INFANT NUTRITION COUNCIL
AUSTRALIA & NEW ZEALAND

20 October 2021

INC SUBMISSION ON PROPOSAL P1028 REVIEW OF INFANT FORMULA: Consultation Paper No.3/2021

This submission has been prepared by the Infant Nutrition Council (INC). The INC represents the majority of companies marketing and/or manufacturing infant formula products and toddler milk drinks (formulated supplementary foods for young children) in Australia and New Zealand. INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula product and toddler milk drink industry in Australia and New Zealand.

INC is a responsible group that voluntarily restricts its marketing practices for infant formula products to support government policies for the protection and promotion of breastfeeding.

INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition for around the first 6 months. It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants who do not receive breast milk.

We welcome the opportunity to provide written comment to Food Standards Australia New Zealand (FSANZ) in response to the *Proposal P1028 Review of Infant Formula: Consultation Paper No. 3/2021.*

Yours sincerely

Jan Carey
Chief Executive Officer

Enclosed: **INC Submission** on *Proposal P1028 Review of Infant Formula: Consultation Paper No. 3/2021*
Annex: Labelling Summary

INFANT NUTRITION COUNCIL
AUSTRALIA & NEW ZEALAND

PROPOSAL P1028 REVIEW OF INFANT FORMULA Consultation Paper No.3/2021

Submission from the Australia New Zealand Infant Nutrition Council

20 October 2021

Executive Summary

1. INC welcomes the opportunity to consider the issues and preliminary views proposed in this Third Consultation Paper in 2021 for Proposal P1028, and to provide comment and information to Food Standards Australia New Zealand (**FSANZ**) relating to the Consultation Paper (**CP3**) on the Regulation of Infant Formula.

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

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

4. Our key concerns relate to the regulatory framework and restriction on sale, the proposals for Schedule 25, some definitional changes and some other product treatments. We are strongly opposed to the application of efficacy to products that are for dietary management and nutritional suitability for particular disease, disorder or medical conditions. These are not therapeutic products.

5. INC supports FSANZ not proceeding with a separate review of novel foods and nutritive substances applicable to IFP under P1028 because these are horizontal standards that apply to IFP and general foods. Consideration of the future regulation of novel foods and nutritive substances must therefore be from the broad perspective.

6. INC supports the use of the term ‘optional ingredients’, as used in Codex. This term, is much preferred to ‘may be used as a nutritive substance’. It is recommended that this is reconsidered as part of a future review.

7. In terms of regulatory framework, INC agrees that IFSPDU sub-categories should be established only where necessary so as to avoid confusion and overlap. INC considers that there are two particular areas where different risk management approaches would be appropriate for high versus low risk IFPSDU. INC proposes this is addressed by creating a sub-category of Division 4 “*IFPSDUs not available at the retail level and exempted from certain labelling requirements*” which might alternatively be named IFPSMP.

8. IFPSDU available in supermarkets are formulated based on compositional requirements of IF for the healthy infant and are safe if taken by healthy infants. INC considers that these low risk products should continue to be made available in supermarkets/general grocery retail.

9. Those IFPSDUs that are intended for infants with clinically serious or potentially life-threatening disorders, disease, or medical conditions could have restricted distribution and market access and should have flexible labelling requirements to ensure international alignment. They are typically prescribed by a doctor or other specialised healthcare worker (eg: dietician), frequently listed in the Australian Pharmaceutical Benefit Scheme (**PBS**) or the New Zealand Pharmac or distributed directly to healthcare institutions such as hospitals e.g. for premature or low birth weight infants.

10. INC is open to support trade and distribution restrictions consistent to that of Standard 2.9.5 for products for premature and low birth weight infants, and for products

for clinically serious or potentially life-threatening disorders, diseases and medical conditions.

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

12. The effects include carers potentially feeding their babies alternatives that may not be suitable and could potentially be harmful. The level of occurrence of functional gastrointestinal disorders has reported prevalence rates in neonates and toddlers between 27.1% and 38.0%. Restricting sale will limit the number of outlets available for carers to obtain these products. Pharmacies have less outlets and limited hours outside of cities and in small rural towns. They also have restricted shelf space and storage capability. Supply chain logisitics for pharmacies will impact timely distribution and less availability can lead to higher prices for consumers. There are obvious delays with online shopping.

13. INC agrees that it is appropriate to regulate products that are the sole or principal source of nutrition for infants with special dietary needs who are under medical supervision for their condition within Standard 2.9.1. But it remains essential that these products may deviate in composition to meet the intended special medical purpose and to ensure supply of IFPSDU. Flexibility in labelling and composition to harmonise with Codex, EU and/or USA is critical to ensure availability of suitability of products for these vulnerable populations.

14. In other areas, INC agrees that:
    - other foods for special medical purpose for infants that are not the sole or principal source of nutrition should be regulated within Standard 2.9.5 rather than Standard 2.9.1
    - IFPSDU must have compositional modifications that are based on acceptable scientific data and address the specific condition and its intended purpose
    - definitions for soy-based infant formula and MCT are not needed. In particular, the maintenance of the current restriction on medium chain triglycerides (**MCT**) is not supported by INC and is not aligned to Codex or EU. If this is to remain, it should be clarified as relating only to refined MCT oil.
    - IF products formulated for the management of lactose malabsorption, which are low lactose or lactose-free conditions, remaining in Division 4.
    - IFPSDU products may be used beyond infancy at the discretion of the healthcare professional and supports maintaining the current approach for products formulated for premature or low birthweight infants to allow deviation.

15. INC's views on principles proposed to apply to IFPSDU are that some are redundant (they apply to all IFP and are not specific to IFPSDU), some appropriate (eg formulated for infants with a specific disease, disorder or medical condition; have a nutrient composition that reflects that of IF or FOF except where necessary to meet the intended purpose of the IFPSMP and used under medical supervision), and some are considered not appropriate (eg requiring efficacy when they support the dietary management of infants with a specific disorder, illness or condition and are not therapeutic).

16. INC supports:
    - the removal of the sub-category based on a protein substitute as this is not required for composition requirements
    - permitting voluntary addition of chromium and molybdenum without any compositional limits for all IFPSDU (option 3)
    - the need for flexibility to allow labels to align globally for IFPSMP is incredibly important to facilitate trade and ensure highly specialised products are commercially viable

17. INC supports the following labelling provisions proposed by FSANZ for all IFPSDU including highly specialised IFPSMP
    - aligning labelling provisions for provisions in Standard 2.9.5—10 since these FSMP labelling requirements offer more flexibility, less prescriptive wording and cover all necessary information for health care professionals and carers.
    - not mandating those statements unnecessary for IFPSDU but required under Standard 2.9.5 (that the food is not for parenteral use)
    - not replicating allergen declaration requirements and advisory and warning statements in subsections 2.9.5 —10(2) and (3) as this is unwarranted
    - adopt an approach consistent with Standard 2.9.5—12(2) for all IFPSDU for date marking information to be able to include 'expiry date'
    - no overarching name being prescribed for all IFPSDU

18. INC supports the following labelling provision proposed by FSANZ for highly specialised IFPSMP but not all IFPSDU
    - for the statement of ingredients to be made in accordance with Standard 1.2.4 or in compliance with EU or US regulations
    - not requiring the prescribed name 'infant formula'
    - the exemption from the 'breast milk is best' warning statement
    - the exemption from the statement about offering other foods in addition to IFPs and that the infant formula product may be used from birth

19. INC supports the following labelling positions that were not considered as part of CP3 for highly specialised IFPSMP but not all IFPSDU to ensure international alignment of labels:
    - not requiring the prescribed name 'follow-on formula'
    - exemption from the requirement statements for follow-on formula- the infant formula product should not be used for infants under the age of 6 months
    - exemption from the warning statement to follow instructions exactly
    - aligning with the nutrition information in accordance with Standard 2.9.5
    - exemption from the storage instruction under standard 2.9.1 and alignment with Standard 2.9.5
    - exemption from the requirement to state protein source.

20. A summary of the labelling changes proposed by FSANZ in CP3 together with the INC position on each is provided in summary form in Annex A enclosed with this Submission.

21. In relation to substances already listed under Schedule 25, INC agrees that substances added to this Schedule that have not been assessed for suitability for infants should not be permitted to be added to infant formula products. However, such conditions of use should be noted when substances are added to Schedule 25, not at some later point of time.

22. INC considers that where risk assessments for novel foods undertook dietary exposures for the population aged 2 years and older, constraints on use in FSFYC should not apply.

Such constraints effectively segment these products from the general food supply. Young children are sharing family foods and, where used, they make up only a small part of foods consumed. It is also not appropriate to propose conditions of use for these products as part of P1028 given they are not included within the scope of this proposal, and the same applies for infant foods. Irrespective of the change mechanism applied, INC remains strongly opposed to the retrospective application of restrictions of use in FSFYC.

23. INC does not agree with:
    - removing the reference to a product that is "based on milk or other edible food constituents" from the definition of IFP as removal of the term from definitions risks creating misalignment with Codex.
    - reference to a specific age for IF which is unhelpful and potentially confusing. It does not bookmark the infant age range applicable for IF which is from birth to 12 months based on part it being *represented as a breast milk substitute for infants*
        - We are firmly of the view that reference instead to "the first months of life up to the introduction of complementary food" is more accurate in relation to being a sole source of nutrition, with the role of the product subsequently moving to the principal liquid source of nutrition.

24. INC agrees with the Ministerial policy guidelines that the composition of infant formula products for special dietary uses should be based on appropriate scientific evidence. However, INC is opposed to the application of efficacy being included in the Standard to products that are for dietary management. It is the nutritional suitability of the products for the disease, disorder or medical condition that is provided, not a therapeutic. Also, this is misaligned with Standard 2.9.5 which does not include this requirement. The potential development of a guidance document is also concerning as this could result in misalignment internationally which is incredibly important for these highly specialised products.

