SECOND CALL FOR SUBMISSIONS – PROPOSAL P1028 INFANT FORMULA

Submission from the Australia New Zealand Infant Nutrition Council

AS AT 6 JULY 2023

7 July 2023

Executive Summary

1. INC welcomes the opportunity to consider the issues and views proposed in this second Call for Submission – Proposal P1028 Infant Formula (the **CFS2**), 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. INC appreciates that this review covering infant formula products as currently covered by Standard 2.9.1 in the Australia New Zealand Food Standards Code (the **Food Standards Code**) has been formally underway for a decade and was preceded by 5 year's development of the policy guidance from the then Australia New Zealand Food Regulation Ministerial Council. We are pleased to see it nearing completion so that infants in Australia and New Zealand can better benefit from developments overseas that have until now passed us by.

5. Overall, INC is generally supportive of the proposed amendments. Nonetheless, we identify a number of amendments that will ensure the efficient operation of Standard 2.9.1 and these are summarised below and covered in more detail in the Comments section. Of particular concern are:

    - restricted sale of low-risk special medical purpose products for infants (**SMPPi**)
    - amendments to some food additives and nutrients
    - maintaining the current permission on L(+) lactic acid producing microorganisms (**LAM**)
    - just five elements of the proposed mandatory format for the nutrition information statement (**NIS**)
    - the explicit prohibition on numbers and words permitted or prescribed on the front of pack from appearing elsewhere on the label
    - the labelling restrictions around the use of provenance statements such as "made with New Zealand milk" or "made with Australian milk".

6. On the framework, INC supports the decision not to proceed with the inclusion of supplementary and modular products within the review of infant formula regulations. In relation to Category One, INC supports that infant formula and follow-on formula can contain partially hydrolysed protein from a compositional perspective and should carry representations about partially hydrolysed for both infant formula and follow-on formula. There is no reason for the distinction between infant formula and follow-on formula.

7. On Category Two, INC is supportive of restricted sale of high risk SMPPi. Such products, almost all exclusively imported, are already of limited availability through hospitals or pharmacy on prescription.

8. Category Two also includes low-risk products for special dietary use in the current Standard 2.9.1 for gastrointestinal conditions and feeding problems (as identified in CFS2 Table 2.3). INC recommends these low -risk SMPPi be exempt from the restriction

of sale. These are infant formula products represented as being specially formulated for the dietary management of the gastrointestinal conditions, gastroesophageal reflux/regurgitation, colic, constipation and lactose intolerance.

9. INC commissioned IQVIA to research the impact of restricted sale of low -risk SMPPi. That research confirmed that a general restriction on the sale of SMPPi will have a negative impact on two major areas:
   - access and availability limited by geography, supply chain logistics and reduced opening hours, and
   - higher cost and reduced choice as a result of reduced competition and increased travelling distance.

10. Additionally, INC believes there would be negative impacts for some health outcomes for infants who require these products and for the parents and caregivers who support the infant.

11. The restriction on sale of low risk SMPPi has the potential to be inequitable and unsafe for those in need, particularly due to limited access in rural and remote communities. IQVIA research demonstrates the impact right across Australia and New Zealand but particularly in rural/remote areas such as NT, Queensland and New Zealand's South Island.

12. INC is generally supportive of the definitions proposed for infant formula products and related terms, SMPPi and protein substitute and the removal of the definitions of 'soybased formula', 'preterm' and 'medium chain triglycerides'.

13. INC agrees with the changes proposed for novel foods. However, the amendment will not address the current ambiguity in the Food Standards Code for the approach to new ingredients being bought to market for use in infant formula products. The classification of nutritive substances (and novel foods) appears open to interpretation. It is also misaligned with other regulatory jurisdictions such as the EU where focus is on safety of an ingredient, and as such INC supports reactivation of P1024 to provide industry and stakeholders regulatory clarity.

14. INC agrees with the proposal to maintain the current permission on L(+) lactic acid producing microorganisms (LAM) since this reflects there are no safety concerns, the long history of use and ubiquitous in products currently on market and alignment with Codex. We also agree that removal of permission would cause large reformulation cost to industry (for minimal benefit), loss of products from the market (possibly permanently) and potentially a large influx of applications to FSANZ seeking permission to add LAM to infant formula products.

15. On food additives and processing aids, INC supports that no changes to the Code related to processing aids are required and is generally supportive of food additives except for amendments, exceptions or additions relating to the following:
   - Sodium Ascorbate (INS 301)
   - Tocopherols, dl-alpha (INS 307c; E 307)
   - Calcium Citrates (INS 333)
   - Phosphoric acid, sodium phosphates and potassium phosphates (INS 338, 339 and 340)
   - Calcium phosphates (INS 341)
   - Locust bean (carob bean) gum (INS 410)
   - Gum Arabic (INS 414)
   - Xanthan gum (INS 415)
   - Diacyltartaric and fatty acid esters of glycerol (INS 472e)

16. On contaminants, INC does not support reducing the aluminium maximum limit (ML) for soy because the reduced ML may not always be met due to varying natural levels in soy ingredients. The current level is safe as it is in line with the JECFA recommendation (2mg/kg bw/week).

17. In relation to nutrient composition, INC's position on amino acids is to align with Codex STAN 72-1981. In addition to the current proposal, there must be the ability to combine the aromatic amino acids (AAA – phenylalanine and tyrosine), and the sulphur amino acids (SAA – methionine and cysteine), to achieve the minimum amino acid requirements. Removing the ability to sum the AAA and SAA will lead to unnecessary addition of L-amino acids and will prevent harmonisation for some infant formula products. The amino acids cysteine, histidine, methionine and tryptophan values should be adjusted.

18. In relation to other compositional proposals INC recommends amendments to docosahexaenoic acid (DHA)**, l**ong chain fatty acids, the follow-on formula vitamin D maximum, the wording for the sucrose/fructose prohibition and medium chain triglycerides (**MCTs**) to clarify that naturally occurring MCTs in vegetable oils are not intended to be included within the scope of the prohibition. INC supports the use of guidance upper limits (**GULs**) and supports a higher GUL for L-carnitine to better reflect naturally occurring levels in dairy ingredients.

19. For the composition of SMPPi, many highly specialised products are imported from Europe and the USA and a continuous supply is critical to infants who require these products for the dietary management of their condition. INC supports FSANZ's proposal to allow the composition of SMPPi products to deviate from the specific compositional requirements for infant formula products, where required to address the product's special medical purpose.

20. With regard to labelling, INC reiterates its position to recommend use of the term 'around' to align with both New Zealand and Australian dietary guidelines for infants and toddlers. This is important for continuing caregiver familiarity with the placement of this information.

21. INC supports many aspects of the proposed mandatory format for the NIS, but does not support the following proposed aspects:
    - Units for Vitamin E and A
    - Folate to be in NIS. Recommend folic acid instead.
    - Inability to voluntarily use unit quantities in addition to per 100mL ready to consume, consistent with Codex and EU to allow for harmonisation with markets that have adopted mandatory Codex provisions. This is especially important for Pacific Island nations and would be inequitable to those markets for Australia and New Zealand to do otherwise
    - Prohibition on use of common terms, acronyms/abbreviations and additional information. There is no evidence that acronyms should not be used on labels and we especially support the acronyms for docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), linoleic acid (LA), alpha linoleic acid (ALA) and arachidonic acid (ARA)
    - An explicit list, prescription of wording and format of the voluntary declaration of macronutrient sub-groups.

22. INC supports the prescribed words 'lactose free' and 'low lactose' to be included with the name of the food on the front of pack but does not support the explicit prohibition of the words elsewhere on the label as they are prescribed terms and not nutrition content

or health claims. We are also seeking to have the term “lactose intolerance” prescribed as well.

23. INC supports the provision for infant formula that is represented as partially hydrolysed, requiring the words ‘partially hydrolysed’ immediately adjacent to the statement of protein source and permitting the words ‘partially hydrolysed’ in the statement of ingredients. However, INC does not support the explicit prohibition of the words elsewhere on the label (as they are prescribed terms) nor the prohibition of the words on follow-on formula. Similarly, INC supports the provision of the use of stage numbering to enable caregivers to differentiate between infant formula and follow on formula but does not agree that this information should only appear on front of pack.

24. INC supports the prohibition of representation made in infant formula or follow-on formula about information relating to another product (a name, number, picture, image, word or words) but opposes the proposed further restriction on ingredient statements.

25. INC is generally supportive of the labelling proposals for SMPPi except in relation to labelling of nutrient modification of vitamins and minerals, prohibited representations, minimum size of type and restrictions to the nutrition information statement. In all cases, these would have the potential to be trade barriers due to misalignment with international regulation and the unintended consequence of prohibiting, or delaying, import of specialty infant formula products for infants.

26. In relation to costs and benefits INC agrees with the statement of the problem but does not consider that all major impacts of the proposed changes to the Standard have been identified. INC does not agree with assessments that suggest lower costs nor that restricted sales of specialised formula may cause some inconvenience. This severely understates the impact. IQVIA analysis of the SMPPi market suggests higher costs and fewer choices as a result of restricted sales.

27. INC challenges the suggestion that all proposed changes provide the benefit of comparability between products. INC strongly disputes the statement that products such as for colic or anti-reflux are not that different compositionally to infant formula. FSANZ states that based on data provided, specialised formulas such as for gastrointestinal conditions already have established sale in some pharmacies. This is true but it fails to acknowledge that two/thirds of these products in Australia and New Zealand are sold through supermarkets. To go on and state that the restriction on sale will not impact health outcomes and may improve health outcomes is simply not true.

28. In relation to industry impacts, trade costs require further consideration especially in relation to seeking exemptions in New Zealand and for both Australia and New Zealand for specific labelling prohibitions related to provenance of some ingredients. If the prohibitions do not proceed for provenance related labelling statements, INC agrees, that industry will generally benefit from greater alignment with international infant formula products. The estimates for the quantifiable costs to industry are considered to be good estimations.

29. On the cost of restricting sale, FSANZ assumes that sales lost by supermarkets (where consumers do not substitute to general infant formula products) will be gained by pharmacies. This is incorrect. There will be a reduction of some size (non-quantifiable) through products being withdrawn as not commercially viable through restricted channels and products not being ranged by the limited shelf space in and footprint of pharmacies. As well, pharmacy products currently cost on average 6% more in Australia and 3% more in New Zealand than the same formula product as is sold in the grocery channel, this would be expected to increase due to the decrease in competition.

30. FSANZ states that “The standards are not expected to result in a change to market access nor significantly reduce market viability for infant and follow-on formula products. FSANZ expects that very few products would be unable to adapt to the new standards and that competition between manufacturers would not be significantly affected.” (p33 SD4). The issue for market access is not about adapting to the local market but rather being able to import inputs that are made for global destinations and remaining competitive in global markets.

31. Of particular concern are the labelling restrictions around the use of provenance statements such as “made with New Zealand milk” or “made with Australian milk”. It is costly and difficult to seek exemptions for export labelling from domestic standards and an overreach of the labelling to prohibit statements that are not nutrition or health claims. Such requirements also limit product placement into the domestic market should that be necessary in the future (such as in a future pandemic situation). The restrictions also impact the ability of domestic products to compete in the global marketplace via cross-border e-commerce channels.

32. INC believes the costs could be higher in the short run (5 years) but agrees benefits in the long run (10 years) could be marginally higher than costs. The key uncertainties are the restricted sales impact on SMPPi products currently sold in the grocery channel moving into pharmacies and the market access and export trade impacts of prohibiting provenance related ingredient statements. If these proceed, it is unlikely benefits will outweigh costs.

33. INC wishes to highlight that during the transition period, communication of changes to healthcare professionals and caregivers is paramount. Any changes to product can cause significant anxiety. Due to INC members adhering to the MAIF Agreement and the INC Code of Practice for the Marketing of Infant Formula (**INC CoP**) in New Zealand there are restrictions on communication regarding changes to infant formula products. The risk for industry is that consumers will believe that individual businesses have chosen to make wholesale changes when that is not the case. FSANZ and jurisdictions need to be supporting the changes over the transition and to provide clear communication of changes to infant formula products in order to reduce the anxiety of caregivers over this period. Industry could then point to these when consumers contact them expressing concerns.

34. INC continues to recommend a transition period of 5 years plus 2 years stock-in-trade. This greater period will reduce cost of change and smooth the impact for consumers.

Introduction

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

36. 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.

37. 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.

38. INC remains of the view 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 minimum necessary levels of prescription, 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, and
    - cost effectiveness to minimise the potential burden on industry and enforcement agencies, and minimise unnecessary cost impact on consumers.

39. INC recommends adherence to the principles of minimum effective regulation.

40. In responding to CFS2, we have located questions with the issues covered in the order they appear in the CFS2 document. We have added a separate attachment that covers the drafting reflecting the issues noted in the body of the submission with drafting and other less significant recommended amendments.

Comments and Responses to questions

1 Introduction

41. INC appreciates that this review has been formally underway for a decade and was preceded by 5 year's development of the policy guidance from the then Australia New Zealand Food Regulation Ministerial Council. We are pleased to see it nearing completion so that infants in Australia and New Zealand can better benefit from developments overseas that have until now passed us by.

2 Regulatory framework

42. FSANZ has proposed a two-tiered framework for the differentiation of products for healthy infants versus products for infants with special medical needs:

    a) Category one comprises infant formula, follow-on formula and some or low risk products
    b) Category two is for SMPPi covering any infant formula specifically formulated for the dietary management of a medically diagnosed disease, disorder or condition.

43. The low-risk products proposed for Category one, are products containing partially hydrolysed protein and low lactose or lactose-free products.

44. CFS2 does not propose to proceed with the inclusion of supplementary and modular products within the review of infant formula regulations since to do so would have expanded the scope of Proposal P1028. INC agrees with this decision.

