Nestlé Submission

Consultation Paper 3 2021

Proposal P1028 - Infant Formula

20 October 2021

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Consultation Paper 3 2021: Proposal P1028 - Infant Formula

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

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

Nestlé welcomes the opportunity to consider the issues and preliminary views proposed in the consultation paper for Proposal 1028 (P1028), and to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the Consultation paper on the Regulation of Infant Formula. We thank FSANZ for its consideration of the comments, issues and views raised in this submission.

Introduction:

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

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

Comments and Responses to Questions

Section 2: Novel Foods and Nutritive Substances

2.1 Pre-market assessment requirements

Novel foods and nutritive substances

Nestlé supports the deferment of consideration of requirements to permit novel foods and nutritive substances in infant formula products to the broader review of the Code's provisions applicable to all foods (P1024).

We support the principle of 'risk-based' consideration of new foods, where the assessment requirements are 'graduated' according to the nature of the new food or food substance.

New ingredients

Nestlé notes that the policy guideline for Regulation of Infant Formula Products requires that regulation of infant formula products should be based on risk analysis, 'taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants'. The guideline goes on to require pre-market assessment of all substances that do not have a history of safe use at the proposed level in these products in Australia and New Zealand[1].

Requiring all new foods or food substances to have a full risk assessment, does not take into consideration the origin, nature, chemical structure or processes to which the new entity may have already been assessed or subjected. That is, applying the extensive requirements of the Application Handbook based solely on the fact that the food or food substance is 'new' to

[1] Policy guideline for Regulation of Infant Formula Products Specific policy principle (i)

Australia and New Zealand ignores the concept of 'risk' and results in unnecessary time and cost when applied to substances that are inherently low risk, or which have been through competent risk analysis processes elsewhere.

In many instances, there are comparable risk assessment and risk management processes applied to these products in recognised, competent international jurisdictions such as the EU, USA or internationally CODEX. Adopting and adapting such international reviews would be time and cost efficient for all Australia and New Zealand food regulation stakeholders.

Section 3: Specialised infant formula products

3.1 Approach to regulation of Infant Formula Products for Special Dietary Use (IFPSDU)

Nestlé supports the FSANZ proposal to retain the regulation of IFPSDU in Standard 2.9.1, as retaining the status quo maintains all IFP which are sole sources of nutrition for infants in a single standard. This Standard collates the many essential matters pertaining to IFP.

The integrity of Standard 2.9.1, as codifying for sole sources of nutrition for infants, is maintained for when it comes to infant formula products for special dietary use, as any compositional variations considered necessary to provide for the varying needs of low birthweight infants or those who suffer from metabolic or malabsorptive conditions can be readily and flexibly accommodated in subclause 1 of Division 4 2.9.1-13 and 2.9.1-14:

> *compositional requirement of this Standard does not apply to the extent that it would prevent the sale of an infant formula product that has been specifically formulated for specific birthweight conditions or metabolic conditions…*

These products have been specifically formulated to meet the specific requirements of those infants, few in number, but whose needs are very specific. Many of these infants are reliant upon imported products from a small number of manufacturers for their nutrition.

The Standard must provide the necessary flexibility, permitting and adapting to the changes in scientific understanding and enabling sale of products imported from markets meeting EU, CODEX or USA requirements, without needing to codify each minor variation. This enables this subgroup of infants access to the best possible products. For the avoidance of doubt, it is essential that certain products can be drawn from the EU, USA or Codex compliant supply chains, without modification to fulfil market requirements in Australia and New Zealand.

In contrast, moving these products into Standard 2.9.5, Foods for Special Medical Purposes (FSMP) has no particular merit, and would see products that are sole sources of nutrition for infants appearing in a 'general population' Standard. This is likely to complicate Standard 2.9.5 with infant-specific requirements and creating confusion as a result.

Nestlé understands that some concerns have been raised as to the appropriate retail channels for these products, and that supermarkets are not appropriate. Nestlé notes that these products are not inexpensive and are generally purchased upon the advice of a medical practitioner. Nestlé is unaware of market failure in current arrangements that would necessitate or justify restriction of IFPSDU product sale channels.

3.2 Human milk fortifier and pre-term supplementary products

Nestlé supports the location of human milk fortifier and pre-term supplementary products in Standard 2.9.5 FSMP. This position recognises that these products are not intended as sole sources of nutrition and are used in conjunction with other sources of nourishment, and accordingly fit better within Standard 2.9.5. We believe that any subsequent provisions relevant to infant products that are needed in Standard 2.9.5 should be considered as part of P1028.

