Nestlé Submission 1.0

Consultation Paper for Proposal 1028 – Infant Formula Products for Special Dietary Use (IFPSDU)

28 September, 2017

Nestlé Submission
Proposal P1028 - Infant Formula Products for Special Dietary Use (IFPSDU)

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

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

Nestlé thanks FSANZ for the consultation paper for Proposal 1028 (P1028), and welcomes the opportunity to consider the issues and preliminary views proposed, and to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the Regulation of IFPSDU. We thank FSANZ for their 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. IFPSDU are modified infant formula products for the particularly vulnerable infant populations, where specific dietary modifications are required for the infant's condition. Nestlé advocates a science–based approach to formulating products specific to those infants with special dietary needs, for the health and well-being of these infants. 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. Additionally, international trade and harmonisation, and therefore supply of these specialised products, for the vulnerable infant population who have special dietary needs, is considered especially important.

Executive summary:

Nestlé appreciates that the scope of P1028 has been expanded to include consideration of infant formula products for special dietary use (IFPSDU). We also appreciate the opportunity to submit on issues explored by FSANZ in the *Consultation Paper – Proposal P1028: Regulation of Infant Formula Products for Special Dietary Use* (the Consultation Paper).

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

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

Industry, together with clinical experts, are leaders in research into infant nutrition. The development and clinical assessment of high quality infant formula in line with current nutritional thinking is an expensive and lengthy process and one that must not be compromised. Formula-fed infants in Australia and New Zealand benefit from the considerable research that is undertaken on a global scale as well as locally. It is important that our local regulatory environment supports these benefits provided by global research and gives consideration to the impact on global trade and harmonisation with international food standards. Regulatory requirements placed on industry must be reasonable and proportionate to the risks presented to infants as the consuming population. A high level of due diligence exists in industry with decades of experience ensuring the safety of products for this vulnerable population.

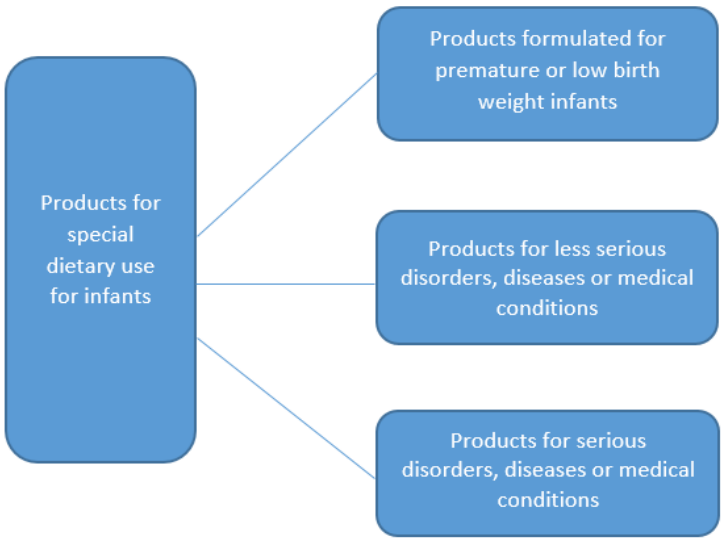
This review is to support regulatory change, and Nestlé requests any transitional period be of reasonable length to allow adequate time to implement changes, particularly for imported infant formula that is not manufactured in Australia and New Zealand.

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

Regulatory framework and Organisation of products subcategories

Nestlé supports a framework that reflects a modification of the current status quo, and FSANZ's Option 3. The proposed framework is based on an overarching category (products for special dietary use for infants) which is differentiated from general purpose infant formula products for healthy infants. Three sub-categories are then proposed, that is based on the disorder, disease or condition, rather than being based on an ingredient. A sub-category approach was considered only where there is a disharmonised approach between the sub-categories, either with composition, labelling, or trade and distribution. In the framework we have proposed, we support a harmonised compositional approach for all three categories. However, in the sub-category for products for premature or low birth weight (LBW) infants we have supported a non-prescriptive labelling requirement distinct from the other sub-categories. Nestlé also supports trade and distribution restrictions aligned to FSC 2.9.5 for the two sub-categories of Products formulated for premature or LBW infants and Products for serious disorders, diseases or medical conditions only. The following figure reflects the proposed modified regulatory framework:

Figure 1.1: Possible new regulatory classification of IFPSDU:



Definitions, product categories and prescribed name

Nestlé supports the introduction of a definition for the overarching category of Products for Special Dietary Use (PSDU). The purpose of this definition should be to differentiate this category to requirements for healthy infants.

Nestlé also supports a definition for the sub-category for products for serious disorders, diseases or medical conditions. This is the only sub-category where we support a definition to be introduced, and the purpose of this definition should be to differentiate this sub-category, against the other sub-categories.

Nestlé also supports the inclusion of human milk fortifiers (HMF) within the scope of FSC 2.9.1, and more specifically, HMF's to be regulated within the sub-category of products for premature or low birth weight (LBW) infants. This is conditional that the final standard relating to the compositional and labelling approach, does not impact on trade and harmonisation and restrict the supply of such products. Definitions may therefore be impacted as we consider these products offer partial nutrition, rather than a sole or principle source of nutrition.

On prescribed names, Nestlé does not support any prescription which may impact on harmonisation and trade. We however support non-prescriptive regulatory requirements in labelling that would ensure correct and appropriate use relating to the condition. We support a requirement for regulating the true nature and intended purpose for the food, to ensure no inappropriate product misuse.

Approach to composition

Nestlé supports the status quo permitting deviation only if relating to the disorder, disease or medical condition, if it prevents the sale of the product and is also scientifically validated. In addition, Nestlé supports for PSDU products for infants, nutrients not relating to the disease, disorder or condition - flexibility to align all nutritional compositional requirements for IFPSDU to other credible regulatory jurisdictions, specifically Codex, EU and USA only, if it otherwise prevents the sale of such products.

Food additives

Nestlé welcomes the FSANZ proposal to extend the current list of permissible food additives for infant formula products to enable harmonisation, particularly for the IFPSDU products that especially rely on harmonisation opportunities to ensure supply to the Australian and New Zealand markets.

Nestlé considers that the most appropriate framework is to have **one category for products for infants**, *instead of* the proposed one category of PSDU for all additional food additives, or devised according to the sub-categories. Additionally, we do not consider the status quo today in FSC 1.3.1, Schedule 15 is optimal. Nestlé is proposing a change to current arrangements which will still achieve the regulatory purpose, but will also facilitate innovation and harmonisation.

Safety: contaminants, renal solute load, safe preparation and use

Contaminants: Nestlé supports FSANZ's view on contaminants with exception of aluminium. We do not support the status quo and support alignment to key international regulations including Codex.

Potential renal solute load (PRSL): we consider this is redundant with respect to protein substitutes as we do not support retaining such a sub-category based on an ingredient approach, rather than a disorder, disease or medical condition. We are however open to retaining the current PRSL requirement if defaulting to current

general purpose norms for follow-on formula. However Nestlé would be proposing a review of such a requirement for general purpose norms in a future proposal to review follow-on formula as a result of the pending Codex Follow up formula revision relating to protein maximum.

Safe Preparation and Use: We consider preparation requirements for PSDU is compatible with those for general purpose infant formula products for healthy infants, with the exception for if human milk fortifiers come within the scope of FSC 2.9.1.

Labelling

Nestlé supports the need to regulate the intent of but not regulate by way of prescribed wording which would then potentially lead to non-harmonisation and therefore threats to trade and supply.

In terms of any specific FSMP labelling requirements from FSC 2.9.5 not currently 'duplicated' or captured by FSC 2.9.1 -

Nestlé **supports** introduction of the following from FSC 2.9.5 to apply to PSDU for infants regulated by FSC 2.9.1:

- *(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (*however optional application, not mandated.)
- *the words 'Expiry Date', or similar words, may be used on the label.*

Nestlé is **not opposed to**:

- *(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food*

Nestlé **DOES NOT support**:

- *(i) a statement to the effect that the food is not for parenteral use;*
- *a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the food, as appropriate.*

For the information relating to ingredients, Nestlé reserves our comments on this matter until such time a more detailed evaluation can be completed to determine compatibility to EU and USA regulations. Depending on the extent of the differences that could lead to a non-compliant outcome, we consider that minimal differences could be accommodated in FSC 2.9.1, rather than an all-inclusive approach as per FSC 2.9.5.

Distribution and access

Nestlé is open to trade and distribution restrictions imposed on two sub-categories only - that for products formulated for premature of low birth weight infants, and products for serious disorders, diseases or medical conditions. The proposed trade restrictions should be identical to those in FSC 2.9.5 for purposes of consistency, and no more.

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

Nestlé Responses:

Q1. Are there any other overseas regulations relevant to IFPSDU?

No – Nestlé considers that FSANZ has covered the relevant key international regulations.

Q2. What are the advantages and/or disadvantages of these options, in particular creating an 'infant formula product for special medical purposes' subcategory? If you support creation of a separate category for IFPSMP, should pre-term products be included?

Nestlé supports FSANZ's option 3, however with modification.

Nestlé does not support Option 1 for one merged IFPSDU single category, for the reasons FSANZ have outlined, in that it does not aid differentiation or assist regulatory clarity. Whilst the advantage is harmonisation to a Codex Framework, we consider this approach only works if we have a harmonised compositional, labelling, and trade/distribution approach. Example - Nestlé is supporting trade restrictions as aligned to FSC 2.9.5 for the very highly specialised products only, but not the less specialised products for less serious conditions, therefore additional sub-categorisation can be useful in this respect. The advantages of Codex is that the framework is broader to allow innovation, however we consider that a modification of the current FSANZ status quo may be able to achieve this without compromising regulatory clarity and differentiation.

Nestlé does not support Option 2 as this proposes moving products for "*transient gastroenterological conditions*" or the partially hydrolysed protein formula into general infant formula. Our view is products for less serious conditions, including those that the current consultation paper has termed "*transient gastroenterological conditions*", are not for healthy infants. While the infant may revert to a healthy state, the medical fact is that at the time the product is needed, the infant is NOT in a healthy state (e.g. diarrhoea, constipation, regurgitation, short-term lactose intolerance etc.). Therefore for technical correctness, and in order to aid differentiation and appropriate product use, it is in our view not appropriate to position such products in general purpose infant formula products when the intent is that the latter is for healthy infants. For partially hydrolysed protein based products, while this can be positioned for healthy infants, at the same time, these are also currently used for products for infants not in a healthy state. Our view is that partially hydrolysed protein products have a place in both general purpose, and products for special dietary use (for infants). Whilst this option is likely modelled in some respects on EU, where a lot of these products are sourced from, we consider that a modification of the current FSANZ status quo is best placed to deliver on regulatory clarity, differentiation, and support innovation through harmonisation with nominated key international regulations.