Category one
Composition: partially versus extensively hydrolysed protein

45. INC supports that infant formula and follow-on formula can contain partially hydrolysed protein from a compositional perspective and should carry representations about partially hydrolysed for both infant formula and follow-on formula. There is no reason for the distinction between infant formula and follow-on formula. Extensively hydrolysed protein is not generally permitted in any infant formula product but can be added to SMPPi where required to address a medical condition, disease or disorder.

Composition: low lactose or lactose free

46. INC believes there is an error in the description and definition of lactose intolerance in CFS2. The definition provided by FSANZ in CFS2 and again in SD3 of CFS2, describes an allergy to cow's milk proteins
    - it is very important that lactose intolerance is not confused for an allergy to the proteins found in cow's milk as currently expressed in CFS2.

47. 'Lactose intolerance is defined as a clinical syndrome that presents as 1 or more of the following: abdominal pain, diarrhea, nausea, flatulence, and/or bloating after the ingestion of lactose or lactose-containing food substances' (Heyman 2006).

48. Lactose is the main carbohydrate source in all mammalian milks including human breast milk. Lactose intolerance is the result of a deficiency or absence of the enzyme lactase,

which then leads to lactose malabsorption, the gastrointestinal symptoms of which are the clinical condition of 'Lactose Intolerance' (Heyman 2006, Fassio 2018).

49. There are 4 recognised types of Lactose deficiency (Heyman 2006, Fassio 2018):

    1) Primary lactase deficiency; Most common form of lactose malabsorption that develops in later childhood
    2) Congenital lactase deficiency: Babies are born with the absence of lactase enzyme and require a lactose free diet from birth;
    3) Developmental deficiency (due to prematurity), these babies require a lactase free or reduced diet for a period of time until their lactase activity increases;
    4) Secondary Lactase deficiency: This is the loss of Lactase activity due to injury or illness affecting the intestinal tract i.e. Gastroenteritis. This is more common in infancy.

50. The dietary management for lactose intolerance is the removal of lactose from the diet. This includes the recommendations for secondary lactose deficiency in infants as a result of illness. In Lo Vecchio et al 2016 a consensus report on the management of infant diarrhoea concludes that for the management of infants with acute diarrhoea 'lactose should always be withdrawn'.

51. INC notes that the compositional requirements for a formula to be labelled 'Lactose Free' requires there to be no detectable lactose. INC is unaware of any powdered, dairy-based infant formula products labelled as lactose-free in the market. At present, powdered dairy-based infant formula products cannot be manufactured to meet the current requirements to be labelled as lactose free. Instead, products with extremely low lactose content (range from 0.0034 to <0.007g/100mL) would be required to be labelled as low lactose under the draft standard.

52. INC considers 3 outcomes that may eventuate based on the current drafting:

    1) Outcome 1: The currently labelled 'Lactose Intolerance' products will be amended to be represented as infant formula with labels updated to remove 'lactose intolerance' and replaced with a statement on front of pack – "Low lactose infant formula"[1]
        a) *Misleading consumers*: INC does not believe this will be helpful to consumers and may in fact mislead them about the true level of lactose (range from 0.0034 to <0.007g/100mL) in the product. The current recommendation for the dietary management of lactose intolerance in infants is the removal of lactose from the diet. With this in mind, INC believes that the labelling of these products as 'Low Lactose' will create considerable confusion for carers.
        b) *Confusing consumers*: If healthcare professionals recommend to a carer that they source a 'lactose free' infant formula but only 'low lactose' infant formulas are available, carers may be at a loss about what formulas are available to meet this dietary need. Consumers would not be provided adequate information on pack to make an informed choice. They could not identify if the product is suitable for a baby with lactose intolerance. Low lactose products may not be suitable for infants who need to avoid lactose, as these products could contain up to 0.3g lactose/100mL.

    2) Outcome 2:The only products available that could be labelled 'lactose free' are soy-based infant formula

[1] Clause 2.9.1—14(2) states that if infant formula is represented as low lactose, it must contain no more than 0.3g lactose/100mL of the formula.

a) INC considers these products could be available for general sale, with no restrictions (if presented as general infant formula). It may encourage parents to purchase these products above dairy--based infant formula (devoid of lactose) due to greater availability and clearer labelling on pack. There are no safety concerns, however it unnecessarily limits consumer choice and the provision of adequate information.

3) Outcome 3: The existing products in the market labelled "for babies with Lactose Intolerance" could be represented as SMPPi as per FSANZ's previous clarification in SD3 if they comply with Division 4 of the draft Standard 2.9.1 including labelling restrictions and restrictions on sale, as:
   a) they are specially formulated for the dietary management of lactose intolerance as diagnosed by a healthcare professional. Infants suffering from lactose intolerance have an impaired ability to digest lactose, leading to clinical symptoms; and
   b) they are the sole source of nutrition for infants who need to avoid lactose, where in most cases, general infant formula contains added lactose; and
   c) lactose intolerance is a condition that can be measured by clinical tests (e.g. hydrogen breath test). Avoidance of lactose in the diet is typically recommended for lactose intolerance; and
   d) the products indicated for lactose intolerance are therefore not suitable for general use. Avoidance of lactose in healthy, term infants is not recommended. Lactose is the main source of carbohydrate in human milk, and for this reason, lactose is added to infant formula to provide a similar source of carbohydrate for formula-fed infants.

53. INC supports FSANZ's position that 'low-risk' products that are either low-lactose or lactose free be widely available with no restrictions on sale.

54. INC therefore strongly suggests that dairy-based infant formula with modified lactose content have either extended labelling provisions (for babies with Lactose Intolerance) or the product represented as SMPPI be exempt from the restriction of sale.

Category two: SMPPi

55. SMPPi products include any infant formulas specifically formulated for the dietary management of a medically diagnosed disease disorder or condition. These products are generally intended for a medical purpose and not for use by healthy infants. These are almost all exclusively imported and INC agrees with their categorisation. They currently have limited availability, often only through hospitals or on prescription, and therefore already have restricted accessibility. They are very costly and often available only with subsidisation and on prescription.

56. The statement that infant formula would not be permitted to reference conditions such as anti-reflux, colic, or lactose intolerance because they would constitute a prohibited health claim is only true if the terms are not prescribed requirements as they are now (e.g. Infant formula products for special dietary use clause 2.9.1—14(2)(d)).

57. INC has consistently and repeatedly pointed this out to FSANZ, that if terms are prescribed requirements, then they are not claims.

2.3.6 Restriction of sale

58. Category two is proposed to be restricted for sale from or by a medical practitioner or dietitian, a medical practice, pharmacy or responsible institution or a majority seller of SMPPi.

59. INC is supportive of restricted sale of high-risk products.

60. Not all SMPPi are high risk. The products for special dietary use in the current Food Standards Code for gastrointestinal conditions and feeding problems (as identified in CFS2 Table 2.3) are low risk. Since only pharmacies are proposed to sell SMPPi to the general public, this restriction is limited by availability within pharmacies, geography and time which in turn limits access, increases cost and potentially increases risks to infants.

61. As we stated in relation to restriction on sale in response to CFS1, a general restriction on the sale of SMPPi will have an impact on three major areas:
    - a negative effect on some health outcomes for infants who require these products and the parents and caregivers who support the infant
    - less accessibility and availability of these products for parents and caregivers, and
    - supply chain logistics.

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

62. The effects include caregivers 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 result in caregivers feeding their babies alternatives that may not be suitable and could potentially be harmful.

Less accessibility and availability of these products for parents and carers

63. 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).

64. With occurrence at the levels stated above, products for these conditions require greater access than can't 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 due to their limited opening hours and absence of home delivery. This is particularly apparent in rural communities. According to the pharmacy guild of Australia website (June 2023)[2] access may further be restricted due to projected closures of up to 600 community pharmacies (mostly regional) as a direct result from changes to current medicine dispensing.

Supply chain logistics

65. 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.

[2] https://www.psa.org.au/australia-cannot-afford-cuts-to-pharmacy-report/
https://www.guild.org.au/__data/assets/pdf_file/0011/132410/ergas-review.pdf

66. 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.

67. At a minimum, INC recommends SMPPi products that are used for gastrointestinal conditions and feeding problems (as identified in CFS2 Table 2.3) be exempt from the restriction of sale. These are infant formula products represented as being specially formulated for the dietary management of the gastrointestinal conditionsgastroesophageal reflux/regurgitation, colic, constipation and lactose intolerance. INC proposes adding a paragraph in Clause 2.9.1—31 'Restriction on the sale of special medical purpose products for infants', to provide an exemption from the prohibition covered in clauses 2.9.1--31(1) and (2) which would read:

> "(3) Paragraphs (1) and (2) do not apply to infant formula products represented as being specially formulated for the dietary management of the gastrointestinal conditions gastroesophageal reflux/regurgitation, colic, constipation and lactose intolerance."

68. Where the restriction on sale does not apply, further labelling and/or compositional requirements could be considered.

3 Definitions

3.1Definitions for infant formula products and related terms

69. INC is generally supportive of the definitions proposed.

3.2 Definition for SMPPi

70. INC is generally supportive of the definition of SMPPi although we consider it could be presented more simply and using plain English as is required by current drafting conventions.

3.3 Definition for protein substitute

71. INC supports the FSANZ proposal to remove the definition of protein substitute for the reasons set out in CFS1.

3.4 Other Definitions

72. INC supports the FSANZ proposal to remove the definitions of 'soy-based formula', 'preterm' and 'medium chain triglycerides' for the reasons set out in CFS1.

4 Novel foods and nutritive substances

4.1 Pre-market assessment requirements

73. FSANZ proposes to amend Standard 1.5.1—3 so that it states that novel foods must not be added to infant formula products unless an express permission is stated in the table to S25—2. This is to provide greater regulatory certainty around the permissions for novel foods in infant formula products.

74. INC agrees that this change provides greater regulatory certainty on permissions for use in infant formula products where a novel food has already been approved and gazetted in S25.

75. This amendment will not address the current ambiguity in the Food Standards Code for the approach to new ingredients being brought to market for use in infant formula products. INC notes that CFS2 states:

> "*FSANZ is unaware of additional changes that would strengthen or clarify the existing requirements for nutritive substances added to infant formula products. FSANZ also considers that the increase in recent applications requesting to add nutritive substances to infant formula products, such as A1253 - Bovine lactoferrin in infant formula products (FSANZ 2022j),* ***demonstrates that the current regulation is clear and functioning effectively***."

76. INC does not believe that an increase in the number of applications demonstrates that the regulation is clear and functioning well. As indicated in our response to A1253, the classification of nutritive substances (and novel foods) appears open to interpretation, making it difficult to interpret and enforce. It is also misaligned with other regulatory jurisdictions such as the EU where focus is on safety of an ingredient, and as such INC supports reactivation of P1024 to provide industry and stakeholders regulatory clarity.

77. It will be important to consider infant formula products in future applications, particularly where the applications are for new sources of existing ingredients permitted for use in infant formula products e.g. docosahexaenoic acid (DHA).

78. INC suggests consideration be given to the labelling of novel food and nutritive substances on infant formula products given the labelling restrictions on the use of certain terms. Applications are very costly, industry requires some understanding of how the novel food or nutritive substance would be presented prior to application to assess the value.

4.2 Schedule 25 permissions

79. FSANZ had initially proposed to make consequential changes to Schedule 25 which would have introduced **new** exclusions for several sources of docosahexaenoic acid in contradiction to previous consultations in 2021 and 2022.

80. INC notes and supports FSANZ's subsequent comment in the living document that clarifies this was an omission and the following permitted sources of DHA will be retained: 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).

S25—2 table item dealing with "Oil derived from marine micro-algae Schizochytrium sp. (American Type Culture Collection (ATCC)) PTA-9695"

81. FSANZ proposes to continue to permit the use of oil derived from marine micro-algae Schizochytrium sp. (American Type Culture Collection (ATCC)) PTA-9695 in infant formula products.

82. INC supports this decision.

S25—2 table item dealing with "Isomalto-oligosaccharide"

83. FSANZ proposes to maintain the current exclusions for use of isomalto-oligosaccharide in infant formula products, foods for infants and formulated supplementary foods for young children.

84. INC supports this decision.

S25—2 table item dealing with "Rapeseed protein isolate"

85. FSANZ proposes to maintain the current exclusions for use of rapeseed protein isolate in infant formula products and foods for infants.

86. INC supports this decision.

4.3 Permission for trehalose in S25

87. FSANZ proposes that the permission for trehalose in Schedule 25 should be retained with the addition of a condition that its use in infant formula products would be restricted to a cryo-preservative purpose (and not as a carbohydrate source).

88. INC appreciates the risk assessment completed after CFS1 and supports the risk management conclusion.

5 L(+) lactic acid producing microorganisms (LAM)

89. FSANZ is proposing to maintain the current permission for the following reasons:
    - *"No safety concerns*
    - *Long history of use and ubiquitous in products currently on market*
    - *Alignment with Codex*
    - *Removal of permission would cause large reformulation cost to industry (for minimal benefit), loss of products from the market (possibly permanently) and potentially a large influx of applications to FSANZ seeking permission to add LAM to infant formula products."*

90. INC agrees with this proposal on the basis that it:
    - reflects a risk-based approach and
    - acknowledges the current level of due diligence applied by infant formula manufacturers in producing safe food while aligning with international regulations.

91. We also agree with FSANZ's reason's for retaining the current permission.

92. INC supports FSANZ's view that novel LAM will require pre-market approval, as they are captured by horizontal standards in the regulation (e.g. Standard 1.2.1 Novel foods and Standard 1.5.2 Foods produced using gene technology etc).

93. Best practice labelling guidance, such as that issued jointly by the Council for Responsible Nutrition and the International Probiotics Association (2019), advises it is important to label the strain and count (CFU) on the labels of products containing microorganisms. INC strongly recommends FSANZ consider this approach.

