Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

31 May 2016

Food Standards Australia New Zealand
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Dear Sir/Madam

The Infant Nutrition Council (INC) appreciates the opportunity to make a submission on Consultation Paper - Proposal P1028 Review of Infant Formula.

INC is the association for the infant formula industry in Australia and New Zealand and represents manufacturers, marketers and brand owners who between them are responsible for more than 95% of the volume of infant formula manufactured, sold and exported in Australia and New Zealand.

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

The INC is a responsible body that voluntarily restricts its marketing practices to support government policies for the protection and promotion of breastfeeding. The companies represented by INC are:

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

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Associate Members:

- Abbott Nutrition Pty Ltd
- Australian Dairy Park Pty Ltd
- Bayer Ltd
- Bodco Dairy Ltd
- Burra Foods Pty Ltd
- Cambricare New Zealand Ltd
- Cargill Australia Pty Ltd
- Dairy Goat Co-operative Ltd
- DSM Ltd
- Fresco Nutrition Ltd
- GMP Dairy Ltd
- GrainCorp Ltd
- Jamestrong Packaging Pty Ltd
- Murray Goulburn Co-operative Co Ltd
- Peerless Foods Pty Ltd
- Nature One Dairy Pty Ltd
- New Image Group Pty Ltd
- New Zealand New Milk Ltd
- Nuchev Food Pty Ltd
- Sonoco Pty Ltd
- Snow Brand Australia Pty Ltd
- Tatura Milk Industries Pty Ltd
- The Infant Food Co. Ltd
- Westland Co-operative Dairy Company Ltd
- Yashili Dairy New Zealand Pty Ltd

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

Yours sincerely

Jan Carey
Chief Executive Officer

Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

PROPOSAL P1028 REVIEW OF INFANT FORMULA

Submission from the Australia New Zealand Infant Nutrition Council

31 May 2016

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Introduction

1. INC welcomes the opportunity to consider the issues and preliminary views proposed in the consultation paper for Proposal P1028, and to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the Consultation paper on the Regulation of Infant Formula. We thank FSANZ for the consideration of the comments, issues and views raised in this submission.

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

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

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

- consistency with the policy objectives outlined in other food-related policy decisions
- the provision of a safe and nutritious food
- a scientific, evidence-based approach which does not unnecessarily restrict the use of ingredients considered to be safe for use in general foods in infant formula
- flexible provisions in the food regulations, with minimal levels of prescription, 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 considering the number of issues raised by FSANZ, INC provides the following general views in the executive summary below, with more detailed responses to the questions asked by the Consultation paper to follow.

Executive Summary

Scope

7. INC recommends that the scope of Proposal P1028 is extended to cover infant formula products for special dietary use as Proposal P1028 will set the basis for composition of the these products (outside of nutritional modifications relevant for the condition).

Composition

8. For INC, harmonisation to the greatest extent possible with Codex and other relevant international standards is critical to ensuring the best science is applied to infant formula in Australia and New Zealand. The Codex work on infant formula reflects current views on nutritional requirements and safety provisions for infant formula. Alignment would also generally eliminate the prospect of trade barriers in the global infant formula market, especially if infant formula composition was able to be harmonised to Codex STAN 72-1981.

9. On **definitions**, INC supports the status quo should prevail until the follow-on formula requirements are reviewed.

10. On **protein**, INC concurs with FSANZ to maintain the minimum and maximum levels of protein (subject to correct conversion to per 100 kJ). For the calculation of protein, INC supports the conversion factor of 5.71 for soy protein sources with further consideration of the conversion factors for milk protein sources. INC agrees with FSANZ on protein quality methodology but the DIAAS method should be considered when more information is available. While INC agrees with FSANZ on the minimums for many amino acids, we suggest alignment with Codex STAN 72-1981 minimums for tyrosine, phenylalanine, methionine, and cysteine. INC considers the quality of protein important but compliance is not straightforward due to the natural variability in amino acid content of milk ingredients and minimising the quantity of excess, naturally occurring amino acids whilst meeting the minimums.

11. On **fat**, INC supports retaining the minimum and lowering the maximum of fat content to align with Codex STAN 72-1981 as proposed by FSANZ. On essential fatty acid composition and units of expression, INC identifies some areas where further work needs to be considered. We suggest the **primary** unit of expression for essential fatty acids for final products should be aligned to other nutrients (mg/100kJ) but suggest that as a secondary alternative, conversion to % total fatty acids also be provided along with assumptions used for calculation. We recommend that for medium chain tryglycerides (MCTs) to be permitted, in line with the rationale for permitting MCTs as a processing aid for infant formula and for use in infant formula products for special dietary use where addition is scientifically substantiated and clinically evaluated for the condition. INC does not support a lowering of the trans fatty acid content because of differences in definitions between the Food Standards Code and Codex.

12. In relation to **carbohydrates,** in the absence of specific safety concerns or evidence of adverse effects in infants and the absence of market failure, no limits should be specified. On definitions and calculations relevant to carbohydrate, INC agrees with FSANZ that the provisions in the revised Code are appropriate for infant formula.

13. In relation to **energy**, INC supports FSANZ's proposal to reduce the maximum energy amount to align with that in Codex STAN 72-1981.

14. On **vitamins, minerals and electrolytes**, INC strongly supports the continued use of non-binding GULs to serve as guidance for industry in designing formulations and therefore GULs should not be formally incorporated into Standard 2.9.1. Legally binding maximums should be used when there is evidence of the need for an upper level. INC therefore supports FSANZ's proposal that some nutrients to retain a GUL in Standard 2.9.1, and others be amended from a prescribed maximum to a GUL to align with Codex (as summarised in Table 7.2 of SD1).

15. INC mostly agrees with FSANZ in relation to many of the vitamins and minerals reviewed. On folate, INC notes that neither Codex nor the Food Standards Code (including Standard 2.9.1) use dietary folate equivalents (DFE) to express the folate content of infant formula. INC suggests alignment with Codex STAN 72-1981 to measure and express the content as folic acid.

16. INC agrees with the proposal to exclude β-carotene from the total amount of vitamin A but needs assurance that β-carotene can still be added into Infant formula. INC agrees to an increased GUL for vitamin C and the proposed minimum for vitamin D but recommends the vitamin D maximum is increased to align with the EU maximum on the basis that otherwise there is currently only a narrow common range between Codex STAN 72-1981 and the EU regulation on vitamin D which is too tight to allow product formulation and manufacture in compliance with both sets of requirements. INC agrees with the current minimum and maximum for iron and supports the status quo for zinc. On selenium, INC suggests retaining the current minimum but having a GUL for selenium and instead of a maximum for chromium and molybdenum, INC suggests that neither a minimum nor maximum or GUL need be set.

17. In relation to permitted forms of vitamins, minerals and electrolytes INC believes all the forms of nutrients permitted in Codex STAN 72-1981 should be permitted in Standard 2.9.1 for reasons of alignment, flexibility for manufacture and avoidance of trade barriers. INC's view is that these forms are safe to use and a technological justification is not necessary as these are added for essential nutritional function.

18. In relation to other **optional substances**, INC supports FSANZ's preliminary view that choline should be listed as a mandatory substance in infant formula and agrees to the minimum proposed but that the maximum should be a GUL. INC supports FSANZ's view that L-carnitine should be mandatory and supports the increased minimum but has significant manufacturing concerns with the proposed maximum, and suggests no maximum be set at this time. Legally binding maximums should be used only when there is evidence of the need for safety reasons and this is not the case for L-carnitine. INC supports the FSANZ preliminary view to mandate inclusion of inositol in infant formula at the current minimum level and supports the current maximum being a GUL. INC supports retention of combined totals of nucleotides in principle but the level of that combined total needs to be determined. It is also important that the Food Standards Code is clear that this limit applies only when nucleotides are added.

Safety and Food Technology

19. In general, INC supports all the FSANZ proposals relating to **directions to prepare bottles individually, directions for the storage of made up formula** (although the statement that it is safe to store prepared formula for up to 24 hours in the refrigerator needs clarification that it is not prescribed and that there is flexibility for the time limit to be for up to 24 hours), **directions on water used to reconstitute powdered infant formula**, **discarding leftover formula, directions for preparation and use, date marking of food**, and **storage instructions for opened infant formula**. INC strongly **opposes standardisation of measuring scoops** for the reasons FSANZ has identified. The powder

density of infant formula is affected by both the ingredients and the manufacturing process used and it is not possible for this to be standardised for all powdered infant formulas. INC considers **indicators on baby bottles to be out of scope** of the Australia New Zealand Food Standards Code.

20. In relation to **other warning, advisory and other statements**, INC supports maintaining the current **legibility requirements** for infant formula and the requirement that the infant formula label contain a statement of the **specific source, or sources, of protein** in the product. INC supports maintaining the **mandatory statement about protein source** and for it to be located immediately adjacent to the name of the infant formula (i.e. the prescribed name 'Infant Formula'). However, INC does not support prescribing where this should be located on the label.

21. INC supports the status quo in retaining all current **warning and advisory statements**. INC does not support additional warning statements in the absence of market failure or strong evidence that misuse is prevalent.

22. INC supports the status quo on the **statement that infant formula may be used from birth** and continuing the requirement for **'Infant Formula', as a prescribed name**.

23. In relation to **nutritive substances and novel foods,** Proposal P1024 excluded Standard 2.9.1 from its scope. INC strongly supports Standard 2.9.1 being included within the scope of Proposal P1024 and the framework proposed in the Proposal going forward. INC believes this is in line with the Policy Guideline on Infant Formula Products. Just as FSANZ drew on a wide range of expertise within FSANZ for the purposes of preparing this Consultation for the Review of Infant Formula, we believe a similar broad input needs to be applied to a broader approach for Proposal P1024.

24. In relation to **contaminants**, INC supports the views in relation to acrylonitrile, tin, vinyl chloride, arsenic and lead but considers that further consideration is needed in relation to aluminium. INC agrees with FSANZ view for melamine, not to introduce a regulatory requirement for this adulterant. INC believes that collocating all MLs for contaminants in a single Standard enhances transparency and usability. INC believes that the appropriate units for MLs relating to contaminants for infant formula should be based on mg/kg as sold. INC suggests that a definition of contaminant is not necessary in the Code.

25. In relation to **food additives**, where it is performing a technological function in the final product, INC considers that, in principle, it is preferable to be aligned with Codex to facilitate innovation and harmonisation of trade where safety and technological justification have already been established. In relation to **processing aids**, INC supports retaining the status quo for infant formula.

26. INC strongly supports **continuation of the carry-over principle for food additives in infant formula**. As well, INC supports alignment with Codex in relation to permitted carry-over additives as we noted in our submission on this issue in 2012. Codex does indeed permit additives that may be present in any food as a result of carry-over from a raw material or an ingredient. These are technologically necessary for the quality of the ingredient in the product.

Labelling

27. In relation to **provision of information**, INC maintains that the declaration of macronutrient sub-groups in a nutrition information statement is permitted and should be retained. To support informed choice, INC suggests that nutrient content and general level health claims on nutrients that allow for brand differentiation and informed choice for the

caregiver is permitted. INC believes this is in line with the Policy Guideline on Infant Formula Products and the WHO Code and its local adaptations (MAIF agreement and INC New Zealand Code of Practice).

28. **In relation to ingredients lists and nutrition information statements,** these are fundamentally different. INC does not support additional prescription on how nutrients are labelled. INC does not believe a **consistent format of nutrition statement** across product labels would reflect this nor assist consumer understanding of this information. A mandated format creates a real barrier to trade both for exports and imports.

Other issues

Conversion factors

29. INC has identified that the primary limits on nutrient composition specified in Codex STAN 72-1981 on a per 100 kcal basis have not all been correctly converted to a per 100kJ basis in this Codex standard. These errors have led to some values being applied in Standard 2.9.1 intended to be aligned with Codex being incorrectly stated. A number of the limits that require correction are documented in the relevant sections of this submission. A full list of values appears in Appendix 1.

Transitional Timings and other Infant Formula Products

30. This review is to support regulatory change, and INC requests any **transitional period** be of reasonable length to allow adequate time to implement changes, particularly for imported infant formula that is not manufactured in Australia and New Zealand.

31. Lastly, while the scope of Proposal P1028 relates to infant formulas only, it is considered that it will, in future proposals, underpin the review of the remaining infant formula products. INC requests that transitional arrangements are considered in the context of those products in Standard 2.9.1 that are not currently within scope of Proposal P1028.

32. As stated above, INC advocates for the scope of Proposal P1028 to be extended to cover infant formula products for special dietary use, but different transitional arrangements may be appropriate for these products if this scope change is implemented.

33. A summary of the key areas of where INC supports FSANZ's preliminary proposals is at Attachment A and a summary of key areas where INC does not agree with FSANZ or where a position is not presented in Proposal P1028 is at Attachment B.

Comments and Responses to Questions

Scope of consideration

34. Section 1.2.2 covering international and overseas regulations focuses on Codex Standards and Guidelines that are relevant to the nutrient composition of infant formula. INC considers that recent updates to the EU regulations covering infant formula and the EFSA guidance to this process are also pertinent to this review and makes reference to these within the submission.

35. A further important development that has occurred is the increased use of non-cow milk proteins in infant formula manufacture. Goat milk based formulas have undergone clinical evaluation leading to an EFSA opinion that goat milk protein is a suitable protein source for infant formula products, goat milk based formula are now produced by multiple manufacturers in New Zealand and Australia and there are also products being manufactured locally from sheep milk. Given these developments INC has highlighted some proposed limits that require reconsideration due to the different natural levels of some components in these milks compared to cows' milk and this is a topic that will be further addressed in individual company submissions.

Definitions and Nutrient Composition

Scope of Proposal P1028

36. INC notes that Proposal P1028 relates to infant formula (for infants aged 0-<12 months) only, and to all types of product whether in powder, liquid concentrate or 'ready to drink' form. We note also that:

- Follow-on formula is excluded
- Infant formula products for special dietary use are excluded
- The application of nutritive substances and novel foods as these apply to infant formula is included.

37. ***Follow-on formula:*** INC supports the rationale for excluding follow on formula for 6-12 months as covered by the current Standard 2.9.1 on the basis that follow-up formula is being reviewed by the Codex Committee on Nutrition and Foods for Special Dietary Uses. Alignment with the outcomes of that review when completed will be an important aspect of a subsequent review of Standard 2.9.1. So saying, INC recognises that the majority of the limits applied currently in Standard 2.9.1 apply to both infant and follow-on formulas. INC has therefore flagged some limits proposed for infant formula as either inappropriate for follow-on formula, or needing further consideration before being applied to follow-on as well as infant formulas. The proposed minimum for L-carnitine for infant formula is an example of the latter.

38. ***Infant formula products for special dietary use***: These products are based on the composition of infant formula for 0-12 months. INC believes there is no rationale for maintaining the current standard for these products. Any amendments made to composition should also apply to infant formula products for special dietary use. However, since many of these products are low volume and/or imported, a longer transition time for implementation of revised requirements could be required for this category compared to other infant formula products. The proposed minimum for iron for infant formula is an example of the latter.

39. ***Application of nutritive substances and novel foods***: INC strongly supports 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 Consultation for the Review of Infant Formula, we believe a similar broad input needs to be applied to a broader approach for Proposal P1024.

40. The INC submission on Proposal P1024 described how the issues and problems identified in that Proposal 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 infant formula products, particularly in relation to definitional issues. INC therefore considered Options 1 (no change) and 2 (amend the current definitions) did not advance the system at all and risked perpetuating the problems and issues into the future. INC therefore proposed that, with appropriate differentiation, the framework proposed in Option 3 (although it required further development) should be applied to Standard 2.9.1. INC identified areas of differentiation designed to address the vulnerability of the target population who are consuming infant formula products.

41. ***Technical corrections***: INC has identified that the primary limits on nutrient composition specified in Codex STAN 72-1981 on a per 100 kcal basis have not all been correctly converted to a per 100 kJ basis in this Codex standard. This issue was notified to CCNFSDU37 held in November 2015. These errors have led to some values being applied in Standard 2.9.1 (intended to be aligned with Codex) being incorrectly stated. The inconsistencies that result from these incorrect conversion calculations create barriers to trade.

42. Some limits that require correction are documented in the relevant sections of this submission and Appendix 1 while others will need to be identified over time. INC would prefer for these technical corrections to be made as soon as possible rather than waiting for the changes from Proposal P1028 to be implemented. If a suitable process is available (such as through the technical amendment process), INC would be very pleased to assist FSANZ to rectify these errors.

Q1.1 For all views presented in this SD, do you agree with FSANZ's preliminary view? * If so, indicate this in your submission and provide your reasons where appropriate. * If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

43. **INC Response:** See the following submission. In many cases, INC agrees with FSANZ's preliminary view (Attachment A for a summary). Where INC does not agree (Attachment B for a summary), reasons are provided as requested.

Definitions and terminology

44. ***Definition of Infant Formula Products***: The definition in the revised Food Standards Code is:

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

45. FSANZ proposes making no further amendment to the definition. INC supports this position and believes the definition is clear.

46. ***Definition of Infant Formula***: FSANZ reports on some confusion around the age range of the infant formula (in relation to the follow-on formula product categories). Stakeholders proposed alternative definitions for consideration which could provide clarity by eliminating the confusion around age range. The current definition is:

"infant formula means an infant formula product that:

(a) is represented as a breast-milk substitute for infants; and

(b) satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months."

47. INC supports the status quo. Our preliminary view is that while there is an overlap between the 0-12 month range for infant formula and the 6-12 month follow-on formula range, it is not appropriate to change the infant formula age range now. Currently, the 6-12 month follow-on formula composition diverges from infant formula in only a few key areas. Should a review of follow-on composition in Standard 2.9.1 reflect more differences, then the overlap could be worthy of revisiting at that time.

48. The nutrient requirements of infants change as they develop as evidenced by the change in breast-milk composition that occurs over time and the need to complement breast-milk with other foods for infants from around 6 months of age. INC considers that it is important to retain the opportunity to offer caregivers follow-on products with a nutrient composition more closely aligned with the nutrient requirements of older infants from 6-12 months than infant formula.

49. For most infants from around 6 months, a follow-on formula provides the better formula composition for developmental needs such as in relation to iron. However, the use of infant formula to 12 months is justified in some cases – the issue is one of individual infant needs and the availability of infant formula suitable for situations outside the norm. Having infant formula for infants 0-12 months does not preclude follow-on formula for older infants 6-12 months depending on the infant's needs. This arrangement is reflected in the current Standard.

Q1.2 Which of the following options to amend the definition (b) of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula? (1) "satisfies by itself the nutritional requirements of infants less than 6 months of age" (2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding " (3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of infants from 6 months of age (4) no change.

50. **INC Response**: INC considers that the definition of 'infant formula' in the revised Code, and set out above is appropriate and agrees with FSANZ that this be retained.

Composition

Protein

51. ***Content***: FSANZ notes that protein amounts are generally aligned with Codex but that there is growing interest in lowering the requirements to potentially lower the risk of obesity in childhood. FSANZ considers that more evidence is required to demonstrate the advantages of lower protein intakes for infants and INC concurs at this time.

52. INC notes that FSANZ considers the protein levels are 'identical' to those in Codex STAN 72-1981 but they are not identical to the primary protein levels specified per 100kcal due to incorrect conversion to per 100kJ in this Codex standard (refer to the section under Other Issues on Conversion Factors on page 80). INC therefore requests that technical amendments be made to both the minimum and maximum levels for protein as follows:

- minimum protein level to be corrected from 0.45 g/100 kJ to 0.43 g/100 kJ, consistent with 1.8 g/100 kcal which is the resultant value when using the FSANZ standard conversion factor of 4.18.
- maximum protein level to be corrected from 0.7 g/100 kJ to 0.72 g/100 kJ consistent with 3.0g/100 kcal when using the FSANZ standard conversion factor of 4.18.

Q1.3 Do you support a higher minimum of 0.5 g/100 kJ for infant formula based on isolated soy protein? Please provide your rationale?

53. **INC Response**: The current minimum (and maximum) for protein in infant formula, based on isolated soy protein, is the same for all product sources. The minimum is therefore 0.45 g/100 kJ (which must be corrected to 0.43 g/100 kJ, consistent with 1.8 g/100 kcal).

54. As FSANZ notes, INC is not aware of any indications that soy-based formulas formulated under either the Codex STAN 72-1981 or Standard 2.9.1 are unable to meet nutritional needs to support normal growth and development. The provisions in Standard 2.9.1 have been in place for many years without evidence of issues related to protein source levels. On this basis, INC does not support a higher minimum for soy-based formulas. However, the current conversion factor for soy is 6.25. If that was to change to 5.71 as is being considered, then this would have a consequential impact on the isolated soy protein content, effectively increasing the minimum level by 10%. If this change is implemented, INC advocates for retaining the same protein limits as in Codex and fully aligning the requirements specified in Standard 2.9.1 by implementing the technical corrections INC is requesting and listed in Attachment A.

55. ***Calculation of protein: nitrogen conversion factors***: Currently Standard 2.9.1 specifies two nitrogen conversion factors: 6.38 for milk proteins and 6.25 for all other protein sources. FSANZ proposes that only two factors should continue to be specified: the conversion factor of 6.25 should apply to mammalian milk and the conversion factor for soy protein sources should be 5.71. Australian and New Zealand infant formula manufacturers have been managing the use of the two alternative nitrogen conversion factors of 6.38 and 6.25 for milk-based formulas since the 2007 revision of the Codex STAN 72-1981 which adopted the use of the factor 6.25 for infant formula products.

56. Some INC members have a preference for a milk protein conversion factor of 6.38, others a preference for 6.25 reflecting the different scope of global activities of individual member companies and the most appropriate factor for internal consistency. Codex STAN

72-1981 has provisions for all three conversion factors (6.38, 6.25 and 5.71) noting that the minimum and maximum for protein in Codex are based on the nitrogen conversion factor of 6.25.

57. Almost all INC members support the nitrogen conversion factor for soy proposed by FSANZ of 5.71 being added to Standard 2.9.1.

58. The conversion factor of 6.38 is used globally for buying and selling milk protein and to report analytical protein results for milk products as appropriate given this is the nitrogen conversion factor generally established by Codex for milk products. The conversion factor of 6.38 is used for label declarations of protein content in Australian and New Zealand milk-based infant formula as per Standard 2.9.1.

59. However, for other markets where 6.25 is the conversion factor specified for use for milk-based infant formula products, for example in the EU which requires 6.25 as the conversion factor for the protein minimum and maximum, the label declarations for protein for these markets must be calculated using this factor. This effectively shifts the minimum and maximum protein limits which apply to a minor extent. The label declarations for carbohydrate calculated "by difference" also change to accommodate use of this factor. As shown in Table 1, the differences in declared values are small when stated per 100ml of prepared formula.

Table1: Example of impact of change from use of conversion factor 6.38 to 6.25 on declared composition for milk-based formula per 100g of powder and per 100ml prepared formula

	NCF of 6.38		**NCF of 6.25**	
	Per 100g powder	Per 100ml	Per 100g powder	Per 100ml
Protein	10.3	1.3	10.1	1.3
Carbohydrate (where calculated by difference)	57.2	7.4	57.4	7.5

60. INC members who suggest retention of the conversion factor of 6.38 consider this is the science-based approach, with this conversion factor for milk protein products and the nitrogen conversion factor of 5.71 for soy protein products having been well-established and documented (International Dairy Federation (IDF) Bulletin 482, 2016; Maubois & Lorient, 2016). These INC members also note that the proposed move to exclude the science based nitrogen conversion factor for milk-based formula of 6.38, while at the same time as recommending adoption of science based nitrogen conversion factor for soy, is seen by many members as inconsistent.

61. Such INC members point out that the use of conversion factors of 6.38 and 5.71 is consistent with the opinions of the New Zealand delegation[1] to the 37th session of CCMAS (Feb 2016).

62. Many INC members consider that the practical importance of including science based nitrogen conversion factors has been widely recognised:

- The physical Working Group on endorsement of Methods of Analysis and Sampling at the 37th session of CCMAS recognised that:

[1] Furthermore, CX/NFSDU 04/6-Add.1. Agenda Item 5b. Outlines the 2004 NZ rationale supporting a NCF of 6.38 for milk protein based Infant Formula.

"*the [nitrogen conversion] factors have severe economic aspects*."

- IDF Bulletin 482 (2016) draws attention to the fact that the determination of protein is important in terms of both nutrition and sustainability:

  "*There is growing interest in the complex relationship between nutrition and environmental sustainability … and this relationship is a significant feature of the United Nations Sustainable Development Goals …"*

63. INC members who suggest a conversion factor of 6.25 recognise this as the well-established compromise since every infant formula has different protein contributions. The compromise was established for infant formula as it obviates the need for calculating different nitrogen conversion factors for different formulations (Koletzko, 2005; EFSA, 2014). These members highlight that a conversion factor of 6.25 has been used to establish other standards such as EU and consider this will give greater flexibility to trade.

64. In summary, almost all INC members support the nitrogen conversion factor of 5.71 for soy protein infant formula, and some INC members support retention of the conversion factor of 6.38 for milk protein infant formula, and others 6.25. FSANZ may wish to consider including both nitrogen conversion factors of 6.38 and 6.25 for milk protein/mammalian milk to address specific market needs and a nitrogen conversion factor of 5.71 for soy protein based formulas.

65. ***Protein source***: Standard 2.9.1 does not specify the source of protein that can be used; the definition of an infant formula product requires that the product must be based on milk or other edible food constituents of animal or plant origin. INC considers that the current approach to sources of protein is appropriate and reflective of current practices providing the current approach of putting emphasis on protein quality is maintained.

66. ***Protein quality***: A recent FAO/WHO report recommended the Digestible Indispensable Amino Acid Score (DIAAS) as a protein quality calculation methodology. FSANZ considers that the amino acid composition of breast milk should still be the reference for determining an infant's amino acid requirements, a position that aligns with Codex. INC agrees with FSANZ's preliminary view that the amino acid breast milk reference pattern with the suggested modifications should remain in Standard 2.9.1 (S29-6). This amino acid reference pattern however should be reassessed at such time as a supporting framework enabling full implementation of the DIAAS protein scoring system method has been completed.

67. The FAO has acknowledged the importance of using human milk as the scoring pattern for protein quality in infants for a number of years (FAO/WHO, 1991), and considers the growth a state of a breast fed infant as the normative standard for this age. The FAO has also acknowledged that the digestibility and bioavailability of amino acids are important factors as not all dietary proteins are digested and utilised to the same extent (FAO/WHO, 1991). A number of regulatory agencies acknowledge this and require adjustment for the quality of the protein, either for infant formula, follow-on formula or foods for special medial purposes (Lewis, 2012) and Codex had previously required quality evaluation for infant formula, in addition to meeting the breast milk amino acid pattern.

68. In 2013, an FAO Expert Consultation on dietary protein quality was held. The expert consultation provided an update and improvements to the Protein Digestibility Corrected Amino Acid Score (PDCAAS) method for measuring dietary protein quality, referred to as the DIAAS method. The key findings of the FAO Expert Consultation report that relate to Proposal P1028 are that dietary amino acids should be treated as individual nutrients, and that, for regulatory purposes, two amino acid scoring patterns are recommended: birth to 6

months; and 6-36 months, and that if protein quality of follow-up formula needs to be assessed then the most up-to-date method should be used.

69. The DIAAS methodology maintains that the breast milk pattern is still the desired target for infant formula, however, the DIAAS methodology provides understanding of whether the protein provides available amino acids to meet the requirements of infants. The FAO Expert Working Group's report (2014) recommended the adoption of the DIAAS method by Codex. However the FAO Expert Working Group also recognised that there was further work to be completed to ensure a supporting framework to enable full implementation of the DIAAS method.

70. PDCAAS (WHO/FAO 1991) is not suitable as a protein quality calculation methodology for use in infant formula or follow-on formula. This is because it is based around the ability of a protein to meet the nutritional requirements of a 2-5 year old child.

71. In summary, the PDCAAS method is unsuitable for infant formula products and it is not appropriate to adopt the DIAAS method at this stage. INC notes that the DIAAS method continues to be developed and when more information is available, the DIAAS method should be considered further to be the protein quality calculation methodology.

72. ***Amino acid content***: The minimum requirements for amino acids in infant formula are mainly based on 'typical' amino acid profiles of breast milk. Some differences exist between the minimum amount of some of the 11 required amino acids in Standard 2.9.1 and Codex STAN 72-1981.

73. INC agrees with the FSANZ proposal to align the minimum levels of isoleucine, leucine, lysine, threonine, tryptophan and valine with those in Codex STAN 72-1981.

74. FSANZ is proposing to maintain the current expression for two sulphur amino acids (SAAs – cysteine or cystine and methionine) and aromatic amino acids (AAAs – phenylalanine and tyrosine) in specifying the minimum for cysteine and phenylalanine and the summed values of the SAAs and AAAs because the expression is clear and not subject to possible misinterpretation. In addition, FSANZ is proposing to retain the current minimums for the SAAs and AAAs in Standard 2.9.1.

75. INC does not agree with the FSANZ preliminary position to retain the current expressions for the amino acids minimums for tyrosine, phenylalanine, methionine, and cysteine. INC considers the quality of protein important but compliance is not straightforward. This is due to the natural variability in amino acid content of milk ingredients and minimising the quantity of excess, naturally occurring amino acids whilst meeting the minimums.

76. INC proposes that the requirements for the amino acids tyrosine, phenylalanine, methionine, and cysteine are amended to be consistent with Codex STAN 72-1981. The Codex minimum amino acid requirements are based on more recent data for breast milk composition. INC notes that the average content of human milk is:

9 mg cysteine/100kJ;
6mg methionine/100kJ and
a ratio of methionine:cysteine around 0.8.

77. INC considers that Codex STAN 72-1981 allows either individual minimums of 9mg cysteine/100kJ and 6 mg/100kJ methionine or a combined total of 15 mg/100kJ provided the methionine:cysteine ratio is less than 2 (or in the case of that the ratio is between 2:1 and 3:1, the suitability of the formula has to be demonstrated by clinical testing). These

levels are safe for infants and INC suggests consistency with Codex STAN 72-1981 can be achieved in at least one of two ways with the same outcome. The intention is to find a way of expressing the methionine/cysteine/cystine requirement that removes the need for a footnote as is currently used in Codex. INC recognises that the expression of this provision in Standard 2.9.1 might be different but presents two examples for consideration, taking cysteine and methionine as the example.

78. **For Example 1**: The specific levels for cysteine/cysteine and methionine are applied then the ratio and a total amount for cysteine/cysteine and methionine is NOT ALSO applied. However, where the ratio of methionine:cysteine/cystine is less than 2:1 (or up to 3:1 where suitability of formula demonstrated by clinical evaluation) then a total of methionine AND cysteine/cystine can be used instead of the specific minimum levels for cysteine/cystime and methionine. This might be expressed as follows:

Example 1 (more closely reflects how requirements are specified in the Codex STAN 72-1981)

L-amino acid	Minimum amount per 100kJ
Cysteine & cystine	9mg
Methionine	6mg

OR, where methionine:cysteine & cystine ratio < 2:1 (or up to 3:1 where suitability of formula demonstrated by clinical evaluation) then

Cysteine, cystine & methionine	15mg

79. **For Example 2**: A total of methionine AND cysteine/cysteine is mandated, then specific levels of methionine and cysteine/cysteine are NOT mandated unless the methionine:cysteine/cystine ratio is greater than 2:1 (or unless suitability of formula demonstrated by clinically evaluation). In this latter situation the specific minimums which apply are set as cysteine & cystine 9mg and methionine 6mg. This might be expressed as follows:

Example 2 (Codex requirements rearranged)

L-amino acid	Minimum amount per 100kJ
Cysteine, cystine & methionine	15mg

OR, where methionine:cysteine & cystine ratio >2:1 (unless suitability of formula demonstrated by clinically evaluation)

Cysteine & cystine	9mg
Methionine	6mg.

80. One interpretation of the current Standard 2.9.1 expression of SAA requirements is that it encourages a higher methionine amount and a higher methionine:cysteine ratio than occurs in breastmilk – where cysteine is at the minimum of 6 mg/100kJ, methionine would need to make up the balance (13mg/100ml) whether naturally occurring or fortified, leading to a ratio of 2:17. This is due to the higher minimum for the combined total of these amino acids required by Standard 2.9.1.

81. The SAA requirements set-out in Codex STAN 72-1981 encourage levels and a ratio more closely in line with breast milk. The preference is a minimum of 9 mg/100 kJ of cysteine and 6 mg/100 kJ of methionine leading to a ratio close to 0.67. Or where the footnote is applied, this could be a cysteine amount of 6 mg/100 kJ and a methionine amount of 9 or 12 mg/100 kJ and a ratio of 1.5 or 2 respectively, both of which are closer to breast milk than the FSANZ expression.

82. Achieving a cysteine amount of 9 mg/100 kJ is not feasible using some milk proteins within the range of total protein permitted. Hence, the inclusion of a combined total together with a ratio is important to avoid unnecessary fortification with cysteine.

83. The additional note regarding clinical evaluation of suitability for formulas with methionine to cysteine ratios between 2:1 and 3:1 is also important. This approach ensures regulations applied do not inadvertently lead to compliance issues for formulas developed with lower protein contents more closely aligned to protein levels in breast milk that have been clinically demonstrated as suitable to support infant growth and development.

84. In addition the current SAA requirements in Standard 2.9.1 create a barrier to trade with other international markets, examples of which will be provided by individual member companies as Commercial-in-Confidence information.

85. For consistency, INC also recommends aligning with Codex requirements for the two aromatic amino acids (AAA) phenylalanine and tyrosine. Given that Codex does not include different requirements based on the ratio of these amino acids, INC recommends applying a minimum of 19mg/100kJ for phenylalanine and 37mg/100kJ for phenylalanine and tyrosine. So saying the current requirements for AAA in Standard 2.9.1 involve lower minimums and do not pose any barrier to trade in the same way as the current SAA requirements in Standard 2.9.1.

Fat

86. ***Fat content***: INC supports retaining the minimum and lowering the maximum to align with Codex STAN 72-1981 as proposed by FSANZ.

87. ***Essential fatty acid composition***: Overall, FSANZ considers that alignment with Codex STAN 72-1981 is appropriate and unlikely to pose a risk to infants for the following essential fatty acids provisions:

*maximum (GUL) for LA
*minimum amount for ALA
*no prescribed maximum for ALA
*LA: ALA ratio range.

88. ***Maximum (GUL) for LA***: INC can accept the replacement of the maximum in Standard 2.9.1 with the lower GUL in Codex STAN 72 -1981.

89. ***Minimum LA -*** On the basis of evidence, FSANZ supports maintaining the Standard 2.9.1 minimum amount for LA rather than aligning with Codex. INC has reservations with this position and prefers to align with the minimum stated in Codex STAN-72 1981 of 70mg/100kJ.

90. ***LA:ALA ratio range*** – INC supports FSANZ's preliminary view to align with the range specified in Codex STAN 72-1981.

91. The requirements for LA and ALA in Standard 2.9.1 are expressed as a proportion of total fatty acids. Codex STAN 72-1981 expresses the essential fatty acid requirements as an amount per energy unit. FSANZ proposes to continue to require the amount of essential fatty acids be expressed as a proportion of total fatty acids. As stated above, INC prefers the **primary** expression on an energy basis for final product in alignment with Codex, but suggests also, as a secondary alternative, stating levels as % fatty acids based on a set of stated assumptions because this alternative mode of expression can be very helpful in some circumstances.

92. ***Units of expression***: INC considers that the units of expression should be expressed in terms of absolute values per 100 kJ of energy. Amending these requirements from a percentage of fatty acids to an energy basis would not only align with the Codex

STAN 72-1981 but better align with general practice and facilitate comparison between different regulations. However, expression on a fatty acid basis is also very useful in certain circumstances such as raw material specifications and generally will continue to be used for this purpose. INC therefore proposes the primary expression for final product be per 100kJ of energy.

93. The following tables were used to confirm the calculations included in the consultation documents.

Table 2: Codex and Food Standards Code levels of fats and fatty acids

	Codex STAN 72-1981	
	Minimum	Maximum
LA (mg/100kJ)	70	330 (GUL)
*LA (g/day)	1.9	9.1
ALA (mg/100kJ)	12	NS
*ALA (mg/day)	330	

*assuming an average energy intake of 2725kJ per day

	Standard 2.9.1		
	Minimum	Maximum (current)	Maximum (proposed)
	Standard 2.9.1	Standard 2.9.1	Standard 2.9.1
Total fat (g/100kJ)	1.05	1.5	1.4
Total FA (g/100kJ)	0.9975	1.425	1.33
LA (% of total FA)	9	26	26
LA (mg/100kJ)	90	370.5	345.8
LA (g/day)	2.5	10.0	9.4

Q1.4 Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale.

94. **INC Response:** In section 4.3 of SD1 FSANZ 's preliminary view is to align the requirements for linoleic acid (LA) and alpha-linolenic acid (ALA) with those in Codex STAN 72-1981, but with the note that the Codex minimum LA amount needs further consideration.

95. Given this note in relation to the LA minimum, INC has given this issue careful consideration.

Table 3: Mandatory essential fatty acid requirements (bold as specified in regulation concerned, otherwise calculated)

Fatty acid	**Standard 2.9.1 Min-Max**	**EU regulations (2016) Min-Max**	**Codex STAN 72-1981 Min-Max**	**INC's recommendations for revised Standard 2.9.1**
Linoleic acid (LA)	**9-26% total FA** 90-371 mg/100kJ 377-1600 mg/100 kcal	**120-300 mg/100kJ** **500-1200 mg/100kcal** *Previously 300-1200 mg/100kcal*	**70-330 (GUL) mg/100kJ** **300-1400 (GUL) mg/100kcal**	**70-330 (GUL) mg/100kJ**

Fatty acid (Cont)	**Standard 2.9.1 Min-Max**	**EU regulations (2016) Min-Max**	**Codex STAN 72-1981 Min-Max**	**INC's recommendations for revised Standard 2.9.1**
Alpha-linolenic acid (ALA)	**1.1-4% total FA** 11-57 mg/100kJ 46-240 mg/100 kcal	**12-24 mg/100kJ 50-100 mg/100kcal** *Previously 50-NS mg/100kcal*	**12-NS mg/100kJ 50- NS mg/100kcal**	**12-NS mg/100kJ**
LA:ALA ratio	**5:1-15.1**	NS *Previously 5:1-15:1*	**5:1-15.1**	**5:1-15.1**
DHA	**Optional**	**4.8-12mg/100kJ** 20-50mg/100kcal	Optional	**Optional** (refer to response to LCPUFA proposals for detailed comments and recommendations)

Assumptions: fat range of 1.05 to 1.5g/100kJ applies in Standard 2.9.1; proposed to be amended to 1.4g/100kJ in revised Standard 2.9.1; fatty acids comprise 95% of fat; fat provides 37kJ/g.

96. The composition of these fatty acids is quite variable and manufacturers have to target levels well within the range. If the minimum is too high, it is very difficult to achieve the ratio. The EU removed the ratio but manages the outcome through maximums, based on mean data not the range.

97. The international expert group that informed the review of Codex STAN 72-1981 (prior to its revision in 2007 – Koletzko et al, 2005) advised that:

> "A linoleic acid (18:2n-6) content of 300 mg/100 kcal (about 2.7% of energy intake) suffices to cover the minimum linoleic acid requirement,"

98. But the basis for this conclusion is not elaborated. The data in Table 4 below is sourced from Koletzko et al, 2001 (which is in turn adapted from Koletzko et al, 1992) and provides a basis for this conclusion. The minimum set is at the lower end of levels experienced in breast milk of European women at this time.

Table 4: Fatty acid and linoleic acid levels

Fatty acid	Europe (from 14 studies) wt/wt%fatty acids median (range)	Africa (from 10 studies) wt/wt%fatty acids median (range)	Europe Min* calculated in mg/100kJ (%E) applying median and min levels	Africa Min* calculated in mg/100kJ (%E) applying median and min levels
LA C18:2n-6	11.0 (6.9-16.4)	12.0 (5.7 – 17.2)	Median Min 69 (2.6)	Median Min 57 (2.1)

Assumptions: fat min 1.05g/100kJ; fat provides 37kJ/g.

* Using median: Min % fatty acids = 1050*95/100*11.0/100 mg/100kJ =110 mg/100kJ OR 4.1% E
Using min: Min % fatty acids = 1050*95/100*6.9/100 mg/100KJ= 69mg/100kJ OR 2.6% E

** Using median: Min % fatty acids = 1050*95/100*12.0/100 mg/100kJ =120 mg/100kJ OR 4.4% E
Using min: Min % fatty acids = 1050*95/100*5.7/100 mg/100KJ= 57mg/100kJ OR 2.1% E

99. The current FSANZ minimum requirement for LA is about 3.4% of energy which is well above the minimum levels recorded in these references for both Europe and Africa. The NHMRC and MOH adequate intake (AI) of 4.4g per day of n-6 polyunsaturated fatty acids is not met by Standard 2.9.1 provision for linoleic acid minimum of 9% of total fatty acids or the Codex minimum of 70 mg/100 kJ. But the AI is for all n-6 polyunsaturated fatty acids not just linoleic acid.

100. INC also notes the recent changes to LA and LN requirements made in the EU regulations but does not recommend that the new EU minimum requirement for LA be applied in Australia and New Zealand. EFSA 2013, the publication which foreshadowed the recent changes to the EU infant formula regulations states:

> "The Panel decided previously not to set a DRV for n-6 PUFAs or n-3 PUFAs in general, but set an AI for LA of 4 E% and an AI for ALA of 0.5 E% for all age groups [0-36 months] based on the lowest estimated mean intakes of LA and ALA, respectively, in different population groups in various European countries, that were not accompanied by LA or ALA deficiency symptoms (EFSA NDA Panel, 2010f)."

And further:

> "The Panel considers that intakes of total fat, essential fatty acids and n-3 PUFA as depicted in Table 5 are adequate for the majority of infants and young children from 0 to < 36 months."

Table 5: Intakes of fat, essential fatty acids and LC-PUFAs considered adequate for the majority of infants and young children

Age (months	Total fat (E%)	LA (E%)	ALA (E%)	DHA (mg/day)	DHA + EPA (mg/day)	ARA (mg/day)
0 to<6	50-55	4	0.5	100	--	140
6 to<12	40	4	0.5	100	--	--
12 to<24	35-40	4	0.5	100	--	--
24 to<36	35-40	4	0.5	--	250	--

Source: EFSA 2013

101. The amount of LA and ALA needed to provide 4% and 0.5% of total energy respectively (assuming both have an energy content of 9 kcal/g) is 440 mg/100 kcal (105 mg/100 kJ) and 55 mg/100 kcal (13 mg/100 kJ). INC notes the LA required to provide 4% of energy is below the new minimum level applied within the EU but the ALA needed to provide 0.5% of total energy is higher than the minimum applied for ARA.

102. INC is of the view that higher minimum levels for linoleic acid may be appropriate where DHA minimum levels are specified that mandate DHA addition to infant formula, but not for Standard 2.9.1 where this is not the case currently or being proposed. This is because the ability of infants to produce DHA from n-3 LCPUFAs in the diet is reduced if the LA:ALA ratio is too high.

103. A review article on the conversions of LA and ALA to LCPUFAs with a focus on pregnancy, lactation and first 2 years of life (Gibson et al, 2011) concludes that diets low in n-6 polyunsaturated fatty acids allow better endogenous conversion of ALA to n-3 long chain polyunsaturated fatty acids and permit better accumulation of n-3 LCPUFS into tissues. Makrides et al 2000, concluded that the ratio of LA:ALA should be < 6:1 in non-DHA fortified infant formula to improve the DHA status of formula fed babies.

104. If the minimum level of LA is set too high, this limits the ability of manufacturers to produce infant formulas with LA:ALA ratios at the lower end of the 5:1-15:1 range generally

accepted as appropriate to maintain a proper balance between LA and ALA as well as the LC-PUFA's and eicosanoids resulting from their metabolism (Koletzko et al, 2005).

105. In this context it is important that the natural variation of fatty acid levels within ingredients is taken into account. In order for all production to comply with the requirements set, manufacturers must target levels higher than the minimum levels and lower than the maximum levels specified. For example, if a level of 20 mg ALA per 100kJ is sought and targeted (this being higher than the AI for ALA according to the EFSA 2013 and 20% below the maximum ALA level now applied in the EU), to achieve a LA:ALA of 5.5 the level of LA required to be targeted is 110 mg/100 kJ. The application of the LA minimum in Standard 2.9.1 of 90 mg/100 kJ allows this level to be targeted, but this would not be possible if the new EU minimum level of 120 mg/100 kJ was applied. The application of the LA minimum in Codex STAN 72 1981 allows for ratios of LA:ALA less than 6:1 without needing to target levels of ALA as close as possible to the maximum levels specified.

106. INC acknowledges that the minimum LA requirement in Codex STAN 72-1981 appears to have been set close to the minimum levels found in breast-milk pre-1992 but is not aware of any safety issues arising from the application of the LA and ALA requirements specified in Codex STAN 72-1981. INC also notes that the general upward trend in LA consumption in the general population is likely to be reflected in more recent breast milk composition data. Given the advantages of harmonisation with Codex, INC recommends that these Codex requirements are adopted when Standard 2.9.1 is revised as a result of changes proposed in Proposal P1028.