Section 4: Definitions

Question 2. Is a definition of soy-based formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

Nestlé agrees with FSANZ that soy-based infant formula is self-explanatory and that a definition for soy-based infant formula is not needed.

Question 3. Is a definition of pre-term formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

Nestlé considers that pre-term infant formula is self-explanatory and that a definition is not needed. If retained, the current definition is appropriate.

Question 4. Are definitions needed for any of the new terms proposed to be introduced as conditions for the use of food additives in CP1 such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism etc.?

Nestlé does not consider that any definitions for the new terms proposed to be introduced as conditions for the use of food additives are needed. These terms are not defined in Codex Stan 72-1981 or EU regulations and are generally well understood. In addition, this avoids any confusion regarding minor differences in phrasing.

Section 5: Regulatory framework for IFPSDU

5.1 Description of IFPSDU in Division 4 of Standard 2.9.1

Nestlé agrees with FSANZ that there is overlap and potential uncertainty related to current subcategories and related definitions. We are aware that some products in this Division are used beyond infancy at the discretion of the healthcare professional.

Nestlé does not agree with FSANZ that the voluntary labelling of 2.9.1-19 (1)(d) "*Important Notice: Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice*" is an indication that the product is not a product for metabolic, immunological, renal, hepatic and malabsorptive conditions (2.9.1-14).

5.2 Options for regulatory framework

Flexibility is essential

The breadth and complexity of diseases, disorders and conditions and the broad range of products required to address these, requires that the Standard provides for flexibility by permitting compositional variation where it is required to address a specific condition, providing that specific condition is clearly identified, rather than codifying each product.

The IFP industry has responded to these nutritional needs by developing and introducing a range of products that can be generally classified as less-specialised (e.g. transient conditions such as reflux and colic) and more specialised (e.g. for premature infants, or for metabolic, immunological, renal, hepatic and malabsorptive conditions).

Nestlé strongly supports an approach to the framework that will provide access to a wide range of products from which healthcare professionals can choose which best suit patient needs, and that these products are made to recognised, national and international standards including those from CODEX, EU and USA.

Preliminary view is not supported by a risk assessment
The preliminary discussion in 2017 considered a number of options for the structure of Division 4 – with the objective of recognising some product sub-categories within IFPSDU (Table 13: Summary of submitters' preferences for Division 4 options in 2017). Unfortunately, there was no consensus on structure.

This consultation paper (CP3) proposes that all IFPSDU be placed in a single category of IFPSMP. The consequences of this are significant, as detailed in sections 5.3 and 5.6.4. of this document.

In brief, the chief consequence is that now all IFPSDU will be classified as IFPSMP, and be considered similarly to Standard 2.9.5, and sharing some of the same risk management measures. For example, restrictions on distribution and sale approaches for that Standard would now be applied to IFPSMP. This is an unwelcome and unjustified change.

Nestlé is deeply concerned that there is no consistent risk to be managed across all IFPSDU (also noted by FSANZ), and no evidence given that there is market failure, justifying such a measure.

Consistency with another standard is an inadequate reason for adopting a more restrictive risk management measure, and this is contrary to Article G of the Overarching Strategic Statement[2] for the Food Regulatory System that requires that 'regulatory decisions are based on sound evidence and are proportionate to the associated risk'.

Nestlé's alternative view is that recognising two classes of IFPSDU i.e. less specialised and specialised, offers the opportunity of providing for a graduated risk management approach rather than a single highly restrictive risk management approach needing to be applied to all products in Division 4.

In 2017, INC provided a suggested definition for Infant Formula Products for Special Medical Purposes to provide for a sub-category in Division 4. As a result of the further discussion in CP3, this could be amended to a single sub-category with definitions as proposed by INC in their submission. The provision of a sub-category for IFPSMP that are intended for those infants with clinically serious or potentially life threatening disorders, disease, or medical conditions and which are usually required for extended periods of time allows for a graduated risk approach.

5.3 Principles for purpose, composition, use and sale of IFPSDU

5.3.2 Nutrient composition and use under medical supervision

These products provide either the sole or principal source of nutrition to infants to support growth and development to support the dietary management of infants with a specific disorder, illness or condition. They are not therapeutic products. Hence the nutrient composition should be based upon the general nutritional needs of infants and provide the necessary flexibility, permitting and adapting to the advances in scientific understanding and enabling imported products meeting EU, CODEX or USA requirements, to be sold without needing to codify each minor variation in a Standard.

