Food Standards Australia New Zealand
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Submission to Food Standards Australia New Zealand Proposal P1028 Infant Formula Consultation Paper 3 – Regulatory Framework and Definitions

To Whom It May Concern

Danone Nutricia (Danone) welcomes the opportunity to comment on Proposal P1028 Infant Formula as a major supplier and manufacturer of infant formula products (IFP) and infant formula products for special dietary uses (IFPSDU) in Australia and New Zealand.

Danone is a member of the Infant Nutrition Council and was active in the preparation of the INC submission on P1028 consultation paper 3. Danone fully supports the Infant Nutrition Council (INC) submission which provides a response to the full proposal.

This submission provides further details about the impact on, and potential costs incurred by Danone. It is presented in two parts: Part 1 is the non-confidential submission and Part 2 contains information to be kept confidential.

[redacted]

[redacted]

About Danone (www.danone.com)

Dedicated to bringing health through food to as many people as possible, Danone is a leading global food and beverage company building on health-focused and fast-growing categories in three businesses: Essential Dairy & Plant-Based Products, Waters and Specialised Nutrition. Danone aims to inspire healthier and more sustainable eating and drinking practices, in line with its 'One Planet. One Health' vision which reflects a strong belief that the health of people and that of the planet are interconnected. To bring this vision to life and create superior, sustainable, profitable value for all its stakeholders, Danone has defined its 2030 Goals: a set of nine integrated goals aligned with the Sustainable Development Goals (SDGs) of the United Nations. Danone commits to operating in an efficient, responsible and inclusive manner; it holds itself to the highest standards in doing business, as reflected by its ambition to become one of the first multinationals certified as B Corp™. With more than 100,000 employees, and products sold in over 120 markets, Danone generated €24.7 billion in sales in 2018. Danone's portfolio includes leading international brands (*Actimel, Activia, Alpro, Aptamil, Danette, Danio, Danonino, evian, Nutricia, Nutrilon, Volvic*, among others) as well as strong local and regional brands (including *Karicare, AQUA, Blédina, Bonafont, Cow & Gate, Horizon, Oikos, Prostokvashino, Silk, Vega*).

Listed on Euronext Paris and on the OTCQX market via an ADR (American Depositary Receipt) program, Danone is a component stock of leading social responsibility indexes including the Dow Jones Sustainability Indexes, Vigeo Eiris, the Ethibel Sustainability Index, MSCI Global Sustainability, MSCI Global SRI Indexes and the FTSE4Good Index.

Danone's Response to the Consultation Paper 3 (CP3)

Part 1 Non-confidential information

Note: when Danone refers to Infant Formula Products for Special Medical Purposes (IFPSMP) throughout the submission this is referring only to highly specialised IFPSDU for clinically serious or potentially life-threatening disorders, diseases, or medical conditions and normally used under intense medical supervision.

2 Novel Foods and Nutritive Substances

2.1 Pre-market assessment requirements

Danone supports the FSANZ proposal to not progress a separate review of novel foods and nutritive substances for IFP under P1028 and for future assessments under P1024 to include all food including IFP.

2.2 Novel Foods

FSANZ Questions 1. To manufacturers, please provide information on whether the substances listed in Table 5 are used in infant formula products, food for infants and formulated supplementary food for young children.

Danone does not currently use any of the substances that FSANZ are proposing to restrict in Table 5 for IFP, food for infants or formulated supplementary food for young children. However, as outlined in the INC submission, Danone is concerned of restricting these novel foods for young children who consume a mixed diet. Formulated Supplementary Foods for Young Children also is out of scope of P1028.

3. Special Infant Formula Products

3.1 Approach to regulation of IFPSDU

Danone supports maintaining the regulation of IFPSDU under Standard 2.9.1 whilst ensuring that labelling requirements are aligned with Standard 2.9.5 which allows for global labels which is particularly important for IFPSMP.

3.2 Human milk fortifiers and pre-term supplementary products

Danone supports the proposal that specialty IFP used under medical supervision that serve a supplementary role (e.g. human milk fortifiers) be regulated under Standard 2.9.5. This is important to ensure the continued supply of these highly specialised products that necessarily have globally harmonised formulations and labels due to the very small numbers that are imported into Australia and New Zealand.

4. Definitions

4.1 Definition of infant formula product

Danone questions whether there is any need for a definition that makes it unique to Australia and New Zealand. We suggest that the Standard could instead refer to a list of products it covers.