107. INC therefore recommends all requirements for LA and ALA in the revised Standard 2.9.1 are aligned with those in the Codex STAN 72-1981 as listed in Table 3 above.

108. ***Long chain polyunsaturated fatty acids (LC-PUFAs)***: INC supports in principle the retention of a voluntary permission for DHA as this is unlikely to pose a risk to the infant. INC's 'support in principle' is predicated on consideration of the text that FSANZ proposes in the standard.

109. This is because FSANZ states that maintaining the permissions as they are stated in Standard 2.9.1 may provide added clarity by explicitly permitting arachidonic acid and setting a maximum (rather than adopting the Codex approach).

110. INC agrees that aligning with Codex in relation to the EPA: DHA ratio is appropriate and supports the current EPA: DHA ratio requirement in Standard 2.9.1.

111. ***Source of fat***: Standard 2.9.1 does not specify or prohibit any particular sources of fat. Instead, criteria for the fat composition in infant formula are outlined. Fatty acids which are considered harmful are restricted or limited to protect infants from adverse health consequences. A similar approach is taken in Codex STAN 72-1981.

112. INC considers the current approach remains appropriate even though this is not exactly aligned with Codex. Standard 2.4.1, Edible oils, regulates many of the concerns that would otherwise need to be addressed in Standard 2.9.1 (and other Standards in Part 2.9). Therefore, in the absence of evidence of adverse impact in the Australia-New Zealand context, maintaining the current approach is appropriate.

Q1.5 What issues, if any, do you have with the current approach to regulation of the source of fat in infant formula? Please provide your rationale.

113. **INC Response**: As noted above, INC does not have issues with the current approach to the regulation of the source of fat in infant formula. The proposed framework for nutritive substances and novel food described in P1024 suggests that new sources of fat in the future would fit the criteria for Eligible Food Criteria.

114. ***Myristic acid (C14:0) and lauric acids:*** FSANZ considers it appropriate to maintain no restriction on the levels of myristic and lauric acids in Standard 2.9.1. This is in line with recent expert opinion but inconsistent with Codex.

115. INC notes that not having a restriction aligns with the most recent expert opinions and also provides for flexibility for industry.

116. Myristic and lauric acids are present in human milk and the content of the levels of these fatty acids in infant formula are comparable. Typical levels of myristric and lauric acid in bovine milk fat are 15% of total fat, however levels can vary with feed and breed (MacGibbon & Taylor 2006). The typical levels of myristric and lauric acid in infant formula range from 8-18% of total fat, however infant formula with levels as low as 0.9% have been reported (Zunin et al 2015).

Restrictions on certain fats

117. ***Medium-chain triglycerides*** (MCTs) As FSANZ notes, the current limitations on the presence of MCT in Standard 2.9.1 are not consistent with Codex which contains no such prohibition. Contrary to the position taken in establishing the limitation on MCTs in P93, breast milk also contains MCTs. We note that at the time the limitation was set (through P93 and Delplanque et al 2015), this was based on safety concerns because there was not a good understanding of the long term impacts of MCTs and no evidence of benefit.

118. There is inconsistency between guidelines for standard infant formula and Standard 2.9.1, Division 3, special dietary use formulas. MCTs have a safe history of use in premature infants as an ingredient for enteral and parenteral nutritional products. The most recent ESPGHAN guidelines for enteral feeds for preterm infant recommend that MCTs can be added up to 40% of total fat (Agostoni et al 2010). In addition, it has been shown that premature infants fed MCT-containing formula, when compared with controls, absorbed more calcium and magnesium and had improved fat and nitrogen absorption (Mohammed et al 2014).

119. As premature infants may be considered a more vulnerable population when compared to full term infants, the permission in the preterm population is incongruent with the prohibition for full term infants, especially when considering current expert, preterm nutrition recommendations and the history of safe use for enteral and parenteral feeds.

120. As noted in Application A563 Final Assessment Report (2006) for permission for MCTs as processing aids, there were no significant safety concerns with the addition of MCTs up to 2% of total fatty acids. The safety report included the following points:

- MCTs are sourced from a traditional food and have a safe history of use.
- Studies in both experimental animals and humans indicate that MCT-based diets do not cause significant adverse health effects.
- MCTs administered in the diet had no adverse effect on rat reproductive or developmental parameters or on terminal gestational development and postnatal survival of pigs.

- There was no evidence of carcinogenicity in the chronic studies with MCT tricaprylin.
- MCTs show little evidence of genotoxic or mutagenic potential in in vitro assays.

121. The nutritional assessment for Application A563 noted that increasing intakes of MCTs have no impact on growth or development (either positive or negative) beyond that conferred with similar intakes of longer chain triglycerides. Therefore, a potential nutrition-related health risk to infant energy intakes was not identified at the time.

122. A recent study (Ekcharoen and Tantibhaedhyangkul 2015) compared the growth and adverse effects of high MCT/high protein content formula and post discharge formula for preterm infants post discharge and found no difference between the groups with both achieving adequate growth and no difference in adverse effects This adds support to demonstrate nutritional adequacy.

123. The conclusion from the nutritional assessment for Application A563 was that there is no nutritional justification for adding MCT oils to infant formula. However, it should also be recognised that conversely, there was no strong scientific justification provided in relation to why MCTs should be prohibited from infant formula.

124. In line with the rationale for permitting MCTs as a processing aid for infant formula, removal of an expressed prohibition would allow companies to greater choice of fat sources. This would allow use of alternative oils. For example, use of oils which do not contain allergens could potentially lead to more allergen free products which would benefit infants with severe allergies. Furthermore, the non-alignment with Codex STAN 72-1981 is a barrier to trade for companies.

125. ***Trans-fatty acids:*** FSANZ proposes lowering the maximum amount of trans fatty acids (TFAs) to 3% total fatty acids and thereby aligning with Codex. Codex states that the TFA limit of 3% is to allow for milk fats.

126. INC does not support the proposal to lower the TFA content from 4% to 3% of TFAs. We support retention of a 4% limit in the context of different TFA definitions between FSANZ and Codex.

127. The FSANZ definition of TFAs differs from Codex. The Food Standards Code defines TFA as *All trans fatty acids*, whereas Codex defines TFA as *Only methylene-interrupted trans fatty acids* (CAC/GL 2-1985) i.e. the former encompasses CLA in the TFA count, and the latter does not. Hence the FSANZ proposal to align with Codex TFA limits on the 3% numerical value of 'TFA' does not align with the scope of fatty acids that are encompassed in this definition, as the Food Standards Code definition includes a higher amount. Differences between the Food Standards Code and Codex definitions are currently accounted for by differing TFA limits in Codex and [Standard 2.9.1] of 3% and 4% of total TFA, respectively.

> "*The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in infant formulae*" (Codex STAN 72–1981)

128. Milk fat serves as an important delivery medium for fat soluble vitamins, various fatty acids and factors beneficial to health. Breast milk contains TFA around 2-5% of fatty acids (Larqué et al 2001). Typical TFA values (measured as C18:1) in bovine milk fat, range from 1.29 to 7.31% of total fat (Precht et al, 2000, review of milkfat from >12 countries).

129. The TFA content of cows' milk may vary with feed, season, breed, etc (Kliem et al 2013; Mansson 2008), with up to 10% TFA of total fat reported under certain feeding regimes (Briard-Bion et al 2008). Pasture-fed cows have higher CLA levels (Kelly et al 1998).

130. CLA in New Zealand milk fat is typically 1.1 % (range 0.8-1.5) of total fat while the methylene interrupted TFA is typically 3.9% (MacGibbon and Taylor 2006). Thus CLA makes up about 22% of the FSANZ TFA definition. It follows that the Food Standards Code already aligns with the Codex STAN 72-1981 TFA maximum levels (because of the different definition) and thus to change to a 3% TFA cap for the Food Standards Code would take it out of alignment (to a value of 2.3% Codex definition equivalent TFA).

131. Note also that the New Zealand Codex opinion from 2004 which advocated for a higher TFA level in Codex STAN 72-1981 of 4% using the Codex TFA definition (CX/NFSDU 04/6-Add.1. Agenda Item 5b).

132. ***Phospholipids***: Standard 2.9.1 does not contain provisions that relate to phospholipids in infant formula while Codex STAN 72-1981 specifies a maximum permitted amount of phospholipids. FSANZ considers total phospholipids should be restricted but is uncertain about what that maximum should be noting that the evidence does not support alignment with the higher Codex maximum.

133. INC does not support the introduction of a restriction specific to phospholipids.

134. Phospholipids are integral structural components of biological membranes, a source of metabolites with various physiological functions and have key functions in signal transduction, neural development and cell functions. In milk and in the intestinal lumen, phospholipids contribute to solubilizing lipophilic compounds. Phospholipids may also be added to infant formulas as a source of long-chain polyunsaturated fatty acids (Koletzko 2005). Phospholipids are an important component of human milk (Koletzko et al 2001, Jensen 1996). In formulas there are two contributions to the phospholipid concentration;

- Lecithin added as a processing aid and dissolution aid, and
- Naturally occurring phospholipids from cow's milk.

135. Lecithin, commonly from soy, may be added for reasons such as to instantize dry infant formula powders for easier dispersion in water, or to the oil blend during the manufacture of infant formula to stabilize the oil droplets during emulsification of the oil blend with the proteins. Soy or other vegetable lecithin are mostly composed of phosphatidylcholine (PC). Bovine phospholipids naturally present in milk and milk ingredients are composed of sphingomyelin (SM), PC, phosphatidylethanolamine (PE), phosphatidylserine (PS) and phosphatidylinositol (PI), similar to that of human milk (Jensen 1990, MacGibbon and Taylor 2006).

136. Expert bodies and both Codex and EU infant formula regulations define a maximum limit of 2g/L of phospholipids as safe and justified;

- Codex STAN 72-1981 maximum for phospholipids in infant formula is 300 mg /100kcal (72 mg /100kJ) which converts to approximately 1.5 g/100g powder or 2g/L of liquid made up formula
- EU Directive 2006/141/EC and (EU) Regulation 2016/127, define a maximum phospholipid limit of 2g/L for infant formula
- The EFSA (2014) and ESPGHAN Coordinated International Expert Group (2005) opinions on the composition of infant formula considered a maximum phospholipid concentration of 2g/L as appropriate, with the latter outlining consideration of the

safety of this level with respect to triglyceride/phospholipids ratios obtained (Koletzko et al 2005).

- In addition, the expert panel coordinated by the Early Nutrition Academy considered a higher maximum level of 3.5g/L phospholipids for older infants in Codex STAN 156-1987 was appropriate:

  "*For IF fed from birth, a maximum phospholipid concentration of 300 mg/100 kcal (equivalent to about 2 g/l) has been set following the precautionary approach. For older infants at the age of FUF feeding, there are few concerns regarding the provision of phospholipids with usual complementary feeds which provide considerable amounts of phospholipids. For example, infants will consume about 3.5 g phospholipids with one hen's egg. Research into the roles of phospholipids in human milk fat globules indicates potential benefits of adding certain phospholipids to FUF, in addition to solubilizing lipophilic compounds and acting as a source of long-chain polyunsaturated fatty acids. Therefore, a concentration of 550 mg/100 kcal (equivalent to about 3.5 g/l) is recommended as the guidance upper level.*"

137. Furthermore,

- the JECFA lecithin Acceptable Daily Intake was previously established as 'not limited for adult lecithin intake (FAO 1973)
- phospholipid ingredients derived from egg yolk were Generally Recognised As Safe (GRAS) for use in term and pre-term formula at levels up to 2g/L (GRN 000411).

138. In summary, in the absence of specific safety concerns or evidence of adverse effects in infants and the absence of market failure currently where no phospholipids limit has been specified, INC concludes that there is no strong justification to set an upper level. Applying a graduated risk assessment and management approach, INC recommends against setting an upper limit which will result in additional testing and compliance costs ultimately reflected in the price of formula products.

Q1.6 What amount of lecithin is used in infant formula for technological purposes?

139. **INC Response:** There is no generic response to the question and member companies may choose to provide a response which may be commercial-in-confidence. Lecithin contains phospholipids, and are found in animal and plant tissues (the natural source) or extracted and added. Manufacturers may add lecithin for technological purposes including instantizing dry infant formula powders for easier dispersion in water, or adding to the oil blend during the manufacture of infant formula to stabilize the oil droplets during emulsification of the oil blend with the proteins.

140. ***Erucic acid*** – INC supports the current arrangement in Standard 2.9.1 that limits erucic acid in alignment with Codex.

Carbohydrates

141. ***Definitions and calculations relevant to carbohydrate***: FSANZ's preliminary view is that definitions and the method of calculation relevant to carbohydrate identity in the revised Code are appropriate for infant formula.

Q1.7 Should the concept of dietary fibre or its prescribed methods of analysis apply to infant formula?

142. **INC Response:** INC position is to align with Codex STAN 72-1981.

143. ***Introduction of maximum and minimum level***: FSANZ states that Standard 2.9.1 does not directly specify a minimum or maximum level of carbohydrate for infant formula as it is indirectly controlled by the provisions for protein, fat and energy content. Codex STAN 72-1981 lists a carbohydrate range of 2.2–3.3 g/100 kJ. FSANZ considers it appropriate to retain the current approach by not specifying a minimum and maximum amount for carbohydrate, noting this is in effect aligned with the Codex range.

144. INC concurs with the FSANZ proposal to retain the current approach by not specifying a minimum and maximum amount for carbohydrate for the same reasons identified as FSANZ.

145. ***Carbohydrate source***: Standard 2.9.1 does not include any provisions relating to the source of carbohydrate in infant formula. Codex STAN 72-1981 includes guidance on the type of digestible carbohydrate to be used but this is not mandatory.

Q1.8 What issues, if any, do you have with the current approach to regulation of the source of carbohydrate in infant formula? Please provide your rationale.

146. **INC Response**: INC supports maintaining the current approach in Standard 2.9.1 not to include provisions relating to carbohydrate source. There is no failure in relation to safety and no trade barrier relating to this area.

147. Member companies advise INC that they are not adding the likes of sucrose etc to infant formula and INC is not aware of any formulas on the Australia/New Zealand market with such substances added. Companies apply an approach similar to that being proposed for Eligible Food Criteria reflected in the proposed framework of Option 3 in P1024, targeting assessment on the infant population to be assured of ingredient safety for the target population.

Energy

148. ***Energy content***: INC supports FSANZ's proposal to reduce the maximum energy amount to align with that in Codex STAN 72-1981. This is supported by expert opinion (Koletzko 2005).

> "The IEG proposes an energy density of infant formulae in the range of 60–70 kcal/100 ml, which is appropriate to support physiological rates of weight gain in healthy infants." (Koletzko et al 2005).
>
> and
>
> "3.1.2 Infant formula prepared ready for consumption in accordance with instructions of the manufacturer shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy." (Codex STAN 72-1981)

149. ***Calculation of energy density***: Standard 2.9.1 specifies that the energy density of infant formula must be calculated using only the energy contributions from fat, protein and carbohydrate ingredients, using the equation and energy factors specified for nutrition labelling in Standard 1.2.8. There has in the past been some confusion as the Food Standards Code also states that the nutrition labelling requirements do not apply to infant formula. FSANZ expects that the relevant modifications in the revised Food Standards Code have resolved that confusion.

150. FSANZ proposes to maintain application of energy factors for calculating the energy density of infant formula and the Food Standards Code's energy factors should continue to

apply to infant formula including both energy factors for available and unavailable carbohydrate.

151. INC concurs with FSANZ that it is appropriate to follow the energy factors in the Food Standards Code for infant formula including energy factors for available and unavailable carbohydrate.

Vitamins, minerals and electrolytes

Approach to setting guidelines or maximum amounts

152. In Standard 2.9.1 all nutrients have either a maximum amount or a recommended guideline maximum amount (GUL). Codex uses a similar approach, but Codex has GULs for 20 micronutrients compared to 14 in the Code. FSANZ is exploring whether the GULs should be formally incorporated into Standard 2.9.1.

153. INC strongly supports the continued use of non-binding GULs to serve as guidance for industry in designing formulations and therefore GULs should not be formally incorporated into Standard 2.9.1. GULs are only applied where there is no safety issue. Where there is a safety issue, maximums are mandated. INC therefore supports FSANZ's proposal that some nutrients to retain a GUL in Standard 2.9.1, and others be amended from a prescribed maximum to a GUL to align with Codex (as summarised in Table 7.2 of SD1).

154. ***Vitamin A***: FSANZ is supporting expressing of vitamin A requirements in units of µg alone (rather than RE), as this clarifies that β-carotene should not contribute to the vitamin A content. The Code would then align with Codex and other international regulations in relation to the contribution of β-carotene to vitamin A content but will differ in relation to the vitamin A units.

155. INC does not object to the proposal to exclude β-carotene from the total amount of vitamin A reported in infant formula in light of uncertainty around its bioavailability. However, in light of FSANZ's view to exclude β-carotene in the contribution to Vitamin A content, we would like have confirmation that β-carotene is still permitted to be added into Infant formula. We note that there are quite a number of products in the market containing β-carotene and if there was an exclusion on addition, it would have a potentially extensive impact for manufacturers to reformulate to exclude β-carotene.

156. INC notes that there are three systems / units of expression to report Vitamin A activity in food: international units (IU), retinol equivalents (RE) and retinol activity equivalents.

157. INC considers it is still useful to retain use of µg RE for consistency with Codex and to the wider Food Standards Code. It makes it clear that each permitted form of Pro-vitamin A must be converted to its vitamin A activity and that it is not referring to IU.
See also INC's response to Q1.22

158. ***Folate:*** Neither Codex STAN 72-1981 nor Standard 2.9.1 currently use dietary folate equivalents (DFE) to express the folate content of infant formula. FSANZ's preliminary view is to retain units of µg of folate even though this differs from Codex STAN 72-1981. FSANZ is unsure whether allowing for natural folate but not adopting the DFE units would make any difference.

159. INC does not support FSANZ's preliminary view for folate expression and instead supports expression of the folate content of infant formula as folic acid. This is aligned with the approach Codex has taken and is reflective of the fact that folic acid is the dominant form of folate in a fortified infant formula.

160. INC notes that neither Codex nor the Food Standards Code (including Standard 2.9.1) use dietary folate equivalents (DFE) to express the folate content of infant formula.

161. INC notes that even though the bioavailability of naturally occurring folate is difficult to determine, ideally the sum of naturally occurring folate and folic acid should be used. So saying, we do not consider expression as Dietary Folate Equivalents (DFE) appropriate at this time. This is because there is significant variability and uncertainty related to the exact bioavailability in infants of natural milk folate forms (Sanderson 2003, Suitor et al 2000, Ohrvik et al 2011). Furthermore, as DFE factors were established in adults and it is unknown whether folic acid in infant formula is more or less bioavailable than folates in human milk, the DFE should not be used to express folate content of infant formula. Consequently, DFE should not be used to express folate content of infant formula.

162. We also know that test methodologies for folate versus folic acid are very difficult. While testing for total folic acid and folate remains the most appropriate approach, it is less challenging to quantify folic acid alone than to capture all folate forms, natural and added (Arcot et al 2005).

Q1.9 Should the minimum folate requirement include or exclude the contribution of naturally occurring folate? Please provide your rationale.

163. **INC Response**: INC is aware of the differences between Codex (folic acid µg) and Standard 2.9.1 (folate µg) for how the minimum requirement of folate is expressed in infant formula. Standard 2.9.1 is expressed as folate (µg) which captures both naturally occurring folate and added folic acid in the amount of folate present in the infant formula. INC does not support FSANZ's preliminary view to retain µg of folate. INC supports folic acid as the nutritional declaration as aligned with Codex.

164. Implementation of a minimum requirement that includes naturally occurring folate is dependent on the capability of the analytical method to capture both natural folate and added folic acid. Currently there are complexities in measuring both (Arcot et al 2005).

165. MacLean et al (2010) mentions that up to 40% of the folate in the finished infant formula comes from the ingredients used to produce the infant formula and folic acid is added due to the losses of natural folates in infant formula during manufacture and shelf life. Despite these losses, natural folates will still be present in the final product at varying amounts.

166. INC recognises that it would be ideal to measure both folic acid and naturally occurring folate but that the current test methodologies for folate are not reliable. In addition some of the naturally occurring folate may well be lost in manufacturing. INC therefore proposes that it be permissible to measure folic acid only.

Q1.10 If you consider minimum folate requirement should include natural folate, should dietary folate equivalents (DFE) be applied?

167. **INC Response**: INC does not support folate being expressed as dietary folate equivalents (DFE), as neither Codex nor the Food Standards Code uses DFE to express

the folate content of infant formula. DFE factors were established in adults and it is unknown whether folic acid in infant formula is more or less bioavailable than folates in human milk.

168. Except for the EU, there appear to be no other countries that use DFE to express the folate content of infant formula. The *EFSA Scientific Opinion Paper on the essential composition of infant and follow-on formulae* (2014) references the 2014 *Scientific Opinion on Dietary References Values (DRV's) for* folate as the reason for moving to DFE's for infant formula. The 2014 DRV paper concludes the following for DFE:

> "The Panel notes that the DFE has been designed to take account of the fact that food folate has a lower bioavailability than folic acid added to foods or consumed as a supplement, **although the evidence base for the figures used by IOM [Institute of Medicine, US] in the DFE definition is somewhat uncertain**" (page 14)
>
> "The Panel also notes that the **validity of the dietary folate equivalency definition has not been confirmed in studies**" (page 14)
>
> "The Panel considers that two of three long-term investigations using whole diets indicate that the **bioavailability of food folate relative to folic acid may be higher than previously assumed.** However, the Panel also considers that results for **folate bioavailability in these studies vary and that there is wide variation in estimates.** "(page 14)
>
> "The Panel considers that the difference in bioavailability between food folate and folic acid needs to be accounted for. **In the absence of better data, the Panel agrees with the previous definition of the DFE**" (page 14-15)

169. And includes the following paragraph under recommendations for research:
> "The Panel suggests that **studies to clarify the bioavailability of folic acid and natural food folates should be undertaken to improve the underlying database for the definition of the DFE**" (page 38)

170. Based on the EFSA conclusions in this document it shows that there is limited evidence to support the use DFE and there is also conflicting evidence on the definition of DFE.

171. ***Vitamin E***: Standard 2.9.1 lists the vitamin E units as mg vitamin E referring to α-tocopherol (α-TE). Codex STAN 72-1981 lists units of vitamin E as α-TE although a note specifies that 1 mg α-TE = 1 mg d-α-tocopherol. It is FSANZ's preliminary view that mg α-TE should be adopted as the units for vitamin E to indicate the relative activities of natural and synthetic forms of alpha-tocopherol. The revised Code specifies conversion factors in section S1—5 for some of the synthetic forms of vitamin E permitted in infant formula and FSANZ proposes that this list could be completed as part of Proposal P1028 if relevant to infant metabolism.

172. Both Standard 2.9.1 and Codex STAN 72-1981 specify a minimum amount of vitamin E per g of polyunsaturated fatty acids (PUFAs). Standard 2.9.1 sets a minimum amount of 0.5 mg vitamin E per g of PUFA. Codex STAN 72-1981 also lists 'factors of equivalence' from 0.5 mg/g for lauric acid and increasing in increments of 0.25 mg/g to 1.5 mg/g for DHA according to the number of fatty acid double bonds in individual PUFAs in an infant formula. These factors are applied to determine the minimum amount of vitamin E for a particular PUFA mixture in infant formula. Following assessment, FSANZ's preliminary

view is that the current approach to vitamin E requirements relating to the PUFA content of infant formula retained.

173. We acknowledge FSANZ's extensive calculations and conclusions that the difference in Vitamin E content derived using the current method in Standard 2.9.1 and that in Codex STAN 72-1981 is minimal and unlikely to provide any effect in terms of risk to infant health.

174. The revised Code specifies conversion factors in section S1—5 for some of the synthetic forms of vitamin E permitted in infant formula and we agree that these should be extended to all permitted forms.

175. INC has no objection to retaining the current approach to vitamin E requirements relating to the PUFA content of infant formula. The proposed GUL for vitamin E would allow for the variation between Standard 2.9.1 and other international regulations which follow Codex STAN 72-1981.

176. ***Niacin****:* FSANZ considers it is appropriate to retain the requirement for niacin amount in infant formula to be limited to the form pre-formed niacin.

Permitted range for micronutrients: minimum and maximum amounts

177. A permitted range is established for each of the 25 vitamins, minerals and electrolytes required in infant formula. The approach adopted in Standard 2.9.1 and Codex STAN 72-1981 is similar, with both setting minimum amounts and either a maximum amount or a GUL for the same range of micronutrients although the actual minimum and maximum amounts may vary.

178. ***Aligned with Codex*****:** INC supports the FSANZ proposal to retain the current minimum and maximum amount for vitamin A, which is already aligned with Codex STAN 72-1981. This position is subject to technical correction to conversion factors applied in the Codex standard.

179. ***Could be aligned with Codex***: INC supports FSANZ's preliminary view to align the minimum and maximum amounts for vitamin B6, vitamin B12, pantothenic acid, riboflavin, thiamine, folate, niacin (preformed), vitamin E, vitamin K, biotin, calcium, manganese, magnesium, copper, potassium, chloride and sodium again, subject to conversion factor correction.

180. ***Uncertainty whether alignment is appropriate***: Further information is sought by FSANZ to inform further assessment for vitamin C, chromium, molybdenum, iodine, zinc, iron and selenium.

181. ***Phosphorus***: FSANZ's preliminary view that it is appropriate to change the current maximum (25 mg/100 kJ) in Standard 2.9.1 to a GUL of 24 mg/100 kJ in alignment with Codex STAN 72-1981. FSANZ also proposes to adjust Standard 2.9.1 to align with the minimum Ca:P ratio of 1:1.

182. In relation to phosphorous, INC supports the provision of a GUL. If there was evidence of a food safety issue, only then would a maximum level be appropriate. INC assumes there may have been a food safety issue in the past from a FSANZ perspective but it is instructional that both NHMRC and MoH state that a GUL is 'Not possible to establish'. There would appear to be no evidence for a maximum level.

Q1.11 Is it appropriate to amend the maximum phosphorus amount in Standard 2.9.1 to a GUL and align with the lower minimum Ca:P ratio?

183. **INC Response**: As noted above, INC agrees that it is appropriate to amend the maximum phosphorus amount in Standard 2.9.1 to a GUL. INC also agrees with the proposal to align with the lower minimum Ca:P ratio applied by Codex of 1:1 while maintaining the existing maximum Ca:P ratio of 2:1.

184. ***Vitamin C*:** FSANZ is considering changing the GUL for Vitamin C to align Standard 2.9.1 with Codex STAN 72-1981.

Q1.12 Should the GUL amount for vitamin C be increased to 17 mg/100 kJ? If not, is the current GUL in Standard 2.9.1 appropriate?

185. **INC Response**: INC considers it is appropriate to increase the GUL of Vitamin C from 5.4 mg/100 kJ to the level in Codex STAN 72-1981 of 17 mg/ 100 kJ. There is no safety or other reason to restrict the level and as Vitamin C is a labile nutrient, there is more reason to increase the GUL. Codex states that the higher level is set to account for possible high losses over the shelf life of liquid infant formulas. While FSANZ notes that there are few liquid formulas, these are required by health care facilities in both Australia and New Zealand. Also, future innovation may extend liquid products to the retail trade as has been seen in other international markets. Aligning with Codex now future-proofs Standard 2.9.1 from the need for amendment in the future in this area.

186. ***Vitamin D*** – INC supports the FSANZ proposal to retain the current minimum amount for vitamin D subject to correction for conversion factors but recommends that the maximum for vitamin D is increased to align with the maximum of 0.72µg/100kJ as adopted by the EU in EC Directive 2016/127. The EU has implemented a higher minimum and maximum for vitamin D compared to Codex STAN 72-1981 based on the scientific evaluation conducted by EFSA (2013). There is currently only a narrow common range between Codex STAN 72-1981 and the EU regulations which is too tight to allow product formulation and manufacture in compliance with both sets of requirements. In this case, INC advocates alignment with the EU requirements to promote broad international harmonisation. If the Standard 2.9.1 requirement for a maximum for vitamin D stays aligned with Codex STAN 72-1981 this could have significant implications for products imported from the EU, including infant formula products for special dietary use.

187. ***Iron***: There is no international consensus on the appropriate minimum amount of iron in infant formula. FSANZ is proposing to retain the current minimum even though this is double the minimum in Codex STAN 72-1981.

Q1.13 Do you support retaining the current minimum and maximum amount of iron required in infant formula? Please provide your rationale.

188. **INC Response**: INC supports retaining the current minimum and maximum for iron for infant formula. INC notes that the minimum for iron listed in Codex STAN 72-1981 (0.1 mg/100 kJ) is half the minimum prescribed in Standard 2.9.1 (Schedule 29 in the revised Code – 0.2 mg/100 kJ). For a range of reasons, FSANZ considers that the use of the lower Codex minimum could potentially pose a risk to infant health in Australia and New Zealand although the extent of risk is uncertain.

189. A maximum amount of iron is prescribed in Standard 2.9.1 (0.5 mg/100 kJ) whereas Codex STAN 72-1981 provides that national authorities may determine their own maximum.

190. INC notes the reasons for FSANZ proposing to retain the current minimum and maximum level of iron, is that there are no products on the Australia / New Zealand market that would be affected if this proceeded and that no trade barriers would result if the current arrangements were retained. However, INC would like to highlight that only infant formulas have been considered and that this may not be the situation for all infant formula products, particularly infant formula for special dietary uses. These products are often produced as a single recipe for all countries and may require a wider range, taking into account the lower minimum in Codex STAN 72-1981. INC notes that the range in the EU regulations is similar. On balance therefore, INC supports retaining the current minimum and maximum for iron for infant formula and further consideration be given to other infant formula products at the appropriate time.

191. ***Selenium***: Standard 2.9.1 and Codex STAN 72-1981 have very similar minimum selenium amounts (0.25µg/100kJ and 0.24µg/100kJ, respectively). Standard 2.9.1 prescribes a maximum of 1.19µg/100kJ whereas Codex lists a GUL of 2.2µg/100kJ. There are significant geographical variations in the selenium content of soil and food crops in many countries particularly New Zealand. P93 recommended a range of 0.42ug per 100kJ to 0.89ug/100kJ in infant formula.

192. FSANZ's preliminary view is that increasing the minimum requirement for selenium in Standard 2.9.1 (to 0.48µg/100kJ) may be appropriate for the Australian and New Zealand context. This level is the same as the level recently updated by the US. However this would not align with Codex STAN 72-1981 and may require reformulation of some products. If the minimum requirement was raised and the Codex higher GUL also adopted, FSANZ notes that the range may remain similar.

Q1.14 Do you support raising the minimum and maximum amount of selenium required in infant formula?

193. **INC Response**: INC considers the current minimum for selenium is appropriate for Australia and New Zealand because manufacturers do not generally target the minimum but rather target a level higher than the minimum in order to be assured of compliance. The FSANZ label survey confirms this, particularly for New Zealand, which has the more serious selenium deficiency. The lowest selenium content of the infant formula was 0.43µg/100kJ in New Zealand samples and 0.29µg/100kJ in Australian products.

Q1.15 Do you support moving the maximum amount to a GUL?

194. **INC Response**: INC supports the proposal to move the maximum amount to a GUL and the increase of the GUL to align with Codex STAN 72-1981. There is no safety issue and excess selenium intake from selenate, selenite or selenocysteine is excreted in urine.

195. ***Iodine***: The minimum iodine amount in Standard 2.9.1 is 1.2µg/100kJ while Codex STAN 72-1981 is 2.5µg/100kJ which is more than double. Codex STAN 72-1981 lists a GUL of 14µg/100kJ while Standard 2.9.1 has a maximum of 10µg/100kJ. FSANZ concludes that a higher maximum of 14µg/100kJ would be unlikely to adversely pose a risk to infant health. FSANZ's label survey showed that the range of iodine content was 2.10–5.92µg/100kJ. FSANZ's preliminary view is that alignment with the higher Codex minimum and maximum (GUL) amount for iodine may be appropriate for Australian and New Zealand infants.

Q1.16 Do you support aligning with the higher Codex minimum and maximum amount and converting the maximum to a GUL?

196. **INC Response**: The iodine content in milk is very variable, which was the reason that Standard 2.9.3 was amended in relation to iodine. INC supports a GUL.

197. INC supports increased iodine levels in infant formula with values of 2.5-14ug/100kJ aligned with Codex STAN 72-1981. This will allow for the considerable variability of iodine in milk. INC considers a GUL is more appropriate than a maximum, given there is no UL established for iodine in infancy, and an absence of safety concern with current Codex levels.

198. Iodine plays a critical role in brain development. Since September 2009, iodised salt has been added to bread in New Zealand to address the re-emergence of iodine deficiency. Since 2010, iodine supplementation of 150µg iodine/day has been recommended by the NHMRC and the New Zealand Ministry of Health for pregnant and breast feeding women to mitigate the risks associated with iodine deficiency in infants (NHMRC 2010).

199. We note that the Australian and New Zealand NRVs recommend an AI of iodine for infants of 90µg/day from 0-6 months old (NHMRC 2006).

200. In light of the FSANZ comments that a proportion of younger infants would not achieve the iodine AI at the current minimum formula iodine levels, it is important this level is increased to align with the higher Codex minimum formula level to support achievement of the AI in infancy.

201. ***Chromium***: Neither Codex STAN 72-1981 nor Standard 2.9.1 set a minimum amount for chromium. Standard 2.9.1 sets a GUL; to allow for the natural chromium in dairy products. Codex STAN 72-1981 does not include a maximum amount or a GUL. FSANZ is uncertain about how to proceed with regulation in this area.

Q1.17 Can you provide data on the chromium levels in commercially available infant formula in Australia and New Zealand? This information can be provided as 'Commercial in confidence' if required.

202. **INC Response**: INC notes that EFSA considered there was insufficient evidence to consider chromium an essential nutrient, that addition of chromium in infant formula was not necessary and a minimum amount was not recommended (EFSA 2014). FSANZ considered the absence of a minimum amount was unlikely to pose a risk to infant health. There are no known adverse effects associated with high intakes of chromium from food. Based on this FSANZ concludes that removal of the guidance level from Standard 2.9.1 to align with Codex STAN 72-1982 is unlikely to impact on infant health.

203. INC does not support minimum, maximum or GU levels being set for chromium.

204. ***Molybdenum***: Neither Codex nor Standard 2.9.1 set a minimum for molybdenum, or permit the addition of molybdenum to infant formula. However, FSANZ notes that molybdenum naturally occurs in dairy products and thus is present in infant formula. Standard 2.9.1 sets a GUL but Codex STAN 72-1981 does not include a maximum amount or a GUL.

Q1.18 Can you provide any data on the molybdenum levels in commercially available infant formula in Australia and New Zealand? This information may be provided as confidential commercial information.

205. **INC Response**: INC advises that if there is no requirement to test for a nutrient, companies do not generally undertake such testing. This appears to be the case for molybdenum and we caution that data from one off testing may not be reliable.

206. INC notes that EFSA had proposed a minimum of 0.1µg/100kJ but that this level did not get into the final revised EU regulations and there was no discussion of a maximum. The NHMRC notes that molybdenum is absorbed very efficiently over a wide range of intakes and recommended an AI for infants 0-6 months of 2ug/day based on the average volume of breast milk of 0.78L/day and the average concentration of molybdenum in breast milk of 2*µ*g/L. NHMRC noted that it was not possible to estimate an upper limit.

207. In light of the foregoing, INC suggests that presence of molybdenum in infant formula needs to be accounted for when considering dietary intakes but that none of a minimum, maximum or GUL need be set.

208. ***Copper***: The minimum and maximum amounts for copper in Standard 2.9.1 are higher than the respective minimum and GUL in Codex STAN 72-1981. The Codex minimum is based on average breast milk content. FSANZ's preliminary view is that alignment with Codex STAN 72-1981 minimum amount and GUL amount is appropriate. However this needs to be considered in the context of the zinc:copper ratio.

209. INC agrees with FSANZ's preliminary view for copper to align with the provisions in Codex STAN 72-1981 and set a minimum and GUL.

210. ***Zinc***: Standard 2.9.1 and Codex STAN 72-1981 are aligned for a minimum level of 0.12mg/100kJ. However, the maximum of 0.43mg/100kJ in Standard 2.9.1 is higher than the GUL of 0.36mg/100kJ in Codex STAN 72-1981. Standard 2.9.1 also prescribes a ratio of zinc to copper, Zn:Cu, of maximum 15:1, whereas Codex STAN 72-1981 does not specify a ratio.

211. Soy-based formula can contain higher amounts of zinc than standard formula. Some suggest that minimum amounts for certain minerals in soy-based infant formula should consider the phytic acid content of soy proteins and the potential for reduced availability of minerals. FSANZ reports that recently EFSA (2014) noted studies show that reduction of phytic acid content completely or even by around half in ready-to-feed formula improves zinc absorption.

212. INC is of the view that even though there may be less efficient zinc absorption from soy protein isolate formulas, higher levels of zinc intake could impact on the absorption of copper (Lõnnerdal 1984) and therefore recommending a separate upper level of zinc for soy formula may not be ideal. The proposed upper level for zinc for all formulas should account for any additional needs for soy formula.

Q1.19 What information can you provide on the phytic acid content of soy-based infant formula?

213. **INC Response**: INC members have no information on the phytic acid content of soy-based infant formula.

Q1.20 Are there any technical issues if the lower Codex minimum and maximum levels for copper were to be incorporated into the Code?

214. **INC Response**: INC considers that the Codex minimum and GUL for copper be adopted.

215. Proposal P1028 SD1 refers to the need to include the copper content of water in Australia when calculating the total Cu provided by an infant formula reconstituted with cooled boiled tap water.

216. The average copper content of Australian drinking water is 0.05mg/L (50mcg/L – NHMRC 2011 Australian drinking water guidelines). Based on an intake of 0.7 L/day as per fluid requirements from the Australian NRV for 0-6 month year olds, Australian drinking water would provide an additional 0.035 mg/day (350mcg/day) (Australian NRV nutrients for water). When this is combined with infant formula (estimated energy composition 280 kJ/100ml), this would provide a total of 0.2 mg/day (202 mcg/day) and a total of 0.57 mg/day (568 mcg/day) when calculated using the Codex STAN 72-1981 minimum and GULs respectively as label claims. This would meet the Australian NRV AI for copper which is 0.20mg/day (Australian NRV nutrients for copper).

217. Care should be taken however in accounting for the copper values in the calculations as they are expressed as an average and as such there is a risk that at the minimum amount recommended by Codex STAN 72-1981, some infants may still not meet the Australian NRV AI for copper.

218. The EFSA minimum for copper was maintained at 14.3/100kJ in 2014, which is more in line with the current FSANZ minimum, and EFSA did not set a maximum. Therefore, nutritional requirements can be still met at these levels when accounting for the average copper content of Australian drinking water.

Q1.21 Should a Zn:Cu ratio be retained. If so, what should it be and why? If not, what is your rationale?

219. **INC Response**: The proposed reduction in copper values to align with Codex STAN 72-1981 may potentially increase the Zn:Cu ratio. As noted previously by FSANZ, the Zn:Cu ratio of human milk is 10:1 but there is no data to inform an ideal ratio for infant formula.

220. As supported by the FSANZ Nutritional Assessment, there has been no recent published studies to provide further insight into the ideal ratio of Zn:Cu to enable informed formulation of infant formula.

221. At the present time, the FDA and EFSA do not provide guidance on a Zn:Cu ratio. The Zn:Cu ratio is also just one factor noted in the literature as influencing the absorption of zinc. Other inhibitory factors such as supplemental iron, casein and phytates are also not currently regulated, perhaps due to the lack of scientific substantiation as to their role and the ideal level for zinc absorption (Lõnnerdal B et al 1989). It was suggested by Lõnnerdal (2000) that modestly increased intakes of copper do not interfere with zinc absorption when zinc intake is satisfactory This provides support to regulating adequate levels of copper and zinc to meet nutritional requirements but not to the regulation of a Zn:Cu ratio per se.

222. The survey of infant formula label declarations from Australia/New Zealand conducted by FSANZ in 2013-2014 indicated that all products available at the time had Zn:Cu ratio ranges of between 9:1 and 13:1 and the zinc and copper label claims were all within the limits set by Codex STAN 72-1981.

Permitted forms of vitamins, minerals and electrolytes

223. A comparison of the permitted forms of vitamins, minerals and electrolytes in Standard 2.9.1 with the list in Codex CAC/GL 10-1979 (Advisory Lists of Nutrient compounds for use in foods for special dietary uses intended for infants and young children) shows there are some differences. INC provides the following views on these matters.

224. **Note** that in relation to **Calcium D-pantothenate, Ferrous sulphate,** INC has reported two errors in the permitted forms of vitamins, minerals and electrolytes in Supporting document 1 – Definitions and nutrient composition. FSANZ have confirmed that they incorrectly stated that Calcium d-pantothenate and Ferrous sulphate are not listed as permitted forms of pantothenic acid and iron respectively for use in infant formula in the Code. As these are permitted for use in Infant Formula Products in the Food Standards Code no further information is required.

Vitamins

225. **Vitamin A**: FSANZ's preliminary view is to retain the permitted forms of Vitamin A, providing alignment between the Code and Codex. INC supports this view.

Q1.22 What is the justification to retain β-carotene as a provitamin A form?

226. **INC Response**: INC supports continued permission for β-carotene as a provitamin A form in infant formula aligned to Codex STAN 72-981. Although it has not been considered appropriate to take the contribution of β-carotene into account when estimating requirements of Vitamin A owing to a lack of knowledge on the bioconversion, the limited data available in children would suggest that there may be some bioavailability.

227. However, since carotenoids are not taken into account in estimating the vitamin A requirements of infants, then INC supports the FSANZ preliminary position that β-carotene should not be counted as contributing to vitamin A.

228. **Vitamin D**: FSANZ preliminary view is to retain the two permitted forms Vitamin D3 (cholecalciferol) and vitamin D2 (ergocalciferol)). INC supports this view.

229. ***Summary of nutrient forms for use in infant formula that differ between Codex GL 10-1979 and Standard 2.9.1***: For reasons of alignment, flexibility for manufacture and avoidance of trade barriers, INC believes all the forms of nutrients permitted in Codex STAN 72-1981 should be permitted in Standard 2.9.1. These are listed in Table 8.1 of SD1 (p58) and comprise: Sodium D-pantothenate, DL-Panthenol, Cupric carbonate, Ferric citrate, Ferrous bisglycinate, Ferrous sulphate, Magnesium hydroxide carbonate, Magnesium hydroxide, Magnesium salts of citric acid, Potassium L-lactate, Zinc lactate and Zinc citrate (either zinc citrate dihydrate or zinc citrate trihydrate).

230. INC's view is that these forms are safe to use, and they would not be permitted by Codex unless that was the case. A technological justification is therefore not necessary. INC also notes that the EU has continued to permit these forms adding weight to their safety and to their nutritional justification. This view applies to each of the following minerals and electrolytes.

Minerals and electrolytes

231. The following sets out FSANZ's preliminary view on each of pantothenic acid, niacin, copper, magnesium, potassium, zinc and iron followed by INC's response.

Pantothenic acid: FSANZ's preliminary view is that it is not appropriate to permit DL-panthenol for use in infant formula and that further information and nutritional justification is required for sodium D-pantothenate as a form suitable for use in infant formula.

Niacin: FSANZ's preliminary view is not to permit nicotinic acid for use in infant formula

Copper: FSANZ is seeking further information and nutritional justification is required for cupric carbonate as a form suitable for use in infant formula.

Magnesium: FSANZ is seeking further information and nutritional justification is required for magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric acid as forms suitable for use in infant formula.

Potassium: FSANZ is seeking further information and nutritional justification is required for potassium L-lactate as a form suitable for use in infant formula.

Zinc: FSANZ is seeking further information and nutritional justification is required for zinc lactate and zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate) as forms suitable for use in infant formula.

Iron: FSANZ is seeking further information and nutritional justification is required for ferric citrate and ferrous bisglycinate as forms suitable for use in infant formula.

Q1.23 What technical justification can you provide for the use of the nutrient forms listed in table 8.2 for use in infant formula?

232. **INC Response**: Firstly, INC notes that it is a nutritional justification, not technological justification, required by the Application Handbook. The permitted forms are discussed in the context of being added for the purpose of nutritional composition, and not for a technological purpose (food additive or processing aid).

233. INC considers that these compounds (including nicotinic acid) are nutritionally justified, since these vitamins and minerals are part of essential composition for infant formula, and as such, are nutritionally mandated by Standard 2.9.1. Therefore INC has restricted its comments to the safety of these compounds in relation to the consuming population.

