Nestlé Submission
Call for Submissions

Proposal P1028 - Infant Formula

17 June 2022

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Call for Submissions1 2022: Proposal P1028 - Infant Formula

This submission is made on behalf of Nestlé Australia Ltd and Nestlé New Zealand Ltd ("Nestlé").

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.

Comments

A L (+) Lactic Acid Producing Microorganisms (Section 5.4)

Nestlé strongly does not support the following preferred options set out in P1028 CFS1:

- to retain the existing permission, however clarify that L (+) lactic acid producing microorganisms may only be added for acidification purposes
- that all microorganisms added to infant formula products for a probiotic purpose require pre-market assessment as a novel food prior to use, effectively meaning 'post-market' assessment for those currently in use

Although earlier permissions in regulation were for acidification, Nestlé questions whether the existing permission in FSC Standard 2.9.1 was intended only for acidification purposes based upon:

1. location of the permission within the Food Standards Code
2. permission for viable microorganisms in powdered infant formula products[1]
3. developments in international regulations around this time[2,3]

Nestlé does not agree that all L (+) lactic acid microorganisms are novel foods. In addition to

[1] Australia New Zealand Food Standards Code - Standard 1.6.1 - Microbiological Limits for Food (Federal Register of Legislative Limits F2009C00366)

[2] Scientific Committee on Food. (2003) Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae. CF/CS/NUT/IF/65 Final

[3] Report of the 24th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses.(2002) ALINORM 03/26A Appendix II

the general information provided in the INC response, Nestlé provides specific information for *Bifidobacterium lactis* CNCM I-3446 and *Lactobacillus reuteri* DSM 17938 which are currently used in Nestlé infant formula products.

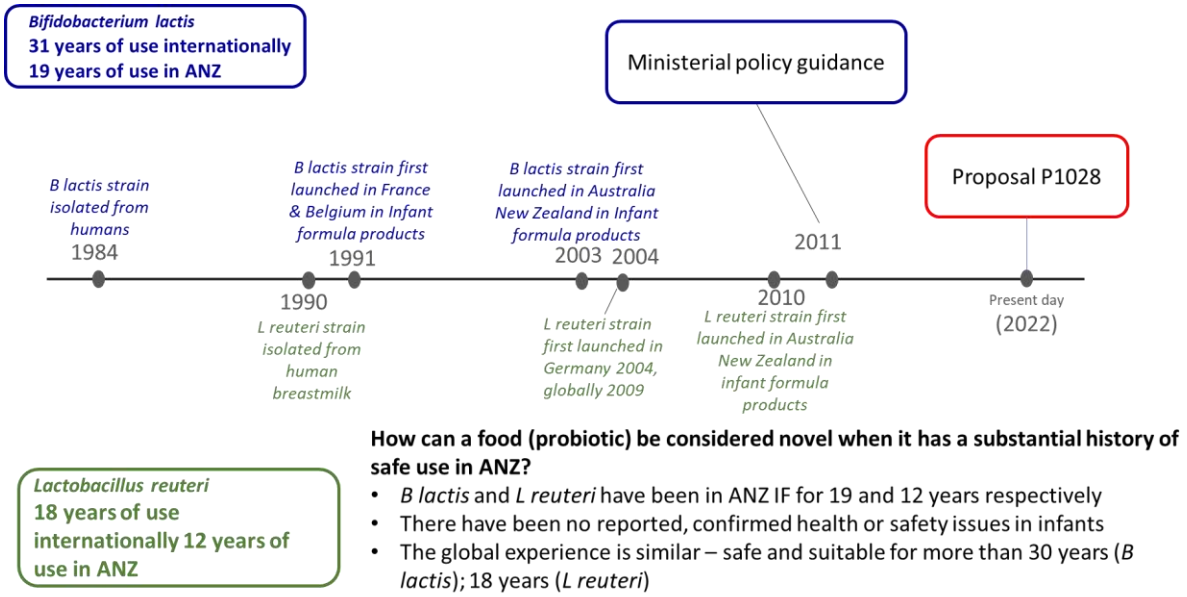
1. *Bifidobacterium lactis* CNCM I-3446 and *Lactobacillus reuteri* DSM 17938 **cannot be considered novel** as they have an extensive history of safe use in foods including infant formula products in Australia (AU), New Zealand (NZ) and international markets (Figure 1) and comply with the Code.

2. *Bifidobacterium lactis* CNCM I-3446 and *Lactobacillus reuteri* DSM 17938 are well characterised and have been scientifically demonstrated to be safe and beneficial.

3. There is no documented evidence of risk arising from use of these probiotics in infant formula products in the AU and NZ markets or any other market, and

4. Determining these ingredients as **novel and requiring post-market assessment** is likely to severely disrupt the AU and NZ infant formula products market, potentially leading to supply issues.

Figure 1 – Timeline showing introduction of *B lactis* and *L reuteri* into AU, NZ and global markets



<u>Use in Nestlé Infant Formula Products</u>

Nestlé incorporates these probiotics in its AU and NZ NAN® infant formula products (IFP) range:

- *Bifidobacterium lactis* CNCM I-3446 (*B lactis*) in Supreme, Supremepro and Optipro IFP
- *Lactobacillus reuteri DSM 17938 (L reuteri)* in Comfort, SensiPro, AR, LI IFP

<u>*B lactis* and *L reuteri* comply with the present Code</u>

Nestlé is of the view that *B lactis* and *L reuteri* comply with the present Code, as Standard 2.9.1 Infant Forumula Products clause 2.9.1-6 states that L (+) lactic acid producing organisms may be add to IFP. There is no further qualification or restriction to limit lactic acid producing microorganisms that have probiotic properties.

Also, Standard 1.5.1 requires pre-market assessment of novel microorganisms whereas *B.lactis* and *L.reuteri* are not considered novel. In addition to traditional use in foods, bifodobacterium spp. and lactobacillus spp. are present in human milk and have been present in fermented infant formula products. Manufacturers have been adding L (+) lactic acid producing probiotic organisms to AU and NZ IFP, safely, for almost 20 years.

History of safe use

B lactis and *L reuteri* have a substantial history of safe use in the Australia (AU) and New Zealand (NZ) markets and are therefore not novel.

Recognition as 'not novel' in infant formula products

B lactis and *L reuteri* have been in Nestlé Infant Formula Products in Australia for 19 and 12 years respectively, and there have been no reported, confirmed health or safety issues in infants. (Figure 1 - Timeline showing introduction into AU and NZ and global markets)

There has been no concern raised by Australian or New Zealand regulatory authorities with respect to compliance with the Code, safety or suitability during the period these products have been in the AU and NZ market.