This leads us to Option 3.

Nestlé supports FSANZ's option 3, however with modification (Figure 1 shown below). The modifications and rationale for modification are as follows:

1. Amend the overarching category name from "Infant formula products for special dietary use" (IFPSDU) to "Products for special dietary use" for infants (PSDU for infants).
This is to allow products that provide partial nutrition, but not a sole or principle source of nutrition. An example of such a product is a human milk fortifier (HMF), where breastmilk is the principle source of nutrition. Nestlé supports that such products better belong to a FSC 2.9.1 standard, in a sub-category for premature or low-birth weight infants, rather than FSC 2.9.5 for the reasons FSANZ have outlined in the consultation paper relating to HMF's.

Additionally, we consider the assessments for FSC 2.9.1 and related horizontal standards are more appropriate for the target population of infants. At the same time however, such products are critical for the breast-fed infant that require specialised nutrition for the conditions of prematurity or low-birth weight. Therefore our support for increasing the scope of FSC 2.9.1 to include such products is also conditional that there are no risks of continued supply and threats to harmonisation, in particular with respect to labelling.

2. Remove the sub-category of protein substitutes.

i. ***Not consistent with the approach of other sub-categories.*** The protein substitute sub-category, is based on an ingredient approach, whereas the other sub-categories is based on a nutritional purpose relating to the disorder, disease or condition.
ii. ***Not consistent with international precedence.*** A 'protein substitute' sub-category in an infant FSMP framework does not exist either for Codex, EU or USA. This is out of step with international precedence, and may cause issues with regulatory clarity as to the nutritional purpose of protein substitutes.
iii. ***Not reflective of current products on market.*** The current framework for protein substitutes does not permit a labelling statement for the disorder, disease or condition for which the product has been specifically formulated. We consider this is not appropriate and poses a risk of potential misuse and consumer /HCP confusion especially for the extensively hydrolysed and elemental formulas that are for the especially vulnerable infants with clinically serious diseases. Nestlé considers that non-intact protein formulas could have multiple positions in the Code, and belong also to the different sub-categories for special dietary use.
iv. ***Not necessary to have differentiating compositional elements.*** Lastly, we consider the compositional requirements differentiating protein substitutes from intact protein for chromium, molybdenum, protein maximum, fat minimum, potential renal solute load and MCT addition is not necessary (rationale to this is provided in detail in the responses to Q13, Q17 and Q18). If these existing compositional parameters are removed, this negates the need for a protein substitute sub-category, and products with non-intact protein could then fit within the compositional, labelling, and trade and distribution approaches of the other categories in FSC 2.9.1.

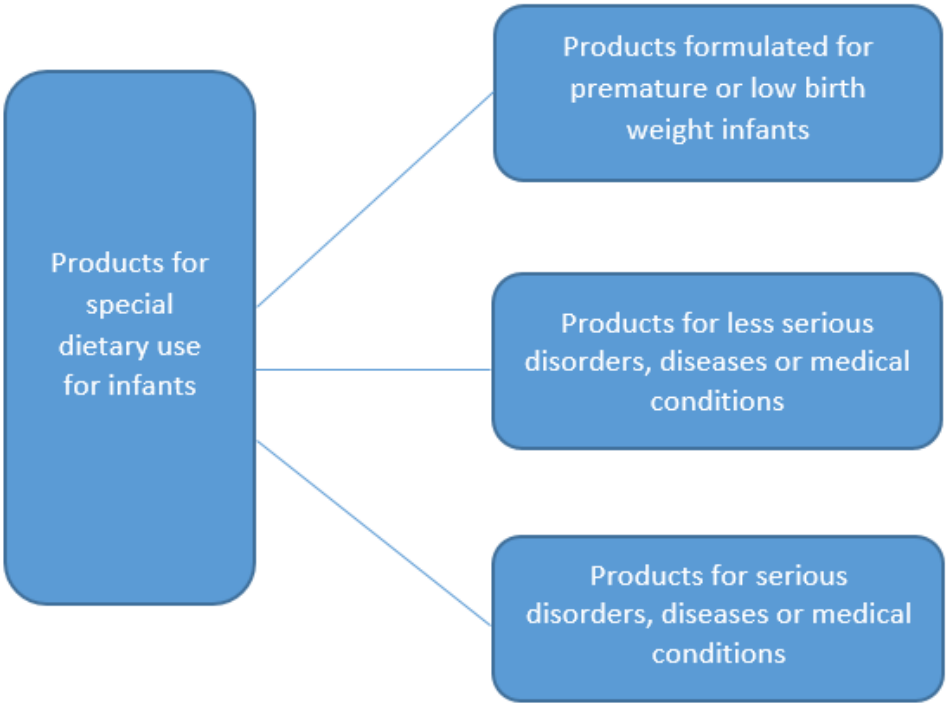
3. Terminology for the divided sub-categories.

i. Nestlé agrees with FSANZ's approach to divide the current sub-category of 'products for metabolic, immunological, renal, hepatic and malabsorptive conditions' into two sub-categories to better differentiate the "*less*" specialised products, from the "*more*" specialised products. Additionally, as Nestlé are open to a more restrictive approach to the current status quo on trade and distribution access for the pre-term/LBW and "more" specialised products only, the division into 2 sub-categories from the 1 existing today, assists to facilitate this differentiation between the sub-categories in relation to trade and distribution access.
ii. However we have potential issues with the terminology currently being proposed, in particular, for the "*Products for transient, gastroenterological conditions*". We consider it may be difficult to interpret what "transient" could mean, given not all of the "more" specialised and serious conditions, disease or disorders are lifelong, and recovery could potentially be possible. Also, "gastroenterological" limits future innovation for products that may not be supporting a gastroenterological condition, yet is still less serious in nature. We consider as one example, that an immunological condition could range in severity and products could support one type of immunological condition that is less serious, and another product could support another type of an immunological condition that is more serious.
iii. Nestlé proposes terminology that better illustrates the intent to differentiate the "less serious" vs "serious" which will then need to be accompanied by a definition for the 'serious' sub-category

(discussed in the response to Q4) to allow regulatory clarity as to product fit for intended purpose and use.

The proposed possible new regulatory classification for products for special dietary use (PSDU) for infants, is shown as follows diagrammatically:

Figure 1.1: Possible new regulatory classification of IFPSDU:



Q3. Do you support inclusion of a category definition for IFPSDU in the Code? Why or why not? Is the proposed definition of IFPSDU appropriate; if not, what should it say?

Nestlé supports the introduction of a definition for the overarching category of PSDU, and one that could capture products such as HMF's within its scope. Nestlé also welcomes consideration of key elements from the Codex and EU definitions.

Nestlé however proposes some modifications to the proposed definition as follows:

~~Infant Formula~~ Products for Special Dietary Use means ~~an Infant Formula~~ Product<u>s for infants</u> that is specifically formulated:

(a) for ~~an infant with~~ a specific disorder, disease or medical condition;
(b) to satisfy, either partially or fully, the ~~special~~ nutritional requirements of that infant; and
(c) to be used under medical supervision.

With the proposed modifications, we considered that:

- 'Infant formula product' is already defined in FSC 2.9.1 as follows: "***infant formula product*** *means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant*." Nestlé is unsure whether products such as human milk fortifiers as one example, that partially satisfies the nutritional requirements of the infant, would fit within the definition in that they are not "*nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment"*. In the example of human milk fortifiers, breastmilk is the principle liquid source of nourishment. Therefore, Nestlé proposes to remove "infant formula" from the definition, and still refer to the target population of infants per the proposed modification above.
- Nestlé also is unsure of the need to include the term "special" in point (b). We believe the product is already "special" as it is defined in point (a) as being for infants with a specific disorder, disease or medical condition. Nestlé also supports a compositional approach that will ensure product availability for such infants in need of PSDU products, and point (b) could possibly imply a compositional approach that supports a nutritional deviation to general purpose norms only for the condition. While this approach is the status quo, there could be a consequence of unavailability of PSDU products for the AU NZ market if a nutritional parameter not related to the disorder, disease or medical condition is compliant to other international regulations (e.g. Codex and key sourcing markets of EU and USA for PSDU), but do not comply with AU NZ general purpose regulations. Relevant examples are discussed later in the response to Q16.

Lastly, while not a proposed modification above, Nestlé wonders if the term "products" should be replaced with "food". This has 2 potential benefits:
[1] harmonisation of the term with EU, Codex and USA in terms of product definitions
[2] in considering labelling, we would prefer "Food for ….". This for a HCP and consumer perspective could also potentially better differentiate food products regulated by FSANZ vs therapeutic products regulated by the TGA.

As such we consider "Products" is ok for purposes of regulatory definitions within a Food Code, however for consistency to labelling for the end user perhaps "Food" could also be considered.

Q4. If you support including a subcategory definition for IFPSMP in the Code, is the proposed definition of IFPSMP appropriate; if not, what should it say?

Nestlé supports the introduction of a definition for the sub-category of products for serious disorders, diseases or conditions. FSANZ has outlined as the reason - to provide "*a clear differentiation for the highly specialised products including those that may pose a risk to healthy infants"*. Nestlé considers however that the latter rationale better fits with the role of the overarching definition for the products for special dietary use, which is an overarching category not suitable for healthy infants.

We consider that the purpose of a definition for the sub-category for serious disorders, disease and conditions, where another definition already exists for products for special dietary use, is to differentiate this sub-category from the other sub-categories, rather than differentiate from products for healthy infants which we consider is the purpose of the definition of the overarching category of PSDU.

Nestlé considers that the proposed FSANZ definition for the sub-category of products for special medical purposes (PSMP) is already covered off by the definition for products for special dietary use:

- "*used under medical supervision*" is similar to "*medically determined nutrient requirements*" since all infants needing a PSDU will have a product recommended by a health care professional who will have the appropriate knowledge and consideration of their nutrient requirement for their condition before recommending the appropriate product for use.
- "*limited or impaired capacity to take, digest, absorb, metabolise or excrete food*" can be satisfied by "*Product for infants that is specifically formulated: with a specific disorder, disease or medical condition*", since those infants with such disorders, disease or medical condition will inherently have the *limited or impaired capacity to take, digest, absorb, metabolise or excrete*.

We also query whether terminology of "special medical purpose" for a sub-category of FSDU which is almost identical to the defined "food for special medical purpose" in FSC 2.9.5 may be confusing if the purpose of a sub-category definition is to differentiate to the other sub-categories. The FSC 2.9.5 definition has a closer fit to a definition for PSDU to differentiate to products for healthy populations.

