Food Standards Australia New Zealand
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SUBMISSION TO FOOD STANDARDS AUSTRALIA NEW ZEALAND PROPOSAL P1028 INFANT FORMULA SECOND CALL FOR SUBMISSION

To Whom It May Concern

Nutricia Australia Pty Ltd (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 ANZ (ANZ). Danone appreciates the significant amount of work Food Standards Australia New Zealand (FSANZ) has done to get the proposal to this stage and trusts that FSANZ will provide due consideration to all submissions.

Danone is a member of the Infant Nutrition Council (INC) and actively participated in the preparation of the INC submission on P1028. To that end, Danone fully supports the INC submission that provides a response to the full proposal.

Danone unequivocally agrees with the view that breast milk and breastfeeding are optimum for infant health. However, for infants that are unable to receive breast milk, infant formula products are the only suitable alternative. Danone's ongoing research and development focuses on delivering to infants, via an infant formula format, as much of the benefits of breast milk that existing science can validate, particularly where there is no choice available to the caregiver to provide their infant with breast milk as their sole source of nutrition.

This submission provides further details about the impact on, and potential costs incurred by Danone. The submission also details the impacts the proposed changes may have on caregivers and infants such as challenges with accessibility and availability of products, and limitations on the provision of adequate information required by caregivers to make an informed choice.

Yours Sincerely

[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 CorpTM. 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.

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READING AND PUBLICATION NOTICE

Please note this response has been redacted

ACRONYMS

Acronyms used throughout the response are noted below.

ACL = Australian Consumer Law
AI = Adequate Intake
ANZ = Australia and New Zealand
AR = Anti-regurgitation
ARA = Arachidonic acid
ASCIA = Australasian Society of Clinical Immunology and Allergy
CCNFSDU = Codex Committee on Nutrition and Foods for Special Dietary Uses
CFS = Call for Submissions
CFU = Colony Forming Units
CMA = Cow's Milk Allergy
CMPA = Cow's Milk Protein Allergy
DHA = Docosahexaenoic acid
DRIS = Decision Regulation Impact Statement
EFSA = European Food Safety Authority
EPA = Eicosapentaenoic acid
ESPHGAN = European Society for Paediatric Gastroenterology Hepatology and Nutrition
EU = European Union
FDA = Food and Drug Administration
FGIDs = Functional gastrointestinal disorders
FMCG = Fast Moving Consumer Goods
FSANZ = Food Standards Australia New Zealand
FOS = Fructo-oligosaccharide
FUF = Follow up Formula
FSFYC = Formulated Supplementary Food for Young Children
GER = Gastroesophageal Reflux
GERD = Gastroesophageal Reflux Disease
GMP = Good Manufacturing Practice
GORD = gastroesophageal reflux disease
GOS = Galacto-oligosaccharide
GST = Goods and services tax
GUL = Guidance Upper Levels
HCP = Healthcare professional
HMO = Human Milk Oligosaccharide
INCCoP = Infant Nutrition Council Code of Practice
IFFO = Infant formula and follow-on formula
IFP = Infant Formula Products
IFPSDU = Infant Formula Products for Special Dietary Uses
INC = Infant Nutrition Council
IRI = Information Resources, Inc.,
JEFCA = Joint FAO/WHO Expert Committee on Food Additives
LAM = Lactic acid producing microorganisms
LCPs = Long chain polyunsaturated fatty acids
MAIF = Manufacturing of Infant Formula Agreement in Australia
ML = Maximum Level
MPI = Ministry for Primary Industries
MPL = Maximum Permitted Level

MT = Metric Tonnes
NASPGHAN= North American Society For Pediatric Gastroenterology, Hepatology & Nutrition
NHMRC = National Health and Medical Research Council
NICE = National Institute for Health and Care Excellence
NIS = Nutrition Information Statement
NZ = New Zealand
OECD = Organisation for Economic Co-operation and Development
PBS = Pharmaceutical Benefits Scheme
R&D = Research & Development
SD = Supporting Document
SKU = Stock Keeping Unit
SMPPi = Special Medical Purpose Products for infants
WHO = World Health Organisation
WTO = World Trade Organisation

OVERVIEW

The following sections sets out Danone's responses to each section in the 2nd Call for Submissions (CFS2).