6 Food Technology for Infant Formula Products

6.1 Food additives

94. FSANZ proposes to make the following amendments to Schedule 8: *Food additive names and code numbers (for statement of ingredients)*; [19] The table to S8—2 (food additive names—alphabetical listing)
    - Insert: Potassium hydroxide 525 Sodium hydroxide 524
    - [20] The table to S8—2 (food additive names—numerical listing)
    - Insert in numerical order: 524 Sodium hydroxide 525 Potassium hydroxide.

95. INC supports these amendments.

96. FSANZ proposes amendments to Schedule S15—5 (food classes 13.1, 13.1.1, 13.1.2 and 13.1.3).

97. INC supports the proposed amendments with the exceptions and additions described below. These are summarised in the following table. A brief commentary on each additive to be amended/added follows the summary Table. More detail on two additives are contained in Attachment A. The amendments we propose reflect industry's current actual usage and are also aligned to either Codex and/or EU regulations.

13.1 Infant formula products

INS	Description	Proposed by INC	Reason
301	Sodium Ascorbate - amend	75 mg/L antioxidant in coating of nutrient preparations containing polyunsaturated fatty acids	Codex
307c	Tocopherol, dl alpha - add	10 mg/L	EU Regs (including SMPPi)
333	Calcium citrates - add	0.1 mg/L total carry-over expressed as calcium	EU Regs (including SMPPi)
338	Phosphoric acid	450 mg/L – also permit for FoF	EU Regs (including SMPPi)
339	Sodium Phosphates	450 mg/L – also permit for FoF	EU Regs (including SMPPi)
340	Potassium Phosphates	450 mg/L – also permit for FoF	EU Regs (including SMPPi)
341	Calcium Phosphates - add	450mg/L	Codex
414	Gum Arabic - add	150 000 mg/kg in the nutrient preparation and 10 mg/kg carry-over in final product	EU Regs (including SMPPi)

98. For SMPPI, a summary table is provided below.

13.1.1 Special medical purpose products for infants

INS	Description	Proposed	Reason
333	Calcium Citrates - amend	GMP	EU Regs (SMPPi)

415	Xanthan Gum	1200 mg/L - amend Only in a powder-based hydrolysed protein, and/or amino acids or peptides	EU Regs (SMPPi)
472e	Diacyltartaric and fatty acid esters of glycerol	2500 mg/L	JECFA/EFSA review

99. **Sodium Ascorbate (INS 301):** In CFS 2 Attachment A Variation to S15—Substances that may be used as food additives, Food Category 13.1 Infant Formula Products, FSANZ proposes:

    INS 301 Sodium Ascorbate 50 mg/L only for follow-on formula products.

100. INC recommends additional permission for this food additive use in nutrient preparations for infant formula and SMPPi to be consistent with EU Regulations, Codex CXG 10-1979 and draft revised Codex CXS 192-1995. The entry in S15—5 Table 13.1 would then read:

    INS 301 Sodium Ascorbate 75mg/L New Note 7 to Table 13.1.
    New Note 7: For use only in coating of nutrient preparations containing polyunsaturated fatty acids

101. INC notes that this was also proposed by FSANZ in CFS2 SD1 Appendix 1 since its technological purpose appears to be most appropriate as an antioxidant food additive and not as a processing aid carrier. INC agrees with this alternate approach and notes FSANZ's comment in the living document that exclusion of sodium ascorbate in the drafting was an omission. Permission for use of this additive in infant formula products will be corrected in the Approval Report.

102. **Tocopherols, dl-alpha (INS 307c; E 307):** In CFS2 SD1, section 3.3.2 notes that FSANZ has stated there is no current permission in the Code for additives tocopherol, d-alpha (INS 307a) and tocopherol, dl-alpha (INS 307c) and that an application would be required to amend the Code.

103. INC requests additional permission for this food additive for use as an antioxidant for infant formula products as it is already permitted in the EU. The entry in S15—5 Table 13.1 would then read:

    INS 307c dl alpha tocopherol 10mg/L.

104. The technological justification for dl-alpha tocopherol is that it is required as an antioxidant in infant formula products, and in nutrient preparations added into infant formula products. Antioxidants prolong the shelf life of food and ingredients by preventing oxidation, such as in oils.

105. Additional information on technological justification, safety, and international alignment is in Attachment A.

106. **Calcium Citrates (INS 333):** In CFS 2 Attachment A Variation to Schedule 15—Substances that may be used as food additives Food Category 13.1.1. Special medical purpose products for infants**,** FSANZ proposes:

    INS 333 Calcium Citrate GMP.

107. INC recommends an additional permission for this food additive use in nutrient preparations for infant formula and follow-on formula to be consistent with EU Regulation 1333/2008 Annex III Part 5 Section B. A total carry-over 0.1 mg/L expressed as calcium and within the limit of the calcium level and calcium/phosphorus ratio as set for the food category.

108. INC also recommends additional permission for all forms of calcium citrates [E333 (i), E333 (ii) & E333(iii)] to be consistent with EU Regulation 231/2012.

109. Standard 1.1.1—15(2) in the Food Standards Code requires that a substance that is *used as a food additive must comply with any relevant specification set out in Schedule 3. Schedule 3—2(1)(d) reflects Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives.

110. Both EU Regulation 1333/2008 Annex II Food Category 13.1.5.1 and Annex III Part 5 Section B reference calcium citrates.

111. **Phosphoric acid, sodium phosphates and potassium phosphates (INS 338, 339 and 340):** In CFS 2 Attachment A Variation to S15—Substances that may be used as food additives, Food Category 13.1 Infant Formula Products, FSANZ proposes:

338	Phosphoric acid	450 mg/L	Not for follow-on formula
339	Sodium phosphates	450 mg/L	Not for follow-on formula
340	Potassium phosphates	450 mg/L	Not for follow-on formula.

112. INC believes this is a drafting error as it is inconsistent with SD1 Section 3.3. INC recommends permission for these food additives in all infant formula products. The entry in S15—5 Table 13.1 would then read:

338	Phosphoric acid	450 mg/L
339	Sodium phosphates	450 mg/L
340	Potassium phosphates	450 mg/L.

113. The technological justification of these additives as an acidity regulator applies equally for when it is used in follow-on formula, not just in infant formula. The restriction from using it in follow-on formula is not appropriate.

114. For sodium and potassium phosphates, INC has additional technological justification for their use as acidity regulators, which are used to change or maintain pH of the formula during production. Phosphates represent a wide range of pH values and can each provide excellent buffering capacity as well as pH modification for stabilization of the formula matrix where necessary. In milk-based formula, the buffering action of phosphates stabilizes the pH thus keeping the calcium micelle intact and preventing curdling/precipitation, in particular during heat treatment. The pH-regulating property and buffering impact of phosphate salts supports ion exchange and the loosening of the protein structure.

115. There are no safety concerns with these substances for follow on formula given they are already permitted for infant formula.

116. Extending the permission to follow-on formula would also align with EU regulations. EU Regulation 1333/2008 permits sodium and potassium phosphates in both infant formula and follow-on formula, the former with an ML of 1000 mg/L expressed as P2O5. This translates to an ML of 450 mg/L. And both within the nutritional composition limits.

117. **Calcium phosphates (INS 341)**: In CFS 2 Attachment A Variation to S15—Substances that may be used as food additives, Food Category 13.1 Infant Formula Products, FSANZ proposes not to provide permission for use of calcium phosphates in infant and follow-on formula. INC recommends permission for this food additive in all infant formula products. The entry in S15—5 Table 13.1 would then read:

    INS 341 Calcium phosphates 450 mg/L.

118. The current Food Standards Code allows for carryover of food additives into infant formula products. Calcium phosphates are permitted at GMP (Schedule 16) and are therefore permitted for use in a range of ingredients used in the manufacture of infant formula products including additives, milk powders and edible oils.

119. The technological justification for calcium phosphates is that they have a number of technological functions in food ingredients including as an acidity regulator, anticaking agent, emulsifying salt and stabiliser.

120. Assessments by other agencies: EFSA completed a re-evaluation of phosphoric acid -phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) as food additives and the safety of proposed extension of use (EFSA, 2019). EFSA noted that the maximum exposure to phosphates was set in regulation 127/2016/EC irrespective of whether phosphorus was delivered from infant or follow-on formula as a nutrient or as a food additive.

121. The re-evaluation Panel concluded that the available data did not give rise to safety concerns in infants below 16 weeks of age consuming formula and food for medical purposes.

122. **Locust bean (carob bean) gum (INS 410)** INC recommends FSANZ considers the outcome of the draft regulation which to our best understanding, will be issued by the EU Commission in 2023. As locust bean (carob bean) gum is used in SMPPi products, levels should be aligned with the EU to prevent the occurrence of a trade barrier.

123. **Gum Arabic (INS 414)**: In CFS 2 Attachment A Variation to S15—Substances that may be used as food additives, Food Category 13.1 Infant Formula Products, FSANZ has not proposed any permissions for Gum Arabic (INS 414).

124. INC seeks an entry in S15—5 Table 13.1 that reads:

    INS 414 Gum Arabic 150 000 mg/kg in the nutrient preparation and 10 mg/kg carry-over in final product.

125. INC notes that this substance is permitted as a processing aid and therefore is already permitted as a carrier for nutrients. However, we seek to extend this permission to allow for other food additive functions in nutrient preparations.

126. This additive is required as a stabiliser in nutrient preparations, which are added to infant formula products. Stabilisers are used to maintain a uniform dispersion of components within the nutrient preparation.

127. EFSA re-evaluated the safety of gum arabic for infants below 16 weeks of age in 2019 and concluded that there was no reason for health concern (EFSA Journal 2019;17(12):5922, 23 pp).

128. EU Regulation 1333/2008 permits gum arabic to be added as an additive in all nutrients for foods for infants and young children, at 150 000 mg/kg in the nutrient preparation and 10 mg/kg carry-over in final product. Therefore, the new entry would be aligned with EU regulations.

129. **Xanthan gum (INS 415)** In CFS 2, Attachment A Variation to Schedule 15—Substances that may be used as food additives Food Category 13.1.1. Special medical purpose products for infants**,** FSANZ proposes:

INS 415 Xanthan Gum	1000 mg/L	Only in a powdered hydrolysed protein and/or amino acid-based product
	1200 mg/L	Only in a product that is: based on amino acids or peptides; and formulated for infants with gastrointestinal tract problems, protein mal-adsorption or inborn errors of metabolism

130. INC supports the permissions for xanthan gum which are aligned with international standards.

131. INC advises that the reported use levels provided by industry to EFSA for its recent review of xanthan gum indicates that there is use in Europe at the highest level permitted in infant formula for special medical purposes (1200mg/L). Also, EFSA concluded “that the use of xanthan gum in formulae for infants below 16 weeks of age up to a concentration of 1,200 mg/L, which results in an exposure of 312 mg/kg bw per day, does not raise concerns.” (EFSA, 2023)

132. INC agrees that it would be preferable to have a single permission at the higher level of permitted use. Manufacturers use only the minimum of a food additive required to achieve the function in the product. An amended condition statement could read:

> “Only in a product based hydrolysed protein, and/or amino acids or peptides”.

133. **Diacyltartaric and fatty acid esters of glycerol (INS 472e):** FSANZ proposes to remove the permission for this additive.

134. INC recommends continued permission for this food additive for use as an emulsifier and listed in “Substances that may be used as food additives” Schedule 15—5, Food Category 13.1.1. Special medical purpose products for infants (SMPPi). The entry in S15—5 Table 13.1.1 would then read:

INS 472e	Diacyltartaric and fatty acid esters of glycerol	2500 mg/L.

135. General safety evaluation information and technological justification is presented in Attachment A.

6.2 Contaminants

136. The contaminant of most concern is the single ML for aluminium of 0.05mg/100mL in infant formula. FSANZ is of the view that, in the absence of any new data or information, the rationale presented in the FSANZ 2016 CP, 2021 CP1 and CFS1 is still valid. FSANZ proposes to retain a single ML of 0.05mg/100mL for aluminium.

137. As a result, INC does not support reducing the aluminium ML for soy-based formula product down from 0.1 mg/100 mL to 0.05 mg/100 mL [1 mg/kg to 0.5 mg/kg]. This is because the reduced ML may not always be met due to varying natural levels in soy ingredients. This could produce an availability issue for infants from 6 months with a cow's milk protein allergy who consume a soy-based infant formula product (in line with Australasian Society of Clinical Immunology and Allergy (ASCIA) guidelines), as well as caregivers wishing to source a plant based infant formula product such as from soy. The current level is safe as it is in line with the JECFA recommendation (2mg/kg bw/week).

138. INC understands commercial-in-confidence data will be provided in this area.

6.3 Processing aids

139. INC supports that no changes to the Code related to processing aids are required.

7 Nutrient Composition for Infant Formula Products (SD2)

140. FSANZ has indicated that there had been unanimous support on the nutrient compositions provided in Table 2 of SD2 and they required no further consideration. It should be noted that Table 2 includes L-Amino acids that did not form part of table 6.3 in CFS1. INC's position on amino acids in CFS1 was to align the minimum amounts with Codex STAN 72-1981.

141. The amino acids cysteine, histidine, methionine and tryptophan are all expressed to two significant figures in Annex I of CXS 72-1981 per 100 kcal. Whilst noting the convention adopted at CCNFSDU of values >5 being rounded to a whole number there is no conversion of amino acid values in the amino acids table in the Codex infant formula standard so there is no cause for adopting this principle in order to match with kJ values within the Codex text. In applying the conversion from kcal to kJ using 4.18 as the conversion factor and applying conventional rounding, the corrected values are 9.1, 9.8, 5.7 and 7.9 respectively. INC recommends adopting these values.

142. **Amino Acids:** In CFS2, it appears that FSANZ has not included the ability to combine for calculation purposes the aromatic amino acids (AAA): phenylalanine and tyrosine, and the sulphur amino acids (SAA – methionine and cysteine), to achieve the minimum amino acid requirements.