4.2 Definition of infant formula

Danone is not supportive of including ages in the definition of infant formula product and supports a definition aligned with the Ministerial policy guidelines and Codex STAN72-1981.

4.3 Other Definitions

FSANZ 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.

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.

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.?

Danone believes these terms are self-explanatory and therefore do not require additional definitions in the Food Standards Code. Definitions would not enhance clarity of meaning. It should be noted that such definitions are not included in international standards, Codex and European Union (EU).

5. Regulatory Framework for IFPSDU

5.1 Description of IFPSDU in Division 4 of Standard 2.9.1

Danone fully supports the INC submission comments.

5.2 Options for regulatory framework

Danone supports the FSANZ position that sub-categories should only be established if needed. Danone supports the proposed INC regulatory framework that a sub-category should be created for highly specialised IFPSDU for clinically serious or potentially life-threatening disorders, diseases, or medical conditions and normally used under intense medical supervision. This sub-category could be known as IFPSMP and could also follow a similar approach to the US and be simply known as “products not available at the retail level”

5.3 Principles for purpose, composition, use and sale of IFPSDU [including IFSMP]
5.3.1 Purpose
5.3.2 Nutrient composition and use under medical supervision
5.3.3 (1) Extension of use beyond infancy
Danone fully supports the INC submission for sections 5.3.1, 5.3.2 and 5.3.3.

5.3.3(2) Restriction on sale
Danone does not support the proposal that restricting sales should be a principle for IFPSDU for the sake of consistency with Standard 2.9.5. This principle was not included in the Ministerial policy guidelines. A higher risk management approach under Standard 2.9.5 should not be applied to all IFPSDU. IFPSDU are based on the highly prescribed composition requirements for IFP, which is not the same as Standard 2.9.5 that has minimally prescribed composition requirements. As stated by FSANZ "that IFPSDU not required under prescription or used in the hospital setting would be based on composition requirements for IF for healthy infants and therefore safe and low risk."

The first Principle of best practice regulation - as published by the Australian Government Department of the Prime Minister and Cabinet - is to examine whether there is a problem and whether any action is required (https://www.pmc.gov.au/ria-mooc/coag/principles-best-practice-regulation). There is no evidence presented of any problems with the current accessibility of IFPSDU or of a market failure. FSANZ has also stated that there is no evidence that the availability of general or specialised infant formulas is a factor associated with breastfeeding cessation. FSANZ alludes in CP3 to anecdotal evidence only from a few healthcare professionals. FSANZ references two government submitters who provided published evidence from overseas describing a negative impact of advertising these products could have on breastfeeding rates. We do not believe that this overseas evidence is applicable in Australia and New Zealand. Advertising and promotion to the general public for IFP 0-12 months is prohibited in Australia and New Zealand due to government initiatives in both countries to restrict advertising and promotion of IFP in accordance with the World Health Organisation Code of Breast-Milk Substitutes (WHO Code). These restrictions are covered in the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement and in New Zealand the Infant Nutrition Council Code of Practice. There is no case that supports any proposal to restrict sale of IFPSDU products.

Best practice regulation principles indicate that FSANZ should consider a range of feasible options only after the need for taking action has been established. The proposal to restriction of trade will also impact competition and therefore principle 4 of the principles of best practice regulation is applicable. This principle states that legislation should not restrict competition unless it can demonstrate that: (1) the benefits of the restrictions to the community outweigh the costs, and (2) the objectives of the regulation can only be achieved by restricting competition. FSANZ has provided no evidence of any benefit of such a restriction for low risk IFPSDU and nor has any other alternatives to trade restriction been investigated.

Danone will outline potential impacts and costs on restriction of trade for health, accessibility, availability and the supply chain under item 5.6.4.

5.4 Name and definition of IFPSDU

Danone supports the INC submission on this point.

5.5. Provisions for IFPSDU and the sub-category IFPSMP- Composition

5.5.1 Products formulated for premature or low birthweight infants

Danone supports the FSANZ proposal to allow compositional deviation from IFP to be retained. This deviation should allow international alignment to the EU, US and Codex IF requirements and therefore be similar to the current Standard 2.9.1-13(1) and the Standard does not apply to the extent that if would prevent the sale of an infant formula product that has been specially formulated for premature or low birthweight infants.