Nestlé agrees that these products should continue to be used under medical supervision.

5.3.3 (1) Extension of use beyond infancy

Nestlé agrees that it is appropriate to consider the continued use of IFPSDU beyond infancy however this should remain at the discretion of the healthcare professional.

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[2] Overarching Strategic Statement for the Food Regulatory System
https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-stategic-statement

5.3.3 (2) Restriction on sale

Nestlé is deeply concerned by the current proposal to restrict sale and distribution of products currently classified as IFPSDU, in the absence of documented, substantive risk.

Considering discussion in 5.3.3 and 5.6.4, FSANZ is proposing to

a) Classify all IFPSDU as IFPSMP group; and to

b) Limit sale and distribution of all IFPSMP to be consistent with Standard 2.9.5

By creating a single category of IFPSMP and adopting similar restrictions on sale and distribution applied to FSMP, less specialised IFPSDU will become less accessible.

The proposed restriction of sale for the sake of consistency with Standard 2.9.5 is without foundation. It is not supported by documented evidence of risk, and there is no documented 'market failure' in respect of IFPSDU currently sold in supermarkets. The impact on mothers and caregivers does not appear to have been considered. (See also Section 5.6.4 Distribution and Access).

Also, due to the highly specialised nature and cost of many of these products, they are currently only available either to institutions such has hospitals or are prescribed by a doctor, frequently being PBS or Pharmac listed. That is, the market is effectively self-regulating.

In summary, Nestlé does not agree that all IFPSDU should be subject to the restrictions on distribution and market access that apply to Standard 2.9.5. If necessary, a graduated approach could be applied.

5.4 Name and definition of IFPSDU

Nestlé supports the INC proposal to simplify the proposed definition features:

- serves as either a breast-milk substitute ~~for human milk, and~~ or replacement ~~of~~ for IF and FoF
- is specially formulated for the dietary management of infants with a disorder, disease or condition based on appropriate scientific evidence
- ~~is for infants:~~
    - ~~who have special medically determined nutrient requirements, or~~
    - ~~who have limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolites of other IFPs, and~~
    - ~~whose dietary management cannot be completely achieved without the use of IFPSMP~~
- is a food ~~that must~~ intended to be used under medical supervision.

5.5 Provisions for IFPSMP – Composition

Nestlé strongly requests that the Standard provides permission for nutrients to deviate from 'baseline' composition not relating to the specific condition but complying to key credible regulations, specifically Codex, EU and USA, particularly as these international regulations change and evolve. This flexibility will enable continuity of supply where variable market offtakes may result in product being sourced from alternative markets.

Currently Division 4 provides for a range of IFPSDU to address these dietary concerns and physiological and metabolic conditions. Flexibility in composition is permitted provided that product is clearly formulated for infants with a specific condition (Standard 2.9.1 Division 4 clause 13(1) and 14(1), allowing only those nutrients substantiated for the condition to vary. However, given the limited population, it is sometimes necessary for the 'essential baseline' composition to vary. These variations may be broader than just those required to address the specific condition and affect other nutrients such as vitamins and trace minerals where requirements of EU Regulations or Codex Standard 72-1981 may not align precisely with

those set out in the Code (Refer to Figure 1- Manufacturing Capability of Vitamin D). These may prevent the trade and supply of these products for vulnerable infants with special dietary needs.

Permitting flexibility from 'baseline' composition will enable specialised products to be shared with and imported from other markets, such as Europe and the USA, where products are made to standards established by other jurisdictions. The low volumes do not justify unique, local development and manufacture, and flexibility enables this subgroup of infants timely access to the best possible products.