REGULATORY FRAMEWORK

- **Recommends** FSANZ provides further clarification on its intent for low lactose/ lactose free products.
- **Does not support** the restriction on sale of SMPPi as described in CFS2.
- **Recommends** that FSANZ conducts a thorough risk analysis (using the best scientific evidence available) on the restriction on sale of SMPPi, to ensure products remain accessible and available to formula-fed infants diagnosed with specific conditions.
- **Recommends** FSANZ conducts a thorough review of the suitability of the pharmacy sector to ensure there is capacity for this change to occur without any unintended, undesired or adverse consequences that will impact the infant and caregiver.
- **Recommends** that FSANZ considers how it will communicate that the restriction on sale is in the best interest of consumers prior to the implementation of the standard and for the duration of the transition period.
- **Strongly recommends** that communication resources can be accessed by caregivers for an extended period of time, with added resources (such as educational campaigns), to avoid undue stress on caregivers.
- **Recommends** that FSANZ implement a monitoring process over the transition period and adapt its communications as necessary.

NOVEL FOODS AND NUTRITIVE SUBSTANCES

- **Supports** nutritive substances and novel foods in infant formula products being considered in P1024.
- **Recommends** that FSANZ consider providing further clarity on the labelling of novel food and nutritive substances on infant formula products prior to gazettal of the proposed new standards. This should be done with further industry consultation

L(+) LACTIC ACID PRODUCING MICROORGANISMS (LAM)

- **Supports** retaining the current permission.
- **Recommends** addition to permitting the strain, permitting the number of colony forming units (cfu) in the ingredients list or NIS.

FOOD TECHNOLOGY FOR INFANT FORMULA PRODUCTS (SD1)

- **Recommends** the entry in S15—5 Table 13.1 INS 307c dl alpha tocopherol 10mg/L.
- **Does not agree** with FSANZ's SD1 statement. It is not clear that INS 307c is not permitted in the Code.
- **Recommends** the entry in S15—5 Table 13.1 INS 340 Potassium phosphates 450 mg/L, for the use in both Infant formula and follow-on formula products. This is consistent with EU regulations
- **Recommends** permission of all forms of calcium citrates for SMPPi (INS 333 (i), INS 333 (ii) & INS 333(iii)) at GMP
- **Strongly recommends** FSANZ consider the draft EU Commission regulation for Locust bean (carob bean) gum (INS (410)) once it has been published and seek further industry consultation thereafter on safe levels in SMPPi

- **Recommends** that for Xanthan gum (INS 415) in SMPPi it would be preferable to have a single level of permission at the higher level of permitted use, i.e. 1200mg/L.

CONTAMINANTS

- **Does not support** reducing the aluminium maximum level (ML) for soy-based infant formula products from 0.1 mg/100 mL to 0.05 mg/100 mL (1 mg/kg to 0.5 mg/kg).
- **Recommends** retaining the current limit for aluminium in soy-based infant formula products.

NUTRIENT COMPOSITION FOR INFANT FORMULA PRODUCTS (SD2)

- **Supports** the prohibition of the presence of added fructose and or/added sucrose in infant and follow-on formula except for formulas manufactured with partially hydrolysed protein.
- **Recommends** clarifying that incidental fructose and sucrose present as carriers or residual form other ingredients would not be considered as carbohydrate sources and therefore continue to be permitted to be used.
- **Does not support** a GUL of 7mg/100kJ is for DHA.
- **Recommends** a maximum of 12mg/100kJ for DHA which is within the range currently permitted and is reported in breast milk and aligns with the EU maximum permitted level.
- **Does not support** a maximum vitamin D level of 0.63 µg /100kJ for follow-on formula.
- **Recommends** that FSANZ align with the Codex and EU Vitamin D maximum of 0.72µg/100kJ for follow-on formula
- **Supports** FSANZ's position on the composition of SMPPi as described in CFS2.
- **Supports** FSANZ's proposal in the proposed draft variation to allow the composition of SMPPi products to deviate from the specific compositional requirements for infant formula products, where required to address the product's special medical purpose.