25. INC does not support:
    - a maximum age being included for products that can be used beyond infancy particularly for serious conditions which will be managed closely under medical supervision for a wide range of conditions.
    - the continuation of the existing labelling requirements in relation to lactose free and low lactose formulas with the requirement to state this in the product name
    - highly specialised IFPSMP having to meet the general directions for preparation and use requirements.
    - IFPSDU formulated for the management of lactose malabsorptive which are low lactose or lactose-free being exempt from the labelling requirements in Standard 2.9.5—10(1) and maintaining the existing labelling requirements. The labelling requirements for these products should be consistent with other IFPSDU.

26. As noted above in INC's submission on Consultation Paper 2, INC proposes a transition period of 5-years from manufacture date which also allows for stock in trade. INC considers this would be appropriate to avoid write off costs for labels and adding to unnecessary food-related wastage. The timing for change is especially important given that composition and/or additive changes may be required in addition to the labelling changes implemented, and these will be required across all infant formula products, as a result of the revised Standard.

Introduction

1. INC welcomes the opportunity to consider the issues and preliminary views proposed in this third 2021 consultation paper for Proposal P1028, and to provide comment and information to FSANZ relating to CP3 on the Regulation of Infant Formula.

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

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

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

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

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

6. In responding to CP3, we have located questions with the issues covered in the order they appear in CP3.

Comments and Responses to questions

2 Novel Foods and Nutritive Substances

2.1 Pre-market assessment requirements

7. FSANZ considered several factors relating to novel foods and nutritive substances:
   - the extent of use of substances in the marketplace that might be regarded as novel foods or 'used as a nutritive substance' without a permission in the Code – 67 infant formula (**IF**), follow-on formula (**FOF**) and infant formula for special dietary use (**IFPSDU**) products in 2021 were sampled with 4 substances identified by FSANZ as having uncertain regulatory status added in a total of 11 products representing 16% of all surveyed products (Table 4).
   - number of enquiries to the Advisory Committee on Novel Foods (**ACNF**) which received one request for advice about novel foods proposed to be added to infant formula products (**IFP**) between 2016 and 2021
   - the continued permissions sought by industry to add new nutritive substances and novel foods to IFP.

8. As a result of these factors and the relatively small number of substances having uncertain regulatory status, FSANZ proposes not to proceed with a separate review of novel foods and nutritive substances applicable to IFP under P1028.

9. INC supports FSANZ not proceeding with a separate review of novel foods and nutritive substances applicable to IFP under P1028 but for somewhat different reasons. We do not consider that all the substances identified by FSANZ in its survey of IF, FOF and IFPSDU products in 2021 were necessarily added without permission. Some of these substances, for example, alpha-lactalbumin, is naturally present in milk (whey) protein ingredients, *and addition supports delivery of the required protein and amino acid profile*. Other substances, for example, β-palmitin (also known as SN-2 palmitate or OPO) vegetable oil has been considered by ACNF and deemed to not be a novel food. ACNF commented that it is, "Used in infant formula products overseas with no safety concerns identified based on its use. No concerns regarding composition."

10. As noted, INC supports FSANZ not proceeding with a separate review of novel foods and nutritive substances applicable to IFP under P1028. We support Standard 2.9.1 being included within the scope of Proposal P1024 going forward. Just as FSANZ drew on a wide range of expertise within FSANZ for the purposes of preparing this suite of Consultation Papers for the Review of Infant Formula, we believe a similar broad input needs to be applied to a broader approach for Proposal P1024.

11. Any issues and problems identified in P1024 that apply to the general food supply are the same as the issues and problems of the regulatory arrangements for nutritive substances and novel foods for IFP, particularly in relation to definitional issues.

12. The reason for this position is:
   - the current regulation of novel foods in relation to Standard 2.9.1, is no different to the regulation of novel foods in the general food supply. The need to take account of specific Policy Guidelines and the characteristics of the intended population group apply to other parts of the Food Standards Code
   - the term 'nutritive substances', outside the structure and definitions of the Food Standards Code, is used in 6 standards in the Food Standards Code and Standard 2.9.1 is only one of these Standards (Standard 1.3.2 Vitamins and Minerals and other standards in Part 2.9).

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

14. The same applies to novel foods, that the future regulation of novel foods cannot effectively be conducted from the perspective of one of the standards within the Food Standards Code to which novel foods apply. Consideration must be from the broader perspective. So saying, an interim measure that could reduce the current ambiguity in the novel foods definition could be helpful, e.g. by addition of underlined text in Standard .5.1-2 (1) Novel food means a non-traditional food for the intended [consumer] population that requires an assessment of the public health and safety considerations having regard to:...". The Food Standards Code is not currently clear with regard to need to take into account the intended consumer population.

15. INC would also take this opportunity to reinforce the view on use of the term 'optional ingredients', as used in Codex, as a much preferred term to use instead of 'may be used as a nutritive substance'. It is recommended that this is reconsidered as part of the future review.

2.2 Novel foods – Schedule 25

16. Schedule S25 – Permitted Novel Foods, indicates the conditions of use for novel foods added recently in relation to IFP, infant foods and formulated supplementary food for young children (**FSFYC**) aged 1 to <4years or conversely restrictions to use in these product categories. However, for other substances listed, the Schedule is silent which could be construed as being permitted in IFP, infant foods and FSFYC. FSANZ lists these substances in Table 5 (pp13-14 CP3).

17. Those substances in Table 5 that FSANZ proposes must not be added to IFP, food for infants and FSFYC are:
    - α-cyclodextrin
    - γ-cyclodextrin
    - Diacylglycerol oil (DAG oil)
    - Isomaltulose
    - D-tagatose
    - Trehalose.

    FSANZ notes that the original risk assessments for these substances undertook dietary assessments for the population aged 2 years and older.

18. Those substances in Table 5 that FSANZ is proposing not to set conditions for are:
    - Dried marine micro-algae (Schizochytrium sp.) rich in docosahexanoic acid (DHA)
    - Oil derived from marine micro-algae (Schizochytrium sp.) rich in docosahexanoic acid (DHA)
    - Oil derived from marine micro-algae (Ulkenia sp.) rich in docosahexanoic acid (DHA).

19. The scope of INC does not extend to foods for infants and young children other than IFP and FSFYC aged 1 to < 4years (also known as "toddler milks"). We will leave others to comment on foods for infants and young children outside of INC's scope. However, the issues we comment on may be applicable to those products.

20. Infants are a particularly vulnerable population and certain ingredients that are suitable for the general population may not be suitable for them. INC agrees that substances

added to Schedule 25 that have not been assessed for suitability for infants should not be permitted to be added to infant formula products but such conditions of use should be noted when substances are added to Schedule 25 not at some later point of time.

21. INC considers that constraints on the use in FSFYC should not apply where risk assessments for novel foods undertook dietary exposures for the population aged 2 years and older. Such constraints effectively segment these products from the general food supply which does not make sense. Young children are sharing family foods and, where novel foods might be used, they make up only a very small part of foods consumed. It is also not appropriate to propose conditions of use for these products as part of P1028 given they are not included within the scope of this proposal, and the same applies for infant foods.

22. As a result, INC does not support the inclusion of conditions of use to the substances identified in Table 5 as proposed by FSANZ. We understand that the original risk assessments for these substances undertook dietary assessments for the population aged 2 years and older. As such it would have been appropriate to apply constraints on use in infant formula products and infant foods at the time they were added to Schedule S25. FSANZ is seeking information to ascertain if any of these substances are currently used in IFP as part of this consultation. INC is not aware of any such use of these substances in IFP in Australia and New Zealand and, if this is borne out from this consultation, INC could accept the retrospective addition of conditions of use restricting use in infant formula products.

23. If FSANZ seeks to pursue the inclusion of conditions, then these should be restricted to the most vulnerable group of infants consuming IF or FoF and that are within the current scope of P1028. If such conditions are to be extended to infant foods then it would possibly be more appropriate to implement these changes as a technical amendment rather than under the umbrella of P1028. Irrespective of the change mechanism applied, we remain strongly opposed to the retrospective application of restrictions of use in FSFYC.

Question 1. To manufacturers, please provide information on whether the substances listed in Table 5 are used in infant formula products, food for infants and formulated supplementary food for young children

24. As far as INC is aware, none of the substances in Table 5 are used in infant formula products for the Australian or New Zealand markets. Further information will be provided by individual companies on any such use.

25. We are aware that isomalto-oligosaccharide (not part of Table 5 but a novel food already excluded for use in IFP) has been used in IFP for markets outside Australia and New Zealand.

26. We consider it inappropriate to place conditions on foods for young children over 12 months since these children are increasingly sharing family foods. Although the substances under discussion might not currently be in use, they could be considered in the future and, in the absence of evidence of harm, conditions should not be arbitrarily added.

3 Specialised Infant Formula Products

3.1 Approach to regulation of IFPSDU

27. FSANZ proposes to retain the regulation of IFPSDU in Standard 2.9.1. Regulating IFPSDU in Standard 2.9.1 means it would be an IFP as defined. FSANZ discusses the classification of supplementary products for pre-term infants in greater detail in CP3 section 5.5.1.

28. INC agrees that it is appropriate to regulate products that are the sole or principal source of nutrition for infants with special dietary needs who are under medical supervision for their condition within Standard 2.9.1.

29. This is appropriate given the reference to some ingredient sources e.g. additives and nutrient composition of IF. However, it remains essential that the products may deviate in composition to meet the special medical purpose for which they are intended and, to ensure the supply of IFPSDU, it is also essential they have flexibility in labelling and composition to harmonise with Codex, EU and USA.