The global experience is similar, where these products have been considered safe and suitable for more than 30 years (*B lactis*); 18 years (*L reuteri*).

There has been extensive published literature on both safety and beneficial effect for both *B lactis* and *L reuteri.*

Recognition as 'not novel' in the general food supply

B lactis and *L reuteri* have a history of safe use and consumption in the general food supply, where they are included in many fermented foods including yoghurt, sauerkraut, kefir, kimchi and sourdough bread. The Advisory Committee on Novel foods (ACNF) convened by FSANZ has determined *B lactis* and *L reuteri* as not novel. The record of views from the ACNF includes:

Bifidobacterium lactis (probiotic bacteria) 2008	• Traditional food • Not novel food	Long history of use in yogurt and fermented milk products.
Lactobacillus reuteri (NCIMB 30242 strain) 2013	• Traditional food • Not novel food	History of consumption *L. reuteri* in general population. *L. reuteri* NCIMB 30242 is a strain that is present in, and consistent with the characteristics of the *L. reuteri* species as a whole. View is for NCIMB 30242 strain only.

There is no documented evidence of risk arising from use of *B lactis* or *L reuteri* in IFP in the AU and NZ or other markets

FSANZ risk assessment in P1028 CP1 SD2 2021 included several studies that used these two probiotics in IFP and which made the following conclusion:

"in healthy full term infants infant formula supplemented with non-pathogenic and non-toxigenic L and DL lactic acid producing microorganisms does not present a risk to the public health and safety for healthy full term infants"

Nestlé is unaware of any documented evidence of risk to infant health and safety arising from the presence of *B lactis* or *L reuteri* in IFP in the AU and NZ markets.

Review of Nestlé international NutriVigilance[4] data does not suggest that there is evidence of risk to infant health and safety arising from the presence of *B lactis* or *L reuteri* in IFP in the AU, NZ or international markets.

[4]https://www.anses.fr/en/content/everything-you-need-know-about-nutrivigilance-scheme

Use of *B lactis* and *L reuteri* predates Ministerial policy guidance

Nestlé's view is that requiring post-market assessment on the basis of Ministerial Policy guidance is not justified or reasonable, as the sale of IFP incorporating of *B lactis* and *L reuteri*

a) commenced in 2003 and 2010 respectively, and predates publication of the 2011 policy guidance,
b) complied with the Standard at that time, and
c) have, and continue to have, a substantial history of safe use in global markets

The clear history of safe use of *B lactis* and *L reuteri* nullifies the threshold criterion of 'does not have a history of safe use' set by the Ministerial policy guidance.

FSANZ references the Ministerial Policy Guideline on the Regulation of Infant Formula Products[5] as requiring pre-market assessment of any substance proposed to be used in infant formula products.

Specific Policy Principle - Composition (i) states

i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that:

i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand

Nestlé's view is that requiring post-market assessment on the basis of Ministerial Policy guidance is not justified or reasonable, as the sale of IFP incorporating of *B Lactis* and *L reuteri* commenced in 2003 and 2010 respectively, and these probiotics have a substantial history of safe use in global markets.

That is, the demonstrated history of safe use **nullifies** the threshold criterion '*does not have a history of safe use'* set by the Policy and should not be required to have post-market assessment.

International recognition of probiotics

The European Union (EU), Codex, USA and numerous other jurisdictions permit the addition of probiotics in IFP.

a) **EU:** Most probiotic-containing infant formula comprise *Bifidobacterium spp*. and/or lactic acid bacteria such as *Lactobacillus spp*., which are generally regarded as safe for food use in the European Union based on the QPS-list (Qualitative Presumption of Safety) of bacteria.[6] The probiotics used by Nestlé are present in the QPS listing.

   The use of probiotics is not explicitly regulated by specific laws in the EU, however the use of probiotics in Infant Formula and Follow-On Formula is supported by Article 3 to Regulation (EU) 2016/127, which states that 'other ingredients may be added to IF and FoF where their suitability for infants from birth has been established by generally accepted scientific data'. Article 3 indicates that such suitability shall be demonstrated through systematic review. The probiotics used by Nestlé are both supported by systematic review done at strain level.

b) Codex: Codex Standard 72-1981 permits the use of L (+) lactic acid producing cultures as optional ingredients.

[5] Policy Guideline on Regulation of Infant Formula Products, 2011
[6] Salminen, S., *et al,* 2020. Infant Formula Supplemented with Biotics: Current Knowledge and Future Perspectives. Nutrients 2020, 12, 1952; doi:10.3390/nu12071952

Codex draft Follow-on Formula Older Infants (at step 7)[7] states:

> The safety and suitability of the addition of specific strains of L (+) lactic acid-producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.

c) **USA**: In the United States, a non-mandatory system of safety evaluation is in place, provided by the U.S. Food & Drug Administration (FDA). On request, it evaluates safety assessment filings of specific probiotic strains to be included in the so-called GRAS (Generally Recognized as Safe) Notice Inventory, which is continuously updated.[6]

Probiotic strains used by Nestlé in the USA have notified as GRAS for use in infant formula products.

<u>Conclusion regarding requirement for post-market assessment</u>

It is Nestlé's view that the probiotics *B lactis* and *L reuteri* **do not require post-market assessment** as:

1. They are **not novel** as they have a **history of safe use** in infant formula products and in the general food supply
2. There is no documented evidence of risk arising from use of *B lactis* or *L reuteri* in IFP in the AU and NZ market or any other market
3. They are internationally recognised, and
4. They comply with the present Code.

<u>Infant Formula Product market implications if post-market assessment is mandated for *B lactis* and *L reuteri*</u>

a) Nestlé products are well established in the market and any disruption or market uncertainty, such as a need for post-market assessment of an existing product, carries with it a significant risk.
b) Australia and New Zealand would be out of step with international Standards and markets – which already recognise and approve probiotics in general and *B lactis* and *L reuteri* in particular, in infant formula and follow-on formula.
c) Overall, should post-market assessment of probiotics already in the AU and NZ markets proceed, disruption of the market is highly likely, with significant ongoing implications such as potential supply issues.

<u>Closing statement</u>

1. Nestlé asserts that *B lactis* and *L reuteri* are not novel, as they are proven to be safe and have a history of safe use in AU, NZ and globally. They comply with the present Code.
2. Requiring post-market assessment without evidence of risk is unwarranted and carries significant market and infant health and safety consequences.
3. The requirement for post-market assessment of *B lactis* and *L reuteri* should be removed from Proposal P1028.