234. INC's view is that these forms are safe for use in infant formula products. The Preamble and Criteria for the Inclusion and Deletion of Nutrient Compounds from the Advisory Lists of Codex CAC/GL 10-1979 states that:

> "*Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists* ***only if (a) they are shown to be safe*** *and appropriate* ***for the intended use as nutrient sources for infants*** *and young children*."

As such, INC considers that safety has been already been established at a CODEX level.

235. The Advisory list can also be reviewed at any time, and Clause 2.2 in Codex CAC/GL 10-1979 allows countries to either add or delete from the list if new evidence is found to contradict the stipulated criteria in Clause 2.1 of Codex CAC/GL 10-1979. Amendments since initial adoption by Codex in 1979 have been made in: 1983, 1991, 2008, 2009 and 2015. Therefore, to date, no member state including Australia and New Zealand, has provided scientific justification that would support deletion from the list of DL-

panthenol, sodium D-panthothenate, nicotinic acid, cupric carbonate, magnesium hydroxide carbonate, magnesium hydroxide, magnesium salts of citric acid, potassium L-lactate, zinc lactate, zinc citrate, ferric citrate and ferrous bisglycinate.

236. Forms used for nutritional composition need to be evaluated based on safety, and the general principles as outlined in Clause 2.1 of Codex CAC/GL 10-1979. INC therefore considers that, for such forms included in CAC/GL 10-1979, evidence of application and use in the international marketplace is not needed as additional criteria for inclusion for use in the Australia New Zealand Food Standards Code.

237. For reasons of alignment to Codex, flexibility for manufacture, avoidance of barriers to innovation and trade barriers, INC believes all the forms of nutrients permitted in Codex STAN 72-1981 should be permitted for nutritional use in Infant formula, on the basis that they are safe for infants.

238. Also, INC notes that the EU continues to permit the following forms sodium D-panthothenate, nicotinic acid, cupric carbonate, magnesium hydroxide, magnesium salts of citric acid, potassium L-lactate, zinc lactate, zinc citrate and ferrous bisglycinate adding weight to their safety.

Other Optional Substances

239. ***Choline***: Standard 2.9.1 permits choline as an optional substance in infant formula, whereas Codex STAN 72-1981 prescribes the mandatory addition of choline. Both standards specify the same minimum amount, but different maximum amounts. Also Codex STAN 72-1981 lists the maximum as a GUL:

"f) Other Substances
Choline

Unit	Minimum	Maximum	GUL
mg/100kcal	7	--	50
mg/100kJ	1.7	--	12 "

240. Choline is now classed as an essential nutrient in the Australia and New Zealand Nutrient Reference Values; however there is no upper level.

Q1.24 Do you support inclusion of a mandatory requirement for choline in infant formula? Please provide your rationale.

241. **INC Response**: FSANZ's preliminary view is that choline should be listed as a mandatory substance in infant formula with a mandatory range of 1.7 -12mg/100kJ.

242. INC agrees that choline should be mandatory in infant formula and supports a minimum of 1.7mg/100kJ. However, we are of the view that the maximum level proposed of 12mg/100kJ should be a GUL aligned with Codex STAN 72-1981.

243. Choline is an essential nutrient and INC supports the proposal for an increased maximum in line with Codex levels since only at mid-point levels of the new range are AIs met. However the upper level is proposed by FSANZ as a maximum rather than a GUL based on a recent review publication by Tang and Hazen (2014) which identifies a potential role of choline in CVD in the presence of certain gut microbiota. The new evidence for the role of choline in CVD has not been demonstrated in infants or children. The only source of

choline for this age group would be breast milk or infant formula thus it is important that sufficient is provided, allowing for natural variation and manufacturing capability. Our preliminary view would be the relevance of the new evidence to infants has not been determined hence it would be more appropriate to maintain consistency with Codex STAN 72-1981 that in the absence of a UL, a GUL should be set.

Q1.25 What is the technological justification can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?

244. **INC Response**: As noted above, FSANZ recognises that choline is an essential nutrient. INC is of the view that while the forms choline citrate and/or choline hydrogen tartrate may be rarely used, they may be in the future and contribute to the provision of an essential nutrient. The forms are safe and Standard 2.9.1 should therefore include the forms: choline citrate and/or choline hydrogen tartrate.

Q1.26 If you have provided a technological justification for these forms of choline can you provide: (a) reference to a specification for choline citrate and/or choline hydrogen tartrate in an internationally accepted monograph of specifications (including those referenced in Standard 1.3.4)? (b) evidence to demonstrate safety can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?

245. **INC Response**: Not applicable.

246. ***L-carnitine***: L-carnitine is considered an indispensable nutrient for newborn infants because of a short term, insufficient synthesising capacity. L-carnitine is naturally present in breast milk, cows' milk and goats' milk. FSANZ is proposing to mandate L-carnitine with limits of 0.3-0.8mg/100kJ whether added or not.

Q1.27 Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.

247. **INC Response**: FSANZ's preliminary view is that L-carnitine should be listed as a mandatory substance in infant formula with a mandatory range of 0.3-0.8mg/100kJ.

248. INC agrees that L-carnitine should be mandatory in infant formula and support a minimum of 0.29 mg/100kJ (see conversions discussion). However, we do not support setting a maximum of 0.8 mg/100 kJ for both nutritional and technical reasons as outlined below.

249. L-Carnitine is considered an indispensable nutrient for newborn infants because of a short term insufficient synthesising capacity. In studies investigating L-carnitine concentrations in milk from different species, mean total carnitine concentrations have been reported to be in the range 0.9-1.6mg/100kcal in human milk (Sandor et al 1982, Penn et al 1987, Ferreira 2003). Expert recommendations for a minimum are in line with the upper range at 1.2mg/100kcal (LSRO 1998, Koletzko 2005). Hence INC support FSANZ view that L-carnitine should be mandatory and that a minimum content (conversion corrected) of 0.29mg/100kJ (1.2mg/100kcal) is appropriate.

250. However, INC has significant concerns with the proposed maximum of 0.8mg/100kJ. The basis of setting the maximum at 0.8mg/100kJ dates back to LSRO, 1998 which gave a recommended range as observed in breast milk. This range was increased (0.21-0.8mg/100kJ) to accommodate the typical contribution found in cows' milk infant formula at that time. Neither the SCF (2003) nor EFSA (2014) Opinions considered the

maximum. In the absence of indications of any untoward effects of higher L-carnitine intakes in infants, the ESPGHAN (Koletzko 2005) concluded that no maximum level needed to be set.

251. FSANZ has indicated the need for an upper level based on a recent review publication by Koeth et al (2013) which identifies a potential role of L-carnitine in CVD in the presence of certain gut microbiota. The new evidence has not been demonstrated in infants or children. The only source of L-carnitine for this age group would be breast milk or infant formula thus it is important that sufficient is provided, allowing for natural variation and manufacturing capability. Our preliminary view would be the relevance of the new evidence to infants has not been determined hence it would be more appropriate to maintain consistency that in the absence of a UL, no maximum should be set.

252. Also, the revised tolerance does not take into consideration the natural and variable contribution of L-carnitine from cow or goat milk to the infant formula base. Wollard, Indyk & Wollard (1999) analysed the level of L-carnitine in a range of infant formulas. Their survey indicated a range of values from 6.9-30.1mg/100g. Assuming an example reconstitution ratio of 13.0g of powder/100ml formula and an energy value of 280 kJ/100ml the upper figure of the range would be equivalent to 1.4mg L-carnitine /100 kJ.

253. INC notes that not all manufacturer's currently label the L-carnitine content on products and that the New Zealand *Animal Products (Dairy Based Products - Food Standard Exemption) Notice 2015* lists a number of exemptions for L-carnitine for dairy-based infant formula again supportive of INC concerns regarding the tolerance proposed by FSANZ.

Q1.28 What is the technological justification can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?

254. **INC Response**: INC notes that the nutritional justification for L-carnitine has been confirmed. Both L-carnitine hydrochloride and L-carnitine tartrate are safe to use as evidenced by their inclusion in Codex STAN 72-1981. INC is of the view that while the forms L-carnitine hydrochloride and L-carnitine tartrate may be rarely used, they may be in the future and contribute to the provision of an essential nutrient. The forms are safe and Standard 2.9.1 should therefore include the forms: L-carnitine hydrochloride and L-carnitine tartrate.

Q1.29 If you have provided a technological justification for these forms what evidence to demonstrate safety can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?

255. **INC Response**: As noted above, nutritional justification for L-carnitine has been confirmed and both L-carnitine hydrochloride and L-carnitine tartrate are safe to use as evidenced by their inclusion in Codex STAN 72-1981.

256. **Inositol:** FSANZ states that inositol is considered to be conditionally essential for infants mainly because they may lack the developmental maturity for endogenous synthesis. Inositol is one of the phospholipids found in breast milk. It is present in human tissues predominantly as myo-inositol in free or phosphorylated forms endogenously synthesised from glucose.

257. FSANZ also states that Standard 2.9.1 and Codex STAN 72-1981 permit the same range 1.0-9.5mg/100kJ, although Codex lists inositol as a mandatory inclusion with a GUL.

Many infant formulas contain this substance and no adverse effects in infants consuming these formulas have been reported.

Q1.30 Do you support inclusion of a mandatory minimum requirement for inositol in infant formula?

258. **INC Response**: INC supports the FSANZ preliminary view to mandate inclusion of inositol in infant formula at the current minimum level 0.96mg/100kJ. This would align a conditionally essential nutrient for infants and would align with Codex STAN 72-1981.

259. INC supports an upper limit of 9.5mg/100kJ but supports this being set as a GUL in line with Codex STAN 72-1981.

Q1.31 Do you support listing the permitted form of inositol as myo-inositol to provide clarity and consistency with Codex?

260. **INC Response**: INC supports the listing the permitted form of inositol as myo-inositol. Myo-inositol is the primary form of inositol found in breast milk. The majority of studies conducted on the safety of inositol have been undertaken using myo-inositol.

261. ***Nucleotides*:** Standard 2.9.1 permits the optional addition of five specific nucleotides to infant formula, and outlines a minimum and maximum for each of the permitted nucleotides. It also states that "infant formula product must contain no more than 3.8mg/100kJ of nucleotide 5'-monophosphates". Codex STAN 72-1981 permits the addition of nucleotides at the discretion of national authorities. INC notes that Codex does not prescribe a maximum or minimum for nucleotides.

262. FSANZ is aware that there has been confusion amongst submitters between the prescribed maximum amount for individual nucleotides, and the combined total limit of nucleotides. The revised Code clarifies this issue. FSANZ's preliminary view is to retain the current permission and maximum combined total limit of nucleotides. FSANZ is seeking feedback on the clarity of the drafting in the revised Code.

263. INC supports the continued inclusion of nucleotides as optional ingredients. INC considers the revised Code is clear that for each nucleotide added, then the individual maximum is the total of that nucleotide, including any naturally-occurring amount. We note that other aspects, such as labelling, may not be clear.

264. INC is concerned that Australia and New Zealand are out of step globally in setting a minimum for nucleotides. No minimums are set by the US, Canada or the EU. We note also that there are no minimum or maximum set in 21 CFR 107 Infant Formula or in the Canadian FDR Infant Formula. While a minimum might have been based on the need to be above the innate level, INC does not believe this is sufficient justification for mandating a minimum for total nucleotides.

265. INC supports retention of combined totals in principle but the level of that combined total needs to be determined. It is also important that the Code is clear on the limits applying only when nucleotides are added.

Q1.32 Are there any issues with the clarity of the drafting for the maximum amount of nucleotides in the revised Code?

266. **INC Response**: INC notes that the key issue with drafting for the maximum amount is to ensure that the maximum applies only when nucleotides are added.

Safety & Food Technology

267. The protection of public health and safety is a primary objective for FSANZ and is of paramount importance to manufacturers of infant formula. Infant formula must be safe for formula-fed infants to consume, and caregivers need to know how to safely prepare, use and store the product. The issues FSANZ covered in this section generally relate to:

- safety concerns about certain substances in infant formula
- clarity and enforceability of the Code
- international trade barriers created by existing regulations
- the communication of public health messages
- concerns with caregiver practices when preparing and storing infant formula.

Q2.1 For all views presented in this SD, do you agree with FSANZ's preliminary view?
If so, indicate this in your submission and provide your reasons where appropriate.
If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

268. **INC Response**: See the following submission. In many cases, INC does agree with FSANZ's preliminary view. Where INC does not agree, reasons are provided as requested.

Microbiological Criteria for Infant Formula

269. INC notes this issue is being considered in Proposal P1039 – Microbiological Criteria for Infant Formula, and therefore is not being considered as part of Proposal P1028.

Preparation, use and storage directions to manage microbiological hazards

270. ***Directions to prepare bottles individually***: INC supports the FSANZ proposal to retain the current labelling requirement for an instruction that each bottle should be prepared individually.

271. ***Directions for the storage of made up formula***: The evidence demonstrates that it is safe to store prepared formula for up to 24 hours in the refrigerator, if the refrigerator temperature is operating at 4°C or less. FSANZ considers that the current labelling requirement for an instruction (that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours) remains appropriate.

272. INC suggests clarification is needed that the statement is not prescribed and that there is flexibility for the time limit for refrigerated storage to be for up to 24 hours eg if the parent or caregiver wanted to feed immediately after 4 hours, 8 hours etc, up until a maximum of 24 hours then they should be able to do so. We maintain the view that if a

bottle of made up formula is stored in a refrigerator at 4°C or below before use and that can be used up to 24 hours, then any lesser period of storage at the correct temperature must be safe as well.

273. ***Directions on water used to reconstitute powdered infant formula***: FSANZ is of the view that the current requirement to use cooled previously boiled water does not need to be modified, as there are no public health and safety concerns with caregivers following labelling directions regarding the use of potable, previously boiled water when the other instructions are followed. The requirement also reflects both the Australian and New Zealand infant feeding guidance.

274. INC supports the FSANZ proposal to maintain this labelling requirement as one of a group of risk reduction strategies.

275. ***Discarding leftover formula***: The Code requires the label of infant formula to include words and pictures instructing that formula left in the bottle after a feed must be discarded. FSANZ is proposing to retain the existing requirement based on findings from studies examining this practice and as it is consistent with Australian and New Zealand infant feeding guidance.

276. INC supports the FSANZ proposal that requires the label of infant formula to include words and pictures instructing that formula left in the bottle after a feed must be discarded.

277. ***Standardised directions for preparation and use***: The words and pictures for the directions for preparation and use of infant formula are not prescribed. FSANZ has received little evidence to indicate that caregivers are confused by the presentation and information differences in directions between products.

278. INC supports the FSANZ proposal to maintain the existing overarching requirement, which does not prescribe the words and pictures for the instructions.

Other safe preparation and storage issues

279. ***Date marking of food***: INC supports the FSANZ proposal to maintain the existing requirement that the label on infant formula must carry a date mark complying with the current requirement of the Food Standard Code.

280. ***Storage instructions for opened infant formula***: INC supports the FSANZ proposal to maintain the existing requirement that the label on the infant formula contain storage instructions covering the period after the package is opened noting that this approach aligns with Codex STAN 72-1981.

281. ***Measuring scoop****:* INC strongly opposes standardisation of measuring scoops for the reasons FSANZ has identified, most particularly because infant formula powder bulk density varies across brands and product ranges for a number of reasons including processing technology, composition and other physical attributes. In fact, this is technically impossible.

282. INC strongly supports the continued use of the statement that only the enclosed scoop in the can should be used for preparing the powdered infant formula contained in the can. INC opposes any extension of the statement since it is already used across the board and no evidence of a problem has been presented.

283. **Inaccurate volume indicators on infant feeding bottles**: INC considers indicators on baby bottles to be out of scope for the Australia New Zealand Food Standards Code and hence P1028. INC supports FSANZ approaching the relevant industry sector about the issues.

Q2.2 For all views presented in section 4, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons and evidence as appropriate. If not, indicate this in your submission and provide your reasons including further relevant evidence, current practice, impact on manufacture, or other relevant information.

284. **INC Response**: See responses above.

Warning, advisory and other statements

285. ***Legibility requirements for warning statements***: INC supports maintaining the current legibility requirements for infant formula on the basis that FSANZ has not identified any evidence to indicate that the current requirements for infant formula requirements are inadequate.

286. ***Adding other foods to formula*****:** FSANZ states in SD2 that:
"Adding other foods to formula: It is recommended that powdered infant formula is prepared according to the instructions on the product label, and that it should not be concentrated, diluted or have any other foods added to it unless on the advice of a health practitioner."
and
"Some stakeholders cited anecdotal evidence of caregivers adding other foods, particularly baby cereal products, to bottles of infant formula. This practice is often on the assumption that it will delay hunger and prolong sleep for the infant. Comments also suggested another reason these foods are added is to reduce the cost of feeds."

287. INC notes that FSANZ's search of the literature suggests that it may be common practice to add other foods to infant formula though FSANZ notes it is not possible to estimate the prevalence of this behaviour.

Q2.3 What evidence can you provide that could be used to estimate the prevalence of the practice of caregivers adding other foods to infant formula in Australia and New Zealand?

288. **INC Response**: INC does not have data on the existence of the practice of caregivers adding other foods to infant formula in Australia and New Zealand. In our view this is an area where FSANZ needs to engage with the Australian Department of Health and the New Zealand Ministry of Health to educate the relevant groups. INC does not consider it appropriate to manage such consumer practice via the infant formula pack label. While we suspect that this activity might be practiced, we also suspect it is limited, of low prevalence and not Australia or New Zealand-wide.

Q2.4 What evidence can you provide on whether this practice is more common with powdered infant formula products compared to liquid concentrate or 'ready to drink' products?

289. **INC Response**: INC has no evidence concerning the practice of adding food to infant formula nor about whether it might be more common with liquid than with powdered infant formula. To note, liquid infant formula is currently not available in retail in Australia and New Zealand.

Q2.5 What evidence can you provide that caregivers add other foods to infant formula to reduce the cost of the feed?

290. **INC Response**: INC is not aware that this would be a driver for caregivers. In the consumer survey conducted by Jigsaw in November 2014 (n=501 mothers), in response to a question concerning deciding on a specific infant formula brand, when prompted, 16% of respondents (Question C3d) were looking at price of the infant formula. Eleven other factors were ranked ahead of price. The top three concerns were for the 'best formula based on nutritional needs', 'the difference between gold and standard formulas' and that best formula substitute for breast milk'. Separately, when asked an open-ended, unprompted, question about the information they look for specifically on-pack when making a decision (Question C4c), only 3% identified price.

291. ***Statement on protein source***: INC supports maintaining the requirement that the infant formula label contain a statement of the specific source, or sources, of protein in the product.

292. INC does not support mandating a list of permitted protein sources for declaration on the label for the same reasons as FSANZ has identified: that protein quality and quantity are regulated in the Food Standards Code for health and safety reasons.

293. ***Co-location of protein source statement with the name of the food***: INC supports maintaining the mandatory statement about protein source and for it to be located immediately adjacent to the name of the infant formula (i.e. the prescribed name 'Infant Formula').

294. INC does not support prescribing where the prescribed name (and by association, the protein source statement) should be located on the label. INC members are not aware that location of the information on the package is an issue for consumers.

Q2.6 What evidence can you provide that demonstrates that caregivers have difficulty finding protein source information on the labels of infant formula, and that this affects their ability to make an informed choice?

295. **INC Response**: INC does not have evidence that consumers are finding this difficult. Member companies have no reported contacts on this issue. In our view, this demonstrates a lack of concern by consumers.

Q2.7 What evidence can you provide that demonstrates consistent placement of the statement of protein source on the label would provide a benefit to caregivers?

296. **INC Response**: INC has no evidence that there is any benefit from caregivers in a consistent placement of the statement of protein source.

Q2.8 If so, should there be a requirement to prescribe the position of the statement of protein source on the label e.g. on the front of the package?

297. **INC Response**: INC does not support prescribing the position of the statement of protein source on the label.

Q2.9 What are the cost and trade implications of prescribing the position of the statement of protein source ion the label?

298. **INC Response**: All prescribed label changes require a packaging change which involves artwork and cost. Infant formula already has a significant quantity of mandated requirements and additional requirements need to be based on strong evidence of benefit. In terms of trade impacts, such a requirement would be inconsistent with other jurisdictions and potentially result in less competitive export products, less likelihood that imported products would enter the Australian and New Zealand markets and potentially jeopardise supply to a vulnerable population group.

299. ***Warning statement about following instructions exactly***: INC supports the current requirements that prescribe the wording about following the instructions exactly to ensure the correct preparation of the powdered, concentrated, or 'ready-to-drink' formula.

300. In the consumer survey conducted by Jigsaw in November 2014 (n=501), in response to a question concerning what type of changes do you want to know about, the highest ranked information was preparation instructions (24% of respondents, Question E6a)). Clearly the preparation instructions are of singular significance to caregivers and therefore should not be changed.

301. ***Warning statement that 'breast is best'***: INC represents an industry that supports both breast feeding and the use of infant formula as appropriate. INC therefore supports the current requirement that the infant formula label contain the prescribed warning statement: 'Breast milk is best for babies' and 'Before you decide to use this product, consult your doctor or health worker for advice'.

302. INC does not support a risk-based statement about the risks to infant health of not breastfeeding. The risks are clearly communicated by health care professionals when a caregiver makes contact with them. Access to health care professionals is provided by INC member companies via their care line.

303. ***Statement that infant formula may be used from birth***: INC supports the current requirement for a statement indicating that infant formula may be used from birth. When an infant does not receive breast milk, the only suitable and safe alternative is a scientifically developed infant formula.

304. ***Statement about age to offer foods in addition to formula***: INC supports the current requirement for a statement on infant formula labels indicating that infants over the age of around 6 months should be offered foods in addition to the infant formula. INC notes this statement is consistent with current Australian and New Zealand infant feeding guidance.

305. ***Guidance statement about additional vitamin and mineral supplementation***: INC notes that the Guidelines attached to Standard 2.9.1 (S29—10) include a guideline statement regarding additional vitamin and mineral supplementation; to the effect that consumption of vitamin or mineral preparations are not necessary. As this is guidance only, companies can choose whether to provide this information on their product labels.

306. INC considers the non-regulatory measure of including a statement in the Guidelines is sufficient. Any further action around communicating this more broadly should be a matter for health care professionals and relevant health authorities to consider.

307. ***Prescribed name***: INC supports the requirement that 'Infant Formula', as a prescribed name, is included on infant formula labels.

Q2.10 What evidence can you provide on the prevalence of vitamin and mineral preparation use by Australian and/or New Zealand infants, either with or without medical supervision?

308. **INC Response**: INC is aware of vitamin and mineral preparations that are provided to Australian or New Zealand infants only in hospitals under medical supervision. INC has no evidence or information about the use of vitamin or mineral preparation use in the general infant population. INC is aware that vitamin D drops for infants from birth are available as medicinal preparations or dietary supplements. INC assumes that such practices would be under medical advice.

309. INC suggests a survey of pharmacists may reveal prevalence or further information about any such practice. Similarly a survey of TGA registered or Medsafe products appropriate for infants from birth may also indicate the product range.

Q2.11 Is the prevalence of vitamin and mineral preparation use higher in formula-fed infants than breastfed infants (or vice versa)?

310. **INC Response**: INC has no information on the practice or prevalence of vitamin and mineral preparation use in infants and therefore no information concerning prevalence in formula or breast fed infants. It is possible vitamin D supplementation might be provided to breast fed infants because different jurisdictions screen such infants for different vitamin and mineral deficiencies. Having screened for a deficiency, the health care professional may well be obligated to suggest ways of addressing deficiencies identified.

Q2.12 What data are available on intake levels of vitamins and minerals for Australian and New Zealand infants due to use of supplements (in addition to their normal diets)?

311. **INC Response**: As noted above, INC has no information about the use of vitamins and minerals for Australian and New Zealand infants due to use of supplements. However, pharmacists and TGA or Medsafe may have information that could assist.

Q2.13 What advice is given by health care professionals and/or state and territory government agencies on whether vitamin and mineral supplementation is needed for formula-fed (or breastfed) infants?

312. **INC Response**: Not applicable.

Q2.14 What are the cost and trade implications of mandating advice regarding vitamin and mineral preparations on infant formula packages?

313. **INC Response**: All prescribed label changes require a packaging change which involves artwork and cost. Infant formula already has a significant quantity of mandated requirements and additional requirements need to be based on strong evidence. In terms of trade impacts, such a requirement (regarding vitamin and mineral preparations) would be inconsistent with other jurisdictions and potentially result in less competitive export products, less likelihood that imported products would enter the Australian and New Zealand markets and potentially jeopardise supply to a vulnerable population group. There are other avenues of communicating information that should be exhausted before resorting to adding more to an already very full label on infant formula.

Nutritive substances and novel foods in infant formula products

314. At this stage, FSANZ is seeking input on the principles for the overarching regulatory approach.

Proposal P1024 should include Infant Formula Products

315. In the Call for submissions – Proposal P1024, the infant formula products standard was excluded from its scope. INC strongly supports 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 Consultation for the Review of Infant Formula, we believe a similar broad input needs to be applied to a broader approach for Proposal P1024.

316. The reason for this position is, as was set out in the INC response to Proposal P1024, was:

- 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 population group apply to other parts of the 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. All but one standard (Standard 1.3.2 Vitamins and Minerals) are in Part 2.9 including Standard 2.9.1. Consideration of the future regulation of nutritive substances cannot effectively be conducted if most of the Standards that apply the term are excluded from the scope of Proposal P1024; and
- Proposal P1028 (in Supporting Document 2, Section 6) states that the reason for Proposal P1028 to be considering the regulation of nutritive substances and novel foods in infant formula is "*because infant formula products (and foods for infants) are excluded from the scope of Proposal P1024*". INC suggests this is not justification for consideration by Proposal P1028. Further, Proposal P1028 only covers infant formula and Standard 2.9.1 also covers follow-on formula products and infant formula products for special dietary use.

INC position on Proposal P1024 and Application to Infant Formula Products

317. At the outset, INC expressed support for the framework proposed in Proposal P1024 as Option 3 for general foods but also supported this framework being applied to infant formula products, with consideration of some differential elements specific to the target population that would also address the specific Policy Guideline on the Regulation of Infant Formula Products.

318. The INC submission on Proposal P1024 described how the issues and problems identified in that Proposal 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 infant formula products, particularly in relation to definitional issues. INC therefore considered Options 1 (no change) and 2 (amend the current definitions) did not advance

the system at all and risked perpetuating the problems and issues into the future. INC therefore proposed that, with appropriate differentiation, the framework proposed in Option 3 (although it required further development) should be applied to Standard 2.9.1. INC identified areas of differentiation designed to address the vulnerability of the target population who are consuming infant formula and the unique role of infant formula as the sole source of nutrition for infants 0 to around 6 months where breastfeeding is not undertaken.

319. INC also considered that applying the same framework for the future regulation of new substances (currently nutritive substances and novel foods), but adjusting elements of that framework to address the specific considerations necessary for infant formula products, ensured consistency of approach across the Food Standards Code. INC therefore recommends that future work on Proposal P1028 not include consideration of nutritive substances and novel foods and that this work transfer, and come within an amended scope of Proposal P1024.

Q2.15 Should all or only certain substances proposed for use in infant formula require pre-market assessment?

320. **INC response:** As described in the INC submission on Proposal P1024, INC proposes that, with appropriate differentiation, the framework proposed in Option 3 (although it required further development) should be applied to Standard 2.9.1.

321. INC considers that all substances used in infant formula must be safe and fit for purpose. In line with Policy Guidelines, INC advocates that infant formula ingredients under discussion for future pre market safety assessments, as per pathways defined by Option 3 in Proposal P1024, should include new and existing ingredients not previously used in infant formula. Such assessment should not include retrospective assessments of ingredients currently used in the manufacture of infant formula in compliance with the current Food Standard Code. This is not warranted due to safe history of use.

322. INC therefore supports all substances for use in infant formula requiring pre-market assessment but notes that not all pre-market assessment needs to be undertaken by FSANZ. INC notes that The Eligible Food Criteria pathway and Pre-Market Self-Assessment with notification pathway in the proposed P1024 framework also constitute pre-market safety consideration.

323. As described in its submission on Proposal P1024, INC believes this would meet the Policy Guidelines on Infant Formula Products. The Policy Guidelines do not explicitly restrict pre-market assessment to FSANZ only. INC identified areas of differentiation designed to address the vulnerability of the target population who are consuming infant formula and the unique role of infant formula as the sole source of nutrition for infants 0 to around 6 months where breastfeeding is not undertaken.

324. These differentiating criteria could include:

- documentation on safety for *all* pathways that includes a focus on safety assessment and data that is relevant to infants as the target population group
- clear criteria for the Eligible Food Criteria Pathway in terms of defining eligibility with information to be held relevant to infants as the target population group, for example, comparable levels to human breast milk (if applicable)
- for the Pre-market Self-assessment with Notification Pathway (industry self-assessment), Gateway Criteria such as:
    - extensions of use; or
    - minor deviations from the Eligible Food Criteria

- an option for an expert panel assessment in the Pre-market Self-assessment with Notification pathway (industry self-assessment) to provide expert review of the safety assessment.

325. More work however will be needed on these elements and to map differentiating factors for infant formula products within the Pathways.

326. The framework could also recognise assessment of an ingredient or product in another reputable jurisdiction. Specifically:

- As a general principle, any ingredient or product that qualifies under the Eligible Food Criteria could be eligible for the Eligible Food Criteria pathway, including if it has been assessed under other recognised jurisdictions regulatory systems.
- Ingredients or products that have been assessed under other recognised overseas jurisdictions' regulatory systems could be eligible for the Pre-market Self-assessment with Notification pathway.
- However, considering issues such as speed to market and protection of intellectual property, companies should also be able to choose the FSANZ Pre-market Approval pathway, even if the ingredient/product is eligible for the Pre-market Self-assessment with Notification pathway.
- To support such a choice, the framework could include a streamlined facility for the FSANZ Pre-Market Approval pathway for substances that have already been assessed by other overseas jurisdictions.

327. INC also raised several concerns with the Eligible Food Criteria proposed in Proposal P1024, which would need to be addressed before the proposed framework is adopted for infant formula:

- Eligible Food Criteria 2: We note that commonly used infant formula dairy-based ingredients that have a long history of safe consumption go through a number of processes outlined in Eligible Food Criteria 2. From a dairy ingredient perspective, the boundaries between Eligible Food Criteria 2, Eligible Food Criteria 3 and Eligible Food Criteria 4 are not clear. Almost all dairy products are produced using the criteria listed as eligible processing techniques in the P1024 consultation materials, so it is not clear where a dairy ingredient stops being "simply processed" and becomes an extract or a substance.
- Eligible Food Criteria 3 and Eligible Food Criteria 4: Innovation in infant formula generally emerges from the efforts of manufacturers to mimic breast milk as closely as possible. The source commodity of a substance is not therefore always the benchmark but rather also breastmilk. From this perspective, a differentiation of Eligible Food Criteria 3 and 4 for infant formula could be the option to compare that an extract, when added to infant formula does not exceed the levels naturally occurring in breast milk (if the substance is present in breast milk).
- Further, for dairy ingredients, Eligible Food Criteria 3 and 4 need to be shaped to ensure it is possible to use existing dairy ingredients that may be used in infant formula as a point of comparison for addition of more concentrated ingredients. This is important so that pre-market assessment should not be required for concentrated dairy ingredients that deliver key components at levels that could feasibly be achieved through addition of other dairy ingredients commonly used in infant formula at a higher addition rate. For example, whey protein concentrate can be used at a lower addition rate as an alternative to whey powder as a protein source.

Q2.16 What would be the cost and trade implications of your preferred position?

328. **INC response:** As described in the INC submission on Proposal P1024, INC considered this would in many areas be a continuation of current arrangements (eg in

relation to novel foods which would continue to require pre-market assessment) but would also address the problems and issues identified by FSANZ in Proposal P1024. This approach would close gaps but would do so at costs that may well be able to be addressed over time.

329. As also proposed in Proposal P1024, recognition of assessments undertaken overseas would address costs and trade implications to the greatest extent possible while still meeting Australia and New Zealand's legal and sovereignty concerns. This would also be consistent with the Australian Government's position on minimising regulation.

Q2.17 If only certain substances for use in infant formula should require pre-market assessment, where should the 'line' be drawn for the substances that do require pre-market assessment and those that do not? What is your rationale?

330. **INC response:** See the response to Question Q2.15 above. As described in Proposal P1024, INC proposed that, with appropriate differentiation, the framework described for Option 3 (although it required further development) should be applied to Standard 2.9.1. INC therefore supports all substances for use in infant formula products requiring pre-market consideration but not all requiring pre-market assessment by FSANZ. As described in its submission on Proposal P1024, this would meet the Policy Guidelines on Infant Formula Products. INC identified areas of differentiation designed to address the vulnerability of the target population who are consuming infant formula products.

Q2.18 If only certain substances, how would you suggest we define or characterise the group of substances that should require pre-market assessment?

331. **INC response:** See the response to Question Q2.15 above. INC gave some examples in its submission on Proposal P1024 and would be pleased to work further with FSANZ on the definition and characterisation of the grouping of substances that should require pre-market assessment.

Contaminants

332. ***Acrylonitrile***: The current ML in the Food Standards Code is set at a 0.02 mg/kg (Schedule 19, S19—5). This ML already aligns with Codex and applies to all foods including infant formula. No amendments are proposed and INC supports this position.

333. ***Tin and inorganic tin compounds***: The Food Standards Code and Codex are currently aligned for the ML of tin (250 mg/kg for all canned foods). The FSANZ proposal is to maintain status quo which INC supports.

334. ***Vinyl chloride***: The Food Standards Code and Codex are currently aligned for the ML/GL of vinyl chloride (0.01 mg/kg). The FSANZ proposal is to maintain the status quo which INC supports.

335. ***Aluminium***: FSANZ considers it is appropriate to retain an ML for aluminium and is proposing to set an ML of 0.05 mg/100 mL to apply to all infant formula.

336. INC is of the view that any new contaminant limit should be based upon risk. Aluminium could occur in infant formula as a result of its natural occurrence in ingredients (from the environment), or leaching from food contact materials.

337. Whilst UK researchers have recently questioned the levels of aluminium in infant formula (*BMC Pediatrics*, 2013, **13**:162), those researchers did not take into account the fact that aluminium had been re-evaluated by JECFA in 2012, and the Provisional Tolerable Weekly Intake (PTWI) for aluminium was revised upwards to 2 mg/kg-bodyweight (JECFA 2012). A Cochrane review of the safety of soya-based infant formulas concluded that whilst aluminium levels may be higher in soy-based infant formula there was no published evidence of a negative health effect of aluminium in full-term infants fed modern soy-based infant formula (Vandenplas *et al* 2014).

338. There are three typical packaging materials that contain aluminium:
- aluminium foil (by itself or as a layer of a laminate)
- metalised (aluminium deposited on a substrate)
- aluminium oxide (in high barrier packaging)

339. Of these, the only infant formula packaging material in contact with infant formula is foil and the aluminium in foil is in a fixed state such that aluminium molecules will not transfer to the infant formula.

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

341. In any event, expressing a limit in units of 'mg/100 mL' does not make use of the convenient prefixes provided for by the Système International d'unités (SI) which would have been either 'mg/L' or 'mg/kg'.

Q2.19 What evidence can you provide as to whether this proposed ML would/would not be achievable in soy-based formula? Reference should be made to relevant concentration data in soy-based formula products where possible.

342. **INC Response:** Typically aluminium in soy-based infants formula does test higher than milk based infant formula however company test results indicate that the levels of aluminium in soy-based infant formulas are below 0.05mg/100ml. INC is of the view that the proposed lower ML (0.05mg/100ml) for soy-based infant formula is achievable.

Q2.20 What are the cost and trade implications of reducing the ML for aluminium in soy-based formula?

343. **INC Response:** Based on the above there would be no cost or trade implications with reducing the ML for aluminium in soy-based infant formula to 0.05mg/100ml.

344. ***Arsenic****:* There is no current ML for arsenic (inorganic) or 'arsenic, total' in the Food Standards Code specific for infant formula. FSANZ advises that due to the limited detections of arsenic in infant formula, there is no evidence of a risk to public health and safety from residues of arsenic in infant formula.

345. INC agrees with the FSANZ proposal that there is no specific need to establish an ML for arsenic (inorganic) or arsenic (total) for infant formula in the Code. This approach is consistent with Codex.

346. ***Lead***: The Code includes an ML for lead of 0.02mg/kg in infant formula (Schedule 19, S19-4).

347. INC supports the FSANZ proposal to lower the ML for lead to 0.01 mg/kg in ready-to-consume infant formula in view of the withdrawal of the PTWI by JECFA and the recent adoption of the lower level by Codex. Lowering of the limit for lead in infant formula would be equal to that described by Codex STAN 193-1995 (2015 update) Codex General Standard for Contaminants and Toxins in Food and Feed.

348. The proposed level of 0.01mg/kg in ready-to-consume infant formula has been recently subject to evaluation by JECFA and assessment by Codex, therefore INC suggests that there should be no need for FSANZ to duplicate this work with any further assessment.

349. Further consideration could be given to the limit being expressed on an "as sold" basis, rather than on an 'as consumed' basis. The vast majority of infant formula manufactured and sold in Australia and New Zealand is in powdered form.

350. Codex has previously applied a 7-fold concentration factor between powdered and ready-to-consume infant formula (REP11/CF and REP12/CF). Therefore, the limit for lead in infant formula should be 0.01mg/kg in ready-to-feed infant formula and 0.07mg/kg in powdered infant formula.

351. INC notes that countries (eg Singapore) are beginning to amend national legislation to reflect the lower Codex level for lead and for Australia and New Zealand to do otherwise would put us out of step globally.

Q2.21 What are the cost and trade implications of reducing the ML for lead in infant formula?

352. **INC Response**: Lowering the ML for lead has cost implications that can be spread out over time. This approach would manage the expected future trade requirements of importing countries as national legislation is aligned to Codex. Any further impacts will be provided by company-specific submissions.

353. ***Melamine***: INC is aware that no MLs have been established for melamine in the Food Standards Code. Based on the absence of any associated risk, and that the Codex ML was specifically set to control illegal adulteration of infant formula, INC concurs with FSANZ that there is no rationale for the incorporation of the Codex ML for melamine into the Food Standards Code.

It is also worth noting that the Codex ML was the basis for melamine testing in exports destined for the China market and not for product sold on the Australian or New Zealand markets.

Q2.22 What if any, issues are associated with not including the Codex ML in the Code for melamine?

354. **INC Response:** As noted above, INC does not consider that there are any issues with not including the Codex ML in the Food Standards Code for melamine.

Location of MLs in the Code

355. FSANZ proposes to consolidate all MLs for contaminants in Standard 1.4.1, including those set for infant formula and infant formula products.

356. INC concurs with this proposal and believes that co-locating all MLs for contaminants in a single Standard enhances transparency and usability.

Concentration units for infant formula MLs

357. The default unit for all contaminant MLs in Standard 1.4.1 is mg/kg unless specified otherwise. The ML for lead for infant formula in Standard 1.4.1 is in 'mg/kg', however, the ML for aluminium currently included in Standard 2.9.1 is expressed in terms of 'mg/100mL'. While FSANZ proposes to consolidate all MLs for contaminants in Standard 1.4.1, INC notes that the consistency of expression of these MLs is yet to be determined.

358. Also, it is proposed that MLs for infant formula apply to a reconstituted ready-to-feed form, rather than to a product prior to drying, dehydration or concentration.

Q2.23 Please provide comments on the recommendation to apply all MLs to a reconstituted ready-to-feed form.

359. **INC Response**: INC's preference is for regulations to control the base commodity as sold. The vast majority of infant formula that is both manufactured and sold in Australia and New Zealand is powder. Therefore, we consider the primary limits for contaminants should be expressed on a dry powder basis. Manufacturer testing is most readily undertaken of the powdered product. This means that all testing would exclude the variability of contaminants in potable water supplies throughout Australia and New Zealand which are beyond the manufacturer's control.

360. INC suggests further consideration of secondary limits for Ready-to-Feed products where appropriate. This is the approach taken by some other regulatory bodies such as the EC (2006) in relation to lead.

361. In addition, INC would prefer that the conventional prefixes that are provided for by the Système International d'unités (SI) should be used. Limits for contaminants should be expressed as either 'mg/L' or 'mg/kg' rather than as mg/100mL which is cumbersome not aligned with international practice. Using the units of mg/kg on a powdered basis makes the contaminants easier to regulate and enforce.

Contaminant definition

362. The current MLs in the Code do not usually specify a contaminant definition. FSANZ suggests that this may lead to confusion as to the nature of the analyte for which testing is applicable and that it may be useful to include contaminant definitions for some of the metals relevant to infant formula for clarity. FSANZ is not proposing to change the definition of analytes which are common to both infant formula and other foods, but will address this issue as part of a proposed future review of Standard 1.4.1.

363. INC notes the intention of FSANZ and suggests that a definition of contaminant is not necessary in the Code. No definition of contaminant is included in State, Territory or New Zealand Food Acts. If inclusion of a definition is determined to be necessary, then alignment with Codex would be favoured. The definition in the *Codex General Standard for Contaminants and Toxins in Food and Feed* (Codex STAN 193-1995) defines contaminant as:

> "Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation,

treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter".

Q2.24 Should the contaminant definitions for the contaminant which apply specifically to infant formula (aluminium) be addressed as part of a future review of Standard 1.4.1?

364. **INC Response**: INC concurs with FSANZ that a definition of 'contaminant' be considered as part of a proposed future review of Standard 1.4.1.

Q2.25 Should the contaminant definition for those substances which apply to general foods, including infant formula, be considered later as part of a review of metal contaminants in standard 1.4.1?

365. **INC Response:** INC concurs with FSANZ that a definition of 'contaminant' be considered as part of a proposed future review of Standard 1.4.1. At this stage, however, INC does not see a need for such a definition.

Food Additives

Aligning food additive permissions in the Food Standards Code with Codex

366. FSANZ notes that if the Food Standards Code was to be aligned with Codex, then a range of amendments to the Code would be needed, such as additional permissions, changes to maximum permitted levels (MPLs), and revision of some nomenclature and INS numbers.

367. ***Acidity regulators***: FSANZ has identified 12 food additives that are listed in Codex STAN 72-1981 as acidity regulators: sodium dihydrogen phosphate (INS 339i), disodium hydrogen phosphate (INS 339ii), trisodium phosphate (INS 339iii), potassium dihydrogen phosphate (INS 340i), dipotassium hydrogen phosphate (INS 340ii), tripotassium phosphate (INS 340iii), sodium carbonate (INS 500i), sodium hydrogen carbonate (INS 500ii), potassium carbonate (INS 501i), potassium hydrogen carbonate (INS 501ii), sodium hydroxide (INS 524), and potassium hydroxide (INS 525).

368. Many of these acidity regulators are listed in Standard 1.3.1 (S16—2 of Schedule 16) as food additives. They can also be used as processing aids under Standard 1.3.3 (subsection 1.3.3 and 1.3.4). All are permitted forms of minerals for use in infant formula in Standard 2.9.1 (S29—7 of Schedule 29). FSANZ notes therefore, these 12 substances could be used as either food additives (technological purpose of acidity regulators), processing aids or as permitted forms of minerals in the manufacture of foods. FSANZ is concerned that their permissions and uses are different in overseas markets and such products could be exported to Australia and New Zealand. If it is determined that there is a technological purpose and need for these food additives then FSANZ may consider their safety and suitability by conducting a safety and technical assessment of them at the next stage of this Proposal.

369. INC considers that these 12 substances could be used as either food additives (technological purpose of acidity regulators) as in other countries as well as processing aids or as permitted forms of minerals in the manufacture of foods including infant formula as currently permitted by Standard 2.9.1. All are approved for use by Codex and therefore technological justification and safety assessments have been completed.

370. INC advises that many of the acidity regulators are approved and used as food additives in infant formula overseas: sodium carbonates (INS500i and INS500ii), potassium carbonates (INS501i and INS501ii), sodium hydroxide (INS524), potassium hydroxide (INS525), sodium phosphates (INS339i, INS339ii, INS339iii) and potassium phosphates (INS340i, INS340ii, INS 340iii). They are approved for use in both Codex and the EU and INC supports their inclusion.

371. ***Citric and fatty acid esters of glycerol***: FSANZ could consider an extension of use for these food additives as part of the future work of this Proposal.

372. INC supports the extension of use for Citric and fatty acid esters of glycerol (CITREM) (INS 472c) for use in infant formula. INS472c is currently permitted for use in the Food Standard Code for infant formula products for special dietary use based on protein substitutes (Schedule 15, Class 13.1.3 Infant formula products for special dietary use based on a protein substitute).

373. In 2015 the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, CODEX STAN 72 – 1981, was amended to include new provisions for INS 472c. The provisions for CITREM/INS 472c are now listed in Section 4 Table 1 of this standard.

All types of liquid infant formula	0.9g/100ml of the product ready for consumption
All types of powder infant formula	0.75g/100ml of the product ready for consumption

374. Additionally, CITREM/INS472c is permitted in infant and follow on formula in EU (Commission Regulation No 1129/2011 of 11 November 2011 amending Annex II to Regulation No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives).