LABELLING FOR INFANT FORMULA PRODUCTS (SD3)

- **Does not support** restricting reference to the protein source statement, lactose free or low lactose, partially hydrolysed protein or stage information to the front of pack only.
- **Recommends** that FSANZ remove the over prescription to only allow for the following statements on front of pack, lactose free or low lactose, partially hydrolysed protein, stage labelling.
- **Recommends** that FSANZ allow familiar and commonly used abbreviations and acronyms in the NIS.
- **Does not support** the restriction of reference to ingredients except in ingredients list.
- **Recommends** that FSANZ remove the over prescription of only allowing reference to ingredients in the ingredients list.
- **Recommends** reflecting the intent in the drafting that restriction on "information" is only in relation to another product.
- **Recommends** that FSANZ adopts flexibility in labelling of SMPPi for nutritional modifications of vitamins and minerals
- **Recommends** that the prohibited representations applicable to SMPPi are aligned with international regulation
- **Recommends** amendments to the requirements for the nutrition information statement for SMPPi.

FSANZ ACT ASSESSMENT REQUIREMENTS

- **Disagrees** that some of the proposed variations to Standard 2.9.1 are improvements to the interpretation and enforceability of the infant formula product standard.
- **Disagrees** with some of the proposed variations to Standard 2.9.1 on the basis that they will lead to unintended and irreversible adverse consequences for consumers, industry, and government.
- **Disagrees** with the cost and benefits analysis conclusion reached by FSANZ.
- **Disagrees** that FSANZ has met its obligations under section 59(2) of the FSANZ Act 1991 when assessing the proposal and, in that regard, Danone has provided additional information that FSANZ must consider for it to fulfil its section 59(2) FSANZ Act 1991 obligations.
- **Recommends** a reassessment of the proposal by FSANZ to include consideration of matters highlighted in the SD4 Response.

INC SUBMISSION

Danone fully supports the INC submission that provides a response to the full proposal.

However, given its position as an industry body, the INC submission incorporates diversity in opinions.

Danone's response may have further information that is relevant to its business which means that where there is a conflict between a response provided by an INC response, the views contained in this response shall prevail.

Put another way, Danone's submission focuses on areas of the proposal which Danone does not support or provides further recommendations for consideration by FSANZ.

REGULATORY FRAMEWORK (Section 2 CFS2)

Danone supports some parts of the proposed framework for Infant Formula Products as proposed in CFS2 but does not support other parts.

Danone notes that FSANZ has split the infant formula products under the Framework into Category one products – infant formula and follow-on formula, and Category two products – Special Medical Purpose Products for infants (SMPPi).

Category one

Nutritionally complete infant formula products with a modified formulation relating only to low lactose/lactose free.

Danone recommends FSANZ provide further clarification on its intent for low lactose/ lactose free products. CFS2 has not clearly and accurately differentiated between low lactose and lactose free products.

Due to the differential diagnosis between cow's milk allergy (CMA) and lactose intolerance, there is a risk of misuse of 'low lactose/lactose free' products for CMA, if over-prescriptive and over-restrictive labelling requirements are applied to Category one products, or the restriction on sale applies to Category two products. This has the potential to develop into a public health concern as some infants with dairy allergies may not receive the best dietary management for their condition.

The definition of a 'lactose free' claim across Australia and New Zealand (ANZ) requires the product to contain no detectable lactose. This is inconsistent with other major international regulations, such as the Regulation (EU) No 2016/127 on compositional and information requirements for infant formula and follow-on formula [Regulation (EU) 2016/127] whereby the term 'lactose free' can be used for products containing no greater than 2.5mg/100kJ of lactose. This level is set to enable consumers, such as lactose-intolerant individuals, to make informed choices and select products which are safe to consume. This inconsistency is not in line with FSANZ's objective of achieving consistency between domestic and international food standards.