3.2 Human milk fortifier and pre-term supplementary products

30. FSANZ proposes to regulate IFPSDU that are sole or principal sources of nutrition as IFP, whereas other infant products for special medical purposes that serve a supplementary role are proposed to be regulated by Standard 2.9.5. Consideration would be given to any particular provisions relevant to infant products needed in Standard 2.9.5 at a later stage.

31. INC agrees that other foods for special medical purpose for infants that are not the sole or principal source of nutrition should be regulated within Standard 2.9.5 rather than Standard 2.9.1. The regulatory framework of Standard 2.9.5 would better accommodate the variable modular products for conditions, sometimes serious/severe or life threatening, produced in small quantities and with often special distribution arrangements.

32. INC agrees that it may be appropriate to consider regulatory provisions for human milk fortifiers and other supplementary modular products where they are not otherwise provided for within the existing requirements in the Foods Standards Code provided this is aligned internationally with Codex, EU and USA. In the meantime, it is essential that the ongoing supply of such products, sometimes for serious or life-threatening conditions, are not interrupted

4 Definitions

4.1 Definition of infant formula product

33. FSANZ is proposing a change to the definition of IFP to remove reference to a product that is “based on milk or other edible food constituents”. The definition proposed is:

    An infant formula product means a product that is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants depending on the age of the infant.

34. INC notes that IFP is a term specific to the regulatory framework of Australia and New Zealand and is not used elsewhere in the world. It is a collective term used for IF, FoF

and IFPSDU. The group term could be used without definition, and instead list the products it covers to substitute as the definition.

35. INC considers that the phrase “based on milk or other edible food constituents of animal or plant origin.” proposed to be removed from the IFP definition is important. It needs to be retained with modification within 2.9.1 for alignment with the Codex IF standard and the part of the Follow-up formula standard currently under revision covering Follow-up Formula for older infants. The relevant Codex texts are as follows:

    From the Codex IF Standard:
    Section A: Standard for Infant Formula
    3.1 Essential Composition
    3.1.1 Infant formula is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding.
    Section B: Formula for Special Medical Purposes Intended for Infants
    3.1 Essential Composition
    3.1.1 Formula for Special Medical Purposes intended for Infants is a product based on ingredients based of animal, plant and/or synthetic origin suitable for human consumption.

    From the revision of the Codex Follow-up Formula standard currently in progress:
    Section A: Follow-up formula for older infants
    3.1 Essential composition
    3.1.1 Follow-up formula for older infants is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have proved to be safe and suitable for the feeding of older infants.

36. We have underlined the text included in each of these sources that overcome the limitation of stating, "based on milk or other edible constituents of animal or plant origin,” identified by FSANZ of not covering the full scope of ingredients used in infant formula production

37. INC proposes the following definition which aligns more closely to wording used by Codex for consideration:
    An infant formula product means a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have proven to be safe for infant feeding that is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants depending on the age of the infant.

38. This definition is suitable for IFPSDU as well as IF and FoF.

4.2 Definition of infant formula

39. FSANZ proposes that for IF, the age range is changed from “under the age of 4-6 months” to “under the age of 6 months”. To assist interpretation, FSANZ proposes to repeat the definition of an infant “means a person under the age of 12 months” as a note to section 2.9.1—3. The proposed definition for an IF is:
    An infant formula product that:
    (a) is represented as a breast milk substitute for infants; and
    (b) satisfies by itself the nutritional requirements of infants under the age of 6 months.

40. INC notes that, of the three other definitions of IF described in CP3 (from the Ministerial Guideline, Codex STAN 72-1981 and EU Regulation 2016/127), none use an age range. We consider that the reference to a specific age as in proposed definition (b) (*satisfies*

by itself the nutritional requirements of infants under the age of 6 months) is unhelpful and potentially confusing. It does not bookmark the infant age range applicable for IF which is from birth to 12 months based on part (a) (*is represented as a breast milk substitute for infants*) and the definition of 'infant' applied within the Food Standards Code. Thís amended definition therefore does not, in our view, "allow for a more certain determination of nutritional adequacy from which to set compositional criteria", as suggested.

41. We are firmly of the view that reference instead to "the first months of life up to the introduction of complementary food" is more accurate in relation to being a sole source of nutrition, with the role of the product subsequently moving to the principal liquid source of nutrition.

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

43. Five years on from our submission in 2016, we consider removing reference to an age range is the preferred approach. This allows policy departments such as the Ministry of Health in New Zealand and the Department of Health in Australia to provide additional guidance for health professionals as appropriate. It also allows science to determine needs in specific circumstances. INC proposes that the wording of (b) is amended to read:

    "satisfies by itself the nutritional requirements of infants for the first months of life until the introduction of complementary feeding as recommended by health authorities and is subsequently [or continues to be] suitable as the principal liquid source of nourishment."

44. Wording along these lines aligns with wording used in part (b) of the definition of FoF:

    follow-on formula means an infant formula product that:

    (a) is represented as either a breast-milk substitute or replacement for infant formula; and

    (b) is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

4.3 Other definitions

45. FSANZ notes that three other definitions are used in Standard 2.9.1: soy-based infant formula, pre-term formula and medium chain triglycerides (**MCT**). FSANZ proposes to retain the definition of pre-term formula at this time but that definitions for soy-based infant formula and MCT are self-explanatory and not needed.

46. INC agrees that definitions for soy-based infant formula and MCT are not needed. As noted in the INC submission on Consultation Paper 2, the maintenance of the current restriction on MCT is not supported by INC and is not aligned to Codex or EU. If this term is to remain, it should be clarified as relating only to refined MCT oil. Consistent with that position, INC would support a definition of 'MCT oils' and that, where used in Standard 2.9.1, the reference should be to MCT oils. This would remove ambiguity in ensuring MCT oils are considered predominately C8:0 and C10:0 and while excluding other oils which may contain a small proportion of naturally occurring MCTs.

Question 2. Is a definition of soy-based formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available

47. INC considers a definition for soy-based infant formula is not needed and agrees with FSANZ that it is self-explanatory nor needed for aluminium requirements. We noted in our Submission on Consultation Paper 1 that Standard 2.9.1 should align with Codex which does not include limits on aluminium as a contaminant metal in infant formula (Codex STAN 193-1995). The EU does not list aluminium as a contaminant metal in infant formula (nor any foods) (Commission Regulation (EC) No 1881/2006). In the US, limits for aluminium as a contaminant metal in infant formula are also not included (CFR, Chap 21, parts 106 & 107).

Question 3. Is a definition of pre-term formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

48. INC considers a definition for pre-term formula is not needed for aluminium requirements. We noted in our Submission on Consultation Paper 1 that Standard 2.9.1 should align with Codex which does not include limits on aluminium as a contaminant metal in infant formula (Codex STAN 193-1995). The EU does not list aluminium as a contaminant metal in infant formula (nor any foods) (Commission Regulation (EC) No 1881/2006). In the US, limits for aluminium as a contaminant metal in infant formula are also not included (CFR, Chap 21, parts 106 & 107).

Question 4. Are definitions needed for any of the new terms proposed to be introduced as conditions for the use of food additives in CP1, such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism etc.?

49. INC is firmly of the view that definitions for the new terms proposed to be introduced as conditions for the use of food additives are NOT needed. These terms are not defined in EU regulation and are generally understood.

5 Regulatory Framework for IFPSDU

5.1 Description of IFPSDU in Division 4 of Standard 2.9.1

50. Division 4 of Standard 2.9.1 does not currently include a definition of IFPSDU but consists of three subcategories of IFPSDU:
    - Products formulated for premature or low birthweight infants
    - Products for metabolic, immunological, renal, hepatic and malabsorptive conditions
    - Products for specific dietary use based on a protein substitute.

51. FSANZ noted the regulatory uncertainty and overlap related to the broad nature of the current subcategories, the range of products in each subcategory and related definitions.

52. Submitters informed FSANZ that some specialised products are also intended for use beyond 1 year of age.

53. INC agrees that there is overlap between the current sub-categories.

54. INC considers that the voluntary labelling of Standard 2.9.1—19(1)(d) "*Important Notice: Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice*" is not an indication of whether or not the product is a product for metabolic, immunological, renal, hepatic and malabsorptive conditions (Standard 2.9.1—14).

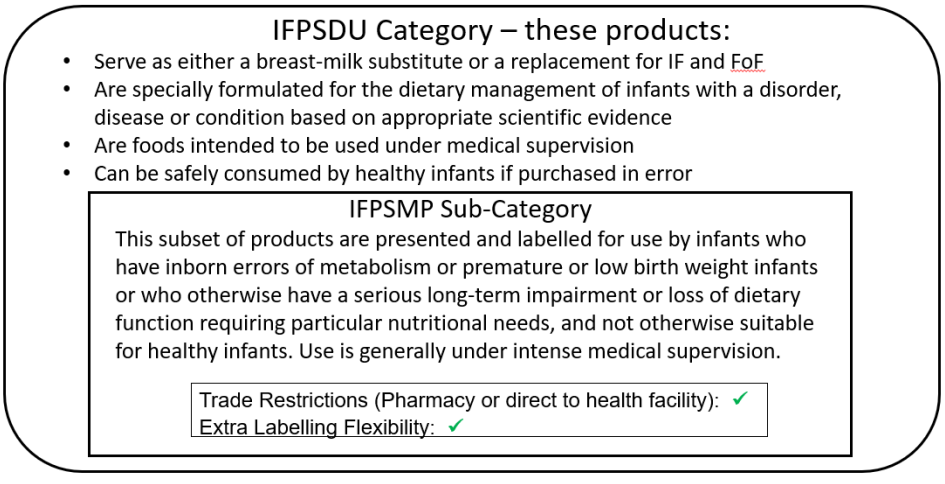
5.2 Options for regulatory framework

55. FSANZ proposes that sub-categories should only be established if specific regulation beyond that set for all of Division 4 is needed. This may or may not be accompanied by definitions.