375. ***Starch sodium octenyl succinate***: FSANZ consider an extension of use outside of the future work of this Proposal.

376. Although this is not within the scope of Proposal P1028, INC supports the inclusion of Octenyl succinic acid (OSA)–modified starch (starch sodium octenyl succinate) (INS 1450) for infant formula products for special dietary use based on a protein substitute (Schedule 15, Class 13.1.3) as per the agreement at CCNFSDU 36 (November 2014) and confirmed by CAC38 (July 2015). JECFA79 concluded that the consumption of OSA-modified starch in infant formula or formula for special medical purposes intended for infants is not of concern at concentrations up to 20 g/l.

Q2.26 What is the technological purpose for using the following 12 substances in the production of infant formula – INS 339i, 339ii, 339iii, 340i, 340ii, 340iii, 500i, 500ii, 501i, 501ii, 524 and 525? i.e. are they best described as food additives, processing aids or permitted forms of minerals? Please explain and provide examples of how they are used in the manufacture of infant formula.

377. **INC Response:** INC considers that the 12 substances (INS 339i, 339ii, 339iii, 340i, 340ii, 340iii, 500i, 500ii, 501i, 501ii, 524 and 525) could be used as food additives as well as processing aids or permitted forms of minerals. INC considers they should be listed as food additives as provided for by Codex.

Q2.27 What justification can manufacturers and suppliers of infant formula in Australia and New Zealand provide to expand the permission for the food additive citric and fatty acid esters of glycerol (INS 472c) to all infant formula?

378. **INC Response:** Infant formula, follow on formula as well as formulas for special medical purposes intended for Infants manufactured with amino acids and hydrolyzed proteins have different hydrophobic/hydrophilic characteristics and lower emulsifying capacity than products based on whole protein. CITREM/INS 472c improve the stability and organoleptic properties of products containing (partially) hydrolysed proteins, peptides or amino acids. Emulsifiers are therefore a technological requirement for these formulas to ensure both palatability and prevention of separation of the formula after reconstitution.

Q2.28 What, if any, information can you provide to support an assessment of an extension of use of a food additive in infant formula?

379. **INC Response**: The 79th JECFA Committee (2014) concluded that there are no toxicological concerns about the use of CITREM/INS 472c in infant formula and formula for special medical purposes at concentrations up to 9g/L. At the higher use levels, there is a possibility of diarrhoea from free citric acid released from formula containing CITREM/INS

472c. Given the paucity of clinical data and the fact that exposure assumptions for citric acid have been maximized, it is difficult to estimate the risk of diarrhoea, but it is considered to be low. Therefore the use of CITREM/INS 472c does not present an appreciable health risk to consumers.

380. Prepared at the 79th JECFA (2014) and published in FAO JECFA, Monographs 16 (2014) superseding specifications prepared at the 35th JECFA (1989), published in FNP 49 (1990) and in FNP 52 (1992). Metals and arsenic specifications revised at the 61st JECFA (2003). An ADI 'not limited' was established at the 17th JECFA (1973). The specification for lead is under consideration for CCFA 48, 2016. Data has been provided by industry to support this consideration.

Q2.29 To what extent is 472c used in IFPSDU? Is it widely used, and are the levels used close to the maximum permitted level in the Code?

381. **INC Response**: INC is not certain of the extent of use of citric and fatty acid esters of glycerol (INS472c). This may be commented on in individual company submissions.

382. ***Updates to nomenclature and INS numbers***: FSANZ advises in SD2 that Codex uses the INS (as listed in CAC/GL 36-1989), such that permissions in Codex STAN 72-1981 and Codex STAN 192-1995 are listed by the specific name and INS number for individual food additives. The Food Standards Code refers to chemical families written as the plural term with the same INS number.

383. FSANZ advises that if the Food Standards Code was to align with Codex then several changes would be required (eg specific food additive name and number of individual additives rather than refer to chemical families, or the plural form of additives, lecithin and locust bean (carob bean) gum). There would then be flow on consequences for food categories other than infant formula. FSANZ is proposing that such changes are beyond the scope of Proposal P1028 but that it may prepare a proposal at a later date to address the issue.

Q2.30 What, if any issues would a lack of consistency in the nomenclature of food additive names for infant formula cause?

384. **INC Response**: Manufacturers of infant formula products and indeed general food products have managed with a lack of consistency in the nomenclature of food additive names to date. While consistency is helpful, manufacturers are comfortable using either the INS or the name.

385. ***Changes to maximum permitted levels***: FSANZ notes in SD3 that there is a difference in the MPL for hydroxypropyl starch between the Food Standards Code and Codex. To align with Codex, the MPL for hydroxypropyl starch for use in soybased infant formula would need to be lowered from 25000 to 5000mg/L, singly or in combination. The MPL of hydroxypropyl starch (INS 1440) in soy-based infant formula is 25000mg/L, which FSANZ understands to be an error. The recommended MPL in P93 was 5000mg/L. The limit in Codex is also 5000mg/L. Lowering the MPL for hydroxypropyl starch would create consistency with Codex and with the original intent of the decision made in P93.

Q2.31 Will lowering the MPL of hydroxypropyl starch to 5000 mg/L create any difficulties for infant formula companies?

386. **INC Response**: INC advises that lowering the MPL of hydroxypropyl starch to 5000mg/L will not create difficulties for infant formula companies. The MPL has long been recognised as erroneous and companies have been working to lower limits.

Carry-over principle for food additives and infant formula

387. FSANZ states there has been confusion about how the carry-over principle in the Code operates for infant formula. For clarity, and to be consistent with the Codex approach, FSANZ proposes that the carry-over principle for food additives should not apply to infant formula.

388. However Codex STAN 72-1981 Section 4 Food Additives outlines food additives as listed in this Section, or in the *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* CAC/ GL 10-1979, may be present in infant formula products, as a result of carry-over from raw material or ingredient.

389. Thus, INC does not agree with FSANZ that Codex does not allow for carry-over of food additives into infant formula and strongly believes that the food additive carry-over principle should continue to apply to infant formula. INC therefore supports the status quo.

390. INC supports alignment with Codex in relation to permitted carry-over additives as noted in our 2012 submission on this issue, that is, INC supports permission for all food additives outlined in Codex STAN 72-1981 Section 4, as well as CAC/GL 10-1979, that may be intentionally added or carried over into infant formula. Trade barriers may exist where additives are permitted to be carried over from raw ingredients under Codex, but not permitted for use in infant formula products in the Food Standards Code.

Q2.32 Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.

391. **INC Response:** See above. In summary, INC strongly supports the continuation of the carry-over principle for food additives to infant formula as has been the interpretation applied by manufacturers to date. INC suggests that to do otherwise would place all infant formula supplies for Australia and New Zealand in jeopardy and create significant trade barriers.

Clarifications to the Code

392. ***Carrageenan permission for liquid soy-based infant formula***: FSANZ advises that the hierarchy of the food categories in the Code lists liquid infant formula as a separate subcategory to soy infant formula. The permission for carrageenan is listed only for liquid infant formula and there is no permission for carrageenan in soy-based infant formula.

393. FSANZ is aware that there is some confusion about whether the subcategories of infant formula are mutually exclusive.

Q2.32 (second occurrence) Is there a technological justification for permitting carrageenan in liquid soy-based infant formula products?

394. **INC Response:** Carrageenan provides a technical effect in liquid infant formula, whether milk or soy-based, which cannot be duplicated by other additives used as stabilizers:

- Builds viscosity – Helps to stabilize the sedimentation of dense components such as insoluble calcium and phosphate salts; Slows the upward migration of fat, which is less dense
- Deters separation – Without carrageenan for stabilization, formulas would be more likely to produce insoluble sediments or creaming (separation of fat); Assures uniformity of all nutrients throughout shelf life and prevents suboptimal delivery of nutrients
- Promotes emulsion – Creating an emulsion during manufacture of formulas made with hydrolyzed proteins would be difficult without carrageenan as oil would immediately separate
- Promotes proper mouthfeel – Through proper suspension of insoluble components of formulas, carrageenan creates a smooth, pourable liquid with suitable mouthfeel
- Efficacy – Carrageenan does not influence the efficacy of other components in formulas, particularly vitamins and minerals
- Lower use needed to achieve function – Carrageenan can be used at lower levels as compared to other stabilizers to achieve the necessary functionality.

Q2.33 Do submitters believe the current permissions in the Code permit carrageenan in soy-based infant formula?

395. **INC Response:** INC supports the continued permission of Carrageenan (INS 407) for use in both milk-based and soy-based liquid infant formula.

Q2.34 Will the correction of the hydroxypropyl starch MPL to the lower level of 5000 mg/L cause any issues? Are you aware of any infant formula marketed in Australia and New Zealand that uses hydroxypropyl starch as a food additive at levels above?

396. **INC Response:** As above, INC advises that lowering the MPL of hydroxypropyl starch to 5000 mg/L will not create difficulties for infant formula companies. The MPL has long been recognised as erroneous and companies have been working to lower limits.

397. ***Permitted starches, removal of qualification statement***: FSANZ's preliminary view is to remove the qualification statement that subclause 6(1) of Standard 1.3.1 applies, as it automatically applies for all food additives used to perform the same function in a food. INC concurs with this view.

Provision of information

Claims about ingredients

398. FSANZ considers there appears to be a lack of regulatory clarity in the Code about ingredient claims on packaged infant formula. Requirements could be specified in the Code for such claims when used in relation to infant formula.

399. INC considers that with the Nutrition, Health and Related Claims Standard 1.2.7 coming into force on Jan 2016, and that Standard's coverage of implied and expressed claims, there is no longer an issue around regulatory clarity and no gap in regulatory coverage now exists. However, INC considers that there is a serious gap in information available to consumers to make informed choices about the formula that's best for their baby.

Q3.1 Should claims about specific ingredients be permitted on packaged infant formula?

400. **INC Response**: INC believes that breast milk is unequivocally the best source of nutrition for infants due to its unique benefits. In circumstances when an infant cannot receive breast milk the only suitable and safe alternative is a scientifically-developed infant formula which satisfies the nutritional requirements of infants aged up to six months. INC recognises that some infants are not breastfed, for a variety of medical, practical or personal reasons. Information provided on pack does not trigger the initiation of formula-feeding, and caregivers will usually only look for this information ***after*** the decision has been made to initiate formula feeding.

401. INC believes it is very important that the needs of formula-fed infants are supported. Often caregivers are struggling to find adequate information on formula feeding. Ideally, caregivers should seek infant formula information from a health care professional before starting the use of a formula but this will not always be the case. On-pack information is a very important source of information for caregivers to improve the prospect of being able to make an informed choice. Equally, access of infant formula representatives who are able to provide scientific and factual information on products to health care professionals is pivotal for infant health and safety. Once a decision to use formula is made in consultation with their health care professional, caregivers should be able to make informed choices about the infant formula they buy. Above all other foods, this is possibly the most important purchasing decision as infant formula may be the sole source of nutrition for infants in the first 6 months of life.

402. It is clear that any decision made to use infant formula is made well before any consideration of the type of formula and is, as noted above, usually made in consultation with a health care professional. In other circumstances the decision might be made in discussion with family or friends. On-pack labelling has little or no role in the decision making associated with the cessation of breastfeeding. Rather, information about the formula is sought after this decision is made.

403. **INC proposes that this review of infant formula includes improvements to existing labelling requirements to assist parents and caregivers once they have made the decision to formula feed and select an infant formula that will best suit their infant. INC believes this review of infant formula regulation can address the current lack of information on-pack available to parents and caregivers.**

404. **Specifically, INC proposes:**

- **Permission for nutrient content claims for optional or differentiating essential nutrients**
- **Permission for general level health claims for optional or differentiating essential nutrients.**

405. **INC is open to maintaining the status quo in prohibiting claims on vitamins and minerals for infant formula only, however this view does not extend to follow-on formula.**

406. **If permitted, permissions for nutrient and general level health claims could be regulated by incorporating such permissions into either Standard 1.2.7 or Standard 2.9.1.**

407. While mandatory standards must be met in formulating an infant formula, not all infant formulas are the same, therefore packaging labels are an appropriate means through which to communicate information about ingredients and/or particular nutrients. This information is essential for parents and caregivers to help differentiate between products

and inform their choice based on the advice of their health care professional. The current prohibition on nutrient content and health related claims does not assist the needs of formula feeding caregivers.

408. For formula-fed infants less than 6 months old, the only source of nutrition is infant formula and therefore infant formula is only consumed for a nutritional reason. These products are extensively researched and scientifically formulated to be **safe**, and to provide adequate nutrition to achieve, at minimum, normal growth and developmental outcomes for the infant.

409. Additionally, a lack of differentiation between brands is a significant disincentive to innovation, which is not in the best interest of the formula-fed infant. Formula feeding is sometimes not a choice – and infants that receive formula need to benefit from the substantial clinical research and innovation that goes into improving infant formula, in the best interest of the infant.

410. INC recognises that FSANZ must meet its high order principles and statutory objectives (Food Standards Australia New Zealand Act 1991, section 18), to develop food regulatory measures and to ensure:

a) The protection of public health and safety;
b) The provision of adequate information relating to food to enable consumer to make informed choices; and
c) The prevention of misleading or deceptive conduct

411. The current situation does not allow all these high order principles and statutory objectives are met. INC is concerned that the Food Standards Code (Standards 1.2.7 and 2.9.1) does not meet the FSANZ objective to provide adequate information relating to food to enable consumers to make informed choices. The protection of public health and safety can also in certain situations be compromised if caregivers are influenced by inaccurate information to use a breast-milk substitute other than a scientifically formulated infant formula to feed their babies – e.g. a "home-made" infant formula based on the Paleo diet.

412. In the following pages, INC will provide evidence that labels on infant formula do not provide sufficient information to allow parents and caregivers to make informed decisions. We will also explain why the inclusion of such information is compatible with the International Code of Marketing of Breast-milk Substitutes (WHO Code), the MAIF Agreement in Australia, the Code of Marketing in New Zealand and the Ministerial Council Policy Guideline on the Regulation of Infant Formula Products.

Evidence and Comments Supporting the Need for Nutrient Content and General Level Health Claims on Infant Formula to Enable Informed Choice

[1] <u>International Landscape</u>

413. In other developed countries, such as Canada, the United States and Singapore, infant formula packaging can display information such as "*Omega 3 DHA, which helps support brain and eye development*". This type of information enables parents to understand the differences between products. In general these types of claims can only be made if specified criteria are met and the levels of the nutrient concerned are provided in what would be considered the nutrition information statement. This approach provides additional comparative product information as well as ensuring that levels are nutritionally significant.

414. By contrast, this type of information cannot be provided on infant formula packs in Australia and New Zealand, as Standard 1.2.7, section 1.2.7—4, prohibits nutrient content claims and health claims on infant formula products. Australia and New Zealand are out of step with permissions around informed choice for consumers for infant formula enabled by a range of other credible regulatory authorities.

[2] Consumer market research

415. In 2014, INC commissioned a third party organisation (Jigsaw) to undertake consumer research to investigate the following:

(i) Identify the key influencers in a mother's decision to use infant formula
(ii) Identify the other sources of information and the type of information then needed to make an informed decision when choosing an infant formula
(iii) Understand the role packaging plays in providing information to mothers.

416. Please refer to Appendix 2 for the complete study results and discussion. An overview and summary of key findings is discussed here.

417. ***Study Design:*** The consumer research entailed an online questionnaire:

- Mothers, aged 18-44 years, were recruited to participate if they had babies and/or toddlers aged 0-24 months
- Mothers with newborns (0-12 months) were asked to refer to their current situation and mothers with young children (13-24 months) were asked to think back to the situation when their child was 0-12 months
- Only mothers that used infant or follow-on formula were eligible to continue with the survey
- A total of 501 mothers completed the survey with 231 being first time mothers and 270 having more than one child.

418. ***Results and key findings***

1. Infant formula labels are not key influences for initiating formula use:
   a. Challenges with breastfeeding is the key driver to initiating formula use within the first 6 months
   b. For mothers with infants 7 - 12 months, the key drivers to initiate formula use were to supplement feed (still continue with breastfeeding and introduce formula feeds) and returning to work.

2. Health care professionals should be the key source of information regarding the appropriate feeding options for infants, but this is not always the case with family/friends presenting a large group:
   a. Health care professionals as a group are the most common information source for mothers (57%)
   b. Friends and family play an almost equal role in providing information (54%)
   c. Almost half of the mothers looking for information online use company websites (45%)
   d. 26% (1st ranking) ranked family members (non-authoritative sources) as the most useful *(almost double that of any health care professional group).*

3. It can be difficult for the consumer to differentiate between different brands of infant formula solely based on the ingredient listing and nutrition information.
   a. Regardless of how many children the mother had, the information most mothers look for when first making a decision about formula (having made a decision already to use formula) is:
      i. What brand of formula to use
      ii. What ingredients are in the formula

iii. What are the benefits or risks of the formula.

b. Information most mothers look for when choosing a specific product included:
   i. Best product to meet the nutritional needs of her infant
   ii. The difference between products e.g. gold and standard varieties
   iii. Ingredients and nutritional benefits.

c. Information most mothers look for on-pack to help make a decision:
   i. Nutritional/health benefits
   ii. Ingredients
   iii. Age information/stage.

4. Labels on infant formula do not provide sufficient information:
   a. 1 in 3 feel they received insufficient information from the label when buying formula for the first time
   b. 40% aren't aware of ingredients (e.g. nutrients) in the formula they buy
   c. Only 3% found product labelling to be the most useful (therefore indicating an opportunity to improve labelling).

5. Label information including ingredients and product benefits is key with respect to a decision to purchase a particular product:
   a. Around 4 in 10 claim that their decision about what product or brand to buy was not finalised until at the shelf
   b. When making a decision, the most useful information on the label was
      i. Age / stage information
      ii. Feeding table and preparation guide (*consulted by almost all mothers at some point in time*)
      iii. Ingredients and product benefits (*seen to be useful by nearly 75% of surveyed mothers*).

6. Communication of formulation changes is very important to the surveyed mothers:
   a. 93% of mothers felt it was very important or important to be informed about formulation changes
   b. They wanted to know what has actually changed. Preparation instructions and ingredients are the key changes that would need communicating
   c. An overwhelming majority (85%) expect that product packaging labels have a role in communicating product changes.

419. ***Discussion of Consumer market research***: The consumer research identified a number of key influences on a mother's decision to formula feed, the sources of information and how useful this was when making an informed decision about a specific infant formula.

420. Challenges with breastfeeding remain the primary driver for use of formula. This finding is consistent with other surveys and studies investigating the barriers to breastfeeding (see Section 3 "Reasons why Mothers stop breastfeeding" below). Australian mothers are educated on the benefits of breastfeeding and Australia can boast a high percentage of mother's breastfeeding at the time of hospital discharge. This survey demonstrates that challenges with breastfeeding (e.g. inability to latch, provide adequate breast milk supply, painful or cracked nipples, stressed), the need to supplementary feed (mix both formula and breast milk) and returning to work are the main reasons for any subsequent introduction of formula. Only a small percentage of the mothers surveyed revealed that they chose to introduce formula simply from seeing the product on shelf.

421. Health care professionals should be the key source of information, but this is not always the case with family/friends presenting a large group. In the current environment, mothers identified family members as the most useful source of information; almost double that of any health care professionals group. Many health care professionals are often unable to provide the necessary information about infant formula or infant formula feeding to mothers and caregivers as they are bound by local feeding guidelines (e.g. in NZ).

422. Furthermore, the Feeding Queensland Babies Study found information sources for infant formula were less often accessed, compared with information sources for breastfeeding. The survey revealed that while 51% of mothers had given formula their child, only 38% had ever received information about formula feeding from a health care professional and even fewer had accessed information on the internet (Newby et al 2015). Additional information on a label that is regulated can be a credible source of information when mothers are unable to seek advice from a professional.

423. Once a decision has been made to formula-feed, health care professionals and family/friends were shown to be useful sources of information about formula. Yet 4 mothers in 10 claim that their decision about what specific product or brand to buy was not made until at the shelf. This again highlights the importance of the information a mum has available to make an informed decision at the time of purchase.

424. It can be difficult for the parent or caregiver to differentiate solely based on the ingredient listing and nutrition information. Only 3% found product labelling to be the most useful and 40% of mothers were not aware of the ingredients in the product they were buying and feeding their child. The research identified most mothers were seeking information on brands, ingredients, benefits/risks of formula, nutritional benefits and differences between the varieties of formula (e.g. ‘gold’ vs ‘standard’). When asked about what information they look for particularly on-pack to help make a decision, nutritional/health benefits and ingredient information was critical. Product labels can help address this need as most of this information relates to the formulation of the product and is within the regulatory remit of the Food Standards Code.

425. When asked an open ended question about what other information they feel is missing or would be a useful addition to infant formula packaging, only 30% said they wanted more information and this should include information about ingredients and feeding instructions. The majority of mothers (70%) said they don’t require any more information. However, when prompted, 50% wanted additional information on the difference between the ‘gold’ and ‘standard’ varieties.

426. A stand out result of this survey indicated how important it was to communicate any change about the formula to mothers. Almost all mothers surveyed (93%) felt it was important to communicate changes. Parents want to be informed about the product they are feeding their children. The top three changes they want to know about were preparation instructions, generally what has changed and changes to ingredients. Furthermore, 85% of mothers expected to be informed via product packaging/labels; 53% expected to see change notifications on brand websites and only 26% expected their health care professional to advise them of the change. As mentioned above, company websites are visited by a significant number, however, with the prohibition on nutrient content and health related claims extending to websites (and advertising) under the Food Standards Code, using websites for education would not be compliant.

427. The on-pack feeding table and preparation instructions were seen to be important sources of information for mothers. Almost all mothers surveyed either always referred to

the on-pack instructions or used the information until they were educated and comfortable enough to prepare and feed formula without the guides. When compared to an American survey that found a third of mothers using formula did not read the preparation and storage instructions on the label (Labiner-Wolfe J et al. 2008), the Australian mothers surveyed here appeared well educated about the importance and relevance of labelling information.

428. In conclusion, the data and evidence presented by the consumer research commissioned by INC supports that permissions around nutrient content and general level health claims should be granted that would allow caregivers to make an informed choice.

[3] Reasons why mothers stop breastfeeding

429. The 2010 Australian national infant feeding survey reported breastfeeding was initiated in 96% of children aged 0-2 years. This demonstrates that Australian mothers and caregivers are educated on the benefits of breastfeeding and understand it is the ideal source of nutrition for infants. Unfortunately, not all mothers are able to continue breastfeeding exclusively. A number of studies have identified barriers to breastfeeding for Australian mothers. The Healthy Beginnings Trial found problems with milk supply, unsettled baby, problems latching baby to the breast and pain as the main barriers to breastfeeding (Wardle K et al 2014). Barriers to breastfeeding were explored in depth in the 2007 government report on the inquiry into the health benefits of breastfeeding, 'The Best Start' (Australian House of Representatives 2007). The Report found that breastfeeding management, challenges, education and support were all factors impacting continuation of breastfeeding.

430. The 2010 Australian National Infant Feeding Survey revealed the most cited reason for not continuing breastfeeding in the first 6 months was 'not enough breast milk for child' followed by 'child was not attaching properly' and 'baby was unsettled'. Of the 52, 000 mothers/carers surveyed, 4% did not provide any breast milk to their child. And only 26% of these mothers/carers did so because they felt infant formula was as good as breast milk (equals approximately 1% of total population in survey). The more prevalent reason was previous unsuccessful experience with breastfeeding.

431. Indeed, decisions around infant feeding can be a complex pathway to navigate, as explored in Sheehan's 2013 qualitative research study. In-depth interviews with Australian mothers found that the decision making process involved multiple factors specific to individuals and complex and competing goals were involved in the decision to continue breastfeeding (Sheehan A et al 2013).

[4] The Voice of the formula feeding mother

432. Companies have provided some insights to support the need for informed choice from caregivers from consumer contacts and data has been generated through INC via a third party consumer research agency (Jigsaw). However, this forms a small proportion of caregivers who have made a choice to formula feed. INC considers that the views of this group, the "Voice of the Formula Feeding Mother", tend to be largely absent from stakeholder submissions. INC suggests that FSANZ seeks specific and targeted engagement with this stakeholder group to gather information that may not be available from the insights already provided.

433. INC suggests that FSANZ conduct this work as they are both an interested and independent party. In parallel, we also propose that to ensure the topic is comprehensively covered, and to close the gaps in evidence required to allow for informed choice, FSANZ evaluates and provides strong evidence that would, conversely, support the current prohibitions on nutrient content and health claims on labels and advertisements.

434. In addition to the data provided by INC above, INC provides the following quotes/verbatims and anecdotal evidence from some Voice of the formula feeding mother sources, that may demonstrate some of the views of this stakeholder group.

435. ***Submissions to FSANZ in relation to this topic (2012):*** We suggest that FSANZ refers back to the 2012 submission by Lisa Watson, on behalf of Bottle Babies Inc. (a non-profit organisation, '*to bring all parents together to supply advice, encouragement and information to those of us who bottle feed our children, no matter of the circumstances surrounding that decision and to support one another no matter of the way in which we personally feed our children*"), which conducted surveys within its community to inform it's 2012 submission.

436. Some key themes that came out of this were:

- Choice of infant formula was based on many outside influencers (recommendations from friends, family, health care professionals, 'own research', suitability for baby)
- More information is desired for brand differentiation and in order to make an informed choice:
    - When asked the question: "*Would additional information on formula packaging about nutritional benefit differences between formula brands, have helped you make a more informed choice on which brand to choose?*", **over half (50.4%)** of the respondents answered "*Yes, it would be good*".
    - Supporting comments: "*Bottle Babies recognises that the responses to both these questions indicate that while formula feeding parents do not rely on the information about extra benefit advantages between different brands of formula and that claims made on formula packaging is not strong influence on choosing which brand to feed their baby, they would like the ability to have the information available to them so that they are able to make informed choices… omitting health benefit information differences between different brands of formula denies parents the ability to make informed choices. Formula feeding parents deserve easy access to information regarding ingredients in formula which may be of benefit*".

- Claims on infant formula labels are **not** a main reason to cessation of breastfeeding:
    - Supporting comments: "*We also feel that health claims on formula packaging do not influence the decision on breastfeeding initiation or continuation. To claim that an Australia or New Zealand family may choose to use formula to feed their baby instead of breastfeeding because of the health claims on formula packaging under the current guidelines, is in Bottle Babies' opinion, disrespectful of the intelligence levels of parents throughout these countries*."

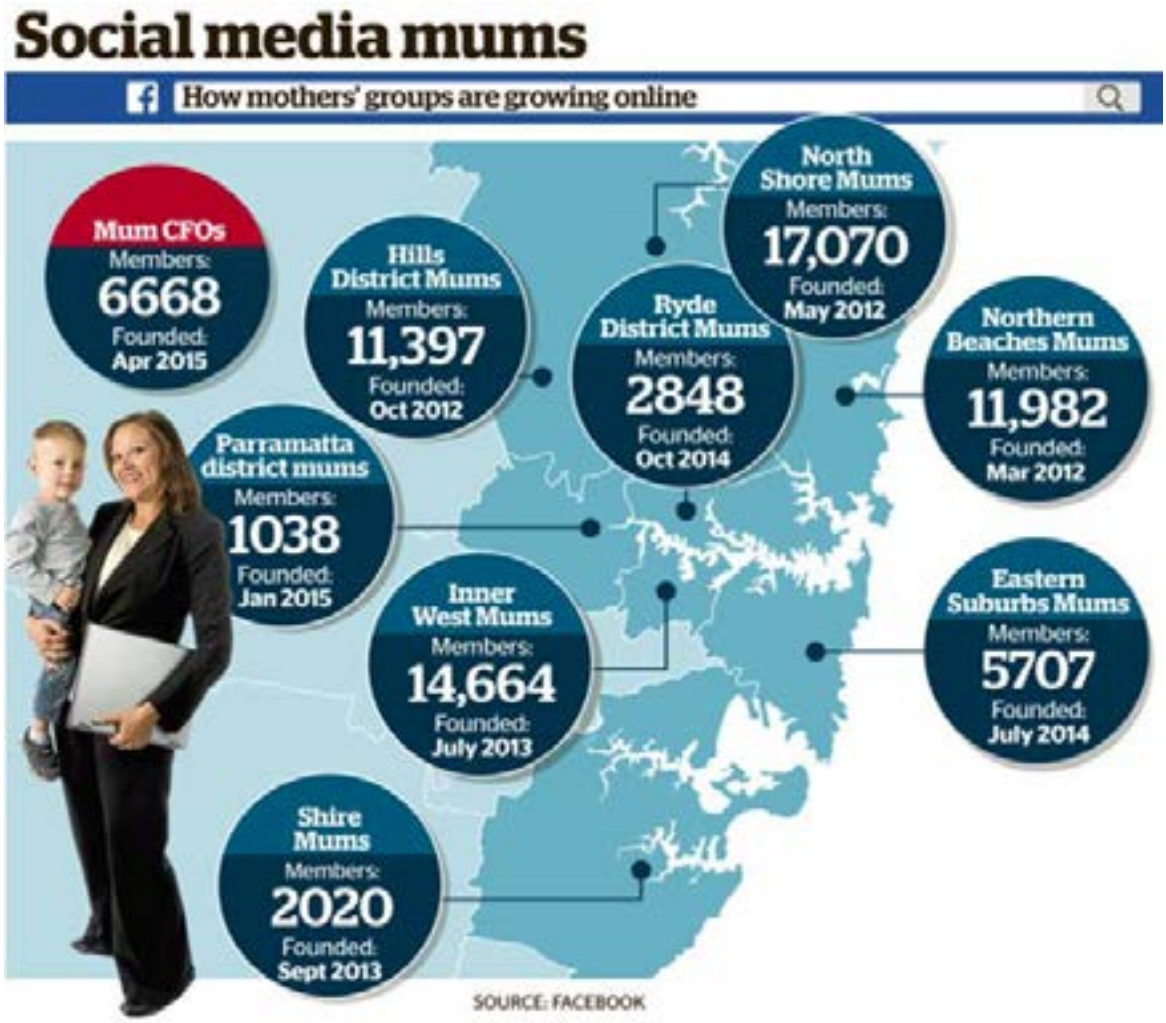
437. Based on the above, INC considers that:

- there is an opportunity for a CREDIBLE source of information on pack
- the **Voice of the formula feeding mother** is in support of more information on packaging to support brand differentiation.
- the **Voice of the formula feeding mother** does not consider labelling information a primary factor influencing a mother's choice not to breastfeed.

438. ***Caregivers within the Digital channel – Social media (Facebook/Twitter), Community forums (Online parent forums), Blogs, Brand websites, Parent websites*** There is a wealth of information and content online. Since 2004, the growth of social media has been near exponential. 72 percent of all Internet users are also social media users. That means we're well beyond early adopters and social media is becoming as ubiquitous as the computer itself, and a powerful influencer (Morrison, 2014).

439. As such, engagement platforms such as Facebook, Twitter, community forums, blogs etc. have grown significantly, and caregivers are using these platforms to share or seek information and views. Recently, as caregivers become more digitally savvy in a multi-device connected society, digital as a source for information gathering and engagement, has become the norm. With the growth of such platforms, more 'traditional' means of obtaining information such as visiting a health care professional, has likely been diluted.

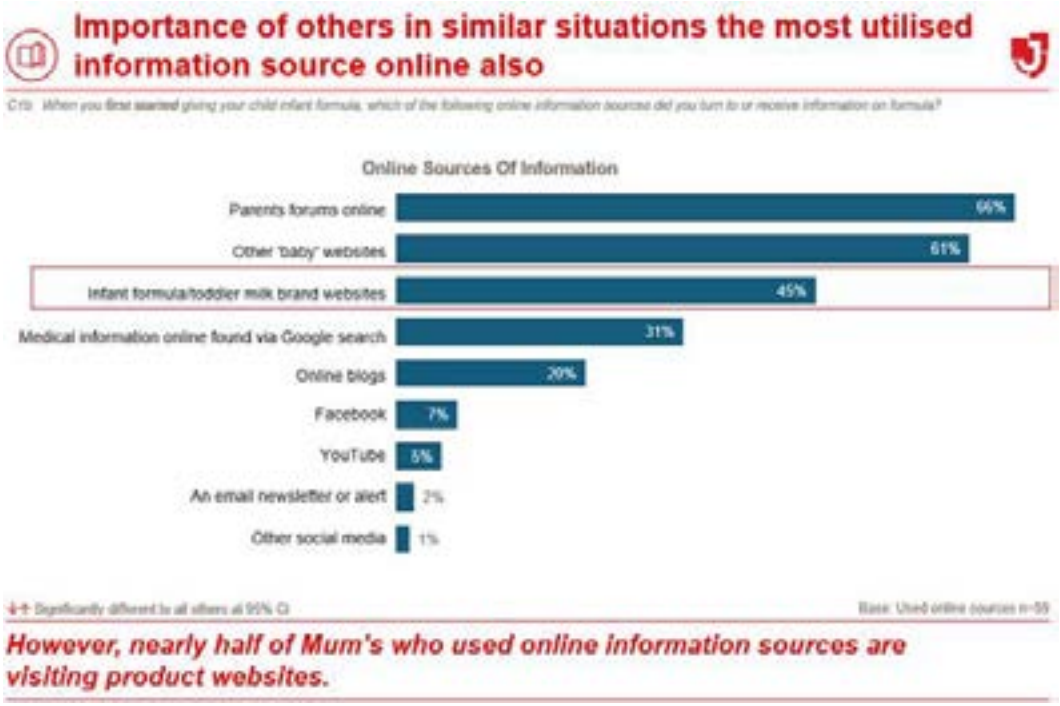
440. Online, caregivers are sharing information on every possible topic including formula feeding, and potential reach can be staggering – while traditional mothers' groups meeting in person may number about 10-20 in size exchanging views, mothers' groups online may be huge. A recent article in The Sydney Morning Herald (Cormack and Han, April 2016) describes the explosion of mothers groups on Facebook in the city of Sydney alone, with members numbering in the thousands:



441. Social media along with other digital platforms as a source of influence cannot be denied. If one caregiver is not correctly informed and shares their views online, this can be a concern if industry cannot help play a role in providing credible and accurate information.

442. The Jigsaw research (2014) showed that the respondents then, indicated that Online Parent Forums was the top source of information in the digital space. But additionally, nearly half (45%) of caregivers who used online information sources also

visited company product websites, indicating an opportunity to source ***CREDIBLE*** information to share in parents' forums, if product websites were able to provide sufficient information on their products, to enable informed choice. Product websites are currently regulated in the same manner as product labels.



443. Across the various digital platforms, we see a more comprehensive range of questions and views from the Voice of the formula feeding mother, as compared to those that can be sourced from company contacts.

444. Around the topic of informed choice, key themes are evident:

- Caregivers want more information, and express their frustrations at the lack of information available
- There is a lot of choice in the market of infant formula, and caregivers are confused as to what the differences are between them
- When seeking advice online, not all advice may be correct and is certainly not credible
- When seeking information from some health care professionals, some mothers are made to feel guilty about not being able to breastfeed, and they sometimes walk away with insufficient information
- Caregivers often rely on information obtained through online research to complement the advice from their health care professional
- Insufficient information may lead to caregivers providing inappropriate foods to the young infant (e.g. 'home-made' infant formula such as those based on the Paleo diet).

445. Some views (de-identified) expressed across Digital platforms are shown below, to demonstrate the above themes. These are only a small handful, amongst many other views in the Digital space:

[redacted] Post breast surgery breast feeding just didnt work. Yes breast is best. Yes I went to the enth to make it working pouring over $300 to help with pumps and aids and spent excessive hours trying over and over to get supply. So when I needed to find help selecting an appropriate formula. . A big fat naddaH! Recommendation to get information was to contact formula companies . . . What new mum has the time to get stuck on the phone calling various companies. I agree with [redacted] it wont entice Mums away from breast feeding but is one more avenue of information that is readily available. At the costs of formula and care re bottle care it is not the 'easy route' that its portrayed to be. Rant over . Still annoyed by the narrow mindedness

Like · Reply · March 5, 2015 at 3:51pm

[redacted] This really winds me up. Mum's need to make informed decisions and making formula a 'Taboo' subject in all faucets is setting mums up for failure. ALL mums should be able to make an informed and educated choice in what formula they choose to give their child, Not an 'On the spot my baby is hungry and I need to feed them and I've no idea what i'm doing' decision. So disappointing

Like · Reply · March 5, 2015 at 3:06pm · Edited

[redacted] That's just stupid! Parents need to know what is out there and available if they are to need formula for their baby. I am pro breastfeeding and have fed all three of my babies but I feel that there is too much pressure on new mums to breastfeed. To be able to make informed decisions on how to care for out babies we need to know our options.
due to our paid parental leave only being 16 weeks many mums end up back at work before their baby is 6 months often needing to put their babies on formula. Not all of us have had supportive employers who made breastfeeding while working full time possible. I do believe the advertising should be limited to not make it seem like it is the best option, but give the parents the knowledge that it is an option

Like · Reply · 16 · 6 March at 09:15 · Edited

[redacted] I have had this problem with medical staff! After 6 weeks of breastfeeding/expressing my body stopped producing milk. I continued to pump for a whole week hoping that it would kick back in but produced nothing other than very sore boobies!

The judgement given to mothers because they formula feed and the amount of pressure given by medical staff and other mothers is appauling.

I'd done the breastfeeding classes, seen lactation consultants, used different feeding positions, bought nipple shields, manual pumps, double electric pumps to no avail.

I spent weeks feeling embarrassed and depressed that i was unable to feed my child with breast milk and it really took me weeks to feel like i wasn't a complete failure as a mother.

I wish there had of been more information available for how to bottle feed. My little one has a bit of colic and thankfully i had family to guide me.

I believe it is a topic that needs some serious addressing.

Like · Reply · 3 · April 22 at 12:15pm · Edited

bellybelly

PREGNANCY · BIRTH · BREASTFEEDING · BABY · PARENTING · HEALTH & LIFESTYLE

Choosing Baby Formula – 5 Facts to Help You Decide

While 96% of Australian mothers intend to breastfeed, 34% of babies have been given formula in their first month, and by 6 months, almost 70% of babies have been introduced to formula, either partially or fully.

Many new parents aren't aware of the different types of formula.

If you live in an area where formula samples are common, you might select a formula brand and type based solely on having a sample handy.

Does it really matter what brand of formula you choose?

Is the type of formula you select an important decision?

Whether your baby is mixed-fed or fully formula fed, you need to use an appropriate breastmilk substitute until twelve months of age.

While the range of products on supermarket shelves can seem overwhelming, the differences between brands are minimal.

[redacted] The NZ Media have warned us that this "Dangerous" book is now available

Like · Reply · 1 · May 30, 2015 at 12:16am

[redacted] As did the aussie media.

Like · Reply · May 30, 2015 at 5:14am

[redacted] Write a reply...

[redacted] Nothing 'dangerous' about healthy, non-processed food! I'll be buying it

Like · Reply · 4 · May 30, 2015 at 12:31am

[redacted] Thank you Pete Evans for making Paleo Way of eating more known. Despite any public ignorance and all backlash, I hope you keep speaking out. You have my support and kudos to you having to deal with ignorants! Cheers

Like · Reply · 1 · June 5, 2015 at 2:03pm

[redacted] Ignorant people like the Dieticians Association of Australia and the Australian Medical Association who have both said recipes in this ebook are unsafe and dangerous for kids?

Like · Reply · 2 · June 7, 2015 at 9:25pm

[redacted] Exactly, Georgie [redacted]. Too funny.

Like · Reply · 1 · July 29, 2015 at 1:17am

[redacted] Not sure if trolling or serious *

Like · Reply · September 9, 2015 at 9:30pm

Questions & Answers

Which one is better than [redacted] original and gold?

[redacted] asked on Mar 03, 2015

Answer this

I have not tried gold but I have been told the original is better. Alot of Babies (especially younger) tend to find it hard to break down the gold formulas. That was the case for my son.

[redacted] replied on Mar 04, 2015

446. In conclusion, the Voice of the formula feeding mother (caregivers) is often missing during public consultations when changes to regulations are made. That directly impacts their ability to obtain credible information and therefore being able to make an informed choice about one of the most important considerations – the appropriate nutrition for their child.

447. INC strongly suggests that FSANZ reaches out to the Voice of the formula feeding mother.

448. As already expressed, INC believes that breastfeeding is best for babies, and breast milk is unequivocally the best source of nutrition. There is no doubt that breast milk is superior and far better than all infant formula. INC recognises that protection of breastfeeding and support for the breastfeeding mother is paramount. However, at the same time, if an infant does not receive breastmilk, **adequate** support and information should also be available to the formula-feeding mother.

449. INC considers that there needs to be a balance between the protection of breastfeeding, and the ability for the caregiver of a formula-fed infant to be able to easily access and understand information about a product that is being provided as a sole source of nutrition, particularly as evidence has shown that the primary reasons for not breastfeeding do not include claims on infant formula labels.

[5] Labelling changes are compliant with the WHO Code and Ministerial Policy Guidelines

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

451. INC understands that Proposal P1028 and subsequent proposals relating to Standard 2.9.1 (foods for special dietary use and follow-on formula) will need to 'give regard' to the Ministerial Council Policy Guideline on the Regulation of Infant Formula Products.

452. The WHO Code is also an important consideration in the development of infant formula regulations. As signatories and members of WHO, the Australian and New Zealand governments have taken into consideration the adoption of the WHO Code within their own legislative frameworks. Indeed, FSANZ has incorporated the requirements of Article 9 (Labelling) of the WHO Code into Standard 2.9.1.

453. INC is of the view that permissions for nutrient content and general level health claims are consistent with the WHO Code, and the Policy Guideline on the Regulation of Infant Formula Products and would meet FSANZ's objectives.

454. ***The WHO Code*:** Article 9 of the WHO Code outlines recommendations for the labels of infant formula:

> *9.1 Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding*
>
> *9.2 Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the following points: (a) the words "Important Notice" or their equivalent; (b) a statement of the superiority of breast-feeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use; (d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation. Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product as a breast-milk substitute and for illustrating methods of preparation. The terms "humanized", "materialized" or similar terms should not be used. Inserts giving additional information about*

the product and its proper use, subject to the above conditions, may be included in the package or retail unit. When labels give instructions for modifying a product into infant formula, the above should apply.

9.3 Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant. Since sweetened condensed milk is not suitable for infant feeding, nor for use as a main ingredients of infant formula, its label should not contain purported instructions on how to modify it for that purpose.

9.4 The label of food products within the scope of this Code should also state all the following points: (a) the ingredients used; (b) the composition/analysis of the product; (c) the storage conditions required; and (d) the batch number and the date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.

455. Article 9 of the WHO Code makes recommendations about the information that should be included in relation to the importance of breast milk and hazards around preparing formula. It also provides prohibitions on specific words and pictures that may idealise formula. However, Article 9 of the WHO Code does not explicitly prohibit nutrient content and general level health claims. In fact, many other countries in markets that recognise the WHO Code permit claims in varying degrees.

456. As a general principle, claims are not permitted in relation to nutrients that form part of the mandated composition of infant formula and INC supports this approach. Claims for products that provide higher levels of iron (above a level set higher than the mandatory minimum requirement) are, however, permitted in a number of markets.

457. ***The WHO Code and Standard 2.9.1***: The directions and specific prohibitions in the WHO Code are adequately captured by Standard 2.9.1—24:

2.9.1—24 Prohibited representations

(1) The label on a package of infant formula product must not contain:
- *(a) a picture of an infant; or*
- *(b) a picture that idealises the use of infant formula product; or*
- *(c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or*
- *(d) words claiming that the formula is suitable for all infants; or*
- *(e) information relating to the nutritional content of human milk; or*
- *(f) subject to subsection 2.9.1—14(2), a reference to the presence of any nutrient or substance that may be used as a nutritive substance, except for a reference in:*
  - *(i) a statement relating to lactose under subsection 2.9.1—14(6); or*
  - *(ii) a statement of ingredients; or*
  - *(iii) a declaration of nutrition information under section 2.9.1—21; or*
- *(g) subject to Division 4, a representation that the food is suitable for a particular condition, disease or disorder.*

*(2) Subject to subsection 2.9.1—14(2), the label on a package of infant formula product must not contain a reference to *inulin-type fructans or *galacto-oligosaccharides except for a reference in:*
- *(a) a statement of ingredients; or*
- *(b) a declaration of nutrition information under section 2.9.1—21.*

458. ***Claims and Policy Guidelines on the Regulation of Infant Formula Products***: INC believes nutrient content and general level health claims can be permitted within the context of the Policy Guidelines on the Regulation of Infant Formula Products. We have provided our rationale for each relevant

specific policy principle applying to the labelling and advertising of all infant formula.

459. ***Policy Principle: (k) The labelling and advertising of infant formula products should be consistent with the World Health Organisation International Code of Marketing of Breast Milk Substitutes as implemented in Australia and New Zealand:*** In June 2009, the Food Regulation Policy Options Consultation Paper for the Regulation of Infant Formula Products was released for public comment. The paper outlined the rationale that underpinned some of the policy principles. Page 35 states "*The labelling provisions in the Food Standards Code are consistent with the International Code and do not permit claims to be made on infant formula products*". INC considers that the Food Standards Code is indeed consistent with the International Code (WHO Code).

