Nestlé Submission
in response to
Call for Submissions CFS2

Proposal P1028 - Infant Formula

7 July 2023

Nestlé Submission

Call for Submissions 2 2023: 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 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 formulated to an appropriate, recognised standard is the most 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.

Overarching Comments

Nestlé appreciate the considerable work that has gone into this proposal from FSANZ and all stakeholders.

Overall, Nestlé supports the draft Variation in Call for Submissions 2 with a number of amendments and clarifications as set out in our response below.

A L (+) Lactic Acid Producing Microorganisms (LAM) (Section 5)

At CFS1, Nestlé considered that the removal of permission to add LAM without evidence of risk was unwarranted, and carried significant market and infant health and safety consequences

Nestlé supports FSANZ amended approach to retain the current permission for the addition of LAM to infant formula products in 2.9.1—11**.**

Nestlé agrees that the addition of live non-pathogenic, non-toxigenic L- and DL-lactic acid producing bacteria such as *Bifidobacteria* and *Lactobacillus* does not pose a risk to public health and safety.

Nestlé notes that *Bifodobacterium* spp. and *Lactobacillus* spp. are present in human milk and have a long history of use in infant formula products[1,2]. Manufacturers have been adding

[1] Lyons KE, Ryan CA, Dempsey EM, Ross RP, Stanton C. Breast Milk, a Source of Beneficial Microbes and Associated Benefits for Infant Health. Nutrients. 2020 Apr 9;12(4):1039.
[2] Łubiech K, Twarużek M. Lactobacillus Bacteria in Breast Milk. Nutrients. 2020 Dec 10;12(12):3783.

living L (+) lactic acid producing micro-organisms to infant formula products in Australia and New Zealand for over 20 years and they are ubiquitous across the market.

The continued permission for addition of L(+) Lactic Acid Producing Microorganisms is aligned with Codex and consistent with the permissions in Europe, USA, China and numerous other international jurisdictions.

At CFS1, Nestlé considered that the removal of permission without evidence of risk was unwarranted and carried significant market and infant health and safety consequences.

Nestlé appreciates the further detailed consideration of the FSANZ risk assessment (2021) and the data provided in response to CFS1 and supports the outcome proposed by FSANZ in CFS2.

B Special Medical Purpose Products for Infants (SMPPi)

General

Nestlé supports the revised regulatory framework and definition for SMPPi. Limiting the regulatory framework and definition of SMPPi to infant formula products is consistent with the Policy Guidelines for Infant Formula Products and with the purpose of the review of the infant formula standard.

Nestlé considers that products which are formulated for the dietary management of infants should be used following advice from a healthcare professional, whether for inborn errors of metabolism, low birth weight or functional gastrointestinal conditions.

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 ensure that the infant continues to thrive. It is important that these products are readily identified by a statement indicating the medical purpose of the food and must be used under medical supervision, to minimise self-selection.

Restriction on the sale of special medical purpose products for infants

Nestlé continues to have reservations with regard to access for consumers with the introduction of a restriction on sale of special medical purpose products for infants.

Level of occurrence of functional gastrointestinal disorders

Functional gastrointestinal conditions tend to occur more frequently than inborn errors of metabolism. As FSANZ notes in SD4, it is common for around 50% of infants to experience functional gastrointestinal symptoms.[3] By way of comparison, according to the Metabolic Dietary Disorders Association, phenylketonuria effects 1:10,000, babies born in Australia.[4]

Functional gastrointestinal symptoms are not a reason to stop breastfeeding however dietary intervention may be one approach considered by a healthcare professional for formula-fed infants. Hence, many consumers will be impacted by these changes.

Shopper purchase patterns

In Australia, grocery outlets account for 44% of SMPPi volume sold whilst in New Zealand, this is 76%[5]. Limiting sales to pharmacy and majority sellers will have considerable impact on access. It cannot be presumed that the proportion of pharmacy outlets selling the products will increase hence in addition to potential price increases due to reduced

[3] Vandenplas, Y., *et al*. Prevalence and Health Outcomes of Functional Gastrointestinal Symptoms in Infants From Birth to 12 Months of Age. Journal of pediatric gastroenterology and nutrition, 2015 61(5), 531–537.
[4] https://www.mdda.org.au/diagnosis/pku/ accessed 26 June 2023
[5] IQVIA market research data 2023

competition, the distance travelled to purchase products may increase for many carers. Also, pharmacy opening hours are considerably shorter. Overall, this will add considerable inconvenience and potential costs to carers of infants who have been recommended these products by a medical professional.