143. In CFS2 SD2, FSANZ states that Codex CXS 72-1981 minimums for sulphur-containing amino acids (SAA) such as methionine and cysteine are not expressed as a summed amount because they were derived using a more accurate analytical methodology that quantified individual SAA.

144. INC queries this assessment as CXS 72-1981 3.1.3(a)(3) states:
"For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing."

145. Similarly, EU Commission Delegated Regulation (EU) 2016/127 Annex I states:
"For an equal energy value, infant formula manufactured from cows' milk or goats' milk proteins must contain an available quantity of each indispensable and

conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3)."

146. INC disagrees that introducing minimums for methionine and cysteine allows the removal of summed requirements. Removing the ability to sum the AAA and SAA will lead to unnecessary fortification of L-amino acids and creates issues with harmonising recipes from different jurisdictions for common sale. Manufacturers commonly use summed figures to formulate, while the ratio is used to confirm suitability to the nutritional needs of infants.

147. We also recognise that FSANZ notes in SD2 that for "*calculation purposes cysteine and methionine can be added together, however the minimum requirement for each amino acid will be prescribed separately in Schedule 29*." Despite this, the draft variation does not include the ability to sum since 2.9.1—6(4) states amino acids should be "*at a level no less than the corresponding minimum*". Further, FSANZ fails to comment in SD2 on the ability to sum phenylalanine and tyrosine.

148. There are express clauses that permit addition for SAA and AAA's within Codex and EU requirements. In addition, these regulations state '*at least equal to*' such that manufacturers have flexibility to meet the summed figures without the need to fortify with additional amino acids to meet minimums. Using the FSANZ draft amino acid requirements as an example:
    a) Cysteine is 9mg/100kJ, Methionine is 6mg/100kJ. Sum = 15mg/100kJ.
    b) Naturally occurring amino acids in cows' milk produce a profile whereby cysteine is slightly below the proposed minimum and methionine is slightly above. On balance, using the ability to sum, cows' milk will typically meet the summed requirement without the need to fortify with additional amino acids. The use of the ratio helps ensure there is sufficient methionine to act a precursor to be converted into cysteine. If industry was not able to sum these amino acids, manufacturers would be required to fortify with additional cysteine.

149. The ability to sum and account for the *in vivo* conversion of amino acids helps to support compliance to 2.9.1-6(6) which requires amino acids "*must only be added to infant formula or follow-on formula in an amount necessary to improve protein quality*." While also supporting trade through harmonisation with international regulations.

150. Based on the above, INC propose the below text:
- "2.9.1-6(4) *The L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at a level [~~no less than~~ equal to] the corresponding minimum level specified in the table. For calculation purposes concentrations of 'tyrosine and phenylalanine' and 'methionine and cysteine' may be added together."*

151. **Docosahexaenoic Acid (DHA)**: In CFS 2 Attachment A Variation to S29—4, a GUL of 7mg/100kJ is proposed for DHA. INC supports retaining the voluntary permission for DHA in infant formula products and appreciates the discussion in SD2 Section 4.5.3. Noting the concerns raised, INC recommends instead, a maximum of 12mg/100kJ to align with the EU maximum. This is within the range currently permitted and reflects what is reported in breast milk of 0.06-1.4% (Brenna et al. 2007).

152. Additionally, the declared level of DHA in infant formula currently on the market in Australia and New Zealand exceeds the proposed GUL of 7 mg/100kJ. These safe and suitable products have been on the market for a number of years. They would have to be reformulated or withdrawn from the market. INC members have provided further commercial-in-confidence data on this area.

153. The proposed GUL does provide some flexibility as noted in the discussion by FSANZ, However, in considering formulations for export, INC recommends a higher maximum of 12mg/100kJ to support greater flexibility and alignment with international regulators.

154. **Long Chain Fatty Acids:** In CFS 2 Attachment A Variation to Schedule 29—4, the maximums for long chain omega 6 series fatty acids (C> = 20) and long chain omega 3 series fatty acids (C> = 20) are retained.

155. FSANZ first consulted on these maximums in 2016 and consolidated the preliminary view in SD1 Table 4.4. INC had understood that in subsequent consultations, this position had remained unchanged, noting the discussions on DHA:
    "...if the maximum for all n-3 LC-PUFAs in the Code were replaced by a GUL for DHA (and other relevant ratios)."

156. Hence INC was surprised by the retention of these maximums and requests further explanation/reconsideration. We consider their inclusion as unnecessary regulation.

157. **Follow-on Formula Vitamin D Maximum**: In CFS2, the draft variation to the Code proposes the same maximum Vitamin D for both infant and follow-on formula.

158. INC does not support this approach. The maximum for follow-on formula in the more recent EU regulations and the draft revised Codex Standard for FUF is 0.72 µg/100kJ. The lack of international alignment of the proposed maximum creates a barrier to trade. INC supports the adoption of the draft Codex Follow up Formula for Older Infants and EU maximum for follow-on formula of 0.72 µg /100kJ to allow for recipe harmonisation.

159. As stated in our submission on CFS1, the NHMRC AI for Vitamin D is based on outdated science which is 2-3 decades old (1982 – 1995) and uses data that is not expressly from an Australia and New Zealand population. While we appreciate there is work underway to start a review of current NRVs, we consider the Codex FuF figure to be based on the most recent science available for vitamin D and helps to future proof the Code. This is especially the case when considering more recent dietary reference values have been set in the US, Canada, Europe and China which all set a RDI for 0-12 months of 10µg/day, double the existing Australia New Zealand NHMRC value and the current FSANZ RDI for infants in Schedule 1.

160. FSANZ has previously considered the EFSA updated UL for Vitamin D for infant formula (CP2 2021). EFSA (2018) revised the UL for older infants from 25 µg/day to 35 µg/day. EFSA determined that older infants consuming both follow-on formula containing the maximum amount of vitamin D of 3 µg/100kcal (0.72 µg/100kJ) and fortified foods would not exceed the upper level. Also, the addition of Vitamin D is not permitted in infant foods in Australia and New Zealand and there are limited fortification permissions of foods for the general population. Therefore, it is highly unlikely that the higher maximum would result in older infants exceeding a safe level.

161. Recognising that in Australia and New Zealand 0-6 months and 6-12 months currently have the same NRV (5.0 ug/day) and considering the RDIs for other markets outlined above are also 0-12 months (10 ug/day). We can expect in future that the NRV for

vitamin D to be increased in both the 0-6 and 6-12 months age group. While we seek to future proof for follow on based on the latest scientific data for this age group at Codex, we reflect that FSANZ should also consider a future review on the maximum for infant formula.

162. Australia and New Zealand do not have such supplementation programs, despite the risk of vitamin D deficiency being highlighted: We repeat, the maximum for follow-on formula neds to change to is 0.72 µg/100kJ which would align with the EU and Codex.

163. **Sucrose/Fructose:** FSANZ is proposing to prohibit the presence of added fructose and or/added sucrose in infant and follow-on formula except for formulas manufactured with partially hydrolysed protein.

164. INC notes that the draft variation in clause 2.9.1—5(2) states that *"...infant formula and follow on formula must not contain added fructose and or added sucrose*". This strict prohibition is viewed as a tighter requirement than the guidance provided in Codex.

165. Sugars can be common processing aids as carriers for delivering micronutrients into formula and are not added as a carbohydrate source. In addition, low levels can occur naturally in other ingredients such as fructo-oligosaccharides (FOS).

166. To remove ambiguity in how this clause may be interpreted, INC recommends that the wording be amended to read:

> "... infant formula and follow on formula must not contain added fructose and/or added sucrose <u>as a carbohydrate source</u>".

167. **Medium Chain Triglycerides (MCTs):** FSANZ is proposing to remove the definition of MCTs. While we support this removal, the lack of definition in the Food Standards Code now creates ambiguity for naturally occurring MCTs in vegetable oils as they are not covered by the provision outlined in clause 2.9.1—7(2) as being either a natural constituent in milk or a carrier for a fat-soluble vitamin.

168. We consider the intent of the regulation is not to prohibit naturally occurring MCTs in vegetable oils since these are not 'predominately' MCTs as outlined in the current definition, and any ability to restrict use of vegetable oils containing low levels of natural MCTs (e.g. Coconut oil) will create formulation challenges for industry. These oils are considered safe and suitable for infants with use in infant formula products globally. We ask FSANZ to comment on this in the approval report to clarify that naturally occurring MCTs in vegetable oils are not intended to be included within the scope of clause 2.9.1—7(2).

169. **Guidance Upper Limits:** INC support the use of GULs throughout the composition section as an important mechanism for manufacturers to flexibly manage formulations. FSANZ has included a note to inform on the intent of how GUL's shall be applied. We support the inclusion of the note however, the wording is not exactly the same as Codex which includes the term 'usually' (i.e.'...should <u>usually</u> not be...'). We consider this inclusion provides for more flexibility and our preference would be to retain the word 'usually'.

170. **L-carnitine:** FSANZ proposes to retain the maximum for L-carnitine within Schedule 29 but present as a GUL in infant formula.

171. INC continues to maintain that there should be no maximum or GUL for L-carnitine in infant formula. FSANZ's proposed approach is not aligned with international regulations (EU, CODEX, GB) nor expert scientific opinions (SCF 2003, EFSA 2014, Koletzko 2005), which do not recommend any maximum or GUL for L-carnitine.

172. INC can however support a GUL for L-carnitine if this is increased to acknowledge inherent baseline levels in dairy-based infant formula products. Formula L-carnitine levels are variable due to the natural seasonal variation in dairy ingredients and in particular, that attributed by the whey portion of dairy. Members have previously provided commercial-in-confidence data on the natural variation levels in response to CFS 1. INC would appreciate it if FSANZ revisited this data.

173. INC continues to support the mandatory addition of L-carnitine in infant formula and no maximum being required for L-carnitine in follow-on formula.

Nutrient Composition for SMPPi

174. Products for metabolic, immunological, renal, hepatic and malabsorptive conditions are specifically formulated for these conditions and have composition to reflect this. INC thanks FSANZ for the recognition that the SMPPi category encompasses many highly specialised products that are imported from other countries and that a continuous supply is critical to infants who require these products for the dietary management of their condition. Hence, international harmonisation of standards is critical to prevent a trade barrier and allow these products to reach the sick infant as quickly as possible.

175. INC supports the proposed draft variation to allow the composition of SMPPi products, as described in CFS 2, to deviate from the specific compositional requirements for infant formula products, where required to address the product's special medical purpose. Deviations from the composition requirements would also be permitted where it would otherwise prevent the sale of a product.

176. All food sold in Australia and New Zealand must be, by law, safe and suitable. INC supports FSANZ's approach for SMPPi to be safe, beneficial and effective for the infants for whom they are intended, based on generally accepted scientific data.

177. 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. Parents and healthcare professionals should not be restricted from accessing the most up to-date and efficacious products for their infant's specific condition.

178. INC also notes that in SD1 – Food Technology, FSANZ states that:
"*To ensure there are no supply issues for infants with specific medical conditions FSANZ has aligned the permissions as well as the condition requirements of the EU Regulations with the Code, almost without exception*".

179. There is a wide diversity of SMPPi and rapidly evolving scientific understanding of the dietary management of specific conditions. As such, there is a need to ensure flexibility to import or develop innovative products. Substances permitted internationally that have previously undergone rigorous assessment should not require pre-market assessment from FSANZ.

180. INC supports the drafting under clause 2.9.1—30(a) on application of other standards for SMPPi, including that section 1.1.1—10(6)(b) (foods used as nutritive substances)

and section 1.1.1—10(6)(f) (novel foods) will not apply to SMPPi. This aligns with Standard 2.9.5. Many SMPPi will be regulated under standards for foods for special medical purposes in other markets globally. INC supports provision being made for this flexibility. INC notes the proposed draft variation does not prescribe a permitted form requirement for substances used as a nutritive substance in SMPPi however there is an error in the drafting of Schedule 29—3 which refers to infant formula products.

181. This is a different approach to products for a sole source of nutrition under Standard 2.9.5 Food for Special Medical Purposes. To ensure infant health and safety is put first and foremost, INC understands that FSANZ's intention for not mandating permitted forms, is that if a substance present in an SMPPi deviates from the compositional requirements of Standard 2.9.1, it is permitted due to regulatory permissions internationally and it must be safe and suitable.

182. INC notes the concerns of several jurisdictions in response to CFS1 regarding regulatory controls and expert panels. The regulatory controls in place in the countries of source of SMPPi, for composition, pre-market assessment, evidence base and labelling are excellent for low volume, high risk, specialist products within the SMPPi category, to deliver the life-saving nutritional requirements of infants requiring them. Even if an expert panel was established to assess every SMPPi product imported, it could have a dire public health impact if there was any hold up or delay to imports.

183. FSANZ responded that the FSANZ Act does not permit the Food Standards Code to establish an independent expert panel as it does not come within the list of matters that can be included in a proposed draft variation as per section 16 of the FSANZ Act. This is a matter for the jurisdictions to consider.

8 Labelling for Infant Formula Products (SD3)

184. FSANZ has proposed new safety-related labelling requirements in CFS2, Table 8. The following headings are drawn from that table.

185. **Statement that follow-on formula should not be used for infants aged under 6 months:** FSANZ proposes to maintain the existing requirement, as well as introducing a new requirement for this statement to appear on the front of the package of a product. INC supports the intent of this statement which is aligned to both Australian and New Zealand infant feeding guidelines.

186. INC appreciates FSANZ's clarity in the discussion paper that "*the wording of the age statements would not be prescribed, and manufacturers would retain flexibility (for example, "0 to 6 months", "from birth")*" (SD3, Section 3.4.2). INC supports the new requirement for inclusion of the statement on front of pack as this aligns with current approaches by industry in provision of information to consumers. However, we are concerned that the age-labelling statement for follow-on formula could lead to a strict interpretation for a negative statement rather than encompassing positive statements with the same intent. INC requests the final report to provide clarity that a positive statement is permitted for follow-on formula (e.g. "from 6 months").