460. The WHO Code itself does not expressly prohibit nutrient and health claims on infant formula (as noted above in Article 9). INC is also aware of subsequent World Health Assembly (WHA) Resolutions also published by the WHO. WHA resolution WHA58.32 urges member states to "*ensure that nutrient and health claims are not permitted for breast-milk substitutes, **except where specifically provided for in national legislation***". FSANZ is therefore within its bounds to consider and provide some permission for such claims on infant formula in the Australia New Zealand Food Standards Code, as have many other countries around the world that still permit claims to varying degrees. We also point out that the Policy Guideline refers specifically to the WHO Code and its local adaptions only.

461. The Food Regulation Policy Options Consultation Paper for the Regulation of Infant Formula Products goes on to state "*The International Code is prescriptive as to how breast milk substitutes should and should not be advertised. The prohibited label representations set out in Clause 20 of Standard 2.9.1 mirror the provisions of the International Code. Clause 13 of Standard 1.1.1 of the Food Standards Code applies these label-specific provisions to advertising*." INC agrees that Standard 2.9.1 has adequately captured the prohibited label representations described in Article 9 of the WHO Code. As listed in Standard 2.9.1—24, these are limited to particular pictures and words that may idealise infant formula.

462. INC is concerned that the WHO Code has been incorrectly applied to claims. Allowing certain claims on infant formula would not contradict what is written into marketing codes, and therefore reflects Policy Principle (k). The vast majority of infant formula manufacturers in Australia and New Zealand are signatories to, and adhere to, the MAIF Agreement and the INC Code of Practice, respectively.

463. ***Policy Principle: (l) The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better food than, breast milk***: Standard 2.9.1 includes prohibitions that address Policy Principle (l). In addition to Standard 2.9.1—24, there is a direction that must be included on an infant formula label highlighting the superiority of breast milk. Standard 2.9.1—19(d) states:

> *"Subject to subsection (2), a heading that states 'Important Notice' (or words to that effect), with under it the warning statement – 'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.*"

464. INC believes that permitting nutrient content and general level health claims does not create an impression that infant formula is equivalent to, or better than breast milk. INC would support any restrictions on the claims that preclude reference to breast milk or breast feeding. Claims are important to assist mothers to make informed choices when choosing

an infant formula for their infants, once they have already made the decision to formula feed.

465. ***Policy Principle: (m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products:*** Standard 2.9.1—19(1) provides the following safety statements that must be included on a label of infant formula:

2.9.1—19 Requirement for warning statements and directions

(1) For the labelling provisions, the following 'warning statements are required:

(a) for infant formula product in powdered form—'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill';

(b) for concentrated infant formula product—'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of concentrate except on medical advice. Incorrect preparation can make your baby very ill';

(c) for ready-to-drink infant formula—'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not dilute or add anything to this 'ready-to-drink' formula except on medical advice. Incorrect preparation can make your baby very ill';

466. Member companies of INC are committed to ensuring adequate, factual and scientific information is available to support appropriate use of infant formula where necessary. The permission to include nutrient content and general level health claims (with some restrictions) would enable informed choice and therefore the appropriate use of a particular product.

467. The information is factual and limited to on-pack labels. The Food Standards Code regulates labels and advertising of foods. However, infant formula is unique in that companies voluntarily adopt a code of practice relating to the marketing of infant formula. In the case of infant formula, product claims would be factual and limited to on-pack labelling. In line with the terms of the MAIF Agreement and the INC Code of Practice in New Zealand, promotion of infant formula to the general public is prohibited. INC member companies would not promote this information to consumers.

468. INC believes that in the existing regulated environment for the marketing of infant formula, permission of nutrient content and general level health claims would support Policy Principle (m).

469. ***Policy Principle: (n) The Authority should:***

i. ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and

ii. consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product:

INC is supportive of clear and effective regulation of infant formula and the application of relevant prohibitions and restrictions to health claims. INC supports prohibiting therapeutic and prophylactic claims and high level health claims as described in Standard 1.2.7. The restrictions and prohibitions in Standard 2.9.1—24 would also need to be considered when developing claims.

470. INC considers nutrient content and general level health claims adequate and necessary information to inform consumers about the composition of the product. Infant formula is regulated by the Food Standards Code to ensure complete nutrition for infants from birth. Essential nutrients including vitamins and minerals must be included for the product to be compliant and to deliver sufficient nutrition for the formula-fed infant. However, not all infant formulas are the same. There are a number of optional ingredients that can be added (e.g. probiotics, prebiotics, lutein, omega LCPUFAs DHA/AA). Also,

companies can choose different sources of macronutrients to enhance the nutritional profile of the formula appropriate for the younger infant, for example, whey protein concentrates and isolates to create a whey dominant protein composition. Inadequate information on labelling could lead to consumers being misled about the quality and effectiveness of an infant formula (e.g. 'home-made' infant formulas being preferred to infant formula).

[6] FSANZ framework for permission of claims on infant formula

471. Permissions for nutrient content and general level health claims should be regulated through Standards 1.2.7 and 2.9.1. At the same time, if there are hurdles to amending Standard 1.2.7, INC considers that express permissions can be granted in Standard 2.9.1 that would still allow for consistency with the current Policy Principle (n). An example is current foods for special dietary use products which have express permissions on lactose related claims, as well as indicating the condition, disease or disorder for which the food has been specially formulated (in itself potentially a 'health claim'). Another suggested example would be a positive list of pre-approved claims, which would still reflect the 'prohibitions and restrictions' in that those not in a pre-market schedule of approved claims were "prohibited and restricted".

472. INC believes that the current review process provides for further consideration of claims on infant formula labels further to that in Proposal P293 (FSANZ 2012).

473. INC requests that FSANZ consider the new evidence supporting informed choice for mothers needing to purchase an infant formula. INC considers nutrient content and general level health claims (with INC being open to maintaining the restriction on claims for vitamins and minerals) and a prohibition on therapeutic and prophylactic claims (high level health claims) can be incorporated into Standard 2.9.1 and still meet the obligations and requirements set out in the WHO Code and the Policy Guideline on the Regulation of Infant Formula Products. FSANZ may wish to consider the Standard 1.2.7 framework for claims or provide a separate positive list in Standard 2.9.1.

Q3.2 Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?

474. **INC Response**: INC is aware that health care professionals may at times recommend whey dominant infant formulas, or those with omega LCPUFAs. As such, any on-pack information that could help the caregiver to identify products that contain these is helpful for caregivers to make an informed choice and appropriate product selection in line with the health care professional's recommendation.

475. Macronutrient subgroups contribute to the overall information on pack available to consumers to make an informed choice of product. Macronutrients are more complex than simply protein, fat and carbohydrate. Through advances in nutritional science and technology, infant formulas offer different **types** of proteins, fats and carbohydrates for formula-fed infants. INC believes this information is valuable for informing health care professionals and consumers about the formulation of specific products.

476. INC commissioned a consumer survey in 2014 that helps support the notion that caregivers are very clearly seeking information about ingredients of infant formula. One of three objectives of this research was to "Identify the other sources of information and the type of information needed to make an informed choice when choosing an infant formula product".

477. The survey of 501 mothers revealed that the most information they look for when first making a decision about formula (having made the decision to use formula) is what

brand of formula to use and what ingredients are in the formula. Specifically, the mothers looked on-pack for nutritional/health benefits and ingredients when making a decision. With 4 in 10 claiming their decision about what product or brand to buy was not finalised until at shelf, INC believes this survey supports the value for macronutrient subgroups for consumers. Please see INC response to Q3.1 for more information..

Other Labelling Concerns

Q3.3 Should the Standard include permissions to declare nutrition information about macronutrient subgroups (in addition to mandatory nutrition information currently set out in clause 16 of the existing Code and section 2.9.1–21 of the revised Code) in the nutrition information statement?

478. ***INC Response*: *Nutrition declaration requirements*:** INC considers that Standard 2.9.1 already includes permissions to declare factual nutritional information about macronutrient subgroups.

479. SD3, section 2.3, indicates that the infant formula industry labels demonstrate macronutrient subgroups being declared in the nutrition information statement and that these constitute a claim when added voluntarily.

480. INC contests this and believes there is a broader interpretation that would lead to a conclusion that there is no explicit prohibition of sub-group(s) of a macronutrient in a nutrition information statement for infant formula. INC members strongly refute the suggestion that members' labels are currently non-compliant with the Food Standards Code.

481. There is a significant difference between the provisions for general foods and infant formula in this area. For general foods, a nutrition information panel is required and is regulated under Standard 1.2.8 – Nutritional Information Requirements. Standard 1.2.8 sets out the manner in which such information must be provided and Schedule 12 sets out the mandatory format. The format clearly shows that for fat and protein it refers to 'total' fat and 'total' protein. Furthermore, Standard 1.2.8 provides a definition of fat used in Standards 1.2.7 and 1.2.8, and Schedules 4 and 11, and is defined as 'total fat'. In addition, the note under section 1.2.8—2 states that:

> "*Information provided voluntarily in a nutrition information panel is a nutrition content claim*".

482. This is reiterated in Standard 1.2.7 which states that:

> "*inclusion of voluntary information in nutrition information panel might constitute a nutrition content claim*".

483. Hence, for general food, voluntarily declaring macronutrient subgroups and macronutrient specific nutrients in the nutrition information panel is expressly prohibited if the claim is not qualified but this prohibition is clearly **not** applicable to infant formula.

484. For infant formula, a nutrition information panel is not required but instead, a statement of nutrition information is required. Standard 2.9.1—21 lists the information that must be included but it makes no reference to ***total*** protein or ***total*** fat. Standard 2.9.1—21(1)(a)(ii) states:

> "*the average amount of protein, fat and *carbohydrate expressed in g/100 mL*";

We note this does not state "... average amount of the **total** protein and **total** fat".

485. Also, Standard 2.9.1—21(1)(a)(iii) requires nutritive substances, which include optional ingredients, to be declared. This is illustrated in the Guidelines for the Nutrition Information relating to infant formula. Optional ingredients, are 'voluntary' by nature. These are not typically mandatory references in a nutrition information statement.

486. Additionally, under "Prohibited Representations" in Standard 2.9.1—24(1)(f), a reference to the presence of any nutrient (and this would include sub-groups of a macronutrient), or any substances that may be used as a nutritive substance, is permitted in a declaration of nutrition information, and the prohibitions relate only to a reference of a nutrient or nutritive substance outside a statement of ingredients or nutrition information. As such, it expressly allows a reference to the presence of any nutrient to be made as a declaration of nutrition information.

487. Lastly, it is important to consider that the labels of infant formula must state that parents or carers should consult their Health Care Professional before deciding on formula feeding and choosing an appropriate formula. The breakdown of the protein of an infant formula, for example the whey:casein ratio, is an extremely important consideration for Health Care Professionals when advising a parent or carer. Health care professionals must have easy access to the ingredients and nutrition profiles to guide their clients/patients. In the example of whey:casein ratios, this information is not available in a list of ingredients.

488. INC also considers that to fully prohibit such declarations would create further confusion with caregivers because of already extremely limited information on pack. Consumers already find it difficult to differentiate between different infant formulas in the market and would like more information about ingredients (INC commissioned consumer research conducted by Jigsaw, 2014).

489. Therefore, to avoid ambiguity, INC supports regulatory clarity and the inclusion of expressed permissions in Standard 2.9.1 to declare nutrition information about macronutrient subgroups in the nutrition information statement.

Q3.4 Should it be mandatory to declare all or only specified macronutrient subgroups in the nutrition information statement? If so, which macronutrient subgroups and for what reason? For example, any subgroup of protein (whey, casein, alpha-lactalbumin etc.), or specific proteins (only whey and casein).

490. **INC Response**: INC believes flexibility in the inclusion of macronutrient subgroups is important and should be included in the nutrition information statement to help caregivers and health care professionals differentiate between different infant formulas. Furthermore, INC does not support mandating only specified macronutrient subgroups as not all infant formulas are the same and this does not support brand and product differentiation.

491. INC therefore supports status quo and the provision for macronutrient subgroups to be added to nutrition information as needed.

Q3.5 If only specified macronutrient subgroups, what principles should be applied to determine which nutrients may be declared (e.g. for those fats with a specific compositional requirement, or for those nutrients that caregivers have a general understanding of their nutritional purpose in foods).

492. **INC Response**: INC considers that the overarching principle would be that product differentiation is allowed for. INC does not support prescriptive principles, and for nutrition information statements, particularly since infant formula already requires an extensive range of mandated information. Given limited space in the nutrition information statement,

additional prescribed requirements would be difficult to accommodate. INC suggests, however, that while the education process with health care professionals communicates this information, voluntary inclusion can allow companies to identify the ingredients, all of which are safe, that they consider are particularly relevant to caregivers to supplement the health care professionals' information. However, if macronutrient subgroups are declared, then the levels of those macronutrient subgroups should also be declared in order not to be misleading. In such circumstances the average quantity should be met. INC is strongly of the view that consumers should have the information to show how products differ.

Q3.6 If nutrition information about macronutrient subgroups is provided, is there potential for caregivers of formula-fed infants to be misled about the nutritional value of formula?

493. **INC Response**: INC considers there is no prospect for caregivers of formula-fed infants to be misled about the nutritional value of formula if nutrition information about macronutrient subgroups is provided because the information declared in the nutrition information statement must be correct and truthful. Whether the level is innate or added, the total amount on the label of the infant formula will be correct. A declaration on the nutrition information statement will trigger analytical verification, therefore we do not consider that there is potential for misleading information about the nutritional value of that declared sub-macronutrient.

Q3.7 What would the cost and trade implications of mandating macronutrient subgroups or conversely expressly prohibiting them?

494. **INC Response**: As with any prescribed requirement in the Food Standards Code, new labels would be required and the associated costs with conducting a label change. Depending on the number of macronutrient sub-groups to be mandated, there could also be challenges for additional information on small packs in relation to trade impacts because of the inability to harmonise nutrition statements with overseas market requirements. Additionally, there would be quality related analytical testing costs related to those additional macronutrient subgroups mandated that are not currently voluntarily labelled for by a particular company. There could also be trade implications if such a change was not reflected in major markets elsewhere.

495. ***Inter-relationship between declarations in the nutrition information statement and the ingredient list*:** Standard 2.9.1 does not require the name of ingredients declared in the ingredients list to be the same as the mandatory declarations in the nutrition information statement. Consequently, there can be a difference in terminology used. For example, whey protein declared in the ingredient list and alpha-lactalbumin in the nutrition information statement, indented under protein (notwithstanding the issue of whether macronutrient subgroups are permitted to be declared in the nutrition information statement).

496. FSANZ notes that the purpose of these two labelling elements differs, but is not aware of evidence to suggest confusion among caregivers and health professionals about this label information. There is a question about whether the names of ingredients should align with nutrient declarations in the nutrition information statement on packaged infant formula.

Q3.8 Is there any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations?

497. **INC Response**: Ingredients lists and nutrient lists are fundamentally different. INC advises that the industry practice is for the more complex vitamins and minerals to be used

in the ingredients list, *together* with the common term (e.g. sodium ascorbate (vit C)), and the common term to be used in the nutrition information statement. Declaration of the more complex term aligned to permitted forms, is a practical solution to enable the relevant enforcer to readily see that permitted forms of an ingredient are being used. As well, the ingredients list groups vitamins and minerals and other substances according to use, which may allow for more information for the consumer and therefore alleviates 'confusion'.

498. The nutrition information statement is relevant only to specific vitamins and minerals but is more general in relation to macronutrients. Nutrients come from a wide range of sources (either added or innate, or a combination of both) and often the summation is in the nutrition information statement whereas the sources are usually listed in the ingredients list.

499. INC companies do not have any evidence from company care lines that there is confusion on this amongst caregivers and health care professionals.

Q3.9 Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?

500. **INC Response**: INC does not support aligning the names of ingredients with nutrient declarations in the nutrition information statement. The information serves different purposes and as noted above, the ingredients list includes additions of, for example vitamins and minerals, while the nutrition information statement includes total amounts (naturally occurring and added) and not necessarily information about its source.

501. ***Base units of expression***: FSANZ states that nutrition information is required to be expressed per 100 mL for ready-to-drink products, as well as for powdered and concentrated products (where they have been reconstituted according to the directions). However, the recommended format for nutrition information (in the Guidelines attached to Standard 2.9.1) suggests that in addition to the per 100 mL requirement, nutrition information per 100 g for powdered formula and per 100 mL for liquid concentrate as sold be expressed.

502. The pros and cons of expressing the nutrition information as sold, in addition to the current requirement, are discussed. The merits of additional base units of expression that differ from the current requirement are explored, and whether the declaration of these base units should be mandatory or voluntary.

Q3.10 Which base units of expression do stakeholders find to be of greatest value?

503. **INC Response**: INC supports the continuation of the requirement that nutrition information be expressed per 100ml stays. However, INC would support the option for manufacturers to voluntarily include the base units of per 100g. This would be particularly useful for those markets that have adopted the Codex provision of using per 100g allowing harmonisation with those requirements on an as needs basis.

Q3.11 Is there any evidence that caregivers are confused by the use of different base units of expression?

504. **INC Response**: INC is not aware of any evidence of confusion. Company care lines are rarely asked for any clarification of this nature.

Q3.12 In addition to the current requirement to declare nutrition information per 100 mL as consumed, should it be mandatory or voluntary to declare per 100 g of powder (or per 100 mL for liquid formula) as sold?

505. **INC Response**: INC believes the provision to declare per 100 g of powder as sold should be voluntary. Mandating the inclusion of such information would result in a higher cost for any label changes since another column of label information must be checked. As previously stated in this submission, infant formula already requires an extensive range of mandated information. Given limited space on the label, additional prescribed requirements would be difficult to accommodate.

506. For per 100mL liquid formula, as it is already commercially reconstituted, per 100mL as consumed, equates to per 100mL as sold, so we consider this is not relevant for infant formulas as the applicable base unit of measure can be 100mL (either *already* reconstituted, or as sold).

507. As well, health care professionals can get the information elsewhere should it be required and can always contact the company concerned for this information. Currently companies voluntarily provide base unit 100 kcal or /100kJ where requested outside of the label to health care professionals.

Q3.13 What would the cost and trade implications be of mandating these base units?

508. **INC Response**: Mandating additional information in the nutrition information statement would require significantly more checking and rechecking values for substances involved. This is resource intensive for industry when labels are changed since there is an additional column of nutritionals compared to the status quo. It would also be particularly difficult to find the space on smaller pack sizes and still maintain the mandated font size for relevant information. As well, mandating such a requirement could potentially present as a trade barrier and jeopardise supplies of imported product to the Australia and New Zealand markets.

Q3.14 Should the voluntary use of the base unit of per 100 kJ be permitted?

509. **INC Response**: INC has no objection voluntary use of the base unit of per 100 kJ being permitted. However, INC queries the need for this based on prevalence of interest and use of this base unit. ***IF*** however this voluntary use is introduced, we would also propose to introduce the voluntary expression of the per 100kcal base unit. This approach is also consistent to the permission in Codex STAN 72-1981: "*9.3 Declaration of Nutritive Value: c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (**or** per 100 kilojoules) is permitted*."

510. In our experience, per 100kcal is more frequently requested by some health care professionals, rather than per 100kJ.

511. ***Average amount***: The 'average amount' of macronutrients and micronutrients is required to be declared in the nutrition information statement for an infant formula. However, the term 'average amount' is not defined in the Code, but a term with the same intent is (i.e. 'average quantity').

Q3.15 What impacts, if any, would there be if the declaration requirements for macronutrients, micronutrients, nutritive substances, inulin-type fructans and galacto-oligosaccharides are based on 'average quantity', instead of 'average amount'?

512. **INC Response**: INC suggests that average quantity would be supported. While this would require a label change, over time, there may well be other label changes resulting

from the review of Standard 2.9.1 that could be combined at the same time. To the lay consumer, average amount is the more user friendly term.

513. ***Format of the nutrition information statement***: FSANZ advises that an infant formula label must include a statement declaring certain nutrition information expressed per 100 mL for the product as consumed. Standard 2.9.1 and the attached Guidelines recommend that this information is presented in a tabular format. FSANZ is considering whether to mandate, remove or retain the format for the nutrition information statement.

Q3.16 Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?

514. **INC Response**: INC advises that in reality, the nutrition information is the only credible source of information the caregiver has to inform their purchase decisions. However, INC believes the information may not be easily comprehensible, or sufficient to allow consumers to determine differences between products. Information outside the nutrition information statement would be helpful especially when formulations change.

Q3.17 Would a consistent approach to format across product labels assist consumer understanding of this information?

515. **INC Response**: INC does not believe a consistent format across product labels would assist consumer understanding of this information. Manufacturers of general foods also note that the mandated format of the nutrition information statement creates a real barrier to trade both for export (where nutrition information has to meet destination market requirements) and for imports where either specific labelling is required for the Australia and New Zealand market or oversticking has to be applied to bring products into compliance. Both experiences are costly and mean some products never reach this market because of the costs involved are too high to meet the small market demand when compared to global markets.

516. The issue is one of evidence to sustain the case for change and that such change would assist consumer understanding. Flexibility is vital in this area and pack size would preclude additional formatting where font sizes are already a feature for aspects of infant formula label information.

Q3.18 If the format was prescribed, what would be the impacts including costs to industry and trade considerations of changing labels?

517. **INC Response**: As noted above, the costs would be significant, creating trade barriers, adding costs to exports and imports.

518. ***Notification of product reformulation***: FSANZ notes that The Code does not explicitly permit or prohibit a labelling statement to alert caregivers to changes in product formulation. However, references to nutrition information outside the nutrition information statement and the statement of ingredients may constitute a nutrition content claim, which is prohibited on infant formula labels.

519. A number of stakeholders suggested that product labels should include information about compositional changes to alert caregivers and health professionals, as some infants may experience side-effects when transitioning to an infant formula with a new formulation.

Q3.19 How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?

520. **INC Response**: To alert caregivers that an infant formula has been reformulated is usually via lid stickers or on company websites. However, this communication is only limited to the extent that we can only tell the caregiver that the product has changed (eg new or improved). Due to the current prohibitions on nutrient content and health claims, labels cannot be a means to communicate clearly and specifically what has changed compositionally.

521. INC proposes to allow communication of product compositional changes to caregivers via the product label to allow for an informed choice when purchasing an infant formula.

522. For health care professionals, changes in composition are communicated by company representatives, either via written communications, or face-to-face visits. However INC points out that given the size in number of all relevant health care professionals in all of Australia and New Zealand, not any one company has comprehensive access and reach, to them. Additionally, increasing access restrictions means that not all health care professionals can be kept up to date. Therefore the current means on communicating changes is not optimal, and INC considers there are opportunities to improve this situation by allowing information on pack, as this would reach *every* caregiver purchasing the product, and offers a credible source of information, exactly relevant to the product to be consumed.

Q3.20 What information about the change in composition would caregivers and health professionals find useful?

523. **INC Response**: Caregivers are interested in ANY change to their infant formula they are currently feeding their infant, particularly when the product they are feeding their child plays the role of a sole source of nutrition.

524. Communicating new allergens is likely also of key relevance to caregivers and health care professionals. For example, if a product is improved to include an optional ingredient like DHA, some sources are from fish, which would be introduction of a new allergen.

Q3.21 What are the cost and trade implications of a standardised approach to a product reformulation on infant formula packages?

525. **INC Response**: INC seeks clarification on what is meant by a “standardised approach to a product reformulation”. Until we have that clarification, we are not able to comment on the cost and trade implications.

Other Issues

Conversion factors

526. INC had previously identified errors in the energy conversion factors from kcal to kJ applied by Codex Alimentarius in the course of commenting on the Revision of the Codex Follow-up Standard at the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). These errors were not limited to the Follow-up formula standard, but also extended to other standards – in particular, the Codex Infant formula standard.

527. INC found significant inconsistency, some of which may be attributable to the number of significant figures used for the statement of nutrient requirements and other rounding, but other reasons included an inconsistent application of energy conversion factors not related to rounding. For example, minimum protein/100kcal is 4.0 times the value expressed/100kJ, whereas maximum protein /100kcal is 4.268 times the value /100kJ.

528. The inconsistent conversion factors may introduce international trade barriers, which are of concern to INC.

529. As Australia and New Zealand uses the per 100kJ values, such values were sourced from the per 100kJ values from the Codex infant formula when comparing Standard 2.9.1 nutrient values to Codex. Therefore, a number of calculation errors from Codex have carried through into the most recent consultation paper, Proposal P1028 Review of Infant Formula. INC recommends that FSANZ also consider correcting the values it has used to convert calories (kcal) to kilojoules (kJ), and in proposed areas of harmonisation to Codex, to apply a conversion from the per 100kcal values in the Codex STAN 72-1981.

530. At the 37th Session of CCNFSDU (2015), the New Zealand delegation, proposed a correction of the calculation error in both Codex STAN 156-1987 , as well as Codex STAN 72-1981, as consequential mathematical amendments. This has been reflected in the conclusions reached in the pWG report prepared for the plenary session (CRD-2) as follows:

> *"17. During the review the eWG it was noted that there were inconsistencies in the conversion of the essential compositional requirements of the Codex Standard for Infant Formula from kilocalories to kilojoules. At times rounding inconsistencies occurred when using the international standard unit (ISU) conversion factors. The conversion factors for kilojoules and kilocalories are: 1kJ = 0.239 kcal; and 1kcal =4.184 kJ. This is currently specified in the Codex Standard for Follow-Up Formula under the definition for kilocalorie.*
>
> *18. There was an agreement within the pWG to amend these inconsistencies, these are recorded in Appendix 2 of the Agenda paper [a reference to agenda paper for agenda item 5]. The Secretariat informed the pWG that once the corrections were finalised in this standard then consequential amendments can be made for the Codex Infant Formula Standard."*

531. In light of corrections for the Codex infant formula standard having been agreed to, INC requests that Proposal P1028 moves forward to correct these values by the next consultation paper, rather than waiting for the conclusion of Proposal P1028. INC also requests consideration is provided to the energy conversion factors at Codex being proposed at 3 significant figures (4.184) while the Food Standards Code sets it at 2 significant figures (Schedule 11, Calculation of values for nutrition information panel, S11-2).

Transition

532. This review is to support regulatory change, and INC requests any transitional period be of reasonable length to allow adequate time to implement changes, particularly for imported infant formula that is not manufactured in Australia and New Zealand.

533. While the scope of P1028 relates to infant formulas for 0-12 months only, INC recognises that it will in future underpin the review of other infant formula products, and will therefore:

- set the basis for composition of the infant formula products for special dietary use (outside of nutritional modifications relevant for the condition), and
- the labelling for both infant formula products for special dietary use and follow-on formula.

534. As such, INC requests that transitional arrangements are considered in the context of those products which are not currently within the scope of Proposal P1028.

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Attachment A

Elements of P1028 INC Agrees with the FSANZ Preliminary View

Definitions & Nutrient composition

Scope of P1028
INC agrees with excluding follow-on formula (currently under review by Codex).

Definitions – INC agrees with the status quo for definition of infant formula product, infant formula.

Protein
Protein levels – Subject to correcting the minimum and maximum levels currently in Standard 2.9.1 for the conversion factor of 4.18, INC agrees there should be no changes at this time.

Protein sources – INC supports status quo.

Protein quality – INC supports status quo but recommends that the DIAAS method be reconsidered when further information is available.

Amino Acid Content – INC agrees with aligning the minimum levels of isoleucine, leucine, lysine, threonine, tryptophan and valine with those in Codex STAN 72-1981.

Fat
Fat content – INC supports retaining the minimum and lowering the maximum to align with Codex STAN 72-1981 as proposed by FSANZ.

Essential fatty acid composition – INC agrees with the FSANZ preliminary position to change the maximum of LA to a GUL.

Long chain polyunsaturated fatty acids (LC-PUFAs) – INC supports in principle the retention of a voluntary permission for DHA. INC supports the current EPA: DHA ratio requirement in Standard 2.9.1.

Source of fat – INC considers the current approach remains appropriate.

Myristic acid (C14:0) and lauric acids – INC agrees with maintaining the current arrangements for myristic and lauric acids of no restriction of the levels in infant formula.

Carbohydrates
Introduction of maximum and minimum level – INC concurs with the FSANZ proposal to retain the current approach by not specifying a minimum and maximum amount for carbohydrate.

Carbohydrate source – INC supports maintaining the current approach in Standard 2.9.1 not to include provisions relating to carbohydrate source.

Energy

Energy content – INC supports FSANZ's proposal to reduce the maximum energy amount to align with that in Codex STAN 72-1981.

Calculation of energy density – INC concurs with FSANZ to maintain application of energy factors for calculating the energy density of infant formula.

Vitamins, minerals and electrolytes

Approach to setting guidelines or maximum amounts – INC strongly supports the continued use of non-binding GULs to serve as guidance for industry.

Vitamin A – INC does not object to the proposal to exclude β-carotene from the total amount of vitamin A in infant formula. INC seeks confirmation that β-carotene will still be permitted to be added into Infant formula. INC supports the FSANZ proposal to retain the current minimum and maximum amounts for vitamin A subject to correction for conversion factors.

Vitamin C – INC agrees to an increased GUL for vitamin C.

Vitamin D – INC agrees with the proposed minimum for vitamin.

Vitamin E –INC has no objection to retaining the current approach to vitamin E requirements relating to the PUFA content of infant formula and the proposed GUL for vitamin E would allow for the variation in overseas regulations.

Other vitamins and minerals – minimum and maximum amounts – INC supports FSANZ's preliminary view to align the minimum and maximum amounts for vitamin B_6, vitamin B_{12}, pantothenic acid, riboflavin, thiamine, folate, niacin (preformed), vitamin E, vitamin K, biotin, calcium, manganese, magnesium, copper, potassium, chloride and sodium again, subject to conversion factor correction.

Phosphorus – INC supports amendment of the maximum phosphorus amount in Standard 2.9.1 to a GUL and alignment with the lower minimum Ca:P ratio with the Codex ratio of 1:1 and the maximum Ca:P ratio of 2:1.

Vitamin C – INC agrees to an increase in the GUL of Vitamin C from 5.4 mg/100 kJ to the level in Codex STAN 72-1981 of 17 mg/ 100 kJ.

Iron – INC supports retaining the current minimum and maximum for iron in Standard 2.9.1 but recommends alignment with the Codex minimum for infant formula products for special dietary use.

Selenium – INC supports the proposal to move the maximum amount to a GUL and the increase of the GUL to align with Codex STAN 72-1981.

Iodine – INC supports increased iodine levels in infant formula with values of 2.5-14ug/100kj aligned with Codex STAN 72-1981 (higher minimum and a GUL).

Copper – INC agrees with aligning the minimum and GU levels with Codex STAN 72-1981.

Zinc – INC agrees with retaining the already aligned minimum level. However, the maximum in Standard 2.9.1 is higher than the GUL in Codex STAN 72-1981 but Codex STAN 72-1981 does not specify a ratio. Any change in the maximum would have to account for this ratio.

Permitted forms of vitamins, minerals and electrolytes

Vitamins

Vitamin A – INC agrees with FSANZ's preliminary view to retain the permitted forms of Vitamin A.

Vitamin D – INC supports FSANZ's preliminary view to retain the two permitted forms Vitamin D3 (cholecalciferol) and vitamin D2 (ergocalciferol)).

Other Optional Substances

Choline – INC agrees that choline should be mandatory in infant formula and supports a minimum of 1.7 mg/100kJ.

L-carnitine – INC supports FSANZ's view that L-carnitine should be mandatory and that a minimum content (conversion corrected) that is increased to 1.2 mg/100kcal (0.287 mg/100kJ) is appropriate.

Inositol – INC supports the FSANZ preliminary view to mandate inclusion of inositol in infant formula at the current minimum level 1.0 mg/100 kJ. INC supports the current maximum being set as a GUL.

Nucleotides – INC supports FSANZ's preliminary view to retain the current permission and maximum combined total limit of nucleotides.

Safety & Food Technology

Preparation, use and storage directions to manage microbiological hazards

Directions to prepare bottles individually – INC supports the FSANZ proposal to retain the current labelling requirement for an instruction that each bottle should be prepared individually.

Directions on water used to reconstitute powdered infant formula – INC supports the FSANZ proposal to maintain this labelling requirement as one of a group of risk reduction strategies.

Discarding leftover formula – INC supports the FSANZ proposal that requires the label of infant formula to include words and pictures instructing that formula left in the bottle after a feed must be discarded.

Standardised directions for preparation and use – INC supports the FSANZ proposal to maintain the existing overarching requirement, which does not prescribe the words and pictures for the instructions.

Other safe preparation and storage issues

Date marking of food – INC supports the FSANZ proposal to maintain the existing requirement that the label on infant formula must carry a date mark.

Storage instructions for opened infant formula – INC supports the FSANZ proposal to maintain the existing requirement that the infant formula label contain storage instructions covering the period after the package is opened.

Measuring scoop – INC strongly opposes standardisation of measuring scoops for the reasons FSANZ has identified. INC equally strongly supports the continuation of use of the statement that only the enclosed scoop in the can should be used for preparing the can's

powdered infant formula. INC opposes any extension of the statement or it being mandated since it is used across the board and there is no evidence of a problem.

Inaccurate volume indicators on infant feeding bottles – INC supports FSANZ approaching the relevant industry sector about the issues.

Warning, advisory and other statements

Legibility requirements for warning statements – INC supports maintaining the current legibility requirements for infant formula requirements

Statement on protein source – INC supports maintaining the requirement that the infant formula label contain a statement of the specific source, or sources, of protein in the product.

Co-location of protein source statement with the name of the food – INC supports maintaining the mandatory statement about protein source and for it to be located immediately adjacent to the name of the infant formula (i.e. the prescribed name 'Infant Formula').

Warning statement about following instructions exactly – INC supports the current requirements that the labels of infant formula display warnings that prescribe the wording about following the instructions exactly to ensure the correct preparation of the powdered, concentrated, or 'ready-to-drink' formula.

Warning statement that 'breast is best' – INC supports the current requirement that the infant formula label contain the prescribed warning statement: 'Breast milk is best for babies' and 'Before you decide to use this product, consult your doctor or health worker for advice'.

Statement about age to offer foods in addition to formula – INC supports the current requirement for a statement on infant formula labels indicating that infants over the age of around 6 months should be offered foods in addition to the infant formula.

Guidance statement about additional vitamin and mineral supplementation – INC supports the Guidelines attached to Standard 2.9.1 (S29—10) continuing with inclusion of a guideline statement that consumption of vitamin or mineral preparations are not necessary.

Prescribed name – INC supports continuing the requirement that 'Infant Formula', as a prescribed name, is included on infant formula labels.

Contaminants

Acrylonitrile – INC supports no amendments to current ML in the Food Standards Code which already aligns with Codex.

Tin and inorganic tin compounds – INC supports the FSANZ proposal to maintain status quo in relation to the ML.

Vinyl chloride– INC supports the FSANZ proposal ML/GL to maintain the status quo in relation to the ML/GL.

Arsenic – INC agrees with the FSANZ proposal that there is no specific need to establish an ML for arsenic (inorganic) or arsenic (total) for infant formula in the Code consistent with Codex.

Lead – INC supports the FSANZ proposal to lower the ML for lead to 0.01 mg/kg in ready-to-consume infant formula.

Melamine – INC agrees with FSANZ that there is no rationale for the incorporation of the Codex ML for melamine into the Food Standards Code.

Location of MLs in the Code
INC agrees with FSANZ's proposal to consolidate all MLs for contaminants in Standard 1.4.1, including those set for infant formula and infant formula products.

Contaminant definition
INC agrees with FSANZ that a definition of 'contaminant' be considered as part of a proposed future review of Standard 1.4.1.

Food Additives

Aligning food additive permissions in the Food Standards Code with Codex – INC considers that, in principle, it is preferable to be aligned with Codex in relation to food additives.

Citric and fatty acid esters of glycerol – INC supports FSANZ's intention to consider an extension of use for these food additives as part of the future work of this Proposal.

Citric and fatty acid esters of glycerol – INC supports consideration of an extension of use for these food additives as part of the future work of this Proposal.

Updates to nomenclature and INS numbers – INC supports the continuation of the Food Standards Code referring to chemical families written as the plural term with the same INS number rather than listing by the specific name and INS number for individual food additives.

Changes to maximum permitted levels – INC agrees with FSANZ's proposal to lower the MPL for hydroxypropyl starch for use in soybased infant formula from 25000 to 5000 mg/L, singly or in combination.

Inter-relationship between declarations in the nutrition information statement and the ingredient list – INC considers ingredients lists and nutrient lists are fundamentally different and no change should be made to nomenclature used in each.

Base units of expression – INC supports the continuation of the requirement that nutrition information be expressed per 100ml.

Average amount – INC supports changing the declaration from 'average amount' to 'average quantity' in the Code.

Attachment B

Elements of P1028 INC DOES NOT Agree with the FSANZ Preliminary View

Definitions & Nutrient composition

Scope of P1028
INC does not agree with the exclusion of infant formula products for special dietary use nor that the consideration of nutritive substances and novel foods should be dealt with separately from P1024.

Protein

Calculation of protein: nitrogen conversion factors – [INC proposes two conversion factors be provided for mammalian milk – 6.38 and 6.25 and a third for soy at 5.71].

Amino Acid Content – INC does not agree with the FSANZ preliminary position to retain the current expressions for the amino acids minimums for tyrosine, phenylalanine, methionine, and cysteine.

Fat
Units of expression – INC does not support use of percentage of total fatty acids as the primary expression of required amounts of particular fatty acids. INC proposes aligning with Codex and supports g/100kJ as primary units of expression. However, INC supports provision of information on percentage of fatty acids as a secondary expression.

Essential fatty acid composition – INC recommends all requirements for LA and ALA in the revised Standard 2.9.1 are aligned with those in the Codex STAN 72-1981 including the minimum requirement for LA.

Restrictions on certain fats – Medium-chain triglycerides (MCTs) – INC does not support continuation of a prohibition for MCT.

Trans-fatty acids – INC does not support the proposal to lower the TFA content from 4% to 3% of TFAs in alignment with Codex due to differences in definition applied.

Phospholipids – INC does not support the introduction of a restriction specific to phospholipids. If a limit is to be specified, alignment with Codex STAN 72-1981 and recent EU/ESPGHAN/ EFSA expert opinion for a phospholipids limit of 2g/L could be supported.

Vitamins, minerals and electrolytes
Vitamin A – INC does not agree to the removal of expressing vitamin A in units of RE and considers it is still useful to retain RE for consistency with Codex.

Vitamin D – INC recommends that the maximum for vitamin D is increased to align with the maximum of 0.72kJ/100kJ as adopted by the EU in EC Directive 2016/127. There is currently only a narrow common range between Codex STAN 72-1981 and the EU regulations which is too tight to allow product formulation and manufacture in compliance with both sets of requirements.

Folate – INC does not support FSANZ's preliminary view for folate expression and instead supports expression of the folate content of infant formula as folic acid. This is aligned with the approach Codex has taken.

Niacin*:* INC does not support the FSANZ view to not permit nicotinic acid for use in infant formula as this is inconsistent with Codex.

Selenium – INC does not agree to an increase in the minimum requirement for selenium in Standard 2.9.1.

Chromium – INC does not support minimum, maximum or GU levels being set for chromium (FSANZ has not formed a position).

Molybdenum – INC does not support minimum, maximum or GU levels being set for molybdenum (FSANZ has not formed a position).

Permitted forms of vitamins, minerals and electrolytes

Summary of nutrient forms for use in infant formula that differ between Codex GL 10-1979 and Standard 2.9.1 – INC believes all the forms of nutrients permitted in Codex STAN 72-1981 should be permitted in Standard 2.9.1. These are: Sodium D-pantothenate, DL-Panthenol, Nicotinic acid, Cupric carbonate, Ferric citrate, Ferrous bisglycinate, Ferrous sulphate, Magnesium hydroxide carbonate, Magnesium hydroxide, Magnesium salts of citric acid, Potassium L-lactate, Zinc lactate and Zinc citrate (either zinc citrate dihydrate or zinc citrate trihydrate).

Other Optional Substances

Choline – INC does not agree that there should be a maximum for choline but that a GUL of 12mg/100kJ should be set.

L-carnitine – INC has significant concerns with the maximum proposed by FSANZ of 0.8mg/100kJ whether added or not. INC recommends that no maximum be set for L-carnitine in infant formula at this time.

L-carnitine forms (L-carnitine hydrochloride and/or L-carnitine tartrate) – INC supports the use and inclusion of the forms L-carnitine hydrochloride and L-carnitine tartrate in Standard 2.9.1.

Nucleotides – INC does not support a minimum level being set. INC notes that the key issue with drafting for the maximum amount is to ensure that the maximum applies only when nucleotide 5' monophosphates are added.

Safety & Food Technology

Preparation, use and storage directions to manage microbiological hazards

Directions for the storage of made up formula – INC suggests clarification is needed that the statement is not prescribed and for flexibility for the time limit to be up to 24 hours so that if the parent or caregiver wants to feed after 4 hours, 8 hours etc then they should be able to do so.

Warning, advisory and other statements

Statement on protein source – INC does not support mandating a list of permitted protein sources for declaration on the label for the same reasons as FSANZ has identified: that protein quality and quantity are regulated in the Food Standards Code for health and safety

reasons. INC does not support prescribing the position of the statement of protein source on the label.

Warning statement that 'breast is best' – INC does not support a risk-based statement about the risks to infant health of not breastfeeding.

Nutritive substances and novel foods in infant formula

INC strongly supports Standard 2.9.1 being included within the scope of Proposal P1024 going forward.

INC supports the framework proposed in Proposal P1024 as Option 3 for general foods being applied to infant formula products, with consideration of some differential elements specific to the target population that would also address the specific principles in the Policy Guideline on the Regulation of Infant Formula Products.

Contaminants

Aluminium*:* INC does not agree with FSANZ that an ML of 0.05 mg/100 mL to apply to all infant formula and is of the view that Standard 2.9.1 should align with Codex which does not list an ML for aluminium.

Concentration units for infant formula MLs
INC considers the default unit for all contaminant MLs in Standard 1.4.1 should be mg/kg or mg/L not 'mg/100 mL'. INC also considers it is logical, sensible and preferable for limits for contaminants to be expressed on a dry powder basis not on a reconstituted ready-to-feed form, rather than to a product prior to drying, dehydration or concentration.

Contaminant definition
INC does not support a definition of contaminant is necessary in the Code. If inclusion of a definition is determined to be necessary, then alignment with Codex would be favoured.

Acidity regulators – INC considers that the current arrangements whereby 12 substances could be used as either food additives (technological purpose of acidity regulators), processing aids or as permitted forms of minerals in the manufacture of foods including infant formula should remain.

Food Additives

Starch sodium octenyl succinate – INC supports consideration of an extension of use for these food additives as part of the future work of this Proposal.

Carry-over principle for food additives and infant formula
INC does not agree with the FSANZ that Codex does not provide for carry-over nor with the FSANZ proposal that the carry-over principle should not apply to infant formula.

Provision of information

Claims about ingredients
INC considers that there is a serious gap in information available to consumers to make informed choices about the formula that's best for their baby. INC supports claim statements being made on packaged infant formula to assist consumers make informed choices.

- On-pack information is very important for caregivers for making an informed choice.
- Equally, access of infant formula representatives who are able to provide scientific and factual information on products to health care professionals for infant health and safety.
- Once a decision to use formula is made in consultation with their health care professional, caregivers should be able to make informed choices about the infant formula they buy.
- Above all other foods, this is possibly the most important purchasing decision as infant formula may be the sole source of nutrition for infants in the first 6 months of life.

INC proposes that Proposal P1028 improve existing labelling requirements to assist parents and caregivers once they have made the decision to formula feed and select an infant formula that will best suit their infant.
INC proposes:

- **Permission for nutrient content claims for optional and differentiating nutrients**
- **Permission for general level health claims for optional and differentiating nutrients potentially from a permitted list.**
- **Maintaining the status quo in prohibiting claims on vitamins and minerals for infant formula.**

Declaration of permitted nutritive substances
INC supports the declaration of nutritive substances on a label (i.e. the statement of ingredients or the nutrition information statement).

Nutrition declaration requirements
The INC contests the statement that the infant formula industry labels demonstrate macronutrient subgroups being declared in the Nutrition information statement and that these constitute a claim when added voluntarily.

INC believes there is a broader interpretation that would lead to a conclusion that there is no explicit prohibition of sub-group(s) of a macronutrient in a nutrition information statement for infant formula.

INC also considers, that to fully prohibit such declarations would create further confusion with consumers because of already extremely limited information on pack.

Format of the nutrition information statement – INC does not believe a consistent format across product labels would assist consumer understanding of this information.

Notification of product reformulation – INC strongly supports provision for permitting a labelling statement to alert caregivers to changes in product formulation.

Nutrition content claim and health claim prohibition – INC strongly supports provision of nutrition content claims (and general level health claims) for infant formula.

