Nestlé Submission 1.0

Consultation Paper for **Proposal 1028 -** Infant Formula

31st May, 2016

Nestlé Submission
Proposal P1028 - Infant Formula

This submission is made on behalf of Nestlé Australia Ltd and Nestlé New Zealand Limited.

Nestlé is a manufacturer and importer of a wide variety of foods for the Australian and New Zealand markets and is globally one of the largest manufacturers of infant formula and other foods. Nestlé currently imports and markets infant formula products which are regulated in section 2.9.1 of the Australia New Zealand Food Standards Code ('the Code').

Nestlé welcomes the opportunity to consider the issues and preliminary views proposed in the consultation paper for Proposal 1028 (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 its consideration of the comments, issues and views raised in this submission.

Introduction:

Breast milk is the best nutrition for infants. Nestlé fully supports this and optimal breastfeeding for optimal health outcomes for infants. We welcome the consultative effort of FSANZ to determine the best nutrition advice and outcomes for Australian and New Zealand infants.

In situations where the infant cannot receive breast milk, an infant formula is the only suitable and safe alternative, as a sole source of nutrition. Nestlé advocates a science–based approach to formulating products for the health and well-being of infants and young children. It is important that health recommendations and regulations focus on the best interests of the child, and are based on the latest body of scientific evidence.

Executive Summary:

Nestlé welcomes the purpose and objectives of Proposal P1028:

- To revise and clarify standards relating to infant formula in the Code, taking into consideration that:
    - the health and safety of infants are protected
    - there is consistency with advances in scientific knowledge
    - industry innovation or trade is not hindered
- To consider the application of ministerial policy guidance and alignment with international regulations.

Breastfeeding is best for babies, however in situations where the infant cannot receive breast milk, an infant formula is the only suitable and safe alternative, as a sole source of nutrition.

The Code is an essential part of the implementation of the International Code of Marketing of Breast-milk Substitutes (WHO Code) in Australia and New Zealand, protecting and promoting breastfeeding, requiring the provision of safe and adequate nutrition, as well as ensuring the proper use of breast milk substitutes, when these are necessary. It is important to note that self-regulation also plays a significant role through the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement) in Australia and the Infant Nutrition Council Code of Practice for the Marketing of Infant Formula (INC Code) in New Zealand.

Nestlé supports the principles of minimum effective regulation. An excessively restrictive regulatory environment in Australia and New Zealand would not support innovation and hence the availability of products that provide for the optimal health of non-exclusively breast-fed infants. A regulatory environment that is significantly out of step with international standards will lead to reduced choice and a less competitive marketplace and could inhibit trade, and damage established export business.

Nestlé supports a product standard which is efficient, transparent, and encourages industry to continue investment in research which promotes innovative, evidence-based and globally competitive food products.

Industry, together with clinical experts, are leaders in research into infant nutrition. The development and clinical assessment of high quality infant formula in line with current nutritional thinking is an expensive and lengthy process and one that must not be compromised. Formula-fed infants in Australia and New Zealand benefit from the considerable research that is undertaken on a global scale as well as locally. It is important that our local regulatory environment supports these benefits provided by global research and gives consideration to the impact on global trade and harmonisation with international food standards.

Regulatory requirements placed on industry must be reasonable and proportionate to the risks presented to infants as the consuming population. A high level of due diligence exists in industry with decades of experience ensuring the safety of products for this vulnerable population.

Nestlé supports the provision of adequate information to ensure the proper use of infant formula products when a decision has been made to formula feed. This should include information to enable an informed choice about the infant formula product they buy after appropriate discussion with a healthcare professional.

This review is to support regulatory change, and Nestlé 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.

While the scope of P1028 relates to starter infant formulas only, it is considered that it will in future underpin the review of other infant formula products, and will therefore:

- Set the basis for composition of the IFPSDU products (outside of nutritional modifications relevant for the condition), and
- The labelling for both IFPSDU and Follow-on formula.

As such, Nestlé requests that transitional arrangements are considered in the context of those products not currently in scope of P1028.

In considering the number of issues raised by FSANZ, Nestlé provides the following general views:

Essential Composition:

Nestlé supports:

- Harmonisation to CODEX as per FSANZ's preliminary views but with consideration of the most recent scientific evidence. We would support further review to eliminate potential trade barriers wherever possible for the following nutrients: cysteine, methionine, tyrosine, phenylalanine, essential fatty acids, selenium, choline, L-carnitine and nucleotides;
- improved regulatory consistency and clarity, and considers that in most cases, it is important to give consideration to the Code for general foods to avoid introducing confusion;
- Flexibility - Nestlé considers it unnecessary to introduce new restrictions where regulation is already sufficient to ensure safe and suitable infant formula and is flexible enough to allow harmonisation. Where there is no evidence of adverse issues, regulatory maximums need not be established.

Food Additives:

Nestlé supports:

- Harmonisation to CODEX - technological justification and safety have been considered at a global level and Nestlé suggests that FSANZ's evaluation takes a proportionate approach.
- The carryover principle, where safe and technologically necessary.

Contaminants:

Nestlé considers:

- That limits for contaminants should only be established where there is strong evidence of sustained risk.
- That international standards and the latest evidence should be considered to avoid introducing excessive regulatory burden – as such we propose a further evaluation of risk relating to Aluminium.

Labelling:

Nestlé considers:

- That Caregivers who need to use infant formula should be able to make **informed choices** about the infant formula product they buy. There is an opportunity to improve on-pack information, so that more information about ingredients is available to enable caregivers to tell products apart. The inclusion of such information is compatible with the WHO Code and its local interpretations in Australia (the MAIF Agreement) and New Zealand (the INC Code). We propose Regulatory permissions to be introduced around nutrient content and general level health claims that would allow improved differentiation between brands and within brands, and therefore an informed choice by caregivers. Also, we are open to maintaining the current prohibitions on nutrient content and health claims for non-differentiating ingredients – specifically: vitamins and minerals.
- That no changes to the status quo or further restrictions are warranted for date marking, legibility requirements, prescribed names, nutrition information, protein source statements, preparation and storage.
- Where relevant, there could be opportunities for improved regulatory clarity on safe preparation and storage, specifically on advanced preparation and storage.
- The general principles that it is impossible to label for every possible scenario of misuse. Where such labelling is warranted, we consider that it should be based on strong evidence of market failure. As such, we are of the view that no additional warning and advisory statements are warranted, as well as standardisation of scoops, due to possible misuse by caregivers. We would like to highlight that to standardise scoops requires that powder densities be standardised across all recipes and across all manufacturers- this is technically i**mpossible**.
- Where relevant, there could be opportunities for improved regulatory clarity on safe preparation and storage, specifically on advanced preparation and storage.

Nutritive substances and Novel foods:

Nestlé supports:

- Adherence to the principles of minimum effective regulation. We highlight the importance of avoiding unnecessary duplication of approval processes for ingredient use in infant formula products. We propose that these products are considered within the Scope of Proposal 1024, and to allow aspects of pre-market self-assessment in the framework of Eligible Food Criteria's (EFC's) and Notification pathways, however considered for the consuming population of infants.

Detailed responses to the issues raised in the Consultation Paper relating to the above are described in the later part of this submission.

Supporting Document 1: Definitions and Nutrient Composition

No.	Section of the SD	Question
Q1.1	All	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.

Nestlé Response:

Nestlé supports the general approach taken by FSANZ, however there remain some areas where we do not support the preliminary view outlined. A summary of Nestlé's preliminary positions can be found in Appendix I.

We would like to draw FSANZ's attention to another area for consideration - in the course of commenting on the revision of the CODEX Follow-up Standard, significant inconsistency has been identified in the application of energy conversion factors. This has resulted in trade barriers for various recipes. Nestlé, together with the INC, would request that P1028 moves forward to correct these values by the next consultation paper, rather than wait for the conclusion of P1028. Appendix II provides a summary of the proposed minimum, maximum and GULs calculated with the Code conversion factor of 4.18 (FSC 1.2.8, Schedule 11).

In this section, Nestlé has provided relevant evidence where specific questions have not been included in a specific section of the Supporting Document in the order in which they are discussed in the consultation.

1. Protein Content

Nestlé supports FSANZ's preliminary view of setting the minimum protein level at 1.8g/100kcal for starter formula.

There is strong evidence to keep protein levels to the minimum required to meet the essential amino acid requirements for formula-fed infants. The evidence supporting the proposed minimum of 1.8g/100kcal from birth is strong, led by the European Childhood Obesity Project (Koletzko 2009; Socha 2011, Escribano 2012, Weber 2014, Escribano 2016), but by no means limited to this group (Raiha 2002, Turck 2006, Trabulsi, 2010, Haschke-Becher 2016).

We consider that lowering this minimum to 1.61g/100kcal for older infants from 6 months of age, should be given further consideration in a future proposal for follow-on formula. There is accumulating evidence for lowering this minimum further for older infants (Inostroza, 2014; Ziegler, 2015). We would foresee lowering the protein minimum, whilst ensuring essential amino acids are delivered, under the condition that clinical safety and efficacy in infants from 6 months (for follow-on formula) is demonstrated.

Also, Nestlé notes that while FSANZ sees that the Code is already in line with CODEX STAN 72-1981 in relation to protein minimum, there is a numerical difference in allowable minimums with the Code stating a minimum of 0.45 g/100kJ and CODEX STAN 1.8 g/100kcal which when converted using a 4.18 is actually lower (0.43 g/100kJ). Therefore Nestlé requests that technical amendments be made to the 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 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.

No.	Section of the SD	Question

2. Calculation of protein: nitrogen conversion factor

Nestlé considers that a nitrogen conversion factor (NCF) of 6.25 is most relevant for an infant formula product based on mammalian milk and that a nitrogen conversion factor of 5.71 is most relevant for an infant formula based on soy protein isolate.

Nestlé recognises that a NCF of 6.38 is appropriate to unmodified milk products as these are casein dominant. However, most infant formula products are now whey dominant, reflecting the predominant whey protein found in breast milk. Whey proteins tend to have a lower nitrogen conversion factor. In addition, the conversion factor of 6.25 is a well-established compromise since every infant formula has different protein contributions. The compromise was established for infant formula as it removes the need for calculating different nitrogen conversion factors for different formulations (Koletzko, 2005; EFSA, 2014). And reflects the primary NCF that has been used to establish minimum and maximums and in labelling in other international standards (CODEX, EU) and hence will give greater flexibility to innovation and trade.

Nestlé agrees that a NCF of 5.71 for infant formula products based on soy protein isolate better reflects the nature of the proteins present and is consistent with CODEX STAN 72-1981.

3. L-Amino Acid Content

Nestlé supports FSANZ in setting minimums for isoleucine, leucine, lysine, threonine, tryptophan and valine in line with CODEX STAN 72-1981.

However, we do not support the FSANZ preliminary position to retain the current expressions for the minimums for tyrosine, phenylalanine, methionine, and cysteine. Instead we propose the requirements are amended to be consistent with CODEX STAN 72-1981 since there is no safety concern.

The minimum requirements for amino acids in infant formula are mainly based on 'typical' amino acid profiles of breast milk. Protein quality is important to ensure infants receive all the essential amino acids. Compliance is not straightforward due to the natural variability in amino acid content of milk ingredients. The ambition is to minimise the quantity of unnecessary excess naturally occurring amino acids whilst meeting the minimums, and the desire not to fortify with unnecessary single L-amino acids.

***Cysteine and methionine**:*

The average content of human milk is 9 mg cysteine/100kJ and 6mg methionine/100kJ and therefore a ratio of methionine:cysteine around 0.7 (Koletzko, 2005; Zhang, 2013).

The current Code allows cysteine to be at the minimum of 6 mg/100kJ with methionine, whether naturally occurring or fortified to make up the balance (13mg/100ml) and hence a ratio 2.17. One interpretation may be that only single L-methionine is be added to achieve the combined minimum should the addition of a single amino acid be required e.g. at low protein levels.

A frequent interpretation of the CODEX STAN 72-1981 is to allow 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 that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing).

The CODEX STAN expressions would encourage levels and a ratio more closely in line with breast milk. The preferred being a minimum of 9mg cysteine/100kJ and 6 mg/100kJ methionine leading to a ratio close to 0.67. Or where the CODEX footnote is applied this could be a cysteine amount between 6 and 9 mg /100kJ and a methionine amount of around 6 to 9 mg/100kJ and a ratio of 1.5 or lower, which might be considered closer to breast milk than the FSANZ expression.

Achieving a cysteine amount of 9mg/100kJ 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 allow for the range of products currently available on the market. 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 normal infant growth and development outcomes.

No.	Section of the SD	Question

4. Restrictions on certain fats

Human milk contains medium chain triglycerides (MCTs) in amounts of 6-20% of total fat (Genzel-Boroviczény 1997; Novak and Innis, 2011). MCTs in Australian and New Zealand standard infant formula come innately from the milk ingredient sources only.

There is inconsistency between guidelines for standard infant formula and FSC 2.9.1 Division 3, IFPSDU. MCTs represent a very common fat source used in formulations designed for preterm infants. They have a long history of safe use in premature infants as an ingredient for enteral and parenteral nutritional products in levels reaching 40 or 50% of total fat (Goldsmith 2011; Klein 2002). 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).

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.

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. The assessment concluded 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.

In line with the rationale for permitting MCTs as a processing aid for infant formula, removal of an expressed prohibition would allow greater choice of fat sources and alignment with Codex STAN 72-1981.

5. Vitamin A

Nestlé has no objection to the FSANZ preliminary view to exclude β-carotene from the total amount of vitamin A reported in infant formula in light of uncertainty around its bioavailability, however Nestlé supports retaining retinol equivalents (RE). This unit 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 and for consistency with CODEX STAN 72-1981.

6. Vitamin E

Nestlé agree with FSANZ 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 naturally occurring RRR-α-tocopherol (formally d- α-tocopherol) is considered to be the only physiologically active form.

We have no objection to retaining the current approach to vitamin E requirements relating to the PUFA content of infant formula. The permitted range for vitamin E (also proposed maximum is a GUL) would allow for the variation between Standard 2.9.1 and other international regulations which follow CODEX STAN 72-1981.

7. Vitamin D

Nestlé supports the FSANZ preliminary view to retain the current minimum 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.

Nestlé agrees that the current minimum is unlikely to pose a risk to infant health however prefers a broader common range between FSANZ, Codex STAN 72-1981 and the EU regulations which might otherwise be too tight to allow product formulation and manufacture in compliance with these sets of requirements.