187. **Statement about age to offer foods in addition to formula**: INC reiterates its position 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). Although these are guidelines, they are based on the most up-to-date science. This change would also

support the specific policy principle that the regulation of infant formula products should not be inconsistent with national nutrition guidelines.

188. While we understand FSANZ's view that standards are legislative instruments that must be clearly drafted, we also recognise the importance of ensuring caregivers are not provided with contradictory information across different platforms (e.g. labels, dietary advice etc.)

189. INC does not agree with FSANZ's statement that the term "around", "could likely result in uncertainty and consequently, be open to interpretation". There is no evidence that this is the case.

190. **Declaration of nutrition information – mandatory format:** FSANZ has proposed a mandatory format for the nutrition information statement (**NIS**). 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 ready to consume
    - 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 consistent order, names and required units for each nutrient.

191. INC does not support the following proposed elements in the NIS. Each of these is commented on further below:
    a) Units for Vitamin E and A
    b) Folate to be in NIS. Recommend folic acid.
    c) The inability to voluntarily use base unit quantities in addition to per 100mL ready to consume, consistent with Codex and EU
    d) Prohibition on use of common terms, acronyms/abbreviations and additional information.
    e) Labelling of nutritive substances and voluntary inclusion of nutrients in the NIS.

192. **a) Units for Vitamin E and A** – these shown in S29—10 should reflect those provided in Table 7 of CFS2 (Vitamin E mg α-TE and Vitamin A μg RE)

193. **b) Folic acid, not folate, to be in NIS** – FSANZ proposes to declare 'folate' in the NIS. INC do not support this and supports 'Folic acid', not folate to be listed in the NIS. Folic acid is listed in Table 7 of CFS2 and the min and GUL values in S29—6 are also listed as 'folic acid'. The label statement on the NIS will be folic acid (not including naturally occurring folate) and therefore the term folic acid is more correct.

194. We note that FSANZ has stated "caregivers are more likely to be familiar with the term 'folate' than folic acid." No evidence is provided to support this statement. FSANZ has decided to restrict the use of terms that consumers are more familiar with, for example, pregnant women are instructed to take 'folic acid' during pregnancy suggesting this term would be known to most caregivers. Advice on supplementation[3] (e,g. FSANZ and New Zealand Ministry of Health) talks specifically to micrograms of folic acid, not as folate. It is also common in other food products to declare 'folic acid' rather than folate, for

[3] (https://www.foodstandards.gov.au/consumer/generalissues/pregnancy/folic/pages/default.aspx and Folic acid, iodine and vitamin D | Ministry of Health NZ)

example in formulated supplementary foods for young children and in bread fortification. All these have heightened public awareness of folic acid.

195. FSANZ suggests that healthcare professionals contact manufacturers to get a clearer understanding of the nutrients within infant formula products (CFS2 p17). Healthcare professionals are under enough pressure without having to get a manufacturer to translate the information mandated for their product. Again, this does not support providing clear information that does not mislead caregivers or healthcare professionals.

196. **c) Use of voluntary base unit quantities in addition to per 100mL ready to consume, consistent with Codex and EU** – INC does not support prohibition of the use of voluntary unit quantities in addition to per 100mL ready to consume. Codex Standard CXS72-1981 mandates the declaration of per 100g or 100mL [concentrate] as sold, as well as per 100mL as consumed. Excluding expression per 100g on label will mean manufacturers will no longer be able to harmonise labels with markets which have adopted Codex provisions. This could result in a public health issue if existing products were required to be withdrawn from sale in countries with small populations in the South-West Pacific that have adopted Codex labelling and currently share products with Australia and New Zealand.

197. Whilst INC agrees that per 100mL base units of expression should be mandatory, we do not agree that extra columns for other unit quantities would affect caregiver's ability to make product comparisons. Most manufacturers only declare nutrition information using additional unit quantities where necessary, for example, for harmonisation with other markets. This is consistent with FSANZ's observation that most infant formulas and follow-on formulas currently only declare nutrition information using the per 100mL base unit. Furthermore, the prescribed nutrition information panel for general foods requires a both per serving and per 100g/100mL, therefore consumers in Australia and New Zealand are familiar with nutrition information presented with more than one unit quantity.

198. INC recommends the voluntarily permission for base units per 100g or 100mL [concentrate] as sold, to allow for harmonisation with markets who have adopted mandatory Codex provisions. This is similar to the approach that has been taken by some overseas regulators like the US and EU, which mandate one base unit of expression whilst also permitting another.

199. **d) Prohibition on use of common terms, acronyms/abbreviations and additional information** – INC does not support the following restrictions:
    - use of common terms, acronyms/abbreviations and additional information.
    - an explicit list, prescription of wording and format of the voluntary declaration of macronutrient sub-groups

200. There is no evidence of issues with the current flexibility in the use of acronyms within the NIS. Restrictions on the use of common terms (e.g. folic acid) and acronyms (e.g. DHA) 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.

201. Companies currently 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 about and compare products. Therefore, it is counter to the FSANZ Act objective of provision of adequate information. INC supports the ability to declare whey, casein, docosahexaenoic acid and eicosapentaenoic acid voluntarily in the NIS if

present, however, we also recommend the below components and voluntary inclusion of acronyms in addition to the scientific name:

a) docosahexaenoic acid (DHA)
b) eicosapentaenoic acid (EPA)
c) Linoleic acid (LA)
d) Alpha linoleic acid (ALA)
e) Arachidonic acid (ARA)

202. It is also important to provide the notation for vitamins as these are helpful to consumers generally and non-English speaking consumers in particular:

a) Niacin (B3)
b) Pantthenic acid (B5)
c) Riboflavin (B2)
d) Thiamin (B1).

203. There is no evidence that acronyms should not be used on labels. The consumer research commissioned by FSANZ is equally critical of chemical names and acronyms used on labels but makes no determination for one or the other. The FSANZ research does not sufficiently distinguish acronyms from full names for this purpose. For example, "This included claims that stated either the full name or acronym of a nutritive substance (e.g. 'DHA' which stands for docosahexaenoic acid). For some caregivers this was on account of claims being too 'scientific'." (SD3 Att 1, p17) and further, by stating "…explaining the scientific names/acronyms" (Malek et al 2022) did not allow acronyms to be evaluated alone.

204. There is evidence in the body of academic research that favours acronyms over full word strings in reading development (Laszlo et al 2007). In fact, Laszlo reports that this "supports theories of visual word recognition in which familiarity, rather than orthographic regularity, plays a critical role in gating processing." If we are wanting consumers to be comfortable with information presented on a label, then familiarity with terms of long standing such DHA, EPA and ALA have as much validity as SARs, HIV and COVID since they are sufficiently sanctioned by long and frequent use to be accepted. Simple acronyms help consumers to focus on the information they need or are searching for instead of being mired in chemically correct but unhelpful text.

205. To our knowledge, in no other country or region are acronyms prohibited in their entirety for labelling. INC strongly recommends rationality over pedantry in the use of common acronyms for labelling of infant formula products.INC supports the listed components and use of voluntary acronyms in addition to the scientific name within the NIS, specifically docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), linoleic acid (LA), alpha linoleic acid (ALA) arachidonic acid (ARA),

- As listed above, INC members currently declare linoleic acid (LA) and alpha linoleic acid (ALA) on products, we would like to be able to provide consumers with continuity of labelling and therefore request these be permitted to be labelled through addition to the list under 2.9.1—25(2).

206. **e) Labelling of nutritive substances and voluntary inclusion of nutrients in the NIS** – INC would appreciate consideration from FSANZ on how it will treat the labelling of nutritive substances on infant formula products during the assessment of the application. We note that recent approvals have placed unprecedented restrictions on terminology used. FSANZ states that approvals will consider labelling, however the Application Handbook does not currently sufficiently address this. The Handbook's section on information on the proposed food label only states "This includes details of the proposed labelling statements relating to the presence of the nutritive substance in food". Industry

needs clarity prior to submitting an application on the permitted labelling to determine the value it may bring.

207. INC does not support some of the specific elements in the proposed NIS and the explicit list of permitted nutrients to be declared. We support the approach as outlined by Codex which permits components such as LAM to be declared in the NIS voluntarily (CXS 72-1981 9.3(b)). This provides manufacturers with the ability to declare nutrients of interest to consumers (e.g. A2 beta casein) to enable informed choice and align current labelling declarations such that caregivers have continuity as formulations and labels are updated.

Other information requirements

208. **Prohibition for nutrition content and health claims, and therapeutic claims**: FSANZ proposes a new note that explains that existing prohibitions for nutrition content and health claims, and therapeutic claims in Standard 1.2.7, apply to infant formula and follow-on formula.

209. INC supports this proposal noting that the current prohibition on nutrition content and health claims, and therapeutic claims are well understood and followed by industry.

210. Nutrition content claims and health claims are defined in Standard 1.2.7—2 and claims that are therapeutic in nature are defined in Standard 1.2.7—8. These are the only claims that are not permitted on infant formula products.

211. It is important to note that prescribed terms are NOT claims, even if they appear within Standard 1.2.7 (e.g. lactose free). This is aligned internationally, and these are important to ensure caregivers are provided with adequate information to make informed choice.

212. **Requirements for lactose free and low lactose formulas**: FSANZ proposes that the words ‘lactose free’ or ‘low lactose’ be included with the name of the food on the front of the package and an explicit prohibition for the words ‘lactose free’ and ‘low lactose’ elsewhere on the label.

213. INC supports the prescribed words ‘lactose free’ and ‘low lactose’ to be included with the name of the food on the front of pack. However, INC does not support the explicit prohibition of the words elsewhere on the label as they are prescribed terms and not nutrition content or health claims. We are also seeking to have the term “lactose intolerance” prescribed as well for the reasons set out below.

214. In accordance with clause 2.9.1—14, products labelled ‘lactose free’, must have no detectable lactose. Due to the advancements in analytical technology, this is not possible for dairy-based powdered products, where trace levels of lactose (ranging 0.0034 to <0.007g/100mL) can be detected despite these products being suitable for infants who are unable to digest lactose. A non-detectable result is also required under the ACCC and the New Zealand Commerce Commission for ‘free from’ claims to address misleading and deceptive conduct. For these reasons, INC recommends FSANZ provide additional permitted wording of “lactose intolerance”, to capture these dairy-based products designed to remove lactose from the product.

215. **Partially hydrolysed protein**: FSANZ proposes a new provision for infant formula that is represented as partially hydrolysed, requiring the words ‘partially hydrolysed’ immediately adjacent to the statement of protein source; permitting the words ‘partially hydrolysed’ or any word or words having the same or similar effect in the statement of

ingredients; applicable only to infant formula. Representations about partially hydrolysed follow-on formula would not be permitted.

216. INC supports the provision for infant formula that is represented as partially hydrolysed, requiring the words 'partially hydrolysed' immediately adjacent to the statement of protein source and permitting the words 'partially hydrolysed' or any word or words having the same or similar effect in the statement of ingredients. However, INC does not support the explicit prohibition of the words elsewhere on the label as they are prescribed terms and not nutrition content or health claims. Nor does INC support the prohibition of the words on follow-on formula. FSANZ has noted that this approach is consistent with current industry practice for products currently marketed as suitable for 'Colic', 'Anti-reflux' or 'Constipation'. However, some partially hydrolysed formulas currently in market are general infant formulas and follow-on formulas. Older infants' needs are as important as infants in this regard and the words 'partially hydrolysed' should be permitted on follow-on formula.

217. **Stage labelling**: FSANZ proposes new provisions to voluntarily permit the use of the number '1' on infant formula and the number '2' on follow-on formula to identify for consumers that the product is infant formula or follow-on formula, respectively. If used, the number must appear on the front of the package of the product and immediately adjacent to the relevant age statements for infant formula and follow-on formula.

218. INC supports the provision of the use of stage numbering to enable caregivers to differentiate between infant formula and follow on formula. Research has supported the importance of this information to caregivers.

219. INC does not agree that this information should only appear on front of pack. We recommend the ability to also use the relevant stage labelling on other parts of the label including on back of pack. This is important because it helps to provide important information to the consumer on their product choice. Raising awareness for users of the correct product is confirmatory of the appropriateness of their choice.

220. INC recognises that it is currently common practice to repeat the stage number on back of pack in relation to the product name, further informing caregivers on who the product is for. This is supported by FSANZ's research that this is important information alongside the age statements in determining the right product for infants. Some companies may have numbers included within their brand trademarks and some brands have the same product name across both stage 1 and 2 with the stage number being the main differentiator. In this situation, where we are unable to declare the number on the back of pack, we risk misleading consumers on the nature of the product and suitability for their infant. In addition, the numbering front and back is very useful for non-English speaking caregivers and ensures they select the correct product.

221. INC strongly opposes the prohibition on use of stage labelling information elsewhere on the label.

222. **Product differentiation:** FSANZ proposes a new provision requiring that a food represented as infant formula or follow-on formula must not be also represented as another food contained in clause 2.9.1—15 *Representations about food as infant formula or a follow-on formula*.

> "(2) A food represented as infant formula or follow-on formula must not be also represented as another food. Example: A food represented as infant formula must not be also represented as, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children."

223. INC notes the new provision that a food represented as infant formula or follow-on formula must not be also represented as another food. While INC does not believe there has been market failure in Australia or New Zealand, INC supports the clause as written. To ensure product differentiation, INC notes that age information will be mandatory on front of pack and stage labelling will also be expressly permitted to further differentiate between infant and follow-on formula.

224. INC also notes FSANZ's comment that industry will have the flexibility to ensure product differentiation. In addition to the optional stage labelling, companies may consider the use of colours, texts and images to differentiate between products.

225. **Prohibited representations (including proxy advertising):** Existing prohibited representations are retained. FSANZ proposes new provisions that, unless expressly permitted or required by the Code, prohibiting representations made in infant formula or follow-on formula about information relating to another product (a name, number, picture, image, word or words), ingredients, animal or plant sources of protein, the words 'partially hydrolysed' (or any word or similar words in the statement of ingredients), the words 'lactose free' or 'low lactose' and a number used to identify for consumers that the product is infant formula or follow-on formula.