Energy Conversion factors
(Not raised by FSANZ) INC requests that P1028 moves forward to correct limits expressed on an energy basis intended to be aligned with Codex by the next consultation paper.

Transition

(Not raised by FSANZ) INC requests any transitional period be of reasonable length to allow adequate time to implement changes, particularly for imported infant formula that is not manufactured in Australia and New Zealand.

Appendix 1

Comparison Table of Conversion Factors used in Infant Formula Products (kJ to kCal)

INFANTFORMULA		CODEX 2007				FSANZ Current		FSANZ Proposed P1028		INC Proposed Value		
Nutrient	**Units**	**Min**	**Conversion factor**	**Max**	**Conversion factor**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**	**Conversion factor**
Protein intact cow's milk protein – CODEX	g/ 100 kcal	1.8	4.000	3	4.286			*1.88*	*2.93*	1.8	3	4.18
	g/100kJ	0.45		0.7		0.45	0.7	0.45	0.7	*0.43*	*0.72*	
Carbohydrate	g/ 100 kcal	9	4.091	14	4.242							N/A
	g/100kJ	2.2		3.3								
Fat	g/ 100 kcal	4.4	4.190	6	4.286			*4.39*	*5.85*	4.4	6	4.18
	g/100kJ	1.05		1.4		1.05	1.5	1.05	1.4	*1.07*	*1.44*	
Linoleic Acid C18:2 n-6	mg/ 100 kcal	300	4.286	1400 GUL	4.242						*1400 GUL*	4.18
	mg/100kJ	70		330 GUL						*90*	*335 GUL*	
	% TFA					9	26	9	26			
Alpha-Linolenic Acid C18:3 n-3	mg/ 100 kcal	50	4.167	N.S	-					50	N.S	4.18
	mg/100kJ	12		N.S						12	N.S	
	% TFA					1.1	4	1.1	NS			
Vitamin A (Retinol)	mcg RE/ 100 kcal	60	4.286	180	4.186			*58.52*	*179.7*	60	180	4.18
	mcg RE/100kJ	14		43		14	43	14	43	*14*	*43*	

INFANTFORMULA		CODEX 2007				FSANZ Current		FSANZ Proposed P1028		INC Proposed Value		
Nutrient	**Units**	**Min**	**Conversion factor**	**Max**	**Conversion factor**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**	**Conversion factor**
Vitamin B_1 Thiamin	mcg/100kcal	60	4.286	300GUL	4.167			*58.52*	*301.0*	60	300GUL	4.18
	mcg/100kJ	14		72 GUL		10	48 Guideline	14	72 GUL	*14*	*72 GUL*	
Vitamin B_{12} (Cyanocobalamin)	mcg/100kcal	0.1	4.000	1.5 GUL	4.167			*0.10*	*1.50*	0.1	1.5 GUL	4.18
	mcg/100kJ	0.025		0.36 GUL		0.025	0.17 Guideline	0.025	0.36 GUL	*0.024*	*0.36 GUL*	
Vitamin B_2 (Riboflavin)	mcg/100kcal	80	4.211	500 GUL	4.202			*79.42*	*497.4*	80	500 GUL	4.18
	mcg/100kJ	19		119 GUL		14	86 Guideline	19	119 GUL	*19*	*120 GUL*	
Vitamin B_6 (Pyridoxine Base)	mcg/100kcal	35	4.118	175GUL	3.889			*35.53*	*188.1*	35	175GUL	4.18
	mcg/100kJ	8.5		45 GUL		9	36	8.5	45 GUL	*8.4*	*42 GUL*	
Vitamin C	mg/100kcal	10	4.000	70 GUL	4.118			*10.45*	*71.06*	10	70 GUL	4.18
	mg/100kJ	2.5		17 GUL		1.7	5.4 Guideline	2.5	17 GUL	*2.4*	*17 GUL*	
Vitamin D	mcg/100kcal	1	4.000	2.5	4.167			*1.045*	*2.508*	1	3.0	4.18
	mcg/100kJ	0.25		0.6		0.25	0.63	0.25	0.6	*0.24*	*0.72*	
Vitamin E (Tocopherol)	mg TE/100kcal	0.5	4.167	5 GUL	4.167			*0.5016*	*5.016*	0.5	5 GUL	4.18
	mg TE/100kJ	0.12		1.2 GUL		0.11		0.12	1.2 GUL	*0.12*	*1.2 GUL*	
Vitamin K	mcg/100kcal	4	4.000	27 GUL	4.154			*4.18*	*27.17*	4	27 GUL	4.18
	mcg/100kJ	1		6.5 GUL		1	5 Guideline	1	6.5 GUL	*1*	*6.5 GUL*	

INFANTFORMULA		CODEX 2007				FSANZ Current		FSANZ Proposed P1028		INC Proposed Value		
Nutrient	**Units**	**Min**	**Conversion factor**	**Max**	**Conversion factor**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**	**Conversion factor**
Biotin	mcg/100kcal	1.5	3.750	10 GUL	4.167			*1.672*	*10.032*	1.5	10 GUL	4.18
	mcg/100kJ	0.4		2.4 GUL		0.36	2.7 Guideline	0.4	2.4 GUL	*0.36*	*2.4 GUL*	
Choline	mg/100kcal	7	4.118	50 GUL	4.167			*7.106*	*50.16*	7	50 GUL	4.18
	mg/100kJ	1.7		12 GUL		1.7	7.1	1.7	12	*1.7*	*12 GUL*	
Folic acid / Folate	mcg/100kcal	10	4.000	50 GUL	4.167			*10.45*	*50.16*	10	50 GUL	4.18
	mcg/100kJ	2.5		12 GUL		2	8 Guideline	2.5	12 GUL	*2.4*	*12 GUL*	
Niacin	mcg/100kcal	300	4.286	1500 GUL	4.167			*292.6*	*1504.8*	300	1500 GUL	4.18
	mcg/100kJ	70		360 GUL		130	480 Guideline	70	360 GUL	*72*	*359 GUL*	
Pantothenic Acid	mcg/100kcal	400	4.167	2000 GUL	4.184			*401.28*	*1998.04*	400	2000 GUL	4.18
	mcg/100kJ	96		478 GUL		70	360 Guideline	96	478 GUL	*96*	*478 GUL*	
Inositol	mg/100kcal	4	4.000	40 GUL	4.211			*4.18*	*39.71*	4	40 GUL	4.18
	mg/100kJ	1		9.5 GUL		1	9.5	1	9.5 GUL	*1*	*9.6 GUL*	
Calcium (Ca)	mg/100kcal	50	4.167	140 GUL	4.000			*50.16*	*146.3*	50	140 GUL	4.18
	mg/100kJ	12		35 GUL		12	33 Guideline	12	35 GUL	*12*	*34 GUL*	
Chloride (Cl)	mg/100kcal	50	4.167	160	4.211			*50.16*	*158.84*	50	160	4.18
	mg/100kJ	12		38		12	35	12	38	*12*	*38*	
Copper (Cu)	mcg/100kcal	35	4.118	120 GUL	4.138			*35.53*	*121.22*	35	120 GUL	4.18
	mcg/100kJ	8.5		29 GUL		14	43	8.5	29 GUL	*8.4*	*29 GUL*	
Iodine (I)	mcg/100kcal	10	4.000	60 GUL	4.286			10.45	58.52	10	60 GUL	4.18
	mcg/100kJ	2.5		14 GUL		1.2	10	2.5	14 GUL	*2.4*	*14 GUL*	
Iron (Fe)	mg/100kcal	0.45	4.500	-				*0.418*	-	0.8	2.1	4.18
	mg/100kJ	0.1		-		0.2	0.5	0.2	0.5	*0.2*	0.5	

INFANT FORMULA		CODEX 2007				FSANZ Current		FSANZ Proposed P1028		INC Proposed Value		
Nutrient	Units	Min	Conversion factor	Max	Conversion factor	Min	Max	Min	Max	Min	Max	Conversion factor
Magnesium (Mg)	mg/100kcal	5	4.167	15 GUL	4.167			*5.016*	*15.048*	5	15 GUL	4.18
	mg/100kJ	1.2		3.6 GUL		1.2	4	1.2	3.6 GUL	*1.2*	*3.6 GUL*	
Manganese (Mn)	mcg/100kcal	1	4.000	100 GUL	4.167			*1.045*	*100.32*	1	100 GUL	4.18
	mcg/100kJ	0.25		24 GUL		0.24	24	0.25	24 GUL	*0.24*	*24 GUL*	
Phosphorus (P)	mg/100kcal	25	4.167	100 GUL	4.167			*25.08*	*100.32*	25	100 GUL	4.18
	mg/100kJ	6		24 GUL		6	25	6	24 GUL	*6*	*24 GUL*	
Potassium (K)	mg/100kcal	60	4.286	180	4.186			*58.52*	*179.74*	60	180	4.18
	mg/100kJ	14		43		20	50	14	43	*14.4*	*43.1*	
Sodium (Na)	mg/100kcal	20	4.000	60	4.286			*20.9*	*58.52*	20	60	4.18
	mg/100kJ	5		14		5	15	5	14	*4.8*	*14.4*	
Zinc (Zn)	mg/100kcal	0.5	4.167	1.5 GUL	4.167			*0.5016*	*150.48*	0.5	1.5 GUL	4.18
	mg/100kJ	0.12		0.36 GUL		0.12	0.43	0.12	0.36 GUL	*0.12*	*0.36 GUL*	
Selenium (Se)	mcg/100kcal	1	4.167	9 GUL	4.091			*2.0064*	*9.196*	1	9 GUL	4.18
	mcg/100kJ	0.24		2.2 GUL		0.25	1.19	0.48	2.2 GUL	*0.24*	*2.2 GUL*	
L-Carnitine	mg/100kcal	1.2	4.000	N.S				*1.254*	*3.344*	1.2	N.S	4.18
	mg/100kJ	0.3		N.S		0.21	0.8	0.3	0.8	*0.3*	N.S	
L- Cysteine, cystine, methionine	mg/100kcal	62						79		62		4.18
	mg/100kJ					19		19		*15*		
L- methionine	mg/100kcal	24								24		4.18
	mg/100kJ									6		
L- Cysteine, cystine	mg/100kcal	38								38		4.18
	mg/100kJ					6				9		
Histidine, L-	mg/100kcal	41						41		41		4.18
	mg/100kJ					10		10		*10*		

INFANT FORMULA		CODEX 2007				FSANZ Current		FSANZ Proposed P1028		INC Proposed Value		
Nutrient	**Units**	**Min**	**Conversion factor**	**Max**	**Conversion factor**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**	**Conversion factor**
Isoleucine, L-	mg/100kcal	92						92		92		4.18
	mg/100kJ					21		22		*22*		
Leucine, L-	mg/100kcal	169						169		169		4.18
	mg/100kJ					42		40		*40*		
Lysine, L	mg/100kcal	114						114		114		4.18
	mg/100kJ					30		27		*27*		
Phenylalanine + Tyrosine	mg/100kcal	156								156		
	mg/100kJ					32		32		37		
Phenylalanine, L-	mg/100kcal	81								81		4.18
	mg/100kJ					17		17		*19*		
Tyrosine	mg/100kcal	75								75		4.18
	mg/100kJ									*18*		
Threonine, L-	mg/100kcal	77						77		77		4.18
	mg/100kJ					19		18		*18*		
Tryptophan, L-	mg/100kcal	33						33		33		4.18
	mg/100kJ					7		8		*8*		
Valine, L-	mg/100kcal	90						90		90		4.18
	mg/100kJ					25		22		*22*		
Total Nucleotides	mg/100kcal											
	mg/100kJ						3.8		3.8		3.8	
Adenosine 5'-monophosphate (AMP)	mg/100kcal											
	mg/100kJ					0.14	0.38	0.14	0.38		0.38	

INFANT FORMULA		CODEX 2007				FSANZ Current		FSANZ Proposed P1028		INC Proposed Value		
Nutrient	**Units**	**Min**	**Conversion factor**	**Max**	**Conversion factor**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**	**Conversion factor**
Cytidine 5'-monophosphate (CMP)	mg/100kcal											
	mg/100kJ					0.22	0.6	0.22	0.6		0.6	
Guanosine 5'-monophosphate (GMP)	mg/100kcal											
	mg/100kJ					0.04	0.12	0.04	0.12		0.12	
Inosine 5'-monophosphate (IMP)	mg/100kcal											
	mg/100kJ					0.08	0.24	0.08	0.24		0.24	
Uridine 5'-monophosphate (UMP)	mg/100kcal											
	mg/100kJ					0.13	0.42	0.13	0.42		0.42	
Molybdenum (Mo)	mg/100kcal	1.5	3.75	10 GUL	4.17							
	mcg/100kJ	0.4		2.4 GUL			3					
Chromium	mg/100kcal	1.5	3.75	10 GUL	4.17							
	mcg/100kJ	0.4		2.4 GUL			2					

N.S = Not specified

4.18 is the conversion factor set out in FSC 1.2.8 Clause 1 (4).Converted values indicated by *italics*.

The above is not an exhaustive compositional list. The above values relate to those only where a conversion factor is applicable. Ratios and nutrients presented in units of percentage total fatty acids have been omitted

JIGSAW

EST. 1994

INFORMED CHOICE FOR CONSUMERS

Consumer Research commissioned 2014

OBJECTIVE OF CONSUMER RESEARCH

Research Goals

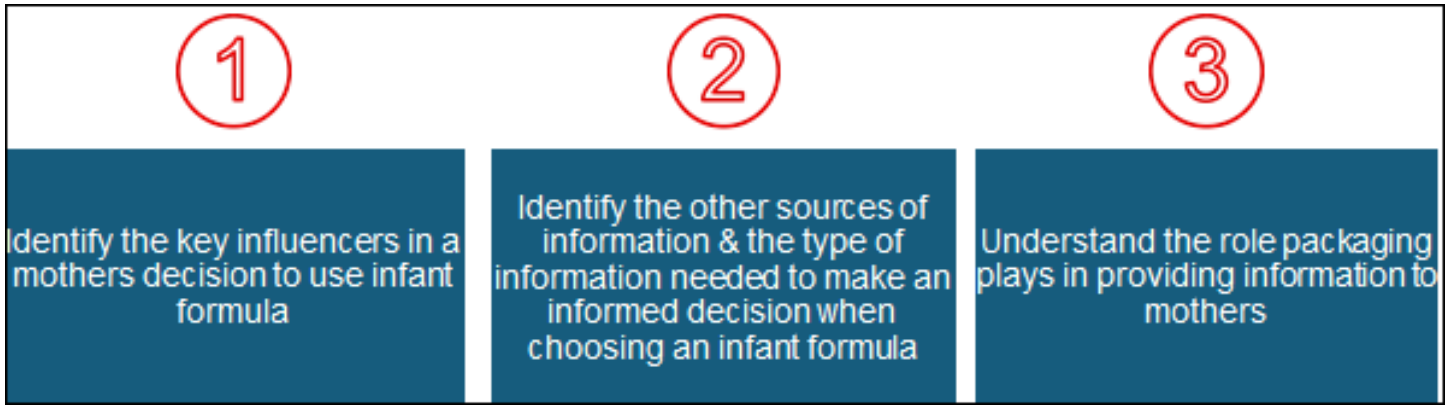
- The overall objective of this research commissioned by the INC was to provide empirical evidence that helps support the Infant Nutrition Council's submissions in relation to the review of Standard 2.9.1. and the re-authorisation of the MAIF Agreement.

- Specifically:

1. Identify the key influencers in a mothers decision to use infant formula
2. Identify the other sources of information & the type of information then needed to make an informed decision when choosing an infant formula product
3. Understand the role packaging plays in providing information to mothers

Scope of this presentation

This presentation will focus on Informed Choice for Consumers and the research outcomes relating this.



STUDY DESIGN

Overview of methodology

Study Design

- This quantitative research will entail a 20 minute questionnaire administered online
- Questionnaires to be sent to a representative spread of geographic locations

Inclusion criteria

- Mothers, females aged 18-44 years
- Mums of babies and toddlers 0-24 months
  - Mums with newborns (0-12 months) to refer to current situation
  - Mums with young children (13-24 months) to think back to situation when child was 0-12 months
- Mums currently using infant formula or used infant formula when child was 0-12 months old

Exclusion criteria

- Mums who work in industries relating to pharmaceuticals and/or market research
- Males
- Live in an unidentified area
- Females with no children and pregnant women
- Mums that did not use any formula when their child was 0-12 months

RESULTS & DISCUSSION

Study population

Online survey

- Average survey length 15 minutes duration
- Fieldwork conducted 17th – 27th October 2014
- Sample sourced from Jigsaw's field partner, The Digital Edge
- Only mums who used formula were included

Speaking to mothers who use infant formula

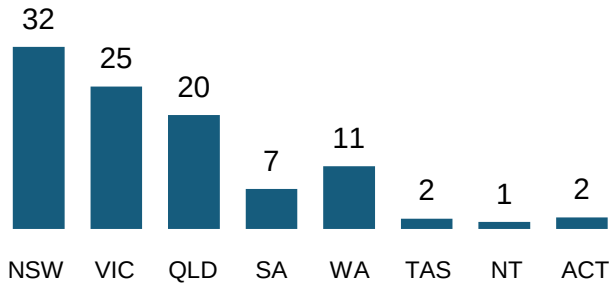
- A total of 2,082 mums started the survey with 1,581 screened out due to the following reasons:
  - 4% had no children or didn't answer
  - 61% had no children between 0-24 months of age
  - 10% were not using infant formula between 0-12 months of age
- n=501 completed the survey in total
- N=231 first time Mums, n=270 subsequent mums

Questionnaire flow

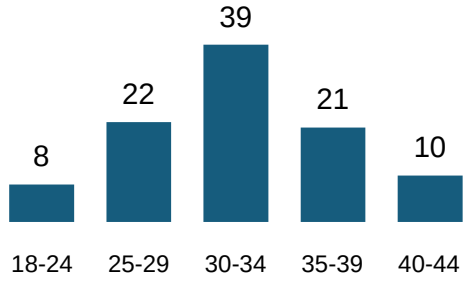
- Screener and formula usage
- Behaviour
- Influences and Information
- Role of Health Care Professionals
- Labelling, Ingredients and Information

A nationally representative sample for this study (1)

Location

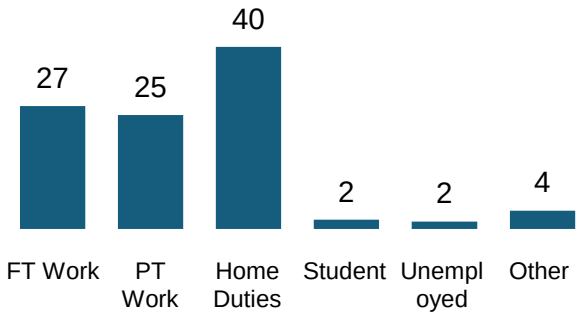


Age



Average age 32

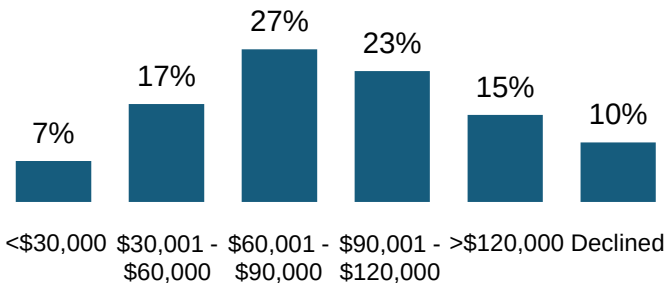
Work status



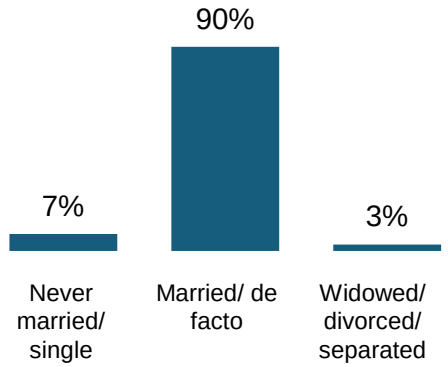
Base: all n=501

A nationally representative sample for this study (2)

Household Income



Marital Status



Base: all n=501

The data is weighted to reflect the Australian population regarding first time vs. subsequent Mums

A5: Which of the following best describes you?

One Child

42%

Two Children

39%

Three Children

14%

Four + Children

6%

FIRST TIME MUM'S = 42%

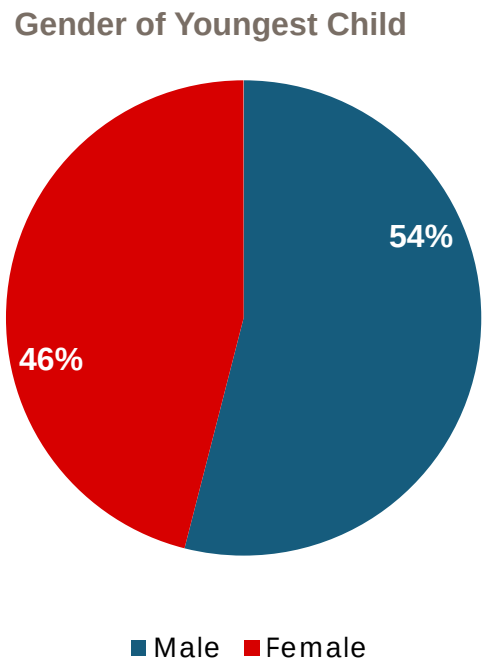
SUBSEQUENT MUM'S = 58%

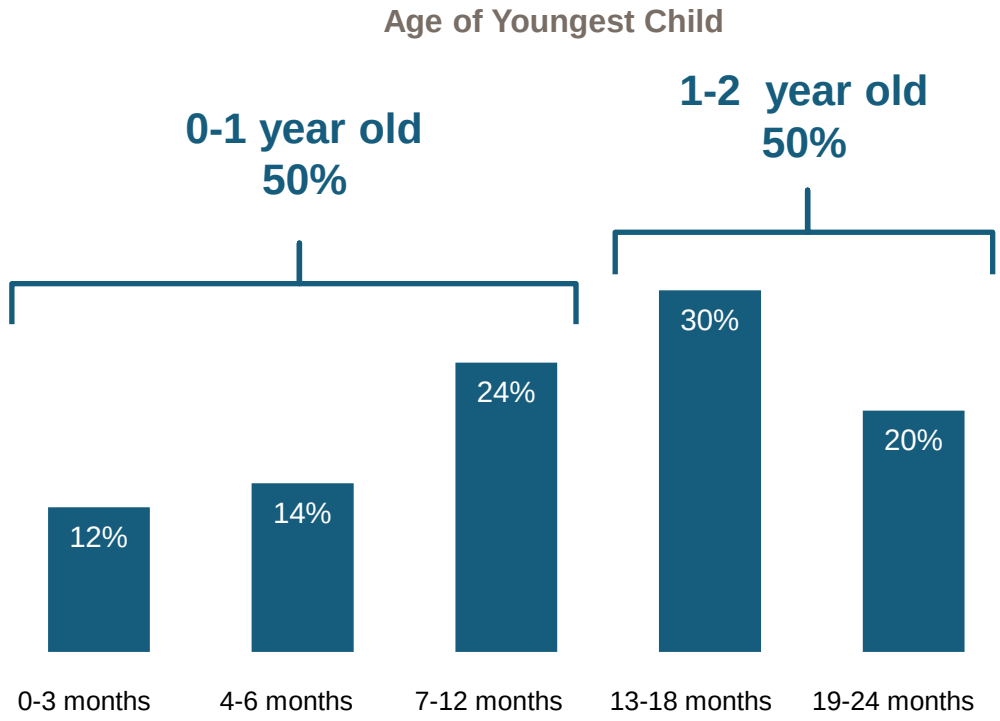
Base: all n=501

We have highlighted where noticeable/significant differences by these two groups.

Gender and age of youngest child

A6: Please indicate the gender of each of your children, starting with your youngest
A7. Please let us know how old each of your children is





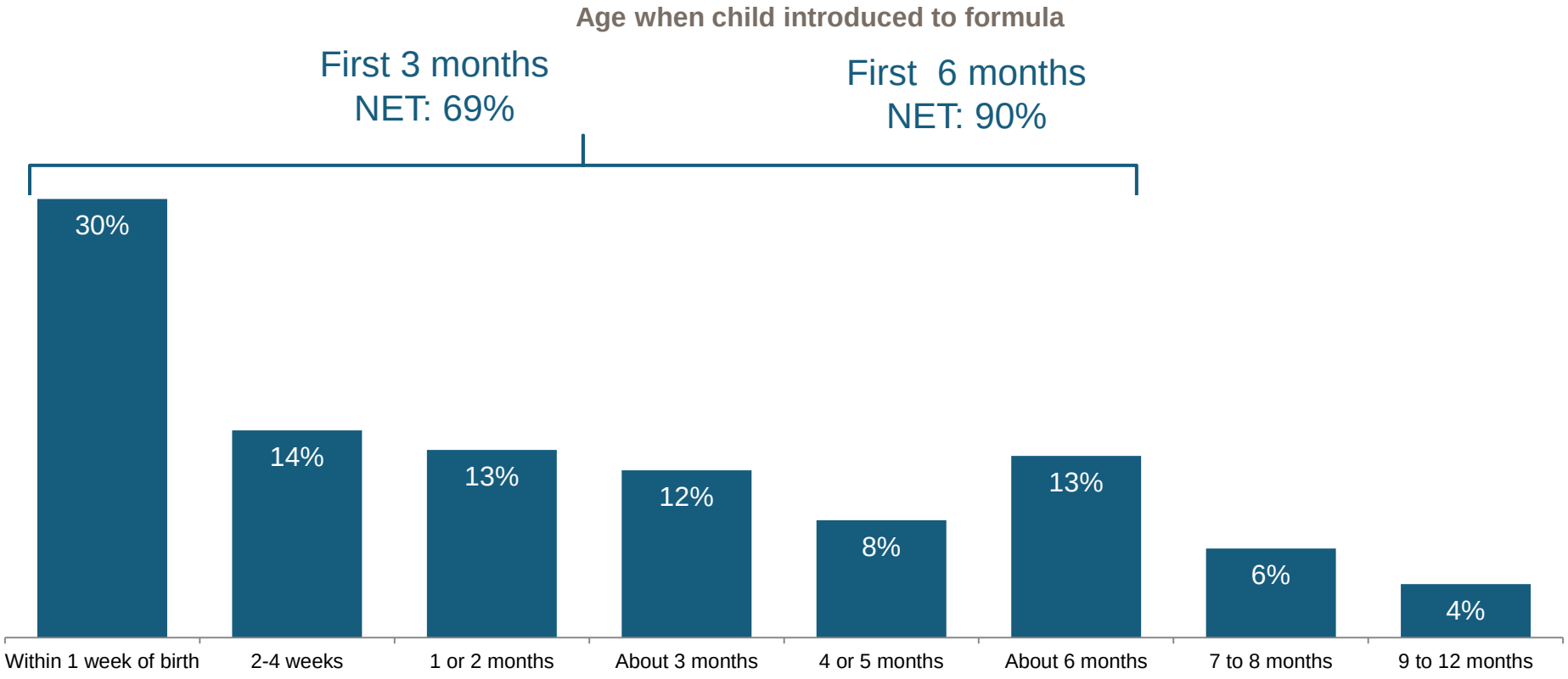
Base: all n=501

NOTE: Respondents with children between 1-2 years were asked to base their views from when their child was 0-12 months of age.

INITIATING FORMULA USAGE

How old was your child when you first introduced them to formula?

B1. How old was your child when you first introduced them to formula?



Base: all n=501

7 in 10 children who are formula fed are introduced within the first 3 months

How are you currently using the infant formula product?

B4a. How are you currently using infant formula product in your child's diet?

Exclusive use of formula

26%

Mixed feeding (formula and breast milk)

29%

Formula and/or Breast milk + solids

45%

Base: all n=501

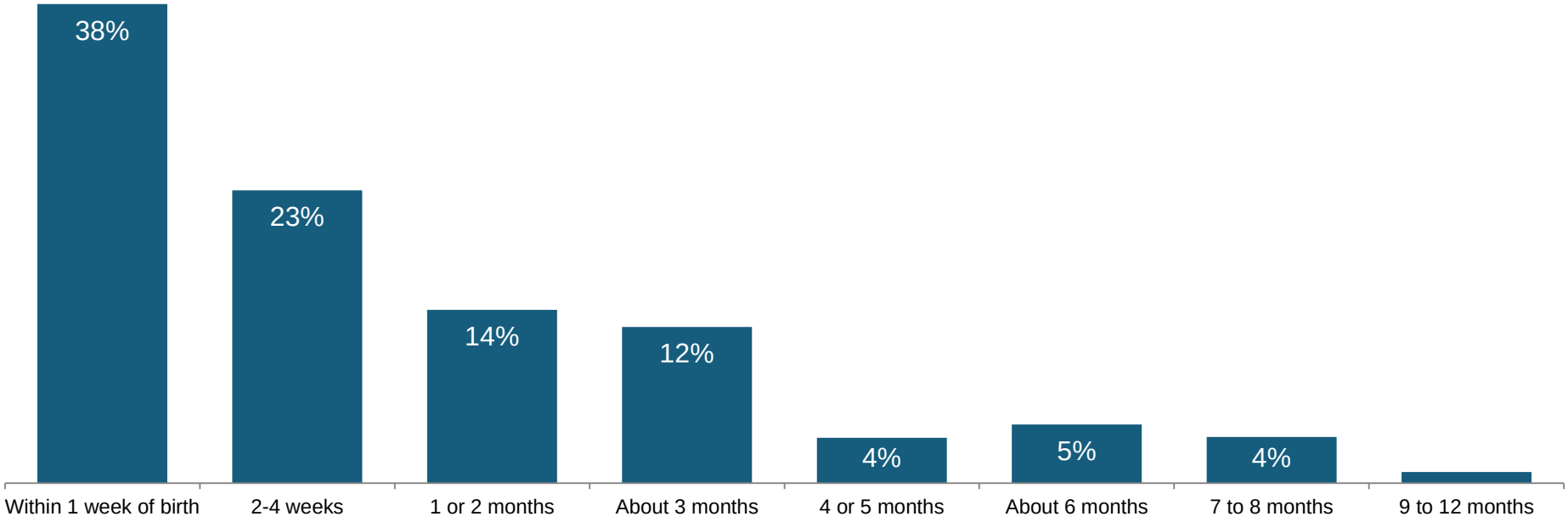
With only a quarter using formula exclusively.

Of those currently using IF exclusively, 6 in 10 start using IF within 4 weeks of birth

B1. How old was your child when you first introduced them to formula?

Age when child introduced to formula
Among those currently using IF exclusively

Overall 26%
IF exclusive



Base: all n=501

However, mums did not necessarily use IF exclusively when starting on formula.

Use of infant formula for those who commenced using infant formula within 3 months of child's birth

B4a. How are you currently using infant formula product in your child's diet?

	Within 3 months of birth	More than 3 months after birth
My infant is only on liquids and I am using infant formula exclusively i.e. my infant only receives infant formula	32% ↑	11%
My infant is only on liquids and I am using infant formula as a supplementary product i.e. my infant receives both breast	30%	29%
My infant is on both liquids and solids and I am using infant formula as a supplementary product, along with solid foods	38%	60% ↑

Base: Started using formula within 3 months of birth n=344, more than 3 months n=157

Use of infant formula for those who are first time Mums and subsequent Mums

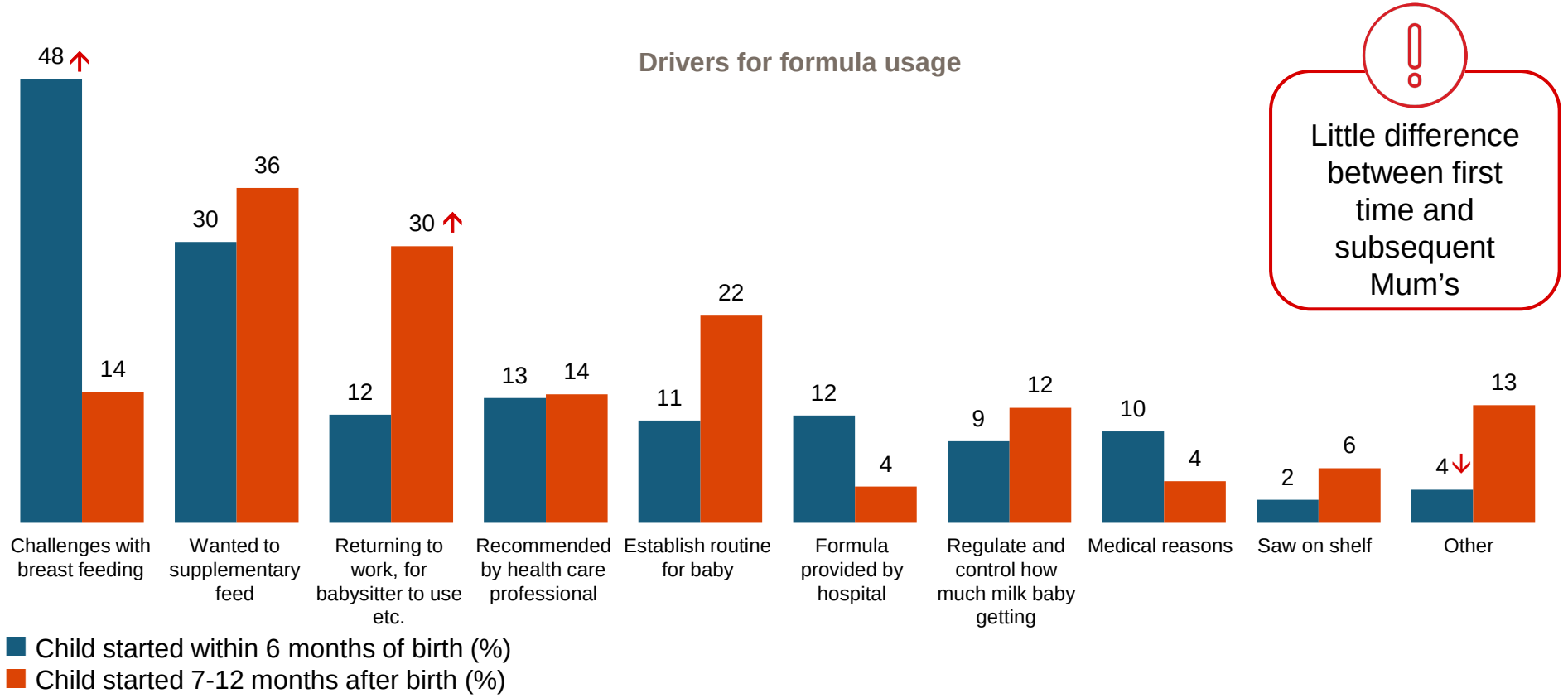
B4a. How are you currently using infant formula product in your child's diet?

	First time mum	Subsequent mum
My infant is only on liquids and I am using infant formula exclusively i.e. my infant only receives infant formula	23%	27%
My infant is only on liquids and I am using infant formula as a supplementary product i.e. my infant receives both breast	31%	29%
My infant is on both liquids and solids and I am using infant formula as a supplementary product, along with solid foods	46%	44%

Base: First time Mum n=231, Subsequent Mum n=270

Why did you start using formula?

B2: Why did you start using infant formula product (either exclusively or for supplementary feeding)



↓↑ Significantly at 95% CI – better, or worse, than average chance of being selected

Base: Child started within 6 months of birth n=450, More than 6 months n=51

Breastfeeding issues are the key driver behind use of infant formula with infants under 6 months

Why did you start using formula? Cont'…

B2: Why did you start using infant formula product (either exclusively or for supplementary feeding)

	Within 3 months of birth	More than 3 months after birth
Challenges with breast feeding (e.g. inability to latch, provide adequate breast milk supply, painful or cracked nipples, stressed)	55 ↑	22
Wanted to supplementary feed (mixed feeding, both formula and breast milk)	27	40 ↑
Returning to work, for babysitters to feed, feeding in public/on the go	7	28↑
Was recommended by a health care professional (e.g. doctor, midwife, community nurse)	13	14
Wanted to establish a routine for my baby	9	18 ↑
Formula was provided by the hospital (e.g. due to prematurity, time spent in neonatal unit)	14 ↑	4
Wanted to regulate and control how much milk my baby was getting	8	11
Medical reasons (e.g. needing to take medication which makes breast feeding inadvisable)	10	9
Other (specify)	2	9 ↑
I had never considered formula feeding before until I saw it on shelf and decided to purchase a product	3	3

Base: Started using formula within 3 months of birth n=344, more than 3 months n=157

Drivers for use of infant formula by whether Mum is first time or subsequent Mum

B2: Why did you start using infant formula product (either exclusively or for supplementary feeding)

	First time mum	Subsequent mum
Challenges with breast feeding (e.g. inability to latch, provide adequate breast milk supply, painful or cracked nipples, stressed)	43	45
Wanted to supplementary feed (mixed feeding, both formula and breast milk)	32	30
Returning to work, for babysitters to feed, feeding in public/on the go	10	16
Was recommended by a health care professional (e.g. doctor, midwife, community nurse)	16	12
Wanted to establish a routine for my baby	10	13
Formula was provided by the hospital (e.g. due to prematurity, time spent in neonatal unit)	13	9
Wanted to regulate and control how much milk my baby was getting	11	8
Medical reasons (e.g. needing to take medication which makes breast feeding inadvisable)	11	8
Other (specify)	7 ↑	3
I had never considered formula feeding before until I saw it on shelf and decided to purchase a product	3	3

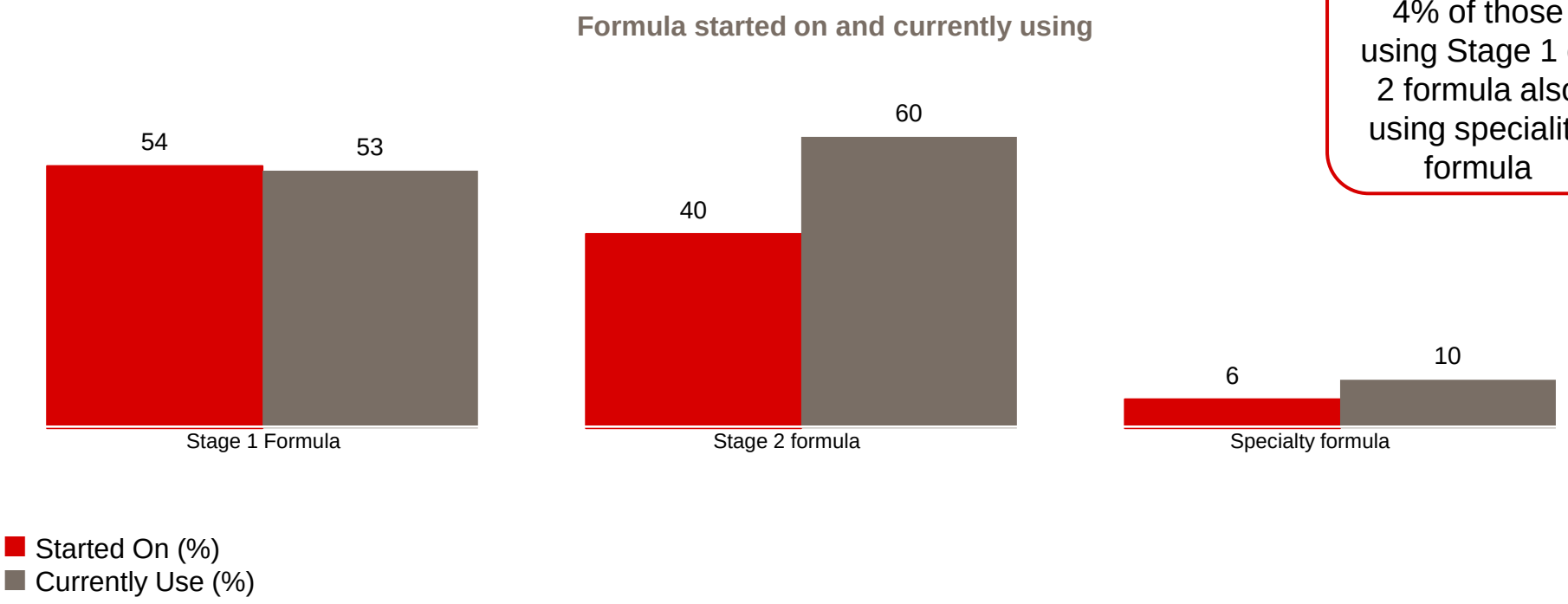
Challenges with breastfeeding remains key driver for mum to start using formula, whether or not she was a first time or subsequent mum

Base: First time Mum n=231, Subsequent Mum n=270

More than half start their child on Stage 1 formula

A9a: What type of infant formula product did your 0-12 month old child start on?
A9b: What type of infant formula product are you currently using for your 0-12 month old child?
A9d: Thinking back, what type of infant formula product did your 13-24 year old child start on?
A9e Thinking back, what types of infant formula product did you feed your child when they were 0-12 months old?

4% of those using Stage 1 or 2 formula also using speciality formula

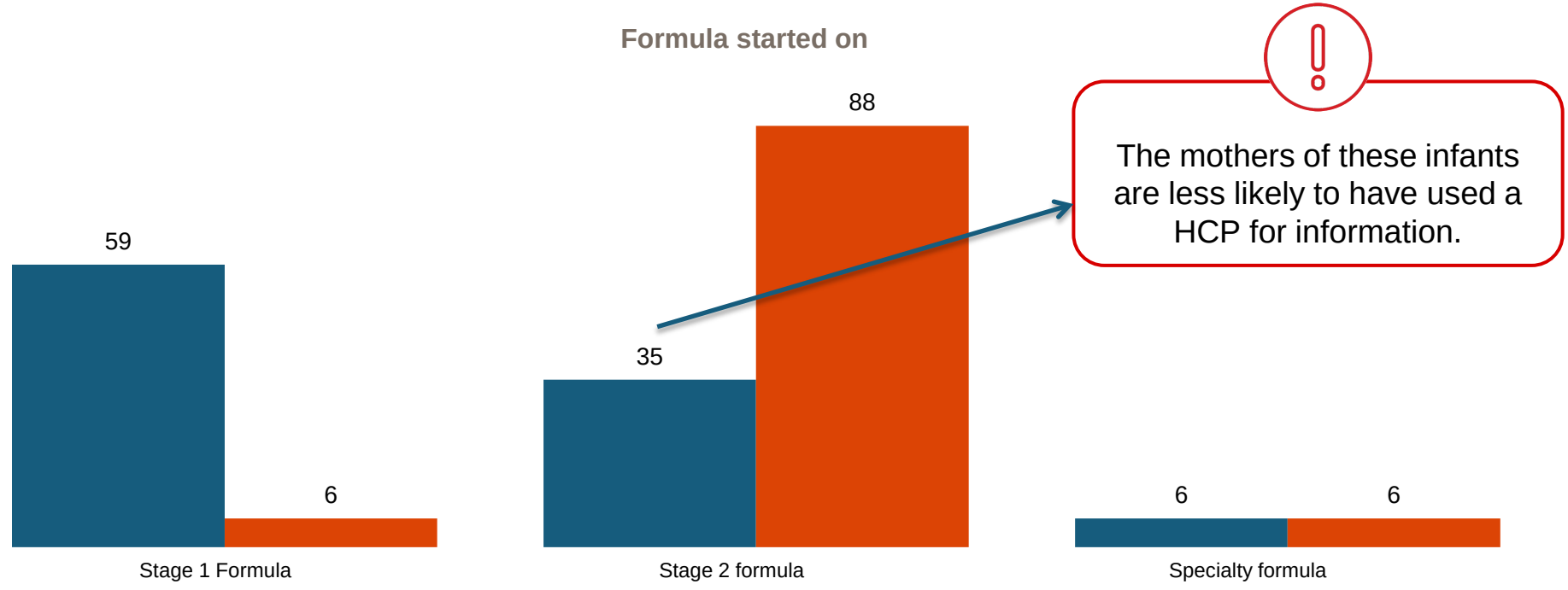


Base: all n=501

Specialty formulas are part of a repertoire for 1 in 10 mothers who are currently using formula.

What formula product (stage) did you start on?

A9a: What type of infant formula product did your 0-12 month old child start on?
A9d: Thinking back, what type of infant formula product did your 13-24 month old child start on?