As already mentioned, Nestlé considers that if a definition for the sub-category of products for serious disorders, disease and conditions is to be supported, rather than to provide differentiation to products for healthy infants, this definition should instead have a purpose to provide differentiation to the other IFPSDU product subcategories. We consider as one example that *"limited or impaired capacity to take, digest, absorb, metabolise or excrete food*" applies to both sub-categories of the 'less serious' vs the more 'serious' conditions, disease or disorder.

As such Nestlé proposes a definition that can differentiate against the products for the 'less serious' conditions to the products for 'serious conditions', since an infant with a 'less serious' condition could recover to a healthy state and subsequently switch to a general purpose product for healthy infants.
In our experience, the products for the 'more' serious conditions is not only typically medically diagnosed by the HCP, but usually also accompanied by follow-up and recurring HCP consultations. For example, if the infant has a mal-absorptive condition that could impair normal growth and development, follow-up checks with the HCP is necessary to check that appropriate weight gain is achieved, that the infant is tolerating the product well, etc. The HCP would also need to advise if continued specialist nutrition is required, vs the carer being able to self-determine that specialist nutrition is no longer needed.

Products for the 'less' serious conditions in our experience may require initial medical supervision and recommendation for the appropriate product, however recurring HCP consultation is much less likely as compared to those for more serious conditions. For example, if an infant has watery diarrhoea that is not self-limiting but extended, they will seek HCP advice on an appropriate product for use. The HCP may recommend a product for use in the short term, then when the stools are checked by carers whilst changing nappies and found to be normal, follow-up and repeated HCP consultation may not be necessary. Conditions such as diarrhoea, constipation, less serious allergic responses, colic (excessive crying) are symptoms easily recognisable by the carer. The cessation of such symptoms are also easily recognisable by the carer.
As such Nestlé considers there could be 2 regulatory elements to be considered in the definition: that of a condition, disease or disorder that is [1] serious, and [2] has follow-up HCP consultations.

Nestlé therefore favours one element from the US FDA FMSP regulations (Title 21 of the Code of Federal Regulations 107 subpart C: Exempt Infant Formula), which talks to "*specific diseases or conditions that are clinically **serious** or life-threatening and generally are required for **prolonged periods of time***."

The proposed modification is as follows:

~~Infant formula p~~[Products for serious disorders, diseases, or medical conditions] ~~special medical purposes~~ means a~~n infant formula~~ product for special dietary use that is specifically formulated for infants:

(a) who have

~~(i) medically determined nutrient requirements, or~~

~~(ii) limited or impaired capacity to take, digest, absorb, metabolise or excrete food including another type of infant formula product~~

(i) [specific diseases or conditions that are clinically serious, or potentially life-threatening and are generally required for prolonged periods of time]

Alternatively, if 'prolonged' could be difficult for purposes of regulatory clarity, Nestlé is also supportive of the INC view relating to wording to the effect that this sub-category of products is otherwise not suitable for healthy infants. These products are then for infants who have (i) specific diseases or conditions that are clinically serious, or potentially life-threatening, and are otherwise not suitable for a healthy infant.

The above is only a suggestion to reflect the intent as elaborated above, and it may be necessary that FSANZ considers if the above is sufficient to differentiate between the sub-categories.

Lastly, the same comments we have from the response to Q3 on "infant formula product" and "product" vs "food" applies here too.

Q5. Are there any issues with the current definition for protein substitutes?

Nestlé considers that there are no issues with the current definition for protein substitutes. Manufacturers are well aware these relate to non-intact protein and there is no failure in the market in terms of appropriate differentiation between intact vs non-intact protein.

Per our comments previously on the proposed Regulatory framework, Nestlé however considers that given we do not support a sub-category for protein substitutes which is ingredient based rather than nutritional purpose/condition based, then the continued need and purpose for a definition for protein substitutes will need to be considered. There are protein substitute products that can be used as general purpose infant formula products, those for prematurity and low birth weight conditions, and those for metabolic, immunological, renal, hepatic and mal-absorptive conditions otherwise to be proposed as PSMP or products for transient conditions. Nestlé therefore questions the validity of such a category, and a definition for products, that could otherwise be relocated to other categories in FSC 2.9.1. Additionally, as already outlined by this consultation paper, Codex and EU do not have definitions for protein substitutes.

Q6. Is there a benefit to defining one or more of the following in the Code:
– Hypo-allergenic formula
– Partially hydrolysed formula
– Extensively hydrolysed formula
– Amino acid-based infant formula?
If yes, what are the benefits of including these definitions? And what should be the key elements of each definition?

Nestlé believes it will be very difficult to define these terms – with the exception of amino acid based infant formula – as there is no generally accepted definition globally for hypoallergenic; partially hydrolysed; and extensively hydrolysed infant formula.

Hypoallergenic has vastly different meanings in different parts of the world, as discussed in a recent review by Vandenplas 2017 – *"The meaning and definition of a "hypo-allergenic formula" varies in different parts of the world. While in Europe a "hypo-allergenic formula" means a formula that contains hydrolyzed protein and thus a reduced allergenicity, the American Academy of Pediatrics defined it as a formula that is effective in the treatment of at least 90% of the children with CMA, with a 95% confidence interval".*

As such, a 'partially hydrolysed' formula may be considered "hypoallergenic" in Europe but not – for example - in the USA.

Partially & extensively hydrolysed infant formulas have been studied for many years yet still there is no generally accepted definition, even though this has been a discussion topic since the 1999 ESPACI position paper. The topic was discussed at length by Host & Halken in 2004, and again more recently by Vandenplas in 2015. Host & Halken (2004) stated "*Attempts have been made to classify products according to the degree of protein hydrolysis ['extensive' or 'high degree' (EHF) vs 'partial' or 'low degree' (PHF), but there is no unanimous agreement on firm criteria on which to base such a classification*".

More recently, Vandenplas (2015) commented that "*There is no general agreement on standards to define pHF and eHF specifically and protein/peptide size is generally used to identify each of them…The technique of hydrolysis and thus the end result, the partially hydrolysed protein, differ for each company*".

Q7. Are there any issues with the current definition for pre-term products?

Nestlé considers there are no issues with the current definition for pre-term products except that if the proposed framework is to capture all products for pre-term/LBW targeted at infants in FSC 2.9.1 including those for partial nutrition, then the issue is human milk fortifiers will be excluded from the current definition for pre-term products as it is not an infant formula product providing a sole or principle source of nutrition.

Q8. What, if any, are the benefits of including age and weight parameters in the regulatory definition for pre-term products?

Nestlé considers that additional parameters referring to specific age and weight for pre-term products are not necessary. "Pre-term" is already well defined globally as being less than 37 weeks gestation, while low birth weight is defined by the WHO as being less than 2500g. Additionally, these products are only to be used under medical supervision, *usually* as a hospital inpatient, so there is no need to place additional prescription on these products. Additionally, there is no evidence of failure with the use of these products without any additional age or weight parameters.

Q9. What is the general composition of human milk fortifiers for premature or low birthweight infants? ….and composition and uses for groups other than premature or low birthweight infants?

General Composition:
Human milk fortifiers (HMFs) currently on the market generally comprise of protein, energy and micronutrients that would be suitable for catch up growth in the condition of prematurity and/or low

birthweight. At least one fortifier also contains additional fat, in particular DHA. Fortified breastmilk is considered essential for pre-term infants as breast milk alone is nutritionally inadequate for pre-term infants (Koletzko *et al*., 2014). HMF aims to increase the energy density of breastmilk by including macronutrients being protein (predominantly), carbohydrates, and/or fats. Both energy and protein are necessary to produce normal rates of growth (Koletzko *et al*., 2014). Protein is a key nutrient because it is limiting for growth and neurodevelopment (Koletzko *et al*., 2014). HMFs exist to fill a gap in the nutritional needs of pre-term infants fed breastmilk. The manufacturer would usually consider *the sum of* the HMF composition, together with breastmilk composition so that the intended purpose of HMF as a fortifier of breastmilk targeted for the condition is fulfilled. As such the composition of human milk fortifiers would consider key scientific recommendations for pre-term nutrient intakes (ESPGHAN 2010, Koletzko *et al*. 2014, LSRO 2002) which are supported by strong clinical evidence, along with the composition of breastmilk, to ensure HMFs fill the nutritional gaps for the condition of prematurity and/or low birthweight.

Uses of these products:
These products are solely used for the condition of prematurity and/or low birthweight as they are formulated for this purpose in the compositional approach. They are purposely designed to be used in combination with breastmilk, to fortify breastmilk with additional macro and micronutrients, to promote catch up growth. Nestlé would consider these products could fit in the sub-category for products for prematurity and low birth weight infants within FSC 2.9.1.

Q10. Is there a need to prescribe a name for IFPSDU – what are the implications for subcategories?

Nestlé considers there is not a need to prescribe a name for IFPSDU, especially if implications are that it doesn't allow for label harmonisation with other countries, since "PSDU" is quite unique to Australia and New Zealand. Furthermore, as mentioned previously, if the new framework includes products that provide partial nutrition, "infant formula products" is not appropriate since it is already defined in FSC 2.9.1 and part of its definition (sole or principle source of nutrition) would most likely exclude products that provide partial nutrition.

Additionally, we would question whether a consumer knows what is a "Product for special dietary use". With respect to terminology - Consumers might understand the difference between a 'medicine" (regulated by TGA) vs a 'food' (regulated by FSANZ). But beyond that we do not believe there is consumer lay understanding of what a "product for special dietary use" is.

Nestlé recognises there is a need for a requirement that distinguishes a general purpose product for healthy infants, to those with a specific disorder, disease or medical condition. This however may not necessarily need to rely on a prescribed name but other elements such as labelling for the condition, and a warning statement that warrants the product is used under medical supervision. Depending on the outcomes of trade and distribution access, this is also another potential element to consider that would further reduce any possible risk of incorrect product selection or misuse.

Fundamentally, regulating AU NZ specific prescription for any labelling elements increases risks of non-harmonisation and therefore threats to product supply. Nestlé would propose other avenues that can be considered sufficient to allow differentiation to products for healthy infants, and the status quo today that requires labelling for the condition as well as a statement for medical supervision does not demonstrate any market failure.

Q11. Is there a need to prescribe names for any the IFPSDU subcategories? If yes, what benefit would this provide?

Nestlé does not support regulatory prescription of names for any of the IFPSDU subcategories as this has potential implications with not being able to harmonise labelling with other countries and therefore increases threats to product supply.

Nestlé however supports non-prescriptive regulatory requirements in labelling that would ensure correct and appropriate use relating to the condition. We support a requirement for regulating the true nature and intended purpose for the food, to ensure no inappropriate product misuse. As such we support the Codex approach that there could be a regulatory requirement for any appropriate designation indicating the true nature of the product, which does not for example preclude a reference to 'pre-term' or 'for Prematurity' in the product name. EU and USA take a similar approach so by not prescribing names this facilitates harmonisation plus it is also in line with key international precedence.