226. INC supports the prohibition of representation made in infant formula or follow-on formula about information relating to another product (a name, number, picture, image, word or words). However, the drafting relating to this prohibition (2.9.1—29(2)) encompasses any reference to "information" in 2.9.1—29(1). Section one does not just prohibit information related to another product, but other information such as ingredients and protein source. Based on the discussion in CFS2 INC does not believe this is FSANZ's intent as reference to "a name, a number, a picture, an image, a word or words" has only been discussed in relation to another product. INC therefore recommends FSANZ specify that 2.9.1—29(2) only relates to 2.9.1—29(1)(c).

227. Numbers, pictures and images are important to assist with easy identification of these infant formula and follow-on formula products. These are used to support other statements made on the label, to enable informed choice, and ensure differentiation between products. This is especially important for caregivers who are not very familiar with the product, have low literacy levels and where English is not their first language.

228. INC opposes the proposed further restriction on ingredient statements that are more accurately described as provenance ingredient statements. The proposed restriction on these statements is not internationally aligned with Codex, EU or the US. Internationally, only nutrition content and health claims are restricted. Due to the proposed prohibition, it appears that provenance statements, such as "Made with New Zealand/Australian milk", would not be permitted on the labels in Australia or New Zealand despite them being permitted internationally.

229. INC does not consider that the justification for this restriction has been sufficiently considered by FSANZ. This restriction does not support adequate description of products to ensure caregivers are not misled and are provided with adequate information. Further, the restriction fails to address the key driver for the proposal which was a perception that some ingredients may be considered implied health and nutrition content claims (e.g. use of fish oil as a proxy for DHA) (2016 consultation paper).

230. INC considers provenance and other ingredient source related statements do not imply nutrition or health benefits to consumers and suggests they may have been inadvertently captured by the general nature of the draft variation. The inability to put "made with New Zealand/Australian milk" will restrict the provision of information to consumers to make

informed choices and have substantial implications for the competitiveness of the Australian and New Zealand infant formula industry. See below further comments in the cost/benefit section.

231. INC understands that an individual ingredient as listed in the ingredient list is not permitted to be repeated elsewhere on pack. INC has sought clarification from FSANZ and understands that this does not preclude a general statement about ingredients, for example “high-quality ingredients” or “sustainably sourced ingredients” or “organic ingredients”. This is not clear from the drafting and could raise interpretation issues between different jurisdictions. We would appreciate comment in the approval report to clarify the intent of this requirement.

232. INC strongly opposes the prohibition of the following terms on back of pack: animal or plant sources of protein, the words ‘partially hydrolysed’ (or any word or words having the same or similar effect), the words ‘lactose free’ or ‘low lactose’ and a number used to identify for consumers that the product is infant formula or follow-on formula. These terms are prescribed wording and therefore not considered claims by INC and neither should they be by FSANZ.

233. Having permission to repeat these prescribed requirements or terms elsewhere on pack will ensure adequate information for consumers. INC understands that the requirement to have these statements front of pack is to clearly communicate the information to consumers and ensure informed choice. Prohibiting the terms elsewhere on pack is counter-intuitive to the intended goal and unhelpful for consumers. We note duplication can be an important driver for consumer awareness as well recognised during the plain English allergen labelling discussion which now requires allergens to be labelled multiple times within the ingredients list and summary statement.

234. INC recommends aligning the prohibitions and restrictions with those internationally. The proposal overreaches into a marketing regime which could have several unintended consequences.

235. In Australia, the MAIF agreement, and in New Zealand, the INC CoP, outline the requirements for ethical marketing practices of infant formula products. INC Members adhere to these and do not advertise or promote infant formula or follow-on formula. We believe these marketing codes are best suited to address the required marketing practices of infant formula products. We note that several jurisdictions made reference to these codes. These are effective in their goals.

236. The proposed restrictions lack sufficient evidence to support such significant changes and misalignment internationally. There is no clear evidence that there is an issue with the status quo.

Labelling Requirements for SMPPi

237. It is critical that the label of an SMPPi includes a description of the properties and/or characteristics that support the dietary management of the disease, disorder or medical condition the product is intended. This information is necessary for healthcare professionals to easily compare products and indicate the products recommended use to parents and carers.

238. INC supports the proposed draft variations for SMPPi as described in CFS2, except where otherwise detailed below. In principle, it generally promotes consistency between domestic and international food standards and allows for flexibility in labelling. INC thanks FSANZ for its position on not having a prescribed name for SMPPi.

239. INC also supports the drafting under clause 2.9.1—30 on application of other standards for SMPPi, which aligns with Standard 2.9.5. Many SMPPi will be regulated under standards for foods for special medical purposes in other markets globally.

240. However, INC has a few critical concerns in the proposed labelling requirements which would have the potential to be trade barriers due to misalignment with international regulation. These may have the unintended consequence of prohibiting, or delaying, import of specialty infant formula products for infants:
    a) Labelling of nutrient modification (vitamins & minerals);
    b) Prohibited representations;
    c) Mandatory minimum size of type for warning statements; and
    d) Restrictions on nutrition information statement.

a) Labelling of nutrient modification

241. FSANZ is proposing to apply mandatory statements and declarations to SMPPi under clause 2.9.1—38 of the draft variation.

242. INC has concerns with clause 2.9.1—38(g)(ii) and does not support this clause. FSANZ has proposed that if the food is represented as being suitable for use as a sole source of nutrition, the label is required to include a statement on the nutrient or nutrients which have been modified if it does not meet the criteria under clause 2.9.1—32.

243. Due to the breadth of products that fall under SMPPi and the misalignment of Standard 2.9.1 with international regulations in a few areas, there is a risk that an imported product's label will not be compliant. Furthermore, in the cost/benefit analysis outlined in SD4, FSANZ states that SMPPi would not be required to be re-labelled. This would not be the case if clause 2.9.1—38(g)(ii) applies unchanged.

244. For products such as pre-term formulas, there will be a significant number of nutrients which vary from the compositional requirements of clause 2.9.1—32. These modifications are due to the requirements of the condition and are underpinned by scientific evidence that supports their usage at certain levels.

245. Another key issue is that the baseline composition for infant formula products under the draft variation for Standard 2.9.1 varies from Codex, EU and US for infant formula products. In addition, in many other markets, SMPPi are regulated as foods for special medical purpose. This inconsistency with international food standards has the potential to create a trade barrier.

246. For a large number of SMPPi, products are not re-labelled prior to entry to Australia and New Zealand; a single product will share a label with a number of different markets globally. If an imported product's label is checked by Australian or New Zealand regulators at the border and found not to comply with clause 2.9.1—38(g)(ii), it could be stopped at the border or not allowed entry. This could lead to a delay in the infant receiving the product and may result in poorer health outcomes for the infant. For some conditions, there is no suitable alternative.

247. To provide an 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. Therefore, iron will not be labelled as a nutritional modification on the label.

248. INC retains its position that if FSANZ believes such information is important for SMPPi, an alternative approach would be for companies to provide this information to healthcare professionals upon request.

b) Prohibited representations

249. FSANZ has listed the prohibited representations applicable to SMPPi in clause 2.9.1—35 of the draft variation. INC notes that this is a reversal of its position of CFS1 where it proposed that prohibited representations would not apply to SMPPi.

250. INC notes there were concerns raised in response to CFS1 that if there was no restriction on the text or pictorials used on an SMPPi, that there was potential for the manufacturer to idealise the use of a product. This concern could be addressed with some restrictions on labelling, which INC is supportive of. However, it is important to note that SMPPi are primarily used or discussed in a healthcare setting. For this reason, there must be allowances for ease of identification of the product, its specific properties and characteristics that make it suitable for a condition, as well as methods of preparation. In their current form, FSANZ's proposed prohibited representations do not promote consistency between domestic and international food standards.

251. Any risk to preventing or delaying import of highly specialised products only puts the infant at risk. There is no viable option to import the majority of these products, other than to share a label with other markets.

252. Any restrictions placed on SMPPi should be aligned with international regulation and should not be more restrictive. Given a large number of SMPPi products are imported from the EU, INC recommends that clause 2.9.1—35 of the draft variation is aligned to the restrictions under Article 8 of Delegated Regulation (EU) 2016/128 on Food for Special Medical Purposes.

253. INC supports restrictions that include prohibitions on any pictures or text which may idealise the use of the product, but it must not prevent an SMPPi from providing information on the properties and characteristics for the condition for which it is suitable. INC also agrees that an SMPPi should also be clearly differentiated from an infant formula or follow-on formula. INC recommends that clauses 2.9.1—35(c) and 35(d) referring to human milk oligosaccharides and human identical milk oligsaccharides are deleted.

254. INC also recommends FSANZ consider the reasoning behind including "(e) information relating to another food". Many infants who use SMPPi are on restricted diets and the label may include information on other products, and/or nutrients which are suitable for their condition. This is to ensure the infant receives adequate nutrition. Not including this information on additional food may be a patient safety risk. INC recommends deleting clause 2.9.1—35(e).

255. 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.

(c) Mandatory size of type for warning statements.

256. INC does not support the mandatory minimum size of type for warning statements required by 2.9.1—37(2). The minimum size of type is not aligned with Articles 13 of Regulation (EU) No 1169/2011 on the provision of food information to consumers which requires a minimum text height of 1.2mm. This could impact access to SMPPi products where it is not viable to have unique labels.

(d) Restrictions on Nutrition Information Statement

257. INC supports the requirement for a nutrition information statement however does not support the current drafting of 2.9.1—41 as it may limit the use of shared labels. The nutrition labelling requirements of other international standards differ considerably from those that would be permitted by 2.9.1—41. Examples of additional labelling permitted by these provisions include:
    - Information on the amounts of essential and non-essential amino acids and/or essential fatty acids
    - Information on osmolality or osmolarity and/or on acid-base balance shall be given when appropriate
    - Information on the components and/or modification of proteins, fats or carbohydrates or other nutrient whereby its presence is appropriate for product's intended medical purpose.

9 Risk Communication

9.2 WTO

258. INC supports the proposed amendments to Standard 2.9.1 being notified to the WTO.

10 FSANZ Act assessment requirements

10.1 Section 59

10.1.1 Consideration of costs and benefits (SD4) and conclusions from cost and benefit analysis in SD4

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SD4 2 What is the problem?

259. FSANZ states in SD4 that, at a high level, the problem with Standard 2.9.1 is that it is regarded as:
    - out-of-date with current scientific knowledge for some issues
    - not harmonised with international and overseas regulations
    - difficult to interpret in some respects.

260. INC agrees with this assessment.

SD4 4 What options are being considered?

261. FSANZ summarises 14 of the most significant amendments as a “multitude of small problems” within the Food Standards Code” relevant to Infant formula products. We do not agree the problems are small but they are numerous. Had they been small, this review would not have taken over 10 years to complete.

SD4 4.2.1 Amend the categorisation of medical infant formula products

SD4 4.2.1.1 Changes for partially hydrolysed formula

262. INC strongly disagrees that statement in 4.2.1.2 (p9 SD4) that states that “for ‘colic’ or ‘anti-reflux’, which are prohibited health claims under the current and proposed standard”. As INC states at the outset of this submission, this is not true if the terms are prescribed requirements as they are now (see clause 2.9.1—14(2)(d)). The lack of appreciation of this fact is untenable and has unnecessarily denigrates industry.

SD4 4.2.4 Removal of automatic carry-over provisions for food additives

263. INC appreciates the proposal by FSANZ to “align as best as possible with relevant international regulations, especially Codex standards and EU Regulations”. To ensure the removal does not impact supply of product, it is important that FSANZ aligns with international regulations for requested additives, as stated above. In addition to this, it is important that FSANZ provides sufficient resource to provide for approvals within the

transition period for unforeseen consequences from the removal of carry-over provisions.

SD4 5 Consideration of costs and benefits and likely net benefit

Question 1: Have all major impacts of the proposed changes to the Standard been identified? Please provide evidence (data, studies or other information) to support the inclusion and magnitude of other impacts

264. The subsequent comments make it clear that not all major impacts of the proposed changes to the Standard been identified.

Table 5-1 *Major potential impacts by social group*

265. Table 5-1 *Major potential; impacts by social group* in summarising potential impacts for Infant formula consumers, General retailers (supermarkets) and Other retail (pharmacies etc) refers to "Long term potentially lower cost formula", "Potential lower cost of goods" and "Increased sales (specialised formula), lower cost of goods" respectively. INC does not agree with these assessments of lower costs. We cover this in the subsequent paragraphs.

266. INC considers that the statement in relation to costs for "infant formula consumers-Restricted sales of specialised formula may cause some inconvenience" to be severely understating the impact. We recommend the cost be characterised as "Restricted sales of specialised formula may cause ~~some~~ inconvenience and negatively impact infant health through restricted availability".

267. IQVIA has identified costs of SMPPi products shifting from grocery to pharmacy channels and estimated the impact on families in Australia and New Zealand.

268. The costs for finished product manufacturers should have added to it "Short term increases to calls to manufacturer hotlines when products change composition, labelling and sales channels".

269. Only the reformulation and relabelling costs have been quantified. INC considers that costs to trade and export of specific changes (restriction on sales and prohibition on provenance ingredient statements) could be estimated and we have identified these in the following sections.

5.2 Consumer impacts

5.2.1 Summary of impacts on consumers

270. Restricting sales channels is characterised as "may impact price and availability". These are certain impacts: in relation to price this would be due to the lack of shelf space for pharmacies to carry the range of infant formula products not subject to prescription but subject to supermarket sale prohibitions [70 products in Australia and 10 in New Zealand] and the consequent loss of competition. There will be impacts on availability due to pharmacy limitations in locations, shelf space to carry the products and hours of operation.