[7] Report of the 42nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses. (2021) REP22/NSFDU Appendix III Draft Follow-up Formula for Older Infants at Step 7

B Special Medical Purpose Products for Infants

Section 2: Regulatory Framework

Nestlé does not support the regulatory framework as presented in P1028 CFS1 however believes that it can be developed further.

Nestlé's principal concern is the inclusion of foods for special medical purpose for infants within SMPPi that have not previously been considered within the consultation process. An infant formula product (IFP) means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant. The Code does not specifically include a definition of Infant Formula Product for Special Dietary Use (IFPSDU) however the Policy Guidelines for Infant Formula Products describes them as:

Infant formula products for special dietary uses refers to products specifically formulated to meet the dietary needs of:

• premature or low birth weight infants; or

• infants with metabolic, immunological, renal, hepatic and malabsorptive conditions.

There are other foods for special medical purpose that do not meet this definition, and which have not otherwise been considered. We suggest that these products remain regulated in Standard 2.9.5. to ensure that infants who need these products to thrive continue to have access to products imported from overseas, particularly from Europe or USA.

Nestlé does not agree with the modified infant formula products as presented. These products are formulated for the dietary management of infants with a functional gastrointestinal condition, often a transient condition, and are based on generally accepted scientific evidence. These products should be used following advice from a healthcare professional.

A healthcare professional would advise use of these products when an infant has presented with symptoms, and the use of such products is recommended to ease discomfort and ensure that the infant continues to thrive. It is important that these products are readily identified by a statement "For the Dietary Management of" to minimise self-selection. Also, it is suggested that there is a clear statement (important notice) regarding use only on the advice of a healthcare professional on the pack. These conditions tend to occur more frequently than for example, inborn errors of metabolism, hence it is likely to add further distress to a parent or carer to limit these products to sale in pharmacy only. Further, limiting to pharmacy is likely to reduce retail competition which may result in increased consumer pricing with minimal change to the opportunity for self-selection.

Section 8: Special Medical Purpose Products for Infants

Nestlé does not agree with the preferred approach of FSANZ as set out in P1028 CFS1 where a **Special Medical Purpose Product for infants** means a food that is

(a) specially formulated for the dietary management of infants

(i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and

(ii) whose dietary management cannot be completely achieved without the use of the food; and

(b) intended to be used under medical supervision; and

(c) represented as being

(i) a food for special medical purposes intended for infants; or

(ii) for the dietary management of a disease, disorder or medical condition in infants.

In previous consultations, we have interpreted the FSANZ consultation on Infant Formula Products for Special Dietary Use (IFPSDU) to include those products which are intended to replace infant formula products used by formula fed healthy infants and bovine human milk fortifier (HMF). In our response to P1028 CP3 2021, Nestlé did not agree with FSANZ proposed approach to include bovine HMF in Standard 2.9.1. Nestlé suggested that any subsequent provisions relevant to FSMP for infants, excluding IFPSDU, that are needed in Standard 2.9.5 should be considered as part of P1028.

Nestlé is particularly concerned that previous consultations have not taken into consideration the range of nutritionally incomplete special medical purpose products for infants. The consequences of this oversight to continuity of supply could create a serious health risk.

Nestlé strongly suggests further targeted consultation with manufacturers of these products ahead of P1028 CFS2.

Nestlé **does** support FSANZ preferred approach to retain the regulation of IFPSDU in Standard 2.9.1, as retaining the status quo maintains all IFP which are sole source of nutrition for infants in a single standard. This Standard collates the many essential matters pertaining to IFP.

8.1 Composition

General nutrient composition

Nestlé supports FSANZ preferred approach that the compositional requirements for SMPPi are flexible enough to ensure undisrupted access to these special medical purpose products, as the wellbeing and sustenance of infants rely on their availability.

In order to avoid any unintended restrictions for import and supply from international manufacturers, and consequential health risks, deviation from the Australia New Zealand Food Standards Code IFP composition requirements for healthy infants must be allowed. These should not be limited to deviations for special medical purpose. Specifically, the deviations from baseline compositional requirements should alternatively be able to meet the mandatory compositional requirements set out in:

- Codex Standard 72-1981 Infant Formula and Formulas for Special Medical Purposes Intended for Infants Part B; or
- EU 2016/128 as regards the specific compositional and information requirements for food for special medical purposes

Composition for premature or low birthweight infants

Nestlé supports FSANZ preferred approach not to propose specific nutrient composition for SMPPi formulated for premature or low birthweight infants. Products for premature or low birth weight infants will differ from baseline composition prescribed in 2.9.1, where this deviation is required to meet the specific nutritional purpose.]

Nestlé IFPSDU recipes for premature and low birthweight infants, where they deviate from the compositional requirements for healthy infants, are based on peer review scientific evidence e.g. ESPGHAN Guidelines[8] and, where appropriate, additional clinical studies.

[8] Agostoni C, *et al* for the ESPGHAN Committee on Nutrition: Enteral nutrient supply for preterm infants: Commentary from the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition Committee on Nutrition. J Pediatr Gastroenterol Nutr 2010; 50: 85–91.

Other Composition

Nestlé supports FSANZ preferred approach:

- to allow manufacturers to tailor the manganese content of SMPPi where appropriate to meet the formula's special medical purpose or to comply with international regulations.
- that the compositional requirements noted in section 2.9.1—15 are no longer required
- to include a permission for the addition of MCT to SMPPi
- to include a permission for the addition of molybdenum and chromium to SMPPi to address the products medical purpose

Nestlé is very concerned that the absence of permissions for specific forms of nutrients may result in unintended risks to supply which could have negative health outcomes for these vulnerable infants. This has occurred previously leading to P1046 L-amino acid acetate in Food for Special Medical Purposes.

Instead, Nestlé would suggest reference to the permitted forms allowed for:

- FSMP for infants and young children in CAC/GL 10-1979 Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children
- Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control Official Journal L 181, 29.6.2013, p. 35–56.

Measuring scoop for SMPPi

Nestlé supports FSANZ preferred approach so that SMPPI, where needed, may deviate from the measuring scoop requirement.

