Food Standards Australia New Zealand
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Submission to Food Standards Australia New Zealand Proposal P1028 Infant Formula First Call for Submission

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 (INC) and was active in the preparation of the INC submission on P1028. Danone fully supports the INC submission that 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 (redacted) submission and Part 2 contains information to be kept confidential.

Yours Sincerely

[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 & 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.

Acronyms

ANZ = Australia and New Zealand
CFS1 = First Call for Submissions
FSANZ = Food Standards Australia New Zealand
IFP = Infant Formula Products
IFPSDU = Infant Formula Products for Special Dietary Uses
INC = Infant Nutrition Council
MPL = Maximum Permitted Level
SMPPi = Special Medical Purpose Products for infants

Contents

Part 1: Redacted Submission

We would first like to restate that Danone aligns with the views that breast milk and breastfeeding are optimum for infant health.

Our ongoing research and development focus on delivering to infants, via an infant formula format, as much of the benefits of breast milk that existing science can provide, where there is no choice available to the caregiver to provide their infant breast milk as their sole source of nutrition. We actively invest in research and development to continuously improve our offerings in the infant formula category. We compete with other infant formula manufacturers to create products backed by the most up-to-date science.

2. Framework

2.4.1 Infant formula products

Danone supports maintenance of the current regulatory framework.

2.4.2 Modified infant formula products

Danone appreciates FSANZ trying to consider all stakeholders views and provide a framework that considers infant formula products for special dietary uses (IFPSDU.) Danone does not support the proposed new category as it adds significant complexity and confusion between products suitable for healthy infants, and products that should only be used for specific conditions under medical supervision. Formulas designed for gastrointestinal conditions must be able to state the condition it is used for to provide adequate information for both healthcare professionals and carers.

2.4.3 Special Medical Purpose Products for infants (SMPPi)

Danone aligns with INC's position on Special Medical Purpose Products for Infants (SMPPi). We do not support the new framework in its current form. The proposed framework for SMPPi appears to extend category to multiple other special medical infant products that do not meet the current overarching concept of Standard 2.9.1: to "*form the sole or principal liquid source of nourishment*" for infants.

The inclusion of products currently regulated under Standard 2.9.5 presents as a new area and requires thorough consideration. Danone is concerned that other products have been inadvertently brought into the scope of 2.9.1 and the changes to the regulation of these products may not have been thoroughly assessed by FSANZ for risks. This framework could significantly impact over 30 of Danone's SKUs that currently fall under Standard 2.9.5.

Danone is concerned about the risk to public health and safety and the unintended trade-restrictive consequences. Additionally, it remains unclear what additional protection FSANZ might propose to include for these products under Standard 2.9.1. If the widening of the scope of Standard 2.9.1 is the intent of FSANZ, then a targeted consultation is needed.

It is our view that only SMPPi that form the sole or principal liquid source of nourishment and, are specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition should be included under Standard 2.9.1. It does not support the extension of SMPPi to include all specialty infant foods.

2.4.4. Human milk fortifiers and pre-term supplementary products

Danone cannot support the proposal put forward in the CFS1 in the framework currently proposed. Human milk fortifiers and pre-term supplementary products are not based on the composition of infant formula, nor intended to be used in the same manner. It is not explicitly clear what provisions currently under Standard 2.9.5 will need to be duplicated under Standard 2.9.1.

Human milk fortifiers form a supplementary role in the diet of a very small number of infants. It is important that there is international alignment in the regulation of these products, to ensure continued supply of this specialty product into Australia and New Zealand. Danone is obliged to share labels with its other markets and order set minimum quantities of stock or else the production and shipment is no longer economically viable. This could mean that infants requiring HMF could miss out on accessibility to this product, which can have detrimental public health outcomes.

3. Definitions

3.1 Definitions for infant formula products

Danone supports maintaining the current definitions for "infant" and "follow-on formula". Danone supports further consideration of the definition of "infant formula" and "infant formula products" as provided in the INC submission.

3.2 Definition for SMPPi

CFS1 has proposed the following definition for SMPPi

> *A Special Medical Purpose Product for infants means a food that is*
> *a. specially formulated for the dietary management of infants*
> *(i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and*
> *(ii) whose dietary management cannot be completely achieved without the use of the food; and*
> *b. intended to be used under medical supervision; and*
> *c. represented as being*
> *(i) a food for special medical purposes intended for infants; or*
> *(ii) for the dietary management of a disease, disorder or medical condition in infants.*

Danone supports the INC position on the definition for SMPPi.

Danone does not support the proposed definition for SMPPi in its current form. We believe it extends the scope of the Policy Guidelines. The Australia and New Zealand Food Regulation Ministerial Council Policy Guideline on the Regulation of Infant Formula Products is only intended to cover infant formula, follow-on formula and infant formula for special dietary uses for infants from 0 to 12 months of age. The proposed definition also brings ambiguity to the enforcement of the category and does not provide international alignment.

Extension of scope

In CFS1, FSANZ indicates the scope of P1028 now includes the topics of specialised infant formulas and follow-on formula. Table 1.3 of the first CFS indicates the following IFPSDU are included: lactose free formula and low lactose infant formula; for premature or low birthweight infants; for metabolic,

immunological, renal, hepatic and malabsorptive conditions; for specific dietary use based on protein substitutes; hydrolysed (partially or extensively) infant formula.

The list above does not include supplementary or modular products specifically suitable and formulated for use in infants within Standard 2.9.1. Danone is very concerned that with the lack of clarity in the proposed framework and definition of SMPPi, other products have been inadvertently brought into the scope of 2.9.1 and not been thoroughly assessed by FSANZ for risks.

This could have unintended trade barriers or other public health and safety-related consequences. The proposed definition appears to extend the SMPPi category to multiple other special medical infant products that do not meet the current overarching concept of Standard 2.9.1 being "form the sole or principal liquid source of nourishment" for infants.

Ambiguity

Danone is highly concerned about the interpretation of the proposed definition as proposed by different regulatory bodies. Danone's reading of the definition of SMPPi means that it could be interpreted to cover all special medical purpose formulated foods that are suitable for consumption by infants with a diagnosed disease, disorder or medical condition.

The proposed definition could include modular products to supplement an infant's diet through to low protein pasta products eaten as a family food, for example. These products are not designed to be the principal or sole source of a nutrition for an infant. Danone supplies products represented as being for the dietary management of a disease, disorder of condition in its portfolio and some are suitable for broad age ranges such as infants, children and adults.

It is not clear if only products that provide liquid nourishment for the infant are included. It is important for Danone to gain clarity on this as we supply weaning products and spoonable products for specific diseases e.g. PKU that are suitable from 6 months of age. These FSMP products do not form part of the liquid nourishment of an infant's diet but are specially formulated for infants less than 12 months of age.

It could also be argued that a product has been specifically formulated for infants less than 12 months of age, if it states on the label that it is "suitable for infants, children and adults". However, the intention of the manufacturer is not to represent the product as an infant FSMP, but instead a FSMP for all ages. In some instances, there may also not be an age-related statement on the label. This information is only provided on material to healthcare professionals.

It is important to industry, enforcement agencies and public health that there is no ambiguity in the regulations that may cause delays at the border, for example. We have also provided some examples in the table below of products that could be considered SMPPi under the new proposal. These products are currently represented as FSMP and Danone considers them regulated under Standard 2.9.5.

Examples of FSMP that could fall under the proposed SMPPi definition under the Infant Formula Products Standard

Danone Product	Representation	Age Suitability	Sole Source	Current Standard	P1028 Classification
Essential Amino Acid Mix	FSMP For use as a supplementary protein source eg in acute liver failure	Infants, children, and adults	No	2.9.5	SMPPi

PKU Anamix First Spoon	Semi-solid FSMP for use as a very low phenylalanine, amino acid based, protein substitute	6 months – 5 years	No	2.9.5	SMPPi
Loprofin Animal Pasta Shapes	FSMP For inherited metabolic conditions where low protein is required	None	No	2.9.5	SMPPi
Aptamil Feed Thickener	For special medical purposes. Suitable for use with infants 0-12 months of age. Use under medical supervision	Infants	No	2.9.5	SMPPi
Bovine-derived Human Milk Fortifier	Supplement human milk for feeding preterm and low birthweight infants	Infants	No	2.9.5	SMPPi

FSANZ also needs to provide clarity in the definition of related products. Under Standard 1.1.2 and 2.9.5, the definition of a food for special medical purposes states that an FSMP cannot be "an infant formula product."