56. INC agrees that sub-categories should be established only where necessary so as to avoid confusion and overlap. We do see a need for a sub-category as we describe below. INC supports a framework that facilitates harmonisation, trade access and distribution and provides regulatory clarity including purpose, composition and labelling and we consider the sub-category proposed meets these requirements.

57. INC has reviewed the discussion through CP3 Section 5 and considers that two different risk management approaches would be the most appropriate for high versus low risk IFPSDU. We suggest that this is addressed by creating a sub-category of Division 4 "*IFPSDUs not available at the retail level and exempted from labelling requirements*" which might alternatively be named Infant Formula Products for Special Medical Purposes (IFPSMP) while retaining the broader term 'IFPSDU' for the Division. This is described in Figure 1.

Figure 1: Regulatory framework based on risk management for Standard 2.9.1 Division 4



58. IFPSDU available in supermarkets are formulated based on compositional requirements of IF for the healthy infant and are labelled as for IF for healthy infants except for the additional information required by Division 4. Unlike the sub-category IFPSMP, they can be safely consumed by healthy infants if purchased in error. As such INC considers that these low risk products should continue to be made available in supermarkets.

59. Whereas those IFPSMPs that are intended for infants with clinically serious or potentially life-threatening disorders, disease, or medical conditions and are usually required to be under intensive medical supervision could be restricted distribution and market access and should have flexibility in labelling to allow international alignment. They are typically prescribed by a doctor, frequently PBS or Pharmac listed or are those distributed directly to institutions such as hospitals e.g. for premature or low birth weight infants.

60. IFPSMP as proposed by INC are intended for those infants with clinically serious or potentially life-threatening disorders, disease, or medical conditions.

61. INC proposes that the definition is:

> 'serve as a breast-milk substitute and replacement of IFP and IFPSDU presented and labelled for use by infants who have inborn errors of metabolism or premature or low birth weight infants or who otherwise have a serious long-term impairment or loss of dietary function requiring particular nutritional needs, and are not otherwise suitable for healthy infants.'

62. For clarity in taking this forward and in responding to all the subsequent sections in CP3, INC makes it clear when we are referring to the general IFPSDU category (which includes the IFPSMP sub-category) and when we are referring to just the IFPSMP sub-category.

5.3 Principles for purpose, composition, use and sale of IFPSDU [including IFPSMP]

5.3.1 Purpose

63. FSANZ proposes that the principles that should apply to IFPSDU are:
    - To serve as a safe sole or principal source of nourishment
    - To serve as a safe replacement for human milk, infant formula and follow-on formula.

64. INC understands that the principles will not form part of the Food Standards Code and suggest they could be limited to those specific to guiding the Framework of Division 4. Also, INC considers it is not necessary to repeat those principles that are already included by definition of an infant formula product.

65. INC does not consider the principles for purpose are necessary to the discussion. In addition, it is recognised that healthcare professionals may continue to recommend Division 4 products beyond infancy.

5.3.2 Nutrient composition and use under medical supervision

66. FSANZ proposes that the principles that should apply to IFPSDU [and IFPSMP] related to nutrient composition, scientific evidence, and appropriate use are as follows:
    - should meet the nutritional requirements of infants to support growth and development
    - are intended for the dietary management of infants with a specific disorder, illness or condition
    - the nutrient composition should be based on
        - IF or FOF other than where necessary to meet the purpose of the product (compositional deviation)
        - appropriate scientific evidence
    - should be used under medical supervision to manage the risk to unhealthy infants.

67. INC agrees with the principles of supporting growth and development, are intended for the dietary management of infants with a specific disorder, illness or condition and the nutrient composition should be based on IF or FoF and deviate where necessary to meet the intended purpose based on either generally accepted science and/or specific scientific evidence.

68. It should also be clear, though, that the nutrient composition for imported products can be based on the infant formula requirements for US, EU or Codex where it would otherwise prevent sale. This is as provided for in the current requirement under Standard 2.9.1—13(1) and 2.9.1—14 (1), that a compositional requirement of the Food Standards Code does not apply to the extent that it would otherwise prevent the sale of an IF or FoF that has been specially formulated for a specific condition. This is particularly important for the subcategory of IFPSMP, and for severe conditions such as Inborn Errors in Metabolism (IEM) where globally aligned formulations are imported. INC agrees that these products should continue to be used under medical supervision.

69. FSANZ proposes to include the need for IFPSDU to be specially manufactured and formulated in accordance to appropriate scientific evidence that demonstrates the efficacy of the product in meeting its intended purpose.

70. INC does not support efficacy being included in this principle. INC considers that these products are not therapeutic, but support the dietary management of infants with a specific disorder, illness or condition. These products provide either the sole or principal source of nutrition to infants to support growth and development. INC supports instead a principle in relation to scientific evidence which is aligned with the Minsterial policy guidelines “the composition of infant formula products for special dietary uses should be based on appropriate scientific evidence”.

5.3.3 (1) Extension of use beyond infancy

71. FSANZ considers there is merit in considering the continued use of IFPSDU beyond infancy and proposes the following principle:
    - IFSPDU used in infancy and beyond should be accommodated in regulation.

72. INC agrees that these products, including the sub-category of IFPSMP may be used beyond infancy at the discretion of the healthcare professional. However, this does not need to be included in the Code.

73. INC notes that the NHMRC recommends the continuation of breast milk beyond 12 months of age. As a breast milk substitute this can also be extended to IFP and IFPSDU. In addition, the Australasian Society of Clinical Immunology and Allergy (**ASCIA**) states that IFPSDU can be suitable for use beyond 12 months under medical supervision.

5.3.3 (2) Restriction on sale

74. FSANZ considered arrangements for highly specialised products and less specialised products and reached the view that, to be consistent with the risk management strategy established for Standard 2.9.5, a restriction on sale should be imposed on the entire range of IFPSDU. On this basis, FSANZ proposed the following principle:
    - IFPSDU should be subject to a restriction on sale.

75. INC does not agree that the highest risk management approach should be applied to all low and high risk products within IFPSDU and that the distribution and access to the

entire range of IFPSDU, irrespective of risk profile as proposed to be categorised, should be subject to the same level of constraint.

76. We consider that the current risk management approach should be retained and that it is not necessary to adopt the risk management strategy of Standard 2.9.5 for the entire range of IFPSDU. Adopting the same approach to both IFPSDU and products under Standard 2.9.5 for the sake of consistency with Standard 2.9.5, is not supported by evidence of risk.

77. We point to FSANZ's statement in CP3 that "restrictions under Standard 2.9.5 as part of their overall risk management strategy given their minimal prescribed composition" (INC emphasis). IFPSDU have strong composition requirements. Products not required under prescription are safe and low risk as stated by FSANZ under CP3 section 5.6.4: "that IFPSDU not required under prescription or used in the hospital setting would be based on compositional requirements for IF for healthy infants and therefore safe and low risk". Rather, each product type should be treated on its own merits. The evidence is that there is no 'market failure' in respect of IFPSDU and that only those products for less serious/transient conditions are sold in supermarkets (see INC response to CP3 Section 5.6.4). This principle was also not included in the Ministerial policy guidelines.

78. In addition, there no evidence for the other concerns raised by submitters that the availability of IFP is a factor in the cessation of breastfeeding or inappropriate use of IFPSDU. CP3 Table 16 states that government submitters provided published evidence from overseas describing a negative impact that advertising these products could have on breastfeeding rates. Advertising and promotion to the general public for IFP 0-12 months is not permitted under both the Marketing in Australia of Infant Formula (MAIF) Agreement and the New Zealand INC Code of Practice of Marketing of Infant Formula, which are government supported in both countries to restrict advertising and promotion of IFP in accordance with the WHO Code. Therefore, the applicability of this overseas evidence is not directly relevant in Australia/New Zealand context.

79. Notably, the sub-category of IFPSMP for more serious disorders, diseases and conditions are normally provided under prescription and are therefore not generally available currently despite the Food Standards Code not restricting sale under Division 4.

80. Nonetheless, INC would support adopting the risk management strategy of Standard 2.9.5 for a separate sub-category for high risk IFPSMP.

81. INC is concerned that a general restriction on sale of IFPSDU will have an impact on three major areas: a negative effect on some health outcomes for infants who require these products; less accessibility and availability to, and of, these products for parents and carers; and supply chain logistics.

5.3.4 Proposed consolidated principles

82. As noted above, INC considers the following:

Principle	INC View
Serve as a sole or principal source of nourishment (IFP definition) AND Serve as a substitute for human milk AND	INC notes that these principles apply to all IFP and are not specific to IFPSDU. It is not necessary to repeat principles that are already included by definition of an infant formula product.

Are intended to meet an infant's nutritional requirements to support growth and development.	INC considers these principles are therefore redundant.
Serve as a replacement for infant formula and follow-on formula.	INC notes that healthcare professionals' may recommend beyond infancy.
Are formulated for infants with a specific disease, disorder or medical condition	INC agrees that these products are formulated to meet the nutritional needs and thereby to support the growth and development of infants with a specific disease, disorder or condition.
Are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended purpose	INC considers that these products should be safe and effective in supporting the growth and development of the infant for whom they are intended. INC does not agree that efficacy should be included in this principle. These products are not therapeutic, but support the dietary management of infants with a specific disorder, illness or condition. They provide either the sole or principal source of nutrition to infants to support growth and development. A principle aligned to the Ministerial policy guidelines would be appropriate "the composition of infant formula products for special dietary uses should be based on appropriate scientific evidence".
Have a nutrient composition that reflects that of IF or FOF except where necessary to meet the intended purpose of the IFPSDU	INC agrees that the energy and nutrient composition should be similar to that of IF or FoF and modified where needed to meet the particular nutritional needs of the infant for whom it is intended. In addition, flexibility is needed to allow alignment with compositional requirements applied by EU or US for IFPSMP to ensure availability. This is particularly important for severe conditions such as Inborn Errors in Metabolism (IEM) where globally aligned formulations are imported. The formulations are still based on infant formula composition however rather than Food Standards Code requirements are based on the requirements in US, EU or under Codex.
Are intended for use under medical supervision to manage risk to unhealthy infants	INC agrees that these products are intended to be used under medical supervision since they are for consumption by infants with a disease, disorder or medical condition.
Used in infancy and beyond should be accommodated in regulation	INC agrees that these products may be used beyond infancy at the discretion of the healthcare professional.