Food additives

Nestlé agrees with FSANZ that permissions for food additives may differ substantially from IFP depending on the specific disease, disorder or medical condition the product is intended for and the product matrix. The description of SMPPi is broader than IFPSDU and as such previous consultations will not have considered all requirements. Permissions would need to align with or reference:

- CXS 192-1995 categories 13.1 for infant formula products and FSMPs for infants is sub-category 13.1.3
- EU 2008/1333 category 13.1.5.1 for FSMPs from birth (additives for standard infant formula and follow on formula are permitted); and 13.1.5.2 for FSMPs from 6 months of age to 3 years)

If FSMP for infants are to be included in SMPPi, then consideration is also required to ensure that qualification notes/conditions for SMPPi in Table 5.1 do not overly restrict permissions to a narrow range of medical conditions or product matrices.

8.2 Labelling

Application of Standard 2.9.5 labelling requirements

Nestlé supports FSANZ preferred approach to apply the Standard 2.9.5 labelling requirements to SMPPI as listed below:

- the requirement to label food as 'genetically modified' in section 1.5.2—4
- inner packages in subsection 2.9.5—8(3)
- transportation outers (in subsection 2.9.5—8(4)
- mandatory labelling information in section 2.9.5—9

- mandatory statements and declarations in section 2.9.5—10 (a) – (f)
- nutrition labelling requirements in subparagraphs 2.9.5—13(b)(i) and (ii)
- a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

Also that the labelling requirements from Standard 2.9.5 that would not apply are:

- name of business address in section 1.2.2—4
- characterising ingredients and components in Standard 1.2.10
- nutrition information requirements in subparagraphs 2.9.5—13(b)(iii) or (iv)
- requirements for claims in relation to lactose and gluten content in sections 2.9.5—14 and 15 and the existing conditions for 'lactose free' and 'low lactose' for IFP (see section 5.1 of SD3).

FSANZ has presented its preferred option remains to adopt 2.9.5-9 however has not specifically stated whether this includes 2.9.5-11 and 2.9.5-12, although these were both included in the preferred options presented in P1028 CP3, 2021. Nestlé strongly supports the approach to apply 2.9.5-11 and 2.9.5-12 as in FSANZ preferred position from 2021.

2.9.5-11 Information relating to ingredients—food for special medical purposes

(a) a statement of a statement of ingredients; or
(b) information that complies with Articles 18, 19, 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or
(c) information that complies with 21 CFR § 101.4

2.9.5-12 Date marking information—food for special medical purposes

1. *For paragraph 2.9.5—9(1)(f), the required date marking information is date marking information in accordance with Standard 1.2.5.*
2. *Despite subsection (1), for subparagraph 1.2.5—5(2)(a)(ii), the words 'Expiry Date', or similar words, may be used on the label.*

Also, Nestlé supports the labelling permissions in 2.9.5-14(4) and 2.9.5-15(5) which form part of the provision included in 2.9.5-9.

Nestlé agrees that if the food is represented as being suitable for use as a sole source of nutrition, then a statement to the effect that the food is not for parenteral use should be included on the label.

Nestlé does not support applying the provision in paragraph 2.9.5—10(1)(g)(ii) as described in P1028 CFS1. We agree with additional statements for products that are the sole source of nutrition indicating:

- the nutrient or nutrients which have been modified for the medical purpose, and
- unless provided in other documentation about the food - whether these modified nutrients have been increased, decreased or eliminated from the food, as appropriate.

However, we do not agree that these additional statements should apply to all nutrients that vary from the baseline compositional requirements for IFP in Standard 2.9.1 and Schedule 29. As described in relation to composition, SMPPi should be able to deviate from baseline composition in Standard 2.9.1 and Schedule 29 for IFP where these deviations are to comply with mandatory limits in Regulation EU 2016/128 or CXS 72-1981.

Nestlé supports the FSANZ proposed approach that the generic requirements in subsections 2.9.5—10(2) and (3) relating to advisory or warning statements about the presence of bee

pollen, propolis, guarana and aspartame and the declaration of allergens should apply to SMPPi.

Nutrition Information

Nestlé supports FSANZ preferred approach to apply 2.9.5-13 (a) and (b)(i) to SMPPi without the specific format requirements for nutrition information proposed for IFP labels. This approach would provide flexibility to accommodate the differing overseas nutrition labelling requirements on imported products and ensure products for this vulnerable group can continue to remain available.

Nestlé supports a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

Nestlé is concerned that other information in the nutrition statement on shared labels of specialist products which may be present as a result of requirements in international markets may be considered nutrition claims.

Nutrition and health claims

Nestlé does not agree that the Policy Guideline on Infant Formula Products applies to all SMPPi as described in P1028 CFS1, only to those that are within scope. The SMPPi category as described in P1028 CFS1 now includes products that do not meet the definition "nutritionally adequate to serve as the principal liquid source of nourishment for infants".

Nestlé agrees that nutrition and health claims should not be permitted on infant formula products for special dietary uses that are nutritionally adequate to serve either as a sole source of nutrition or as the principal liquid source of nourishment for infants.

Nestlé supports that where the lactose or gluten content is a feature of the SMPPi formulation, this information would be provided in the statement describing the properties or characteristics which make the food appropriate for the medical purpose and in the nutrition information statement.

Application of Standard 2.9.1 labelling requirements

Nestlé supports FSANZ preferred option which is to:

• not apply prescribed names 'Infant formula' and 'Follow-on formula' in section 2.9.1—17

• not apply a prescribed name for SMPPi

• exempt SMPPi from warning statements for IFP in subsection 2.9.1—19(1)

• exempt SMPPi from age-related statements for IFP in subsection 2.9.1—19(4)

• not apply the protein source statement in accordance with paragraph 2.9.1—23(1)(a)

• not apply provisions relating to prohibited representations for IFP in section 2.9.1—24

• for directions for preparation and use, requirements in paragraph 2.9.5—9(1)(g) will prevail over requirements for IFP in subsection 2.9.1—19(3).

C Infant Formula Products

Section 5: Safety and Food Technology

5.1 Food additives

Nestlé is unable to support the current FSANZ proposal for only two food categories in the Code for food additive permissions, being 13.1.1 Infant formula products and 13.1.2 SMPPi, due to the lack of consideration of the inclusion of foods for special medical purpose (FSMP) for infants within SMPPi. Nestlé would support this approach if FSMP for infants other than infant formula products for special dietary use were excluded.