Q1.2	2.2	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

Nestlé Response:

Nestlé supports retaining the status quo at this time. It is not appropriate to change the infant formula age range until follow-on formula composition is reviewed, so as to identify the extent of differences in nutritional requirements between younger and the older infants. Exclusive breastfeeding is recommended until the introduction of complementary foods at around six months of age with continued breastfeeding until at least one year of age, or beyond. The composition of breast milk varies over this time and the opportunity to offer follow-on formula, with a correspondingly different nutrient profile, for the formula-fed infant may be important to their development. However, having follow-on formula providing a targeted range of nutrients to support the introduction of complementary feeding should not preclude the continued use of infant formula for older infants 6-12 months depending on the individual infant's needs.

Q1.3	3.1	Do you support a higher minimum of 0.5 g/100 kJ for infant formula based on isolated soy protein? Please provide your rationale?

Nestlé Response:

Nestlé supports an increased minimum of 0.5 g/100kJ when considered together with a conversion factor of 5.71 for infant formula based on isolated soy protein. Nestlé supports a nitrogen conversion factor of 6.25 for animal milk-based infant formula.

Soy-based formulas formulated under either the CODEX STAN72-1981 or FSC 2.9.1 are able to meet nutritional needs to support normal growth and development. FSC 2.9.1 stipulates a lower minimum for protein but stipulates a conversion factor for isolated soy protein of 6.25. Whereas CODEXSTAN 72-1981 applies a higher minimum of 2.25 g/100kcal but allows a conversion factor of 5.71. Taking the conversion factors into account, the difference is small. In either case, the infant formula will provide the required essential amino acids.

Nestlé supports the rationale provided by INC with regard to the use of a conversion factor of 5.71 for soy protein isolate.

Q1.4	4.3	Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale.

Nestlé Response:

Nestlé supports the FSANZ preliminary view to align the requirements for linoleic acid (LA) and alpha-linolenic acid (ALA) and the ratio of these macronutrients with those in CODEX STAN 72-1981, but with

the note that the CODEX minimum LA amount needs further consideration. Nestlé suggest that further consideration should be given to the units of expression which also might be aligned to CODEX.

Nestlé is of the view that higher minimum levels for linoleic acid may be appropriate where a DHA minimum level is specified for addition to infant formula, but not for FSC 2.9.1 where this is not the case currently nor is it being proposed. An infant's ability to produce DHA from n-3 LCPs in the diet is reduced if the LA:ALA ratio is too high. A diet low in n-6 polyunsaturated fatty acids allows better endogenous conversion of ALA to n-3 long chain polyunsaturated fatty acids and permits better accumulation of n-3 LCPs into tissues (Gibson et al, 2011). Makrides et al (2000) also 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.

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 that is generally accepted as appropriate to maintain a proper balance between LA and ALA as well as the LCPs and eicosanoids resulting from their metabolism (Koletzko et al, 2005).

Also, the natural variation of fatty acid levels within ingredients should be taken into account. Manufacturers set target levels higher than the minimum levels, and lower than the maximum levels specified, to ensure that products always meet the nutrient requirements of infants.

Nestlé is not aware of any safety issues arising from the application of the LA and ALA requirements specified in CODEX STAN 72-1981.

FSANZ currently expresses fatty acid requirements as a percentage of total fatty acids. Expression on an energy basis would be more consistent with general practice for finished product and better align with the CODEX STAN 72-1981. Expression on a fatty acid basis is useful in certain circumstances such as raw material specifications and generally will continue to be used for this. The different approaches can create unnecessary specification differences.

Q1.5	4.5	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

Nestlé Response:

Nestlé supports the FSANZ preliminary position that the current approach remains appropriate in the absence of evidence of adverse impact in the Australia and New Zealand markets.

Q1.6	4.6.5	What amount of lecithin is used in infant formula for technological purposes?

Nestlé Response:

Nestlé supports the continued permission of lecithin for use in infant formula as currently permitted by FSC 1.3.1 (Schedule 15).

Q1.7	5.1	Should the concept of dietary fibre or its prescribed methods of analysis apply to infant formula?

Nestlé Response:

Nestlé agrees that the definition and calculation relevant to carbohydrate should be consistent with the revised Code and that the classification of individual carbohydrate sources should be made by the manufacturer. We have no objection to extending the concept of dietary fibre or its prescribed methods of analysis to infant formula.

FSC 2.9.1 permits the optional addition of inulin-type fructans or galacto-oligosaccharides. These are largely undigested in the small intestine and thus would not be considered available carbohydrate. They have a degree of polymerisation (DP) value > 2, and hence we consider the permissions for addition of these substances within FSC 2.9.1 be aligned to the definition of dietary fibre in FSC 1.1.2 and therefore

should be considered as unavailable carbohydrate.

While the energy factor is not aligned to CODEX, we also recognise that CODEX has a different definition for dietary fibre, which is based on carbohydrate polymers with > 10 monomeric units (or between 3 and 10 according to national decision) which are not hydrolysed by endogenous enzyme in the small intestine. The energy factor of 8kJ/g for Australia and New Zealand is *closely* aligned to Europe, where dietary fibre is based on carbohydrate polymers with > 3 monomeric units which are neither digested nor absorbed in the small intestine.

The energy contribution of these optional substances (inulin-type fructans and/or galacto-oligosaccharides) at the maximum levels currently permitted in FSC 2.9.1, do not have a significant impact on total energy.

As such, Nestlé considers there are unlikely any significant trade barriers, and therefore in the interests of improvement to regulatory clarity and consistency to the horizontal application of FSC 1.2.8 (Schedule 11) to all foods including infant formula products, we support extending the concept of dietary fibre or its prescribed methods of analysis to infant formula.

Q1.8	5.3	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.

Nestlé Response:

Nestlé supports maintaining the current approach to the regulation of carbohydrate source.

Nestlé has observed no issues with the current approach to carbohydrate level and carbohydrate source in FSC 2.9.1. We are not aware of any failure in relation to safety and there are no trade barriers relating to this area that would warrant any regulatory limits to be imposed. Carbohydrates are an essential contributor to the energy requirements of infants and the level is controlled through provisions for energy, protein and fat. Lactose is the predominant carbohydrate in breast milk and is the preferred source of carbohydrate used in the manufacture of infant formula.

Q1.9	7.2.1	Should the minimum folate requirement include or exclude the contribution of naturally occurring folate? Please provide your rationale.

Nestlé Response:

Nestlé considers that the expression of the folate content of infant formula be 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. We note that the bioavailability of naturally occurring folate is difficult to determine and that DFE factors were established in adults hence at this point in time it is more appropriate to retain µg of folic acid.

Also neither CODEX STAN 72-1981 nor the Code uses dietary folate equivalents (DFE) to express the folate content of infant formula.

Q1.10	7.2.1	If you consider minimum folate requirement should include natural folate, should dietary folate equivalents (DFE) be applied? Please provide a rationale in support of your view.

Nestlé Response:

Please see the response above to Q1.9. Nestlé does not support that dietary folate equivalents (DFE), be applied.

Q1.11	7.3.2	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? Please provide a rationale in support of your view.

Nestlé Response:

Nestlé supports the FSANZ preliminary position to amend the phosphorus maximum to a GUL of 100 mg/100kcal (24 mg/100kJ) and to align with the lower minimum Ca:P ratio.

A GUL is appropriate since it has not been possible to establish a UL for phosphorus (NHMRC, 2006). This phosphorus GUL and Ca:P ratio is consistent with several international expert opinions (LSRO, 1998; SCF, 2003).

We are not aware of any adverse effects of the proposed limits that are aligned with CODEX Standard 72-1981.

Q1.12	7.3.3.1	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? Please provide a rationale in support of your view.

Nestlé Response:

Nestlé supports the increase to the GUL in line with CODEX STAN 72-1981.

We consider 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 this is a heat-labile nutrient with losses in processing and through the shelf life, 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. Liquid formulas are required by healthcare 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.

Vitamin C is heat-labile and losses are seen with both powder and liquid formula.

Q1.13	7.3.3.2	Do you support retaining the current minimum and maximum amount of iron required in infant formula? Please provide your rationale.

Nestlé Response:

Nestlé suggests further consideration of the minimum content. We have no concerns with the proposed maximum of 0.5 mg/100kJ.

Australia and New Zealand have reported that older infants and young children may not consume adequate intakes of iron (Wall, 2008) hence a higher minimum might be warranted. However ESPGHAN (Koletzko *et al*, 2005) reported that during the period when infant formula may be fed exclusively, i.e. before the introduction of complementary foods, there was no significant difference between the iron status of infants fed formulae containing 0.25 mg, 0.6 mg and 1.0 mg per 100 kcal, and there were no infants with inadequate iron status in any group.

It might be preferable to retain consistency with the global standard to facilitate harmonisation of trade, particularly in light of infant formula for special dietary uses which often use a single global recipe.

The proposal to maintain the current maximum can be supported given that the UL is not exceeded and there have been no adverse events reported. It is also noted that the USA has a higher maximum limit of 3.0mg/100kcal.

Q1.14	7.3.3.3	Do you support raising the minimum and maximum amount of selenium required in infant formula? Please provide your rationale.

Nestlé Response:

Nestlé suggests further consideration of the minimum and maximum for selenium.

LSRO (1998) gave a range of selenium in breast milk of 5 – 22 µg/L although recent studies suggest that the selenium content of breast milk may be in the upper half of that range.

Manufacturers do not generally target the minimum but rather a level higher than the minimum in order to be assured of compliance.

Should a change to the minimum be introduced, the transition period should take into consideration that this change is not aligned to CODEX STAN 72-1981.

Q1.15	7.3.3.3	Do you support moving the maximum amount (of selenium) to a GUL? Please provide your rationale

Nestlé Response:

Nestlé supports the FSANZ preliminary position to move the maximum to a GUL.

Although the NHMRC set an upper limit of 60 µg per day, this was based on levels in breast milk observed to have no adverse effect (NHMRC). The levels of selenium in breast milk are variable and higher levels of selenium have been reported in European breast milk samples (EFSA, 2014).

No adverse events have been observed with the levels permitted by current international regulations. Alignment with CODEX STAN 72-1981 supports harmonised trade.

Q1.16	7.3.3.4	Do you support aligning with the higher CODEX minimum and maximum amount (of iodine) and converting the maximum to a GUL? Please provide your rationale.

Nestlé Response:

Nestlé supports the FSANZ recommendation to adopt the minimum 2.4 µg/100kJ and GUL of 14 µg/100 kJ from CODEX STAN 72-1981.

Q1.17	7.3.3.5	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.

Nestlé Response:

Nestlé does not support a minimum, maximum or GUL for Chromium.

There was insufficient evidence to consider chromium an essential nutrient (EFSA, 2014) and we agree with FSANZ preliminary view that the absence of a minimum amount is unlikely to pose a risk to infant health.

Q1.18	7.3.3.6	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.

Nestlé Response:

Nestlé does not support a minimum, maximum or GUL for Molybdenum.

Molybdenum is absorbed very efficiently over a wide range of intakes and the recommended AI for infants 0-6 months is 2 µg/day based on the average volume of breast milk (0.78 L/day) and the average concentration of molybdenum in breast milk (2 µg/L) (NHMRC, 2006). NHMRC noted that it was not possible to estimate an upper limit.

Q1.19	7.3.3.8	What information can you provide on the phytic acid content of soy-based infant formula?

Nestlé Response:

Soy Protein Isolate, which is the protein source used in soy-based infant formula, contains 1–2% of phytates (Vandenplas, 2014). This Systematic Review with Meta-Analysis found that feeding soy-based infant formula to young infants did not result in any negative impact on the levels of certain minerals including zinc and calcium nor on overall growth.

Q1.20	7.3.3.8	Are there any technical issues if the lower CODEX minimum and maximum levels for copper were to be incorporated into the Code?

Nestlé Response:

Nestlé support the inclusion of CODEX STAN 72-1981 lower minimum and maximum levels of copper being adopted into the Code.

We are not aware of any technical issues with these lower levels and support harmonisation.

Q1.21	7.3.3.8	Should a Zn:Cu ratio be retained. If so, what should it be and why? If not, what is your rationale?

Nestlé Response:

Nestlé supports alignment with CODEX STAN 72-1981.

We agree with the FSANZ nutrition assessment that the minimum and GUL stated within the CODEX STAN is unlikely to pose a risk to infant health and the additional requirement for a Zn:Cu ratio is not necessary.

Q1.22	8.1.1	What is the justification to retain β-carotene as a provitamin A form?

Nestlé Response:

Nestlé supports retaining β-carotene as a provitamin A form.

We support retaining the permission for β-carotene as a provitamin A form in infant formula aligned to the CODEX Advisory Lists of Nutrient Compounds for use in foods for special dietary uses intended for infants and young children (CAC/GL 10-1979). The contribution of β-carotene is not taken into account when estimating requirements of Vitamin A owing to a lack of knowledge on the bioconversion rather

than any concern regarding safety.

The retention of β-carotene as a provitamin A permitted form would facilitate innovation and harmonisation of trade.

Q1.23	8.3	What technical justification can you provide for the use of the nutrient forms listed in table 8.2 for use in infant formula?

Nestlé Response:

Nestlé supports the additional nutrient forms already included in the Advisory Lists of CODEX CAC/GL 10-1979 being adopted into the Code.

In relation to Calcium D-pantothenate and Ferrous sulphate, two errors have been reported in the permitted forms of vitamins, minerals and electrolytes in Supporting document 1 – Definitions and nutrient composition. We thank FSANZ for confirming 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 Code no further information is provided.

We consider that a nutritional justification, not technological justification, is required by the FSANZ Application Handbook. These compounds are nutritionally justified, since these vitamins and minerals are part of essential composition for infant formula, and as such, are nutritionally mandated by FSC 2.9.1. Therefore comment is restricted to the safety of these compounds in relation to the infants.

Nestlé consider these forms to be 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, we consider that safety has already been established at a CODEX level.

The Advisory list can be reviewed at any time. 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. To date, neither Australia or New Zealand (or other member state), 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.

Nestlé notes that many of these forms are also permitted in other international regulations adding weight to confirmation of their safety.

For reasons of alignment to CODEX, flexibility for manufacturers, avoidance of barriers to innovation and trade, we believe all the forms of nutrients permitted in CODEX Advisory Lists of Nutrient Compounds for use in foods for special dietary uses intended for infants and young children (CAC/GL 10-1979) should be permitted for nutritional use in Infant formula products.