However, under the SMPPi definition, it states:

> *(c) (i) "represented as being a food for special medical purposes intended for infants"*

There is a potential overlap in the definitions provided in different Standards in the Code. This may have a direct impact on products imported into ANZ. Danone's imported products primarily come from the EU and will be labelled as "food for special medical purposes," (as this is what the regulation mandates in the EU). The product may, or may not, be represented as intended for infants, even though it can be consumed by infants.

International alignment

FSANZ states its proposal to introduce a category, SMPPi, will more clearly align with international regulations and with the intended purpose of specialised products for infants. The approach will also retain these specialised infant formula products within Standard 2.9.1. FSANZ also state in the CFS1 that Codex standards are the main regulation to which FSANZ has compared requirements.

Danone asks FSANZ to consider the scope of Codex 72-1981 on formula for special medical purposes intended for infants as more appropriate. This states that the products are *"substitutes for human milk or infant formula in meeting the special nutritional requirements arising from the disorder disease or medical condition for whose dietary management the product has been formulated"* (Codex 72-1981 Section B Clause 1.1)

For these reasons, Danone cannot support that the proposed definition of SMPPi as there is a substantial risk that the proposal may hinder, not help, import of these products into ANZ. This is a public health and safety risk. The definition and scope of SMPPi must be further considered so that there is no confusion for enforcement agencies or potential risk of hold up at the border.

3.3 Definition for Protein Substitutes

Danone supports the removal of this definition as it is no longer required under the proposed new framework for SMPPi.

3.4 Other Definitions

Danone supports FSANZ preferred option to remove definitions for protein substitute, soy-based infant formula and pre-term formula.

Danone **does not** support the restriction of MCT, however if this remains, we do not support the removal of the definition of medium chain triglycerides (MCT) as this will increase ambiguity and therefore is not regulatory best practice. Danone supports the INC position to amend the definition to the following "MCT oils means oils commercially manufactured via fractionation and /or esterification to yield a high proportion of medium chain saturated fatty acids (designated by 8.0 or 10.0)."

New Definitions

Danone supports the FSANZ preferred option to not set definition for terms such as gastrointestinal reflux, gastrointestinal disorders or impairment of the gastrointestinal tract, inborn errors of metabolism or related.

Danone supports a new definition for guidance upper limits, as the FSANZ Code does not have notes. The definition should be aligned with the Codex note. As per the INC position Danone suggests the following: "Guidance Upper Limits are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. The Guidance Upper Levels should usually not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons."

4. Novel foods and nutritive substances

4.1 Premarket Assessment Requirements

Danone strongly supports FSANZ preferred approach for the requirements for novel foods and nutritive substances in infant formula products to be considered as part of boarder review of these substances for all food categories in P1024.

Danone's position is that the term "optional ingredients," as used in Codex should replace the term "may be used as a nutritive substance" as part of P1024.

4.2 Novel foods- Schedule 25

Danone supports FSANZ preferred option to amend Schedule 25 to restrict the following substances from being used in infant formula products: α-cyclodextrin, γ-cyclodextrin, diacylglycerol oil (DAG oil), isomaltulose, D-tagatose, and trehalose.

5. Safety and food technology (including SD1 Safety and food technology)

5.1 Food Additives (including SD1 Section 3)

Framework

Danone is supportive of only two categories, one for IFP and another category for SMPPi.

Removal of Carry-over

The removal of carry over permissions for food additives is not supported by Danone as this will be a major change from the status quo which will require substantial work with suppliers.

International alignment

Although FSANZ has done a substantial amount of work there is still international misalignment for food additives.

As highlighted in the INC submission, FSANZ has not conducted an assessment against additives in the draft Codex Follow-Up Formula for Older Infants. Further consideration for addition of these additives is required to ensure international alignment.

It is also clear that keeping international alignment for additives is difficult and hence the number of food additive permissions being considered as part of P1028. For SMPPi, in which international alignment is crucial to ensure vulnerable infants have access to products, Danone's preferred approach is to reference international requirements such as EU 1333/2008 category 13.1.5.1 where there is thorough on-going assessment of additive safety and suitability. New additive permissions are being added, or the ML of current additives revised higher or lower. If international alignment into the future is not achieved Australia and New Zealand infants would not benefit from the most up-to-date science in-regards-to additives. This is also a public health issue where the ML is lowered for an additive, or a new additive is added that is beneficial for dietary management of a disease, disorder or condition which infants in ANZ will not get access to these products. Companies simply do not have the resources to get additive permissions changed via applications for highly specialised SMPPi in a small market.

Table 5.1 Proposed MPL for infant formula products and SMPPi

Danone supports INC position and wants to highlight that FSANZ is currently inconsistent in its approach on additives used in nutrient preparations, this will create ambiguity. Permissions for food additives to be used in nutrient preparation is new under the proposal and it does not seem fully considered. FSANZ propose only explicitly permitting INS 333 and 341 additives in nutrition preparations. Both these additives are permitted processing aids and there are many other additives that are used in nutrition preparation that FSANZ is not explicitly permitting and have previously stated this is because they are permitted as processing aids (e.g. 414, 551, 421, 1450, 301.)

5.2 Contaminants

Danone supports FSANZ preferred approach for most contaminants in mg/kg (not mg/L) including the reduction in lead maximum level to 0.01mg/L, the only exception is aluminium.

Aluminium

Danone does not support the proposed soy reduction in maximum level from 0.1mg/100mL to 0.05mg/100mL. This reduced contaminant maximum level is unlikely to be able to be always met and could lead to supply issues due to levels varying naturally in soy ingredients.

Plants take up aluminium from the soil. For dairy products, the plant material is processed by the cow before coming out as milk, hence some levels of the contaminant are processed out by the cow's liver. For plant-based products, there is no cow to process some contaminants, so contaminant levels are higher and reduction difficult. Therefore, the contaminant limits should not be the same between dairy & soy.

Impact on public health and safety

Not being able to source safe and suitable soy IFP is a public health and food safety issue for babies as demonstrated clearly with the recent significant issues in the US.

Carers will go to extortionary lengths and costs to get IFP for example driving from pharmacy to pharmacy, calling carelines multiple times, getting family members to get product and send it. Lack of accessibility of products also creates significant stress for carers trying to source essential nutrition for babies and this ultimately has impact on their mental health.

As FSANZ is proposing to restrict all other plant-based protein sources for healthy infants it is therefore very important that soy products are still accessible for carers that are passionate about only providing a plant-based IFP to their infant. Otherwise, carers may seek out other plant-based alternative products that are not safe or suitable. There are some very tragic examples of carers using unsuitable plant-based milks for infants and toddlers that has resulted in severe malnourishment.

Soy protein infant formula can be recommended by healthcare professionals for cow's milk allergic infants over the age of 6 months according to the Australasian Society of Clinical Immunology and Allergy (https://allergy.org.au/patients/food-allergy/cows-milk-dairy-allergy)

5.3. Processing aids

Danone supports FSANZ preferred approach of maintaining the status quo.

5.4. L(+) lactic acid producing microorganisms

Danone does not support FANZ position to clarify that only L(+) lactic acid microorganisms may only be added for acidification purposes. For the following reasons:

- No public health issue and therefore benefit in this change: the position is not supported by FSANZ's own risk assessment which demonstrated "no public health and safety concerns, there is no scientific or technical basis to restrict addition of L(+) lactic acid producing microorganisms" (FSANZ, CP1, 2021.).
- As outlined in the INC submission this is not internationally aligned as suggest by FSANZ with either Codex or EU.
- There has been no market failure over the decade that L(+) lactic acid microorganisms have been added to infant formula.