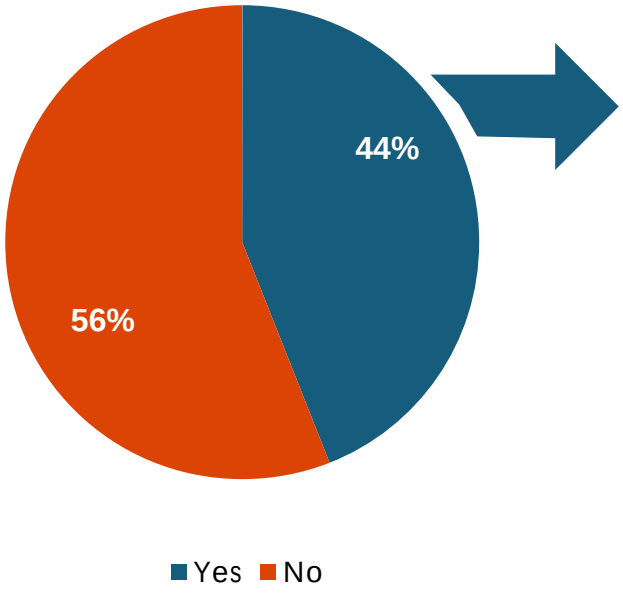


Base: Child started within 6 months of birth n=450, More than 6 months n=51

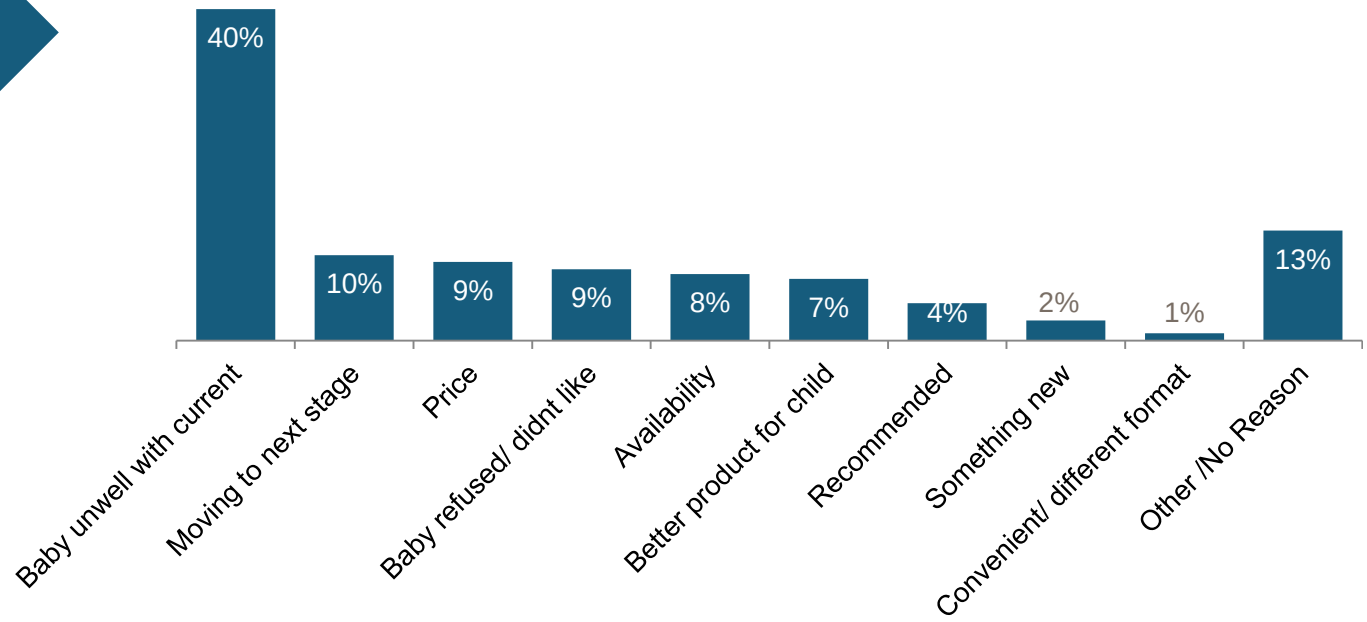
Have you ever switched formula products?

B8. Since you have started formula feeding, have you switched products in that time?
B8c: Why did you change infant formula products? CODED

Ever Changed Formula



Reasons for Changing (n=221)



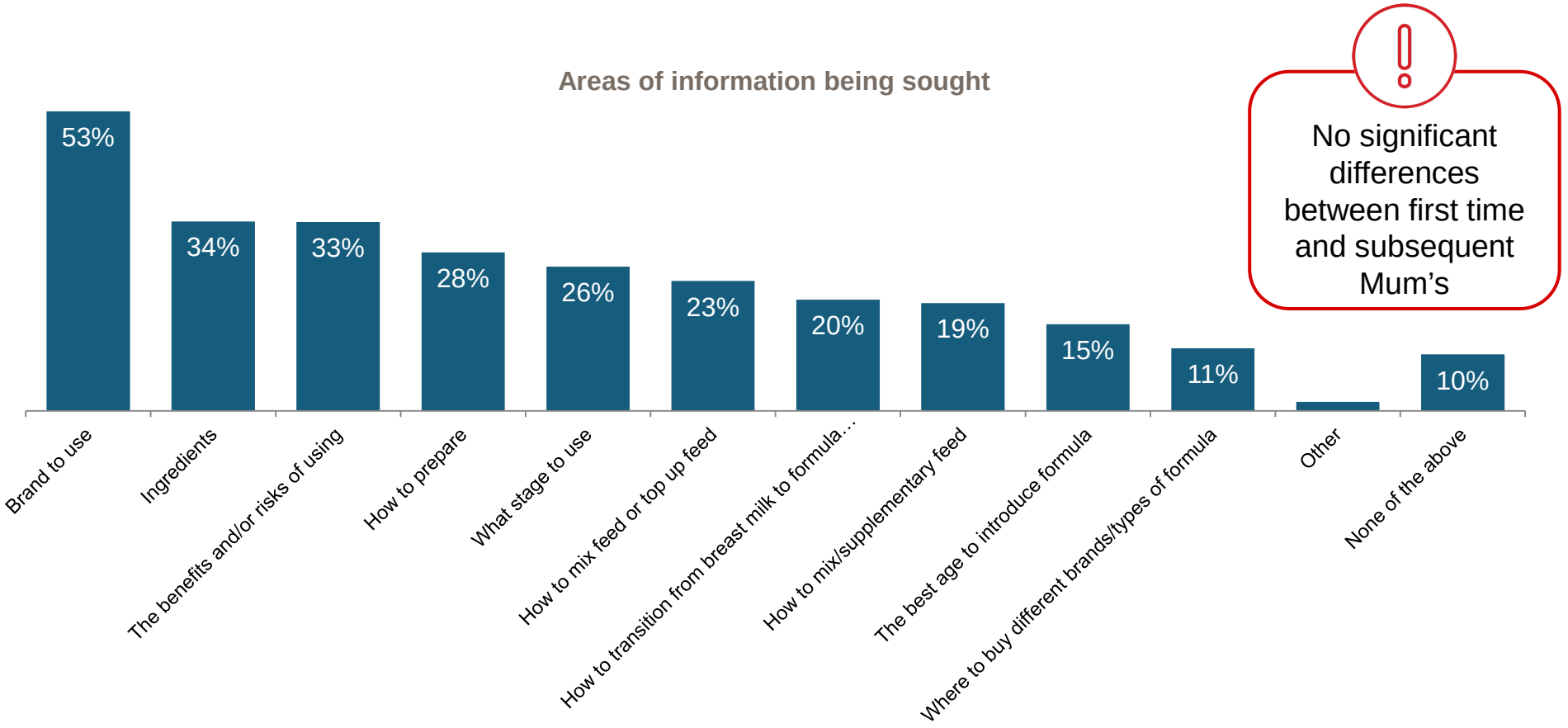
Base: all n=501

With problems with the health of the child being the key driver behind changing infant formula.

INFLUENCES AND INFORMATION (INITIAL CHOICE OF FORMULA)

When looking at formula in general, what type of information did you seek?

C2c: When looking at infant formula in general, which of the following topics were you seeking information about?



Base: n=501

Brands, formulation and benefits or risks are the hot topics.

General information topics by age child started on infant formula

C2c: When looking at infant formula in general, which of the following topics were you seeking information about?

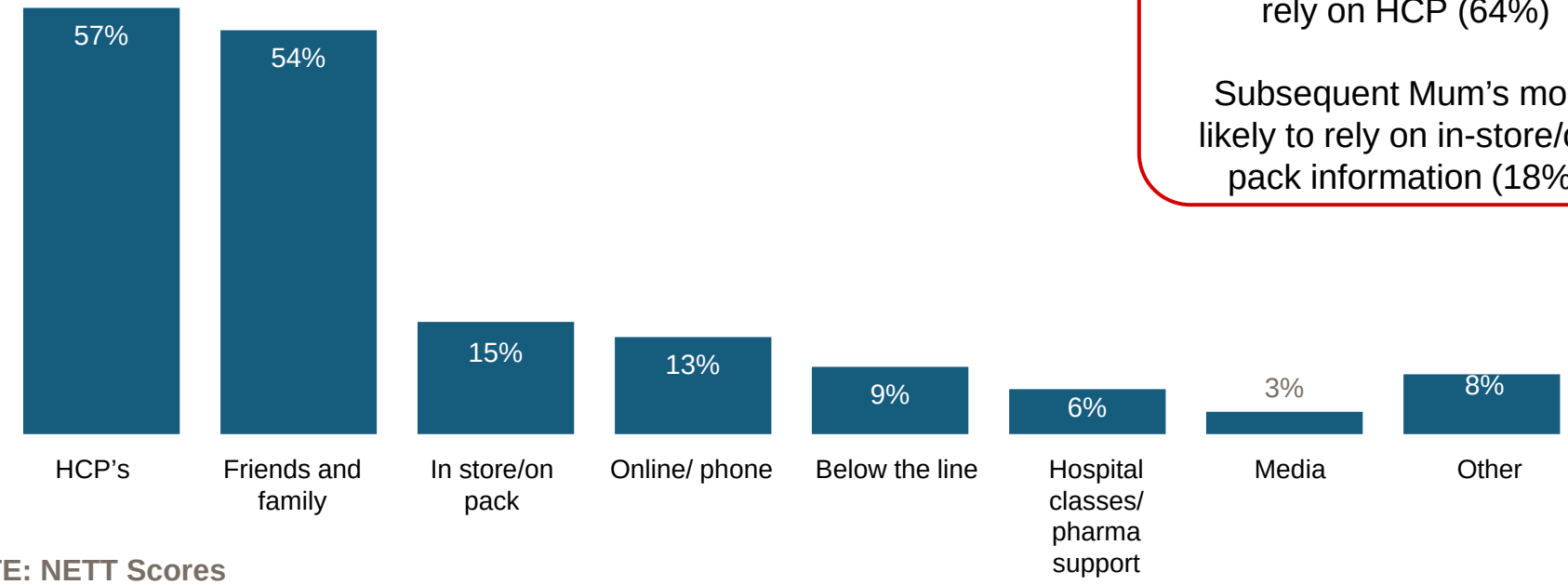
	Within 3 months of birth	More than 3 months after birth
What brand of formula to use	52%	55%
Ingredients in formula	34%	32%
The benefits and/or risks of using formula	34%	33%
How to prepare formula	25%	34%
What stage of formula to use	24%	28%
How to mix feed or top up feed	24%	21%
How to transition from breast milk to formula feeding	14%	32%↑
How to mix/supplementary feed	19%	20%
The best age to introduce formula	13%	22%↑
Where to buy different brands/types of formula	12%	9%
Other (please specify)	2%	1%
None of the above	11%	8%

Base: Started using formula within 3 months of birth n=344, more than 3 months n=157

Who/where did you go to for information about formula?

C1a: Who did you talk to/where did you receive information on formula?

Information Sources for first formula purchase



First time Mum's more likely to rely on HCP (64%)

Subsequent Mum's more likely to rely on in-store/on-pack information (18%)

NOTE: NETT Scores

Base: n=501

HCPs and Family and Friends are the 2 most common sources of information

Who/where did you go to for information about formula? Cont'…

C1a: Who did you talk to/where did you receive information on formula?

	Within 3 months of birth	More than 3 months after birth
HCP	62↑	47
Friends and Family	51	59
In-Store/On Pack	11	23↑
Online/phone	11	19↑
Below the line	7	14↑
Hospital classes/Pharma	5	9↑
Media	2	4

Base: Started using formula within 3 months of birth n=344, more than 3 months n=157

Initial information Sources by whether Mum is first time or subsequent Mum

C1a: Who did you talk to/where did you receive information on formula?

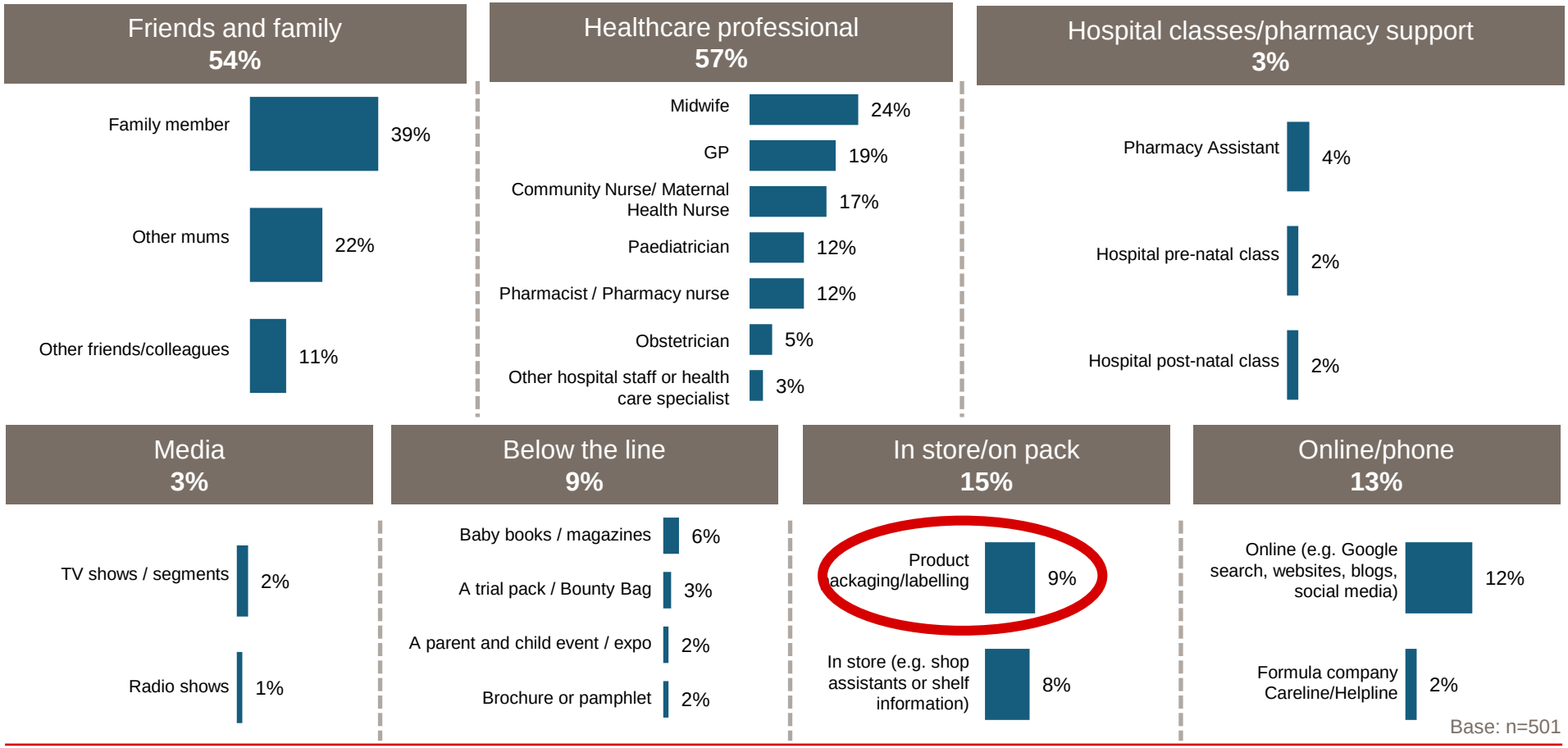
	First time mum	Subsequent mum
HCP	64 ↑	52
Friends and Family	58	50
In-Store/On Pack	11	18 ↑
Online/phone	15	12
Below the line	8	10
Hospital classes/Pharma	5	8
Media	2	3

Subsequent mums more likely to rely on in-store/on pack information

Base: First time Mum n=231, Subsequent Mum n=270

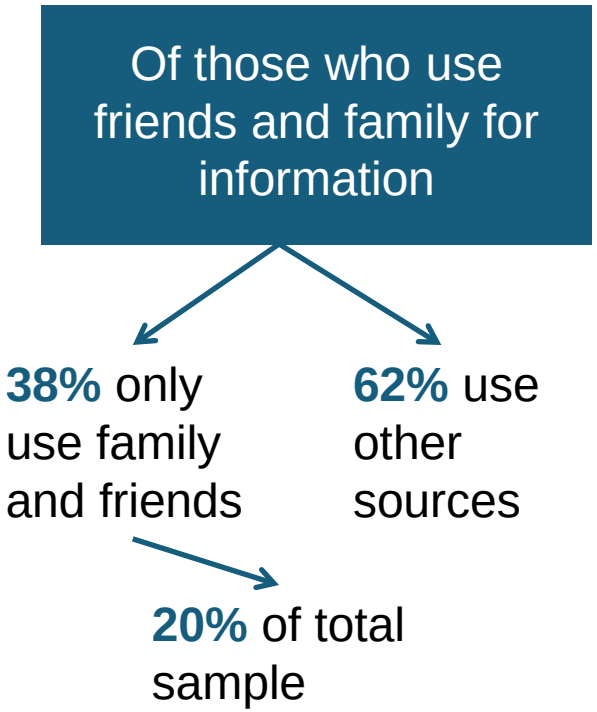
And when you look more closely, family members are the most relied upon specific information source

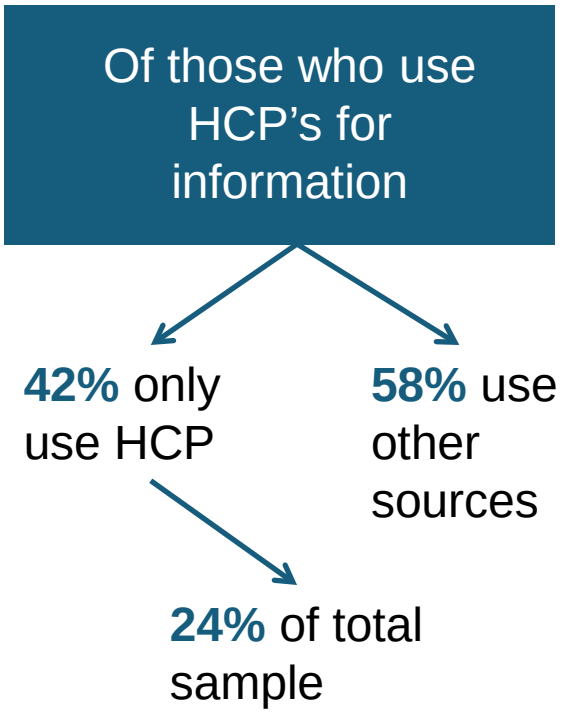
C1a: Who did you talk to/where did you receive information on formula?



1 in 10 are sourcing information on pack prior to purchasing infant formula.

1 in 5 women using infant formula are only going to family members for information

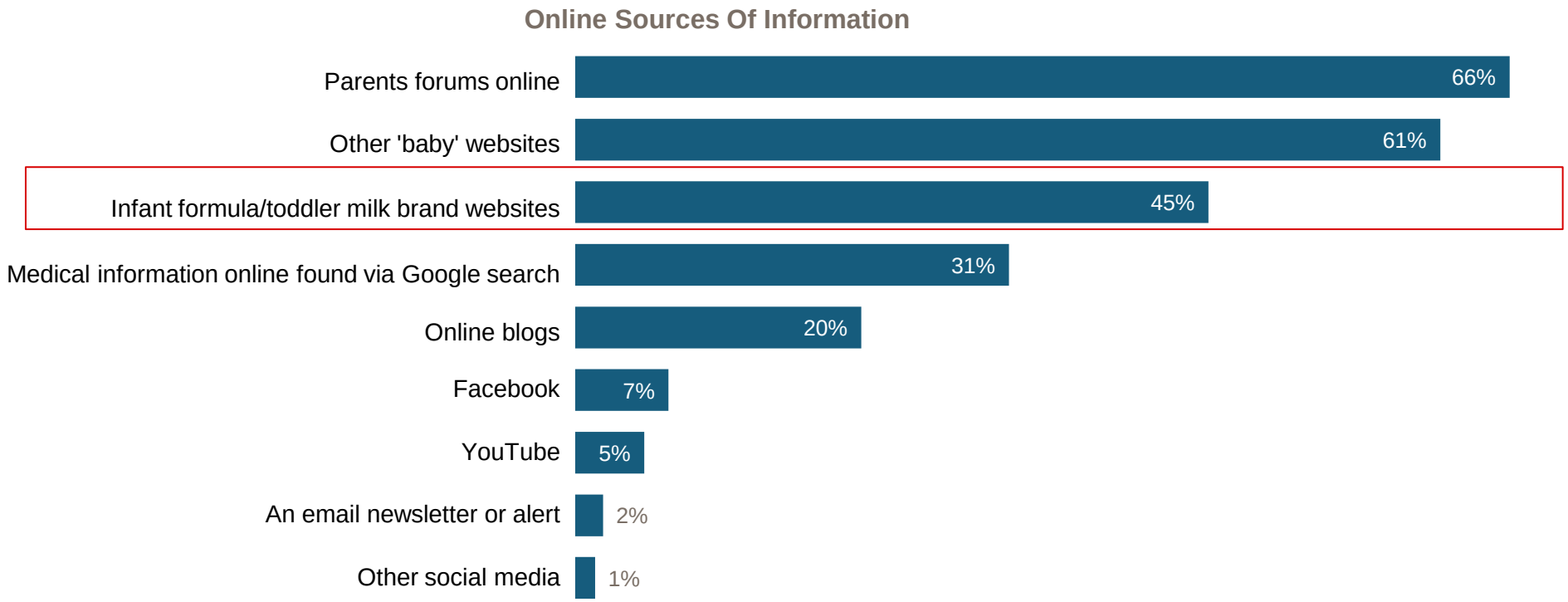




A lot of influence placed on previous experience from family members, and not expert information

When you first started using formula, which of the following *online* information sources did you turn to or receive information?

*C1b: When you **first started** giving your child infant formula, which of the following online information sources did you turn to or receive information on formula?*



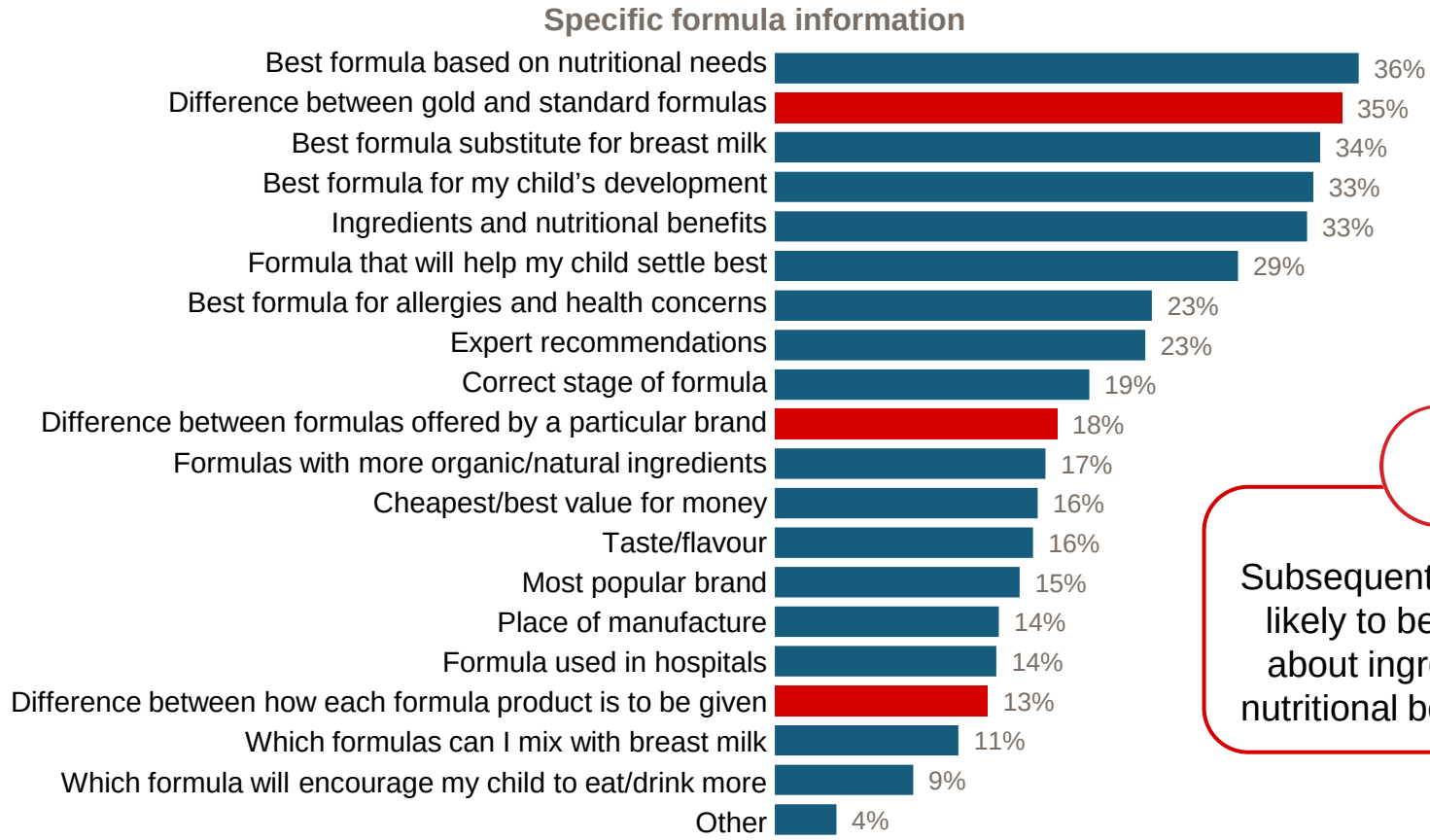
↓↑ Significantly different to all others at 95% CI

Base: Used online sources n=59

However, nearly half of Mum's who used online information sources are visiting product websites.

When deciding on a specific product/brand, what information did you seek?

C3d: When making a decision on a particular product or brand of infant formula, what questions did you ask or information did you seek?



Subsequent Mum's more likely to be concerned about ingredients and nutritional benefits (37%)

Base: n=501

The nutritional needs are key in terms of aiding decisions

The differences between gold and more standard variants also scrutinised

Information sought when making decision by age child started on infant formula

C3d: When making a decision on a particular product or brand of infant formula, what questions did you ask or information did you seek?

	Within 3 months of birth	More than 3 months after birth
What is the best formula based on nutritional needs	33%	43% ↑
What is the difference between gold and standard formulas	36%	34%
Which formula is the best substitute for breast milk	30%	43% ↑
Which formula is best for my child?s development	34%	33%
What are the ingredients and nutritional benefits	32%	35%
Which formula will help my child settle best/provides most comfort	31%	23%
What is the best formula for allergies/rashes/constipation/diarrhoea or other health concerns	24%	21%
What do experts recommend	23%	23%
What is the correct stage of formula to give my child	18%	24%
What is the difference between formulas offered by a particular brand	19%	14%
Which formulas have more organic/natural ingredients	16%	19%
Which is the cheapest/best value for money	15%	18%
Which formula will my child like the taste of	14%	19%
What is the most popular brand	13%	19%
Where are the formula products manufactured	15%	12%
Which formula is used in hospitals	16%	9%
What is the difference between how each formula product is to be given (e.g. volume, frequency	13%	13%
NETT: DIFFERENCES BETWEEN PRODUCTS	47%	44%
Which formulas can I mix with breast milk	11%	12%
Which formula will encourage my child to eat/drink more	7%	11%
Other	5%	2%

Base: Started using formula within 3 months of birth n=344, more than 3 months n=157

Information sought when making decision by whether Mum is first time or subsequent Mum

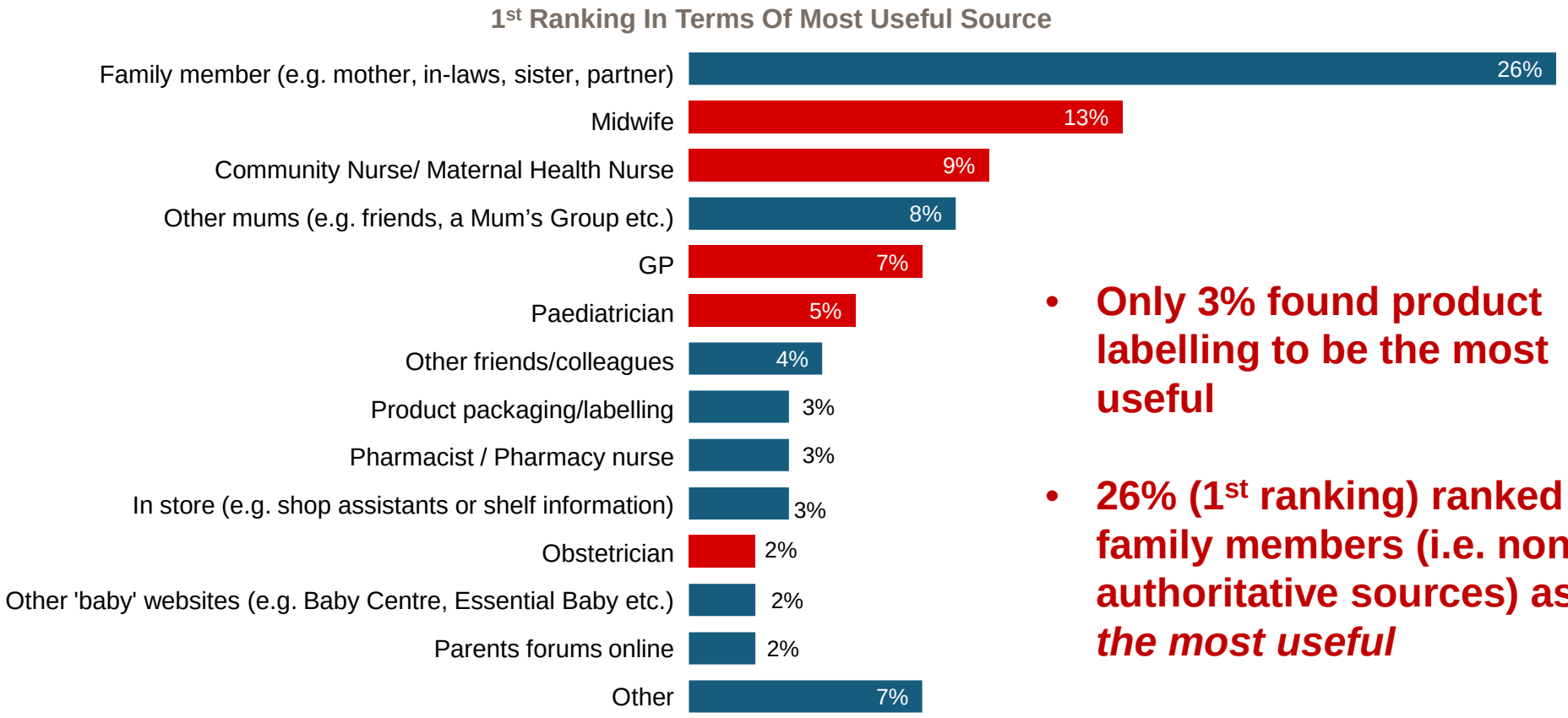
C3d: When making a decision on a particular product or brand of infant formula, what questions did you ask or information did you seek?

	First time mum	Subsequent mum
What is the best formula based on nutritional needs	36%	36%
What is the difference between gold and standard formulas	36%	35%
Which formula is the best substitute for breast milk	35%	33%
Which formula is best for my child?s development	35%	32%
What are the ingredients and nutritional benefits	27%	37%↑
Which formula will help my child settle best/provides most comfort	28%	30%
What is the best formula for allergies/rashes/constipation/diarrhoea or other health concerns	22%	25%
What do experts recommend	25%	22%
What is the correct stage of formula to give my child	21%	18%
What is the difference between formulas offered by a particular brand	20%	16%
Which formulas have more organic/natural ingredients	17%	17%
Which is the cheapest/best value for money	16%	16%
Which formula will my child like the taste of	14%	18%
What is the most popular brand	15%	15%
Where are the formula products manufactured	13%	14%
Which formula is used in hospitals	15%	12%
What is the difference between how each formula product is to be given (e.g. volume, frequency	15%	12%
NETT: DIFFERENCES BETWEEN PRODUCTS	48%	45%
Which formulas can I mix with breast milk	11%	11%
Which formula will encourage my child to eat/drink more	6%	10%
Other	1%	6%↑

Base: First time Mum n=231, Subsequent Mum n=270

Who/what was the most useful in providing information on formula?

C2a: Which of the following were most useful in providing information on formula?

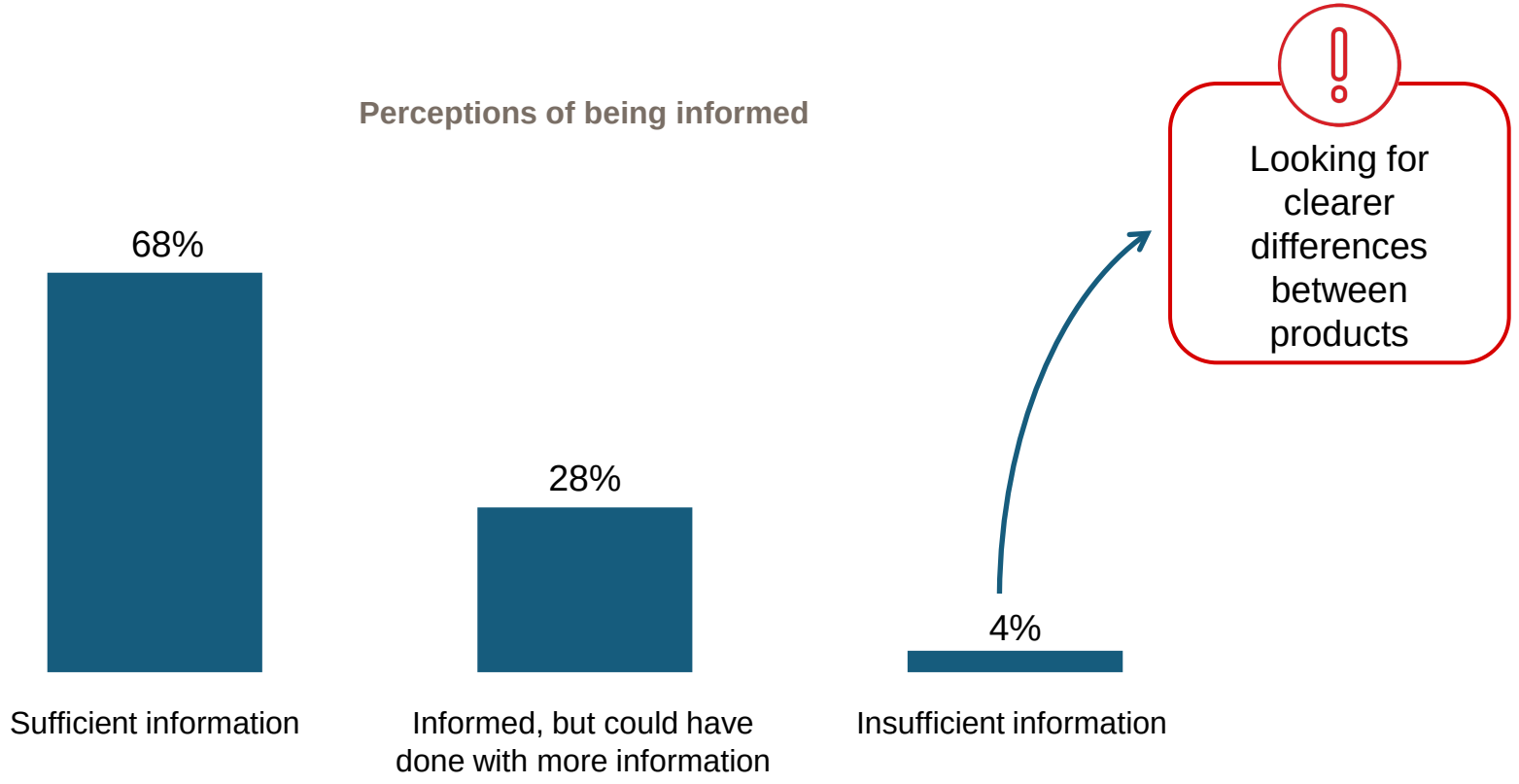


- **Only 3% found product labelling to be the most useful**
- **26% (1st ranking) ranked family members (i.e. non-authoritative sources) as *the most useful***

Base: n=501

Did you receive sufficient information about formula before making a decision?

C3f: Overall, thinking about all the information you gathered before making a decision about infant formula, did you receive sufficient information in order to make a decision?
C3g: What further information would you have liked to know before starting your child on formula?

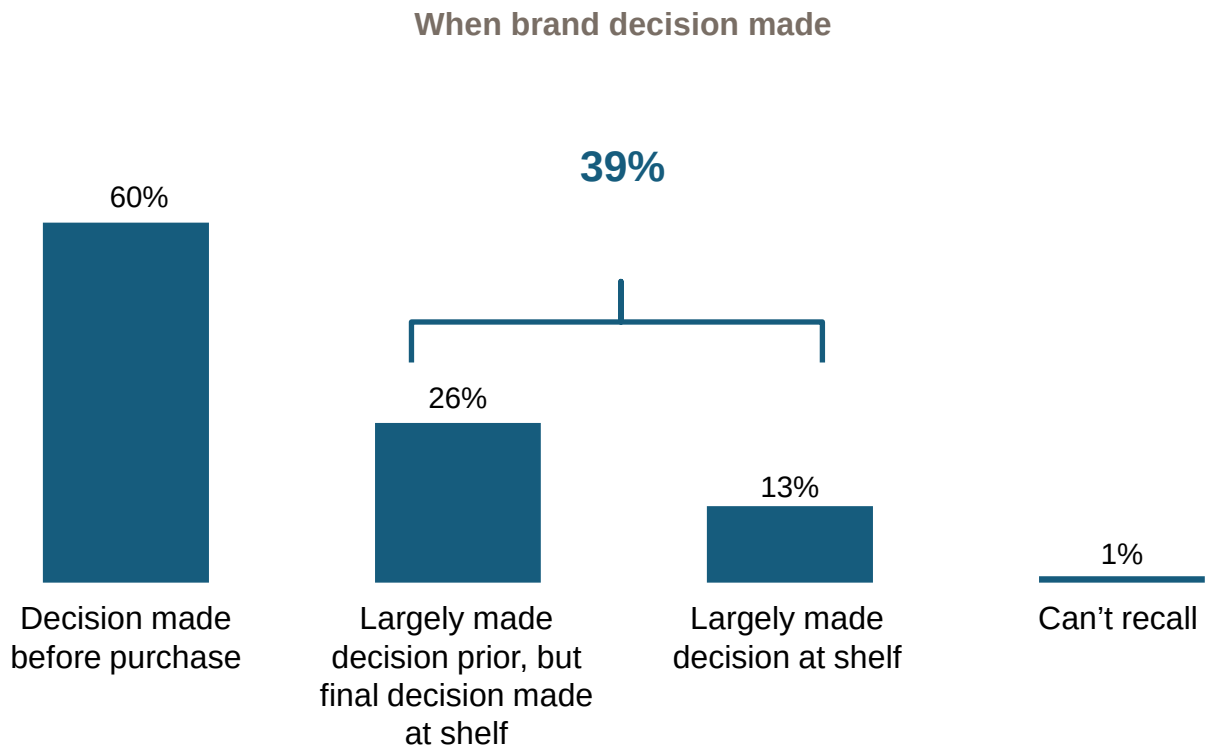


Base: n=501

This represents a sizable proportion of mothers who did not have enough information to make an informed decision.

Around 4 in 10 claim that their decision about what product or brand to buy was not finalised until at the shelf

C4a: Did you make a decision about which infant formula product to buy before you got to the shop or while you were there?



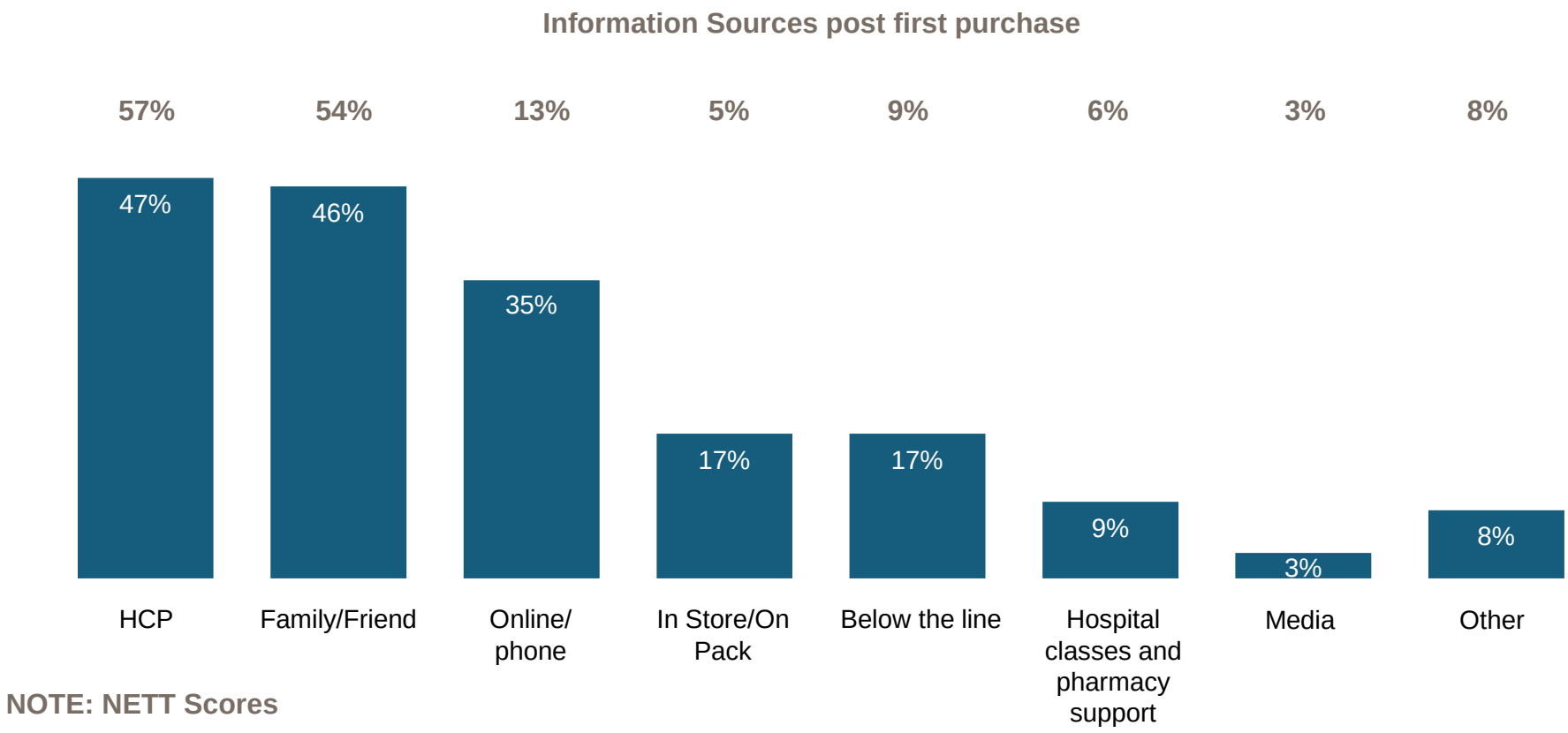
Base: n=501

Big opportunity for on pack information to be clearer.

INFLUENCES AND INFORMATION (ONGOING after the mum has already purchased formula)

Post the initial purchase, role of HCP's, friends and family *remain* key sources of information

C5a: After buying infant formula for the first time, who have you since talked to/received information from?