Q1.24	9.1	Do you support inclusion of a mandatory requirement for choline in infant formula? Please provide your rationale.

Nestlé Response:

Nestlé supports the mandatory presence of choline in infant formula. We support a minimum of 1.7 mg/100kJ. However, we are of the view that 12mg/100kJ should be a GUL.

Choline is an essential nutrient and hence should be considered mandatory. We support an increased maximum to ensure that adequate intakes can be met. However the upper level is proposed 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 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 choline is provided, allowing for natural variation and manufacturing capability. Our preliminary view would be that the relevance of the new evidence to infants has not been determined hence it would be more appropriate to maintain consistency, and that in the absence of a UL, a GUL should be set.		
Q1.25	9.1	What is the technological justification can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?
Nestlé Response: Nestlé supports the inclusion of choline citrate and choline hydrogen tartrate as safe and suitable forms of an essential nutrient, choline. Choline is considered a conditionally essential nutrient for young infants. Inclusion of permitted forms in line with the CODEX Advisory Lists of Nutrient Compounds for use in foods for special dietary uses intended for infants and young children (CAC/GL 10-1979) are safe and would facilitate innovation and harmonisation of trade.		
Q1.26	9.1	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?
Nestlé Response: Nestlé supports the additional nutrient forms of choline already included in the Advisory Lists of CODEX CAC/GL 10-1979 being adopted into the Code.		
Q1.27	9.2	Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.
Nestlé Response: Nestlé supports the mandatory presence of L-carnitine in infant formula. We propose that the minimum content be in line with the CODEX Stan 72-1981 value of 1.2 mg/100kcal (0.287 mg/100kJ). We do not support the proposed maximum of 0.8 mg/100kJand would propose not to set a maximum at this time. L-Carnitine is considered an indispensable nutrient for newborn infants and concentrations in human milk have been reported to be in the range 0.9-1.6 mg/100 kcal (Sandor et al., 1982; Penn et al., 1987; Ferreira, 2003). Expert recommendations agree that L-carnitine should be mandatory in infant formula at 1.2 mg/100kcal (LSRO, 1998; Koletzko *et al.*, 2005). We understand that the current maximum of 0.8 mg/100kJ was set based on the observed range in breast milk and the typical contribution found in cows' milk infant formula at that time. Neither the SCF, 2003 nor EFSA, 2014 considered it necessary to set a maximum. In the absence of indications of any untoward effects of higher L-carnitine intakes in infants, ESPGHAN concluded that no maximum level needed to be set (Koletzko *et al.* 2005). FSANZ have 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 L-carnitine 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.

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

The INC notes, in their submission, that not all manufacturers 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-carntine for dairy-based infant formula products again supportive of the concerns regarding the tolerance proposed by FSANZ.

Q1.28	9.2	What is the technological justification can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?

Nestlé Response:

Nestlé supports the inclusion of L-carnitine hydrochloride and L-carnitine tartrate as safe and suitable forms of the essential nutrient, L-carnitine for use in infant formula.

L-carnitine is considered a conditionally essential nutrient for young infants and the inclusion of permitted forms in line with the CODEX Advisory Lists of Nutrient Compounds for use in foods for special dietary uses intended for infants and young children (CAC/GL 10-1979) is safe and would facilitate innovation and harmonisation of trade.

Q1.29	9.2	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?

Nestlé Response:

Nestlé supports the additional nutrient forms of L-carnitine already included in the Advisory Lists of CODEX CAC/GL 10-1979 being adopted into the Code.

Q1.30	9.3	Do you support inclusion of a mandatory minimum requirement for inositol in infant formula? Please provide your rationale.

Nestlé Response:

Nestlé support the mandatory presence of inositol in infant formula and that the range permitted be in line with the CODEX STAN 72-1981 values of 4 mg/100kcal (0.96 mg/100kJ) and GUL of 40mg/100kcal (9.57 mg/100kJ).

Inositol is recognised as an essential nutrient (LSRO, 1998; Koletzko *et al.*, 2005) with a range in breast milk of 130-325 mg/L (EFSA, 2014).

Q1.31	9.3	Do you supporting listing the permitted form of inositol as myo-inositol to provide clarity and consistency with CODEX?

Nestlé Response:

Nestlé supports this approach.

Q1.32	9.4	Are there any issues with the clarity of the drafting for the maximum amount of nucleotides in the revised Code?

Nestlé Response:

Nestlé supports the continued inclusion of nucleotides as optional ingredients. The revised Code is clear that for each nucleotide added, the individual maximum is the total of that nucleotide, including any naturally-occurring amount. However, for the total maximum amount it could be made more explicit that the maximum applies only when nucleotides are added.

However other aspects e.g. labelling may not be clear. In line with other International regulations, we do not consider that it is necessary to define a minimum amount for labelling purposes and indeed this could be considered confusing and create a barrier to trade. Further that the existing interpretation that added nucleotides may be labelled individually or in combination be retained.

Supporting Document 2: Safety and Food Technology

No.	Section of the SD	Question
Q2.1	All	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.

No.	Section of the SD	Question

Nestlé Response:

Nestlé supports a number of FSANZ's preliminary views, however there are areas where we would have another view.

Preparation, use and storage directions to manage microbiological hazards

1. Nestlé supports the continued labelling requirement for an instruction that each bottle should be prepared individually and that formula left in the bottle after a feed must be discarded.
2. Nestlé supports that it is safe to store prepared formula for up to 24 hours at 4°C or less. Nestlé 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 e.g. feed immediately. If a bottle of prepared formula is stored in a refrigerator at 4°C or below before use and can be used up to 24 hours, then any lesser period of storage at the correct temperature is also safe.
3. Nestlé supports the continued overarching labelling requirements for directions for preparation and use, including the use of cooled previously boiled water, however not to prescribe the words and pictures for these instructions.

Contaminants

1. Acrylonitrile

Nestlé supports the FSANZ proposal to maintain the current ML. The current level in the Code is set at a maximum level of 0.02 mg/kg. This applies to all foods including infant formula products. This aligns with CODEX.

2. Arsenic

Nestlé supports the FSANZ proposal to maintain the status quo. There is no current ML for Arsenic in the Code which aligns with CODEX. There is no evidence to suggest there is a risk to public health and safety.

3. Tin

Nestlé supports the FSANZ proposal to maintain the current ML. The Code and CODEX are currently aligned for the ML of tin (250 mg/kg for all canned foods). The ML applies to products in containers other than tinplate containers (in CODEX STAN 193).

4. Vinyl chloride

Nestlé supports the FSANZ proposal to maintain the current ML. The Code and CODEX are currently aligned for the ML/GL of Vinyl chloride (0.01 mg/kg).

Q2.2	4	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.

Nestlé Response:

Nestlé supports the continued requirement that the label must carry a date mark.

Nestlé supports maintaining the existing requirement that infant formula labels provide storage instructions covering the period after the package is opened.

Nestlé supports the inclusion of a statement that only the enclosed scoop should be used – where a package contains a measuring scoop. The inclusion of this statement is already required. Nestlé do not

No.	Section of the SD	Question
support the idea of a standardised scoop – it would not be technically possible to standardise powder density across different recipes and across different manufacturers. Nestlé agrees that volume indicators on infant feeding bottles is beyond the scope, and not within the remit, of FSANZ and the infant formula manufacturers.		
Q2.3	5.2	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?
Nestlé Response: Nestlé does not have evidence that would estimate the prevalence of caregivers adding other foods to infant formula in Australia and New Zealand. While we are aware that this practice may exist, the absence of reference e.g. in the NHMRC Infant Feeding Guidelines (2013) suggest that, as a population, this is not happening. There may be sub-groups of the population where this may be a practice, but it would be small and likely dealt with at a local community level. Nestlé is not aware of any studies or review papers that address this as an issue in Australia and New Zealand. We consider that an absence of feedback from the research community would indicate this is low prevalence and not really an issue. Therefore, we do not support any additional warning or advisory statements in relation to this.		
Q2.4	5.2	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?
Nestlé Response: Nestlé is not aware of any retail ready liquid concentrate or 'ready to drink products' currently available on the Australian and New Zealand markets. 'Ready to Drink' products were available on the retail market until 2013, and newborn 'Ready to Feed' liquid products remain available to healthcare facilities, but Nestlé has no evidence regarding the addition of foods to these liquid products. Therefore, we do not support any additional warning or advisory statements in relation to this.		

Q2.5	5.2.	What evidence can you provide that caregivers add other foods to infant formula to reduce the cost of the feed?

Nestlé Response:

Nestlé does not have evidence that supports the view that caregivers add other foods to infant formula to reduce the cost of the feed. From some available insights in other international markets and cultural groups, it appears the reason for adding foods (usually rice-based infant cereal) to infant formula may be for settling the infant at night, as a night feed before sleep. As such, cost of feed is not the primary driver in the small number of instances where caregivers may add other foods to infant formula.

Australia and New Zealand are developed countries, where the substantial market share of products are in the premium category, therefore we would not anticipate pricing to be a key driver for the dilution of infant formula.

Nestlé also stresses that such practice, to the best of our knowledge, is not common in Australia and New Zealand.

Therefore, we do not support any additional warning or advisory statements in relation to this.

Q2.6	5.4	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?

Nestlé Response:

Nestlé is not aware that caregivers have difficulty finding the protein source information on the labels of infant formula. In general, most consumers are well aware that most infant formulas on the market, are based on cow's milk.

As an observation, non-cow's milk based formulas such as Goat or Soy are prominently labelled on front of pack and we believe that this sufficiently differentiate those other protein sources from cow's milk based infant formula. If a consumer is still unsure, this information can also be found elsewhere on a product label, and additionally, they are able to contact the company's consumer contact lines.

For these reasons, we do not support prescribing the position of the protein source statement on the label.

Q2.7	5.4	What evidence can you provide that demonstrates consistent placement of the statement of protein source on the label would provide a benefit to caregivers?

Nestlé Response:

Nestlé is not aware of any issues with the placement of the statement of protein source.

In general, we are not aware that current labelling confuses caregivers who would otherwise be concerned about a particular protein source. For example, most consumers wanting a vegan diet for their child, would select a soy-based formula.

Nestlé supports the retention of the statement as we consider it to be an important statement of information that allows the consumer to verify the protein source. We consider that location of protein source on a label should not be defined, therefore we do not support consistent placement and location of the statement of protein source.

Q2.8	5.4	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?

Nestlé Response:

Nestlé does not support prescription of the position of the statement of protein source e.g. front of pack labelling.

The Code currently prescribes a requirement for the statement to be immediately adjacent to the name of food ("Infant formula" as the prescribed name) which may result in a lengthy statement for front of pack labelling. The significant portion of the marketplace are cow's milk based infant formula (In Australia, Goat (6.8%), Soy (0.6%) of total Infant Formula and Toddler, remainder is based on cow's milk – Source Nielsen ScanTrack MAT 06/03/2016). It is more appropriate to differentiate only goat or soy milk based formula and this is already done by brands such as Clever Natural, S-26, Holle and Karicare. Further, CODEX STAN 72– 1981 does not prescribe the location of the protein source statement.

Nestlé considers that there could be other information that caregivers seek that would allow differentiation between brands for an informed choice that may otherwise be placed voluntarily on front of pack if regulation allows.

Q2.9	5.4	What are the cost and trade implications of prescribing the position of the statement of protein source on the label?

Nestlé Response:

Nestlé can provide estimated costs associated with a single label change as commercial-in-confidence when a RIS is done.

In terms of trade implications, this would add another unique specificity to the Australian & New Zealand label. The implications would be primarily for the IFPSDU products. The labelling for infant formula products are largely similar, and if the position for such a statement was mandated (e.g. to front of pack labelling), it is likely applicable to all infant formula products sometime in the future. In relation to IFPSDU products, Nestlé does share some labels with other markets, and is concerned that the sum of unique specificities across different markets together, could potentially lead to some markets dropping out of a clustered group with Australia and New Zealand, as they may not necessarily accept new labelling requirements. Therefore this could lead to trade barriers for the specialty infant formulas, which are typically low volume products where Australian and/or New Zealand volumes alone, may not justify a unique label.

Q2.10	5.9	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?

Nestlé Response:

Nestlé is not aware that additional vitamins and mineral preparations are routinely added to infant formula, in Australia and New Zealand, for healthy infants born at term.

The NHMRC Infant Feeding Guidelines (2013) and New Zealand Ministry of Health for Healthy Infants and Toddlers (2008) support breastfeeding as the normal food of choice for healthy infants in the first 6 months of life and this requires NO supplementation. From around 6 months, when solid foods are introduced, they recommend appropriate nutrient-dense complementary foods with continued breastfeeding. Infants eating a balanced, varied diet do not usually require nutritional supplements.

There are a few sub-groups which may require multi-vitamin or vitamin-specific supplementation, and these would be recommended after special dietary assessment by a specialist. These include, but potentially not limited to:

- Low birth weight infants: Individual clinical advice should be sought to determine supplementation needs.
- Infants on vegan diets: After dietary assessment may require nutritional supplements, especially iron and vitamin B_{12}.
- Exclusively breast-fed infants with delayed introduction of iron-rich foods: may require iron supplementation.
- Breast-fed infants of mothers at risk of vitamin D deficiency: would be recommended vitamin D supplementation of 10µg/day.

Q2.11	5.9	Is the prevalence of vitamin and mineral preparation use higher in formula-fed infants than breastfed infants (or vice versa)?

Nestlé Response:

Nestlé notes that the prevalence may be more relevant for breast-fed infants.

In some situations, as already outlined above, vitamin and mineral preparation use may occur.

There is evidence for the routine supplementation of vitamin D in breast-fed babies as vitamin D deficiency and rickets has re-emerged as a paediatric health issue in specific population sub-groups within Australia and New Zealand (Grant *et al,* 2013; Munns *et al*., 2006; Wheeler, 2015). NHMRC infant feeding guidelines (2013) states that while most breast-fed infants receive adequate amounts of vitamin D through breast milk and casual exposure to sunlight, if mothers don't get enough Vitamin D then their breast milk could be deficient, putting exclusively breast-fed babies at potential risk of deficiency. The sub-groups considered at risk, include – breast-fed infants of dark-skinned mothers, as darker skin (skin pigmentation naturally rich in melanin) requires considerably longer exposure to sunlight to produce vitamin D; and breast-fed infants of women wearing full-coverage clothing, including veils, who have limited exposure to sunlight. Additionally, location may also impact vitamin D levels in breastfeeding mothers – with New Zealand and southern states of Australia at increased risk due to limited exposure to sunlight over many months of the year.