Composition

Nestlé supports the FSANZ draft variation as it enables the compositional requirements for SMPPi to be flexible enough to ensure continuous and uninterrupted access to these special medical purpose products, thereby supporting the wellbeing and sustenance of those infants who rely on the availability of SMPPi.

Nestlé's SMPPi are formulated to meet the nutritional needs of infants with a diagnosed medical condition, disease or disorder. Nestlé's SMPPi recipes, where they deviate from the compositional requirements for healthy infants, are based on peer review scientific evidence e.g. ESPGHAN Guidelines[6] and, where appropriate, additional clinical studies.

The flexibility in compositional requirements permitted by Division 4 will allow Nestlé and other manufacturers of these products to harmonise formulations with 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

Schedule S29-23 Permitted forms of vitamins and minerals

Nestlé notes that Table to S29-23 (permitted forms of vitamins and minerals) includes IFP (IF, FoF, SMPPi) and asks if it is intentional that the forms of vitamins and minerals for SMPPi are specified (limited), given the overall flexibility for composition. This is a misalignment to 2.9.1-32 where it stipulates composition for vitamins, minerals and other essential substances as per S29-5 but it does not limit the permitted forms.

Schedule S29-9 Permitted forms of nutritive substances in infant formula and follow-on formula

Nestlé notes that the drafting of the Table to S29-9 has a subheading of "Infant formula products – substances permitted for use as nutritive substances which is inconsistent with the heading and is not stipulated in 2.9.1-32.

Labelling

Nestlé generally supports the variations proposed by FSANZ for SMPPi products in Division 4 which largely replicate the approach in Standard 2.9.5 but a number of concerns remain.

Nestlé does not support 2.9.1—37 (2) even though this approach is consistent with Standard 2.9.5. Nestlé notes that the requirements of F.S.C. 1.2.1-25 minimum size of type are not aligned to the presentation of mandatory information in information that complies with Articles 13 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 (a minimum text height of 1.2mm). This could impact access to SMPPi products where it is not viable to have unique labels.

Nestlé supports the mandatory statements and declarations required for 2.9.1-38 with the exception of 2.9.1-38(1)(g)(ii) discussed below.

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[6] 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 astroenterol Nutr 2010; 50: 85–91.

Nestlé does not support the provision in paragraph 2.9.1—38(1)(g)(ii) as described in the draft variation. We suggest an option that the additional statements for SMPPi in 2.9.1-38(1)(g)(ii), may be provided off-label.

Nestlé considers that the statements required under 2.9.1-38 (1)(g)(ii) should only be provided to Healthcare Professionals. Healthcare Professionals are best placed, in their professional capacity, to share information about nutritional modification with consumers/patients and provide the necessary context to the consumer/patient to satisfy any concerns that they may have.

Nestlé is concerned that other information in the nutrition statement on shared international labels of specialist products which may be present as a result of requirements in those markets and may be considered nutrition claims, for instance the amount of components of protein, carbohydrate and fat required by Commission Delegated Regulation (EU) 2016/128.

Nestlé supports the requirement for a nutrition information statement however does not support the current drafting of 2.9.1-41 as it may limit the use of shared labels, when other jurisdictions permit or even require more information to be provided in the nutrition information statement for SMPPi. We suggest further consideration of the requirements of:

- 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
- Code of Federal Regulations for Exempt Infant Formula

Examples where drafting revisions are needed:

A Nestlé suggests that 2.9.1-41 (c) is amended as follows:

(c) any other substance:

*(i) *used as a nutritive substance in that product; ~~and~~*

(ii) added to or removed from that product to achieve that product's intended medical purpose as described in the statement required by paragraph 2.9.1—38(1)(c).