Due to improvements in testing methodologies, products in ANZ cannot be considered 'lactose free'. Despite them meeting the EU requirements for a 'lactose free' product (Danone's Lactose Intolerance product contains <0.006g/100mL). Low lactose is not an accurate descriptor, and it may

impact a consumer's ability to make an informed choice. Conversely, it may confuse consumers if they are intent on finding a lactose-free product, based on a recommendation from a healthcare professional (HCP).

Category two

Restriction on sale of SMPPi

Danone does not support the restriction on sale of SMPPi as described in CFS2.

Danone supports the INC position on the restriction on sale, supported by the research and insights provided by IQVIA.

The proposed restriction on sale will remove a number of products for the dietary management of gastrointestinal conditions and feeding problems (as identified in CFS2 Table 2.3) and allergy management from the grocery retail channel. Danone has significant concerns about restricting or reducing accessibility and availability of these products across ANZ, particularly in rural and remote areas.

Danone recommends that FSANZ conducts a thorough risk analysis (using the best scientific evidence available) on the restriction on sale of SMPPi, to ensure products are remain accessible and available to formula-fed infants diagnosed with specific conditions.

Currently in Australia, the grocery retail channel has a 64% share of volume of products sold for gastrointestinal conditions compared to 36% in the pharmacy channel [(Circana (Formerly IRI) Australia Grocery and Pharmacy Infant Milk Formula Scan Sales Data MAT to 30/04/2023]. Danone's data from locations of grocery stores and pharmacies across the electoral postcodes in Australia shows that there are 115 rural, regional and provincial postcodes where there are no pharmacies.There are only stores in the grocery retail channel to service the locations. There are 87 rural, regional and provincial postcodes with only 1 pharmacy that support stores in the grocery retail channel, exacerbated further by the fact that the opening of new pharmacies is heavily regulated and restricted to set location rules. This equates to over 7% of all electoral postcodes in Australia having no, or limited, ability to access products currently available in the grocery retail channel. FSANZ's proposal also assumes all pharmacies stock all specialty infant formula products currently available in the grocery retail channel, which is not the case. Danone's response to the cost/benefit analysis of CFS2 provides further details.

HCPs will always play a vital role in providing education and advice to caregivers and helping to assist with the diagnosis of conditions. The caregiver's decision to use a product designed for a gastrointestinal condition or CMA is closely tied in with HCP first interactions and recommendation. Where the products are not listed on the Pharmaceutical Benefit Scheme (PBS) or Pharmac, purchase is more a convenience than a choice at shelf. Further, still distribution of these products is established and, consumers and HCPs, alike, know where to find the products and they are readily available to those in need.

Danone has concerns about the veracity of the evidence that supports that the restriction on sale of products designed for the dietary management of gastrointestinal conditions and feeding problems will not have negative implications, particularly related to public health outcomes. Danone is unaware of any reported instances of misuse of products for gastrointestinal conditions or feeding problems over the last 20 years that these products have been available in the grocery channel.

A restriction on sale for SMPPi that are currently available in the grocery retail channel is likely to have adverse impacts on short and long-term health, accessibility, availability, and supply chains. Some of these adverse impacts are set out in more detail below.

Health:

- Gastrointestinal conditions and allergy are classified as a disease / disorder with well-defined, objective, and broadly accepted diagnostic criteria in the absence of obvious structural or biochemical alterations (Benninga et al. 2016; EFSA, 2015; Vandenplas et al. 2015a.). When left unmanaged, the condition will impact the infant and caregiver, physically and mentally.
- Functional gastrointestinal disorders (FGIDs) such as regurgitation and gastroesophageal reflux disease (GORD), constipation and colic occur in almost half of the infants (Vandenplas et al. 2019). Experts have agreed that the likely prevalence of colic, regurgitation, and functional constipation were 20%, 30%, and 15%, respectively (Vandenplas et al 2015a).
- For gastrointestinal conditions e.g., reflux, internationally recognised NICE clinical guidelines (UK) indicate a role for products suitable for the conditions. The NICE clinical guidelines state that for formula-fed infants with frequent regurgitation associated with marked distress, a thickened formula should be tried before alginate therapy.
- Should these products have reduced access and availability or be able to communicate modifications to the end user, caregivers could revert to purchasing a standard infant formula product which are not suitable for their infant (who suffers from a condition). This in turn could result in negative health outcomes for infants by delaying the intervention by an HCP, putting extra pressure and costs on tertiary care.
- Limited and poorer availability and inconvenience of purchase could lead to added stress on parents and caregivers in sourcing and providing the most suitable product for infants.
- The restriction on sale may also break the point of contact between the HCP and the consumer, if the consumer feels that they only need to speak to someone in the pharmacy, rather than get a clinical diagnosis from their HCP.

Accessibility (where shoppers find the product is ranged):

- There are broadly 3,300 grocery distribution points throughout Australia where products for transient gastrointestinal conditions are ranged. Removing these distribution points will significantly reduce not only access, but ease/convenience of access of these products for caregivers. Concurrently the Australian Federal Government changes to the PBS may challenge the viability of small regional local pharmacies in the coming years, which would lead to further reduced convenience of access.
- There has been sales channel shift to the grocery retail channel 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.
- Not being able to source infant formula products is a health and safety issue for babies as demonstrated clearly with the lack of supply in the US in 2021. 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 the caregivers' mental health.
- If the product is easier to access online, there is a risk that more caregivers will purchase it outside of a physical store, where there will be no contact with an HCP.

Availability (the products are stocked on shelf, available to buy):

- 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 and unnecessary stress on the caregiver.
- Pharmacies, especially those in rural/regional communities may not have the space or financial status to stock all types of products to suit the needs of all in. They also often have reduced opening hours. This may also result in pharmacies having a limited range of products, thus limiting parents' and caregivers' 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.

Danone recommends FSANZ conducts a thorough review of the suitability of the pharmacy sector to ensure there is capacity for this change to occur without any unintended, undesired or adverse consequences that will impact the infant and caregiver.

Approach to restriction on sale

If the availability of some SMPPi products could be retained on the grocery retail channel, Danone would support additional clear labelling and/or compositional requirements.

Communication of regulatory change

If the restriction on sale for the SMPPi category is enforced, it is imperative that the change is properly communicated over an extended period of time, Under Part 2, Division 1, clause 13 of the FSANZ Act, it states that the Functions of the Authority are:

(i) in co-operation with the States and Territories, to develop food education initiatives, including the publication of information to increase public awareness of food standards and food labels; and

(ia) to provide information, on request by a member of the public, about the Australia New Zealand Food Standards Code.

As such, it should be a requirement of FSANZ to effectively communicate the change to all those affected over the transition period, including, but not limited to, caregivers, HCPs, supply chain and the grocery retail sector. Communication should include changes to availability, changes to labels and also emphasise there are no health and safety concerns related to previous products; rather, this is a result of regulatory change. There should also be explanatory statements given to these stakeholders to explain why the changes are occurring.

Danone is a signatory of the Marketing of Infant Formula Agreement in Australia (MAIF) and in New Zealand and adheres to the Infant Nutrition Council (INC) Code of Practice (INCCoP). These agreements prohibit the communication of information on infant formula products to the general public and to HCPs in certain circumstances. It is likely that, given the length of the transition period, there may be some differences as to where different products can be found and as to when they will be removed from the grocery retail channel.

For the reasons above, Danone recommends that FSANZ considers how it will communicate that the restriction on sale is in the best interest of consumers prior to the implementation of the standard and for the duration of the transition period.

Danone strongly recommends that communication resources can be accessed by caregivers for an extended period of time, with added resources (such as educational campaigns), to avoid undue stress on caregivers.

Danone also recommends that FSANZ implement a monitoring process over the transition period and adapt its communications as necessary.