Although vitamin D supplementation for all breast-fed infants is not routinely practiced in Australia and New Zealand at this point in time, recommendations do exist overseas - (e.g. The American Academy of Pediatrics (AAP) recommends that all breast-fed infants receive a daily supplement of 400 IU (10 µg) of vitamin D). Locally, the New Zealand Ministry of Health (2008) recommends Vitamin D supplementation in babies who are at high risk of deficiency under medical supervision. In Australia, the recommendation to use vitamin D supplements (10 µg/day) is limited to 'at risk' breast-fed infants of dark-skinned and women wearing clothing with full coverage (Munns, 2006).

Supplementation of iron may also be appropriate for some infants. This is not routine in Australia or New Zealand and would be performed after a specialist assessment. In Australia, iron deficiency is the leading risk factor for the burden of disease in children under 5 years of age and biochemical evidence shows that up to 30 % of Australian infants and toddlers are at risk for iron deficiency (Atkins LA *et al*. 2006). And in New Zealand, around 14% infants and young children are estimated to be iron deficient (Grant, 2007). Also, the Growing-Up in New Zealand study found iron deficiency present in 7% of newborns (Morton, 2014). This is of public health concern because, in early childhood, iron deficiency that progresses to iron deficiency anaemia has been shown to limit brain development and inhibit healthy long-term development. For the 6-12 month old infant, where growth is rapid, blood volume expands and breast milk is exhausted of iron, iron requirements are far greater than at any other time of life, so if dietary sources are poor, supplementation may be required.

Q2.12	5.9	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)?

Nestlé Response:

Nestlé does not have this data, however suggest that further work is undertaken to determine the market prevalence or vitamin and mineral preparations targeted at infants/babies in complementary medicines regulated by the Therapeutic Goods Administration (TGA) or Food Supplements by Medsafe.

Q2.13	5.9	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?

Nestlé Response:

As in the response to Q2.10 and Q2.11, such vitamin and mineral supplementation is not needed for *healthy* growing infants – either breast-fed or formula-fed.

Currently there are no national guidelines that we are aware of in relation to vitamin and mineral supplementation for formula-fed infants. For healthy formula-fed infants, to the best of our knowledge, we are not aware that healthcare professionals advise caregivers to supplement infant formula with additional vitamin and mineral preparations.

In relation to breast-fed infants, in situations where deficiencies could be a risk – the advice from National infant feeding guidelines and clinical studies have been outlined in the response to Q2.10 above.

Q2.14	5.9	What are the cost and trade implications of mandating advice regarding vitamin and mineral preparations on infant formula packages?

Nestlé Response:

Nestlé infant formula products already include a voluntary statement on the label with this advice.

However, Nestlé advocates, as a general principle, that it is impossible to label for every possible scenario of misuse. Additionally, there are already prominent warning statements on infant formula labels to follow instructions exactly. In the absence of evidence of significant prevalence of vitamin and mineral preparation that is not under medical advice and supervision and no evidence of market failure, then such advice, in our view, should not be mandated.

Q2.15	6	Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?

Nestlé Response:

Nestlé supports the responses previously provided by the INC in the submission for Proposal 1024.

Nestlé supports that all new substances are pre-market assessed, however we consider that pre-market assessment is broader than being limited to FSANZ accountability:

- For low risk new ingredients such as those proposed for general foods, Nestlé proposes that industry is accountable for the pre-market assessment of those relating to an Eligible Food Criteria (EFC).
- For low-med risk new ingredients, Nestlé proposes that industry is accountable for the notification and dossier requirements.
- For higher risk new ingredients, we would suggest FSANZ conducts the pre-market assessment.

In all the above cases, relevance to infants as the consuming population needs to be considered.

The rationale for the preferred position is as follows:

- The current status quo allows for elements of an EFC pathway, as well as a FSANZ pre-market assessment pathway. There has been no evidence of market failure with the current status quo for infant formula products, however we recognise that improvements to regulatory clarity can facilitate a more innovative and developed approach to new ingredients.
- EFC and notification pathways provide industry with speed to market, and encourages innovation, in turn fostering healthy competition which will only result in positive outcomes for the infant, as industry continues to innovate to better achieve the health outcomes of the breast-fed infant.

Q2.16	6	What would be the cost and trade implications of your preferred position?

Nestlé Response:

Nestlé considers that the preferred position as outlined in full in the INC submission for Proposal 1024, will be positive cost improvement for a company, as compared to the status quo. These improved costs would be due to reduced regulatory burdens, and speed to market. Trade implications are also likely to be improved – for example, if a mutual recognition approach with authoritative bodies/agencies was considered in a notification pathway, innovation that is available for example in a European market, will improve harmonisation opportunities for the recipe composition of an infant formula.

Q2.17	6	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?

Nestlé Response:

Nestlé suggests that pre-market assessment by FSANZ would relate to higher risk ingredients – as an example, novel ingredients that have not been pre-market approved by authoritative government agencies elsewhere in the world. Or, changing the maximum limits of currently permitted nutrients above what is approved anywhere else in the world. The question as to where the 'line' is drawn will need to be evaluated and further considered in more detail in future consultations on this topic.

For all other pathways reflected in P1024 - EFC's and notification pathways – we consider that pre-market assessments would in any case be warranted, however we propose this would be a company-specific pre-market assessment, in relation to ingredients that are not considered high-risk (where the 'line' is drawn, leading to a pre-market assessment pathway by FSANZ).

We further suggest that criteria would need to be further developed in future consultations. As an example, we consider that ingredients approved for the general population should not automatically be assessed by a company as suitable for use in infant formula. The relevance to the consuming population of infants needs to be considered.

Q2.18	6	If only certain substances, how would you suggest we define or characterise the group of substances that should require pre-market assessment?

Nestlé Response:

As mentioned above criteria would need to be further developed in future consultations. At this preliminary stage, we have not fully mapped out how groups of substances requiring FSANZ pre-market assessment will be defined or characterised. We also consider it may be premature to define or characterise those substances requiring pre-market assessment until FSANZ proposes a regulatory framework and pathways that is relevant to infant formula products.

We consider the policy for the regulation on infant formula products is sufficiently broad enough so as not to restrict pre-market assessment of all products to a singular party. We are concerned that this approach is stricter than the status quo and will unnecessarily restrict innovation and create potential trade barriers.

Q2.19	7.3	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.

Nestlé Response:

Nestlé suggests that the Code should align with CODEX which does not list an ML for aluminium however the proposed lower ML (0.05mg/100ml) for soy-based infant formula is achievable if retained.

As a general principle, Nestlé considers that contaminant limits should be based upon risk.

The JECFA evaluation of aluminium in 2012 revised the Provisional Tolerable Weekly Intake (PTWI) for aluminium upwards to 2 mg/kg-bodyweight (WHO Food Additive Series 65). Recently reported levels of aluminium in infant formula would not exceed this revised PTWI (Burrell and Exley, 2010). A Cochrane review of the safety of soya-based infant formulas concluded that whilst aluminium levels may be higher in soy-based infant formula than in breast milk or cows-milk 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).

In addition to aluminium that might be present in raw materials, aluminium could be present from contact with food packaging. 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)

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.

Nestlé would suggest further evaluation by FSANZ as to whether the existing requirements for Aluminium as a contaminant is retained.

Q2.20	7.3	What are the cost and trade implications of reducing the ML for aluminium in soy-based formula?

Nestlé Response:

Nestlé suggests that any ML for aluminium places unnecessary regulatory burden by way of analytical verification testing on the manufacturer. There would be no cost or trade implications with reducing the ML for aluminium in soy-based infant formula.

No major international market sets an ML for aluminium.

Q2.21	7.5	What are the cost and trade implications of reducing the ML for lead in infant formula?

Nestlé Response:

Nestlé supports reducing the ML for lead to 0.01 mg/kg in infant formula in view of the withdrawal of the PTWI by JECFA and the recent adoption of the lower level by CODEX.

Reducing the limit for lead in infant formula would be equal to that described by Codex STAN 193-1995 Codex General Standard for Contaminants and Toxins in Food and Feed (2015 update).

Reducing the ML for lead has cost implications that can be distributed over time to manage trade requirements as national legislation is aligned at different rates.

Q2.22	7.6	What if any, issues are associated with not including the CODEX ML in the Code for melamine?

Nestlé Response:

Nestlé supports not including a melamine ML in the Code.

In the absence of any associated risk, it is not necessary to introduce the CODEX ML which was specifically set to control illegal adulteration of infant formula.

Q2.23	7.10	Please provide comments on the recommendation to apply all MLs to a reconstituted ready-to-feed form.

Nestlé Response:

Nestlé suggests that the ML for infant formula apply to the form as sold, whether powder or liquid.

The majority of infant formula (both manufactured and purchased at a retail level) in Australia and New Zealand is sold as powder. Hence it is appropriate for limits for contaminants to be expressed first on a dry powder basis. On a secondary basis, as in the provision expressed in CODEX, EU and FDA standards it is suggested that values are also provided for ready to feed formula.

Nestlé prefers that limits for contaminants should be expressed as either 'mg/L' or 'mg/kg' rather than as mg/100 mL which is not aligned with international practice.

Q2.24	7.11	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?

Nestlé Response:

Nestlé supports the FSANZ preliminary view that a definition of 'contaminant' may not be necessary and in any case should be considered as part of a proposed future review of Standard 1.4.1.

No definition of contaminant is included in State, Territory or the New Zealand Food Acts. If inclusion of a definition is considered in a future proposal, then alignment with CODEX would be preferred. The definition in the CODEX General Standard for Contaminants and Toxins in Food and Feed (Codex STAN 193-1995) is:

"*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*".

Q2.25	7.11	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?

Nestlé Response:

Please refer to Q2.24

Q2.26	8.2.2	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.

Nestlé Response:

Nestlé supports the inclusion of acidity regulators sodium carbonates [INS500i and INS500ii], potassium carbonates [INS501i and INS501ii], sodium hydroxide [INS524] and potassium hydroxide [INS525], sodium phosphates [INS339i, INS339ii, INS339iii] and potassium phosphates [INS340i, INS340ii, INS 340iii to the list of approved food additives for infant formula products.

The function and choice of acidity regulator / processing aid / mineral form is dependent upon the other ingredients present and processing conditions for the infant formula product. The substances have been demonstrated as safe and suitable for use in an infant formula product and typically the amount added when used as a food additive or processing aid would be lower than when used as a permitted form of mineral and electrolyte for which they are already included in the FSC Schedule 29-7.

Q2.27	8.2.2	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?

Nestlé Response:

Nestlé supports the response provided by the INC in the submission for Proposal 1028.

Infant formula products as well as Infant formula products for special dietary use manufactured with amino acids and hydrolysed proteins have different hydrophobic/hydrophilic characteristics and lower emulsifying capacity than products based on whole protein. CITREM/INS 472c improves the stability and organoleptic properties of products containing partially or extensively 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	8.2.2	What, if any, information can you provide to support an assessment of an extension of use of a food additive in infant formula?

Nestlé Response:

Nestlé supports the response provided by the INC in the submission for Proposal 1028.

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 9 g/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 scarcity 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.

http://www.fao.org/3/a-at861e.pdf

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.

http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-136.pdf

Also, the European Scientific Committee on Food considered that the use of E472c is acceptable in products which contain partially hydrolysed proteins for infants and children in good health and for FSMP containing extensively hydrolysed proteins or amino acids at the safe levels as JECFA.

http://ec.europa.eu/food/fs/sc/oldcomm7/out06_en.html

Q2.29	8.2.2	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?

Nestlé Response:

Nestlé is aware of use of CITREM INC 472c in IFPSDU in other international markets.

Q2.30	8.2.3	What, if any issues would a lack of consistency in the nomenclature of food additive names for infant formula cause?

Nestlé Response:

Nestlé supports consistency however any inconsistency in the nomenclature of food additive names to date has been managed as the legislation allows use of both the names or INS.

Q2.31	8.2.4	Will lowering the MPL of hydroxypropyl starch to 5000 mg/L create any difficulties for infant formula companies?

Nestlé Response:

Nestlé supports lowering the MPL of hydroxypropyl starch (INS1440) to 5000 mg/L.

Nestlé supports alignment with CODEX where the MPL for hydroxypropyl starch for use in soy-based infant formula is 5000 mg/L, singly or in combination. Lowering the MPL for hydroxypropyl starch would create consistency with CODEX and with the original intent of the decision made in Proposal P93.

Q2.32	8.3	Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.

Nestlé Response:

Nestlé supports retaining the carryover principle, where safe and technologically necessary.

CODEX STAN 72-1981 Section 4 Food Additives outlines that food additives as listed, 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.

Hence Nestlé considers that Codex does allow for carryover of food additives into infant formula and strongly believes that the food additive carryover principle should continue to apply to infant formula.

A prohibition on carryover could create significant technological challenges as well as barriers to innovation and trade.

Q2.33	8.4	Is there a technological justification for permitting carrageenan in liquid soy-based infant formula products?

Nestlé Response:

Carrageenan provides a technical effect in liquid infant formula products which cannot be duplicated by other additives used as stabilizers.

- Builds viscosity – Helps to stabilise 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 stabilisation, 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 hydrolysed 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.

Q2.34	8.4	Do submitters believe the current permissions in the Code permit carrageenan in soy-based infant formula?

Nestlé Response:

Nestlé supports the response provided by the INC in the submission for Proposal 1028.

We support the continued permission of Carrageenan (INS 407) for use in both milk-based and soy-based liquid infant formula products. We acknowledge that there could be some confusion as to whether carrageenan is permitted in liquid soy-based infant formula given the clarification in the revised Code [S15-2] regarding hierarchy.

Q2.35	8.4	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?

Nestlé Response:

Nestlé is not aware of any difficulties with lowering the MPL of hydroxypropyl starch (INS 1440) to 5000 mg/L.

Supporting Document 3: Provision of Information

No.	Section of the SD	Question
Q3.1	2.1	Should claims about specific ingredients be permitted on packaged infant formula? • If no, then why not? • If yes, then how should they be regulated?

Nestlé Response:

Nestlé strongly believes that breastfeeding is the best for infants. However, for those infants unable to receive breast milk, infant formula is the only suitable sole source of nutrition, and as such, caregivers should be provided sufficient information in order to make an informed choice.

There is substantial potential for confusion by consumers at the point of purchase, with so many brands facing them.

Recently, there has been a significant increase in the number of companies which market infant formula. There are currently approximately 22 Infant formula brands and 125 SKUs on the Australian market alone. (Source: Nielsen ScanTrack MAT to 06/03/2016).