Removal of the '*and*' from the end of 2.9.1-41 (c)(i) is suggested as this will allow for all nutritive substances to be included in the nutritional information statement for SMPPi, including those that may not be present to achieve the product's intended medical purpose e.g. taurine.

Another example of where amendment to 2.9.1-41 (c) may be necessary is when the lactose level has been modified for a nutritional purpose. This information should 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 in the form of lactose and galactose levels.

B Nestlé suggests that permission is given for information on osmolality or osmolarity and/or on acid-base balance when appropriate as CXS 72-1981.

C Infant Formula Products

Nutrient Composition (Section 7 and SD2)

Nestlé supports the revised FSANZ approach to overcome the technical calculation errors identified in the nutrient composition specified in Codex Stan 72-1981.

Nestlé supports FSANZ proposed nutrient composition for infant formula products in CFS2 Attachment A Variation to Standard 2.9.1 and Schedule 29 with the following exceptions:

Amino acids

Nestlé does not support the draft variation to Standard 2.9.1-6(4).

The draft variation to Standard 2.9.1-6(4) does not include the expressions for the summed minimums for tyrosine and phenylalanine and for methionine and cysteine as provided for by the CXS 72-1981 and draft standard for Follow-Up Formula for Older Infants (FuFOI). Nestlé does not agree with this omission as this would result in unnecessary addition of amino acids and create a barrier to trade whilst not being a safety concern.

Nestlé agree that protein quality should be controlled by amino acid minimums to ensure normal growth and development and excess protein is minimised so as to not stress the infant's waste nitrogen handling capacity. The minimum requirements for amino acids in infant formula and follow-on formula are based on 'typical' amino acid profiles of breast milk. Infant and follow-on formula needs to meet the minimum for each individual amino acid however for calculation purposes it should be permitted to add together tyrosine and phenylalanine and, also add together methionine and cysteine when the ratio of methionine and cysteine, in the formula, is less than 2:1. This minimises the quantity of excess naturally occurring amino acids and the desire not to fortify with unnecessary single L-amino acids.

CXS 72-1981, and similarly in the draft FuFOI, essential composition for protein includes the following footnote:

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

Commission Delegated Regulation (EU) 2016/127 provides a similar permission.

These expressions encourage levels and a ratio more closely in line with breast milk.

Achieving the cysteine minimum is not achievable with some milk proteins without the addition of the single amino acid which is not necessary, will add cost and complexity. For example, naturally occurring amino acids in cows' milk exhibit a profile where cysteine is below the proposed minimum and methionine is above. Using the sum, cows' milk will typically meet the summed requirement without the need to fortify with additional amino acids. The use of the ratio ensures there is sufficient methionine to act a precursor to be converted into cysteine.

Nestlé supports alignment of the minimums for amino acids with Codex Stan 72-1981 and the draft Codex Standard for Follow-Up Formula for Older Infants.

Follow-on Formula

Vitamin D

Nestlé does not support FSANZ proposed maximum for vitamin D of 0.63ug/100kJ for follow-on formula.

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 the lower maximum limits the opportunity for recipe harmonisation with international jurisdictions. For example, a product shared by countries that have adopted the EU limits and Food Standards Code requirements would require a vitamin D range of 0.48 – 0.63µg/100kJ. This range is narrow and does not allow for raw material, analytical and processing variability. Nestle supports the adoption of the draft Codex FuFOI and EU maximum for follow-on formula of 0.72 µg /100kJ

to allow for recipe harmonisation.

Nestlé notes that the FSANZ consideration of the EFSA updated UL for Vitamin D for infants was for infant formula (CP2 2021). EFSA (2018) revised the UL for older infants from 25 µg/day to 35 µg/day. And determined that older infants consuming both FoF containing the maximum amount of vitamin D of 3 µg/100kcal (0.72 µg/100kJ) and fortified foods would not exceed the upper level. Also, the addition of Vitamin D is not permitted in infant foods in Australia and New Zealand and there are limited fortification permissions of foods for the general population. Thus, reducing the likelihood still further of exceeding a safe level.