5.2.2 Infant formula consumption

271. INC acknowledges that FSANZ has corrected its statement that a "significant portion of these [purchases through supermarkets and pharmacies] are online" since "[O]nline sales account for half of purchased consumer goods by Australian households, of which FSANZ assumes infant formula products are included" (p19 SD4). While a number of Australian consumers are already doing some food shopping online, less than 5% have switched to ordering most or all of their groceries on the internet.

SD4 5.2.3.3 Improved labelling increasing comparability of infant formula products

272. INC believes that any benefits from improved labelling increasing comparability of infant formula products will be offset by the cost to consumers of removing the ability for the use of common acronyms of long-standing and familiar terms such as ALA, DHA etc. Consumers instead will face an array of complex bio-chemical terms to decipher.

273. CFS2 creates significant labelling restrictions and prohibitions. INC challenges that all proposed changes provide the benefit of comparability between products.

274. INC strongly supports the provision of adequate information to enable consumers to make informed choices. Restrictions of the use on terms that would help consumers better understand the product such as reference to the ingredients does not allow for comparability. The restriction on terms has the potential unintended consequence to stifle innovation due to the lack of ability to differentiate products and state nutrients in a meaningful way to caregivers.

SD4 5.2.3.4 Removing proxy advertising and misleading claims from labels

275. FSANZ states that "The presence of these representations [descriptions as colic or anti-reflux] can therefore influence consumer choice when purchasing formula and these products are typically sold at a higher price point despite not being that different compositionally." (p21 SD4). INC strongly disputes the products are not that different compositionally. Extensive research and development has been applied to these products before they are ever released onto the market. FSANZ's off-handed statement is neither true nor helpful to the issues under discussion.

276. In Australia, there is the MAIF Agreement and in New Zealand the INC Code of Practice (for marketing infant formula) that outline requirements of signatories on the marketing and advertising of infant formula products. INC believes these marketing codes provide the most appropriate method for navigating ethical marketing practices. The Food Standards Code is not a marketing code, INC sees this as an overreach of the Food Standards Code and does not see benefit in additional prohibitions.

SD4 5.2.3.5 Further reducing the presence of chemical contaminants in some products

277. FSANZ has stated that "feedback from industry has confirmed that this will only impact some infant formula products (particularly soy), as most already meet the new standard", which would result in "a risk of an increase in the cost or decrease in the availability of soy milk where industry is unable to source ingredients that meet the proposed standard." INC does not consider that this cost has been sufficiently considered by FSANZ. At the aluminium levels set, there is significant risk that this will result in supply issues or the removal of soy infant formula from the market in Australia and New Zealand. This was not considered in the cost to consumers either.

Question 2: Do you have any information that can be used to quantify the value of any of the health benefits identified in this impact analysis?

278. INC has no information to assist in this area.

SD4 5.2.4 Costs to consumers

279. FSANZ minimises the impact to caregivers of addressing such conditions as colic, regurgitation and constipation by stating (p23 SD4) that 1-5% of cases is dietary or medical intervention indicated. It is not clear how this statistic was derived.

280. Another paper by Vandenplas (Vandenplas et al 2019) reviewed functional gastrointestinal disorders in infancy and its impact on the health of the infant and family. The most common functional gastrointestinal disorders in infancy are regurgitation, infantile colic and functional constipation. In the 2019 Vandenplas review, the authors outline the guidance to healthcare professionals to manage these symptoms in infants. Reassurance and support for the mother/caregiver is paramount, and then dietary intervention for formula-fed infants with colic, constipation or uncomplicated reflux are recommended, prior to any medical intervention. The rationale for nutritional intervention is to avoid inappropriate use of medication where widespread overuse of medication for functional gastrointestinal disorders has been reported.

281. Vandenplas et al (2019) concluded that "*nutritional guidance is essential with some evidence regarding efficacy as it is devoid of the risks of inducing adverse effects*". It is reasonable to expect that continued access to this particular subset of SMPPi products in grocery, that are low-risk, would be a positive impact for infants and caregivers.

282. FSANZ states that based on data provided, specialised formulas such as for gastrointestinal conditions already have established sale in pharmacies. This is true but it fails to acknowledge that 44% of these products in Australia and 76% in New Zealand[4] are sold through supermarkets.

283. FSANZ goes on to state that "This restriction will not have impact on health outcomes and may improve health outcomes". INC strongly disagrees with this statement. These products should be used under medical supervision however accessibility, choice and caregiver panic and confusion at limited access will have a negative impact on health outcomes not just for the infant who will suffer as a result but also the mental health of the caregiver.

284. INC commissioned IQVIA for conduct market research and analysis of the impact of restriction on SMPPi sales for consumers. The key research themes aimed to:
    - identify current availability and consumption trends for SMPPi across Australia and New Zealand;
    - evaluate if there were any locations that could be impeded due to the proposed change;
    - determine if there were any disparities in access between urban and remote areas;
    - examine the prospective impact on distance, travel time and affordability of SMPPi products;
    - determine the extent of the affected population; and
    - understand if there were and public health inequalities as a result of the proposed change.

285. The research focused on SMPPi that were accessible exclusively through retail outlets such as grocery stores and pharmacies.

286. As well, to further understand the number of carers impacted by the restriction of sale, a target population of children under 2 years of age was identified by IQVIA (the lowest age group available). This target encompassed all children in this age group, not limited to those consuming SMPPi products since the latter data was not available. The research highlights the location of these children across Australia and New Zealand and the areas where accessibility of SMPPi products might be impacted. Expanding the distribution of SMPPi beyond the pharmacy outlets currently selling low risk SMPPi could

[4] IQVIA research

potentially present significant challenges for pharmacy retailers due to factors such as low stock turn and limited floor or shelf space. The inability to stock SMPPi product in some pharmacy outlets may cause accessibility issues for carers.

287. A summary of the key findings is as follows noting that some SMPPi products are sold in both grocery and pharmacy in both Australia and New Zealand:

Australia

- Accessibility for consumers purchasing SMPPi would likely be impacted as grocery outlets account for 44% of SMPPi volume sold nationally across grocery and pharmacy. Carers living in Queensland (**QLD**), Tasmania (**TAS**) and Northern Territory/South Australia (**NT/SA**) will likely be most impacted by the proposed restriction of sale, where grocery accounts for 54%, 53% and 51% of total SMPPi volume sales, respectively.
- Removal of the channel necessitates transition of approximately 700K cans of SMPPi into pharmacies.
- Possible challenges in distribution may arise, and the availability of these products for carers could potentially be affected.
- The restriction on the grocery channel may lead to unintended consequences such as fewer hours of store availability, due to the different opening hours of the pharmacy outlets.
- Currently, 80% of SMPPi unit sales are in 807 pharmacy outlets, despite 3,807 outlets registering at least one can of SMPPi sale in the last year.
- Expanding the distribution of SMPPi beyond the current pharmacy outlets could potentially present significant challenges for retailers due to factors such as low stock turn, limited floor or shelf space. Inability to stock SMPPi products in certain pharmacy outlets could result in accessibility issues for carers.
- The impact of the proposed changes will be most significant for carers who rely on SMPPi products to manage infants with functional gastrointestinal disorders such as reflux/regurgitation, colic, constipation, and lactose intolerance. Currently, these products are primarily sold through grocery outlets. In fact, grocery sales account for 63% of volume sales for reflux/regurgitation products, 55% for colic/constipation products, and 61% for sensitivity/intolerance products.
- Of note, the SMPPi products formulated for infants with milk allergy are sold primarily through pharmacy.
  - *IQVIA utilized geo-location modelling to evaluate the proximity of pharmacies to grocery stores and assess the potential impact on carers who purchase these products, if sales restrictions are imposed*.
- It was found that 483 Australian grocery outlets lack a pharmacy within 1.5km driving distance, affecting 398 postcodes with impeded access. For 24 of these grocery outlets, the nearest pharmacy is more than 10km away. This may negatively affect the accessibility of SMPPi products for the families in these areas.
  - *To further understand the number of carers impacted by the restriction of sales, a target population of children under 2 years of age was identified. Please note this target encompasses all children in this age group, not limited to those consuming SMPPi products. For the purposes of the research, it highlights the location of these children across Australia and NZ and the areas where accessibility of SMPPi products might be impacted*.
- In Australia, within the target population of 846,000 individuals, approximately 161,000 (19%) would experience restricted access, requiring their carers to travel a distance greater than 1.5km to reach the nearest pharmacy. Among them, 31%

would need to travel over 3km, 23% over 5km, and 4% over 10km to access the nearest pharmacy.

- NT and QLD have the highest proportion of the affected population, with over 20% of the target population being impacted in each states. Many of these individuals reside in regional or remote areas.
- IQVIA conducted a comparison of SMPPi product cost between grocery stores and pharmacies. The findings revealed that, on average, SMPPi products were priced approximately 6% higher in pharmacies compared to groceries. Consequently, households purchasing these products for an infant's first year could potentially incur an additional cost of $94. If SMPPi products are removed from grocery outlets, this may have a negative impact on the pricing of SMPPi products sold in pharmacies.

<u>New Zealand</u>

- The situation is more pronounced with the majority of SMPPi volume sales (76%) sold through grocery.
- Removal of the channel necessitates transition of approximatel 77K cans of SMPPi into pharmacies.
- Currently, 80% of SMPPi unit sales are in 80 pharmacy outlets, while 346 outlets registered at least one can of SMPPi sale in the last year.
- Availability of these products to carers will likely be negatively impacted where the restriction on the grocery channel in New Zealand may lead to a gap of over 60 hours where access to SMPPi is unavailable, due to the different opening hours of the retail stores.
- A higher proportion of SMPPi products for functional gastrointestinal disorders (reflux/regurgitation, colic, constipation) and lactose intolerance are sold through grocery, greatly impacting access of these product. Grocery accounts for 93% volume sales of reflux/regurgitation, 88% of colic/constipation and 85% of sensitivity/intolerance.
- Carers and infants requiring products for milk allergy will not be affected as the products are not present in grocery.
- Geo-location modelling found 320 grocery outlets lack a pharmacy within 1.5km driving distance, affecting 203 postcodes with impeded access. For 118 of these grocery outlets, the nearest pharmacy is more than 10km away. This situation has the potential to negatively impact the accessibility of SMPPi for families residing in these areas
- Within the population of 169,000 children under 2 years old in New Zealand, approximately 82,000 (48%) would face difficulties accessing a nearby pharmacy, as their caregivers would need to travel a distance greater than 1.5km to reach one. Out of these, around 37,000 would need to travel over 5km, while approximately 23,000 would need to travel over 10km to reach the nearest pharmacy.
- The lower North Island and the South Island have the highest proportion of affected population, predominately living in urban areas.
- IQVIA conducted a comparison of the cost of SMPPi products between grocery stores and pharmacies in New Zealand. It was found that SMPPi cost an average of 3% more in pharmacies compared to groceries & this price difference increases to 7% in the South Island. Households residing in the South Island of New Zealand who purchase SMPPi products for their infant's first year may incur an additional $61 when obtaining these products through the pharmacy channel
- In a separate study conducted by IQVIA in 2018, which surveyed parents of children in New Zealand who had recently purchased SMPPi, GPs were identified as most important source of influence. Among respondents with a child under 2 years of age, 82% ranked GPs within the top 3 most influential, while only 30% ranked pharmacists within the top 3 as most influential.

- These findings suggest pharmacists may not currently play a significant advisory role in SMPPi for carers with a child under 2 years, hence questioning the effectiveness of removing access in grocery for improved advisory services.

SD4 5.2.4.2 Impact on consumers of changing elements of IFP labels

288. Contrary to FSANZ research (2022), prescribed requirements are not nutrition content claims and there is no evidence that acronyms pose any different level of confusion compared to full biochemical terms and indeed may be more familiar to consumers. Elsewhere in this Submission we have commented on acronyms and full terms and recommend this be considered by the economic analysts.

SD4 5.3 Infant formula industry impacts

289. There is an error in the statement (p25 SD4) that “Although most infant formula manufactured locally is sold in Australia and New Zealand, others are for export only.” In fact, most infant formula manufactured locally is exported as the text under 5.3.1.3 states: “Most finished product produced in Australia and New Zealand is exported.”

290. This is followed (p26 SD4) by a statement that “In New Zealand, infant formula that is manufactured for export can be issued with an exemption from the compositional requirements of the Code by the Ministry for Primary Industries under the Food Act 2014.” These are costly and time consuming.

291. A significant potential cost to industry is from restriction on ingredient statements. Not being able to make a provenance statement which has been used for more than three decades 'Made from New Zealand (or Australian) Milk’ could have a direct economic impact on products for export/cross border ecommerce (CBEC). Made from New Zealand milk can be accompanied by pictures of grazing cows. In New Zealand, both are part of the New Zealand story and history. They describe origin which would be very difficult to describe any other, succinct way. Such a prohibition would have a major impact on the industry for export and CBEC.

292. INC has significant concerns on the cost of the proposed prohibited representations, specifically in relation to information about the provenance of ingredients in the product, i.e. statements such as ‘New Zealand milk’ on the label of the infant formula product. This has not been considered as part of the cost and benefit analysis in SD4 of CFS2. This will, almost certainly, have negative trade implications and a significant impact on the annual export sales of infant formula. This will directly impact the Australian and New Zealand dairy industry.

293. Cross border e-commerce is an important sales channel for Australian and New Zealand manufacturers. The inability to state “made with New Zealand (or Australian) milk” on packaging will have substantial implications for the competitiveness of the Australian and New Zealand infant formula industry. It is one of the few statements that is permitted on pack to help differentiate our Australian and New Zealand products in a global marketplace. Increasing restrictions on Australian and New Zealand products impacts our ability to commercially compete in cross border e-commerce (CBEC) since other markets don’t have these same restrictions.

294. The provision of information around provenance of key ingredients in infant formula is a key component in consumers making an informed choice, particularly in export markets. This is further commented on in the market access section below.