With such a wide choice of infant formulas on the Australian market, many at different price points, consumers struggle to understand the differences that lead to a brand being priced at $15 or $30.

For an infant formula suitable from birth, Nestlé proposes that:

- Nutrient content claims on nutrients that allow for differentiation between brands, is permitted.
- General level health claims on nutrients that allow for differentiation between brands, is permitted, under the regulatory framework of FSC 1.2.7.

It is considered that companies may invest significant R&D into specific nutrients, not only optional ingredients. Significant innovation has occurred, for example, in the area of protein (whey dominance, hydrolysation, etc.).

Nestlé would be open to supporting – for starter infant formula – maintenance of the current prohibitions on nutrient content and health claims for non-differentiating ingredients, specifically: vitamins and minerals.

If permitted, permissions where relevant should be regulated in FSC 2.9.1 and FSC 1.2.7.

The permissions requested above, is also aligned to the INC position, Nestlé supports the full and detailed response provided by the INC in the submission for Proposal 1028.

Also, Nestlé supports the INC view that permissions for claims to support informed choice for the consumer is aligned to policy guidelines for the regulation of infant formula products.

Q3.2	2.3	Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?

Nestlé Response:

Nestlé is aware that healthcare 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 informed choice and appropriate product selection in line with the healthcare professional's recommendation.

Q3.3	2.3	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?

Nestlé Response:

Nestlé supports the Code including permissions to declare nutrition information about macronutrient subgroups in the nutrition information statement. However the nutrition information needs to reflect the nutritional needs of this age group which can be different to those of other age groups.

Research into where parents get infant formula information from, or how they choose one formula over another is scarce. It is reported that most parents will actively seek advice from their healthcare professional about which formula is best for their infant (Wirihana & Barnard, 2012) however it is not uncommon for this advice to be limited, and as a result mothers do not feel empowered to make appropriate decisions around which formula is best for their infant (Lakshman, 2009).

From Nestlé field staff experience, it is evident that the advice a parent receives about which formula is best for their baby varies depending on their healthcare professional. It is quite common that a healthcare professional will recommend features of a formula (e.g. whey dominance, or DHA levels) rather than recommending a specific brand or type of formula.

In addition, readily accessible nutrition information via the internet, print, radio etc. (Newby, 2015) means parents can be much more aware of, and interested in, these macronutrient subgroups, and will lead them to choosing one formula over another for the benefit of their child. In these instances, the inability to declare such information on pack undermines a parent's ability to follow such advice or preference, and may contribute to feelings of anger, worry, uncertainty and a sense of failure, which are commonly experienced by mothers who bottle feed their baby (Laksman, 2009).

Q3.4	2.3	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).

Nestlé Response:

Nestlé supports declaration of specified macronutrient subgroups, where this is based on a voluntary permission (that would not constitute a claim). We do not support this information being mandated. This is because not all macronutrient sub-groups relate to essential composition (for example, DHA and ARA). For alpha-lactalbumin, this may be a differentiating factor for some brands. Those brands not currently declaring alpha-lactalbumin, would then be mandated into an obligation to test and verify the declared values in the Nutrition Information Panel (NIP), and may not necessarily have the analytical experience in this nutritional parameter.

As such, the basis for voluntary declaration of added ingredients in the NIP is to allow for product differentiation between brands and informed choice for the consumers. The current NIP is a guideline only (not part of the legally binding standard), and the regulations do not explicitly prohibit such declarations. We would support the status quo in this respect, however welcome improved regulatory clarity that would be in support of more information for the consumer to enable brand differentiation, and an informed choice.

Q3.5	2.3	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).

Nestlé Response:

Nestlé considers that any permitted voluntary declarations in the Nutrition Information Panel, needs to be in regard to an added ingredient, that allows for product differentiation between brands.

Q3.6	2.3	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?

Nestlé Response:

Nestlé considers there is no potential for caregivers to be misled, since those declarations that exist currently in the marketplace would require a nutritional verification of the average quantity (i.e. any declaration in the Nutritional Information Panel would trigger a need for analytical verification), and therefore would be a true representative of the average nutritional value of that formula.

Q3.7	2.3	What would the cost and trade implications of mandating macronutrient subgroups or conversely expressly prohibiting them?

Nestlé Response:

Costs involved would be those associated a single label change. 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.

Nestlé can provide these estimated costs as commercial-in-confidence when a RIS is done.

In terms of trade implications, this may potentially impact shared labels with other countries. The current status quo allows flexibility for a manufacturer to not declare these macronutrient subgroups should the company wish to share a label with another country.

Q3.8	2.4	Is there any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations?

Nestlé Response:

Nestlé is not aware that either caregivers or health professionals are confused by the differences between ingredient declarations and nutrition information.

Q3.9	2.4	Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?

Nestlé Response:

For the nutrition information statement, our preference is to use the common names of vitamins and minerals, rather than permitted forms, due to limitations of space, and simplicity for the consumer.

Nestlé supports the flexibility that would allow a company to voluntarily label the chemical names of vitamins and minerals to reflect permitted forms in the Regulation. We also consider that CODEX STAN 72-1981 is sufficiently broad in the labelling for the list of ingredients (Clause 9.2) to allow such flexibility, and as such our view is not to prescribe a further restriction to align names of ingredients in a list of ingredients to nutrient declarations in the Nutrition Information statement. For the list of ingredients, Nestlé considers that there may be a benefit in, to voluntarily labelling the specific permitted forms of ingredients such as vitamin and minerals. This may assist more accessible compliance assessment by some authorities, such as border control for imported products. At the same time, the generic common name description that is more easily understandable for consumers, is *also* available in the list of ingredients.

Q3.10	2.5	Which base units of expression do stakeholders find to be of greatest value?

Nestlé Response:

Nestlé considers that the base unit of per 100mL prepared formula, is the most relevant expression for the key stakeholders, which are is the caregivers that purchase the product, and are interested in the nutritional value of the reconstituted serve.
Caregivers who read labels are generally familiar with per 100mL labelling from their purchase of general foods.

Q3.11	2.5	Is there any evidence that caregivers are confused by the use of different base units of expression?

Nestlé Response:

Nestlé is not aware of any evidence that caregivers are confused by the use of different base units of expression. This is because the label does not provide the opportunity for confusion, given only a single base unit of expression (per 100mL) is typically used.

Q3.12	2.5	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?

Nestlé Response:

Nestlé considers that declaration per 100g of powder as sold should remain voluntary.

CODEX STAN 72-1981 requires the declaration of average values per 100g powder as sold. Although not commonly used in Australia or New Zealand, the flexibility to include this information on the label will facilitate trade, for example shared labels. As discussed in Q3.10 our experience is that most caregivers and healthcare professionals find per 100mL expression sufficient.

Note that declaration of per 100mL for liquid formula as sold is not relevant as this is already addressed by the current requirement to declare nutrition information per 100mL as consumed. Any liquid infant formulas are already reconstituted as sold, to also equate to the nutritionals as consumed.

Q3.13	2.5	What would the cost and trade implications be of mandating these base units?

Nestlé Response:

Cost implications: Apart from the cost associated with a label change, there would be additional regulatory personnel resource costs involved in mandating these base units. These would increase the total time spent for a label review by qualified regulatory industry personnel, which is multiplied across many labels and all future renovations. Nutritionals are recipe specific and a new list for verification per 100g as sold would add additional resource costs. As such, Nestlé does not support mandating these base units of 100g of powder (as sold).

Trade implications: Labels are often limited to Australian and New Zealand even, where composition is harmonised to CODEX or another country. Mandatory inclusion of additional base units may create trade barriers and we consider that the voluntary approach currently allowed today, provides the appropriate degree of flexibility.

Q3.14	2.5	Should the voluntary use of the base unit of per 100 kJ be permitted?

Nestlé Response:

Nestlé has no objection to the **voluntary** use of the base unit per 100kJ, but would query whether there is a 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*."

Q3.15	2.6	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'?

Nestlé Response:
Nestlé does not consider there would be any major impact and would support average quantity in the interests of consistency. While this would mean a label change, in light of many other changes likely, due to P1028, this would likely be incorporated into a mass change in a single label.

Q3.16	2.7	Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?

Nestlé Response:

The nutritional information panel could *possibly* be used to allow easier comparison of nutrition information between products. However Nestlé does not have the evidence to demonstrate the prevalence of caregivers' use of nutrition information on infant formula packaging, and we concur and agree with FSANZ's comments in SD3, 2.7.4.

However – outside the nutrition information panel, at the same time we consider that there is an opportunity to improve product labelling to provide more information for caregivers to inform their purchase decisions, especially to assist in differentiating one brand from another.

Q3.17	2.7	Would a consistent approach to format across product labels assist consumer understanding of this information?

Nestlé Response:
Nestlé does not support a consistent approach to the nutrition information format, and this would rely on a mandated regulatory approach which we consider is not warranted in the absence of evidence, as outlined also by FSANZ, in SD3, 2.7.4 in a clear benefit for the caregivers.

A mandated format of the nutrition information panel would also create a barrier to trade.

Q3.18	2.7	If the format was prescribed, what would be the impacts including costs to industry and trade considerations of changing labels?

Nestlé Response:
Costs involved would be those associated with a single label change. Additionally, a mandated format of nutrition information that is inconsistent with requirements for other countries outside of Australia and New Zealand, would lead to barriers to innovation and/or overstickering costs, particularly for small volume products. This would particularly affect IFPSDU products if in the future, the same approach is applied.

Nestlé can provide these estimated costs as commercial-in-confidence when a RIS is done.
This may potentially impact shared labels with other countries and therefore affect trade opportunities. The current status quo allows flexibility for a manufacturer that would satisfy the regulatory requirements of Australian and New Zealand, and well as other countries, in circumstances where the company needs to share a label with another country.

Q3.19	2.8	How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?

Nestlé Response:

Healthcare professionals – currently, as communications to healthCare professionals are factual and informative, these are not in scope of the Food Standard Code and accordingly, references to new ingredients do not apply. Currently, Nestlé would communicate a change in the composition to healthcare professionals via: e.g. mail-outs, and face-to-face visits. However we mention that while we can communicate to healthcare professionals these changes in composition, companies face ever increasing challenges with access restrictions to healthcare professionals. As such, with no access to all healthcare professionals, we are unaware as to how a particular healthcare professional may keep up to date with changes in the composition of an infant formula.

Caregivers: Changes in composition usually relate to nutrients and nutritive substances. Such references outside of a list of ingredients and nutrition information panel are currently prohibited for both labels and advertisements. Nestlé considers that it is key that references to differentiating ingredients outside a list of ingredients and nutrition information panel, are permitted for infant formula, so that companies can communicate the changes in composition to caregivers. Currently, companies are limited to telling caregivers that changes are coming, and caregivers are invited to contact the company for more information either via stickers on lids, or on our product websites during the transition phase to a new / improved recipe.

This however does not necessarily reach all caregivers. Nestlé is aware that some caregivers purchase multiple tins for pantry fill – particularly where they are concerned about stock levels in store or where prices are discounted. As such, since a tin of infant formula can last up to four weeks, caregivers that stockpile and pantry fill may miss out on stickers informing caregivers of impending changes during the transition phase. Additionally, not all caregivers contact companies for information.

As such, information provided by other forums and means do not reach all caregivers. However, the information on the label that is being purchased will **always** reach the caregiver.

Other non-industry sources such as “friends and families”, blog sites etc. are not always credible. For this reason the label of the product should be the preferred avenue for communicating changes in the composition of an infant formula to caregivers and health professionals and recognised as the authoritative source of information.

Q3.20	2.8	What information about the change in composition would caregivers and health professionals find useful?

Nestlé Response:

Our insights via caregivers contacting us is that they fundamentally wish to know what is different about the new recipe, as compared to the current/old one they have been feeding their child.

Q3.21	2.8	What are the cost and trade implications of a standardised approach to a product reformulation on infant formula packages?

Nestlé Response:

Nestlé considers that it is premature to comment on the cost and trade implications of a standardised approach to a product reformulation on infant formula packages, without knowing exactly what this standardised approach may be.

It was suggested in SD3, 2.8.2 that alternative approaches to nutrient claims may be in the form a labelling statement that does not constitute a prohibited representation, or may involve communicating the information using methods other than on the product label. These approaches however are not currently fully elaborated on or refined, therefore we are unable to comment.

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APPENDIX 1

Supporting Document 1: Definitions and Nutrient Composition

Topic and Specific Issues		Section in SD1	Preliminary View by FSANZ and Comments from Nestlé
Definitions and terminology	Definition of infant formula product	2.1	**FSANZ Preliminary View:** *Standard 2.9.1 includes this as an overarching definition to capture all products regulated by the Standard. There is no similar overarching definition in Codex STAN 72-1981.* **Nestlé Comment:** Nestlé supports maintaining the current definition.
	Definition of infant formula	2.2	**FSANZ Preliminary View:** *The definition of infant formula relates to product representation and purpose in the diet of infants up to certain age. There is some confusion around the age range of the infant formula (in relation to the follow-on formula product categories).* **Nestlé Comment:** Nestlé supports maintaining the current definition, but proposes that definitions are re-visited when the review of Follow-on-formula is completed.
Protein	Content	3.1	**FSANZ Preliminary View:** *Protein amounts are aligned already, however there is growing interest in lowering the requirements to potentially lower risk of obesity in childhood.* **Nestlé Comment:** Nestlé supports aligning the total protein content with Codex Standard 72-1981. FSANZ has concluded this to be identical to Standard 2.9.1 but an incorrect energy conversion creates recipe differences and should be corrected.
	Calculation of protein: nitrogen conversion factors	3.2	**FSANZ Preliminary View:** *Currently Standard 2.9.1 specifies two conversion factors: 6.38 for milk proteins and 6.25 for all other protein sources. This is effectively aligned with Codex STAN 72-1981. However soy proteins have a different molecular weight and therefore different total nitrogen content.* **Nestlé Comment:** Nestlé supports the proposal that only two factors should be specified, a conversion factor of 6.25 should apply to mammalian milk and a conversion factor of 5.71 should apply for soy protein sources.
	Protein source	3.3	**FSANZ Preliminary View:** *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. Codex STAN 72-1981 defines infant formula as a product based "on milk of cows or other animals or mixture thereof and other ingredients proven to be suitable for infant feeding.* **Nestlé Comment:** Nestlé considers that it is not necessary to further define the sources of protein.
	Protein Quality	3.4	**FSANZ Preliminary View:** *Stakeholders suggested that FSANZ should consider the recent FAO/WHO report recommending the Digestible Indispensable Amino Acid Score (DIAAS) as a protein quality calculation methodology.* **Nestlé Comment:** Nestlé agrees that it is not appropriate to adopt PDCAAS or DIAAS methods at this time. The amino acid composition of breast milk should still be the reference for determining an infant's amino acid requirements.