6. Nutrient composition and SD2 Nutrient composition for infant formula products

6.1 Infant formula & 6.2 Follow-on formula (including SD2 Part A: Infant Formula and Part B: Follow-on formula)

Danone supports most of FSANZ preferred composition options for infant formula products apart from the following exceptions where Danone does not support the FSANZ preferred approach:

- Protein source restriction for mammalian milks (SD2 2.1 & 3.2)
- DHA GUL of 7.2mg/100kJ (SD2 2.1 & 3.2)
- Medium Chain Triglycerides restriction (SD2 2.1)
- Inclusion of a maximum lecithin requirement in composition of 1g/L (SD2 2.1)
- Vitamin E minimum and ratio (infant formula 2.2 & 2.4 and follow-on formula SD2 3.3 & 3.4)

- Iron minimum for infant formula (SD2 2.2)
- Flouride limit requirement for the composition once reconstituted (SD2 2.5.3.1 & 3.5.3.1)
- Vitamin D maximum for follow-on formula (SD2 3.3)

Protein Source (SD2 2.1 & 3.2)

Danone does not support a restriction and positive list of permitted proteins **from animal sources**.

The main concerns from FSANZ and submitters in 2021 are in-regards-to plant-based protein sources and anti-nutritive factors. If there are further protein restrictions, Danone suggests FSANZ should consider limiting the restriction to plant-based protein sources.

New Zealand government authorities currently accept sheep milk formula, this includes:

- The New Zealand Food Safety Authority did not support a restriction for mammalian milk in its submission in 2021.
- The New Zealand Ministry of Health "…when breast milk is not available, a dairy-based infant formula (made from cows', goats' or sheep milk) is the next best choice for most babies. Research suggests that no particular infant formula offers benefits over any other"
- New Zealand Ministry of Primary Industries in the New Zealand Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children "dairy based means the formula contains, as its predominant protein constituent, protein derived or processed from milk extracted from a milking animal such as a cow, goat or sheep.

Sheep milk, like all mammalian milks, is a highly nutritious source of high-quality protein. Sheep's milk, like goats' milk, contains high amino acid sequence identities with cows' milk protein ranging between 85 and 95% (Maryniak et al. 2022.) This is not surprising given the relationship between species. The *Ovis aries* (sheep) species belongs to the same suborder (*Ruminantia*) and family (*Bovidae*) as *Bos Domesticus* (cow) and Capra hircus (goat.) This similarity also unfortunately means that sheep's milk cannot be used as an alternative protein source for infants diagnosed with cows' milk protein allergy. Similar to cows' milk, sheep's milk also contains a ratio of caseins to whey proteins at 80:20 and contains all necessary amino acids for infant formula.

Reference

Maryniak, N.Z., Sancho, A.I., Hansen, E.B., and Bøgh, K.L. (2022) "Alternatives to Cow's Milk-Based Infant Formulas in the Prevention and Management of Cow's Milk Allergy," Foods, 11.

DHA GUL of 7.2mg/100kJ (SD2 2.1 & 3.2)

Danone does not support the GUL aligning with Codex 7.2mg/100kJ but supports alignment with the EU level of 12mg/100kJ. Danone provides data in the Confidential section that the current restrictions on total long chain omega-3 do not completely align with the proposed GUL of 7.2mg/100kJ and some products will need to be reformulated to meet this.

Medium Chain Triglycerides (SD2 2.1)

Danone does not support the restriction on MCT as it is international misaligned, if the restriction is to remain then FSANZ must consider clarifying the restriction relates to medium chain triglyceride oil not medium chain fatty acids, to reduce unnecessary ambiguity. Danone supports the INC position to maintain and update the MCT definition.

Inclusion of a maximum lecithin requirement in composition of 1g/L (SD2 2.1)

Danone does not support the additional limits for lecithin of 1g/L in composition to the 5g/L requirements under food additives. Setting 2 limits of the same substance under 2 different areas in the FSANZ Code creates ambiguity and complexity. The composition requirement of 1g/L is not internationally aligned to Codex. As lecithin is an additive and not a nutritive substance the levels should be set in the food additive section.

Vitamin E minimum and ratio (infant formula 2.2 & 2.4 and follow-on formula 3.3 & 3.4)

Danone's strong preference is to align with the EU approach. Vitamin E is the only nutrient that requires a complex, calculation-based check to determine regulatory minimum levels. The fact that there are 2 minimum level requirements for vitamin E can create confusion and this check can therefore be missed by manufacturers who only focus on 0.12mg/100kJ. Danone supports the EU approach of setting a slightly higher vitamin E level and remove the polyunsaturated ratio: this removes the calculation complexity and possibility of errors.

Iron minimum for infant formula (SD2 2.2)

Although Danone understands the FSANZ rationale, we do not support the minimum iron level because it is not internationally harmonised. Alternatively, Danone supports one limit for 0-to-6-month infant formula and another limit for 6-to-12-month follow-on formula.

Vitamin D maximum for follow-on formula (SD2 3.3)

Danone strongly recommends that FSANZ review the maximum level of vitamin D permitted in follow-on formula and increase it to 0.72µg/100kJ. This is based on:

- The NHMRC adequate intake level for infants is not based on local data, or recent evidence, and is not internationally harmonised.
- The contribution of vitamin D from foods will be limited as FSANZ does not permit the fortification of infant foods.
- The EU permits fortification of infant foods and has no safety concerns with the maximum of 0.72µg/100kJ for older infants.

Fluoride limit requiring composition once reconstituted (SD2 3.5.3.1)

To ensure the fluoride limit is clear it should be specified as the limit in the "product as sold." Since the limit is per 100kJ, this is the same limit as for a powdered product "once reconstituted." Our proposed wording reduces regulatory ambiguity. Ambiguity is introduced for powdered products as the water used in reconstitution may contain different levels of fluoride, depending on geographical location. Should this be considered or not? By removing the reference to reconstitution, any regulatory ambiguity is removed.

6.3 Infant Formula Products (including SD2 Part C: infant formula products)

SD2 Part C 4.1

Danone supports FSANZ preferred approach for permitted forms. Noting the permitted forms for SMPPi require international alignment (e.g. methyl-folate) as covered below from SMPPi.

SD2 Part C 4.2

Danone supports FSANZ preferred approach of removing the guidance on advice regarding additional vitamin and mineral supplementation.

SD2 Part C 4.3

Danone supports FSANZ preferred option to maintain existing requirements for scoop to be required in powder products and not to standardise scoop size or dilution ratio

SD2 Part C 4.4

Danone does not support the classification of modified formulas as proposed

7. Labelling

7.1 Labelling- Safety and technology (including SD1)

SD1 8.2 Directions for preparation and use

Danone supports FSANZ preferred option, noting the permitted use of synonyms.

SD1 8.3 Standardised wording or pictures for directions for preparations and use

Danone supports the current approach not to prescribe the exact wording or pictures of directions for preparation and use of infant formula products. However, we wish to seek clarification under subsection 2.9.1—19(3) to ensure it is clear to enforcement agencies that the exact wording is not prescribed. This is detailed in the INC submission.

SD1 8.4 Date marking

Danone supports FSANZ preferred option.

SD1 8.5 Storage instructions

Danone supports FSANZ preferred option.

SD1 8.6 Legibility requirements for warning statements

Danone supports FSANZ preferred option.

SD1 8.7 Warning statements about following instructions exactly

Danone supports FSANZ preferred option.

SD1 8.8 "Breast milk is best for babies" warning statement

Danone supports FSANZ preferred option.

SD1 8.9 Prescribed name

Danone supports FSANZ preferred option.

SD1 8.10 Statement that infant formula product may be used from birth

Danone supports maintaining the current requirements indicating infant formula may be used from birth.

FSANZ reported that *"age information was considered the most useful/important piece of information"* by participants in the online study (Attachment 1 to SD3, page 21.) Danone understands that carers find this information useful and important and already voluntarily provide age indications on the front of

label. This finding is consistent with the Codex requirement *"products shall be labelled in such a way as to avoid risk of confusion between infant formula, follow-on formula..."* (Codex STAN 72-1981 clause 9.6.5.)

Danone therefore proposes that this requirement could be updated to mandating an age statement in a prominent position on the label. The age indication statement should be permitted to vary, for example "0 to 6 months," "from birth," or other equivalent terms.