Q12. Are any specific compositional requirements (energy/macronutrient etc) needed in the Code for formula intended for premature or low birthweight infants, or for those suffering metabolic etc. conditions? If so, what are they?

Nestlé supports the status quo with no additional compositional prescription, relating to the condition. This is in line with the current AU NZ status quo, Codex, EU and USA approach. As mentioned, "*The EU regulations acknowledge the need to ensure adequate flexibility to develop innovative products, and state that it is not appropriate to lay down detailed compositional rules for such food products*." Additional prescription that could lead to dis-harmonisation would lead to increased risks and threats to product supply.

For premature and/or low birth weight infants, manufacturers may deviate typically to higher protein and energy relevant for the condition, in order for catch up growth to occur. Most macro and micro nutrients are formulated to comply with the Code, unless parameters relating to the condition require deviation. Manufacturers have formulated such products to be scientifically substantiated for the condition, to support rapid growth requirements in the premature or low birth weight infants. These products and their nutritionals are also typically extensively scrutinised by the hospital and health care professional before a product is selected for the hospital (for nutritional suitability and clinical evidence to support), to satisfy the needs of the infant born of prematurity or low birth weight. As such the risk of any possible market failure is low, as these products are typically used under strict medical supervision in the neonatal ward.

For metabolic, malabsorptive etc. conditions, it is difficult to prescribe any specific compositional requirements, since the categorisation is broad and a 'one size fits all' approach will not work. For example, diarrhoea and constipation are opposite physiological effects/symptoms of the same condition of malabsorption. The nutritional parameters that supports diarrhoea vs constipation could differ, as infants with prolonged or chronic diarrhoea may require additional nutrition (such as higher protein) in their formula to allow for growth and repair of the affected gastrointestinal mucosa.

In conclusion, introducing a specific compositional requirement is not in line with international regulatory precedence, and will not facilitate flexibility for innovation and therefore continued supply for the infant in need of such products. Additionally, the number of possible medical conditions vs the proposed regulatory framework of sub-categories is contradictory in nature if a harmonised compositional approach per sub-category cannot be achieved, which we consider is the case if specific compositional requirements are to be introduced.

Q13. Are any specific compositional changes needed in the Code for protein substitutes? If so, what are they and what is your justification for them?

Nestlé considers that the current specific requirements for chromium, molybdenum, protein maximum, fat minimum, potential renal solute load (PRSL) and permission for medium chain triglycerides (MCT) that differs from general purpose infant formula products are not necessary and as such redundant. This then supports also a redundant need for a sub-category for protein substitutes, where such products based on non-intact protein can otherwise use an aligned compositional approach for other categories in FSC 2.9.1. The rationale for chromium and molybdenum is provided in detail in the responses to Q17 and Q18. The rationale for protein, fat, PRSL and MCT's is as follows:

For protein maximum:
Protein maximum for protein substitutes is currently 1.4g/100kJ. This differs from the general purpose IF section where protein maximum for an infant formula is 0.7g/100kJ and for a follow-on formula 1.3g/100kJ. As such, a non-intact protein starter infant formula for special dietary use would be using the range for a general purpose follow-on formula, albeit a slightly higher maximum.

We consider that the protein levels for all infant formula products, including those for special dietary use should be based on breastmilk levels unless the condition dictates otherwise. The latest science as recently reviewed via the Codex Follow-up formula standard revision for 6-12m aged infants, is that a protein maximum of 3.0g/100kcal (0.72g/100kJ) is appropriate, and already well above breast-milk levels. For products for special dietary use, Nestlé considers that – depending on the condition for which the product is formulated for – higher levels of protein may be warranted for catch up growth (for example in situations where infants have compromised gastrointestinal function who may require a higher protein content due to a mal-absorptive condition). Even so, these levels, irrespective of whether an intact, or non-intact protein base, would be nowhere close to current 1.4g/100kJ maximum in the code. This is supported by a review of current infant formula products on the market.

The rationale from Proposal 93 appears to be as follows:

> Protein content: The protein content recommended for standard formula is 1.26-1.97 g/100 mL but in protein hydrolysate formulae on the Australian market, protein content ranges to 2.5 g/100 mL (Alfare). This is within the Codex regulations (1.2 - 2.7g/100 mL), and the R7 regulation for follow-on formula (< 2.8 g/100 mL). Considering the limited data suggesting a fall in plasma protein if fed whey protein hydrolysed formula with a protein content of 1.6 g/100 mL (Rigo et al 1994), and the possibility of protein losing enteropathy in some conditions for which a protein hydrolysed formula may be prescribed, it seems appropriate to increase the upper limit for protein allowable in these formula.

The rationale from P93 is over 15 years old and - specific to this point - largely out-dated. Alfare (an extensively-hydrolysed protein formula which historically was used for chronic diarrhoea) is referenced as having a declared protein content of 2.5g/100ml. Alfare still exists on the Australian market however it is now prescribed primarily for the dietary management of cow's milk protein allergy (much rarer in the early 2000's) and currently has a declared protein level of 2.0g/100ml. Protein losing enteropathy, mentioned in P93, is rare in children and even rarer in infants (Braamskamp, 2010), additionally one possible cause of infectious diarrhoea being that from rotavirus has declined sharply since the introduction of the rotavirus vaccine in Australia in 2007, with a 71% decrease in rotavirus-related admissions (Dey, 2012).

It should be noted that the current protein level of Alfare of 2.0g/100ml is still ~ 50% higher than the current protein minimum for infant formula. Such products have been specifically formulated to meet the needs of

infants with cow's milk protein allergy, where it is possible that these infants require more protein than a general purpose infant formula due to their compromised gastrointestinal function upon diagnosis (Nowak-Wegrzyn, 2015). However, to the best of our knowledge, no non-intact protein infant formula products for special dietary use for conditions other that prematurity or low birth weight, currently exist on the Australia-New Zealand market with protein levels up near the protein maximum level. Additionally, if extra protein was required in a specific instance, this protein could be supplemented modularly (using protein supplements) as is done on occasion by neonatal/paediatric dietitians and suitably trained medical staff.

In summary, the compositional approach to the products for special dietary use is to permit deviation to general purpose norms, if scientifically substantiated for the condition. Any conditions where higher protein may be needed, is able to follow this compositional approach. As such we consider there should be no issues to remove this parameter of maximum 1.4g/100kJ and apply the compositional approach for products for special dietary use, if higher protein in certain situations is required for the disorder, disease or condition.

For fat minimum:
Fat minimum for protein substitutes at 0.93g/100kJ differs to general purpose infant formula products at 1.05g/100kJ.

We are unsure as to the full rationale for this lower level for protein substitutes, but assume that it was perhaps regulated to compensate for the higher protein maximum, yet equivalent energy requirements to a general purpose infant formula. If however, the higher protein parameter of 1.4g/100kJ is not necessary, and instead defaults to general purpose norms but with permission to deviate for the condition when scientifically substantiated, then we consider the lower fat parameter of 0.93g/100kJ becomes redundant. In trying to better understand the legacy of this lower fat minimum of 0.93g/100kJ, the rationale from Proposal 93 was reviewed which appears to be as follows:

> The lipid content of one protein hydrolysate formula on the Australian market (Nutramigen) is lower than that recommended for standard formula. However, the carbohydrate content is relatively high, achieving a nutritional profile which may be desirable in infants with fat malabsorption. Therefore it is probably not unreasonable to reduce the minimal requirement to embrace this formula **(2.60 - 3.93 g/100 mL)**. The sources of lipid currently used in commonly used formula for children with special needs are listed in Table 3.

To the best of our knowledge, Nutramigen hasn't been on the market since 2001, and to the best of our knowledge, no other manufacturer currently formulates to fat minimum levels lower than that which is permitted for general purpose infant formula products. As such we are not sure such a rationale exists today that warrants a lower fat minimum of 0.93g/100kJ.

For Potential Renal Solute Load (PRSL):
The Potential Renal Solute Load (PRSL) is the sum of dietary nitrogen, sodium, potassium, chloride, and phosphorus. Its relevance for protein substitutes was due to a permitted higher maximum for protein. If the protein parameters are adjusted to follow the same compositional approach as all other products for special dietary use, then PRSL is not required for a starter specialty product as the protein maximum defaults to the general purpose norm of 0.7g/100kJ, and if a follow-on specialty product, then a PRSL is required anyway as this is the current requirement for general purpose follow-on formula for healthy infants. Ziegler & Fomon (1989) in their review of this topic stated that decreasing the protein of the infant formula will decrease the PRSL, which is clear given that the nitrogen (protein) is a major contributor to the PRSL.

Additionally, with a general tendency towards lower protein content in infant formula products, the PRSL has become less important clinically, as high solute loads are not being provided. An example here would be with the extensively hydrolysed protein infant formula Alfare, mentioned in P93 as having a declared protein

of 2.5g/100ml in the early 2000's, decreased now to 2.0g/100ml in 2017 - significantly reducing its PRSL and making regulation in this area redundant.

For Medium chain triglycerides (MCTs):
Unless innately present, MCT's are currently prohibited for addition unless added for a specific dietary use related to a disorder, disease or condition. MCT's however are permitted to be added for protein substitutes. Nestlé considers that if MCT's are warranted for any particular condition (such as chronic diarrhoea with inflammation, or preterm infants), then the compositional approach to permit deviation for the condition should address this. We are not sure why MCT is a nutritional parameter to differentiate an intact, from a non-intact protein based formula, but believe this was more a historic reasoning in that some protein hydrolysate formulas had a dual purpose for immunological/allergic conditions, and malabsorptive conditions - as MCT's have been shown to have good absorption even in the presence of low intraluminal bile salts and pancreatic lipases (Koletzko *et al*., 2014). For pre-term infant formula products, MCTs have been used for absorption purposes plus to increase the coefficient of fat absorption and to spare other substrates (glucose; essential fatty acids) from oxidation (Koletzko *et al.*, 2014). ESPGHAN (2010) state that, if added to preterm infant formulas, the MCT content "*should be in the range of up to 40% of the total fat content*".

MCTs have been safely added to some IFPSDU for many years, with Klein's (2001) review of preterm infant requirements stating – "*MCTs account for 40-50% of the total fat content of currently available preterm infant formulas, and these formulas have not been associated with adverse effects related to their content of MCTs*". Additionally, as MCT's are expressly permitted for protein substitutes, they have previously been considered therefore to be safe for the target population of infants.

In summary, Nestlé considers express permission is not needed for MCT addition relating to protein substitutes, and this permission is redundant for the reasons outlined above and should be removed.

Q14. Are any specific compositional requirements (energy/macronutrient etc) needed in the Code if a new subcategory of formula for special medical purposes were created? If so, what are they?