Are subject to a restriction on sale	INC does not agree that those products for less serious, transient conditions should be subject to a regulated restriction on sale.INC does not agree that those products for less serious, transient conditions should be subject to a regulated restriction on sale.

5.4 Name and definition of IFPSDU

83. FSANZ proposes to rename Division 4 as Infant Formula Products for Special Medical Purposes (IFPSMP) and that a range of definitional elements for IFPSMP should be taken from Standards 2.9.1 and 2.9.5. The proposal is that a food that is represented as an IFPSMP have the following features:
    - serves as a substitute for human milk, and replacement of IF and FoF
    - is specially formulated for the dietary management of infants based on appropriate scientific evidence
    - is for infants:
        - who have special medically determined nutrient requirements, or
        - who have limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolites of other IFPs, and
        - whose dietary management cannot be completely achieved without the use of IFPSMP
    - is a food that must be used under medical supervision.

84. INC strongly opposes calling all IFPSDU as IFPSMP since there are special arrangements that are needed only for IFPSMP.

85. INC considers a category definition for the broad IFPSDU category to be useful. INC would suggest the following amendments to simplify the proposed definition features:
    - serves as either a breast-milk substitute ~~for human milk, and~~ or replacement ~~of~~ for IF and FoF
    - is specially formulated for the dietary management of infants with a disorder, disease or condition based on appropriate scientific evidence
    - ~~is for infants:~~
        - ~~who have special medically determined nutrient requirements, or~~
        - ~~who have limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolites of other IFPs, and~~
        - ~~whose dietary management cannot be completely achieved without the use of IFPSMP~~
    - is a food ~~that must~~ intended to be used under medical supervision.

5.5 Provisions for IFPSDU and the sub-category IFPSMP – Composition

5.5.1 Products formulated for premature or low birthweight infants

86. FSANZ proposes that the current arrangement to allow compositional deviation from the composition of IF be retained. This is based on submitters' support for the current arrangement and no suggestions for additional compositional requirements.

87. INC supports maintaining the current approach to allow deviation and for no additional composition requirements. It should also be clear, though, that the nutrient composition for imported products especially the sub-category of IFPSMP can be based on the infant

formula requirements for US, EU or Codex where it would otherwise prevent sale. This is as provided for in the current requirement under Standard 2.9.1—13(1) a that a compositional requirement of the Food Standards Code does not apply to the extent that it would otherwise prevent the sale of an IF or FoF that has been specially formulated for premature or low birthweight infants.

5.5.2 Products for metabolic, immunological, renal, hepatic and malabsorptive conditions

88. Given this sub-category has permission to deviate from the composition of IF, and submitters made no comment, it is proposed to remove the specific guideline maximum amount for manganese in this subcategory in favour of that for IF.

89. Lactose-free and low lactose formulas could also be suitable for general use as infants should be able to tolerate lactose as part of their diet but these formulas are not ideal for long term use by healthy infants. The 'no detectable lactose' criterion was adopted because it affords infants the highest level of protection as it requires the most advanced method of analysis to be used at all times. For low lactose, the 0.3 g lactose/100 mL criterion was determined to protect lactose intolerant infants from adverse symptoms. FSANZ proposes that both these criteria could be retained. Since products in other categories could also be low lactose or lactose-free, these criteria could be applied to the entire category of IFPSMP, if appropriate.

90. INC agrees that IFPSDU may be low lactose and lactose-free and supports the extension to state this outside of the name. There are products that are lactose free or low lactose but not necessarily suitable to be a part of name and therefore should have an option to be able identify as lactose free or low lactose as part of the nutritional modifications which have been made to the product for the condition, disease or disorder for which the product has been specially formulated without the 'lactose free' or 'low lactose' being part of the name. One example is products formulated for the management of lactose malabsorptive conditions. INC notes that lactose content is the only nutritional modification that must also be a part of the name. Hence INC suggests Standard 2.9.1—14(6)(a) be removed.

Question 5. To health professionals: Is there any evidence that current practice in relation to low lactose products or the manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions pose a health concern or risk? If you consider that there is a health concern or risk, please provide relevant details and data, where available.

91. Not applicable.

Question 6. To industry submitters: How many and what types of low lactose IFPSDU are on the market? And what is their maximum level of lactose? Please provide supporting detail and data, where available.

92. INC member companies will provide information on their products as part of their own submissions.

5.5.3 Products for specific dietary use based on a protein substitute

93. FSANZ proposes the subcategory based on protein substitutes may be removed depending on composition requirements.

94. INC supports the removal of the sub-category based on a protein substitute as this is not required for composition requirements.

Question 7. To industry submitters: What types of partially hydrolysed IFP are on the market? And what is their maximum level of protein denaturation? Are any on the pharmaceutical benefits schemes in Australia or New Zealand? Please provide supporting detail and data, where available

95. INC member companies will provide information on their products as part of their own submissions.

Question 8. To health submitters: You have told us that partially hydrolysed IFP are not efficacious in preventing allergy; are they useful in the dietary management of allergy? Please provide supporting detail and data, where available

96. Not applicable.

97. FSANZ considers that there is no need to specifically regulate the protein and fat levels or potential renal solute load (PRSL) in protein substitutes and that the current approach for pre-term and metabolic etc. products would be appropriate and a more flexible approach for imported protein substitutes.

98. INC supports this proposed approach of removing specific requirements for protein, fat levels or PRSL in protein substitutes for protein substitutes and aligning a consistent composition approach across IFPSDU which allows for deviations in the composition as needed for the specific disease, disorder or medical condition.

99. FSANZ proposes that if Division 4 was to become one category, the following options for regulation of molybdenum and chromium are available:
    1. Retain current mandatory requirement to be met naturally and/or through addition for protein substitutes – status quo
    2. Permit voluntary addition within compositional limits to be met naturally and/or through addition for all IFPSMP
    3. Permit voluntary addition without any compositional limits for all IFPSMP
    4. Delete the requirement altogether which then serves to prohibit addition since molybdenum and chromium are classified as nutritive substances, and their permitted forms in section S29–7 become redundant.

Question 9. Regarding options for the regulation of molybdenum and chromium, which option do you prefer and why? Please provide supporting detail and data, where available

100. INC does not support Division 4 becoming one category but nonetheless supports option 3 for all IFPSDU as the addition of chromium and molybdenum is currently permitted to meet the minimum requirement for products for specific dietary use based on a protein substitute. As the sub-category of protein substitutes will not be maintained under the proposed framework option 1 is not supported. Options 2 and 4 are not supported as both Codex Stan 72-1981 Section B and EU Regulation 2016/128 permit addition of chromium and molybdenum but do not set a mandatory minimum across all IFPSDU.

101. If FSANZ retains a GUL for chromium and molybdenum in IFPSDU, then INC suggests alignment of with the GUL in Codex STAN 72-1981 Part B and EU Regulation 2016/128 of 2.4 µg/100kJ (10 µg/100kcal) for chromium. For molybdenum, a GUL of 3.3 µg/100kJ (14 µg/100kcal) aligned to EU Regulation 2016/128.

102. INC also requests that chromium chloride and ammonium molybdenum are included as permitted forms for IFPSDU to allow for international alignment. These forms are permitted for FSMP in: the Food Standards Code Schedule S29—20; Codex for Formula for Special Medical Purpose Intended for Infants; and the EU for Infant Food for Special Medical Purposes.

103. FSANZ proposes that if Division 4 was to become one category, the options in relation to the use of MCT are that permission is:
    - Applied to the entire IFPSMP category, with or without limits
    - Removed from protein substitutes with the effect that Division 4 is silent and possibly unclear with respect to its use but noting the restriction proposed for IF in Consultation paper 2 (FSANZ 2021).

104. As raised in CP2 submission, INC is not supportive of maintaining the current restriction for MCT oil. However, if it is to remain, then INC would support option 1 including MCT for the entire IFPSDU category without specifying limits for MCT oils. The levels of MCT oils used in a product for a specific condition would need to be based on scientific data as safe and suitable. No other jurisdiction has restricted or set limits for MCT oils and therefore setting limits could create an inability to import some of these highly specialised products.

Question 10. To industry submitters: What type of products contain MCT oil? For what purpose and at what levels? Please provide supporting detail and data, where available

105. INC member companies will provide information on their products as part of their own submissions.

Question 11. To health submitters: Are there any health concerns from current practice using products that contain MCT oil? Please provide supporting detail and data, where available

106. Not applicable.

5.5.4 Proposed approach – Composition of [IFPSDU including] IFPSMP

107. FSANZ proposes to retain the permission for compositional deviation generally and extend it to all IFPSDU including IFPSMP. This would permit the nutrient composition of all IFPSMP to reflect that of IF or FOF except where necessary to meet the intended purpose of the product.

108. INC supports extending the permission for compositional deviation to all IFPSDU where needed for meet the intended purposed of the product. Additionally, it is important that all IFPSDU are also allowed to comply to EU, US or Codex IF and FoF requirements where that would otherwise prevent the sale of an infant formula product. This is as provided for in the current requirement under Standard 2.9.1—13 (1) and 2.9.1—14(1), that a compositional requirement of the Food Standards Code does not apply to the extent that it would otherwise prevent the sale of an IF or FoF that has been specially formulated for a specific condition. This is most important in severe conditions such as IEM where only one global formulation and label exist. The below tables summarises

nutrients which are misaligned for importing from EU and Codex against the proposal in CP2 for composition.