SD4 5.3.2 Benefits to infant formula industry

295. INC agrees that industry will generally benefit from greater alignment with international infant formula products. It is pleasing to see 81% of permissions are aligned to the Codex

infant formula standard in the proposed new standard and 79% of the proposed follow-on formula is aligned. We also agree that the composition between infant formula and follow-on formula should only vary where there is substantiated scientific evidence that demonstrates a different nutrient requirement or tolerable upper limit between the age groups in the Australian and New Zealand populations.

296. FSANZ states (p28 SD4) that "Where the permissions for follow-on formula do not align with the Codex Draft Standard for follow-on-formula, they are aligned with the proposed permission for infant formula within the Code." The latter is not beneficial in allowing the infant formula industry to harmonise products since the Codex draft follow-up composition has been finalised and will become enforceable in the future once published.

Question 4: Do you have any information that can be used to quantify the benefits of increased alignment between the Standard and major international standards?

297. INC has no information to assist in this area.

SD4 5.3.3 Costs to infant formula industry

298. FSANZ estimates the quantifiable costs to industry as:
    - Reformulation - $40m one off cost
    - Relabelling - $4m one off cost

299. The estimates are based on information from industry following CFS1.

Question 3: Do you agree with the reformulation cost estimates? Do you have any information that could be used to calculate this figure with greater accuracy? Refer to Appendix B for more information. Question 4: FSANZ has estimated that 200 SKU will need reformulation. This is based on a search method detailed at section 2 of Appendix B. Do you agree with the estimate? Do you have evidence for a different estimate?

300. INC understands the reformulation costs to be a good estimation. INC also agrees with the estimated number of SKUs (200) that will need reformulation.

301. The relabelling costs are represented as one off costs. For 200 products the cost is estimated at $20,000 per SKU.

Question 5: Do you agree with the relabelling cost estimates? Do you have any information that could be used to calculate this figure with greater accuracy (for example a cost per SKU to update product labels)? *Note: more detail on how the costs were estimated is presented at Appendix B.*

Question 6: FSANZ has estimated that 217 SKU will need relabelling. This includes the impact on different packaging for the same product (example, tins and sachets). This is based on a search method detailed at section 2 of Appendix B. Do you agree with the estimate? Do you have evidence for a different estimate?

302. INC members have provided FSANZ with commercial-in-confidence data on relabelling numbers, extent and costs. Should there be any additional information available, members will provide this direct.

303. In SD4 5.3.3.5 Impacts on standardised NIS (p31), a statement is made that "Currently, infant formula manufacturers use the NIS to highlight added ingredients which are marketed as beneficial to infants. These ingredients can be sub-group nutrients (for example, 'alpha-lactalbumin' is a sub-group of protein), or nutritive substances which have no explicit permission for addition and therefore declaration on the label". This is incorrect as the permission is covered by clause 2.9.1—21 as required information.

304. In relation to the cost of restricting sale, FSANZ assumes that sales lost by supermarkets (where consumers do not substitute to general infant formula products) will be gained by pharmacies. This is incorrect. There will be a reduction of some size (non-quantifiable) through products being withdrawn as not commercially viable through restricted channels or not being ranged by the limited shelf space in pharmacies. There will therefore be a cost to consumer choice throughout the region.

305. Restricted sales will result in reduced choice for consumers and some products exiting the market by current suppliers and therefore a cost to consumers and industry. Taken together, these are not insignificant hurdles and could ultimately drive manufacturing offshore resulting in lost employment and revenue to Australasia.

306. The research on the impact of restricted sales conducted by IQVIA suggests that since pharmacy prices of these products are on average 6% higher than grocery channels in Australia and 3% in New Zealand there will be a cost impact of at least that much on products changing channels. IQVIA research also suggests that the smaller footprint, lesser shelf space and lower turnover of the product in pharmacies will likely result in less product availability, fewer choices and higher costs.

Question 7: Do you have any evidence that can be used to quantify the unquantified costs to industry presented in this analysis?

307. INC commissioned research from IQVIA to examine and analyse channel data relating to SMPPi sales in Australia and New Zealand. This is now shared with FSANZ as an enclosure with this submission.

SD4 5.3.3.10 Impact on market access and competition

308. FSANZ states that "The standards are not expected to result in a change to market access nor significantly reduce market viability for infant and follow-on formula products. FSANZ expects that very few products would be unable to adapt to the new standards and that competition between manufacturers would not be significantly affected." (p33 SD4)

309. Both Australia and New Zealand import 20-40% of infant formula inputs and export a significant proportion of both base powder for infant formula manufacture off-shore and finished product. The issue for market access is not about adapting to the local market but rather being able to import inputs that are made for global destinations and remaining competitive in global markets. Of particular concern are the labelling restrictions. It is costly and difficult to seek exemptions for export labelling from domestic standards as is necessary in New Zealand. Such requirements also limit product placement into the domestic market should that be necessary in the future (such as in a future pandemic situation).

310. The prohibition of label statements relating to the provenance of ingredients such as "made with milk" or "made with New Zealand milk", or "made with Australian milk" do not infer specific nutritional benefit and therefore, should not be prohibited. Rather such

statements provide adequate information relating to food to enable consumers to make informed choices in accordance with a FSANZ stated objective. The prohibition of such label statements is:

a) extremely detrimental in ensuring that New Zealand and Australia maintain efficient and internationally competitive food industries since the prohibition disadvantages New Zealand and Australian manufacturers in overseas markets where such restrictions are not placed on our in-market competitors who manufacture in other jurisdictions

b) particularly of concern for CBEC exporters who compete in overseas markets where regulation on ingredients is not prohibited

c) removing the mechanism for communicating consumer trust and informing consumers on the difference related to our products versus others on the market.

311. In the current New Zealand situation, export product must meet FSANZ requirements unless exempt. If the prohibition of ingredient claims is progressed, not only would New Zealand products sold via CBEC channels be significantly impacted but export product will likely be significantly impacted too. This proposed prohibition will further exaggerate the uneven trade field and put New Zealand and Australian exporters at a significant disadvantage to exporters from other countries. The cost cannot be calculated but a loss of even 1% of New Zealand's $1.93bn alone would be $19.3m.

SD4 5.5 Conclusion of analysis: benefits outweigh costs

312. INC believes the costs could be higher in the short run (5 years) but agrees benefits in the long run (10 years) could be marginally higher than costs. The key uncertainties are the restricted sales impact on SMPPi products currently sold in the grocery channel moving into pharmacies and the market access and export trade impacts of prohibiting provenance related ingredient statements. If these proceed, it is unlikely benefits will outweigh costs.

11 Implementation

11.1 Transitional arrangements

313. INC wishes to highlight that during the transition period, communication of changes to healthcare professionals and caregivers is paramount. Any changes to product can cause significant anxiety. Due to INC members adhering to the MAIF Agreement and the INC CoP in New Zealand there are restrictions on communication regarding changes to infant formula products. The risk for industry is that consumers believe that individual businesses have chosen to make wholesale changes when that is not the case. The changes are due to regulatory requirements.

314. Consumers are not always accepting of change in this product category and FSANZ and jurisdictions need to be supporting the changes over this time and to provide clear communication of changes to infant formula products in order to reduce the anxiety of caregivers over this period. It is a requirement Under Part 2, Division 1, clause 13 of the FSANZ Act that the Functions of the Authority include that in co-operation with the States and Territories, to develop food education initiatives, including the publication of information to increase public awareness of food standards and food labels. It is vital that FSANZ and jurisdictions support industry with their collaborative communications.

315. Given the risks involved, if strong statements from FSANZ and jurisdictions are made to address consumer concerns, industry could point to these when consumers contact them expressing concerns.

316. INC continues to recommend a transition period of 5 years plus 2 years stock-in-trade. This greater period will reduce cost of change and smooth the impact for consumers.

12 Draft Standard

317. INC notes the draft variation at Attachment A of the Consultation document and the Explanatory Memoranda at Attachment B. Our comments on the drafting are largely made in the foregoing paragraphs of this Submission.

12.1 Exclusive use permissions

318. INC notes that the exclusive use periods associated with recent applications have not been included in the draft variation as they are expected to have expired by the time the draft Standard is gazetted.

12.2 Numbering issue

319. We note FSANZ will review the numbering of the draft variation prior to gazettal.

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Food Additives – further detail

Tocopherols, dl-alpha (INS 307c; E 307)

1. In CFS2 SD1, section 3.3.2 notes that FSANZ has stated there is no current permission in the Code for additives tocopherol, d-alpha (INS 307a) and tocopherol, dl-alpha (INS 307c) and that an application would be required to amend the Code.

2 INC requests additional permission for this food additive for use as an antioxidant for infant formula products as it is already permitted in the EU. The entry in S15—5 Table 13.1 would then read:

INS 307c dl alpha tocopherol	10mg/L.

3 The technological justification for dl-alpha tocopherol is that it is required as an antioxidant in infant formula products, and in nutrient preparations added into infant formula products. Antioxidants prolong the shelf life of food and ingredients by preventing oxidation, such as in oils.

4 DL-alpha-tocopherol specifically is added to the nutrient preparations to stabilize the active ingredient in the formulation and to increase the chemical stability of the active ingredient in various applications in which oxidative stress is high including premixed nutrient preparations. Tocopherol is chosen as an antioxidant due to its wide availability and using a synthetic (i.e. INS 307c) over a natural ingredient has the advantage of less natural variation in the ingredient, which leads to a more consistent performance of the ingredient.

5 There are no safety concerns with this substance for infant formula products as it is already permitted at much higher levels as a nutrient fortifier. A much lower level is needed for antioxidant functionality.

6 Additionally, the EU permits the use of additive E 307 Alpha-tocopherol in infant formula products with an ML of 10 mg/kg and for uses in nutrient preparations under the condition that the maximum level permitted in infant formula products is not exceeded. The Commission Regulation (EU) No 231/2012 provides specifications for E 307 and states that a synonym for alpha-tocopherol is dl-alpha-tocopherol so it is equivalent to INS 307c. Therefore, the new entry would be aligned with EU regulations. This is of particular concern for SMPPi as these are predominantly imported.

Diacyltartaric and fatty acid esters of glycerol (INS 472e)

7 FSANZ proposes to remove the permission for this additive.

8 INC recommends continued permission for this food additive for use as an emulsifier and listed in “Substances that may be used as food additives” Schedule 15—5, Food Category 13.1.1. Special medical purpose products for infants (SMPPi). The entry in S15—5 Table 13.1.1 would then read:

INS 472e	Diacyltartaric and fatty acid esters of glycerol	2500 mg/L.

9 General safety evaluation information: Diacetyltartaric acid esters of mono- and diglycerides (DATEM) is a food additive (INS 472e) that is readily metabolised to products that are all normal dietary constituents: mono- and diglycerides, tartaric acid,

and tartaric acid esters. DATEM was evaluated for safety by the Joint FAO/WHO Expert Committee on Food (JECFA) in 2003. At that time, JECFA concluded that the acceptable daily intake (ADI) of DATEM was up to 50 mg/kg, based on this ensuring that the intake of one of its primary metabolites (tartaric acid) would not exceed its ADI.

10 More recently, EFSA concluded that the ADI for DATEM was 600 mg/kg, also based on the ADI for tartaric acid (which for EFSA is 240 mg/kg). The JECFA and EFSA conclusions were based on extensive safety studies. These studies demonstrated DATEM to be non-genotoxic in the bacterial reverse mutation assay and the chromosomal aberration assay, and in a 2-year study in rats administered a diet containing 10% DATEM, no adverse effects were seen, including no evidence for carcinogenicity.

11 In addition, a 21-day study in neonatal piglets was conducted to evaluate the potential effects in an infant population. In this study, piglets were administered a liquid control diet or a liquid diet containing the intended concentration of DATEM, (2500mg/L) or a liquid diet containing a concentration of DATEM 2-fold higher than the intended product concentration (5000mg/L). No adverse effects were seen in this study at either concentration of DATEM. The proposed 2500mg/L concentration for DATEM to be added in SMPPi aligns with this piglet study.

12 Technological justification for the use of diacyltartaric and fatty acid esters of glycerol (DATEM, 472e) in SMPPi includes:

a) DATEM is a strongly hydrophilic, anion-active emulsifier derived from edible, refined vegetable fat. DATEM is currently used by industry as an emulsifier in amino acid-based infant formula. We respectfully request that the use of DATEM continue to be allowed as an emulsifier in the manufacture of infant formulas containing isolated amino acids at a maximum level of 2500 mg/L (as consumed).

b) All lipid containing nutritional formulations include an emulsification ingredient. Unlike the sources (e.g. milk, soy) used in standard infant formulas that are intact proteins, amino acids do not have any significant emulsifying functionality. These formulas require the use of a strong emulsifier, such as DATEM, to ensure that the product can be manufactured properly and that the final formulation delivers nutrients in a homogenous matrix. Furthermore, the emulsifiers used in these highly specialized formulas must not contain any intact protein. This eliminates the use of certain naturally derived emulsifiers, such as soy lecithin, as they contain low levels of protein.

c) A stable emulsification is important for two main reasons:

    i) Manufacturability: The product must be homogenous throughout the manufacturing process. A poor emulsion will result not only in an inhomogeneous product and concerns with regards to nutrient delivery, but also difficulties in manufacturing due to product separation, which can lead to equipment fouling and poor physical quality of the final product. Non-homogeneity during the process also creates the potential that the infant formula may not have uniformly distributed nutrients from can to can or even from scoop to scoop.

    ii) Reconstituted stability: Emulsifiers, like DATEM, continue to function after reconstitution. In their absence, the reconstituted product will suffer physical stability defects, such as separation or creaming.

13. In conclusion, DATEM is currently used by industry as an emulsifier in infant formula based on isolated amino acids. Studies evaluating its use have confirmed it provides

the emulsification necessary to ensure homogeneity during the manufacturing process as well as stability after reconstitution.