Nestlé considers that for the same reasons outlined in the response to Q12, the same response applies here where for a new sub-category for "FSMP" type products proposed by FSANZ (otherwise the sub-category with modification we have proposed for products for *serious* conditions), we support the status quo with no additional compositional prescription, relating to the condition. Nestlé emphasizes that it is especially critically important, for these sub-category of products, to ensure continued supply to the infant in need of such specialised nutrition, and any prescribed compositional approach has potential risks of impacts to harmonisation and therefore supply to the Australian and New Zealand market.

Q15. What benefit, if any, would the inclusion of a specific requirement for any IFPSDU to be demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of intended infant subpopulation?

Nestlé considers that the inclusion of a specific requirement for any IFPSDU to be demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of intended infant subpopulation is already fairly representative of the current status quo without needing to explicitly express this in the FSC 2.9.1. Food supplied is regulated to be safe. "Beneficial" and "effective" are interchangeable or leads to a single outcome in terms of needing to substantiate nutritional suitability for

dietary management of the disorder, disorder or condition. As such we do not support the inclusion of what is already status quo and therefore this is not necessary.

Q16. Are there any issues with the current requirements for micronutrients and nutritive substances in IFPSDU products?

Nestlé considers there are issues with the current requirements for all regulated nutritional parameters where there is no permission to deviate from general purpose norms in FSC 2.9.1.

Nestlé supports the status quo permitting deviation only if relating to the disorder, disease or medical condition, if it prevents the sale of the product and is also scientifically validated. In addition, Nestlé supports for PSDU for infants, nutritional parameters not relating to the disease, disorder or condition - flexibility to align nutritional compositional requirements for IFPSDU to other credible regulatory jurisdictions, specifically Codex, EU and USA only, if it otherwise prevents the sale of such products.

The current regulations require that all the nutritional parameters for IFPSDU products including those for micronutrients and nutritive substances default to those norms for general purpose infant formula products in FSC 2.9.1 and several sections in Schedule 29 that list the vitamin, mineral, electrolyte, amino acid and nutritive substance minimum, guideline or maximum amounts and their permitted forms in infant formula products. A deviation is permitted if warranted but *only* for the condition which then needs to be scientifically substantiated. There are current issues in that the current nutritional parameters that are NOT relating to the disease, disorder or condition are not harmonised with Codex or EU, thereby leading to barriers for innovation. Furthermore, the EU regulations have recently changed, with EU implementation in EU markets forthcoming, and the new parameters could be even more challenging for recipe harmonisation to Australian and New Zealand regulations. The general infant formula compositional requirements across FSC 2.9.1 (and related schedules), Codex and EU regulations differ significantly for a few key nutrients which make recipe harmonisation impossible, preventing access and availability to these specialty products that are predominantly sourced for the EU. This is particularly relevant for products for metabolic, renal, hepatic, malabsorptive and immunological conditions, if a nutritional parameter is not related to the condition and is significantly different to the sourcing country, and deviation for this nutrient is not permitted. Speciality products are often always much lower volume products compared with general purpose infant formula products, and as such a shared recipe is required in order to commercialise the product to numerous markets.

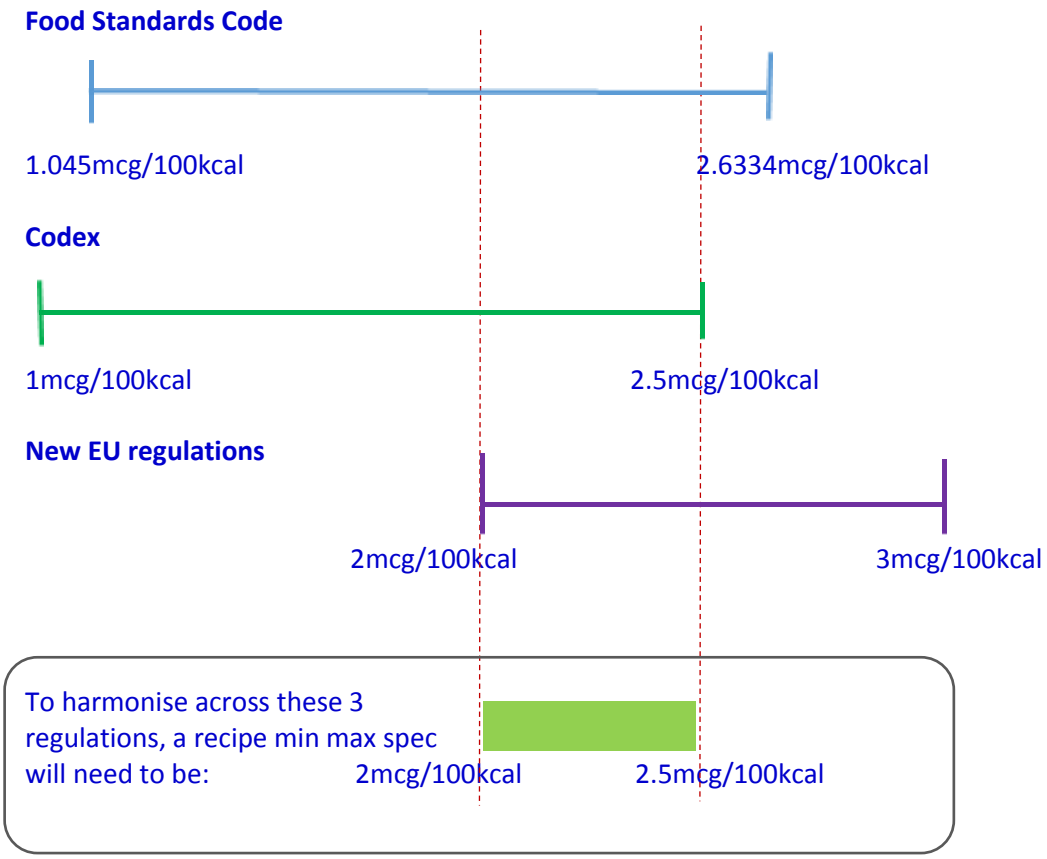
Below is one example of a nutrient not always related to the disorder, disease or condition, with varying compositional permissions across Codex, EU regulations and FSANZ Food Standards Code (FSC), to highlight the issues faced by manufacturers in trying to provide a product that is compliant to all market regulations.

<u>Vitamin D example</u>:

According to FSC 2.9.1 infant formula products compositional requirements, vitamin D composition has a min and max of 0.25mcg-0.63mcg/100kJ (1.045mcg – 2.6334mcg/100kcal). Under Codex standard 72 – 1981 composition for FSMP intended for infants, vitamin D has a min and max of 1mcg – 2.5mcg/100kcal. Under the new EU delegated regulation 2016/128 compositional requirements for FSMP intended for infants, vitamin D composition has a min and max of 2mcg – 3mcg/100kcal.

Recipe compatibility across different markets is **critical** for low volume products like IFPSDU. Market specific recipes for Australia and New Zealand are sometimes near impossible due to population size, and manufacturing technical challenges, etc. A manufacturer will try to harmonise a recipe from different

markets by formulating a product min max specification that is compatible across different markets. We have demonstrated an example using FSC, Codex and the new EU regulations as follows:



The above diagram illustrates the narrow range at which the FSC, Codex, and EU vitamin D compositional ranges are compatible (2mcg – 2.5mcg/100kcal). This narrow range however is far too narrow and technically not achievable for the manufacturer.

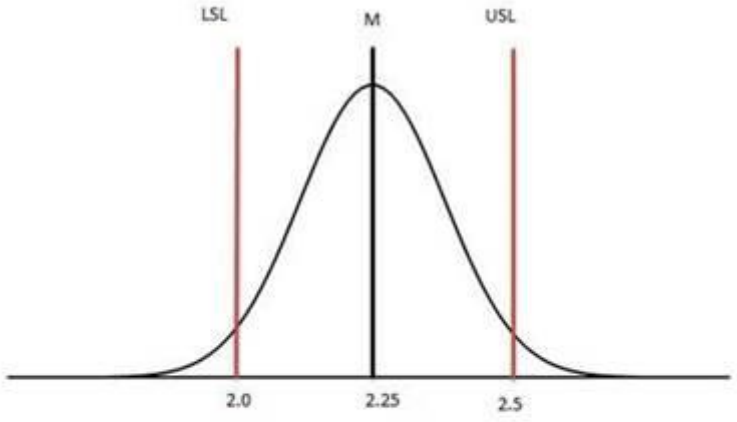
This is an issue for most PSDU products that are sourced from Europe, which we understand is the situation for the significant majority for the PSDU products on the Australian and New Zealand market.

Manufacturers need to consider nutrient variability due to:
[1] the raw materials
[2] the manufacturing process
[3] the analytical method

So in the above example, if a manufacturer targeted the exact middle of this harmonised range, i.e. 2.25mcg/100kcal, this reflects only a +/- 10% tolerance permitted, before the nutrient becomes non-compliant. Therefore, a min-max range that is compatible across multiple countries needs to consider the manufacturer's ability to control **the sum of** 3 variabilities – that of the raw material, manufacturing process, and analytical.

In the vitamin D example, a narrow nutrient range is not achievable for manufacturers as there is a variation allowance of +/- 15% for the recipe target, based on analytical variability *alone*. If we simulate eliminating the Codex countries, and ONLY have EU and FSC 2.9.1, the range then becomes 2-2.6334mcg/kcal with a middle target of 2.3167, which reflects only a +/- 12% tolerance permitted, so with a +/- 15% variability for the analytical method alone, this already means we cannot manufacture the batch to be compliant across both markets.

The +/- 15% analytical variability for Vitamin D comes about as follows –
According to the Standard Method Performance Requirements for Vitamin D in Infant Formula and Adult/Paediatric Nutritional Formula (AOAC SMPR 2001.004 in Appendix 1), the relative Standard Deviation of Reproducibility (RSD_R) is around 15%. Considering only the analytical variability, the probability to be out of 2-2.5 mcg/100 kcal (across 3 regulations) based on a standard deviation of 15% is 48.7% without considering variability from processing methods. See below graph:



Mean	M	2.25
Standard deviation	SD	0.36
Lower specification limit	LSL	2.0
Upper specification limit	USL	2.5
Frequency upper violation	F_u	24.37%
Frequency lower violation	F_l	24.37%
Total refquency of non-conformity	F	48.74%

AOAC SMPR 2011.004

The above is only for analytical variability. We still need to consider raw material and manufacturing process variability. Thus when considering the total variability of the Vitamin D content in Infant Formula, a range of 2 – 2.5 mcg/100kcal cannot be achieved and all batches will statistically fail in practically all cases.