Figure 1: Manufacturing Capability of Vitamin D

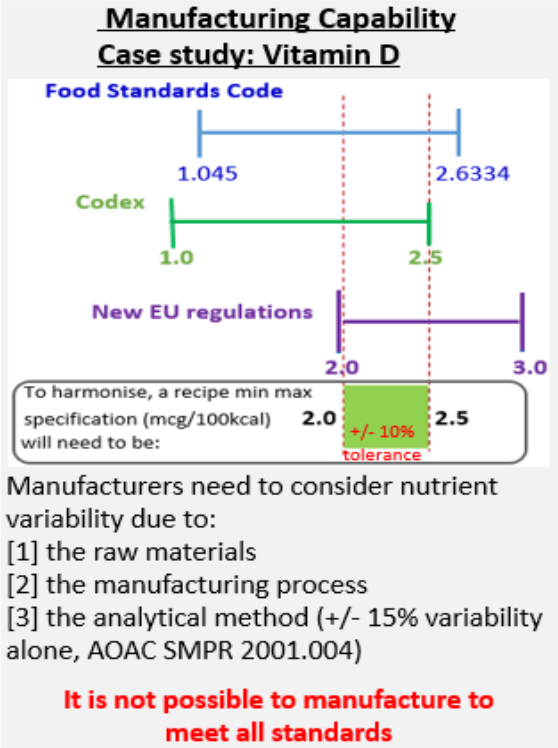

Figure 1 shows differing Vitamin D specifications for IFPSDU across standards set by the EU, CODEX, and the Code. There is an impossibly narrow range where a product could meet all specifications concurrently.

This supports the view that where small volume products (e.g. IFPSDU) are imported, to meet Code requirements, flexibility should be extended beyond compositional changes 'to address specific purpose', to essential baseline composition such as vitamin and mineral specifications.

5.5.1 Products formulated for premature or low birthweight infants

Nestlé agrees with FSANZ that no additional composition requirements are required for products formulated for premature or low birthweight infants.

5.5.3 Products for specific dietary use based on a protein substitute

Nestlé remains of the view that the category of products for specific dietary use based on a protein substitute and its compositional requirements are not required.

Question 7. To industry submitters: What types of partially hydrolysed IFP are on the market? And what is their maximum level of protein denaturation? Are any on the pharmaceutical benefits schemes in Australia or New Zealand? Please provide supporting detail and data, where available

The role of partially hydrolysed IFPs (pHFs) has been widely studied for more than 30 years and in over 20 randomised double-blind clinical trials, and the most recent systematic review examining this type of product was published by Vandenplas *et al* (2019)[3]. They defined partial hydrolysates as typically containing peptides of average molecular weight <5 kDa, as opposed to extensively hydrolysates where > 90% of peptides have a molecular weight

[3] Vandenplas, Y; *et al*. Partially hydrolyzed formula in non-exclusively breastfed infants: A systematic review and expert consensus. Nutrition, 2019, 57, 268-274

<3kDa. It is important to note there is significant overlap in these definitions and extensive hydrolysates will contain some partial peptides, while partial hydrolysates will contain some extensively hydrolysed peptides. Differences also result based on method of hydrolysis (heat, enzymes), protein base (whey or casein), and manufacturer – as some processes are patented.

This systematic review re-affirmed that partial hydrolysates are safe – *"no literature was identified that suggested that pHF would not be an appropriate starter formula compared with intact [Cows' Milk Formula] CMF. From a regulatory perspective, pHFs are an accepted starter formula for infants who cannot be exclusively breastfed, and this is echoed by current guidelines".*

Independent RCT data from the large German Infant Nutritional Intervention (GINI) study now has follow-up to 20 years of age showing no differences in growth between formula groups but some improved health effects (atopic eczema, asthma) in the partially hydrolysed group compared to the intact Cows Milk Protein formula group.[4]

To the best of our knowledge, all of the current partially hydrolysed IFPs on the Australian and New Zealand markets are based on 100% whey, while in other countries there are products based on casein or a whey:casein mix.

Question 8. To health submitters: You have told us that partially hydrolysed IFP are not efficacious in preventing allergy; are they useful in the dietary management of allergy? Please provide supporting detail and data, where available

In Australia and New Zealand, partially hydrolysed IFPs are not recommended in the dietary management of allergy. It should be noted that in some countries – where access to extensively hydrolysed infant formula is not possible or widespread – partially hydrolysed infant formula is used for the dietary management of allergy. This is based on results from clinical trials such as Inuo *et al*[5] and summarised in Vandenplas et al[6], where partially hydrolysed infant formula is recommended as a step-down formula for infants with cows milk protein allergy.