5.5.2 Products for metabolic, immunological, renal, hepatic and malabsorptive conditions

Danone supports the FSANZ proposal to allow composition deviation from IF to be retained. This deviation should allow international alignment to the EU, US and Codex IFP requirements and therefore be similar to the current Standard 2.9.1-14(1) and the Standard does not apply to the extent that if would prevent the sale of an infant formula product that has been specially formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

Danone does not make lactose free or low lactose claims on products as the current requirements under Standard 2.9.1-14(3-6) are too restrictive. Firstly, IFPSDU made from milk-based ingredient for lactose intolerance cannot meet the definition of nil detected even though they are appropriate and meet the EU definition of not greater than 2.5mg/100kJ. Therefore, a lactose free claim in cannot be made on the label. Furthermore a 'low lactose' claim is not made as Healthcare Professionals (HCPs) and carers can find this claim confusing on a product that has negligible levels of lactose. A carer wants a product that is 'lactose free' however this is simply not possible for products made using milk-based ingredients. Secondly, IFPSDU are often designed and appropriate for multiple conditions and therefore the composition is varied from the Code for these conditions and including 'lactose free' or 'low lactose' in the name of the food as required for these claims would not represent the product appropriately.

> 5. To Health professionals: Is there any evidence that current practice in relation to low lactose products or manganese content of products for metabolic, immunological, renal, hepatic, and malabsorptive conditions pose a health concern or risk?
> If you consider that this is a health concern or risk, please provide relevant details and data, where available.

Not applicable.

6. To industry submitters: How many and what types of low lactose IFPSDU are on the market? And what is their maximum level of lactose? Please provide supporting detail and data, where available.

Danone's Lactose-Free and Low Lactose Products on the Market

Product	Lactose Level	Lactose Claim Possible	Lactose Claim on Label	PBS Schemes	Country of Origin
Aptamil Gold+ Lactose Intolerance	<0.006g/100mL	Low Lactose	No	No	Made in the Netherlands
Aptamil Gold+ Colic & Constipation	3.3g/100mL	None	No	No	Made in the Netherlands
Karicare Soy	Nil detected	Lactose Free	No	No	Made in Indonesia
Neocate	Nil detected	Lactose Free	No	Yes	Imported from EU

Note this is not a comprehensive list as it does not include all very highly specialised amino acid IFPSMP.

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 pharmaceutic benefits schemes in Australia and New Zealand? Please provide supporting detail and data, where available.

Danone's Partially Hydrolysed IFP on the Australian and New Zealand Market

Products	Category	PBS Schemes
Aptamil Gold+ Colic and Constipation 0-12months	IFPSDU	No
Aptamil Prosyneo Sensitive 0-12months	IFP	No

Note: none of these products are positioned for the dietary management of allergy or prevention of allergy. Danone is able to provide commercial in confidence details on the protein denaturation if required by FSANZ.

5.5.3 Products for specific dietary use based on a protein substitute

8. To health submitters: You told use 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.

Not applicable.

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.

Danone supports Option 3 that allows the voluntary addition of molybdenum and chromium to all IFPSDU where applicable. In order to align internationally, the GUL should be for Chromium Codex 2.4µg/100kJ and for Molybdenum EU 3.3µg/100kJ. It is important to maintain permission to include chromium and molybdenum for IFPSDU where applicable. These nutritive substances are used in amino acid IFPSDU for allergy or inborn errors of metabolism where milk-based ingredients are not used.

Note that chromium chloride and ammonium molybdenum should be added as permitted forms for IFPSDU to allow for international alignment. These forms are permitted for Food for Special Medical Purposes (FSMP) in the Code Schedule 29-20; the Codex for Formula for Special Medical Purpose Intended for Infants and the EU Infant Food for Special Medical Purposes.

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.

Danone does not support the current restriction on Medium Chain Triglycerides (MCT) for IFP. However, should this restriction remain, it should be changed to "MCT oils."

Danone's Products that contain MCT oil in the Australian and New Zealand Market

Products	**Levels**	**Purpose of Product**
Neocate Gold	1.1g/100mL	For the dietary management of infants from birth (0+ months) with cows' milk allergy, multiple food protein allergy, eosinophilic oesophagitis and other indications where an amino acid-based formula is recommended.
Neocate Syneo	1.1g/100mL	For the dietary management of infants from birth (0+ months) with cows' milk allergy, multiple food protein allergy, eosinophilic oesophagitis and other indications where an amino acid-based formula is recommended.
Peptide Junior	1.6g/100mL	Suitable for infants with malabsorption and/or with confirmed allergy to cows' milk and/or soy protein when partial or total breast milk substitute is required.
Infatrini	0.6 g/100mL	Infants 0 – 18 months (or up to 9kg) with disease related malnutrition and growth failure.
Aptamil Gold+ Preterm	0.34g/100mL	Suitable for premature or low birth weight infants
Monogen	1.8g/100mL (88% of total fatty acids)	For use in infants as a sole source of nutrition or as a supplementary feed for children and adults for the dietary management of the following conditions: • Hyperlipoproteinaemia type 1 • Long chain fatty acid oxidation disorders (LCFAODs) • Chylous ascites • Chylothorax • Fat malabsorption