SD1 8.11 Statement that Follow-on Formula should not be used for infants aged under 6 months

Danone supports the FSANZ preferred option and proposes mandating an age statement in a prominent position on the label. A follow-on formula product would state "6 to 12 months" or similar. This statement makes it clear that the product should not be used for infants under 6 months and is only suitable from 6 months. This information is already voluntarily included on the front of pack of Danone follow-on formulas and carers find it both useful and important as found in Attachment 1 to SD3. If mandatory, then an additional statement that "follow-on formula is not to be used for infants aged under the age of 6 months" would become redundant.

SD1 8.12 Statement about age to offer food in addition to formula (page 75)

Danone strongly supports the 2021 INC position to use the term "around 6 months" to align with both the New Zealand and Australian dietary guidelines for infants and toddlers.

SD1 8.13 Statement on protein source (page 77)

Danone does not support limiting the source of protein. We support the position presented by INC, that information about relevant protein fractions and processing method be maintained within the protein source statement. The proposal does not support informed choice or allow for descriptions of the product that are truthful, complete, and accurate. Nor is it consistent with international food regulations.

The use of the protein source statement as important allergen information is not adequate or appropriate. Using the protein source statement as a substitute to allergen information is a food safety issue. Infants with allergies should always seek advice from a healthcare professional for proper diagnosis and dietary guidance.

SD1 8.14 Co-location of protein source statement with name of food (page 78)

Danone does not support the inclusion of "prominent" in relation to the position of the protein source statement. We support the position presented by INC for the co-location of the protein source statement with the name of the food, and the clarification that this only needs to appear once on the label.

Furthermore, companies are already required under consumer law to provide true and accurate descriptions of their products. When a product is sourced from Soy, Goat milk or Sheep milk we clearly include this on the front of label to ensure carers are able to differentiate between our product portfolios. As cow milk-based formula is the standard source this is often excluded from the front of label, and Danone does not believe including this information more prominently will be of value for carers or healthcare professionals. There are no issues identified with the status quo and Danone is unsure why FSANZ are therefore prescribing requirements in-regards-to prominence which may be interpreted by Jurisdictions as front of label.

7.2 Provision of information (including SD3)

SD3 2.1 Statement of Ingredients

Danone supports FSANZ preferred option.

SD3 2.2 Allergen Declarations

Danone supports FSANZ preferred option. However, we wish to highlight that this is separate from the protein source statement.

SD3 2.3 Labelling as "genetically modified"

Danone supports FSANZ preferred option.

SD3 3 Declaration of Nutrition Information

SD3 3.3 Format of the Nutrition Information Statement

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

Danone does not support the prescribed format of the nutrition information statement shown in SD3 Figure 1. The reasons for this reflect the views outlined in the INC submission:

1. does not allow provision of adequate information for caregivers to make informed choices on what is best for their infant
2. lacks any evidence that there is an issue with the current NIS and the effectiveness of the proposed NIS in Figure 1
3. international food standards do not prescribe the format; and
4. does not allow for an efficient and competitive food industry or for fair trading as differences in formulations will stifle innovation and create a barrier to trade.

Danone want to support carers in choosing the best product for their infants through empowering them to compare and differentiate products easily. However, we are concerned that this proposal could severally limits the ability to do this. The research outlined in Attachment 1 to SD3 to support the highly prescribed format is based on speed of comparison, what should be encouraged is informed choice of product rather than speed of choice of product. The consumer evidence referenced ranges from carers expressing that there is not enough information to those who say that the information is too detailed. We reiterate that the provision of appropriate information about nutrition would be useful to carers to ensure that their choice of formula is informed. Carers who find the information 'too detailed' may elect to read only aspects of the nutrient information that they are interested in.

Further research is needed to understand how the NIS can be used to support carers make informed choices and determine whether the proposed changes will meet these outcomes.

Although Danone does not support this proposal there are several considerations we want to highlight in relation to the NIS in Figure 1:

- The ability to voluntarily include per 100g should be permitted, as it is helpful for healthcare professionals;
- The ability to voluntarily include kcal should be permitted, as it is useful for healthcare professionals;
- Allowing flexibility for inclusion of the powder in the NIS, including weight of one scoop and the proportion of powder or concentrate required to reconstitute the formula. Companies should have the ability to provide this information when deemed appropriate;

- Ordering vitamins and minerals and using units that make sense to consumers and healthcare professionals. Danone recommends alignment with the National Health Medical Research Council Nutrient Reference Values.
- Permitting flexibility in nutrient names and sub-groups, including the use of common terms and acronyms/abbreviations and additional information that are readily understood by consumers. This allows companies to provide the best information to consumers, using language they understand in a limited label space. For example, rather than prescribing the use of 'docosahexaenoic acid,' FSANZ should permit the use of DHA and/or the use of DHA in conjunction with docosahexaenoic acid. The desired outcome would be to support informed choice and appropriate legibility.

Danone supports the issues in the INC submission that provide further details on the considerations above. Rather than prescribing the wording and format of the voluntary listing, it is more appropriate to provide nutrient information in the NIS which is easier to understand for consumers. This should be based on clear evidence of benefit to carers.

Q2 How should the subheadings for "Vitamins, Minerals and Additional" be separated from other text (e.g. using lines, bolding)?

Danone does not support this level of prescription of the formatting, we support the position presented in the INC submission. Their submission outlines issues with alignment to international food regulations. As well as highlighting the Code's legibility provisions, companies require flexibility to ensure legibility in accordance with this requirement.

SD3 3.4 Macronutrient sub-group nutrients in the nutrition information statement

Although Danone is supportive of permitting voluntary declaration of macronutrient sub-groups in the NIS, we do not support an explicit list, prescription of wording and format of the voluntary declaration of macronutrient sub-groups. We support the issues raised in the INC submission outlining how this proposal does not enable informed choice for the carer, or informed recommendation for the healthcare professional, could result in misleading consumers, lacks evidence that there is an issue with the current approach, does not align with international food standards or encourage an efficient or internationally competitive food industry or fair trade.

Industry currently has the ability to use more consumer-friendly language and common terminology, such as prebiotics. This flexibility also allows for inclusion of terms which healthcare professionals might commonly use with their patients. For instance, suggesting they look for a formula that contains prebiotics. It would be unlikely for the specific prebiotic name to be mentioned.

There is significant cost associated with some ingredients such as prebiotics: FOS and GOS. Without the ability to declare the presence of prebiotics on the label, the business will struggle to justify the cost of maintain it in the product or at higher levels. Danone also dedicated significant research into the benefits associated with prebiotics during early life. Companies will also struggle to rationalise the huge cost involved in getting new ingredients approved and therefore there will be less innovation. This all ultimately results in a loss in benefit to the formula fed infant.

Danone also wishes to highlight the point made in the INC submission that the inclusion of lactose and galactose as a sub-group of carbohydrate should always be able to be included as a voluntary listing in the NIS when deemed necessary.

SD3 4.1 Ingredient and nutrient names

Danone supports FSANZ preferred option, however wish to highlight the point that ingredients and nutrients are not the same.

SD3 5.1 Lactose free and low lactose formula

Aptamil Lactose Intolerance has a specified lactose level of <0.006g/100mL; therefore it cannot meet the requirements for a claim of lactose-free. Danone does not support the proposed modified IFP category which would only permit a low lactose claim to be made on lactose-modified dairy-based formula able to be sold in grocery. A low-lactose claim will confuse both healthcare professionals and carers. Furthermore, it does not make it clear that this product should only be consumed if the infant has lactose intolerance. Therefore, Danone supports dairy-based lactose modified products being considered as SMPPi therefore being able to state the condition "lactose intolerance."

SD3 5.2 Partially hydrolysed formula

Q3 Without referencing specific conditions, how should partially hydrolysed formula be labelled to inform caregivers of the nature of the modification from other IFP?

Danone does not support the proposed modified infant formula products category. Furthermore, products that are designed for a special medical condition must be about to label this because this provides useful information to the care and healthcare professional to identify the product referring to a ingredient modification would be confusing. The term partially hydrolysed should be permitted to appear in the protein source statement, where it is relevant.