If FSMP for infants are to be included in SMPPi, then consideration is also required to ensure that qualification notes/conditions for SMPPi in Table 5.1 do not overly restrict permissions to a narrow range of medical conditions. And maximum limits are aligned with:

- CXS 192-1995 categories 13.1 for infant formula products and FSMPs for infants is sub-category 13.1.3
- EU 2008/1333 category 13.1.5.1 for FSMPs from birth (additives for standard infant formula and follow on formula are permitted); and 13.1.5.2 for FSMPs from 6 months of age to 3 years)

Nestlé requests that FSANZ consider additives that continue to be permitted for use in Follow-up Formula for Older Infants internationally[9] in a similar manner to the assessment that was completed for infant formula and infant formula products for special dietary use.

Section 6: Nutrient Composition

Units of Measure

Nestlé does not agree that the FSANZ approach to overcome technical calculation errors identified in the nutrient composition specified in Codex Stan 72-1981, will be achieved by aligning with the minimum or maximum values in this Standard stated per 100kJ.

Instead, Nestlé suggests aligning with the units as stated per 100kcal multiplied by 4.18. This will correct many of the conversion errors we are aware of in Codex Stan 72-1981. Nestlé notes that the draft Codex FUFOI has adopted a similar approach.

There is no nutritional detriment to taking this approach however there are many practical advantages. For example, a batch of product which meets the Codex per100kcal limits for a nutrient may be rejected for Australia and New Zealand if it does not also meet the per100kJ limits. This not only adds cost but could impact supply.

Infant Formula Products

Nestlé generally supports FSANZ proposed nutrient composition for infant and follow-on formula in Table 1 from CFS1 SD 2. Nestlé has made comment by exception and refers to the INC submission for further details and noted inconsistencies.

6.1 Infant Formula

Protein source

Nestlé agrees that protein sources used in the manufacture of infant formula products must be demonstrated safe, suitable and support normal growth and development, while also not interfering with absorption of other essential nutrients. Nestlé prefer maintaining the status

[9] Codex draft Follow-up Formula for Older Infants at Step 7 (Appendix IV REP22/NSFDU Report of the 42nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses

quo. Novel foods are already required to undergo pre-market approval, this includes novel sources of protein (section 1.1.2-8 and section 1.1.1 – 10 (6)).

Nestlé highlights that a new protein source with no additional purpose than to deliver the protein quality and quantity should not be expected to demonstrate any additional benefit beyond normal growth and development of a healthy infant. This would hamper innovation.

Amino acids

Nestlé supports FSANZ preferred option to align the minimum amounts of all amino acids with Codex Stan 72-1981. Nestlé also supports defining the ratio of methionine to cysteine and for tyrosine to phenylalanine in Schedule 29 and continuing to permit L-amino acids only for the purposes of meeting protein quality. This approach ensures regulations do not inadvertently lead to the unnecessary addition of individual amino acids.

In addition, the wording of the additional note regarding the methionine to cysteine ratio should include the option for clinical evaluation of the suitability for formulas with methionine to cysteine ratios greater than 2. This is consistent with both Codex Stan 72-1981 and EU Regulation 2016/127.

Docosahexaenoic Acid (DHA)

Nestlé supports retaining the current voluntary permission for DHA, EPA and AA addition to infant formula, also the AA maximum and AA/DHA and EPA/DHA ratios. Nestlé supports replacing the current maximum for long chain omega-3 series fatty acids, with a DHA GUL, however prefers a higher GUL of 12mg/100kJ, which is within the range reported in breast milk of 0.06-1.4%.[10] The proposed GUL of 7.2mg/100kJ would mean that some products currently on market have a declared values that would exceed this or at least exceed the proposed GUL when considering manufacturing and analytical tolerances.

Phospholipids

Nestlé supports setting a GUL or maximum permitted amount of phospholipids at 2g/L (72mg/100kJ) however we do not support a lecithin maximum of 1g/L.

Lecithin is currently permitted for use in infant formula products as a food additive in Std 1.3.1 and Schedule 15 at a maximum of 5000mg/kg (5g/L). Nestlé proposes that this limit is retained and that an inconsistency is not introduced into the Code. Any concerns relating to phospholipids from lecithin would be directly addressed by the restriction to the phospholipid content.

L-carnitine (GUL: 0.8 mg/100 kJ)

Nestlé does not consider it necessary to set a GUL for L-carnitine. If a GUL is set, then this should take into account the natural variability of L-carnitine content in differing milks, to provide flexibility for manufacturers and to avoid trade barriers.
Nestlé also notes the following;

- ESPGHAN[11] concluded that no maximum level needed to be set as there are no indications of any adverse effects of higher L-carnitine intakes in infants.
- Setting any limit is not aligned with international regulations.
- The contribution from the natural variability of the content of some dairy ingredients used in infant formula is likely to result in the GUL being exceeded.

[10] Brenna *et al.* Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. Am J Clin Nutr. 2007 Jun;85(6):1457-64. doi: 10.1093/ajcn/85.6.1457. PMID: 17556680.
[11] Koletzko *et al*. Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group. J Pediatr Gastroenterol Nutr. 2005 Nov;41(5):584-99.

6.2 Follow-on Formula

Protein Range (Milk Proteins)

Nestlé does not support the proposed minimum of 0.43g/100kJ for milk based follow-on formula. It appears that FSANZ did not take into consideration A1173 – Minimum protein in follow-on formula in P1028 CFS1 (2022). Nestlé understands that this was an oversight and will be revised to align with the outcome of A1173 to include the minimum protein for milk-based follow-on formula of no less than 0.38g/100kJ. Nestlé notes that this minimum should be applied to milk-based follow-on formula.

Vitamin D

Nestlé does not support FSANZ proposed maximum for vitamin D of 0.63ug/100kJ. Nestlé notes that the maximum for follow-on formula in the more recent EU regulations and the draft revised Codex Standard for FUF is 0.72 µg/100kJ. Maintaining this maximum does not allow for recipe harmonisation with international jurisdictions, particularly the EU. A product formulated under the EU and Food Standards Code requirements would require a vitamin D range of 0.48 – 0.63mg/100kJ. This range is too narrow and does not allow for raw material, analytical and processing variability. This lack of international alignment of the proposed maximum creates a barrier to trade. Nestle supports the adoption of the Codex and EU maximum of 0.72 µg /100kJ to allow for recipe harmonisation.

Nutritive Substances

Nestlé supports FSANZ preferred option to retain the existing voluntary permissions for Choline, L-carnitine, Myo-Inositol, Taurine, Nucleotides, Lutein, 2'-fucosyllactose and Lacto-N-neotetraose in Schedule 29 and references the INC response for further comment.