All these products are considered highly specialised IFPSMP and are used under intense medical supervision. Notably Aptamil preterm is only to hospitals, while all other products are listed on PBS and/or Pharmac and therefore generally used under prescription. The addition on MCT oils is considered a nutrition modification and

therefore is highlighted to HCPs as part of information and education about the products. MCTs are considered as being more easily absorbed, particularly in malabsorptive conditions (Traul et al 2000, Bitman et al, 1983). The composition and intended use of each product is documented and assessed by Danone scientists. As part of the PBS and Pharmac process as outlined in section 5.6.1 the products scientific rationale for these highly specialised products is reviewed by independent experts.

Further evidence on MCT oil levels for specific products can be provided in commercial in confidence if required by FSANZ.

11. To health submitters: Are there any health concerns from current practice using products that contain MCT oil? Please provide supporting detail and data, where available.

Not applicable.

5.5.4 Proposed approach- Composition of [IFPSDU including] IFPSMP

Danone supports the FSANZ proposal to extend permission for compositional deviation to all IFPSDU where needed to meet the intended purpose. Danone imports most IFPSDU from the EU. Therefore, deviations should allow for alignment with the EU, US and Codex IF requirements. It should be similar to the current Standard 2.9.1-13(1) and 2.9.1-14(1) does not apply to the extent that if would prevent the sale of an IFPSDU. This is critical to ensure continued availability of IFPSMP which normally have one global harmonised formulation and label. IFPSMP are mostly supplied in low quantities to a particularly vulnerable small population. The importance of undisrupted access to these products is evident by their necessity for the continued well-being, and even sustenance, of the lives of infants with certain inborn errors of metabolism.

Summary of nutrients that will be an issue when importing from the EU under the proposed FSANZ Standard

Nutrient	Issue	EU 2016/127	FSANZ proposed in CP2
Vitamin B6	Min	4.8 µg/100kJ	8.4 µg/100kJ
Vitamin C	Min	0.96 mg/100kJ	1.7 mg/100kJ
Iron	Min	0.07 mg/100kJ	0.2 mg/100kJ
Vitamin B1	Min	9.6 µg/100kJ	10 µg/100kJ
L-Carnitine	GUL	Not Specified	0.8 mg/100kJ
DHA to AA	Ratio	None	DHA≤AA when added voluntarily
DHA	GUL	12mg/100kJ	0.5% GUL
ALA to LA	Ratio	None	5:1 to 15:1

Summary of nutrients that will be an issue when importing under Codex under the proposed FSANZ Standard

Nutrient	Issue	Codex STAN72 1981	FSANZ proposed in CP2
LA	Min	70 mg/100kJ	90 mg/100kJ
Iron	Min	0.1 mg/100kJ	0.2 mg/100kJ

Iodine	Min & Max	2.5 – 14 GUL µg/100kJ	3.6 -10 µg/100kJ
Selenium	Min & Max	0.24 – 2.2 GUL µg/100kJ	0.48 – 2.0 µg/100kJ
L-carnitine	GUL	Not Specified	0.8 mg/100kJ
Vitamin B2	GUL	96 µg/100kJ	119 µg/100kJ

5.6 Provisions for IFPSMP- Purpose, use and sale

5.6.1 Scientific evidence of purpose

There is already a requirement for scientific evidence as part of the overarching jurisdiction food act requirements. Therefore, it is unnecessary to impose additional requirements in the Code including a guideline. Furthermore, this approach would be inconsistent with Standard 2.9.5 FSMP. Danone is concerned that additional requirements could result in international misalignment of requirements and introduce complexities, costs and barriers to trade.

The scientific basis for higher risk IFPSMP products was already assessed by the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia and the Pharmacology and Therapeutics Advisory Committee (PTAC) in New Zealand. These assessments are undertaken by independent, clinical experts. Further details are given below. It would be undesirable and inefficient for FSANZ or jurisdictions to perform its own separate scientific assessment. Less specialised IFPSDU are based on the composition of IFP and therefore of lower risk to healthy infants, hence an independent review of the science is not necessary.