However, it should be noted that the role of partially hydrolysed IFP for reducing the risk of developing an allergy remains controversial. This is well summarised in Vandenplas *et al*[3], who point out that grouping all partial hydrolysates together in a meta-analysis has methodological flaws, and that *"meta-analyses and systematic reviews have offered conflicting results of pooled data regarding such benefits"*. Vandenplas et al[3] also state that there is *"consensus that the potential allergy prevention benefit has been noted only with one particular pHF-W product and that such benefits should not be extrapolated to all pHFs".*

A new publication[7] describes the protein profile of 4 partially hydrolysed IFPs, with median molecular weight of the peptides varying between 343-853 Da (Further details are available in Table 1 of the paper). Importantly, "lower allergenicity was not associated with lower median size distribution nor reduced oral tolerance induction. The pHF-W3 and 4 which had a lower median peptide size had the highest residual allergenicity and did not induce oral tolerance induction". This supports the notion that pHFs should not be clumped together in meta-analyses as a homogenous group as there are very real differences in their protein profiles.

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[4] Gappa, M; *et al*. Long-term effects of hydrolyzed formulae on atopic diseases in the GINI study. Allergy 2021, PMID: 33320352

[5] Inuo, C; *et al*. Tolerability of partially and extensively hydrolysed milk formulas in children with cow's milk allergy. Asia Pac J Clin Nutr, 2019, 28(1); 49-56

[6] Vandenplas, Y; *et al*. Prevention of allergic sensitization and treatment of cow's milk protein allergy in early life: The Middle-East step-down consensus. Nutrients 2019

[7] Bourdeau, T; *et al*. Peptide characterization and functional stability of a partially hydrolyzed whey-based formula over time. Nutrients 2021, 13, 3011

Molybdenum and chromium in protein substitutes

Question 9. Regarding options for the regulation of molybdenum and chromium, which option do you prefer and why? Please provide supporting detail and data, where available

Nestlé supports FSANZ proposal Option 3:

> *Permit voluntary addition without any compositional limits for all IFPSMP*

Nestlé remains of the view that the category of products for specific dietary use based on a protein substitute and its compositional requirements are not required. Codex Stan 72-1981 Section B and EU Regulation 2016/128 permit addition of chromium and molybdenum but do not set minimum mandatory requirements across all IFPSDU.

In its 2014 opinion (section 6.12), the EFSA panel considered that there was no necessity to add chromium to IF and FOF because there was unproven essentiality of chromium and no specific physiological function that could be ascribed to chromium.[8]

In the same opinion (section 6.13), the EFSA 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.[3]

Nestlé's response to P1028 CP2 noted that if FSANZ were to retain a GUL for chromium and molybdenum in IFPSDU, then this should be aligned with the GUL in Codex STAN 72-1981 Part B and EU Regulation 2016/128 (2.4 µg/100kJ (10 µg/100kcal)) for chromium. For molybdenum, a GUL of 3.3 µg/100kJ (14 µg/100kcal) aligned to EU Regulation 2016/128.

Medium Chain Triglycerides

Nestlé notes that international regulations do not include a restriction on medium chain triglycerides.

Question 10. To industry submitters: What type of products contain MCT oil? For what purpose and at what levels? Please provide supporting detail and data, where available

Medium Chain Triglycerides (MCTs), other than those innately present, are present in products for specific dietary use related to a disorder, disease or condition such as chronic diarrhoea with inflammation and preterm infants. MCT's have been shown to have good absorption even in the presence of low intraluminal bile salts and pancreatic lipases.[9] For pre-term infant formula products, MCTs have been used for absorption purposes, to increase the coefficient of fat absorption and to spare other substrates (glucose; essential fatty acids) from oxidation.[3] ESPGHAN (2010)[10] 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. Klein's review[11] of preterm infant requirements states – "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

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[8] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760, 106 pp.

[9] Koletzko, B. Poindexter, B. & Uauy, R. (2014) Nutritional care for preterm infants: Scientific basis and practical guidelines, Karger, Switzerland.

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

[11] Klein CJ (2002) Nutrient requirements for preterm infant formulas. Journal Nutrition; 132: 1395S–1577S

for the target population of infants.