	Amino acid content	3.5	**FSANZ Preliminary View:** *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.* **Nestlé Comment:** Nestle supports aligning the minimum levels of isoleucine, leucine, lysine, threonine, tryptophan and valine with Codex Standard 72-1981. Additionally we propose that tyrosine, phenylalanine, cysteine and methionine should be aligned to Codex Standard 72-1981 as there are no safety issues and this would facilitate innovation and harmonised trade
Fat	Fat content	4.1	**FSANZ Preliminary View:** *Standard 2.9.1 and Codex STAN 72-1981 prescribe the same minimum for total fat; the maximum fat is higher in Standard 2.9.1. We propose to retain the minimum and lower the maximum to align with Codex STAN 72-1981* **Nestlé Comment:** Nestlé supports aligning the total fat content with Codex Standard 72-1981.
	Essential fatty acid composition	4.3	**FSANZ Preliminary View:** *There are requirements for the essential omega 6 and omega 3 fatty acids, Linoleic acid (LA 18:2, n-6) and α- linolenic acid (ALA, 18:3, n-3) in both standards, although there are some differences. Overall, we consider 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.* *However, alignment with the minimum amount of LA needs further consideration and submitter input would be helpful. The evidence supports maintaining the Standard 2.9.1 minimum amount for LA rather than aligning with Codex.* *The amount of LA and ALA in Standard 2.9.1 is expressed as a proportion of total fatty acids. Codex STAN 72-1981 expresses the essential fatty acid requirements as an amount per energy unit. We propose to continue to require the amount of essential fatty acids be expressed as a proportion of total fatty acids.* **Nestlé Comment:** Nestlé supports aligning the essential fatty acid composition with Codex Standard 72-1981 since it is unlikely to pose a risk to infants. We consider that the unit of expression should also be aligned to avoid the need to create different recipes and manufacturing specifications.
	Long chain polyunsaturated fatty acids (LC-PUFAs)	4.4	**FSANZ Preliminary View:** *FSANZ considers that a mandatory minimum amount of DHA is not supported and retaining the voluntary permission is appropriate and is unlikely to pose a risk to infant health. Maintaining this voluntary permission would not impact on the manufacture of infant formula. However, 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). We consider that the intention of the approaches will remain aligned with Codex STAN 72-1981. Therefore, FSANZ proposes to retain the current EPA: DHA ratio requirement in Standard 2.9.1 to reduce the risk of a potential metabolic imbalance between n-3 and n-6 LC-PUFAs.* **Nestlé Comment:** Nestlé supports retaining the voluntary permission for LC-PUFAs

	Sources of fat	4.5	**FSANZ Preliminary View:** *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. We are seeking feedback from stakeholders on whether this approach remains appropriate.* **Nestlé Comment:** Nestlé considers the current approach remains appropriate.
	Restrictions on certain fats: *Medium-chain triglycerides (MCT) *Trans-fatty acids *Myristic acid (C14:0) and lauric acids *Phospholipids *Erucic acid	4.6	**FSANZ Preliminary View:** *FSANZ considers the current limitations on the presence of MCT in Standard 2.9.1 remain appropriate. However this would not be consistent with Codex. Stakeholder feedback would be helpful to determine the final approach.* *We propose to lower the maximum amount of trans fatty acids to 3% total fatty acids. However, we are seeking feedback as infant formula companies may need to adjust their formulations to comply with the lower maximum amount permitted under Codex.* *We consider it is appropriate to maintain no restriction on the levels of myristic and lauric acids in Standard 2.9.1 in line with the recent expert opinion. This approach is inconsistent with Codex but may be less restrictive for infant formula companies.* *Standard 2.9.1 does not contain provisions that relate to phospholipids in infant formula however, Codex STAN 72-1981 specifies a maximum permitted amount of phospholipids. FSANZ's preliminary view is that total phospholipids should be restricted but that more information is needed before a maximum could be established. The evidence does not support alignment with the higher Codex maximum. Any final maximum amount needs to take account of the level of lecithin in infant formula. We are seeking further input from stakeholders. As Standard 2.9.1 is currently aligned with Codex, FSANZ considers an appropriate risk management measure is to retain the limit on erucic acid.* **Nestlé Comment:** Nestlé considers that it is not necessary to maintain the current limits on the use of MCT and would suggest alignment with Codex. As the definition of trans fatty acids differs between FSC and Codex, Nestlé supports retaining the current permission of 4% trans fatty acids. Nestlé supports maintaining no restrictions on the levels of myristic and lauric acids or phospholipids. Nestlé supports retaining the current limit on erucic acid.
Carbohydrate	Definitions and calculations relevant to carbohydrate	5.1	**FSANZ Preliminary View:** *Several definitions relevant Standard 2.9.1 were previously located across different standards in the Code. All of these definitions now apply throughout the revised Code, and section S11—3 sets out how to calculate available carbohydrate and available carbohydrate by difference. This clarifies previous confusion about whether definitions located in other standards did apply to Standard 2.9.1. 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.* **Nestlé Comment:** Nestlé supports that the definition and calculation relevant to carbohydrate should be consistent with the revised Food Standards Code.

	Introduction of maximum and minimum level	5.2	**FSANZ Preliminary View:** *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 regulations on protein, fat and energy content. Codex STAN 72-1981 lists a carbohydrate range of 2.2–3.3 g/100 kJ.* *We consider 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.* **Nestlé Comment:** Nestlé considers the current approach remains appropriate.
	Carbohydrate source	5.3	**FSANZ Preliminary View:** *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 (e.g. 'preferred' sources of carbohydrate and that sucrose and fructose" should be avoided"), but this is not mandatory. As evidence is not strong for mandatory restrictions on the source of carbohydrate in infant formula, FSANZ's preliminary view is to maintain the current provisions in Standard 2.9.1. We recognise this will not align with Codex STAN 72-1981. Submitter views are sought.* **Nestlé Comment:** Nestlé considers the current approach remains appropriate.
Energy	Energy content	6.1	**FSANZ Preliminary View:** *The Code's minimum energy amount is aligned with Codex STAN 72-1981, however its maximum amount for energy is higher. We propose to reduce the maximum amount to align with that in Codex STAN 72-1981.* **Nestlé Comment:** Nestlé supports aligning the energy content Codex STAN 72-1981
	Calculation of energy density	6.2	**FSANZ Preliminary View:** *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 is some confusion as the Code also states that the nutrition labelling requirements do not apply to infant formula. FSANZ expects that the relevant modifications in the revised Code have resolved that confusion. Our preliminary view is to maintain application of energy factors for calculating the energy density of infant formula. Furthermore, that the Code's energy factors should continue to apply to infant formula including both energy factors for available and unavailable carbohydrate.* **Nestlé Comment:** Nestlé supports that the calculation relevant to energy should be consistent with the revised Food Standards Code.
Vitamins, minerals and electrolytes	Approach to setting guidelines or maximum amounts	7.1	**FSANZ Preliminary View:** *In Standard 2.9.1 all nutrients have either a maximum amount or a recommended guideline maximum amount (referred to as GULs). Codex uses a similar approach, though there are some differences as in the Codex standard GULs are assigned to 20 micronutrients compared to 14 in the Code. The GULs in the Code are not binding and serve as guidance for industry in designing formulations. The 2009 audit of the legal efficacy of the Code queried whether the use of GULs in the guideline is appropriate. Thus we are considering whether the GULS should be formally incorporated into Standard 2.9.1.* *Stakeholders support the advisory maximums being retained in the Code. The nutrition assessment identified no evidence to indicate that a voluntary maximum would pose a risk to infant health for most nutrients. Thus, FSANZ's preliminary view that it is appropriate for some nutrients to retain a GUL in*

			Standard 2.9.1, and for others to be amended from a prescribed maximum to a GUL to align with Codex (as summarised in Table 7.2 of SD1). Folate, phosphorus and selenium require further information. **Nestlé Comment:** Nestlé supports that GULs are appropriate for vitamin K, vitamin E, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, pantothenic acid, folate, vitamin C, biotin, calcium, magnesium, manganese, iodine, copper, zinc, phosphorus and selenium.
	Vitamin dietary equivalents and conversion factors • Vitamin A • Folate • Vitamin E • Niacin	7.2	**FSANZ Preliminary View:** *Standard 2.9.1 and Codex STAN 72-1981 differ in the way in which vitamin equivalents are managed and expressed.* *Vitamin A: FSANZ's preliminary view is to exclude β-carotene from the total amount of vitamin A in infant formula in light of uncertainty around its bioavailability, and also to support 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 β-carotene contribution to vitamin A content but will differ in relation to the vitamin A units.* *Folate: As neither Codex STAN 72-1981 nor Standard 2.9.1 currently use dietary folate equivalents (DFE) to express the folate content of infant formula, our preliminary view is to retain units of µg folate although this differs from Codex STAN 72-1981. It is unclear whether allowing for natural folate but not adopting the DFE units would make any difference. We are seeking further information from stakeholders to inform future assessment.* *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 this list could be completed as part of this Proposal if relevant to infant metabolism. Both Standard 2.9.1 and Codex STAN 72-1981 specify a minimum amount of vitamin E per g of PUFA. 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 LA 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.* *Niacin: We consider it is appropriate to retain the requirement for niacin amount in infant formula to be limited to the form pre-formed niacin.* **Nestlé Comment:** Nestlé supports exclusion of β-carotene from the total amount of vitamin A however would suggests the units of µg RE should be used which is aligned to Codex STAN 72-1981. Nestlé supports that units for folate should be µg folic acid since folic acid is the usual form in infant formula. Nestlé supports adopting mg α-TE and the conversion factors in section S1-5. Also retaining the minimum amount of 0.5mg vitamin E per g PUFA in an infant formula. Nestlé supports retaining the current requirements for niacin.

	Permitted range for micronutrients: minimum and maximum amounts • Aligned with Codex • Could be aligned with Codex • Uncertainty whether alignment is appropriate	7.3	**FSANZ Preliminary View:** *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 the Codex standard is similar, with both setting minimum amounts and either a maximum amounts or a GUL for the same range of micronutrients although the actual minimum and maximum amounts may vary.* *Aligned with Codex: We propose to retain the current minimum and maximum amounts for both vitamin A and vitamin D, which are already aligned with Codex STAN 72-1981.* *Could be aligned with Codex: Our preliminary view is 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. However, whether to align the amounts for phosphorus requires further consideration.* *Uncertainty whether alignment is appropriate: Further information is sought from stakeholders to inform further assessment for vitamin C, chromium, molybdenum, iodine, zinc, iron and selenium.* *For phosphorus, it is FSANZ's preliminary view is 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. We also propose to adjust Standard 2.9.1 to align with the minimum Ca:P ratio of 1:1.* **Nestlé Comment:** Nestlé supports alignment of minimums, maximum or GULs with Codex STAN 72-1981 for all vitamins and minerals except iron where Nestlé supports retaining the current requirements for iron.
	Permitted forms	8	*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 shows there are some differences. FSANZ's preliminary views on the nutrient forms for the following individual vitamins, minerals and electrolytes are:* • *Vitamin A: Retain the permitted forms of vitamin A, providing alignment between the Code and Codex. However, we seek further information on the justification to retain β-carotene as a provitamin A form in Standard 2.9.1.* • *Vitamin D: Retain the two permitted forms (i.e. both vitamin D3 (cholecalciferol) and vitamin D2 (ergocalciferol)).* • *Pantothenic acid: Not appropriate to permit DL-panthenol acid for use in infant formula. We are seeking further information and technological justification for calcium D-pantothenate and sodium D-pantothenate as forms suitable for use in infant formula.* • *Niacin: Not to permit nicotinic acid for use in infant formula* • *Copper: Seeking further information on the technological justification for the use of cupric carbonate in infant formula to inform further assessment.* • *Magnesium: Seeking further information on the technological justification for the use of magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric acid in infant formula to inform further assessment.* • *Potassium: Seeking further information on the technological justification for the use of potassium L-lactate in infant formula to inform further assessment.*

			• *Zinc: Seeking further information on the technological justification for the use of zinc lactate and zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate) in infant formula to inform further assessment.* • *Iron: Seeking further information on the technological justification for the use of ferric citrate, ferrous bisglycinate and ferrous sulphate in infant formula to inform further assessment.* **Nestlé Comment:** Nestlé supports alignment of permitted forms of vitamins and minerals with Codex CAC/GL 10-1979 and maintaining permitted forms already allowed in FSC S29-7.
Other optional substances	Choline	9.1	**FSANZ Preliminary View:** *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.* *Choline is now classed as an essential nutrient in the Australia and New Zealand Nutrient Reference Values; however there is no upper level. Our preliminary view is that choline should be listed as a mandatory substance in infant formula with a mandatory range of 1.7-12 mg/100 kJ. We are seeking information on the technological justification for the use of choline, choline citrate and choline hydrogen tartrate as permitted forms of choline in infant formula to inform further assessment.* **Nestlé Comment:** Nestlé supports the mandatory presence of choline with a minimum of 1.7 mg/100kJ. However, Nestlé considers that a GUL of 12 mg/100kJ should be adopted, aligned with Codex STAN 72-1981.
	L-carnitine	9.2	**FSANZ Preliminary View:** *Standard 2.9.1 permits L-carnitine as an optional substance, whereas Codex STAN 72-1981 prescribes the mandatory addition of L-carnitine. Our preliminary view is that L-carnitine should be listed as a mandatory substance in infant formula with a mandatory range of 0.3–0.8 mg/100 kJ. We are seeking information on the technological justification for the additional forms of L-carnitine (L-carnitine hydrochloride and L-carnitine tartrate) and evidence to demonstrate safety of these forms in infant formula to inform future assessment.* **Nestlé Comment:** Nestlé supports the mandatory presence of L-carnitine with a minimum of 0.3 mg/100kJ. However, Nestlé considers that no maximum should be adopted, aligned with Codex STAN 72-1981.
	Inositol	9.3	**FSANZ Preliminary View:** *Standard 2.9.1 and Codex STAN 72-1981 permit the same range 1.0–9.5 mg/100 kJ, although Codex lists inositol as a mandatory inclusion with a GUL. Our preliminary view is that it is appropriate to prescribe the mandatory inclusion of inositol in infant formula at the current minimum amount (which already aligns with Codex STAN 72-1981) and list a GUL of 9.5 mg/100 kJ. We also consider listing the permitted form of inositol as myo-inositol will provide clarity.* **Nestlé Comment:** Nestlé supports the mandatory presence of inositol with a minimum of 1.0 mg/100kJ and a GUL of 9.6 mg/100kJ, aligned with Codex STAN 72-1981 with the correct conversion applied.
	Nucleotides	9.4	**FSANZ Preliminary View:** *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 3.8 mg/100 kJ of nucleotide 5'*

			monophosphates". Codex STAN 72-1981 permits the addition of nucleotides at the discretion of national authorities. Comparison of the permitted forms of nucleotides in each standard shows they are already aligned. *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. We are seeking feedback on the clarity of the drafting in the revised Code.* **Nestlé Comment:** Nestlé supports retention of the current permissions and a maximum combined total limit of nucleotides when they are intentionally added.