The PBAC is an independent expert body appointed by the Australian Government set up in the National Health Act 1953. Members include doctors, health professionals, health economists and consumer representatives. Their role is to "make recommendations to the Minister … which it considers should be made available as pharmaceutical benefits" (Section 101 Clause 3) by giving "consideration to the effectiveness and cost of therapy involving the use of the drug, preparation or class, including by comparing the effectiveness and cost of that therapy with that of alternative therapies, whether or not involving the use of other drugs or preparations." (Section 101 Clause 3A). The PBAC constituted the Nutritional Products Working Party (NPWP) to provide advice to the PBAC on clinical and financial matters for nutritional products (medicinal foods) listed on the PBS – special infant oral formula and food substitutes to treat inborn errors of metabolism. Further information can be found on PBS website at https://www.pbs.gov.au/.

The PTAC provides objective advice to Pharmac. PTAC is Pharmac's primary clinical advisory committee established under the New Zealand Public Health and Disability Act 2000. PTAC's role is to provide objective clinical advice to Pharmac. PTAC is made up of senior health practitioners from a range of specialities, who consider clinical evidence for funding applications, and take into account Pharmac's Factors for Consideration before making recommendations to Pharmac. The Rare Disorders Subcommittee assesses applications in the context of rare disorders treatments and bases its recommendations on PHARMAC's Factors for Consideration and their own clinical expertise. The members include some of New Zealand's leading experts in treating rare disorders. The members' specialties include paediatric nephrology, metabolic disorders, blood disorders and neurology. One member is an Australian genetics and metabolic disorders specialist. Further information can be found on PHARMAC website at https://pharmac.govt.nz/.

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

Yes. All IFPSDU have a scientific dossier on hand as evidence of suitable for the specific condition. Our portfolio of IFPSDU is based on years of scientific research and innovation. Danone is a multinational infant formula manufacturer and most IFPSDU are from EU and therefore based on the EU requirements.

Danone Nutricia Research invests in research in the fields of breast milk composition and functionality, immunity, allergy, gut microbiome and gut health, and hence are committed to providing optimal nutritional care for infants and young children affected by these concerns. The Australia and New Zealand business is in close contact with our global scientific and research experts to develop product dossiers that contain specific scientific evidence to support the purpose of special dietary formulations such as transient or less serious conditions such as reflux and colic. The quality of the evidence is the same as the evidence for more highly specialized products.

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

Danone aims to provide credible scientific evidence to substantiate the health benefits and safety of our products for healthcare professionals and authorities globally. Our scientific teams are present in 55 countries, with three world-class research and development facilities based in The Netherlands, Singapore and Shanghai. These research centres are focused on delivering evidence-based, specialized nutrition for people of all ages.

High quality evidence includes clinical trials and research and technology studies. To ensure our clinical evidence meets the highest quality standards, we perform clinical studies according to internationally applied scientific and ethical guidelines, such as the ICH-GCP guidelines, the Declaration of Helsinki and the WHO code. We conduct clinical studies in collaboration with independent investigators in various healthcare settings and academia. Our extensive network includes key opinion leaders in specific fields, healthcare providers, suppliers, scientists, policy makers, patients, technologists and many more. Clinical studies may be supplemented with scientific research on ingredients, combinations of ingredients and information from external peer-reviewed research, including systematic reviews. Research results may be published in reputable, peer-reviewed journals, in presentations and shared with scientific advisory boards. For further information on our research publications, see our Nutricia Research website at https://www.nutriciaresearch.com/publication-library/

Evidence for all IFPSDU under Division 4 products includes strong levels of evidence that are high level, high quality and statistically significant.

5.6.2 Extension of use beyond infancy

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

Danone supports the extension of IFPSDU use past infancy as many products are used as a supplement to the diet. However, due to the range of conditions IFPSDU are designed to manage and the fact that they are used under healthcare supervision Danone does not support the Code prescribing a maximum age. Appropriateness of a

product is determined by the managing heath professional using a combination of data: the product evidence-base, the medical condition, third-party medical or health professional advice and the individual's health status and data.