Summary of nutrients that will be an issue when importing from EU under the proposed FSANZ standard

Nutrient	Issue	EU 2016/127	FSANZ proposed in CP2
Vitamin B6	Min	4.8 µg/100kJ	8.4 µg/100kJ
Vitamin C	Min	0.96 mg/100kJ	1.7 mg/100kJ
Iron	Min	0.07 mg/100kJ	0.2 mg/100kJ
Vitamin B1	Min	9.6 µg/100kJ	10 µg/100kJ
L-Carnitine	GUL	Not Specified	0.8 mg/100kJ
DHA to AA	Ratio	None	DHA≤AA when added voluntarily
DHA	GUL	12mg/100kJ	0.5% GUL
ALA to LA		None	5:1 to 15:1

Summary of nutrients that will be an issue when importing under Codex under the proposed FSANZ standard

Nutrient	Issue	Codex STAN72 1981	FSANZ proposed in CP2
LA	Min	70 mg/100kJ	90 mg/100kJ
Iron	Min	0.1 mg/100kJ	0.2 mg/100kJ
Iodine	Min & Max	2.5 – 14 GUL µg/100kJ	3.6 -10 µg/100kJ
Selenium	Min & Max	0.24 – 2.2 GUL µg/100kJ	0.48 – 2.0 µg/100kJ
L-carnitine	GUL	Not Specified	0.8 mg/100kJ
Vitamin B2	GUL	96 µg/100kJ	119 µg/100kJ

5.6 Provisions for IFPSMP – Purpose, use and sale

5.6.1 Scientific evidence of purpose

109. FSANZ proposes to enshrine in regulation the principle that IFPSMP are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended purpose.

110. INC considers that ALL IFPSDU (including IFPSMP) must have compositional modifications that are based on acceptable scientific data and address the specific condition demonstrating the product and its intended purpose. Currently manufacturers are required to hold scientific evidence that substantiates the nutritional suitability for the disease, disorder or medical condition in line with its represented purpose. This is required as part of the overarching jurisdictional food act requirements. INC does not support the inclusion scientific evidence as proposed this is not aligned with Standard 2.9.5 for FSMP products. If a statement is to be included in Division 4, INC would support the continuation of this arrangement allowing for a simple statement of requirement

similar to the Ministerial policy guidelines “the composition of infant formula products for special dietary uses should be based on appropriate scientific evidence”

111. INC does not support the use of the term “efficacy” in the Food Standards Code for IFPSDU. These products are not therapeutic but rather are for the dietary management of a specific disease, disorder or medical condition. As such, the composition of IFPSDU are formulated based on sound medical and nutritional principles that have demonstrated through scientifically acceptable evidence (specific to the product and its indication) to support growth and development in the infants for whom it is intended.

112. FSANZ proposes (CP3 p46) that a guidance document be produced either in the Food Standards Code, similar to Schedule 6 for health claims, or elsewhere such as a code of practice, on how the efficacy requirement should be met.

113. INC does not support a guidance document as this could result in additional requirements to those already applicable internationally and would create unnecessary misalignment internationally as guides are not available under any other jurisdiction. This could also result in products not being made available or a significant delay in launching products in Australia or New Zealand for serious or life-threatening disorders, diseases and conditions. Furthermore, IFPSMP (as described under section 5.2 above) for serious conditions are generally listed on the Australian PBS and New Zealand’s Pharmac. In order for IFPSMP to be considered on these schemes, companies are required to provide adequate scientific evidence for their use in the management of a particular medical condition, disease or disorder which is then assessed by their respective clinical experts.

114. This means that IFPSMP for serious or life-threatening disorders, diseases or conditions already currently have the science reviewed independently by experts in both countries before the products are accepted for reimbursement. Notably, these are the higher risk products with significant variations from the IF composition requirements and therefore may not be safe for healthy infants to consume. These products would be unaffordable without reimbursement and are only used under health care professional prescription, hence would not be generally available without going through this process. IFPSDU that are not reviewed by PBS or Pharmac are, according also to FSANZ, considered lower risk and they are based on the composition requirements for IF for healthy infants.

115. As noted above, the reimbursement application process for PBS products through Pharmaceutical Benefits Advisory Committee (**PBAC**) and Pharmac products through the Pharmacology and Therapeutics Advisory Committee (**PTAC** – which involves over 140 clinical experts making up the Pharmac clinical committees). usually follows a detailed review of scientific information provided by the sponsor. This could include, but is not limited to:
    - IFPSDU formulation details
    - critical appraisals of key clinical evaluations
    - complete market and epidemiological information and where relevant impact on relevant populations
    - disclosure on all known ongoing trials and patients and varying indications that the product is prescribed for.

116. Neither FSANZ nor jurisdictional food regulators should be expected to or need to replicate the level of expertise necessary to review this information and it would be best for the relevant agencies to recognise that PBS and Pharmac review the science provided and anything further by FSANZ or jurisdictions would be duplicative.

Question 12. To industry submitters: Do infant formula manufacturers hold scientific evidence that supports the purpose of Division 4 products, including for reflux, colic, diarrhoea, and similar products (i.e. for less serious conditions)

117. IFPSDU have compositional modifications that are based on generally acceptable scientific data and are manufactured to address a specific medical condition, disease or disorder. Other nutrients in the product, not related to the disorder, disease or medical condition default back to the general purpose or standard formula compositional requirements as set out in Standard 2.9.1. All deviations are based on scientific evidence and generally accepted data that justifies the compositional modification in the final product. In addition, for all products that are listed on the PBS and Pharmac, manufacturers have provided adequate scientific evidence for products use in the management of a particular medical condition, disease or disorder.

118. Furthermore, scientific information about IFPSDU is often provided to health care professionals by manufacturers and importers. The majority of IFPSDU manufacturers and importers in Australia and New Zealand are signatories to the Marketing of Infant Formulas: Manufacturers and Importers (**MAIF**) Agreement and/or the New Zealand Infant Nutrition Council Code of Practice. It is required by the MAIF Agreement to provide scientific information about IFPSDU supported by a reference to the scientific literature and reflect the quality and strength of the supporting reference(s)/evidence and have regard to the NHMRC Evidence Hierarchy, while noting limitations on randomisation in nutrition studies involving methods of infant feeding.

Question 13. If so, what type of scientific evidence is held by companies and what is its strength of evidence??

119. INC advises that this will be supplied individually by manufacturers.

5.6.2 Extension of use beyond infancy

120. FSANZ advises it is open to permitting the use of IFPSMP beyond infancy in the regulation of IFP but needs further information to determine what requirements are needed to allow for such use.

Question 14. What is the maximum labelled age on products suitable for use beyond infancy? What are the parameters that indicate when the product is no longer appropriate?

121. INC does not support a maximum age being included for products that can be used beyond infancy particularly for serious conditions which will be managed closely under medical supervision for a wide range of conditions. The suitable use and age for the product will be included on the label as proposed under CP3 section 5.7 to align with labelling to Standard 2.9.5—10.

122. Some products are labelled as a supplementary feed to the main diet up to 3 years and for products managing inborn errors of metabolism up to even 10 years. There are many considerations for determining whether a product is no longer appropriate, and age is not the sole consideration. Other considerations include weight, health (e.g. is the condition resolved or requires ongoing management), how the product is used (sole source or supplement to the diet) and other dietary management options.

123. INC also notes that the NHMRC recommends the continuation of breast milk beyond 12 months of age. As a breast milk substitute this can also be extended to IFP and IFPSDU.

In addition, ASCIA also states that IFPSDU can be suitable for use beyond 12 months under medical supervision.

5.6.3 Lactose-free and low-lactose formulas

124. FSANZ's preliminary view in relation to lactose free and low lactose formulas is to:
    - maintain existing labelling requirements
    - clarify IFPSMP labelling provisions would not apply.

125. INC suggests changes to existing labelling requirements in relation to lactose free and low lactose formulas. While INC acknowledges the ACCC requirements with regard to 'free' to mean 'no detectable presence', we do not support the continuation of the use of 'low lactose' and 'lactose free' being part of the name for these products. This inhibits a manufacturer's ability to convey the lactose content of some products as part of the nutritional modifications which have been made to products for the disease, disorder or condition for which a product has been specially formulated. It also creates confusion from a consumer perspective, as some products may have more than one condition for which it has been formulated.

126. INC does, however, continue to support the continuation of requirements for the lactose level and galactose content currently contained in Standard 2.9.1—14 for IFP and IFPSDU. However, for the IFPSMP sub-category, further flexibility in labelling to allow international alignment including to the EU is required. INC therefore supports an exemption from including the levels on the label as IFPSMP are used under intense medical supervision and there will be a requirement for labelling as proposed in section 5.7.1 that "a statement indicating, if applicable, any precautions and contraindications associated with the consumption of the food" is included. This would therefore provide an option to not include galactose level in the nutrition information and for a precaution or contraindication statement such as "'not suitable for infants with galactosaemia".

5.6.4 Distribution and access

127. FSANZ proposes that, in relation to distribution and access to IFPSDU including IFPSMP, that:
    - supermarket sales of IFP will be restricted to general IF; and
    - access to IFPSDU including IFPSMP will be restricted to those medical practitioners, responsible institutions, or permitted sellers (to be defined in the Food Standards Code, similar to Standard 2.9.5).

128. INC does not agree that IFPSDU should be restricted in sale where these products are for low-risk conditions. As stated above, adopting the same approach for all IFPSDU in accordance with Standard 2.9.5 for the sake of consistency with Standard 2.9.5, is not supported by evidence of risk. This principle is also not included in the Ministerial policy guidelines.

