
Methionine	155	27	80	20	60	17
Cysteine	35	6	46	11	20	6
Phenylalanine	284	49	155	38	160	46
Tyrosine	281	49	179	44	150	43

Note: Products must be assessed to meet aa per g of protein

Protein Profile (g/L) of milk from different mammalian species (adapted from Roy D)

Protein Fractions	**Sheep**	**Goat**	**Cow**
Total casein	41.8-52.6ꝏ	23.3-46.3	24.6 – 28
Total whey proteins	10.2-16.1ꝏ	3.7-7.0	5.5 - 7.0
Casein-to-whey protein ratio	76 : 24	78 : 22	82 : 18
Major caseins			
αs1-Casein	2.4ꝏ-22.1	0 -13.0	8 - 10.7
αs2-Casein	6	2.3 -11.6	2.8 - 3.4
β-Casein	15.6-39.6ꝏ	0 - 29.6	8.6 - 9.3
Κ-Casein	3.2-12.23ꝏ	2.8 - 13.4	2.3 - 3.3
Major whey proteins			
β-Lactoglobulin	6.5-13.5ꝏ	1.5 - 5.0	3.2 - 3.3
α-Lactalbumin	1-1.9	0.7 - 2.3	1.2 - 1.3

Nutrient Content of Different Species (adapted from Park 2006, 2007)

Constituents (100g milk)	Sheep	Goat	Cow
Calcium (mg)	193	134	122
Phosphorus (mg)	158	121	119
Magnesium (mg)	18	16	12
Potassium (mg)	136	181	152
Sodium (mg)	44	41	58
Chlorine (mg)	160	150	100
Iron (mg)	0.08	0.07	0.08
Copper (mg)	0.04	0.05	0.06
Manganese (mg)	0.007	0.32	0.02
Zinc (mg)	0.57	0.56	0.53
Iodine (mg	0.02	0.022	0.021
Selenium (µg)	1	1.33	0.96
Vitamin A (IU)	146	185	126
Vitamin D (IU)	7.2	2.3	2
Thiamin (mg)	0.08	0.068	0.045
Riboflavin (mg)	0.376	0.21	0.16
Niacin (mg)	0.416	0.27	0.08
Pantothenic acid (mg)	0.408	0.31	0.32
Vitamin B6 (mg)	0.08	0.046	0.042
Folic acid (µg)	5	1	5
Biotin (µg)	0.93	1.5	2
Vitamin B12 (µg)	0.712	0.065	0.357
Vitamin C (mg)	4.16	1.29	0.94

Milk Composition Comparison (adapted from park 2006, 2007)

	Sheep[a]	Goat	Cow
Fat (%)	7.9	3.8	3.6
Solids-not-fat (%)	12	8.9	9
Lactose (%)	4.9	4.1	4.7
Protein (%)	6.2	3.4	3.2
Casein (%)	4.2	2.4	2.6
Albumin, globulin (%)	1	0.6	0.6
Non-protein N (%)	0.8	0.4	0.2
Ash (%)	0.9	0.8	0.7
Calories/100 mL	105	70	69

The fatty acid profile of sheep's milk is quite similar to that of goats' milk, and the content of saturated fatty acids is comparable to that of cows' and goats' milk (Verduci et al. 2019)

Attachment C

Data on nucleotide content of goat milk-based formulas to support a GUL or higher maximum for Guanosine 5'monophosphate

The level of guanosine 5'-monophosphate in goat milk-based infant formulas exceeds the current maximum set for this nucleotide of 0.12mg/100kJ.

Table: Nucleotide, polyamine and sialic acid concentrations in whole goat milk (WGM), and young child formula (HMF) and infant formula (LMF) based on goat milk

Component	WGM	HMF	LMF
Nucleotides (mg 100 mL^{-1})			
AMP	0.81 ± 0.20 *(19)*	0.36 ± 0.03 *(12)*	0.31 ± 0.08 *(17)*
CMP	0.89 ± 0.07 *(21)*	0.71 ± 0.05 *(24)*	0.37 ± 0.05 *(21)*
IMP	<LOD	<LOD	<LOD
GMP	1.92 ± 0.13 *(46)*	1.19 ± 0.07 *(40)*	0.85 ± 0.09 *(47)*
UMP	0.58 ± 0.07 *(14)*	0.72 ± 0.05 *(24)*	0.28 ± 0.05 *(15)*
Total	4.22 ± 0.34	2.99 ± 0.13	1.82 ± 0.13

Source: Tolenaars et al, 2021.

Assuming that infant formula has an energy content of 65kcal/100mL (270kJ/100mL) the mean level of GMP is 0.31mg/100kJ with levels as high as 0.4mg/100kJ possible.

INC therefore recommends that FSANZ amends the maximum for GMP to a GUL or increases the maximum 0.40mg/100kJ (1.7mg/100kcal) to accommodates the levels of this free mono-phosphate nucleotide found naturally in goat milk-based formulas. This increased maximum is in alignment with the upper end of average levels found in human milk of 0.2-1.7 mg/100kcal (EFSA, 2014). This converts to 0.05-0.41mg/100kJ.