Examples of various conditions and indication of the appropriate maximum age of use:

- Some conditions such as for reflux, colic, or transient gastrointestinal issues, infants generally outgrow, or the condition resolves in the first year of life; therefore the maximum labelled age is generally 12 months.
- Other conditions such as constipation, there is evidence that this condition can continue beyond 12 months. The Danone products have a recommended age suitability up to 18-24 months.
- Some products are labelled as suitable to be used as supplementary feeds to the main diet to 3 years of age.
- Certain highly specialized IFPSDU products are suitable for children in older age groups, such as up to 10 years or extending into adulthood, for example products to help manage inborn errors of metabolism.

5.6.3 Lactose-free and low-lactose formulas

Danone does not support maintain the current lactose free or low lactose labelling requirements. As already raised above the current requirements are too restrictive to be used and therefore these claims are not currently made on IFPSDU.

Furthermore, IFPSMP label flexibility is needed to align internationally. Therefore, IFSMP should be exempt from providing the levels in the nutrition information. Necessary information on the products in regard to lactose and galactose and covered under section 5.7.1 that "a statement indicating, if applicable, any precautions and contraindications associated with the consumption of the food" is included. This would therefore provide an option to not include galactose level in the nutrition information and instead for a precaution or contraindication statement such as "'not suitable for infants with galactosaemia." This approach would align with the EU.

5.6.4 Distribution and access

Danone does not support the blanket restriction of sale for IFPSDU. Danone does not support the restriction on sale of less specialised IFPSDU. Even though there is no evidence of market failure, Danone supports highly specialised IFPSMP products being restricted for sale via the HCPs and pharmacy channel. Further to our 2017 submission, Danone is still unaware of any evidence of inappropriate access or use of IFPSDU in ANZ over the 20 plus years that these products have been available for families and carers to feed their infants.

The adverse impacts on health, accessibility, availability and supply chain are as follows:

1. Health: There is a significant risk that restricting access and availability of less specialized IFPSDU to parents/carers could have a negative impact on infant health. Up to 30% of infants are affected by Functional Gastrointestinal Disorders. The most common among those up to 12 months of age are reflux, colic and constipation (Vandenplas et al. 2015). These conditions are often temporary and transient (such as reflux and colic).

Danone conducted two qualitative research studies with ANZ mothers in April 2018 and January 2019. We found that the parent/carer journey for those with infant feeding issues is highly stressful. Parents/carers proactively seek out reassurance and advice. HCPs are often their first port of call for advice and are seen early on in the journey. HCPs consulted are usually midwives, nurses, and GPs. They are the key influencers prior to trialling solutions/specialty formula. Should these products have reduced access and availability, parents/carers could revert to purchasing normal IFP meant for healthy infants which in turn could result in negative health outcomes for infants, putting extra pressure and costs on the medical care system that far outweighs any perceived benefit of having the products restricted in sale channels. Limited and poorer availability and inconvenience of purchase could lead to added stress on parents and caregivers in providing the correct product for infants.

2. Accessibility (where shoppers find the product is ranged): Less specialized IFPSDU are currently broadly accessible via approximately 3,300 grocery distribution points throughout Australia. Removing these distribution points will significantly reduce not only access, but ease/convenience of access of these products for parents/carers.
    - Within the less specialized IFPSDU category, there has been channel shifting to grocery since 2019 due to shopper preference. This reflects broader macro channel dynamics of shifting to grocery post COVID (since early March 2020) due to availability and convenience of weekly grocery shop and avoiding highly populated and perceived "riskier" shopping experiences in other channels, such as pharmacy.
    - The accessibility via grocery has not seen an increase in the inappropriate use of IFPSDU. Danone is not aware of evidence of inappropriate use over the past 20 years these products have been available. Conversely there is more evidence that purchasing these products is initiated by healthcare professional referral rather than "self-selection". The "patient journey" is closely tied in with HCP first dealings and recommendation, where purchase is more a convenience than a choice at shelf. Danone, and other IFPSDU companies, continually drive education to HCPs to ensure that these products are used correctly.
    - Danone provides HCP support such as Continuing Professional Development (CPD) accredited category education and clinical tools that cover correct diagnosis of symptoms that indicate a IFPSDU could be used, such as functional gastrointestinal disorders and cows' milk protein allergy for appropriate first line management.
    - Danone explicitly communicates on product labels that these products are to be used under medical supervision and encourages parents and carers to consult their HCP for advice prior to using these products.
    - We have a Careline team comprised of accredited midwives and dietitians that both HCPs and parents/carers can contact for queries regarding breastfeeding advice, choice or comparison of milk, correct product usage, transition advice, and accessibility/product availability support.
    - Typically, the grocery channel is more affordable for shoppers due to operational efficiencies and margins meaning some parents/carers will be disadvantaged in their access of these products, due to increased cost.