Products captured under SMPPi

Danone supports the definition of SMPPi. However, there are unintended consequences of the changes to the composition and labelling of infant formula products for special dietary use and the introduction of the definition of SMPPi, specifically for highly specialised products.

Some of the products which fall under SMPPi are for metabolic conditions. The majority of Danone's products are manufactured in Europe where they are regulated as 'food for special medical purposes' for infants as defined in Commission Regulation (EU) 609/2013 and Delegated Regulation 2016/128 on Food for Special Medical Purposes. These products can be used as a sole source of nutrition for infants and will be labelled as such, but can also be used as a supplementary feed for children and some adults.

It is imperative that there is flexibility in the labelling of SMPPi to ensure that there is no risk to the import of these products that are used by infants and older individuals, and to maintain consistency between domestic and international standards and trade.

Danone recommends that, in the draft variation 2.9.1-38 (f), a note is added that a product may be used as a sole source of nutrition for infants but also a supplementary feed for other age groups. In instances where this is the case, this will be indicated on the label.

NOVEL FOODS AND NUTRITIVE SUBSTANCES (Section 4 CFS2)

Pre-market assessment requirements

Novel Foods

Danone supports nutritive substances and novel foods in infant formula products being considered in P1024. However, Danone has concerns regarding the differences in interpretation of nutritive substances and novel foods. Danone trust that the reactivation of P1024 will provide industry and stakeholders regulatory much needed clarity.

Used as a nutritive substance

Danone notes that FSANZ have stated in CFS2 that: *permitted nutritive substances are required to be listed in the nutrition information statement*. Recent approvals of nutritive substances have not allowed for the provision of consumer-friendly terms. Danone notes that the Application Handbook as it stands does not provide detail on the assessment of labelling terms. There is no mechanism to determine the best term to include on infant formula products to provide consumers with the best information to make an informed choice. Without any clarity on whether permissions will allow for effective communication nutritive substances, there is no incentive for the industry to expend significant investments on gaining permissions.

Danone recommends that FSANZ consider providing further clarity on the labelling of novel food and nutritive substances on infant formula products prior to gazette of the proposed new standards. This should be done with further industry consultation.

L(+) Lactic acid producing microorganisms (LAM) (Section 5 CFS2)

Danone supports retaining the current permission. Danone also supports the recommendation by INC that FSANZ consider, in addition to permitting the strain, permitting the number of colony forming units (cfu) in the ingredients list or NIS.

This aligns with the best practice labelling guidance, such as that issued jointly by the Council for Responsible Nutrition and the International Probiotics Association (2019). Disclosing the cfu allows manufacturers to add a meaningful amount of cfu in their products and, in turn, deters manufacturers from only adding nominal amounts. Ultimately, disclosure of cfu also provides relevant information to consumers so they can make informed decisions about products.

FOOD TECHNOLOGY FOR INFANT FORMULA PRODUCTS (SECTION 6 CFS2 AND SD1)

Food additives (section 6.1)

Danone fully supports the INC position on food additives.

Danone recommends additional permissions to be provided to align with international regulations.

Infant Formula Products Food Additives

Danone strongly supports the INC proposal to recommend additional permission for below food additives in Schedule 15—5 (food classes 13.1 Infant formula products):

- Tocopherols, dl-alpha (INS 307c)
- Potassium phosphates (INS 340)

Tocopherols, dl-alpha (INS 307c; E 307)

Danone recommends the entry in S15—5 Table 13.1 INS 307c dl alpha tocopherol 10mg/L.

In SD1 FSANZ states: *tocopherol, d-alpha (307a) and tocopherol, dl-alpha (307c) – singly or in combination. Neither of these tocopherols are permitted in the Code for any food classes so they are not considered further for permission for IFP. If specific permission is sought for these alternative forms of tocopherols they will require separate assessment outside of this proposal, i.e. an application.*

Danone does not agree with FSANZ's SD1 statement above. It is not clear that Tocopherols, dl-alpha (INS 307c) is not permitted in the Code.