SD3 6.1 Prohibited representations

Danone does not support the prohibition of terms such as "human identical milk oligosaccharide," "HiMO" or "HMO" (or other similar words or abbreviations) outlined in Standard 2.9.1—24(1)(a) to (e) of the Code. Issues with these have been raised through previous submissions (A1155, A1190, A1233 and previous P1028 submissions).

Over restriction on representations on infant formula products disincentives innovation, does not consider matters of value and benefit to the consumers or support investing in product improvements which long-term may have negative implications on public health and safety outcomes.

Government and public health should focus on increasing readily available information about breast milk and how it does or doesn't compare to infant formula products. However, once the informed choice is made that formula will meet the nutritional needs of the infant, then those making the choice between different infant formula products available should have as much information to inform that choice at their disposal.

SD3 6.2 Nutrition content and health claim prohibition

Danone supports the concerns raised in the INC submission in relation to the existing prohibitions on nutrition content and health claims. This prohibition does not allow provision of adequate information, product comparison or support scientifically researched formulas. In contrast there is evidence of benefit to caregiver's understanding of the product.

SD3 6.3 Claims about ingredients

Danone strongly opposes the proposed restriction on ingredient claims. We support the issues raised by INC in their submission:

- does not allow provision of adequate information
- could result in misleading consumers
- is not supported by evidence of issues or associated risks
- is not consistent with international food standards
- does not allow for an efficient and competitive food industry or fair trading; and
- is not aligned to the policy guideline which does not include ingredient claims.

The issue of a definition of an ingredient claim is also raised in the INC submission. As there is no definition of an ingredient in the Code there is confusion regarding what is an ingredient claim. This could make compliance and enforcement of this proposal difficult.

The proposal should ensure that appropriate information is supplied to the carer to increase their understanding of these ingredients, which assists in informing their choice.

SD3 6.4 Line marketing and proxy advertising

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

Danone along with many MAIF signatories use prominent stage numbers on their formula labels. Multiple label components are included to assist parents and carers to identify age-appropriateness of infant formula products.

Consumers who contact our Careline refer to both the stage and age. Stage numbers are often used where English is the second language. We had previously removed the stage numbers from the label of one of our infant formula product brands for a time. Its removal created considerable consumer confusion as to which product was the most appropriate one for their infant. As a response to consumer confusion the label was updated to include the stage number.

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

Danone supports the views outlined in the INC submission. The MAIF Agreement and the INC Code of Practice (New Zealand) do not permit advertising of infant or follow -on formula. Therefore, it is not possible to research caregivers' understanding and behaviours in this category because these products are not advertised.

Reference to follow-on formula on infant formula helps inform infant formula consumers know that there are differences between products based on age. It is not "advertising" as it relates to a sequence of substitute products in the range suitable as a formula-fed baby grows, not "add on" products. Parents and carers of formula-fed babies from 6 months will either continue using starter infant formula or decide to substitute it with follow-on formula, not both. In this sense, reference to the next stage up on labels provides a factual, age-appropriate guide to parents and should not be seen as "promoting" additional products for purchase by infant formula users.

SD3 6.5 Notification of product reformulation

Danone supports FSANZ's approach that manufacturers continue to decide how to inform caregivers and healthcare professionals about the change of the formulation. However, Danone believes this situation

could be improved by allowing further factual and easy to understand information in relation to the change. Communication on product reformulation is limited to the extent that we can only tell the caregiver that the product has changed. We are unable to communicate clearly and specifically about what has changed in the composition. Danone would support further communication being able to be presented in a scientific and factual manner. We believe this is in the best interest of the infant and caregiver. Caregivers are often stressed and alarmed by any changes and permitting clarity of communicating changes will lessen anxiety and ambiguity.

The current permitted method of communication results in an increase in complaints and consumer contacts by Danone. These include complaints - correctly or incorrectly - that the change has caused symptoms (such as vomiting, diarrhoea, rash, stomach cramps, refusal, and constipation.) Most complaints relate to young infants under 6 months. Caregivers ask us to explain why the formulation has changed, what the differences are, and express their concerns that their infant is struggling to adjust to the new formulation. It would be beneficial to Danone to be able to transparently communicate a forthcoming change to prepare caregivers. Danone has found that several caregivers will complain that they did not notice the lid stickers that advise them the formulation has changed.

The MAIF Complaints Committee have recently updated their Guidance to Clause 5(a) on the information about changes and updates to infant formula. It recognises that "information to be presented in a way that is easy to understand and objective" and clarifies that "such provisions of information should have no promotional content. Pack shots are permitted, but there should be no slogans. Information should not promote or encourage use of formula."

Danone supports this approach by the MAIF Complaints Committee. It permits factual and easy to understand information on formulation changes.

SD3 6.6 Trademarks and online advertising

Danone supports FSANZ approach.

8. Special Medical Purpose Products for Infants (including SD4 Special medical purpose products for infants)

Danone is aligned with INC's position on SMPPi under Section 8 (SD4 special medical purpose products for infants). Including INC's response to comments on composition and labelling

We support the need to find a solution of how best to regulate products specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition. This solution must best meet the needs of the infant and carer.

Only products that are nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants should be considered under Standard 2.9.1. All other special infant products that do not meet the definition of an infant formula product should otherwise remain under Standard 2.9.5.

The impact of this proposal is that many products currently regulated by Standard 2.9.5 will change to be regulated by Standard 2.9.1. There is regulatory uncertainly whether current food for special medical purpose (FSMP) products suitable for consumption by infants, children and adults with a diagnosed disease, disorder or medical condition, will be regulated by 2.9.1 on the basis that they may also be consumed by infants.

Danone markets several FSMPs that are suitable for a range of ages, variously suitable as a sole source of nutrition or as supplemental foods for individuals with special medical dietary needs under the supervision of healthcare professionals. Danone suggests that, if it is the intention of FSANZ to pull all such products under Standard 2.9.1, then a further targeted consultation is required.

For the balance of our submission, 'SMPPi' will refer only to nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, unless stated otherwise.

IFPs have a highly prescribed nutritional composition under both the Code and international regulations. Restrictions on sale were put in place under Standard 2.9.5 as part of the overall risk management strategy due to the minimal prescribed composition and lack of advertising restrictions.

Highly specialised products for infants are already restricted due to extremely small number of infants that require them. It is reasonable that any product labelled in accordance with international regulation should not be available in the grocery channel.

Danone supports the proposal put forward by INC in CFS1 2.4.3, to remove the proposed modified IFP subcategory and move all products intended for a special medical purpose to SMPPi. Under the current framework of Standard 2.9.,1, infant formula products for special dietary use (IFPSDU) can provide information to consumers on (a) that the product is not suitable for general use and should be used under medical supervision (b) the condition, disease or disorder for which the product has been specially formulated and (c) the nutrition modifications made to the formulation. This is more aligned with the proposal of SMPPi.

Danone also supports that these products should not be under the same requirements to meet restrictions on sale. In the Policy Guideline on the Intent of Part 2.9 - Special Purpose Foods it states that: consideration, where appropriate, should be given to the application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.

Products that are categorised under the proposed modified IFP subcategory with a special medical purpose have been on the market for a significant period of time. Danone's products are considered safe and suitable for their intended use. By law, any statements made on pack must be substantiated and are subject to consumer law provisions.

Additionally, accessibility of infant formula is a public health issue. Danone has detailed its concerns on distribution and availability below. Access to a reliable and sustainable availability of supply is a critical issue for parents and caregivers. Restricting access adds to the stress and anxiety of parents carergivers. Restricting access results in less shelf spaces for these products. This could potentially lessen competition between pharmacies which may lead to a higher purchase price for consumers.

For this reason, Danone is in line with INC's proposal on the scope of SMPPi and restriction on sale, as detailed below:

Access: SMPPi that do not have a restriction on sale	**Access: SMPPi that have a restriction on sale**
• An SMPPi that may be described in CFS1 as modified infant formula products and that is specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition	• A product that is specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition and nutritionally adequate to serve by itself

	either as the sole or principal liquid source of nourishment for infants • A product formulated and/or labelled in accordance with Codex, EU and US Regulations and Standards.