- If access is restricted to the pharmacy/healthcare institution channels, the likely retail cost to the parent/carer will also increase due to mark-ups deployed by the pharmacy channel as retail pricing is at the sole discretion of the retailer.

3. Availability (the products are stocked on shelf available to buy): Over the past 18 months, parents/carers have struggled to consistently access their preferred product. This is predicted to continue in the foreseeable future.
   - There have been historic product availability issues across the category due to export demand and panic pandemic buying throughout 2020 and 2021.
   - Grocery retailers facilitate very fast replenishment through their end-to-end supply chains whereas the pharmacy channel has a two-step, indirect supply chain via wholesalers, meaning frequent delay to shopper availability. 95% of pharmacy stores have this indirect supply chain making it 2-3 times slower than grocery supply chains, with longer lead times for stock replenishment.
   - There is very limited or no storage capacity in the majority of pharmacy outlets. This adds further to stock availability issues, limiting the amount of product available on shelf for parents/carers in these settings. This lack of availability would be compounded with increased numbers of parents/carers forced to source products if it were removed from the grocery channel. It is more convenient and there is greater availability in the current grocery channel.
   - Smaller and/or independent pharmacies, especially those in rural/regional communities may not have the financial status to stock all types of IFPSDU due to inventory cost, thus parents and carers may not be able to access the correct formula for their child. This can have a detrimental effect on the health status of infants. This may also result in pharmacies having a preference in brands that they stock, thus limiting parents' and carer's ability to make an informed choice.
   - Through the Nutricia 'Careline' call centre, we already receive a large number calls on IFPSDU. This indicates that, if sales channels were restricted further, the expected enquiries would grow exponentially due to limited availability as well as the increased risk of stockpiling also impacting shopper accessibility.
   - On Shelf Availability check: Most of larger retailers provide the opportunity to check in-store availability in real time, giving parents/carers the means to find products. This is important especially when there is limited availability and parents/carers are reliant on the product.

   Note further supporting data provided in commercial in confidence.

4. Supply Chain: Due to the size and scale of the less specialized IFPSDU market in the grocery channel in Australia there is a significant risk that in restricting sale of these products to the pharmacy/healthcare institution channel, these channels will not be able to manage this large volume of product into its supply chain and retail outlets without negatively impacting access and availability of these products to consumers and health outcomes for infants.
   Note further supporting data provided in commercial in confidence

5.7 Labelling of [IFPSDU including] IFPSMP

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?

Danone does not support FSANZ preliminary views for labelling IFPSDU as we do not support 1 category for IFPSDU. Danone supports INC submission for section 5.7 which includes a new framework for FSANZ to consider differentiating between the labelling requirements for IFPSDU and IFPSMP.

Danone supports FSANZ proposal for all IFPSDU aligning with the labelling requirements for Standard 2.9.5-10(1)(a) to (f). Noting that "should be used under medical supervision" rather than "must" is more appropriate for IFPSDU given no medical supervision statement is currently needed under Standard 2.9.1-15 Products for specific dietary use based on protein substitutes and "should" would align with the current wording for Products for metabolic, immunological, renal, hepatic and malabsorptive conditions under Standard 2.9.1-14(2)(c).

General Question
How effective do you believe the current regulatory measures for IFPSDU are? How could they be made more effective? If you think the requirements should be changed to better manage risk, please explain how and why. Please provide supporting detail and data, where available

Danone is of the view the current regulatory measures for IFPSDU are effective particularly as there is no evidence of issues or market failure.

The regulatory measures could be improved by reviewing the current categorisation of IFPSDU to reduce overlap and to align better internationally particularly for composition and labelling.

IFPSMP for more serious disorders, diseases, and conditions are currently not generally available despite no current restriction in trade. This is because that they are normally provided under intense medical supervision, often under prescription or are otherwise very expensive. Nonetheless, although there is no evidence of market failure or issues, a trade restriction consistent with Standard 2.9.5 could be included as these products are generally considered higher risk due to more significant variations from the composition of IFP for healthy infants.

General Question
Do you consider that the options proposed in this paper will ensure that IFPSMP are safe, suitable and meet the nutritional requirements of the infants for whom they are intended? If not, please explain why and provide supporting data and detail, where available

Danone does not support the restriction on trade for low risk IFPSDU and potential additional requirements for scientific evidence. FSANZ need to consider the principles of best practice regulation in regard to these proposed options.