INS 307 is listed as a permitted food additive in Schedule 15, food class 0 Preparations of food additives. FSANZ specifies in CFS1 SD1, section 3.3.4 that: *food class 0 apply for all food classes – with no exceptions for infant formula products*. This means, with current carry over principle applied, 307 is currently permitted to be present in infant formula products as a result of carry over.

Danone interprets INS 307 in Schedule 15 as E 307 in aligning with EU regulations. As shown in the extract below the Commission Regulation (EU) No 231/2012 provides specifications for E 307 and states that a synonym for alpha-tocopherol is *dl-alpha-tocopherol* and (all rac)-α-tocopherol.

E 307 ALPHA-TOCOPHEROL

Synonyms	dl-α-Tocopherol; (all rac)-α-Tocopherol
Definition	
Einecs	233-466-0
Chemical name	DL-5,7,8-Trimethyltocol; DL-2,5,7,8-tetramethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol
Chemical formula	$C_{29}H_{50}O_2$
Molecular weight	430,71
Assay	Content not less than 96 %
Description	Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidises and darkens on exposure to air or light
Identification	
Solubility	Insoluble in water, freely soluble in ethanol, miscible in ether

Danone considers Tocopherols, dl-alpha (INS 307c) be treated similarly to E 307 and be permitted in Schedule 15, food class 0 Preparations of food additives. This will align with international regulations INS 307c should be explicitly permitted in infant formula products.

Food Safety Assessment

Tocopherols, dl-alpha (INS 307c) is a permitted form for Vitamin E to be added in infant formula products as per S29—7 Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements and food for special medical purposes.

There are no safety concerns with this substance for infant formula products as it is already permitted at much higher levels as a nutritive substance. A much lower level is needed for to provide a technological function as an antioxidant.

In EU, E 307 dl-alpha-tocopherol is permitted in infant formula, follow-on formula, infant foods for special medical purpose (FSMP) and FSMP for young children at maximum limit of 10 mg/kg or 10mg/L as consumed. It can be used either single or in combination with E 306 (tocopherol rich extract), E 308 (gamma tocopherol) and E 309 (delta tocopherol).

It is also permitted to be added in all nutrient preparations for use in foods for infants and young children wherein the limit should not exceed 10 mg/kg or mg/L as consumed (EU regulation 1333/2008).

ESFA scientific opinion (EFSA, 2015) on tocopherol as food additives is presently under re-evaluation. The re-evaluation and the EU additives database by application category both supports the use of dl-a-tocopherol as an antioxidant and Maximum Limit of 10mg/kg in infant formula products. The following is an extract from the opinion that highlights that a synonym for 307 is dl-a-tocopherol (European Commission, 2011).

Table 1: General information on the tocopherols used as food additives (E 306–E 309)

Food additive	Synonyms	EINECS number	CAS Registry Number [a]	Name according to CAS number [b]
E 306 "Tocopherol-rich extract" [c]	–	–	–	–
E 307 "*alpha*-Tocopherol"	dl-α-Tocopherol; (all *rac*)-α-tocopherol [d]	233-466-0	10191-1-0	(±)-α-Tocopherol; dl-α-tocopherol; *all-rac*-α-tocopherol
E 308 "*gamma*-Tocopherol"	dl-γ-tocopherol	231-523-4	7616-22-0	(±)-γ-Tocopherol; dl-γ-tocopherol; *all-rac*-γ-tocopherol
E 309 "*delta*-Tocopherol"	–	204-299-0	119-13-1	d-δ-Tocopherol; (*R*,*R*,*R*)-δ-tocopherol

(a): Corresponding to the EINECS numbers (EC Inventory, online) indicated in Commission Regulation (EU) No 231/2012.
(b): From SciFinder.
(c): According to Commission Regulation (EU) No 231/2012, tocopherol-rich extract (E 306) contains tocopherols, such as d-α-, d-β-, d-γ- and d-δ-tocopherols, and tocotrienols.
(d): The composition of E 307, as defined in Regulation 231/2012 "(all *rac*)-α-tocopherol" means a mixture, not necessarily equimolecular, of all four possible racemates (i.e. of all the four pairs of enantiomers) (IUPAC-IUB, 1981). EINECS (EC) number and CAS Registry Number correspond with this definition.
CAS, Chemical Abstract Service; EINECS, European Inventory of Existing Commercial chemical Substances.