The above example of vitamin D compositional dis-harmonisation, highlights the need for compositional flexibility to align with credible regulatory jurisdictions for general infant formula compositional requirements not relating to the disorder, disease or condition, if it would otherwise prevent the sale of these products.

Vitamin D is only one example, and there could be several other examples as well that would result in compositional dis-harmonisation with other countries, thereby leading to a threat of continued supply. Nestlé stresses that IFPSDU products are for the especially vulnerable infants, not in a healthy state that require specialised nutrition. Without these specialised products, the optimal nutrition of that infant and ability to dietary manage and support the disorder, disease or condition the infant has – will be

compromised. Some of these infants will not be able to use any general purpose infant formula products on the market, as their condition will not be able to tolerate those types of products for healthy infants. As such, the unavailability of a suitable PFSDU product could be potentially life-threatening for some of the highly specialised cases. IFPSDU products on the Australian and New Zealand market are currently supplied only by a very small number of suppliers, and with some highly specialised products, there are only 1-2 suppliers available. Nestlé is one of the few suppliers of IFPSDU products, including those products for highly specialised need.

Nestlé supports the status quo in relation to permission to deviate from FSC 2.9.1 general purpose norms, if the condition warrants the deviation and it is scientifically substantiated.

In addition -
It is our strong view that there are threats of non-harmonisation, and therefore major issues, based on the regulatory status quo for nutrients that do not relate to the disorder, disease or condition. Nestlé stresses the need to permit deviation for nutrients not relating to the condition, if it prevents the sale of the product, however the proposed condition is that deviation is only permitted if it defaults to key credible regulations, specifically Codex, EU and USA only.

Q17. Do you have any information to support the inclusion of a minimum and maximum amount of chromium in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?

Nestlé does not support the inclusion of a minimum and maximum amount of chromium in PSDU for infants, and proposes these regulatory requirements are removed.

Minimum amount
Although the Codex STAN 72-1981 specifies a minimum amount for chromium in section 3.1.4, it is mentioned only in situations '*where appropriate*'. Nestlé considers in this respect that chromium is optional for addition and 'if added', then the minimum limit applies. The more recent EU regulations, both Comm Dir 1999/21/EC and the incoming Comm Delegated Regulation (EU) 2016/128 on FSMP do not set a minimum amount, and as such therefore not proven as essential for normal growth and development outcomes. In its 2014 opinion (section 6.12), because there was unproven essentiality of chromium and no specific physiological function that could be ascribed to chromium, the EFSA panel considered that there was no necessity to add chromium to IF and FOF. In conclusion, fundamentally there is no strong evidence that justifies chromium as essential and therefore, a minimum is not necessary.

Maximum amount
The Codex STAN 72-1981 does not specify a maximum amount, only a GUL amount for chromium in section 3.1.4, again only in situations '*where appropriate*'. Nestlé considers that chromium is optional for addition and if chromium is added *where appropriate*, the sum of added and inherent (naturally occurring) chromium shall not be more than the GUL. Although the EU regulations, both Comm Dir 1999/21/EC on FSMP and the incoming Comm Delegated Regulation (EU) 2016/128 on FSMP do set a maximum for chromium in iFSMP, Nestlé still considers this as chromium not being a mandatory addition, however in situations where it is added, only it shall not exceed the maximum value. If not added however, and if minimum regulatory criteria is not necessary, then it is highly unlikely that inherent chromium will ever come close to the maximum.

The NHMRC and NZ MoH (2006) noted that ULs for chromium are unknown as there is insufficient data to establish these values. It was also noted that no adverse side effects were reported in a number of supplementation trials in which subjects received up to 1 mg chromium/day for several months (Flodin 1990,

Hathcock 1997). In conclusion, since both Codex and EU regulations presented that chromium is not a mandatory addition, and with no ULs and adverse effects established for chromium, Nestlé does not support the inclusion of a maximum amount of chromium for any infant formula product including those based on protein substitutes/non-intact protein.

Q18. Do you have any information to support the inclusion of a minimum and maximum amount of molybdenum in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?

Nestlé does not support inclusion of a minimum and maximum amount of molybdenum in IFPSDU.

Minimum amount

Although Codex STAN 72-1981 specifies a minimum for molybdenum in section 3.1.4, it mentioned '*where appropriate*', therefore Nestlé considers in this respect that 'if added', then the minimum limit applies. The more recent EU regulations, both Comm Dir 1999/21/EC on FSMP and the incoming Comm Delegated Regulation (EU) 2016/128 on FSMP do not set a minimum amount. Nestlé considers this as being not mandatory to add molybdenum and therefore not proven as essential for normal growth and development outcomes. In EFSA 2014 opinion (section 6.13), the panel noted that molybdenum deficiency has never been observed in healthy humans. Only one human case of possible dietary molybdenum deficiency has been reported in an adult patient on total parenteral nutrition (TPN) because of short-bowel syndrome (Abumrad 1981 reported in EFSA 2014). In conclusion, fundamentally there is no strong evidence that justifies molybdenum as essential and therefore, a minimum is not necessary.

Maximum amount

The Codex STAN 72-1981 does not specify a maximum, only a GUL amount for molybdenum in section 3.1.4, again in situations '*where appropriate*'. Nestlé considers that if molybdenum is added in the product/ingredients, it shall not be more than the GUL. Although the EU regulations, both Comm Dir 1999/21/EC on FSMP and the incoming Comm Delegated Regulation (EU) 2016/128 on FSMP do set a maximum for molybdenum in iFSMP, INC considers this as being not mandatory to add molybdenum, and only if added, shall not exceed the maximum value.

In addition, the NHMRC noted that there is insufficient information to establish an estimate for UL in infants. There are limited toxicity data in humans which may relate in part to the rapid excretion of molybdenum in urine, particularly at higher intake levels. In conclusion, since both Codex and EU regulations presented that molybdenum is not a mandatory addition, with no ULs and toxicity data available for molybdenum, Nestlé does not support the inclusion of a maximum amount of molybdenum for any infant formula product including those based on protein substitutes/non-intact protein.

Q19. Could one category of IFPSDU be used for all additional food additives, or should additional or modified subcategories be devised (noting the possible four subcategories in section 2.2).

Nestlé welcomes the FSANZ proposal to extend the current list of permissible food additives for infant formula products to enable harmonisation, particularly for the IFPSDU products that especially rely on harmonisation opportunities to ensure supply to the Australian and New Zealand markets.

Nestlé considers that the most appropriate framework is to have **one category for products for infants**, *instead of* the proposed one category of PSDU for all additional food additives, or devised according to the sub-categories. Additionally, we do not consider the status quo today in FSC 1.3.1, Schedule 15 is optimal.

Nestlé is proposing a change to current arrangements which will still achieve the regulatory purpose, but will also facilitate innovation and harmonisation.

The rationale for the Nestlé position is as follows –

General comments:

- It is critical to underline that the use of food additives in the manufacture of formulas for infants is indispensable and unavoidable; they are essential for preserving the nutritional quality, stability and/or aiding in the manufacturing or storage of these products until the end of shelf life.
- There are 2 *main* elements to regulation of food additives – [1] safety for the target population of infants; [2] technological justification.

As safety is not the issue here, Nestlé will focus the response relating to technological justification.

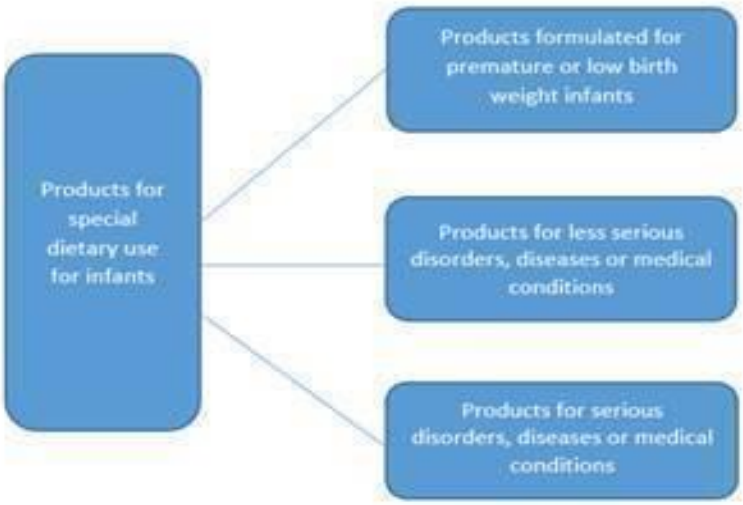
Issues with the food additives framework:

- Currently the framework within Schedule 15 is to limit the use of food additives depending on the ingredient base (i.e. soy or non-intact protein) or liquid vs non-liquid (powder) base. The issues with the current framework is as follows:
- Food additives are chosen appropriately for use by the manufacturer based on *many* technical elements, not limited to just ingredient base or liquid vs non-liquid phase therefore the current framework for use is not all encompassing.
- Regulatory clarity. For example, Carrageenan is permitted for both liquid infant formula products and IFPSDU based on a protein substitute but at a different maximum levels. It may be unclear as to which ML to apply to a liquid IFPSDU based on a protein substitute. Another example, Locust bean (carob bean) gum is permitted for use in all infant formula products however a higher amount would be necessary for the proposed purpose of a thickener in an anti-regurgitation IFPSDU which may also be based on a hydrolysed protein.

Issues with FSANZ proposed revised categories / sub-categories

The new regulatory framework Nestlé is proposing for products for special dietary use is as follows:

Figure 1.1: Possible new regulatory classification of IFPSDU:



In such a sub-categorisation approach, Nestlé is unsure how it is possible a food additive framework can align to a product categorisation framework for PSDU when the principles relating to food additive use is quite specific to the matrix that covers several technical elements -e.g. differences in manufacturing process (e.g. spray dry vs. dry blend etc.), ingredients (e.g. intact vs. hydrolyzed protein etc.), environmental conditions in the country of sale, and product format (e.g. powder vs. liquid), whereas a product categorisation framework is based on the nutritional purpose relevant to the disorder, disease or condition.

For example, a liquid PSDU product could be used across all-PSDU subcategories, as can a non-intact protein base, and manufacturing approach can be the same across all three, as can environmental conditions in a market for sale. Likewise the same scenario applies when considering general purpose infant formula products for healthy infants vs PSDU for special disorders, conditions or disease. This demonstrates that we need a harmonised framework for all infant formula products.