Safety and Food Technology (Section 6 and SD1)

Food additives

Nestlé **supports** the proposed variations to:

- Standard 1.3.1—Food Additives
- Schedule 8—Food additive names and code numbers

Nestlé **supports** the proposed variations to Schedule 15—Substances that may be used as food additives Tables 13.1 and 13.1.1 with the exceptions in the following tables. Additional justification is provided in the INC submission in regard to food additives.

Table 13.1 Infant formula products

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

Table 13.1.1 Special Medical Purpose Products for Infants

INS	Description	Proposed	Reason
333	Calcium citrates	GMP	EU (including SMPPi)
415	Xanthan Gum	1200 mg/L Only in a product that is: based on hydrolysed protein, amino acids or peptides	Codex / EU (including SMPPi)

Labelling (Section 8 and SD3)

Part A - Safety-related labelling for infant formula and follow-on formula

Nestlé supports FSANZ's draft variations in SD3 in relation to:

- 2.9.1—22 (1)(a) Warning statement to follow instructions exactly
- 2.9.1—22 (5) – (8) Directions for preparation and storage, noting that the wording

and pictures for these directions will not be prescribed.

Nestlé supports FSANZ's approach to maintain the current requirements relating to:

- Generic date marking requirements
- 2.9.1—16 Prescribed name
- 2.9.1—18 Storage Instructions
- 2.9.1—20(1) Co-Location of Protein Source Statement with Name of The Food
- 2.9.1—22(1)(b) 'Breast milk is best for babies' warning statement
- 2.9.1—22(2)(c) Statement about age to offer foods in addition to formula
- 2.9.1—23 Legibility requirements for warning statements

Age Related Statements

Nestlé supports the retention of the current age-related statement in 2.9.1—22(2)(a) of the draft variation that infant formula may be used from birth, and the new requirement for this statement to appear on the front of the package of a product. We agree that this information is helpful for caregivers and locating this on the front of a package of a product will assist caregivers in selecting the appropriate product for their child.

However, we do not agree with the drafting of the age-related statement that follow-on formula should not be used for infants aged under 6 months in 2.9.1—22(2)(b). We are concerned that the wording for the statement for follow-on formula could lead to a strict interpretation that this requirement is specifically for a negative statement (i.e., not suitable for infants under 6 months), rather than encompassing positive statements with the same intent.

For follow-on formula, Nestlé includes a positive statement of age suitability on front of pack (e.g., suitable from 6 months) as this is clear and easier to understand for caregivers than a negative statement. FSANZ's market survey observed that all infant formula and follow-on formula products surveyed included age statements on the front of pack, and we have observed it is common for other manufacturers to include a similar positive age statement for follow-on formula.

We note that the age-related statements are not prescribed and welcome the flexibility on the presentation of these statements. To ensure better clarity on the requirement for the age-related statement for follow-on formula, we suggest that examples of compliant statements (e.g., 'from 6 months', '6-12 months') meeting this requirement be included as a note to 2.9.1—22(2)(b).

Part B - Labelling for provision of information about infant formula and follow-on formula

Overall, Nestlé supports FSANZ's approach to ensure greater consistency and clarity in labelling provisions. Specifically, Nestlé supports FSANZ's draft variations in SD3 in relation to:

- 2.9.1—24 Optional format for the statement of ingredients
- 2.9.1—26 (2)(a) – (e) Declaration of nutrition information – format
- 2.9.1—27 How average quantity is to be calculated
- 2.9.1—28 Requirements for use of stage numbers

Nestlé supports FSANZ's approach to maintain the current requirements in relation to:

- Generic allergen declaration requirements
- Apply existing labelling requirements in subsection 1.5.2—4 for GM foods to infant formula products
- Not align declaration of ingredient and nutrient names
- A non-regulatory approach to notification of product reformulation

However, we are concerned that the additional prescription and prohibitions proposed by FSANZ limits the ability of manufacturers to adequately inform caregivers and allow them to differentiate between products.

Declaration of Nutrition Information

Nestlé supports the permission for macronutrient sub-group nutrients to be declared in the nutrition information statement as included in 2.9.1—25(2) of the draft variation. However, we do not support the drafting in S29—10, which does not permit the use of acronyms for docosahexaenoic acid, eicosapentaenoic acid, and arachidonic acid.