Section 7: Labelling

7.1 Safety & Technology

Nestlé supports FSANZ's preferred options in SD1 in relation to:

- Directions for preparation and use (8.2)
- Standardised wording or pictures for directions for preparation and use (8.3)
- Date marking (8.4)
- Storage instructions (8.5)
- Legibility requirements for warning statements (8.6)
- 'Breast milk is best for babies' warning statement (8.8)
- Statement that infant formula product may be used from birth (8.10)
- Statement that FoF should not be used for infants aged under 6 months (8.11)
- Statement about age to offer foods in addition to formula (8.12)

Warning Statements About Following Instructions Exactly (8.7 Of SD1)

Nestlé supports FSANZ's preferred option to relocate the text in the warning statements relating to making up formula to the directions into the preparation instructions. We agree that the preparation instructions are the most appropriate location for a statement on not adding food to the infant formula product. For consistency with powdered and concentrated infant formula products, we would suggest amending this part of the statement for ready-to-drink infant formula products "not to dilute or add *other food* except on medical advice".

Nestlé also supports the FSANZ proposal to consolidate the warning statements for powdered, concentrated and ready-to-drink infant formula products.

Co-Location of Protein Source Statement with The Name of The Food (8.14 of SD1)

Nestlé supports the retention of the requirement for the co-location of the protein source statement and the name of the product. Also, we support clarification of the 'name of product' and that the protein source adjacent to the prescribed name is only required once on the label.

We note the preferred option to require this information in a prominent position on label and understand that part of the rationale is to ensure visibility of this information to caregivers of infants with allergies and intolerances. The protein source statement should not be the primary source of allergen information as it does not contain sufficient information to make safe choices for allergenic infants. Allergens may be present from other ingredients, which are bolded within the ingredients list and located in a summary statement as regulated by Standard 1.2.3.

7.2 Provision of Information

Declaration Of Nutrition Information

Format of the nutrition information statement

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

Nestlé supports some prescription to format for the nutrition information statement including:

- the inclusion of subheadings 'vitamins', 'minerals' and 'additional'
- the requirement for nutrition information (except energy) to be expressed as the 'average quantity' in the NIS, for consistency with Standard 1.2.8.
- clarification that the calculation method for average quantity in paragraph 1.1.1—6(3)(c) will not apply to IFP.

Nestlé requests that the NIS allows some flexibility to harmonise with other markets. IN particular, Nestlé does not support the FSANZ's preferred options on base units and scoop weight.

Base Units

Nestlé agrees with FSANZ to prescribe the base unit of expression (per 100ml) in the NIS. However, we strongly disagree that the voluntary use of other units of expression should be prohibited. This approach is not consistent with Codex CXS 72-1981 and EU 2016/127, which permit other units of expression, as appropriate.

Nestlé does not agree that inclusion of additional expressions would impact public health or confuse consumers as these are consistent with labelling of general foods and helpful to healthcare professionals. Further, in some circumstances, they may increase costs by restricting harmonised labels.

CXS 72-1981 requires the expression of units per 100g as sold for powdered infant formula products. Limiting the unit of expression to per 100ml will prevent harmonisation and hinder trade with markets that have adopted these Codex provisions. Nestlé New Zealand currently shares some infant formula product labels with Codex aligned markets.

Permission for other units of expression will additionally allow for information to presented as appropriate for individual products on a case-by-case basis. For example, ready to feed infant formula for use in hospitals are often in sizes less than 100mL and include units expressed per bottle/feed which are important in such settings for healthcare professionals to calculate the nutrition being provided. Nestlé notes that the 2021 product survey did not include any liquid products referring to additional nutrition information per feed size. Nestlé currently expresses nutrition information per 90mL on all of its liquid infant formula and per 70mL on pre-term liquid infant formula .

Scoop Weight

FSANZ proposes clarification that the nutrition information requirements for the weight of one scoop to be declared (if a powdered product), and the proportion of powder or concentrate required to reconstitute the formula according to directions to be declared (if a powdered or concentrated form of infant formula) must not be located in the NIS.

Nestlé supports maintaining the requirement to declare the weight of one scoop and reconstitution; however, Nestlé does not agree that it is necessary to prohibit this information to be declared in the NIS.
We note that the inclusion of this information is important to aid correct preparation, as well as being "*useful for health professionals when calculating the nutritional value of the formula when reconstituted according to directions on the label*" (section 4.3 of SD2). Therefore, we consider the NIS to be a logical position to position reconstitution information, as it provides the link between the product and the nutrition information expressed of per 100mL in the NIS.
Q2 How should the subheadings for 'Vitamins', 'Minerals' and 'Additional' be separated from other text (e.g. using lines, bolding)?

Nestlé understands that the rationale for including the subheadings 'Vitamins', 'Minerals' and 'Additional' is that grouping nutrients enables caregivers to make faster product comparisons. Whilst we agree with this approach, we do not agree that the format of the subheadings should be prescribed. As the inclusion of subheadings will already achieve the goal of grouping the nutrients, prescribing the format of the subheadings (e.g. using lines, bolding) does not bring additional benefit but adds cost and complexity for manufacturers.
Nestlé also does not agree with prescription for subheadings and prefers flexibility to separate nutrient groups.

Macronutrient sub-group nutrients in the nutrition information statement
FSANZ's preferred option is to include permission for the voluntary declaration of subgroups in the NIS specifically for 'Whey' and 'Casein' under 'Protein', and 'Docosahexaenoic acid', 'Eicosapentaenoic acid' and 'Arachidonic acid', indented under the sub-group nutrient heading 'Long chain polyunsaturated fatty acids'.
Nestlé supports the voluntary permission to declare macronutrient sub-group nutrients in the NIS to allow for informed choice for the consumers. However, Nestlé does not believe this should be limited to 5 nutrients. Whilst we agree that declaration of mandatory macronutrients such as linoleic acid and alpha-linolenic acid is unnecessary, permission to declare other macronutrient subgroups will encourage innovation and allow greater differentiation between products.
To better enable caregivers to make informed choices, we would suggest allowing flexibility to use common terms and abbreviations, especially for 'Docosahexaenoic acid', 'Eicosapentaenoic acid' and 'Arachidonic acid', to enable caregivers to better understand the label. The FSANZ study (Malek, Fowler, Duffy, & Katzer, 2019) described in SD3 indicated limited understanding of the NIS, therefore inclusion of consumer-friendly terms and abbreviations such as DHA/EPA/ARA may assist caregiver's understanding. Nestlé suggests taking a similar approach to Standard 1.2.8 (S12—3), which permits the subgroup 'polyunsaturated' under fats, and allowing flexibility in the declaration of the subgroups below this.