Supporting Document 2: Safety and Food Technology

Topic and Specific Issues		Section in SD2	Preliminary View by FSANZ and Comments from Nestlé
Microbiological criteria	Microbiological Criteria for Infant Formula	2	**FSANZ Preliminary View:** *This issue is being considered in Proposal P1039 – Microbiological Criteria for Infant Formula, and therefore will not be considered as part of Proposal P1028. Proposal P1039 proposes that the existing microbiological limits for powdered infant formula (and follow-on formula) be replaced with microbiological food safety criteria for Salmonella and Cronobacter spp., based on the principles within Codex CAC/RCP 66-2008.* **Nestlé Comment:** Nestlé supports in full, the proposal within P1039.
Preparation, use and storage directions to manage microbiological hazards	Directions to prepare bottles individually	3.2	**FSANZ Preliminary View:** *FSANZ considers it is appropriate to retain the current labelling requirement for an instruction that each bottle should be prepared individually.* **Nestlé Comment:** Nestlé supports to retain the current labelling requirement that each bottle should be prepared individually.
	Directions for the storage of made up formula	3.3	**FSANZ Preliminary View:** *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.* **Nestlé Comment:** Nestlé supports this view, to allow for refrigerated storage of reconstituted powdered infant formula (PIF) up to a maximum of 24 hours. However we request additional regulatory clarity, such that ANY time period, *up until* 24 hours for refrigerated storage, is allowed.
	Directions on water used to reconstitute	3.4	**FSANZ Preliminary View:** *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*

	powdered infant formula		*feeding guidance. FSANZ is therefore proposing to maintain this labelling requirement as one of a group of risk reduction strategies.* **Nestlé Comment:** Nestlé supports to maintain the requirement to use cooled previously boiled water.
	Discarding leftover formula	3.5	**FSANZ Preliminary View:** *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, and the WHO powdered infant formula guidelines.* **Nestlé Comment:** Nestlé supports this view.
	Standardised directions for preparation and use	3.6	**FSANZ Preliminary View:** *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. FSANZ proposes to maintain the existing overarching requirement, which does not prescribe the words and pictures for the instructions.* **Nestlé Comment:** Nestlé supports maintaining the current directions for preparation and use, and does not support additional prescription on the words and pictures for preparation.
Other safe preparation and storage issues	Date marking of food	4.1	**FSANZ Preliminary View:** *FSANZ is unaware of any specific issues concerning date marking for infant formula. It is proposing to maintain the existing requirement that the label must carry a date mark.* **Nestlé Response:** Nestlé supports the continued use of a date mark.
	Storage instructions for opened infant formula	4.2	**FSANZ Preliminary View:** *The Code requires the infant formula label to contain storage instructions covering the period after the package is opened. No issues have been raised by stakeholders and the current approach aligns with Codex STAN 72-1981 specifications. Therefore, FSANZ is proposing to maintain the existing requirement.* **Nestlé Comment:** Nestlé supports to maintain the existing requirement.
	Measuring scoop	4.3	**FSANZ Preliminary View:** *There is concern from stakeholders that some caregivers unintentionally use the wrong measuring scoop (for the particular product) to prepare powdered infant formula. Unintentional over-concentration or dilution of infant formula can have acute and chronic negative health effects for the infant.* *Although there is some evidence that caregivers may misuse the scoop in some way during preparation of infant formula, there is little evidence that this is a result of confusion or lack of understanding of the current labelling instructions. Without stronger evidence of a problem there is limited rationale to consider further the suggestion to standardise the scoop size. Also, standardisation of the scoop size would require all products to have the same powder density, and would present a number of technical challenges and require widespread reformulation of products. There is likely to be significant cost associated with reformulating products to achieve a standardised powder to water ratio for all products.* *Similarly, consideration of mandating the statement "that only the enclosed scoop should be used" may not be justified given the lack of evidence of a problem. FSANZ notes that some industry stakeholders*

			said they would not oppose this change, if there was evidence to justify the change. All products surveyed on the Australian and New Zealand retail market currently include the statement about using the enclosed scoop on the label, and the majority use the exact wording only the enclosed scoop should be used. **Nestlé Comment:** Nestlé supports the inclusion of that statement *only the enclosed scoop should be used* – where a package contains a measuring scoop. The inclusion of this statement is already the current status quo. Nestlé do not support the idea of a standardised scoop – it would not be technically possible to standardise powder density across different recipes and across different manufacturers.
Other safe preparation and storage issues	Inaccurate volume indicators on infant feeding bottles	4.4	**FSANZ Preliminary View:** *There is concern that volume indicators on some infant feeding bottles available in Australia and New Zealand are not accurate. Use of these indicators to measure the volume of water to prepare formula may lead to errors in the ratio of water to powder used, and result in the infant formula being either over-concentrated or excessively diluted. Unintentional over-concentration or dilution of infant formula can have acute and chronic negative health effects for the infant.* *FSANZ acknowledges the issue of inaccurate volume measure indicators on some infant feeding bottles sold in Australia and New Zealand. As infant feeding bottles are regulated as general consumer goods they are not covered by the Code, and as they are not solely for the purpose of feeding infant formula to infants, this issue is outside the scope of this Proposal and will not be considered further by FSANZ.* **Nestlé Comment:** Nestlé consider this is beyond the scope, and not within the remit, of FSANZ and the infant formula manufacturers.
Warning, advisory and other statements	Legibility requirements for warning statements	5.1	**FSANZ Preliminary View:** *FSANZ has not identified any evidence to indicate that the current legibility requirements for infant formula requirements are inadequate, and proposes to maintain the existing requirements set out in Standard 2.9.1*. **Nestlé Comment:** Nestlé supports the existing requirements.
	Adding other foods to formula	5.2	**FSANZ Preliminary View:** *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.* *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.* *FSANZ search of the literature suggests that this may be common practice, though it is not possible to estimate the prevalence of this behaviour. Options to communicate to caregivers that other foods should not be added to infant formula may need to be considered.* *FSANZ is seeking stakeholder comments on three questions to inform further analysis on this issue.* **Nestlé Comment:** Nestlé does not have evidence that would estimate the prevalence of caregivers adding other foods to infant formula in Australia and New Zealand. Insights to date would not warrant any additional warning or advisory statements for situations of potential misuse.

	Statement on protein source	5.3	**FSANZ Preliminary View:** *The Code requires the infant formula label to contain a statement of the specific source, or sources, of protein in the product.* *FSANZ does not consider that there is a need to mandate a list of permitted protein sources for declaration on the label, as protein quality and quantity are regulated in the Code for health and safety reasons.* *We are proposing to maintain the current requirement to label the protein source as it ensures correct identification of products suitable for infants with particular dietary requirements.* **Nestlé Comment:** Nestlé supports maintaining the status quo.
	Co-location of protein source statement with the name of the food	5.4	**FSANZ Preliminary View:** *The Code requires the mandatory statement about protein source to be located immediately adjacent to the name of the infant formula (i.e. the prescribed name 'Infant Formula'). The Code does not prescribe where the prescribed name (and by association, the protein source statement) should be located on the label. Preliminary analysis suggests there is a lack of regulatory clarity on this issue. We are proposing to maintain the existing requirement, and will consider how to make it clearer in the Code that the name of the food is the prescribed name. Also, we are seeking further information from stakeholders to assess whether the position of this information on the label should be prescribed.* **Nestlé Comment:** Nestlé supports maintain the existing requirement. Prescription of position/location of the statement is not warranted.
	Warning statement about following instructions exactly	5.5	**FSANZ Preliminary View:** *The Code requires that the labels of infant formula display warnings about following the instructions exactly to ensure the correct preparation of the powdered, concentrated, or 'ready-to-drink' formula. The wording of these warning statements is prescribed. A few stakeholders suggested to either amend the existing statement on following instructions exactly, or to require an additional warning statement that discouraged this practice.* *There is anecdotal evidence that while some caregivers do not follow instructions exactly when preparing formula, this is often a deliberate practice to address infant hunger and prolong sleep (not related to a misunderstanding of label statements). Several submissions noted there is evidence that suggests a high level of compliance with the information on the preparation of infant formula in general. There is no evidence to show that the current statement influences whether the instructions are followed by caregivers.* *At this stage, we are not proposing any changes to this requirement.* **Nestlé Comment:** Nestlé supports maintaining the existing requirement. Additional warning statements to anticipate this situation of potential misuse is not warranted.
	Warning statement that 'breast is best'	5.6	**FSANZ Preliminary View:** *The Code requires an infant formula label to contain the prescribed warning statement: Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice. Some stakeholders support amending the statement to a risk-based statement about the risks to infant health of not breastfeeding. Others are opposed to a risk-based statement approach.* *FSANZ recognises the body of evidence supporting the importance of breastfeeding for infants. However, we consider there is sufficient rationale to retain the existing 'breast is best' statement.*

			Nestlé Comment: Nestlé supports maintaining the current 'breast is best' statement.
	Statement that infant formula product may be used from birth	5.7	**FSANZ Preliminary View:** *The Code requires a statement indicating that the infant formula product may be used from birth, in the case of infant formula. We are of the view that the statement remains relevant and is proposing to maintain the requirement.* **Nestlé Comment:** Nestlé supports maintaining the existing requirement.
	Statement about age to offer foods in addition to formula	5.8	**FSANZ Preliminary View:** *The Code requires a statement on infant formula labels indicating that infants over the age of 6 months should be offered foods in addition to the infant formula product. This statement is consistent with current Australian and New Zealand infant feeding guidance, and with Codex.* *We consider this labelling statement is appropriate and propose to maintain this requirement.* **Nestlé Comment:** Nestlé supports maintaining this requirement. However, in light of the outcomes of Proposal 274 - Review of minimum age labelling of foods for infants, we suggest the statement should be re-worded to be "around" the age of 6 months. This wording is also aligned to the NHMRC Infant feeding guidelines, and the NZ MoH Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2).
	Guidance statement about additional vitamin and mineral supplementation	5.9	**FSANZ Preliminary View:** *The Guidelines attached to Standard 2.9.1 (S29—10 in the revised Code) 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.* *Background information is provided on the issue and gaps in the evidence base are identified. We are seeking further information to consider the relevance of the advice in the context of public health and safety, and the regulatory and non-regulatory options available to address this issue.* **Nestlé Comment:** Nestlé supports maintaining it as a voluntary statement.
	Prescribed name	5.10	**FSANZ Preliminary View:** *'Infant Formula' is a prescribed name, and the Code requires the label on a package of food to include the prescribed name of the food if one is prescribed. The requirement to use the prescribed name 'Infant Formula' was put in place to alert consumers to the appropriate formula choice for infant age and stage.* *We consider the prescribed name 'Infant Formula' is appropriate and propose to maintain this labelling requirement.* **Nestlé Comment:** Nestlé supports maintaining the current prescribed name.
Nutritive substances and novel foods in infant formula		6	**FSANZ Preliminary View:** *FSANZ is currently undertaking work on the regulation of nutritive substances and novels foods under Proposal P1024 – Nutritive Substances and Novel Foods. Proposal P1028 will consider the regulation of nutritive substances and novel foods in infant formula, as infant formula products are excluded from the scope of P1024. FSANZ will consider the basis for requiring pre-market assessment of new substances for use in infant formula, and subsequently the procedure and information required to determine the safety and the nutritive or health benefit of these substances.* *Background information is provided on the intent of the Code, problems with the current definitions of nutritive substance and novel food, the differing interpretations of the provision for nutritive substances naturally present in an ingredient, stakeholder views, ministerial policy guidance, and international and overseas approaches.*

			The review of the regulatory approach for the addition of new substances to infant formula will progressively develop over the course of P1028. At this stage, we are seeking input on the principles for the overarching regulatory approach. **Nestlé Comment:** Nestlé considers that the framework for this as captured by P1024 is appropriate for infant formula products, however with some caveats relevant to infants the consuming population that will need to be mapped out in greater detail. Nestle does not support that all ingredients need to go through a FSANZ pre-market assessment pathway, as this is a more restrictive approach compared to the current status quo, which will restrict future innovation. There has been no evidence of market failure.
Contaminants	Acrylonitrile	7.2	**FSANZ Preliminary View:** *The ML for acrylonitrile of 0.02 mg/kg applies to all foods, including infant formula, and is listed in the general contaminants standard (Standard 1.4.1). The intent is that the MLs in Standard 1.4.1 apply to infant formula as a default if a specific contaminant is not specifically listed in Standard 2.9.1.* **Nestlé Comment:** Nestlé supports maintaining the ML for Acrylonitrile.
	Aluminium	7.3	**FSANZ Preliminary View:** *FSANZ considers it is appropriate to retain a ML for aluminium. We propose to set an ML of 0.05 mg/100 mL to apply to all infant formula. However we are seeking information from stakeholders on the feasibility of this for soy-based infant formula.* **Nestlé Comment:** Nestlé is proposing the removal of Aluminium ML for Infant Formula.
	Arsenic	7.4	**FSANZ Preliminary View:** *There is no current ML for arsenic (inorganic) or 'arsenic, total' in the Code for infant formula.* *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. Therefore, we see no specific need to establish an ML for arsenic (inorganic) for infant formula in the Code. This approach is consistent with Codex.* **Nestlé Comment:** Nestlé supports that there is no need to establish an ML for inorganic arsenic for infant formula.
	Lead	7.5	**FSANZ Preliminary View:** *The Code includes an ML for lead of 0.02 mg/kg in infant formula. We are proposing to lower the ML for lead to 0.01 mg/kg in infant formula in view of the withdrawal of the PTWI by JECFA and the recent adoption of the lower level by Codex.* **Nestlé Comment:** Nestlé supports the lowering of the Lead ML to 0.01 mg/kg.
	Melamine	7.6	**FSANZ Preliminary View:** *No MLs have been established for melamine in the Code. However, Codex has an ML for melamine in powdered information formula of 1 mg/kg and liquid infant formula (as consumed) of 0.15 mg/kg.* *Based on the absence of any associated risk, and that the Codex ML was specifically set to control illegal adulteration of infant formula, there is no rationale for the incorporation of the Codex ML for melamine into the Code.* **Nestlé Comment:** Nestlé propose that based on the safety risk, a ML for Melamine is not needed.
	Tin and inorganic tin compounds	7.7	**FSANZ Preliminary View:** *The Code includes an ML of 250 mg/kg for tin in all canned foods. Codex takes a similar approach, with a ML of 250 mg/kg for 'canned foods (other than beverages)'.*