Proposed regulatory approach still captures current intent of appropriate selection of the additive fit for the matrix, at lowest possible levels to achieve the technological function

Nestlé considers that the most appropriate framework for Schedule 15 would be to have one category for all products for infants. While Nestlé is proposing to remove the sub-categorisation that is either matrix or ingredient dependant, from Schedule 15 Category 13.1 –

- Nestlé completely endorses the principle that the use of food additives in infant products targeted to the infant population regulated under FSC 2.9.1 should be limited to the lowest possible levels necessary for technological need.
- Nestlé supports an industry manufacturing approach reflecting selection of the most appropriate additive, or combination of additives, at only amounts necessary to achieve the technological purpose (per Schedule 14). The optimal choice regarding the selection of a food additive, or combinations of additives, to achieve the technological purpose, is made by the manufacturer. There has been no evidence of market failure in both these respects.
- We are also open to regulating a principles-based approach in the FSC to the above point on appropriate selection of the most suitable food additive, and the necessary level needed to achieve the technological purpose.

PROPOSED –
[1] Amend Schedule 15 to remove categorisation approach and duplications of food additives

Permissions for food additives

INS (if any)	*Description*	*MPL*	*Conditions*
13	**Special purpose foods**		
13.1	***Infant formula products***		
270	Lactic acid	GMP	
304	Ascorbyl palmitate	10 mg/L	
307b	Tocopherols concentrate, mixed	10 mg/L	
322	Lecithin	5 000 mg/L	
330	Citric acid	GMP	
331	Sodium citrate	GMP	
332	Potassium citrate	GMP	
410	Locust bean (carob bean) gum	1 000 mg/L	
412	Guar gum	1 000 mg/L	
471	Mono- and diglycerides of fatty acids	4 000 mg/L	
526	Calcium hydroxide	GMP	
~~13.1.1~~	~~Soy-based infant formula~~		
~~1412~~	~~Distarch phosphate~~	~~5 000 mg/L~~	
~~1413~~	~~Phosphated distarch phosphate~~	~~5 000 mg/L~~	~~Section 1.3.1—6 applies~~
~~1414~~	~~Acetylated distarch phosphate~~	~~5 000 mg/L~~	~~Section 1.3.1—6 applies~~
~~1440~~	~~Hydroxypropyl starch~~	~~25 000 mg/L~~	~~Section 1.3.1—6 applies~~
~~13.1.2~~	~~Liquid infant formula products~~		
~~407~~	~~Carrageenan~~	~~200~~	
~~13.1.3~~	~~Infant formula products for specific dietary use based on a protein substitute~~		
407	Carrageenan	1 000 mg/L	
471	Mono- and diglycerides of fatty acids	5 000 mg/L	
472c	Citric and fatty acid esters of glycerol	9 000 mg/L	
472e	Diacetyltartaric and fatty acid esters of glycerol	400 mg/L	
1412	Distarch phosphate	25 000 mg/L	
1413	Phosphated distarch phosphate	25 000 mg/L	Section 1.3.1—6 applies
1414	Acetylated distarch phosphate	25 000 mg/L	Section 1.3.1—6 applies
1440	Hydroxypropyl starch	25 000 mg/L	Section 1.3.1—6 applies
xxx	*Add new proposed additives here*	..... mg/L	

[2] The Manufacturer is well placed to determine appropriate additive selection and use. Optimal selection of the food additive for the appropriate matrix and at necessary levels to achieve the technological purpose are principles industry follows.

[3] Status quo for Schedule 14 and need to label technological purposes with the food additive: for example, "Lecithin (emulsifier)" is declared in a list of ingredient.

International precedence

- The amended framework to confirm technological justification is still consistent with Section 3.2 of the Preamble of the General Standard for Food Additives (GSFA).
- Whilst not 100% aligned to the Codex and EU approach to regulating food additives, we consider the proposed framework is aligned to the intent of Codex and EU and will facilitate harmonisation, particularly if different terminologies are used on Codex and EU (e.g. "protein substitutes" terminology does not exist in other key jurisdictions).

Proposed regulatory approach facilitates innovation

Different additives can have a similar technological function, so it is important new additives are considered in order to support continued innovation within the product category as new ingredients are introduced and/or other improvements are made to these products and to manufacturing. Specific additives can be more effective under different product conditions. Regulating food additive permission within the current framework that is limiting in its use based on ingredient matrix alone, or to regulate food additive

permission with the future framework based on sub-categorisation for nutritional purpose for the disorder, disease or condition, does not facilitate innovation.

Other benefits:
The amended framework would minimise restricting access to products from other markets e.g. EU, USA where the sub-categories are inconsistent with those in the Food Standards Code whilst remaining aligned to the intent.

Q20. Do you support the proposed amendments listed in Table 7 for IFPSDU at the amounts shown?

Yes – Nestlé supports the proposed amendments.

Q21. Can you provide information on suitable international safety assessment, a demonstrated history of safe use in the context of IFPSDU, and a technological justification for:
a) Calcium carbonates
b) Calcium citrates
c) Phosphoric acid
d) Sodium alginate
e) Xanthan gum
f) Locust bean (carob bean) gum
g) Pectins
h) Sodium carboxymethylcellulose
i) Sucrose esters of fatty acids
j) Starch sodium octenylsuccinate

Nestlé supports the Infant Nutrition Council (INC) responses to this question.

Q22. Are there any technologically justified concerns with changing the permissions for citric and fatty acid esters of glycerol (472c) to:
a) MPL of 9000 mg/L for liquid products
b) MPL of 7500 mg/L for powdered products?

Nestlé supports changing the permissions for citric and fatty acid esters of glycerol (472c) fatty acid esters of glycerol (472c) as proposed to align to Codex and EU. We don't have any technological concerns with this change.

Q23. What is the technological justification for the use of diacyltartaric and fatty acid esters of glycerol (472e) in IFPSDU? Are there any technologically justified concerns with the removal of this permission?

Nestlé supports the INC response to this question.

Q24. Do you support retaining a maximum PRSL for any IFPSDU? Please provide your rationale.

As noted earlier in this submission, the PRSL is the sum of dietary nitrogen, sodium, potassium, chloride, and phosphorus. Its relevance for protein substitutes was due to a permitted higher maximum for protein. If the protein parameters are adjusted to follow the same compositional approach as all other products for special dietary use, then PRSL is not required for a starter specialty product as the protein maximum defaults to the general-purpose norm of 0.7g/100kJ, and if a follow-on specialty product, then a PRSL is required anyway as this is the requirement currently also for general purpose follow-on formula for healthy infants.

With a general scientific tendency towards lower protein content in most infant formula products in recent years, and to more closely align to breast milk levels, the PRSL has become less important clinically, as high solute loads are not being provided. An example here would be with the extensively hydrolysed protein-based infant formula Alfare, mentioned in P93 as having a declared protein of 2.5g/100ml in the early 2000s, decreased now to 2.0g/100ml in 2017, significantly reducing its PRSL and we believe making regulation in this area redundant.

There is also no key international precedence, e.g. Codex and EU which regulates PRSL.

For follow-on formula, we are open to retaining the current PRSL if defaulting to current general purpose norms. However Nestlé would be proposing a review of such a requirement for general purpose norms in a future proposal to review follow-on formula as a result of the pending Codex FUF 6 – 12 months protein outcome to reduce the maximum permitted level to 3.0g/100kcal.

Q25. To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?

In Australia, there are two categories of pre-term infant formula available, those designed primarily for use in hospital (pre-term formula) and those designed for use post-discharge (pre-term post-discharge formulas, PDF's) which differ in their macronutrient and micronutrient composition, as well as total energy. Generally for the pre-term/LBW infant formula, energy is ~ 24kcal strength per 30ml, with the pre-term post-discharge formula being ~ 22kcal and term infant formula ~ 20kcal, reflecting the different energy needs of the consuming population.

In Australia, pre-term PDF's are available via a home delivery service requiring healthcare professional registration of patients or at selected pharmacies (responsible institutions). Pre-term PDF is not currently available on a pharmaceutical benefits scheme prescription in Australia. However, in New Zealand, the Pharmac schedule permits subsidy of pre-term PDF if the infant meets certain criteria.

For pre-term formula in Australia and New Zealand, currently these products are sold to hospitals and there is no subsidy provided for use after hospital discharge. There is also no general sale currently for these products, neither via manufacturers nor via pharmacy. It is conceivable that the ongoing push towards earlier hospital discharge could lead to a situation where pre-term infant formula may be required in the community under medical supervision. If that was to occur, then accessibility via responsible institutions could take place as it does for pre-term PDF's currently.

Q26. Would you support the requirement for a statement that the product must be used under medical supervision, where the wording is not prescribed (an approach which harmonises with the overseas and international requirements)? Please describe your reasons why you do/do not support.

Nestlé supports the current status quo requirement for a statement that the product should be used under medical supervision, which is also aligned to the international approach. We support a regulatory approach where the wording is not prescribed, as prescription on wording may lead to risks relating to labelling harmonisation, which in turn then increases the risks on threats to supply.

Q27. Are there any specific FSMP labelling requirements that you consider applicable to a particular type of IFPSDU?

Nestlé does not consider any specific FSMP labelling requirements from FSC 2.9.5 (Food for special medical purposes) that is applicable to a particular type of PSDU for infants. Rather, we support a harmonised labelling requirement applicable to ALL PSDU for infants. We could however be open to a specific regulatory requirement for name of food relating to products for prematurity or low-birth weight infants. However we don't support regulatory prescription of "pre-term" as part of the name of food, rather we support similar words which capture the intent to support labelling harmonisation.

Q28. Are there any specific FSMP labelling requirements that should apply to all IFPSDU?

In general, Nestlé considers quite a number of FSMP elements from FSC 2.9.5 are 'duplicated' already in FSC 2.9.1 – both in terms of specific labelling requirements for IFPSDU, and the need for IFPSDU to default to labelling for general purpose norms for healthy infants in all other respects. While the labelling elements from FSC 2.9.5 is not 'duplicated' *exactly*, we consider 'duplication' has respected the labelling intent of FSC 2.9.5.