FSANZ is not permitting the use of acronyms or abbreviations within the nutrition information statement as there is limited evidence that consumers have a better understanding of acronyms and abbreviations of nutrients. FSANZ references consumer research which found consumers generally did not understand nutrition content claims on infant formula products, when stated as either a full name or as an acronym (Malek et al., 2019). However, this study did not compare consumer understanding of nutrients when labelled with the full name compared to acronyms.

The use of plain English language can help consumer understanding, and the importance of this has been discussed previously in P1044 – Plain English Allergen Labelling, which resulted in updated requirements to declare allergens using simple, plain English terms. Whilst there are no plain English terms to describe 'docosahexaenoic acid', 'eicosapentaenoic acid' and 'arachidonic acid', caregivers are more likely to be familiar with acronyms such as DHA, EPA and ARA, over their full names, as these are easier to remember and commonly used in other products including general foods and supplements.

Therefore, we would strongly support the option of using acronyms for these nutrients. To maintain consistency between labels, permitted acronyms could be specified within S29—10 and the use of these acronyms could be optional, in addition to the full name.

Base Units of Expression

Nestlé does not support the prohibition of the use of voluntary units of expression in addition to per 100mL. We do agree that per 100mL should be mandatory.

Limiting the unit of expression to per 100mL will prevent harmonisation and create a barrier to trade with countries that have adopted Codex provisions, which also require base units of expression per 100g (or 100mL for concentrate) as sold. Nestlé New Zealand currently shares some infant formula product labels with Codex aligned markets in the South-West Pacific, such as Fiji, Cook Islands, Tonga and Samoa. The inability to harmonise labels with these countries could result in a public health issue if existing products were required to be withdrawn from sale in these countries

We do not agree that an extra column for another unit quantity would affect caregiver's ability to make product comparisons. The prescribed nutrition information panel for general foods requires both per serving and per 100g/100mL, therefore consumers in Australia and New Zealand are familiar with nutrition information presented with more than one unit of expression. We note that overseas regulators such as the US and EU, which FSANZ has noted do not permit different base units for infant formula and follow-on formula, do however take the approach of mandating one base unit of expression, whilst also permitting another.

Nestlé requests the addition of a permission for additional voluntary declaration of nutrients per 100g in 2.9.1—25 of the draft variation, and the exclusion of per 100g in the prohibition on other unit quantities in 2.9.1—26(2)(f). To maintain consistency between labels, FSANZ could take a similar approach to Standard 1.2.8 – Nutrition information requirements and include a second table for prescribe the format of the NIS when the per 100g unit of expression is included on the nutrition information statement.

Lactose free and low lactose formula

Nestlé does not support the draft Variation 2.9.1-21 for ‘Lactose Free’ and ‘Low Lactose’ formula.

FSANZ’s proposed variation to permit labelling requirements for ‘lactose free’ and ‘low lactose’ of infant formula is not effective in presenting clear information to consumers to ensure appropriate use of the products.

Previous advice from the Australian Competition and Consumer Commission (ACCC) and New Zealand Commerce Commission 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 contain trace levels of lactose and advances in analytical sciences mean that this lactose is 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.

These products could be labelled ‘low lactose’ however this presents a potential safety issue if carers of lactose intolerant infants are advised to purchase a ‘low lactose’ product since the level of lactose present could be up to 0.3g lactose/100mL.

Infant formula from cows’ milk for the dietary management of lactose malabsorptive conditions, will therefore continue to be managed and labelled as SMPPi and labelled with the amounts of lactose and galactose expressed in g/100 mL and an equivalent statement “not suitable for infants with galactosaemia” if appropriate.

Partially Hydrolysed Formula

Nestlé supports the inclusion of the words ‘partially hydrolysed’ with the statement of protein source for partially hydrolysed infant formula, however we do not support the prohibition for this to be labelled on follow-on formula.

Nestlé understands that FSANZ is following the same approach as for lactose free and low lactose formulas. The rationale for only permitting the declaration of ‘low lactose’ and ‘lactose free’ for infant formula is that lactose intolerance typically occurs earlier in an infant’s life, however partially hydrolysed formulas are not necessarily formulated for specific conditions, therefore the same rationale cannot be applied.