Inter-Relationship Between Declarations in The Nutrition Information Statement and The Statement Of Ingredients

Nestlé supports FSANZ's preferred option to maintain status quo and not align the declaration of ingredient names in the statement of ingredients and nutrient names in the NIS, for consistency with the Code.

Lactose free and low lactose formula

Nestlé advises that the FSANZ's proposed option to maintain existing specific labelling requirements for 'lactose free' and 'low lactose' IFP is not effective.

Previous advice from the Australian Competition and Consumer Commission (ACCC) is that 'free' claims mean 'no presence of'. Cow's milk protein based infant formula products that may be labelled 'Lactose Free' in other countries may contain trace levels of lactose and advances in analytical sciences mean that this lactose can be detectable. This limits the ability of manufacturers to use the term 'lactose free' and therefore communicate the lactose content of these powdered products to caregivers of lactose intolerant infants.
Infant formula products containing milk cows' protein for the dietary management of lactose malabsorptive conditions, will continue to be managed and labelled as other IFPSDU with the additional requirement to label the amounts of lactose and galactose expressed in g/100 mL and/or an equivalent statement "not suitable for infants with galactosaemia".

Partially hydrolysed formula

Q3 Without referencing specific conditions, how should partially hydrolysed formula be labelled to inform caregivers of the nature of the modification from other IFP?
Nestle supports FSANZ's view to require the words 'partially hydrolysed' to be labelled for partially hydrolysed formula. We would support the ability to communicate this within the protein source statement, ingredient list and the NIS.
Standard 1.2.4 requires ingredients to be identified using either a name by which the ingredient is commonly known, a name that describes the true nature of the ingredient or a generic name specified in Schedule 10. Therefore, the partially hydrolysed protein source should already be identified within the ingredients list.

REPRESENTATIONS

Claims about ingredients

Nestlé agrees that there is some confusion between nutrient, health and related claims, which are not permitted on infant formula products, and reference to specific ingredients. Nestlé suggests that clarification should be considered rather than new prohibitions. Also, these must continue to allow for reference to the term 'ingredients' as a generic term to allow for descriptions which are required to provide the consumer with a truthful and accurate representation of some products (e.g. organic ingredients)

In summary, we suggest clarification of existing requirements rather than introducing a new restriction.

Line Marketing

In the 2016 Consultation, 'line marketing' was described as the '*labelling of infant formula as stage 1, follow-on formula as stage 2 and toddler milk as stage 3".*

Infant formula product labels currently contain multiple elements indicating age suitability. These include stage numbers in addition to the legal name and age statement. Stage numbers have been used on infant formula and follow-on formula labels in Australia and New Zealand for decades. They are also widely used globally. Our strong view is that stage numbers assist caregivers in clearly distinguishing between infant formula and follow-on formula and:

(a) are simple and easy to recall; and
(b) can help caregivers to identify the correct product quickly, especially when making hurried subsequent purchases; and for partners, family and friends shopping on their behalf.

We note that SD3 mentions that "*Government submitters consider IF needs to be clearly distinguished from FOF and toddler milks to reduce the safety risks associated with the wrong formula being given to an infant*". Requiring the removal of stage numbers from labels could cause confusion for caregivers of formula-fed infants and increase the risks identified by Government submitters.

We also disagree with the views expressed by some submitters that 'line marketing' (i.e. the use of stage numbers on labels) gets around code restrictions on promotion of infant formula products. Nestlé is a signatory to both the MAIF Agreement in Australia, and the INC Code in New Zealand and we take our obligations under those codes very seriously. The inclusion of stage numbers (e.g. Stage 1 or Stage 2 or 1 or 2) on the front of labels is not viewed as promotional under the Marketing of Infant Formulas: Manufacturers and Importers (**MAIF**) Agreement. This was recently reviewed and considered by the Australian MAIF Complaints Committee in the context of Clause 5(a) of the MAIF Agreement, which provides that:

> "*Manufacturers and importers of infant formulas should not advertise or in any other way promote infant formulas to the general public."*

In December 2020, the MAIF Complaints Committee reviewed and revised its guidance on the interpretation of this clause 5(a), relating to information on appropriate age range information on infant formula labels. The MAIF Complaints Committee's guidance is published on the Australian Department of Health website[12]. It provides that the use of numbers (such as Stage 1 or Stage 2, or 1 or 2) on the front of an infant formula product label is acceptable, to further assist consumers in the identification of age appropriateness of the product. It also highlights label information which the MAIF Complaints Committee considers to be inappropriate under the MAIF Agreement, including the use of symbols and/or infographics showing all numbers and/or stages of the product's range, including highlighting where the product being purchased is in the range, and the use of arrows, triangles or flow chart-like symbols.

In response to SD3 noting several concerns raised by submitters that line marketing "*Leads consumers to perceive there are nutritional benefits in moving from Stage 1 to Stage 2*", we do not agree with the premise of this statement. There can be nutritional benefits of follow-on formulas for infants from 6 months, such as a lower protein level that follows the protein decline in breastmilk (FSANZ A1173 - Minimum protein in follow-on formula). Additionally, both infant and follow-on formula products are safe and suitable for infants between 6-12 months.

Nestlé believes that stage numbers should continue to be permitted on infant formula products, to assist caregivers to identify the correct product that is safe and suitable for their infant's age.

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

Data from the Australian Feeding Infants and Toddlers Study (OzFITS)[13], indicated no inappropriate use of follow-on formula or toddler milk drinks. OzFITS is the first Australia-wide cross-sectional survey of dietary intakes of children under two years of age, with 1140 participants surveyed between April 2020 and April 2021. Food records collected from 434

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[12] MAIF Complaint Committee's interpretation of Clauses 5(a) & 9(b) of the MAIF Agreement relating to information on appropriate age range on infant formula labels. See: https://www1.health.gov.au/internet/main/publishing.nsf/Content/B8D64A18E546D9FBCA257BF0001ACE26/$File/Guidance%20document%20-%20age%20range%20information.pdf

[13] Moumin, N.A.; Netting, M.J.; Golley, R.K.; Mauch, C.E.; Makrides, M.; Green, T.J. Usual Nutrient Intake Distribution and Prevalence of Inadequacy among Australian Children 0–24 Months: Findings from the Australian Feeding Infants and Toddlers Study (OzFITS) 2021. Nutrients 2022, 14, 1381. https://doi.org/10.3390/nu14071381

caregivers of infants between 0 – 11.9 months indicated no infants under 6 months consumed follow-on formula or toddler milks, and no infants between 6-11.9 months were consuming toddler milk drinks. This supports that current labelling of infant formula products informs caregivers of the safe and suitable infant formula product for their child's age.