SMPPi that do not have restrictions on sale, should have clear and consistent labelling. Danone is aligned with INC's proposal for additional requirements on SMPPi that do not have a restriction on sale and welcomes further consideration on an approach to labelling of such products. Other provisions in Standard 2.9.1 should apply as necessary for SMPPi that do not have a restriction on sale.

Additional labelling requirements where SMPPi do not have a restriction on sale :

Proposal for additional requirements	Rationale
• **The product has properties and/or characteristics specific to the disease, disorder or medical condition for the dietary management of which the product is intended** • **Any product must include this information on the label**	• Product composition is based on scientific evidence • For protection of public health and safety • Provision of adequate information to help consumers and HCPs make informed choices
• **Carry an important notice in a prominent place, such as "use under medical supervision" to stop carers from self-diagnosing and to allow easy enforcement by regulators**	• For protection of public health and safety • Provision of adequate information to help consumers and HCPs make informed choices
• **Carry a statement in a prominent place that states 'for the dietary management of…' These products are for recognized diseases, disorders or conditions with broadly accepted diagnostic criteria**	• For protection of public health and safety • Provision of adequate information to help consumers and HCPs make informed choices
• **Carry the breastmilk is best statement**	• For protection of public health and safety • Provision of adequate information to help consumers and HCPs make informed choices • INC is supportive of the approach of mandating the 'breast is best' warning statement on these products.

Danone's considerations specific to composition and labelling of SMPPi that have a restriction on sale are detailed in the sections below. These comments refer specifically to those products intended to be used as the sole or principal liquid source of nourishment for infants with special dietary needs, who are under

medical supervision for their condition. Our position on the scope of SMPPi must be considered throughout our response on composition and labelling of SMPPi.

SD4 2.1 General nutrient composition

The majority of Danone's products that would fall under the proposed SMPPi are imported from the EU. In the EU these products are required to have 'pre-market authority' prior to launch. Danone is aligned that it is pertinent that the products are able to be imported into Australia and New Zealand and supports FSANZ's proposal that there will be no unintentional restrictions for import and supply from international manufacturers. This approach will enable this subpopulation of infants' timely access to the best possible product.

This includes permission for SMPPi products to meet specific international regulation – namely CODEX, EU and US. This is critical to ensure continued availability of these products which normally have one global harmonised formulation and one, or a few regional, labels. SMPPi that are considered infant FSMP in other markets, are mostly supplied in low quantities to a particularly vulnerable small population. However, as FSANZ has not been explicitly clear on the regulations which SMPPi are permitted to align with, we cannot conduct a full review of our products and hence, comment on the overall impact.

Danone believes it is imperative that an approach to regulating composition is taken so that, the nutrient composition of SMPPi can be flexible enough to ensure undisrupted access.

For SMPPi, flexibility in deviations from compositional requirements in Standard 2.9.1 must go beyond deviation from baseline nutrient composition and also include deviations from permitted nutrient forms, optional ingredients and additives under 2.9.1.

In order in allow for undisrupted access of products, it will be sometimes necessary for the variations from 'IFP baseline composition' to be broader than those required to address the special purpose of the product. Therefore, FSANZ must allow SMPPi to meet the international regulation in full and not require ANZ manufacturers to provide rationale for each deviation. For example, the Code has a different requirement for levels of particular nutrients (e.g. minimum iron) compared to international regulation e.g. (EU) 609/2013, Delegated Regulation (EU) 2016/127 and Delegated Regulation (EU) 2016/128. Therefore, a product may have a level of iron that is outside the permitted range in the Code, purely to meet the EU regulation, rather than for the benefit of the disease, disorder or condition. The same argument holds for nutrient forms, additives and optional ingredients. An example of nutrient forms is calcium-L-methyl-folate which is permitted under Codex Formula for Special Medical Purposes Intended for Infants but not in the Code for IFP.

Standard 2.9.5 provides flexibility to allow for international alignment by including an explicit exception from nutritive substances and novel foods. This needs to be included for SMPPi to allow international alignment. Requirements specific to SMPPi must be flexible enough to accommodate new ingredients and future innovation for specific diseases, disorders or conditions.

To ensure that there are no trade restrictions or hold ups at the border that could hinder timely availability of SMPPi products to infants. These regulations should be laid out specifically and include:

- Codex: Codex Stan 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. Codex CAC/GL 10-1979 Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children.
- EU: Regulation (EU) No 609/2013 and associated Commission Delegated Regulation (EU) 2016/128
- Regulation (EC) No 1333/2008 on food additives

- US: Under 21 CFR 107 subpart C

SD4 2.2 Composition for premature or low birthweight infants

Danone agrees with FSANZ's proposal.

SD4 2.3.1 Manganese guideline maximum for infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

Danone agrees with FSANZ's preferred option. For SMPPi, there must be permission for products to have compositional variations from 'IFP baseline composition', where they comply to credible international regulations, including Codex, EU and USA.

SD4 2.4 Composition for specific dietary use based on a protein substitute

Danone agrees with FSANZ's preferred option.

SD4 2.5 Composition Medium Chain Triglycerides

Danone agrees with FSANZ's preferred option is to include a permission for the addition of MCT to SMPPi to address the product's medical purpose. The addition of MCT oils should be considered as safe for addition to SMPPi where it helps to address the product medical purpose.

SD4 2.6 Composition for molybdenum and chromium

Danone agrees with FSANZ's preferred option.

SD4 2.7 Measuring scoop for SMPPi

Danone agrees with FSANZ's preferred option. However, we note that a measuring scoop is provided in some of Danone's SMPPi products. Therefore, the Standard should not preclude manufacturers from placing a scoop in the product if they deem it reasonable for the intended product.

SD4 2.8 Food additives

Danone supports the preferred option for two food categories in Schedule 15 of the Food Standards Code. Danone supports INC's approach provided in section 5.1 on Food Additives for INC's full position on food additives for SMPPi. Noting that there must be consideration on how to align food additives into the future and food additive permissions are constantly being considered, therefore Danone is supportive of directly reference international requirements from EU, Codex and US.

SD4 3.2 Application of Standard 2.9.5 labelling requirements

Danone agrees with the INC response to SD4 3.2.

SD4 3.2.1 Mandatory statements and declarations

Danone is aligned to the INC response.

SD4 3.2.2 Nutrition information

Danone is aligned to the INC response. Danone notes that in a proposal to remove the proposed modified IFP subcategory and move all products intended for a special medical purpose to SMPPi, it allows for flexibility in the presentation of the nutrition information.

SD4 3.2.3 Nutrition content and health claims

Danone is aligned to the INC response. It is important to provide all information that is necessary to ensure the appropriate use of SMPPi. This is to ensure infant health and safety and to prevent miss-use of its specialised products.

It is also vital that manufacturers can provide enough information about food to help consumers and healthcare professionals make informed choices. This should include the ability to provide information on the properties and characteristics in relation to, among others, the special processing and formulation, nutritional composition, and rationale on what makes the product useful for its specific intended purpose. This information should not be considered a nutrition and health claim under Standard 1.2.7.

SD4 3.3.1 Prescribed name

Danone is aligned to the INC response

SD4 3.3.2 Warning statements

Danone is aligned to the INC response

SD4 3.3.3 Directions for preparation and use

Danone is aligned to the INC response

SD4 3.3.4 Age-related statements

Danone is aligned to the INC response

SD4 3.3.5 Protein source statement

Danone is aligned to the INC response

SD4 3.3.6 Prohibited representations

Danone is aligned with FSANZ's proposal that all the prohibitions on labels of Infant Formula Products should not apply to SMPPi. Most of these products are highly specialized and intended use under the supervision of a healthcare professional. Given the restriction purely due to the low number of infants who use the products, labels will not be widely viewed by the general public. It is critical that SMPPi must retain flexibility in permissions on labelling, to allow for imported products to meet credible international regulations and prevent any potential trade barriers. This will ensure the relevant population in ANZ has timely access to these specialised products.