Some partially hydrolysed formulas currently in market are general infant formula and follow-on formulas (for healthy infants). Labelling ‘partially hydrolysed’ on such products would be equally as useful for follow-on formula as it would an infant formula to assist caregivers to distinguish between products. Furthermore, if the words ‘partially hydrolysed’ were to be included on an infant formula but not a follow-on formula, this could cause confusion for caregivers, and could suggest that the follow-on formula is an intact protein product.

Therefore, we request that the requirement to include the words ‘partially hydrolysed’ in 2.9.1—20(2) of the draft variation to be extended to apply to follow-on formula.

Additionally, we suggest that 2.9.1—20(2) of the draft variation be amended to allow for the words ‘partially hydrolysed’ within, in addition to adjacent to, the statement of protein source. The draft variation requires the word ‘partially hydrolysed’ to be adjacent to the statement of protein source, and an example is provided, ‘Partially hydrolysed infant formula based on cows’ milk’. A statement such as ‘Infant Formula from partially hydrolysed cow’s milk’ (as provided as an example in 8.3.1 of SD3) would more accurately describe the nature of the modification, as it is the milk protein rather than the product that is partially hydrolysed.

Claims about ingredients

Nestlé does not support the wording of 2.9.1—29 (j) in the draft variation, which prohibits information relating to ingredients as it can be interpreted broadly, which limits the ability of manufacturers to accurately inform caregivers of their product.

We understand FSANZ's view that caregivers may potentially be misled from ingredient claims and note the consumer evidence referenced in CFS1 which indicates limited consumer understanding of ingredient claims, and its impact on caregivers' perceptions on infant formula products. We note that the ingredient claims in these studies only included claims on specific ingredients for example, fish oil, but not broader reference to the term 'ingredients'.

Nestlé is concerned wording of the draft variation may be interpreted to apply a broader range of statements than the specific ingredient claims included in the consumer evidence reviewed by FSANZ. Whilst information relating to specific ingredients is already contained within the ingredients list, general information about ingredients outside of the ingredient list is required for some products to provide caregivers with a truthful and accurate representation of the product, for example, products made with organic ingredients.

We propose modifying the prohibition to allow manufacturers to accurately describe their products e.g., organic, provenance of the milk used etc.

Stage Labelling

Nestlé supports FSANZ's draft variation in 2.9.1—28 to permit the numbers '1' and '2' on the front of the package of the product to assist consumers in identifying if a product is infant formula or follow-on formula.

We do not agree with 2.9.1—29(1)(n) in the primary draft variation, that the use of numbers to identify if a product is an infant formula or follow-on formula should be prohibited elsewhere on label. The numbers '1' and '2' are often used by manufacturers elsewhere on the label as it is a simple and easy mechanism to refer to the product, compared to the terms 'infant formula' and 'follow-on formula'. This also helps consumers to differentiate between infant formula and follow-on formula with other foods, when reading other parts of the label.

Product Differentiation & Proxy Advertising

Nestlé supports 2.9.1—15(2) in the primary draft variation, which requires that a food represented as infant formula or follow-on formula must not also be represented as another food.

Nestlé supports 2.9.1—29(1)(c) in the primary draft variation to prohibit information relating to another product on infant formula or follow-on formula labels

D Novel Foods: Schedule 25 permissions (Section 4.2)

Nestlé notes the correction to in the living document on the FSANZ website.

In CP3 2021 and CFS1 2022, FSANZ previous considerations concluded that a silence in Schedule 25-2 can mean that a novel food was either "…not assessed prior to listing in Schedule 25 or was assessed as safe for consumption." FSANZ proposed to retain the permission for dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA), oil derived from marine micro-algae (*Schizochytrium* sp.) rich in DHA and oil derived from marine micro-algae (*Ulkenia* sp.) rich in DHA as the risk assessments had included the use of these substances in infant formula products.

Food standard 2.9.1 allows for the voluntary addition of DHA and together with Schedule 29 provides the conditions of use for this nutrient. Retaining the existing permissions is consistent with the original applications, which included consideration of use in infant formula products.