129. INC is not aware of any evidence to support concerns regarding inappropriate access to any IFPSDU. Notably, IFPSMP for more serious disorders, diseases and conditions are normally provided under prescription and are therefore not generally available currently despite the Food Standards Code not restricting sale under Division 4. Nonetheless, INC would support trade and distribution restrictions consistent to that of Standard 2.9.5 for the sub-category of IFPSMP within a broader IFPSDU category as detailed above. Effectively this would cover the following products for premature and low birth weight infants, and products for serious disorders, diseases and medical conditions.

130. INC is concerned that a general restriction on sale means less accessibility to a range of products when they might be most needed and will only create stress and heightened concern for carers when dealing with distressed or sick infants. The last 18 months due to the COVID pandemic have been particularly stressful for carers in accessing necessary product. Restricted sale could potentially force carers to feed their babies alternatives that may not be suitable and could potentially be harmful.

131. The level of occurrence of functional gastrointestinal disorders (FGIDs) 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 FGIDs 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). With occurrence at the levels stated above, products for these conditions require greater access then can be provided in the pharmacy setting due to the limited shelf space provided for IFP and less access to the competitive pricing provided by the supermarket setting. In addition, pharmacies do not normally provide the same hours of access to products due to their limited opening hours or at home delivery.

5.7 Labelling of [IFPSDU including] IFPSMP

132. All the following statements refer to the broad IFPSDU category with an IFPSMP sub-category.

5.7.1 FSMP statements [from Standard 2.9.5]

133. FSANZ proposes to replace the labelling provisions for pre-term formula and IFPSDU for metabolic, immunological, renal, hepatic and malabsorptive conditions (except for lactose-free and low lactose formulas) with FSMP provisions in Standard 2.9.5—10(1)(a) to (f).

134. INC supports FSANZ's preliminary view to align all IFPSDU labelling provisions with FSMP provisions in Standard 2.9.5—10(1)(a) to (f) since these FSMP labelling requirements offer more flexibility and less prescriptive wording but also cover all necessary information for health care professionals and carers. For IFPSDU however, it would be more appropriate to use the current wording from Standard 2.9.1—14(2)(c) and state 'should' rather than 'must' The statement would read "should be used under medical supervision" as these are lower risk products. A statement about medical supervision is not currently required for products under the category for protein substitutes. It is appropriate for the IFPSMP sub-category for higher risk products to align with Standard 2.9.5 completely with a 'statement to the effect that the food must be used under medical supervision'. INC also supports not mandating the location of these statements on the label as this would not be aligned with Standard 2.9.5 nor internationally including with Codex.

135. INC agrees that the statements required under Standard 2.9.5—10(g), that the food is not for parenteral use, is unnecessary for IFPSDU and IFPSMP and supports FSANZ's preliminary view to not mandate this statement.

136. INC does not support IFPSDU that are nutritionally modified for lactose malabsorption or other conditions that are to be lactose free or low lactose being exempt from the statements in Standard 2.9.5—10(1)(a) to (f) and required to align with standard IFP labelling. INC believes that the labelling for these products should be consistent with

other IFPSDU. In certain circumstances, multiple nutritional modifications are made for multiple diseases, disorders and conditions and FSANZ should allow manufacturers to communicate this without confusing consumers and healthcare professionals.

5.7.2 Other advisory and warning statements in Standard 2.9.5

137. FSANZ proposes that replicating allergen declaration requirements and advisory and warning statements in Standard 2.9.5 —10(2) and (3) in Standard 2.9.1 for all infant formula products is unwarranted.

138. INC agrees that other than mandatory allergen labelling, none of these requirements are relevant to IFPSDU. Standard 1.2.3—6(4) explicitly allows flexibility for all 4 current categories of IFPSDU. As INC has previously raised, the need for flexibility to allow labels to align globally is incredibly important to facilitate trade and supports maintaining the current requirements which allow flexibility from the mandatory allergen format requirements for all IFPSDU.

5.7.3 Information relating to ingredients

139. FSANZ proposes to adopt an approach consistent with Standard 2.9.5—12 for information relating to ingredients to be made in accordance with Standard 1.2.4 or information that complies with EU or US regulations

140. INC supports FSANZ's view to adopt an approach consistent with Standard 2.9.5—12 for ingredients to be made in accordance with Standard 1.2.4 or in compliance with EU or US regulations for the IFSMP subcategory only. This approach allows flexibility to have global alignment of labels. To enable full alignment with Standard 2.9.5 Ingredients labelling, an exemption from Standard 1.2.10 Characterising ingredients and components of food, is also required.

5.7.4 Date Marking

141. FSANZ proposes to adopt an approach consistent with Standard 2.9.5—12(2) for date marking information to be made either in accordance with Standard 1.2.5 or for the words 'Expiry date' or similar words to be used on the label.

142. INC supports FSANZ's proposal to adopt an approach consistent with Standard 2.9.5—12(2) for all IFPSDU for date marking information to be made either in accordance with Standard 1.2.5 or for the words 'Expiry date' or similar words to be used. This allows for international alignment of labels.

5.7.5 Prescribed Name

143. FSANZ proposes that the prescribed name 'Infant formula' should not be required for all IFPSDU including the sub-category of IFPSMP and that no overarching name should be prescribed for this category. Generic provisions in Standard 1.2.2—2(1)(b) would apply to IFPSMP.

144. INC supports the prescribed name 'infant formula' and 'follow-on formula' not being required for IFPSMP sub-category only, and no overarching name being prescribed for all IFPSDU. Again, this is consistent internationally including with Codex. As proposed, the information under CP3 section 5.7.1 above proposed for the label, will include necessary information to describe the purpose. The name of these products will need to

meet Australian and New Zealand consumer law and provisions in Standard 1.2.2—2(1)(b) sufficient to indicate the true nature of the food.

5.7.6 Exemption from "breast is best for babies" warning statement

145. FSANZ proposes to apply the exemption from the 'breast milk is best' warning statement to all IFPSDU including the sub-category of IFPSMP

146. INC supports the exemption from the 'breast milk is best' warning statement but only for the IFPSMP sub-category. IFPSDU for less serious disorders, diseases and conditions currently voluntarily include this statement even though it may not be required under the Food Standards Code, particularly when these products are available at retailers and to be consistent with labelling of other infant formula products at retail level. IFPSDU available at retailers do not require an exemption.

5.7.7 Exemption from statement about offering foods in addition to IFPs

147. FSANZ proposes to extend the exemption from the statement about offering other foods in addition to IFPs to all IFPSDU including the sub-category of IFPSMP.

148. INC supports extending the exemption from the statement about offering other foods in addition to IFPs to IFPSMP sub-category only.

5.7.8 Statement that the infant formula product may be used from birth

149. FSANZ proposes to exempt all IFPSDU including the sub-category of IFPSMP from the requirement for a statement that the infant formula product may be used from birth.

150. INC does not support exempting all IFPSDU from the requirement for a statement that the infant formula product may be used from birth, but does support the view to exempt only the IFPSMP sub-category, noting that an age indication will be included on the label as proposed under section 5.7.1 in adopting Standard 2.9.5—10(1)(e) for IFPSDU which states that:

> "if the food has been formulated for a specific age group- a statement to the effect that the food is intended for persons within the specified age group".

151. INC also supports an exemption from Standard 2.9.1—19(4)(b) for follow-on formula from the requirement to add to the label: "the infant formula product should not be used for infants aged under the age of 6 months". Again this is covered under section 5.7.1 in the adoption of Standard 2.9.5—10 Labelling statements.

5.7.9 Labelling information on safe preparation and use

152. FSANZ proposes that the general directions for preparation and use requirements are appropriate for all IFPSDU including the sub-category of IFPSMP, and there are no additional, specific directions that should be mandated.

153. INC supports IFPSDU aligning with the general directions for preparation and use but does not support FSANZ's proposal that this applies to the sub-category of IFPSMP. As raised earlier in this submission, international alignment is incredibly important for clinical severe or potentially life-threatening diseases, disorders or medical conditions. INC supports an approach taken in Standard 2.9.5—9(g) directions for use or the storage of the food, if the food is of such a nature to require such directions for health or

safety reasons. Notably, neither EU nor Codex provide all these provisions and hence the request for flexibility with IFPSMP.

Other Labelling

154. To ensure alignment internationally and facilitate trade, INC also raises the following with regard to labelling that was not included in CP3. For the IFPSMP sub-category, INC supports:

- exemption from the requirement to state the specific source of protein as provided in Standard 2.9.1—23(1)(a)

- aligning with the nutrition information in accordance with Standard 2.9.5—13 which allows flexibility for global alignment of labels

- exemption from storage directions under Standard 2.9.1—22 to align with Standard 2.9.5—9 for global alignment of labels

- exemption for the warning statement for the IFPSMP sub-category for preparation. CP1 foreshadowed that the warning statement is proposed to be updated to:

  "Warning - follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of [powder/concentrate] or add anything to this formula except on medical advice. Incorrect preparation can make your baby very ill".

  If this exemption is not provided for the IFPSMP sub-category, it will result in products designed for severe conditions with global compositions and labels being non-compliant. Notably, these products are used under intense medical supervision. To have labels specific for Australia and New Zealand for severe conditions is likely to be commercially unviable for companies, putting this very vulnerable population at risk.

155. INC supports aligning with Standard 2.9.1—24 Prohibited representations for the IFSMP sub-category except from those aspects that are not internationally aligned.

Question 15. Do you support FSANZ's preliminary views for IFPSMP labelling? Why or why not? Please provide supporting detail and data for your position, where available?