MCT is safely added to some IFPSDU for cow's milk and food protein allergies to support absorption in infants with compromised gastrointestinal health due to allergy. MCTs are more rapidly metabolised than long chain triglycerides as they do not require bile salts or pancreatic lipase for digestion and provide a readily available energy source, especially during times of stress or gastrointestinal compromise.[12,13] Infants who are severely gastrointestinally compromised experience important absorption disorders. For these infants, MCT intake favours better tolerance, as well as improved absorption in comparison to long chain triglyceride intake.[14,15]

5.5.4 Proposed approach – Composition of IFPSMP

Nestlé strongly recommends that the Standard recognises that the composition variations to Standard 2.9.1 and Schedule 29 may be broader than just those required to address the specific disease, disorder or condition. Instead nutrients should be permitted to meet the infant formula or infant FSMP requirements of the EU or that of Codex Standard 72-1981. This flexibility would enable continuity of supply for these vulnerable infants whose numbers are such that unique recipes are impractical and uneconomical. (Refer to Section 5.5 above)

5.6 Provisions for IFPSMP — purpose, use and sale

5.6.1 Scientific evidence of purpose

Nestlé is an industry leader in scientific research into infant nutrition and undertakes research in formulating their IFPSDU products. This research underpins the primary responsibilities of a food manufacturer to ensure products are safe and suitable, the fundamental principles of food law.

Nestlé notes that the IFP Policy Guideline defines substantiation as

(j) A substance's role in normal growth and development is substantiated where there

> is appropriate **evidence to link the** physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood[16]

Nestlé would be concerned with the introduction of particular regulation or guidelines that would introduce prescribed approach to scientific evidence.

For example, requiring manufacturers to hold dossiers with prescribed content and format would be unnecessarily burdensome and costly, initially in the development and production of these products, and further in the case of where ongoing development may result in product change. If dossiers were required, there would be an expectation that the dossiers would be reviewed, and it is not clear that each jurisdiction would have the capacity or expertise to do so.

Prescription without risk having been characterised?

IFPSDU have been in the Australian and New Zealand market for many years without evidence of market failure. Nestlé is not aware of issues or concerns regarding safety or suitability, that might lead to questioning the suitability of the product for its purpose. That is there is **no documented evidence of risk**, nor has the potential risk been characterised, either of which might give support to prescriptive regulation as suggested in FSANZ

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[12] Sucher KP. (1986) Medium-chain triglycerides: A review of their enteral use in clinical nutrition. Nutr Clin Pract 1(3):146-150

[13] Ruppin DC, Middleton WR. Clinical use of medium chain triglycerides. Drugs. 1980 Sep;20(3):216-24.

[14] Blaauw R. Malabsorption: causes, consequences, diagnosis and treatment. S Afr J Clin Nutr 2011;24(3).

[15] Bach AC, Babayan VK. Medium-chain triglycerides: an update. Am J Clin Nutr. 1982 Nov; 36(5): 950-62.

[16] Policy guideline for Regulation of Infant Formula Products Specific policy principle (j)

preliminary view on this matter.

Nestlé is not supportive of prescription in this matter. Regulation is not appropriate where there is not a clearly identified and characterised risk.

Question 12. To industry submitters: Do infant formula manufacturers hold scientific evidence that supports the purpose of Division 4 products, including for reflux, colic, diarrhoea, and similar products (i.e. for less serious conditions)

Nestlé holds scientific evidence that supports the purpose of Division 4 products including those for the dietary management of lactose intolerance and for the dietary management of regurgitation.

Question 13. If so, what type of scientific evidence is held by companies and what is its strength of evidence?

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

Manufacturers' of IFPSDU that are listed on the PBS and Pharmac lists are required to provide adequate scientific evidence for products use in the management of a particular medical condition, disease or disorder.

Furthermore, Nestlé is a signatory to the Marketing of Infant Formulas: Manufacturers and Importers (MAIF) Agreement and the Infant Nutrition Council Code which require scientific information provided to healthcare professionals to be supported by a reference to the scientific literature. This information must reflect the totality (quality and strength) of the supporting reference(s)/evidence and have regard to the NHMRC Evidence Hierarchy, while noting limitations on randomisation in nutrition studies involving methods of infant feeding.

5.6.2 Extension of use beyond infancy

Nestlé agrees that there is continued use of IFPSDU beyond infancy as a supplementary food and believes that this should remain at the discretion of the healthcare professional.

Question 14. What is the maximum labelled age on products suitable for use beyond infancy? What are the parameters that indicate when the product is no longer appropriate?

Nestlé labelling on IFPSDU reflects their use for infants 0 - 12 months.

5.6.3 Lactose-free and low-lactose formulas

Nestlé does not agree with the FSANZ preliminary view in relation to lactose free and low lactose formulas:

- maintain existing labelling requirements
- clarify IFPSMP labelling provisions would not apply.