Danone supports a provision in the Code that provides an option for a SMPPi to not be placed under a restriction of sale. These products would be more widely available to the general public, i.e. placed in the grocery channel. As such, Danone supports considerations on prohibited representations pertaining to Section 2.9.1—24 being considered in line with our comments on 'SD3 6 Representations' for standard infant formula products.

One exception is the reference to nutrients and nutritive substances outside of the nutrition information statement, statement of ingredients or a statement relating to lactose. Products considered to be modified IFP with a special medical purpose under the current proposal, have formulations specific to the condition for which they are intended. It is imperative that caregivers and healthcare professionals alike, are provided with clear information on the label, on any modifications in the formulation that are intended to aid in the dietary management of the condition.

Distribution and availability

If products considered to be modified IFP with a special medical purpose, are under SMPPi, a restriction on sale may have adverse impacts on health, accessibility, availability, and supply chain. A summary of the impacts is detailed below.

1. **Health**: There is a significant risk that restricting access and availability of less specialized SMPPi to caregivers 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. 2015a.) These conditions may be considered transient, such as reflux and colic, and can be acute or chronic.
    - These conditions are classified as a disease / disorder with well-defined, objective, and broadly accepted diagnostic criteria in absence of obvious structural or biochemical alterations (Benninga et al. 2016; EFSA, 2015; Vandenplas et al. 2015a.)
    - For gastro-oesophageal conditions e.g., reflux, internationally recognised NICE clinical guidelines (UK) have a place for formulations specific to the condition. These clinical guidelines state that for gastro-oesophageal reflux in children and young people, a thickened formula should be tried before alginate therapy. Moving products to pharmacy places less risk on health and safety as infants suffering from reflux are less likely to go straight onto pharmaceutical products.
    - Danone conducted two qualitative research studies with ANZ mothers in April 2018 and January 2019. We found that the caregiver journey for those with infant feeding issues is highly stressful. Caregivers proactively seek out reassurance and advice. HCPs are often their first port of call for advice and are seen early in the journey. HCPs consulted are usually midwives, nurses, and GPs. They are the key influencers prior to a caregiver trialing a solutions/specialty formula.
    - Should these products have reduced access and availability or be able to communicate modifications to the end user, caregivers could revert to purchasing normal IFP meant for healthy infants. This 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 for sale.
    - 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): Products described as 'modified infant formula products' 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 caregivers.
    - Within this category, there has been sales 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.
    - The accessibility via grocery has not seen an increase in the inappropriate use of products that would be considered "modified infant formula products." 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 continually drives 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 SMPPi could be used. This includes diseases, disorders or conditions, 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 use. Danone is open to including this statement on front of the pack, to make it clear differentiation to consumers between these products and standard IFP.
- Typically, the grocery sales channel may be more affordable for shoppers due to operational efficiencies and margins, meaning some caregivers will be disadvantaged in their access of these products, due to **increased cost**.
- If access is restricted to the pharmacy/healthcare institution sales channels, the likely retail cost to the caregiver will also increase due to less competition and retail prices set at the sole discretion of the retailer.
- Danone has a Careline team comprised of accredited midwives and dietitians that both HCPs and caregivers can contact for queries regarding breastfeeding advice, choice or comparison of milk, correct product usage, transition advice, and accessibility/product availability support.
- Not being able to source infant formula product is a health and safety issue for babies as demonstrated clearly with the recent major issues in the US. Lack of accessibility of products also creates significant stress for caregivers trying to source essential nutrition for babies and this ultimately has an impact on their mental health.

3. **Availability (the products are stocked on shelf, available to buy)**: Over the past 18 months, caregivers 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, panic pandemic buying and freight delays throughout 2020-2022.
    - Grocery retailers facilitate very fast replenishment through their end-to-end supply chains whereas the pharmacy sales 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 most pharmacy outlets. This adds further to stock availability issues, limiting the amount of product available on shelf for caregivers in these settings. This lack of availability would be compounded with increased numbers of caregivers forced to source products if the products were removed from the grocery sales channel. This could lead to additional stress on the caregiver. The number one reason for contacting Danone Careline is consistently due to lack of availability and accessibility of product.
    - Smaller and/or independent pharmacies, especially those in rural/regional communities may not have the financial status to stock all types of products due to inventory cost, thus parents and caregivers 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 for brands that they stock, thus limiting parents' and carers' ability to make an informed choice.

- On-Shelf Availability check: Most of the larger retailers provide the opportunity to check in-store availability in real time, giving caregivers the means to find products. This is important especially when there is limited availability and caregivers are reliant on the product.
- The Nutricia Careline call centre receives a large number of calls about products currently classed as IFPSDU. This indicates that, if sales were further restricted, the expected enquiries would grow exponentially due to limited availability as well as the increased risk of stockpiling also impacting shopper accessibility.

4. **Supply Chain**: Due to the size and scale of the products described as "modified infant formula products" in the grocery sales channel in Australia, there is a significant risk that in restricting sale of these products to the pharmacy/healthcare institution sales channels they **will not be able to manage this large volume of product in their supply chain and retail outlets without negatively impacting access and availability of these products to consumers and health outcomes for infants**.

9. FSANZ Act assessment requirements (including SD5 Consideration of costs and benefits and SD6 Assessment against ministerial policy guidelines)

9.1 Consideration of costs and benefits

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

Danone does not agree with FSANZ's conclusion. We will discuss below many factors that contribute to the costs that far outweigh the stated benefits covered. Danone notes that "cost" is not a defined term under the FSANZ Act. Accordingly, this has been interpreted to include both direct and indirect costs to be reciprocal to direct and indirect benefits referenced in clause 59(2)(a).

It is unclear how OBPR arrived at the conclusion that a separate CRIS would not yield new information about costs and benefits. As noted, there are costs that go beyond direct costs covered in the CFS or SD5. It is overly simplistic to only consider potential direct costs without any accounting for increasing and persisting supply chain and logistic challenges, inflationary pressures, scarcity in raw materials, ingredients, packaging, etc, following on from multiple governmental COVID responses in an environment with continued demand for safe and healthy sources of infant formula that will reach consumers when needed. The recall of Abbott infant formula powders in the USA is a recent example of how these pressures can penalise the most vulnerable. This cost is not accounted for in Section 9 or SD5.

FSANZ should consult to obtain new and up-to-date information on costs and benefits. The previous extensive consultation was not performed under the Act and FSANZ is not obliged to take it into consideration. Furthermore, previous consultation information was obtained over a 10-year timeframe and very likely to now be out-of-date. A correct cost-benefit analysis will account for all the positive and negative effects of the proposed regulation and allow FSANZ to determine on balance whether the community, government and industry is likely to benefit. The Office of Best Practice Regulation provides

guidance on cost-benefit analysis that can also be used for qualitative analyses for those effects where FSANZ could not assign a dollar value.

The costs to industry are further reaching than what is covered here, and we submit that these greater costs far outweigh the stated benefits covered. It is insufficient to only consider the costs of reformulation and relabelling as the most significant costs incurred by these potential changes. Potential additional, indirect and unintended costs including negative health outcomes are possible.

We foresee no cost savings resulting from this proposal; on the contrary costs to industry and consumers are steadily increasing due to multiple factors including inflation and supply chain constraints. Confidential data on potential monetary costs for Danone are provided in the **commercial-in-confidence section** and includes answers to Questions 2-8.

While there is an assertion that *"The standards are not expected to limit market access nor notably reduce market viability for infant and follow-on formula products. FSANZ expects that very few products would be unable to adapt to the new standards and that competition between manufacturers would not be significantly affected,"* this is not substantiated with any evidence or in any SD. A competitor study sponsored by an ANZ government entity such as ACCC in Australia and/or the Commerce Commission and MBIE in NZ, would be welcomed to ensure that unintended consequences of lessening competition do not accrue.

There is also the cost of the loss of innovation through no incentivisation of innovation by manufacturers. This loss of innovation could lead to further pressure on the public sector for research on infant formula if the private sector investment no longer exists. Generations of formula fed infants may be at a disadvantage because they do not have the same access to other technological advances in this space as compared to their non-ANZ peers.