156. INC agrees with the general principle of more alignment with Standard 2.9.5 however INC does not agree with FSANZ's preliminary views for IFPSMP labelling as we do not agree with the categorisation of all IFPSDU as IFPSMP. Adopting the same approach for both IFPSDU and products under Standard 2.9.5 for the sake of consistency with Standard 2.9.5, is not a risk-based approach and not supported by evidence of risk.

157. There is also no justification for products that are safe for healthy infants to be exempted from a range of labelling requirements.

158. INC has provided comment on FSANZ's preliminary views in CP3 Section 5.7 relevant to this question and also a summary of our position for labelling in the Annex accompanying this submission.

General Questions

General Question 1 How effective do you believe the current regulatory measures for IFPSDU are? How could they be made more effective? If you think the requirements should be changed to better manage risk, please explain how and why. Please provide supporting detail and data, where available

159. INC considers the current regulatory measures for IFPSDU have been effective. However, improvements can be made in relation to categorisation and INC supports a reduction in the number of categories. This approach aligns better internationally, will provide a more consistent composition and labelling approach across the category, and will reduce the current issues with overlap between categories. In addition, the introduction of a sub-category for IFPSMP would provide for more flexibility to accommodate additional variation in labelling and distribution for very specialised products imported into Australia and New Zealand and generally used in hospital settings and under intense medical supervision (as noted above).

160. INC is not aware of any evidence of risks not being appropriately managed under the current framework nor of any market failure. INC does not agree with concerns raised by submitters in regard to inappropriate access to IFPSDU. IFPSMP for more serious disorders, diseases and conditions are normally provided by prescription and otherwise would be hugely expensive to purchase. Therefore, they are not generally available currently, despite the Food Standards Code not restricting sale under Division 4. Nonetheless, INC would support trade and distribution restrictions consistent with that of Standard 2.9.5 for the sub-category of IFPSMP within a broader IFPSDU category as detailed above. This would cover products for premature and low birth weight infants, and products for serious diseases, disorders and medical conditions.

General Question 2 Do you consider that the options proposed in this paper will ensure that IFPSMP are safe, suitable and meet the nutritional requirements of the infants for whom they are intended? If not, please explain why and provide supporting data and detail, where available

161. INC agrees that the status quo could be improved but does not consider that the options proposed in this paper relating to a single category for IFPSDU enhance product safety or suitability to meet the nutritional requirements of the infants for whom they are intended because the current categories in Standard 2.9.1 do that now. Had that not been the case, the extensive delays in reviewing Standard 2.9.1 would be inexplicable and potentially of greater concern than for the Standard simply being in need of updating.

162. INC considers that creating a single category of IFPSDU at the highest risk management level does nothing for safety, suitability or meeting nutritional requirements that is not available currently. Instead, it adds unnecessary cost and restrictions, adds regulatory burden for low-risk products and limits their availability to consumers with no safety or suitability benefit. The proposed restrictions on distribution and market access would mean less accessibility to a range of low-risk products when they might be most needed and will create stress and heightened concern for carers when dealing with distressed or sick infants. This could potentially force carers to feed their babies alternatives that may not be suitable and could potentially be harmful. The last 18 months due to the COVID pandemic have been particularly stressful for carers in accessing necessary product and this proposal would exacerbate that stress.

163. INC is also concerned that additional requirements in the Food Standards Code and detailed guides for scientific evidence will create unnecessary misalignment internationally. This could result in products not being made available or create a significant delay in launching products in Australia or New Zealand for serious or life-threatening disorders, diseases and conditions. Very specialised products, where the composition varies significantly from IF requirements, for healthy infants already have the science reviewed as part of PBS and Pharmac listings. Neither FSANZ nor jurisdictional food regulators should be expected to, or need to, replicate the level of expertise necessary to review this information and it would be best for the relevant agencies to recognise that PBS and Pharmac review the science provided and anything further by FSANZ or jurisdictions would be duplicative.

General Question 3 How effective do you believe the options proposed for IFPSMP will be? How could they be made more effective? Do they place an unreasonable cost burden on industry to achieve and/or maintain compliance? Please provide supporting detail and data, where available.

164. There is no evidence of market failure, or health risk or safety reason for categorising all IFPSDU at so high a risk as to warrant more limited access. There is also no justification for products that are safe for otherwise healthy infants to be exempted from a range of labelling requirements.

165. We repeat our comments made above, that INC does not agree with a single category of IFPSDU restricted in sale where these products are for low-risk conditions. Adopting the same risk management approach for all IFPSDU in accordance with Standard 2.9.5 for the sake of consistency with Standard 2.9.5, is not supported by evidence of risk.

166. FSANZ states in CP3 that the restrictions under Standard 2.9.5 are part of their overall risk management strategy given their minimal prescribed composition. FSANZ also states that IFPSDU not required under prescription or used in the hospital setting would be based on compositional requirements for IF for healthy infants and therefore be safe and low risk. Including the same risk management strategy as Standard 2.9.5 by restricting sale for all IFPSDU is not appropriate given the composition requirements and low risk. INC has proposed a more risk-based framework with an IFSMP sub-category for which restrictions are justified.

167. INC has concerns about the cost burden for consumers that could result from limiting the availability of all IFPSDU and the regulatory burden involved. Typically, the grocery channel is more affordable for shoppers due to operational efficiencies and economies of scale meaning some parents/carers will be disadvantaged in their access of these products, due to increased cost. If access is restricted to the pharmacy/healthcare institution channels, the likely retail cost to the parent/carer will also increase due to mark-ups deployed by the pharmacy channel as retail pricing is at the sole discretion of the retailer.

168. INC is also concerned about the potential cost burden that could result from additional requirements in scientific evidence that is misaligned internationally. These products generally enter the market with significantly less volume because of their specialisation. This is why a reliance on global composition and international safety assessments ensures that they are available in Australia and New Zealand. Adding further requirements that deliver no additional benefit to safety and ultimately the consumer could lead to very reduced supply to this regional market. This could significantly delay the access to products for serious or life-threatening disorders, diseases or medical conditions. We cannot stress enough that these products form an extremely

small/minute segment of the market and adding unnecessary barriers to their availability could well see them exit.

Other Issues

Transition

169. As noted in INC's submission on Consultation Paper 2, INC proposes a transition period of 5 -years from manufacture date which also allows for stock in trade. INC considers this would be appropriate to avoid write off costs for labels and adding to unnecessary food-related wastage. As we note above, this is an extremely small/minute segment of the market where any wastage due to short compliance timings would be somewhat irresponsible. The timing for change is especially important given that composition and/or additive changes may be required in addition to the labelling changes implemented, and these will be required across all infant formula products, as a result of the revised Standard.

170. In relation to transition, some IFPSDU also need to regularly update reimbursement registrations which requires additional time and cost when changing formulations. This would require updating both PBS in Australia and Pharmac in New Zealand. PBS in particular currently costs over A$12,000 per product for changes to the formulation or over A$20,000 if it impacts the listing. It takes over 7 months for notification and acceptance. There is also the time and resources required to prepare submissions. This again highlights the complexity and cost for companies implementing labelling and formulation changes and is another reason that flexibility in labelling and composition for these highly specialised products and a significant transition period is needed.

Scoop

171. Standard 2.9.1—18 requires that powdered product must contain a scoop to enable the use of the infant formula product in accordance with the directions contained in the label on the package. INC supports an exemption from this for the IFPSMP sub-category. These products are used under intense medical supervision and some very specialised powder IFPSMP are used where the powder weight is advised from the health care professional and therefore providing a scoop is not appropriate.

REFERENCES

Comberiati P, Costagliola G, D'Elios S, Peroni D. Prevention of Food Allergy: The Significance of Early Introduction. *Medcina* 2019, 55(7), 323. https://doi.org/10.3390/medicina55070323

de Silva D, Halken S, Singh C, Muraro A, Angier E, Arasi S, Arshad H, Beyer K, Boyle R, du Toit G, Eigenmann P, Grimshaw K, Hoest A, Jones C, Khaleva E, Lack G, Szajewska H, Venter C, Verhasselt V, Roberts G. Preventing food allergy in infancy and childhood: systematic review of randomised controlled trials. European Academy of Allergy, Clinical Immunology Food Allergy, Anaphylaxis Guidelines Group. *Pediatric Allergy Immunology*. 2020 Oct;31(7):813-826. doi: 10.1111/pai.13273.

Fewtrell M, Bronsky J, Campoy C, Domellöf M, Embleton N, Fidler Mis N, Hojsak I, Hulst JM, Indrio F, Lapillonne A, Molgaard C. Complementary Feeding: A position paper by the European Society for Paediatric Gastroentolgy, epatology, and Nutrition (ESPGHAN) Committee on Nutrition. *Journal of Pediatric Gastroenterology and Nutrition*, 2017 Jan;64(1):119-132. doi: 10.1097/MPG.0000000000001454.

Heine RG. Food Allergy Prevention and Treatment by Targeted Nutrition. *Ann Nutr Metab,* 2018;72 Suppl 3:33-45. DOI: 10.1159/000487380

SakiharaT, Otsuji K, Arakaki Y, Hamada K, Sugiura S, Io K. Randomized trial of early infant formula introduction to prevent cow's milk allergy.
Journal of Allergy Clinical Immunology, 2021 Jan;147(1):224-232.e8.
DOI: 10.1016/j.jaci.2020.08.021

Schroer B, Groetch M, Mack DP, Venter C. Practical Challenges and Considerations for Early Introduction of Potential Food Allergens for Prevention of Food Allergy. Journal of Allergy Clinical Immunology Practice, 2021:9(1):44-56.e1.
DOI: 10.1016/j.jaip.2020.10.031

Zeevenhooven J, Koppen IJ, Benninga MA. (2017) The Rome IV criteria for functional gastrointestinal disorders in infants and toddlers. *Pediatric gastroenterology, hepatology and nutrition.* 20(1): 1-13. doi: 10.5223/pghn.2017.20.1.1