In terms of any specific FSMP labelling requirements from FSC 2.9.5 not currently 'duplicated' or captured by FSC 2.9.1 –

Nestlé **supports** introduction of the following from FSC 2.9.5 to apply to PSDU for infants regulated by FSC 2.9.1:

- *(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (*However optional application, not mandated.)
- *the words 'Expiry Date', or similar words, may be used on the label.*

Nestlé is **not opposed to**:

- *(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food.*

Nestlé **DOES NOT support**:

- *(i) a statement to the effect that the food is not for parenteral use;*
- *a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the food, as appropriate.*

For the information relating to ingredients, Nestlé reserves our comments on this matter until such time a more detailed evaluation can be completed to determine compatibility to EU and USA regulations. Depending on the extent of the differences that could lead to a non-compliant outcome, we consider that minimal differences could be accommodated in FSC 2.9.1, rather than an all-inclusive approach as per FSC 2.9.5. In the table below, Nestlé has provided specific comment to each of the labelling requirements in FSC 2.9.5 discussed in the consultation paper:

Current FSMP labelling requirements in the Code	In FSC 2.9.1?	Comments as to whether these specific FSC 2.9.5 FSMP labelling requirements should apply to all PSDU for infants (P1028 consultation paper, 2017)
2.9.5—10 Advisory and warning statements—food for special medical purposes		
(a) a statement to the effect that the food must be used under medical supervision;	Yes	Already currently required in FSC 2.9.1 for Prematurity/LBW and IFPSDU for metabolic, immunological, renal, hepatic and malabsorptive conditions. With the proposed redundancy of protein substitutes, and separation of the IFPSDU for metabolic...etc. into 2 sub-categories for less serious vs serious conditions, the medical supervision statement is effectively status quo with exception of our request to not have any prescribed wording (which currently exists for prematurity /LBW products).
(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food	No	While there is no evidence of market failure (e.g. Nestlé voluntarily apply a contraindication for galactosemia for NAN LI for lactose intolerant babies), we are not opposed to the introduction of this requirement into FSC 2.9.1.
(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated	Yes	Already required in FSC 2.9.1 with the exception of protein substitutes. With the proposed redundancy of the sub-category of protein substitutes, this is already covered by status quo in FSC 2.9.1.
(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (c)	No	Nestlé supports the introduction of this labelling requirement into FSC 2.9.1 PSDU products. However we suggest this is optional instead of being mandated. In some products where it is only 1 ingredient, e.g. Lactose free for lactose intolerant babies this is possible to mandate. But for some other more complex products, e.g. preterm formula or HMF's because there are several ingredients that relate to the condition, due to label space restrictions, mandating the need to describe ALL the properties or characteristics of the food appropriate for the disease, disorder or condition, is not supported by Nestlé.
(e) if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group	Yes	Already covered by FSC 2.9.1 due to prescribed names infant formula and follow-on formula and need to label from birth for infant formula. Follow-on formula needs a statement that the product should not be used for infants under 6 months. Manufacturers also typically label the age and staging on all infant formula products.
(f) a statement indicating whether or not the food is suitable for use as a sole source of nutrition	Yes	Covered in a sense in that all infant formula products (except pre-term products) require a statement to recommend that infants over the age of 6 months should be offered foods in addition to infant formula. There is no evidence in market failure to this respect as carers know that infant formula can be used as a sole source of nutrition, and follow-on is a principle source due to introduction of complementary foods. Inappropriate use for a follow-on IFPSDU product has not, to the best of our knowledge, been demonstrated in this market.
(g) if the food is represented as being suitable for use as a sole source of nutrition: (i) a statement to the effect that the food is not for parenteral use; and (ii) if the food has been modified to vary from the compositional requirements of section 2.9.5—7 such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable): (A) a statement indicating the nutrient or nutrients which have been modified; and (B) unless provided in other documentation about the food—a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the food, as appropriate.	(i) No (iiA) Yes (iiB) No	(i) While this is required in Codex, Nestlé is not sure of a need to mandate it in Australia and New Zealand. In a developed market such as in AU NZ, we are not aware of inappropriate nutrient delivery in the consumption of IFPSDU by any carer or HCP providing IFPSDU intraveneously to the infant. There is no evidence to the best of our knowledge of inappropriate use of this nature in Australia and New Zealand to warrant such a statement to be mandated. (ii) (A) Already required by FSC 2.9.1 IFPSDU for the metabolic ....etc. conditions. Nestlé would like to retain this for the proposed less serious and serious sub-categories, the sum of which are equivalent to the current sub-category of metabolic...etc. conditions (B) Nestlé does not support the introduction of this labelling requirement into FSC 2.9.1 PSDU products. This is unnecessary as there is already a requirement to provide a statement indicating the nutrient or nutrients that have been modified, and another regulatory requirement that deviation to general purpose norms is only permitted for the disease, disorder and condition and must be scientifically substantiated. Accordingly, other stakeholders either HCPs or jurisdications can be supplied the relevant documentation on request as to the levels relating to the modification when requested, since the modified nutrients need to be identified. Nestlé also considers that given the current extensive labelling requirements for an infant formula product, any labelling elements that are not necessary could compromise on the ability to fulfil the requirement on minimum print size, especially for smaller sized packs.

2.9.5—11 Information relating to ingredients—food for special medical purposes		
For paragraph 2.9.5—9(1)(e), the information relating to ingredients is: (a) a statement of ingredients; or	Yes	Current status quo
(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	No	Our preliminary investigation appears to show while EU IL's look different to AU NZ, they appear to be possibly compatible in terms of compliance requirements, so this may not be needed, however further detailed evaluation will be needed to conclusively determine this.
(c) information that complies with 21 CFR § 101.4.	No	Our preliminary investigation appears to showwhile EU IL's look different to AU NZ, they appear to be possibly compatible in terms of compliance requirements, so this may not be needed, however further detailed evaluation will be needed to conclusively determine this.
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.	Yes	Current status quo
(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.	No	Nestlé supports the introduction of this labelling requirement into FSC 2.9.1 PSDU products to support labelling harmonisation.

In addition to the responses above on labelling, Nestlé would like to provide comments in relation to the need for label harmonisation for PSDU products for infants, and current issues which could restrict trade due to risks for non-harmonisation.

<u>Prescribed labelling</u>

Prescribed labelling for IFSPDU products currently in FSC 2.9.1 are either specific to an IFPSDU category (e.g. prematurity and LBW products and Lactose free and low lactose products), or in all other respects default to the general purpose labelling norms for healthy infants. The relevant prescriptive statements are in FSC 2.9.1-19.

Nestlé supports the need to regulate the intent of but not regulate by way of prescribed wording which would then potentially lead to non-harmonisation and therefore threats to trade and supply. As such we request the all currently prescribed labelling in FSC 2.9.1, becomes un-prescribed wording.

Q29. What specific labelling requirements for the safe preparation and use of IFPSDUs are being used that contradict the general requirements set out in subsection 2.9.1—19(3) of Standard 2.9.1?

Nestlé is not aware of any labelling issues for IFPSDUs that contradict the general requirements set out in subsection FSC 2.9.1-19(3). Nestlé markets a number of infant formula products for healthy infants, as well as infant formula products for special dietary use and have no issues with the compatibility of safe preparation and use that we have identified to date. Even if there are some differences in preparation, the FSC does not restrict extra information for preparation being placed on a label by the manufacturer (for example, a 2-step reconstitution step for some infant formula products containing thickeners, vs a typical 1-step reconstitution step for infant formula products not containing thickeners).

If however, human milk fortifiers (HMF's) are brought into scope of FSC 2.9.1 PSDU for infants, then there could be specific preparation steps for this type of product that would contradict the general requirements set out in subsection FSC 2.9.1-19(3). For example, boiled water is not relevant for breastmilk that is fortified.

Q30. What evidence can you provide to support concerns regarding inappropriate access to any IFPSDU?

Nestlé does not have any evidence to support concerns regarding inappropriate access. However, we are open to trade restrictions imposed on two sub-categories only, as outlined in the response to Q2 – that of products formulated for premature or low birth weight infants, and products for serious disorders, diseases or medical conditions. The proposed trade restrictions should be identical to those in FSC 2.9.5 for purposes of consistency, and no more.

For products relating to the less serious disorders, diseases or conditions, Nestlé considers the status quo is appropriate, so that the carer, following HCP recommendation, could have greater access to the product especially given grocery trade channels have longer opening hours as compared to pharmacy.

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Appendix 1 – AOAC SMPR 2001.004

AOAC SMPR 2011.009

Standard Method Performance Requirements for Cr, Mo, and Se in Infant Formula and Adult/Pediatric Nutritional Formula

Intended Use: Global Dispute Resolution Method

1 Applicability

Determination of total chromium (Cr), molybdenum (Mo), and selenium (Se) in all forms of infant, adult, and/or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates).

2 Analytical Technique

Any analytical technique that measures all three analytes simultaneously and meets the following method performance requirements is acceptable.

3 Definitions

Adult/pediatric formula.—Nutritionally complete, specially formulated food, consumed in liquid form, which may constitute the sole source of nourishment, made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Infant formula.—Breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding, made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Limit of detection (LOD).—The minimum concentration or mass of analyte that can be detected in a given matrix with no greater than 5% false positive risk and 5% false negative risk.

Limit of quantitation (LOQ).—The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Repeatability.—Variation arising when all efforts are made to keep conditions constant by using the same instrument and operator, and repeating during a short time period. Expressed as the repeatability standard deviation (SD_r); or % repeatability relative standard deviation (%RSD_r).

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility standard deviation (SD_R); or % reproducibility relative standard deviation (% RSD_R).

Recovery.—The fraction or percentage of spiked analyte that is recovered when the test sample is analyzed using the entire method.

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4 Method Performance Requirements[a]

	Cr	Mo	Se
Analytical range	20–1600	20–1000	10–500
Limit of detection (LOD)	7[b]	7	4
Limit of quantitation (LOQ)	20	20	10
Repeatability (RSD_r)	≤5	≤5	≤5
Recovery factor	90 to 110% of mean spiked recovery over the range of the assay		
Reproducibility (RSD_R)	≤15% over the analytical range		

[a] Concentrations apply to (*1*) "ready-to-feed" liquids "as is"; (*2*) reconstituted powders (25 g into 200 mL water); and (*3*) liquid concentrates diluted 1:1 by weight.

[b] µg/100 g expressed as cyanocobalamin in reconstituted final product.

5 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blank check samples, and check standards at the lowest point and midrange point of the analytical range.

Example protocol:

- Blank check samples (reagent blank levels <0.4 µg/L Cr, Mo; <0.2 µg/L Se)
- Calibration verification (CV) standards at the midrange point of the calibration range (valid samples must be bracketed by CVs that agree within 5% of nominal)
- Calibration error must be no more than 5% at the blank check concentration limits listed above (checked once), and all samples must have analytical solution concentrations above this lower linearity limit
- The % RSD of duplicate results for Cr, Mo, and Se concentrations in each sample must be 10% or better (6% for the control sample). A control sample (NIST 1849 or equivalent) must be run with every set of samples. The mean of duplicate control results must be within the certified limit and within local control limits, if a control chart is in place. The relative standard deviation (%RSD) of the mean for Cr, Mo, and Se as calculated from such control chart must be <5%.

6 Reference Material(s)

National Institute of Standards and Technology (NIST) Standard Reference Material® 1849 Infant/Adult Nutritional Formula, or equivalent. The SRM is a milk-based, hybrid infant/adult nutritional powder prepared by a manufacturer of infant formula and adult nutritional products. A unit of SRM 1849 consists of 10 packets, each containing approximately 10 g of material.

7 Validation Guidance

Recommended level of validation: *Official Methods of Analysis*℠.

8 Maximum Time-to-Signal

Eight hours for all three nutrients.