Proxy Advertising

FSANZ has described 'proxy advertising' to be "where the presence of legitimate claims on formulated supplementary foods for young children (toddler milks) may influence caregivers' feeding decisions, for example choosing toddler milks over infant formula because the former were 'better'."

In relation to follow-on formula, Nestlé does not agree that the inclusion of factual information about follow-on formula products on the back of an infant formula label is promotional. The recent MAIF Complaints Committee's guidance also considered this, and provides that[14]:

(a) it is acceptable to include the brand name (in text) and the age appropriateness (in text and/or numbers) of other infant formula products in the same range on the back of an infant formula product label; however
(b) images and/or pack shots of other infant formula products in the range are not appropriate.

Nestlé is aligned with this the MAIF Complaints Committee's guidance. We also agree that pack shots and health claims relating to toddler milk drinks should not be included on infant formula product labels. However, information in text and numbers is factual and should be permitted.

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

SD3 references submitters stating research has identified that proxy advertising causes confusion between products. However, research indicates caregivers are using the appropriate infant formula product for their infant's age.

Data from the Australian Feeding Infants and Toddlers Study (OzFITS)[13], indicated no inappropriate use of follow-on formula or toddler milk drinks. OzFITS is the first Australia-wide cross-sectional survey of dietary intakes of children under two years of age, with 1140 participants surveyed between April 2020 and April 2021. Food records collected from 434 caregivers of infants between 0 – 11.9 months indicated no infants under 6 months consumed follow-on formula or toddler milks, and no infants between 6-11.9 months were consuming toddler milk drinks. This supports that current labelling of infant formula products informs caregivers of the infant formula product that is safe and suitable for their child's age.

FSANZ is also seeking information on how proxy advertising influences caregivers. SD3 references research by Berry and colleagues which suggests a potential for caregivers to associate information about toddler milks with infant formula products. However, these studies are limited by their sampling methodology, with small sample sizes such as 15 expectant mothers (Berry *et al*, 2010)[15] or convenience sampling (n = 439) in one city

[14] MAIF Complaint Committee's interpretation of Clauses 5(a) & 9(b) of the MAIF Agreement relating to information on appropriate age range on infant formula labels. See: https://www1.health.gov.au/internet/main/publishing.nsf/Content/B8D64A18E546D9FBCA257BF0001ACE26/$File/Guidance%20document%20-%20age%20range%20information.pdf

[15] Berry, N., Jones, S.C., Iverson, D., 2010. ''It's all formula to me'': women's understandings of Toddler Milk ads. Breastfeeding Review 17 (3), 21–30.

(Sydney) in one weekend (Berry *et al*, 2012)[16]. This means the results cannot be generalised into national public policy, and the findings firstly require validation in robust studies.

We note that the concern around the advertisement of toddler milk relates to the perceived potential to undermine breastfeeding by some submitters, however toddler milk advertising is not a reason that women reference as a reason they stop breastfeeding. A large study of 290 mothers in Queensland by Newby & Davies (2016)[17] found the most commonly cited reasons were:

1) Mothers feeling they didn't have enough milk;

2) Baby was perceived to have difficulty sucking or latching on;

3) Baby was perceived to have lost interest;

4) Breast milk alone was deemed to be insufficient for the baby; and

5) Health concerns such as pain with cracked nipples or bleeding.

Furthermore, breastfeeding rates have increased in Australia in recent decades, as reported in The Australian Infant Feeding Guidelines (2012)[18], published by the Australian Government and developed by the National Health and Medical Research Council (NHMRC). The guideline states - "*There have been significant increases in both the rate and duration of breastfeeding over the last few decades*" and that "*Australia has been successful in increasing breastfeeding rates over the last few decades…*". If such advertising did have a negative impact on breastfeeding rates, then this correlation should be visible in the statistics.

FSANZ Act assessment requirements (Section 9)

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

Nestlé generally agrees that the benefits will outweigh the costs in the longer term by maintaining a high level of safety and suitability, greater clarity and improved alignment with international requirements.

However, Nestlé does not agree that all of FSANZ's preferred approaches will achieve these goals as discussed above. Also, in the current economic climate, we do not foresee cost reduction however changes to achieve greater international alignment would be expected to lessen cost increases in the longer term.

2. Do you agree with FSANZ's summary of industry costs and that the main costs will be:
    a. one-off product reformulation to meet new domestic standards
    b. processes to further reduce contaminant levels, and
    c. one-off product label changes to meet new standards?

Nestlé does not agree that these are all the main costs if all of FSANZ's preferred approaches are implemented. In particular, we note that the requirement for all currently permitted L (+) lactic acid producing organisms to undergo pre-market assessment will add

[16] Berry, N., Jones, S.C., & Iverson, D (2012). Toddler milk advertising in Australia: Infant formula advertising in disguise? Australasian Marketing Journal. 20(1):24–27.
[17] Newby, R. M., & Davies, P. S. (2016). Why do women stop breast-feeding? Results from a contemporary prospective study in a cohort of Australian women. European Journal of Clinical Nutrition, 70, 1428–1432.
[18] National Health and Medical Research Council. Infant Feeding Guidelines. National Health and Medical Research Council: Canberra, 2012.

considerable extra costs to manufacturers and government. Further information is provided commercial in confidence.

Also, FSANZ has not considered that products listed in the Australian Pharmaceutical Benefits Scheme (PBS) or New Zealand Pharmac Pharmaceuticals Schedules may require notification of changes with associated costs.

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

Nestlé would like to highlight that the changes will require a suitable transition period to allow for reformulation, stability testing, labelling changes, manufacture and distribution, with some infant formula products having a 3-year shelf-life. Equally, it should be possible to move to a harmonised recipe immediately after gazettal where such a recipe is available.

Also, products may be listed in the Australian Pharmaceutical Benefits Scheme (PBS) or New Zealand Pharmac Pharmaceuticals Schedules which require notification of changes.

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

Nestlé believes that FSANZ has considerably underestimated the number of products available in Australia and New Zealand, not all of which would be available in retail. Hence the number of products impacted will be greater. Nestlé will provide further data commercial in confidence.