In the EU, lactose-free infant formula is required to have a lactose content not greater than 2.5 mg/100 kJ (10 mg/100 kcal). Whereas in Australia and New Zealand, Lactose Free infant formula must contain 'no detectable lactose'. Further, previous advice from the Australian Competition and Consumer Commission (ACCC) is that 'free' claims mean 'no presence of'. Cows milk protein based infant formula products that elsewhere are labelled 'Lactose Free' may contain trace levels of lactose and advances in analytical sciences mean that this lactose can be detectable.

Nestlé suggests that those IFPSDU that are for the dietary management of lactose malabsorptive conditions, should be managed and labelled as other IFPSDU with the additional requirement to label the amounts of lactose and galactose expressed in g/100 mL

and/or an equivalent statement “not suitable for infants with galactosaemia”.

5.6.4 Distribution and access

Nestlé is deeply concerned by the current proposal to restrict sale and distribution of products formerly classified as IFPSDU and soon to be classified as IFPSMP, in the absence of documented, substantive risk.

Considering discussion in 5.3.3 and 5.6.4, FSANZ is proposing to

a) Classify all IFPSDU as IFPSMP group; and to

b) Limit sale and distribution of all IFPSMP to be consisted with Standard 2.9.5

By creating a single category of IFPSMP and adopting similar restrictions on sale and distribution applied to FSMP, IFPSDU will become less accessible. Possible effects on mothers and caregivers have not been considered.

One comment is that ‘Some submitters were concerned about the ease of access to less specialised products that may lead to carers selecting these products over breastfeeding based on self-diagnosis’, although there is no substantive evidence provided.

The alternate view is that there is likely to be detrimental effects on shoppers (mothers and caregivers). Importantly, mothers may develop unwarranted concerns around their baby’s health once products are sold in pharmacies-only. Broad availability of these less specialised IFPSDU products for parents is important so they have access following recommendation from a healthcare professional (often small pharmacies close early whereas grocery has longer hours). Regional areas may not have as many pharmacies and these may be smaller and carry limited choice of brands and less stock. Overall, reduced retail competition could lead to increased purchase prices.

Interestingly, there is only one mention of mothers and caregivers in the discussion paper (in relation to overseas uncorroborated research (Table 16)), yet mothers and caregivers are significant stakeholders in any regulatory changes. This is a significant omission.

5.7 Labelling of IFPSMP

Question 15. Do you support FSANZ’s preliminary views for IFPSMP labelling? Why or why not? Please provide supporting detail and data for your position, where available?

Nestlé prefers the inclusion of a sub-category for specialised IFPSMP which would allow for more further consideration of labelling requirements for these products. A detailed approach has been prepared by INC and Nestlé highlights a few key points below.

5.7.1 FSMP statements

Nestlé supports FSANZ’s proposal to align labelling provisions with the provisions in Standard 2.9.5—10(1)(a) to (f). These labelling requirements provide information for healthcare professionals as well as caregivers whilst being sufficiently flexible to accommodate the broad range of diseases, disorders and conditions.

We agree with FSANZ proposal not to mandate those provisions in Standard 2.9.5—10(g).

5.7.2 Other advisory and warning statements in Standard 2.9.5

Nestlé agrees with FSANZ that replicating allergen declaration requirements and advisory and warning statements in Standard 2.9.1 for all infant formula products is unwarranted.

5.7.4 Date Marking

Nestlé supports FSANZ’s proposal for date marking information to be made either in accordance with Standard 1.2.5 or for the words ‘Expiry date’ or similar words to be used. This allows for international alignment of labels.

5.7.9 Labelling information on safe preparation and use

Nestlé agrees that no additional, specific directions should be mandated for IFPSDU. However, we would request further flexibility and exemption from prescribed requirements where they are not aligned to international requirements for the proposed sub-category of IFPSMP. This would allow highly specialised products to be imported without re-labelling.

Other Issues

Transition Period

Nestlé would like to highlight that compositional changes will require a suitable transition period to allow for reformulation, with some infant formula products having a 3-year shelf-life. Equally, it should be possible to move to a harmonised recipe immediately after gazettal where such a recipe is available. Products may be listed in the Australian Pharmaceutical Benefits Scheme (PBS) or New Zealand Pharmac Pharmaceuticals Schedules which require notification of changes.