The restriction on trade for all IFPSDU will not improve the safety and suitability to meet the nutritional requirements for the infants they are intended. It adds regulatory burden for low-risk products and limits there available to carers for no benefit. Danone has provided the data and evidence of potential adverse impacts on

health, accessibility, availability and supply chain in restricting the trade of less specialised IFPSDU under section 5.6.4.

In particular as already outlined for health, there is a significant risk that restricting access and availability of less specialized IFPSDU to parents/carers could have a negative impact on infant health. Should these products have reduced access and availability, parents/carers could revert to purchasing normal IFP meant for healthy infants which in turn could result in negative health outcomes for infants, putting extra pressure and costs on the medical care system that far outweighs any perceived benefit of having the products restricted in sale channels. Limited and poorer availability and inconvenience of purchase could lead to added stress on parents and caregivers in providing the correct product for infants.

Danone also does not consider that additional requirements for scientific evidence of IFPSDU is necessary to ensure IFPSDU are safe, suitable and meet the nutritional requirements of the infants to whom they are intent. As outlined in section 5.6.1 lower risk IFPSDU are based on the composition of IFP for healthy infants and higher risk IFPSMP for serious conditions are generally listed on PBS and/or Pharmac and therefore already undergo extensive review. In order for IFPSMP to be considered on these schemes companies are required to provide adequate evidence for their use in the management of a particular medical condition which is then assessed by independent experts.

> **General Question**
> How effective do you believe the options proposed for IFPSMP will be? How could they be made more effective? Do they place an unreasonable cost burden on industry to achieve and/or maintain compliance? Please provide supporting detail and data, where available.

Danone is concerned the effect of trade restriction on low risk IFPSDU will have on the accessibility and availability as outlined in detail and data in section 5.6.4. In terms of cost typically, the grocery channel is more affordable for shoppers due to operational efficiencies and margins meaning some parents/carers will be disadvantaged in their access of these products, due to increased cost. If access is restricted to the pharmacy/healthcare institution channels, the likely retail cost to the parent/carer will also increase due to mark-ups deployed by the pharmacy channel as retail pricing is at the sole discretion of the retailer.

As proposed in the INC submission a subcategory for highly specialised IFPSMP can ensure that trade restrictions are only included for higher risk products along with further flexibility in labelling to allow international alignment.

Danone is also concerned that additional requirements for scientific evidence could result in international misalignment of requirements and introduce complexities, unreasonable costs and barriers to trade.

Other Issues- Transition Period

To reduce the impact on the market of IFP it is important for FSANZ to consider a reasonable transition period to minimise cost. Major changes are proposed to labelling, additives, and composition. Danone requests a transition period of 5 years from manufacture date and stock-in-trade. This will allow time to manage the product changes within production facilities; minimise write-offs for items such as packaging; and inform and educate our staff, account representatives, the trade, health care professionals, customers, consumers and patients. Any change in IFP formulation and label updates requires considerable transition management. Consumers of IFP are often very sensitive to any change in product which can result in enquiries and complaints (e.g. baby can't tolerate new product, baby is sick, has tummy upset, won't feed). Ideally, both formulations will be available for a period of time to assist consumers transitioning over.

Other Issues- Scoop

To provide alignment with Standards 2.9.5 and internationally Danone requests that exclusion from Standard 2.9.5-18 requirement for a measuring scoop for IFPSMP. Although, IFPSMP normally provide a scoop it is possible for very highly specialised products used under intense medical supervision to be weighed and diluted specific to the infants condition and response to dietary management.

References

Bitman J, Wood L, Hamosh M & Mehta NR. Comparison of the lipid composition of breast milk from mothers of term and preterm infants. American Journal of Clinical Nutrition. 1983; 38:300-12.

Traul KA, Driedger A, Ingle DL & Nakhasi D. Review of the Toxicological Properties of Medium Chain Triglycerides. Food & Chemical Toxicology. 2000; 38:79-98.

Vandenplas Y, Abkari A, Bellaiche M, Benninga M, Chouraqui J P, Çokura F, Harb T, Hegar B, Lifschitz C, Ludwig T, Miqdady M, de Morais M B, Osatakul S, Salvatore S, Shamir R, Staiano A, Szajewska H & Thapar N. Prevalence and Health Outcomes of Functional Gastrointestinal Symptoms in Infants From Birth to 12 Months of Age. Journal of Pediatric Gastroenterology and Nutrition. 2015; 16(5):531-537.

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