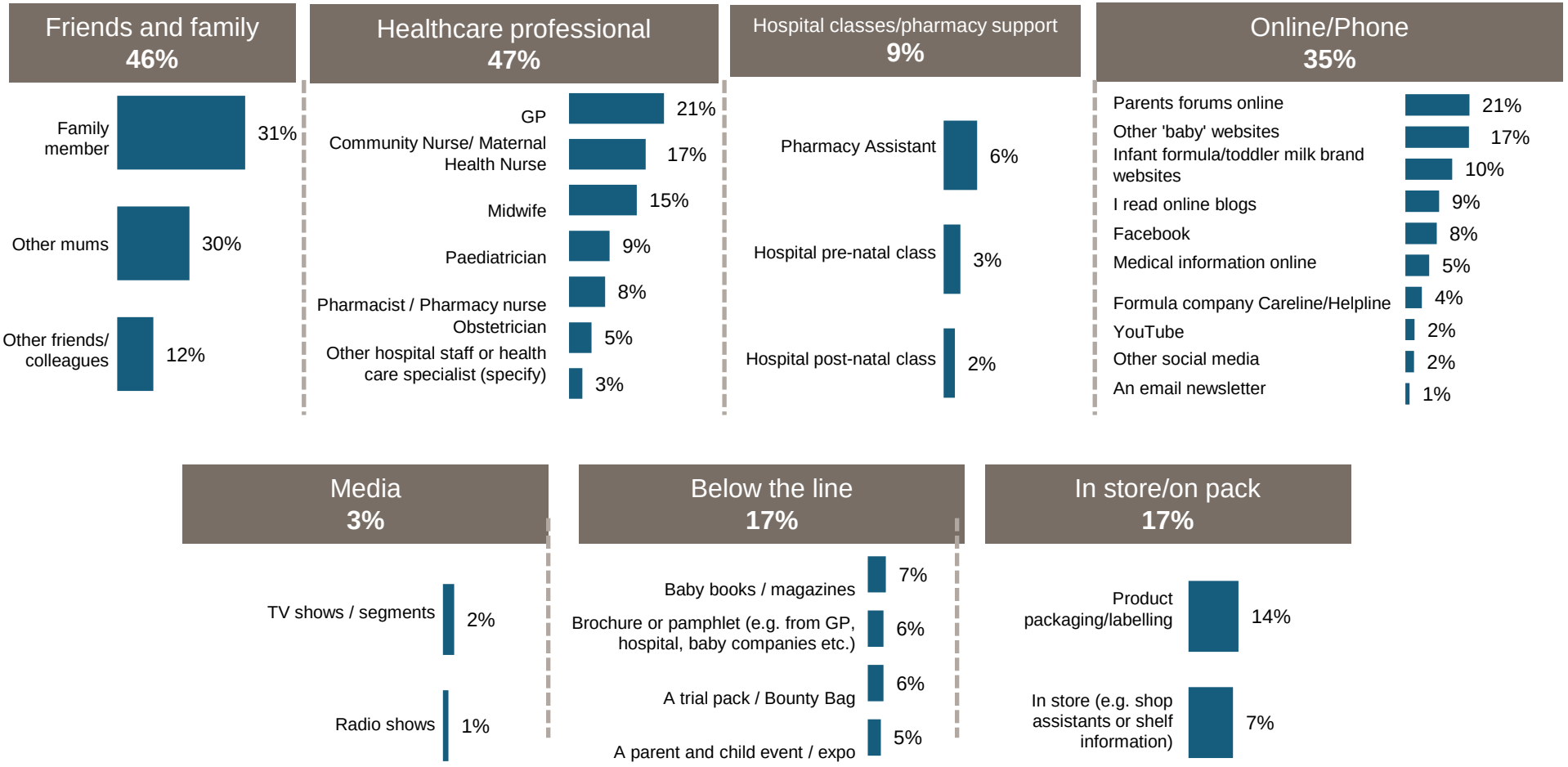
NOTE: NETT Scores

Base: n=501

However, online/phone now plays a bigger role as more users seek out the knowledge of people in similar situations

The role of the midwife is replaced by the GP as the most accessed information source among HCPs post initial purchase

C5a: After buying infant formula for the first time, who have you since talked to/received information from?



Base: n=501

Family members retain top ranking in terms of most useful sources of information ongoing

C5b: And which sources have been the most useful for ongoing support?

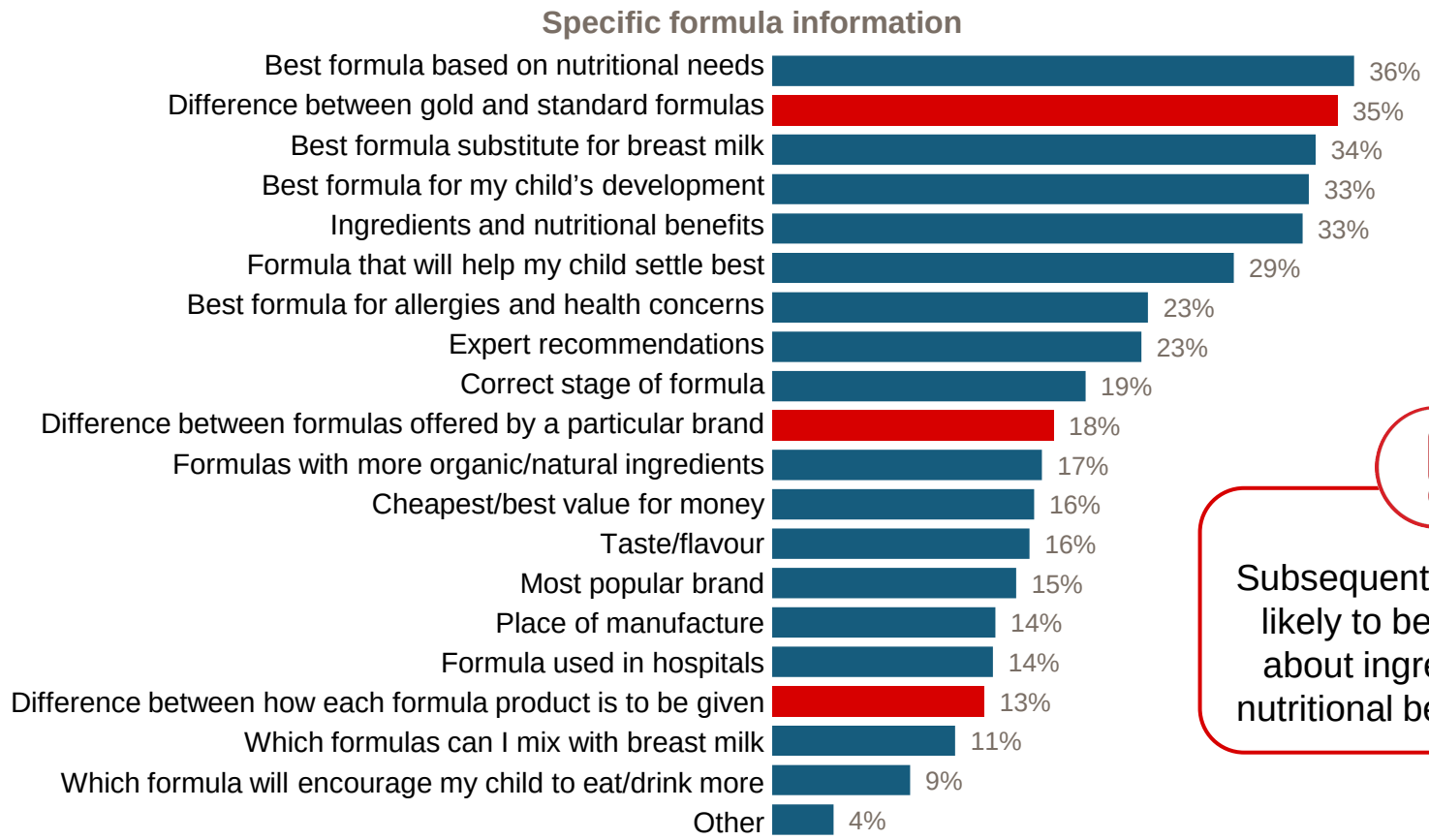
	1st Ranking In Terms Of Most Useful Source	
	Ongoing	Initial
Family member (e.g. mother, in laws, sister, partner)	16%	26%
Other mums (e.g. friends, a Mum's Group etc.)	14%	8%
GP	9%	7%
Other	8%	7%
Community Nurse/ Maternal Health Nurse	7%	9%
Midwife	5%	13%
Paediatrician	5%	5%
Product packaging/labelling	4%	3%
Parents forums online	4%	2%
Other 'baby' websites (e.g. Baby Centre, Essential Baby etc.)	3%	2%
Pharmacist / Pharmacy nurse	3%	3%
A parent and child event / expo	3%	0%
Baby books / magazines	2%	1%
Pharmacy Assistant	2%	1%
Obstetrician	2%	2%
Other friends/colleagues	2%	4%
Infant formula/toddler milk brand websites	2%	1%

Base: n=501

LABELLING, INGREDIENTS AND FORMULATION

When making a decision on an infant formula product, what information did you seek?

C3d: When making a decision on a particular product or brand of infant formula, what questions did you ask or information did you seek?



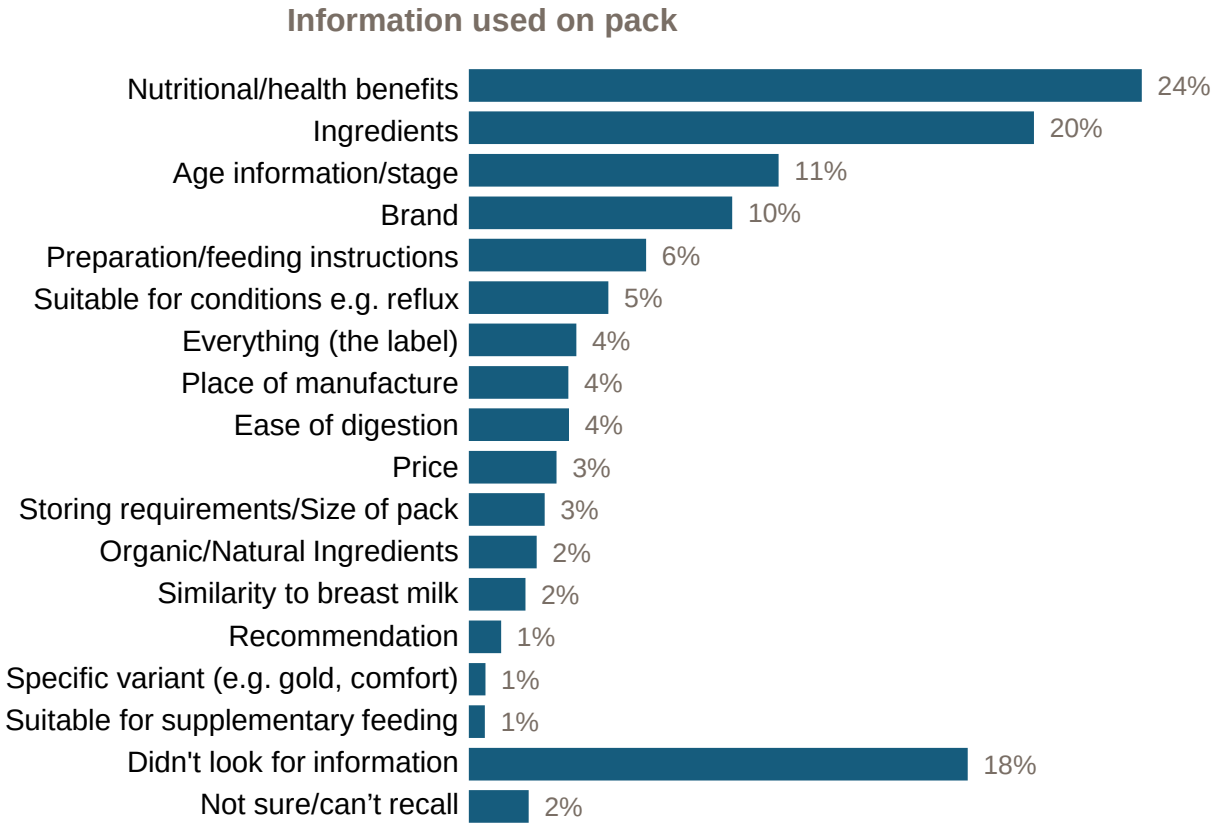
Subsequent Mum's more likely to be concerned about ingredients and nutritional benefits (37%)

Base: n=501

Nutritional needs are key in terms of aiding decisions.

What information did you look for on pack to help make a decision?

C4c: What information on pack (i.e. the label) did you look for to help you make a decision? CODED

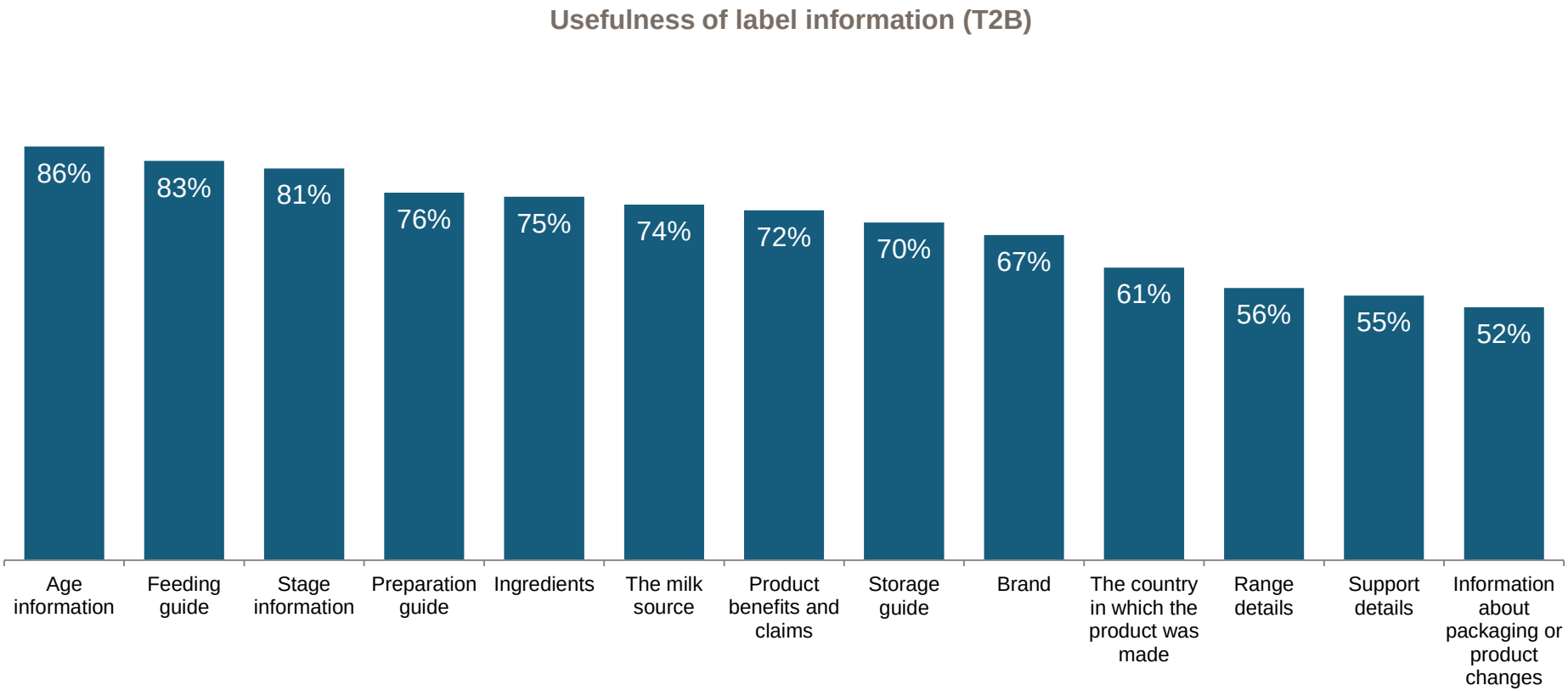


Base: n=501

Ingredients and health benefits are critical information mothers look for on pack to help make a decision

How useful is the current information on the label?

E1. How useful is each part of the label to you when you are making the decision to purchase a particular formula product?

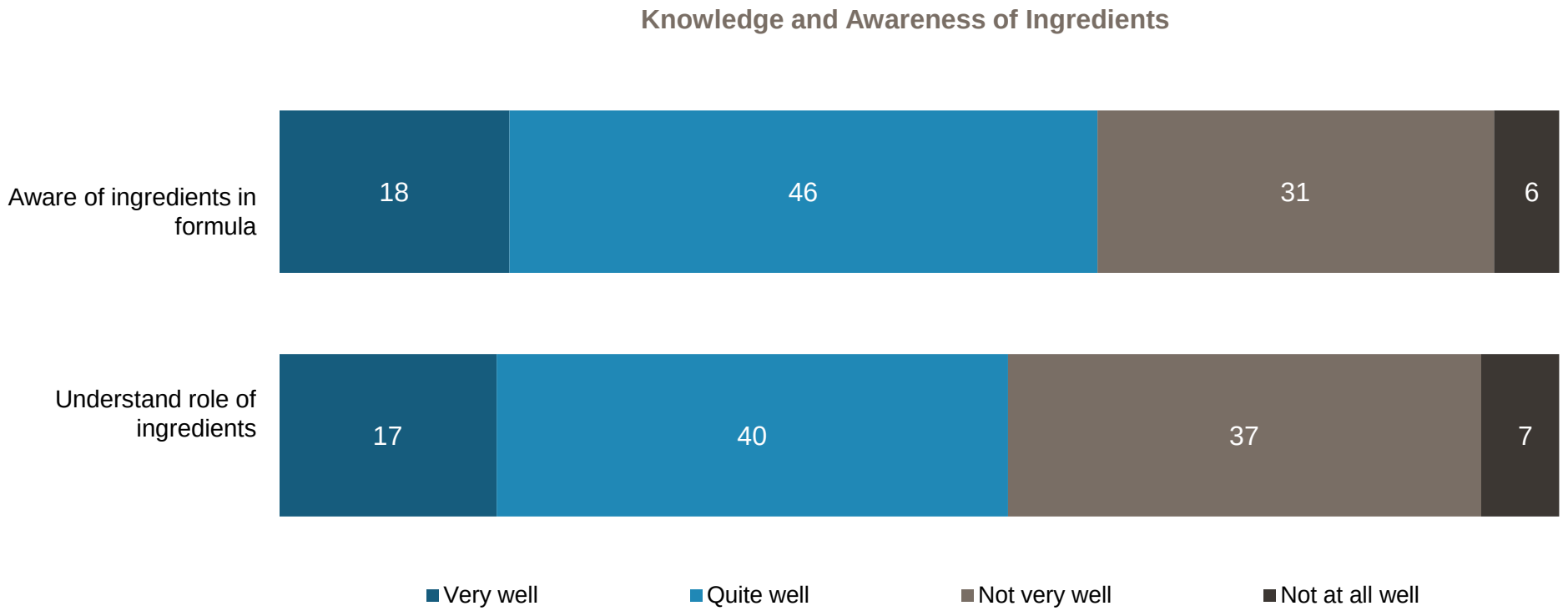


Base: n=501

Current information is seen as useful by mums. Ingredients and Product benefits are seen to be useful by nearly 75% of mums.

How well do you know the ingredient in the formula you buy?

E8a: How well do you feel you know which ingredients (e.g. DHA, Iron) are in the formula you buy?



↑↓ Significant difference at 95% CL

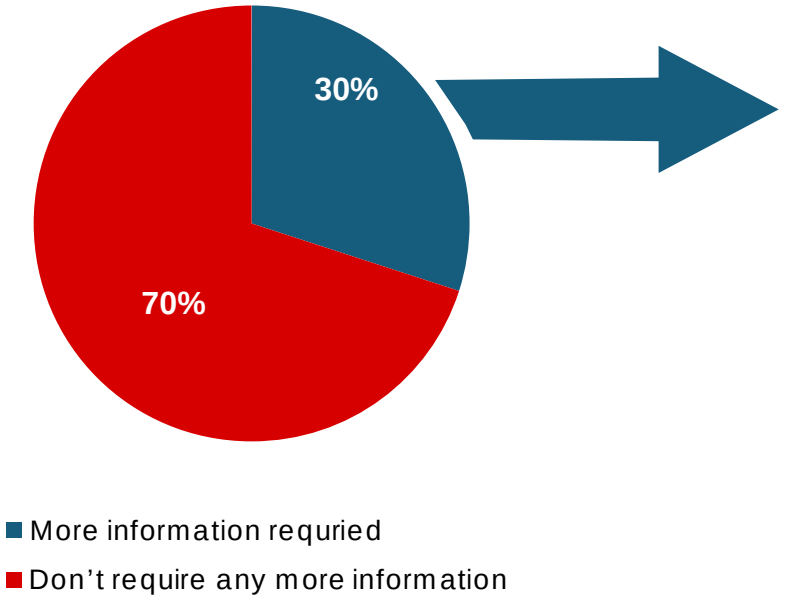
Base: n=501

Around 4 in 10 aren't aware of infant formula ingredients or their role in the formula they are currently buying

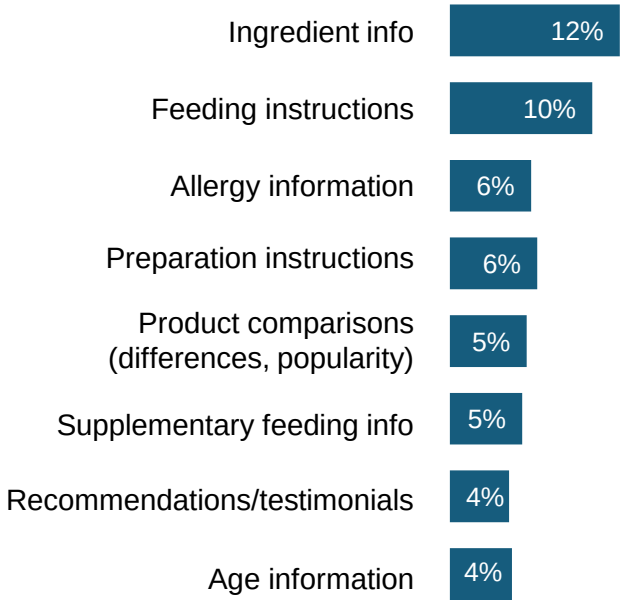
What information is missing/would be useful on pack?
Open ended question

E2: What other information do you feel is missing or would be a useful addition to formula product packaging/labels

Desire for additional information



Potential additional information



Base: n=501

Suggestions for improvements are predominately around information relating to ingredients, feeding and allergies.

Some suggestions relating to information that is missing or would be useful…

E2: What other information do you feel is missing or would be a useful addition to formula product packaging/labels

"It would be good to understand exactly how to scoop the formula into the little spoon provided. I was tapping the scoop against the side of the tin to make it level and my community nurse advised not to do this."

"Ingredients clearly markedly"

"More information on which formula is better suited to baby with sensitive stomach"

"Comparison with other products ingredients"

"Explanation of what "stages" mean. For new mums, we have no idea what is meant by "stages"."

"Information in relation to digestion problems"

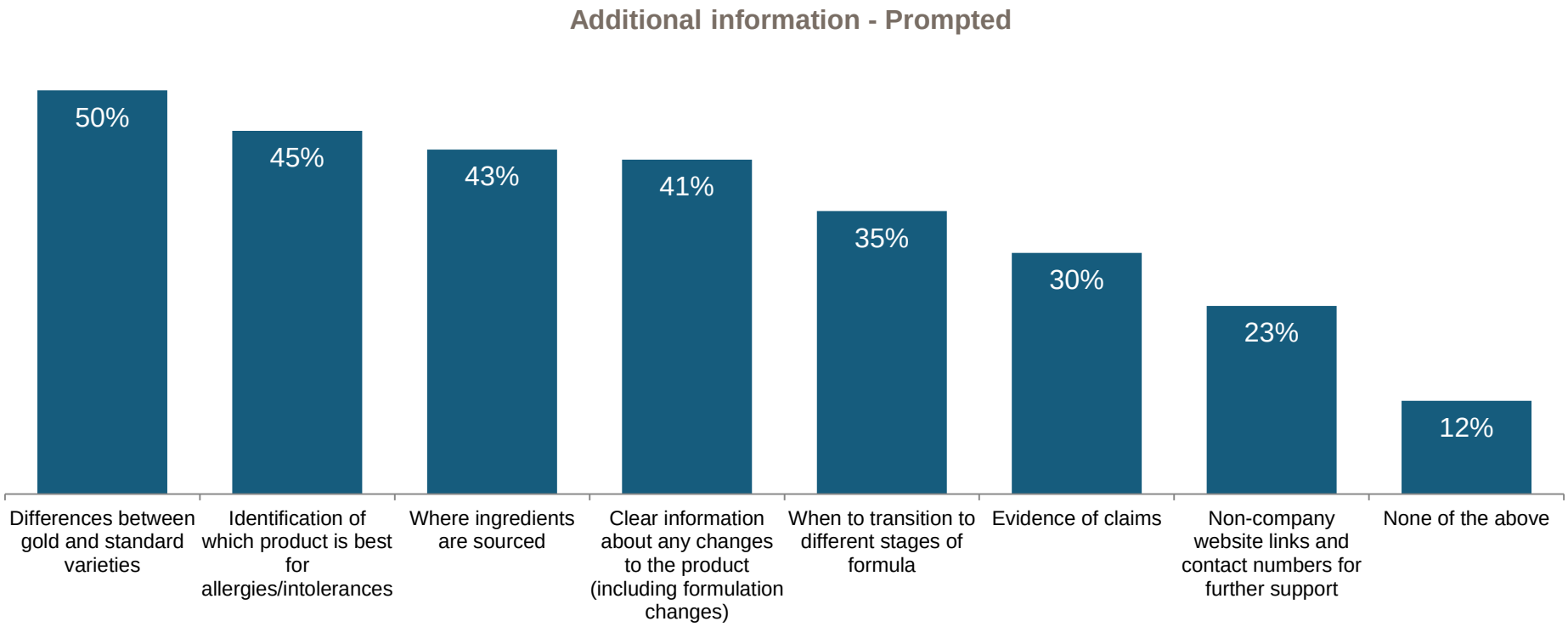
"I just want to know which is best... but as all brands claim to be the best it is hard to include!"

"Changes to formulas ingredients"

Base: n=154

What information would you like to see added to labels?

E3. Which of the following information would you like to see added to product packaging/formula labels?

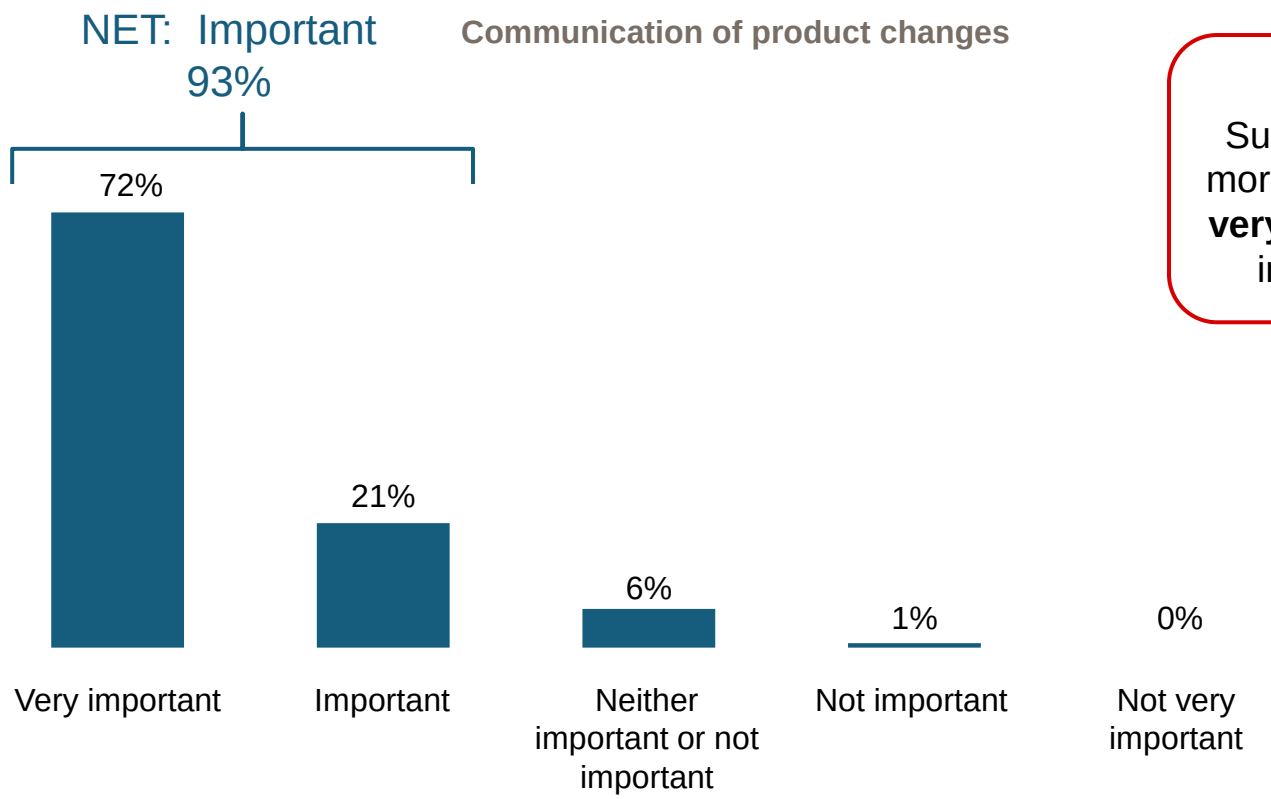


Base: n=501

Mothers like the idea of additional information that enables them to be able to tell products apart

How important is it to be informed of formula changes?

E6a: How important is it to be informed if the formulation changes (e.g. scoop changes, ingredient changes, new ingredients/levels etc.) for a particular infant formula product?



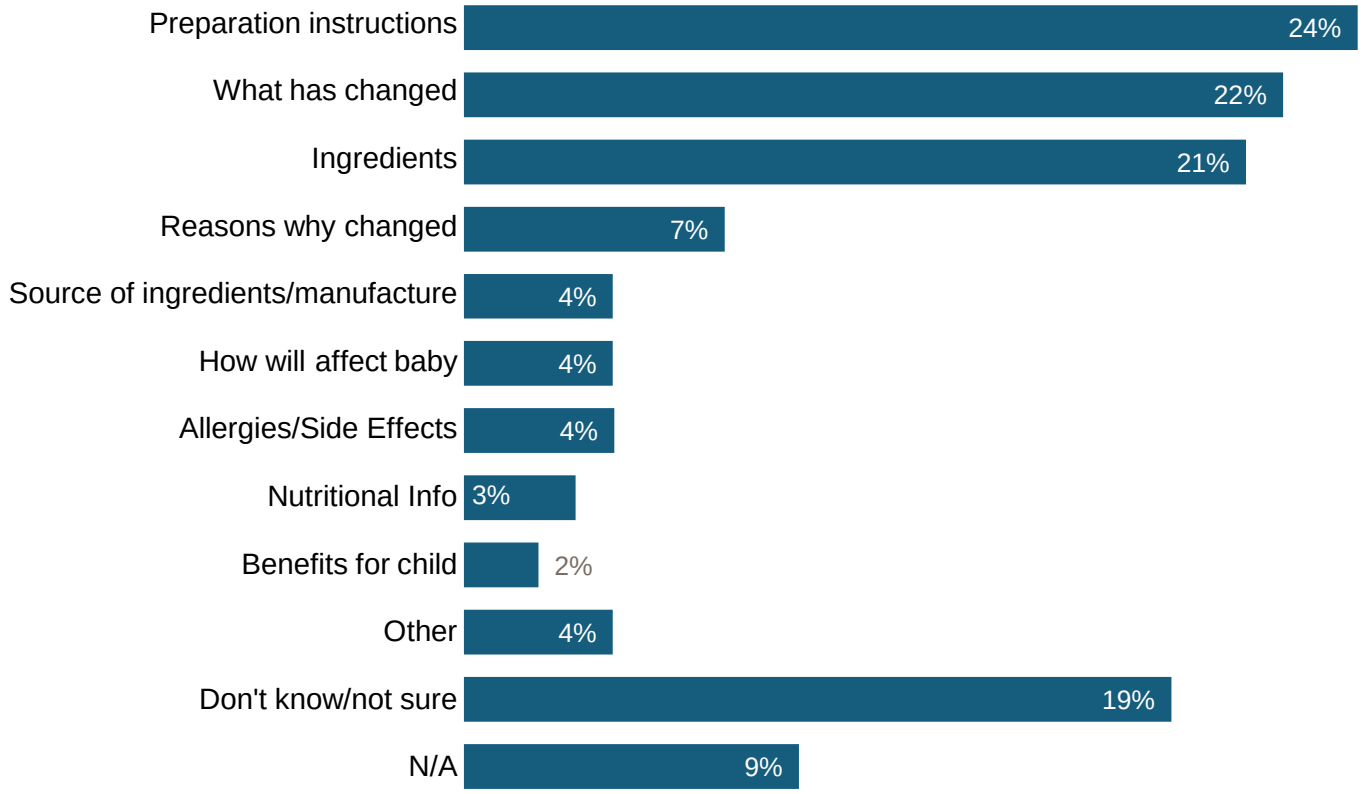
Subsequent Mum's more likely to feel it is **very important** to be informed (76%)

Base: n=501

More a perceived public health and safety risk– if you are going to change something that they give to their child, they want to know what those changes are.

What type of changes do you want to know about?

E6a: What sort of information would you like to know about product formulation changes? - Coded

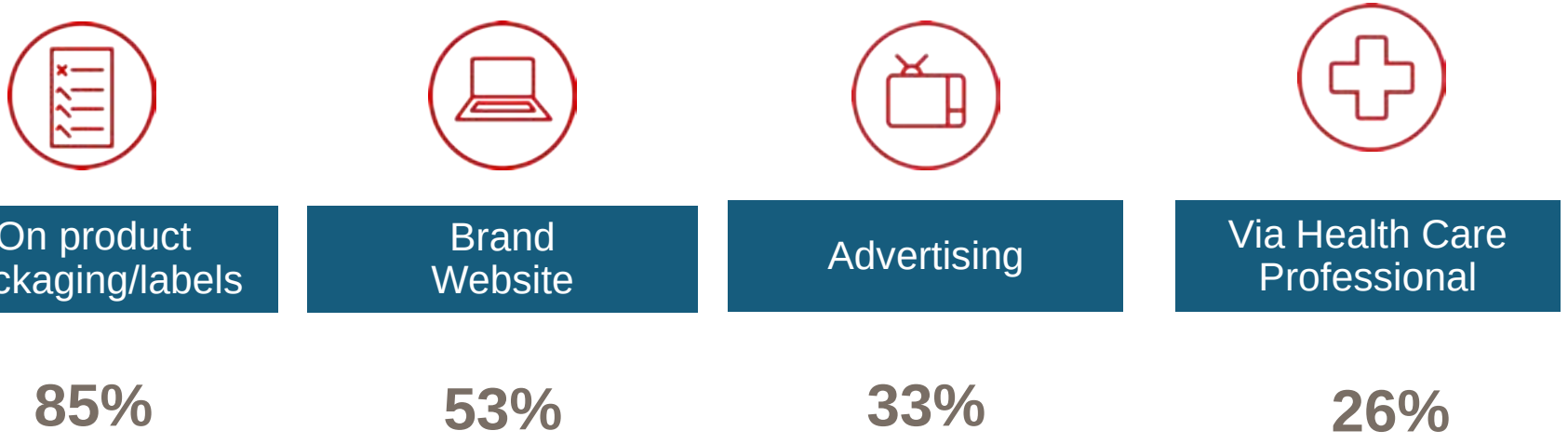


What has actually changed, preparation instructions and ingredients are the key changes that would need communicating

Base: Those who want to be informed of change n=463

Vast majority of infant formula users expect to see product formulation changes noted on pack

E7. Where would you expect to find information about product formulation changes?

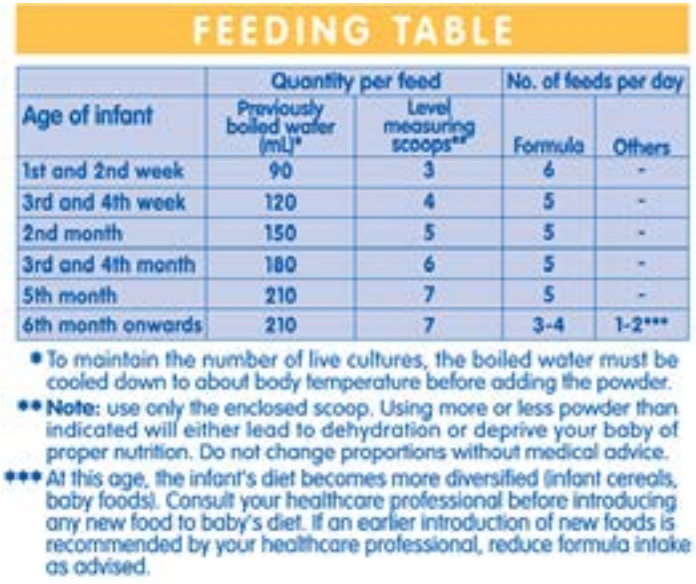


Base: n=501

An overwhelming majority (85%) expect that product packaging labels have a role in communicating product changes.

The feeding table is used by most mothers at some point

E4: Thinking about how you use the feeding guides, please select the statement below that best fits with what you do.



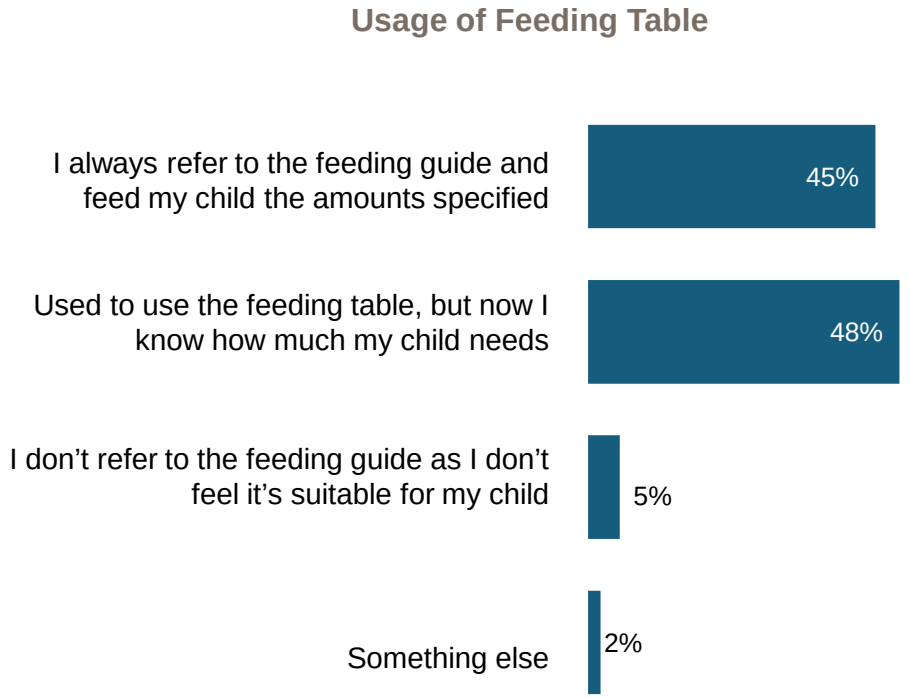
FEEDING TABLE

Age of infant	Quantity per feed: Previously boiled water (mL)*	Quantity per feed: Level measuring scoops**	No. of feeds per day: Formula	No. of feeds per day: Others
1st and 2nd week	90	3	6	-
3rd and 4th week	120	4	5	-
2nd month	150	5	5	-
3rd and 4th month	180	6	5	-
5th month	210	7	5	-
6th month onwards	210	7	3-4	1-2***

* To maintain the number of live cultures, the boiled water must be cooled down to about body temperature before adding the powder.

** **Note:** use only the enclosed scoop. Using more or less powder than indicated will either lead to dehydration or deprive your baby of proper nutrition. Do not change proportions without medical advice.

*** At this age, the infant's diet becomes more diversified (infant cereals, baby foods). Consult your healthcare professional before introducing any new food to baby's diet. If an earlier introduction of new foods is recommended by your healthcare professional, reduce formula intake as advised.

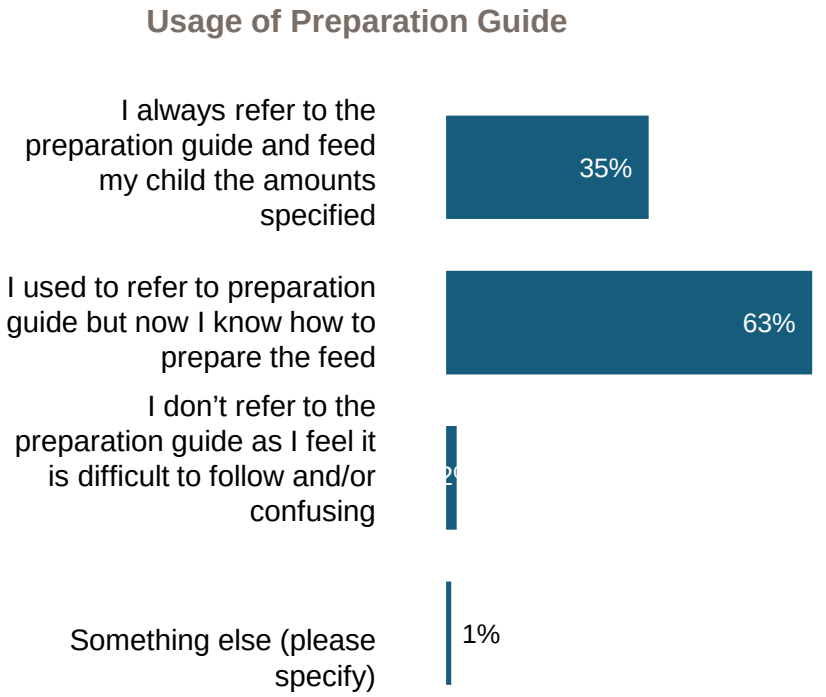


Base: n=501

However nearly half will use their own judgement once they have used for a period of time.

Vast majority of mothers also use the preparation table

E5: Thinking about the preparation guides, please select the statement below that best fits with what you do.



Base: n=501

Most don't continue to review though – any changes to such guides would need to be clearly signposted on pack otherwise they will be missed.

SUMMING UP

Key influences for initiating formula use

- Challenges with breastfeeding is the key driver to initiating formula use within first 6 months

- For mums with infants 7 - 12 mths, the key drivers to initiate formula were to supplement feed (still continue with breastfeeding and introduce formula feeds) and returning to work

Infant formula labels are NOT key influences for initiating formula use

Source of Information

Sources of information for mothers when formula feeding

- HCPs as a group are the most common information source for mothers (57%)
  - Friends and family play an almost equal role in providing information (54%)

- Almost half of the mums looking for information online use company websites – these are an extension of labelling *(current & future)*

The usefulness of the sources of information about formula

- 26% (1st ranking) ranked family members (non-authoritative sources) as the most useful *(almost double that of any HCP group)*

- Only 3% found product labelling to be the most useful *(A missed opportunity to help towards an informed choice*)

- A third feel that more information could have helped them in their initial decision making process

HCP's should be the key source of information, but this is not always the case with family/friends presenting a large group
Informed choice on labels can be a credible source of information

Type of Information

Information mums look for when making a decision about formula

- Information on a wide range of aspects is sought
  - Brands, ingredients and benefits or risks are the key topics
  - This doesn't change regardless of how many children one has

Information mothers look for when choosing a specific product

- Specific information mums wanted to know included:
  - Best product to meet the nutritional needs of her infant
  - The difference between products e.g. gold and standard varieties
  - Ingredients and nutritional benefits

It can be difficult for the consumer to differentiate solely based on the Ingredient listing and Nutrition information
Informed choice on labels can assist in providing the information mothers are seeking

Role of packaging

Experience of the mums when choosing a product

- Around 4 in 10 claim that their decision about what product or brand to buy was not finalised until at the shelf

Usefulness of current information on the label in making a decision

- Age / stage information
- Feeding table and preparation guide (*consulted by almost all mothers at some point in time*)
- Ingredients and product benefits (*seen to be useful by nearly 75% of mums*)

Label information including ingredients and product benefits is KEY with respect to a decision to purchase a particular product

Communicating formula changes

- ***93% said this was very important or important to be informed about formulation changes***
  - ***if you are going to change something that they give to their child, they want to know what those changes are***

- What has actually changed, preparation instructions and ingredients are the key changes that would need communicating

- An overwhelming majority (85%) expect that product packaging labels have a role in communicating product changes

Parents want to know what they are feeding their child

Communication on formulation changes is very important to the parent and the product label and product website are the ONLY sources of information that is targeted, up to date, and accurate

Infant Nutrition Council
Industry supporting both Breastfeeding & Infant Formula
AUSTRALIA & NEW ZEALAND

THANK YOU

Quality assurance information - quantitative

- Jigsaw has no field capacity itself, and so sub-contracts other agencies for both quantitative data collection and qualitative recruitment. Jigsaw only sub-contracts fieldwork to companies with ISO accreditation, which ensures all fieldwork is carried out in accordance with best practice guidelines as prescribed by AMSRO. This in turn provides peace of mind for our clients and also safeguards Jigsaw's hard-earned reputation for high quality research. As part of this commitment, Jigsaw undertakes to ensure all fieldwork sub-contractors are comprehensively briefed on project requirements.
- The target group for this project was women with children ages 0-24 months who had used infant formula when their child was 0-12 months of age
- Sampling details:
  - The final sample size for this project was n=501. The confidence interval (at 95%) for the final sample of n=501 is +/- 4.378 %.
  - The fieldwork for this project was conducted in October and November 2014
- The method of data collection was online
- Participants in this project received an incentive to encourage their participation.
- The data was weighted to location and ratio of first mums to the rest of the population.
- No estimation or imputation procedures were used in the analysis of data for this study.
- The project was carried out in compliance with the international standard 20252-2012.

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