Danone's infant formula products and SMPPi are safe and suitable. The proposed lowering of the maximum level of aluminium in soy may mean that suitable plant-based soy formula products are no longer available in our market. Other specific products will no longer be available under this proposal or will require additional, costly pre-market assessments of currently used ingredients.

If regulatory ambiguity is introduced for many products currently classed as FSMPs, it will result in increased industry and governmental costs to deal with the effects. For example, customs and shipping delays or enforcement agency actions.

Greater international alignment would be achieved for many of the proposed requirements, increasing the viability of continued supply to our markets. However, despite much work from FSANZ to improve alignment there will still be misalignment with Codex for the following proposed requirements:

- Food additives there is misalignment for Draft FuFOI Draft Follow-up Formula for Older Infants.
- Aluminium contaminant limit
- L (+) lactic acid producing microorganisms for acidification only.
- Protein source restrictions
- MCT restrictions
- Iron minimum
- Vitamin D maximum for follow-on
- Selenium minimum
- L-Carnitine maximum for infant formula
- L-Carnitine minimum for follow-on formula

- Optional nutrients min and max (e.g. Taurine, Nucleotides for follow-on, 2FL, galacto-oligosaccharides, inulin-type fructans)
- Lecithin maximum

International alignment is important not just now but for the future, and FSANZ needs to consider how to future proof the standard for this particularly for SMPPi.

If there are no changes affecting special products for high-risk health conditions, then there will be no change to these trade conditions. A trade barrier may be introduced for SMPPi where the food additive Maximum Permitted Level (MPL) varies from the EU. Expanding the scope of the 2.9.1 Standard to FSMP products could introduce unintended trade barriers.

9.2 Subsection 18(1) and 9.3 Subsection 18(2) considerations (including SD6 Assessment against Ministerial Policy Guidelines)

Competition between infant formula companies

We would welcome a competitor study sponsored by an ANZ government entity such as ACCC in Australia and/or the Commerce Commission and MBIE in NZ, to ensure that unintended consequences of lessening competition do not accrue. Additional costs to government will accrue if there is a potential increase in anti-competitive behaviour due to the lessening of competition. Potential impacts to economic recovery initiatives assisted by infant formula manufacturing activity in ANZ may also be impacted - since infant formula manufacture and the dairy inputs into these formulas are regarded as primary industries. Government bodies responsible for ANZ economic recovery should be consulted to ensure that potential detriment to economic recovery arising out of these market participants are considered, accepted and/or mitigated. The ability of ANZ firms to compete effectively in domestic and export markets will also be impaired. The ANZ market may have reduced attractiveness as an export market for overseas infant formula manufacturers, which has impact on consumer access to these products and/or innovations. Where changes result in lessening competition and a potential consolidation of market participants, the recent recall of Abbott infant formula powders in the USA provides a reminder of the potential consequential damage to consumers.

The current and further proposed restrictions to current labelling practices for infant formula, has the potential to effectively remove the current competitive landscape. It is the consumer that will suffer, because future industry investment in improving infant formula will be reduced; and industry may choose to invest research in products and categories that provide a more sustainable return on investment. It effectively creates one type of product available in the infant formula category. Some public health stakeholder submissions seem to want only a standardised base infant formula, to create “equity”. This will require less-innovative companies to invest to get to the same standards as more innovative offerings in the market to date and effectively puts a pause on any willingness by industry to innovate beyond the standardised base offering.

From a public health point of view, we submit that stifling of innovation should not be desired or deemed acceptable. Companies innovate due to the ability to gain a return on investment, which in itself, should not be vilified. Markets are created and innovation occurs because participants are competing for a consumer’s attention and investment. The market concerned in this context is the market created for infant formula because there are infants whose nutritional needs cannot be met by breast milk through no fault of their own. The competition is not between breast milk vs infant formula. The competition is

between one infant formula vs another infant formula where a choice has previously been made that breast milk is unavailable or not a viable option.

The ability to differentiate its products from its competitors with the information it provides is at the heart of consumer choice. This competition for consumer choice drives industry to look at what gives it competitive advantage over other market participants. Participants can choose to compete on price, quality, innovation, brand, channel to market, among other things. Impairing or removing the ability to compete on one or more of these variables will have an impact on the product on offer, not all of which will be of benefit to the consumer. The ability to differentiate on quality because information cannot be provided to the carer means that the carer is left to decide on either price, brand, and/or channel to market among other things. Unintended consequences of this could include:

- Potential innovative market entrants may choose not to enter for inability to compete on price, brand, and/or channel where established players will have the advantage.
- Remaining participants may choose to compete on price by either increasing price where price is seen as a proxy for quality or reducing price to lock in consumers. The latter can lead to other unintended consequences such as price fixing and/or price gouging by unscrupulous participants.
- Those with established brands and greater investment capability may choose to focus its investment on brand spend rather than research and development.
- Potential increase in misleading and/or deceptive conduct if market participants are unable to differentiate between their products and those of their competitors.

Any or all of the above would come at the detriment of the ultimate consumer, i.e., the infant who has no choice in what they are fed.

This would create a disadvantage solely felt by the ANZ businesses and ANZ consumers, when other countries and other industry competitors can continue to make the claims that they are currently able to do and with greater continued incentive for them to continue to invest in R&D in that space.

Internationally competitive food industry

As per Section 9.3 of the CFS, FSANZ "has also had regard to the desirability of an efficient and internationally competitive food industry" and also "the promotion of fair trading in food". Therefore, the standards regulating the infant formula industry have implications for domestically manufactured products for both the domestic and international markets, and internationally manufactured products for the domestic market.

If claims and representations are prohibited in ANZ, but the same is not prohibited in other markets with which ANZ infant formula manufacturers compete, then there is a potential to negatively impact these ANZ infant manufacturers' ability to win market share. While FSANZ is focused on activity in ANZ, the ability of the ANZ infant manufacturer to compete in other markets has the ability to improve public health and safety outcomes in ANZ because of the following:

- The greater the competition in a market, the greater the need for market participants to innovate to gain market share.
- Innovations will focus on matters of value and benefit to the consumers it serves.
- The bigger the competitive market, then the greater the need to innovate, creating impetus for market participants to continually invest in science and technology to improve their competitive offerings and to differentiate themselves from other market participants.
- Increased innovation is of benefit to the consumers.

- Within the context of infant formula, where 'breast is best' is the 'gold standard', then this means that the focus for these market participants is to continue on investing to improve their consumer offerings to make available an infant formula that is an ever-improving proxy for breast milk where the option to consume/provide breast milk is unfortunately unavailable to the carer and their infant.

Increased competition necessarily leads to increased innovation which results in improving health outcomes for consumers.

Human Rights

FSANZ should consider the human rights of carers and infants who cannot elect breast milk as the infant's sole source of nutrition. A check should be made against human rights legislation in ANZ for immediate and potential future discriminatory impacts. Potential discrimination against both carer and infant could be based on the carer's sex, age, physical, social, and/or economic status. There is a potential for future generations of carers and infants who require infant formula to be discriminated against if proposed changes are not checked against their potential costs and negative impacts.

Specific Policy Principles—Special Purpose Foods Policy Guideline

Danone comments on the Special Purpose Foods Policy Guideline in relation to SMPPi:

- No assessment of the risk to public health and safety was presented. This should be done before applying any controls to restrict access to special purpose foods. The risk analysis should use the best available scientific evidence.
- Danone's products are considered safe and suitable for their intended use. By law, any statements made on pack must be substantiated and are subject to consumer law provisions. Products with a special medical purpose have an internal dossier of substantiated evidence as to why the product is suitable for the specific condition. There is no evidence presented of any problem with the current accessibility of products currently under Division 4 of Standard 2.9.1, or of a market failure.
- The proposed stance creates ambiguity around the regulating standard of many foods for special medical purposes that are suitable for both infants, children and/or adults. Products suitable for the physiologically vulnerable cannot necessarily separate infant products from other ages.
- Adequate information should be provided to assist caregivers and healthcare professionals to select the appropriate products for their patients. If this is inhibited, it limits the caregiver's ability to make an informed choice. This includes information on the functional benefits of the product and the necessary modifications to support the product's intent.