			We consider there is no case for the exception of infant formula per se from the scope of the tin ML in the Code. Also, the general contaminant definition for tin as a metal in Standard 1.4.1 should be applied to infant formula. **Nestlé Comment:** Nestlé supports maintaining this ML for tin.
	Vinyl chloride	7.8	**FSANZ Preliminary View:** *The Code includes a ML of 0.01 mg/kg for vinyl chloride in all foods except packaged water. Codex has established a GL for vinyl chloride that is identical to the ML in the Code. We consider the current ML for vinyl chloride remains relevant, and no amendment to the level in the Code is considered necessary.* **Nestlé Comment:** Nestlé supports maintaining the ML for Vinyl Chloride.
	Location of MLs in the Code	7.9	**FSANZ Preliminary View:** *FSANZ proposes to consolidate all MLs for contaminants in Standard 1.4.1, including those set for infant formula.* **Nestlé Comment:** Nestlé supports consolidating all MLs for contaminants in Standard 1.4.1.
	Concentration units for infant formula MLs	7.10	**FSANZ Preliminary View:** *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/100 mL. While FSANZ proposes to consolidate all MLs for contaminants in Standard 1.4.1, the consistency of expression of these MLs is yet to be determined.* *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.* **Nestlé Comment:** Nestlé suggests that the ML for infant formula apply to the form as sold, whether powder or liquid. Nestlé prefers that limits for contaminants should be expressed as either 'mg/L' or 'mg/kg' rather than as mg/100 mL which is not aligned with international practice.
	Contaminant definition	7.11	**FSANZ Preliminary View:** *The current MLs in the Code do not usually specify a contaminant definition. As this may lead to confusion as to the nature of the analyte for which testing is applicable, it may be useful to include contaminant definitions for some of the metals relevant to infant formula for clarity.* *We are 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.* **Nestlé Comment:** Nestlé supports the FSANZ preliminary view that a definition of 'contaminant' may not be necessary and in any case should be considered as part of a proposed future review of Standard 1.4.1.
Food additives	Aligning food additive permissions in the Code with Codex: • acidity regulators • Citric and fatty acid	8.2	**FSANZ Preliminary View:** *We are considering whether to align the food additive provisions in the Code with those of Codex for ease of trade. If the Code were to align 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.* *Additional and extension of food additive permissions: Codex lists 14 food additives that are not currently permitted as food additives for use in infant formula in the Code. These are 12 acidity regulators, as well as citric and fatty acid esters of glycerol, and starch sodium octenyl succinate.*

	esters of glycerol • Starch sodium octenyl succinate • Updates to nomenclature and INS numbers • Changes to maximum permitted levels:		• *12 acidity regulators: As well as use as food additives, the 12 acidity regulators could also be used as processing aids or as permitted forms of minerals in the manufacture of food. Therefore, FSANZ is seeking information on how these substances are used in the manufacture of infant formula.* • *Citric and fatty acid esters of glycerol: FSANZ could consider an extension of use for these food additives as part of future work within this Proposal if there was justification for the use, and information provided in submissions to enable an assessment.* • *Starch sodium octenyl succinate: An extension of use is out of scope for P1028, as the Codex permission relates to hydrolysed protein-based infant formula products.* *Updates to nomenclature and INS numbers: There are some inconsistencies in nomenclature and INS numbers used in the Code and Codex. To align the Code with Codex would have flow on consequences for other food categories, and therefore will not be considered further under this Proposal. We may prepare a proposal at a later date to address this issue.* *Changes to maximum permitted levels: To align with Codex the MPL for hydroxylpropyl starch for use in soy-based infant formula would need to be lowered from 25000 to 5000 mg/L, singly or in combination.* **Nestlé Comment:** Nestlé supports aligning permissions for food additives with Codex STAN 72-1981. These additives have been demonstrated to have a technological justification and safety has already been considered by JECFA. Updates to nomenclature and INX numbers may be addressed in a future proposal.
	Carry-over principle for food additives and infant formula	8.3	**FSANZ Preliminary View:** *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, we consider that the carry-over principle should not apply to infant formula.* **Nestlé Comment:** Nestlé suggests that the status quo be maintained.
	Clarifications to the Code • Carrageenan permission for liquid soy-based infant formula Permitted starches, removal of qualification statements	8.4	**FSANZ Preliminary View:** *Carrageenan: 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.* *FSANZ is aware that there is some confusion about whether the subcategories of infant formula are mutually exclusive. We are seeking information from interested parties in relation to their interpretation of the current permissions, the current use of carrageenan and whether changes are required to ensure permissions reflect the expectation.* *Permitted starches: Remove the qualification statement that subclause 6(1) of Standard 1.3.1 applies, as it automatically applies for all four of the starches.* **Nestlé Comment:** Nestlé considers that carrageenan is permitted in both milk-based and soy-based liquid infant formula.
Processing aids	Comparison between Code and Code permissions	9.2	**FSANZ Preliminary View:** *We are not aware of any issues relating to the permissions for processing aids in the Code for the manufacture of infant formula. Accordingly, we are not considering any changes to Standard 1.3.3 or processing aids in the manufacture of infant formula under P1028.*

			Nestlé Comment: Nestlé supports maintaining current practice for processing aids.
Other issues raised by stakeholders	Issues to be addressed during further consideration of P1028	10.1	**FSANZ Preliminary View:** *The statements on dental fluorosis will be considered in a future report for P1028. The issue of fluoride will be considered from a risk assessment perspective, and the related statements will be considered based on the outcome of this assessment.* **Nestlé Comment:** Nestlé supports this approach.
	Issues that will not be considered further in P1028	10.2	**FSANZ Preliminary View:** *Issues that will not be considered further in P1028 include certain suggested advisory statements (e.g. that formula is not sterile, statement for aluminium content), and declaration of forms of vitamins and minerals.* **Nestlé Comment:** Nestlé agrees that these topics should not be considered further.

Supporting Document 3: Provision of information

Topic and Specific Issues		Section in SD3	Preliminary View by FSANZ and Comments from Nestlé
Provision of information	Claims about ingredients	2.1	**FSANZ Preliminary View:** *There appears to be a lack of regulatory clarity in the Code about ingredient claims on packaged infant formula. We are seeking stakeholder views on whether there is a regulatory gap and if requirements should be specified in the Code for such claims when used in relation to infant formula.* **Nestlé Comment:** Nestlé 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.
	Declaration of permitted nutritive substances	2.2	**FSANZ Preliminary View:** *The intent of labelling requirements in Standard 2.9.1 is to prohibit the declaration of nutritive substances unless certain conditions are met (e.g. minimum and maximum amount), and to limit where a permitted nutritive substance can be declared on a label (i.e. the statement of ingredients or the nutrition information statement).* *We recognise there is potential for ambiguity in the current Standard and will seek to make the intent clear in the drafting of the revised Standard.* **Nestlé Comment:** Nestlé supports that average quantity declarations are based on the nutrients complying with minimum and maximum criteria. The current Regulations (FSC 1.2.7 and FSC 2.9.1) clarify these are restricted to the statement of ingredients or nutrition information statement. When drafting the revised Standard, Nestlé suggests that FSANZ consider the need for informed choice for the caregiver, and whether permissions to provide additional information to the caregiver may be introduced.
	Nutrition declaration requirements	2.3	**FSANZ Preliminary View:** *Standard 2.9.1 sets out the nutrients that must appear in the nutrition information statement and how this information is to be expressed. In addition to the mandatory nutrition information for the macronutrients protein, fat and carbohydrate, many infant formula companies also voluntarily declare subgroups*

			of macronutrients (e.g. omega-3, whey and/or casein) in the nutrition information statement. Where information is provided voluntarily, it is considered to constitute a claim, which is prohibited for infant formula. *We are considering whether macronutrient subgroups should be permitted to be declared in the nutrition information statement for packaged infant formula, and are seeking stakeholder views and evidence to support the assessment of this issue.* **Nestlé Comment:** Nestlé views are that the declaration of macronutrient subgroups are currently permitted in FSC 2.9.1, do not constitute a claim, and should continue to be permitted within a Nutrition Information Panel. Such information is necessary, in the current restrictive void of available information, to allow for product differentiation and informed choice for caregivers.
	Inter-relationship between declarations in the nutrition information statement and the ingredient list	2.4	**FSANZ Preliminary View:** *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).* *The purpose of these two labelling elements differs, and FSANZ is not aware of evidence to suggest confusion among caregivers and health professionals about this label information. However, we are seeking any evidence to demonstrate confusion, and stakeholder views on whether the names of ingredients should align with nutrient declarations in the nutrition information statement on packaged infant formula.* **Nestlé Comment:** Nestlé does not support a need for the names of ingredients to align 'exactly' to the nutrient declarations in the nutrition information statement. Manufacturers should be permitted to label for the permitted forms (for vitamins and minerals).
	Base units of expression	2.5	**FSANZ Preliminary View:** *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.* *The pros and cons of expressing the nutrition information as sold, in addition to the current requirement, are discussed. We are seeking further information from stakeholders on the merits of additional base units of expression that differ from the current requirement, and whether the declaration of these base units should be mandatory or voluntary.* **Nestlé Comment:** Nestlé supports the current voluntary approach. Per 100g as an additional expression is useful for shared labels with Codex countries however our view it is has limited use domestically. For liquids, we highlight that per 100mL is currently expressed as a minimum. Note - We are not aware of liquid *concentrates* being commercially available on the retail market.
	Average amount	2.6	**FSANZ Preliminary View:** *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').*

			We are seeking comment on the impacts of changing the declaration from 'average amount' to 'average quantity' in the Code. **Nestlé Comment:** Nestlé supports the proposal to change to Average quantity for consistency purposes.
	Format of the nutrition information statement	2.7	**FSANZ Preliminary View:** *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.* *Stakeholder views, current industry practice, information for caregivers, and the impact on trade and supply is considered. FSANZ is seeking further information to be able to make a full assessment of this issue.* **Nestlé Comment:** Nestlé supports the status quo rather than a mandated regulatory approach which we consider is not warranted in the absence of evidence of a clear benefit for the caregivers. A mandated format of the nutrition information panel would also create a barrier to trade.
	Notification of product reformulation	2.8	**FSANZ Preliminary View:** *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.* *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.* *We are interested in whether there are alternative approaches to alert caregivers that an infant formula has been reformulated.* **Nestlé Comment:** Nestlé supports that caregivers are appropriately informed about the specific changes in product composition.
	Nutrition content claim and health claim prohibition	2.9	**FSANZ Preliminary View:** *The Code is clear that a nutrition content claim or health claim must not be made about an infant formula (product).* *We believe that the issue of whether to permit claims on infant formula labels should, at first, be considered within the policy arena, particularly given the recent consideration of voluntary nutrition content claims through Proposal P293 and the relevant ministerial policy guidance.* **Nestlé Comment:** Nestlé considers that such permissions do not contravene Policy guidelines or the WHO Code and its local adaptations. We propose that FSANZ considers the breadth of Policy interpretation, and that it is not limited by a restrictive interpretation.
Other issues raised by stakeholders	Issues out of scope for P1028	Attachment A	**FSANZ Preliminary View:** *Issues relating to trademarks, line marketing, proxy advertising and online marketing are considered out of scope for P1028.* **Nestlé Comment:** Nestlé agrees these issues are out of scope of P1028.

APPENDIX II: COMPARISON TABLE of CONVERSION FACTORS USED In INFANT FORMULA PRODUCTS (kJ TO kCAL)

INFANT FORMULA		CODEX 2007				FSANZ Current		FSANZ Proposed P1028		Nestlé 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	3.0	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	6.0	4.18
	g/100kJ	1.05		1.4		1.05	1.5	1.05	1.4	*1.1*	*1.4*	
Linoleic Acid C18:2 n-6	mg/ 100 kcal	300	4.286	1400 GUL	4.242					300	*1400 GUL*	4.18
	mg/100kJ	70		330 GUL						*72*	*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*	
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*	0.10	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*	

INFANT FORMULA		CODEX 2007				FSANZ Current		FSANZ Proposed P1028		Nestlé Proposed Value		
Nutrient	**Units**	**Min**	**Conversion factor**	**Mas**	**Conversion factor**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**	**Conversion factor**
Vitamin D	mcg/100kcal	1	4.000	2.5	4.167			*1.045*	*2.508*	1.0	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	5.0 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*	4.0	27 GUL	4.18
	mcg/100kJ	1		6.5 GUL		1	5 Guideline	1	6.5 GUL	*0.96*	*6.5 GUL*	
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*	7.0	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*	4.0	40 GUL	4.18
	mg/100kJ	1		9.5 GUL		1	9.5	1	9.5 GUL	*0.96*	*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*	-	0.84	2.1	4.18
	mg/100kJ	0.1		-		0.2	0.5	0.2	0.5	*0.20*	0.50	

INFANT FORMULA		CODEX 2007				FSANZ Current		FSANZ Proposed P1028		Nestlé 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*	5.0	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*	1.0	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	*6.0*	*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*	*43*	
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*	0.50	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*	1.0	9.0 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	*0.29*	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									5.7		
L- Cysteine, cystine	mg/100kcal	38								38		4.18
	mg/100kJ					6				9.1		
Histidine, L-	mg/100kcal	41						41		41		4.18
	mg/100kJ					10		10		*10*		
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		

INFANT FORMULA		CODEX 2007				FSANZ Current		FSANZ Proposed P1028		Nestlé Proposed Value		
Nutrient	Units	Min	Conversion factor	Max	Conversion factor	Min	Max	Min	Max	Min	Max	Conversion factor
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		*7.9*		
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	
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