Draft Codex FUF standards includes provisions for INS 307c, along with 307b and 307a, singly or in combination, at the higher MPL of 30mg/kg. With all the above, Danone concludes INS 307c *dl-alpha-tocopherol* at maximum limit of 10 mg/kg or mg/l as consumed in infant formula products is safe and fit for purpose. This also help facilitate trade in aligning with Codex and EU regulation.

Potassium phosphates (INS 340)

Danone recommends the entry in S15—5 Table 13.1 Potassium phosphates (INS 340) 450 mg/L, for the use for both Infant formula and follow-on formula products. This is consistent with EU regulations.

Food Safety Assessment

Potassium phosphates (INS 340) is a permitted form for potassium to be added in infant formula products as per S29—7 Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacement and food for special medical purposes in the Code.

There are no safety concerns with this substance for follow-on formula given it is already permitted for infant formula.

INS 340 potassium phosphate is permitted as nutrient compound in Codex standards CAC/GL 10-1979 for all infant formula products (i.e.including SMPPi).

EU regulation 1333/2008 FC 13.1.1 permits potassium phosphates at the MPL of 1000 mg/L as P2O5 (equivalent to 450 mg/L as phosphorus) for both infant formula and follow-on formula.

Technological justification

The current technological justification of potassium phosphate as a food additive is as an acidity regulator applies equally for when it is used in follow-on formula, not just in infant formula. The

restriction from using it in follow-on formula is not appropriate. For example, INS 340 potassium phosphates are used in some of long chain polyunsaturated fatty acids (LCPs) (such as DHA and ARA) as acidity regulator. These LCPs are commonly used in infant formula and follow-on formula in ANZ.

Potassium phosphates work as acidity regulators by changing or maintaining the pH of infant formula products during production. Such phosphates represent a wide range of pH values and can each provide excellent buffering capacity as well as pH modification for stabilisation of the formula matrix where necessary. In milk-based formula, the buffering action of phosphates stabilises the pH thus keeping the calcium micelle intact and preventing curdling/precipitation, in particular during heat treatment. The pH-regulating property and buffering impact of phosphate salts supports ion exchange and the loosening of the protein structure.

SMPPi Food Additives

Danone supports many of FSANZ's positions for food additives used in SMPPi.

Danone fully supports the INC submission on food additives used in SMPPi and reiterates some of the INC recommendations for the proposed changes:

- Calcium Citrates (INS 333)
- Locust bean (carob bean) gum (INS 410)
- Xanthan gum (INS 415)

The recommended changes emphasised below are to help ensure the continued supply of SMPPi and to reduce any risk of creating an unintended trade barrier.

Calcium Citrates (INS 333)

Danone supports INC's position on INS 333 and the recommended permission of all forms of calcium citrates [INS 333 (i), INS 333 (ii) & INS 333(iii)] at GMP.

Locust bean (carob bean) gum (INS 410)

As locust bean (carob bean) gum is used in SMPPi products, levels should be aligned with the EU to prevent the creation of a trade barrier. Danone strongly recommends FSANZ consider the draft EU Commission regulation once it has been published and seek further industry consultation thereafter.

Xanthan gum (INS 415)

Danone agrees that the permissions for Xanthan gum as they are aligned with international regulations.

Danone supports the INC position and recommends that it would be preferable to have a single level of permission at the higher level of permitted use, i.e. 1200mg/L. Manufacturers only include the amount of additive required to achieve the technological function required. However, Danone recommends a transfer of condition of use, so that the condition statement includes products based on hydrolysed protein, and/or amino acids or peptides.

Contaminants (Section 6.2)

Danone supports many of the variations to requirements for contaminants proposed in CFS2., However, Danone does have concerns regarding the proposed maximum aluminium levels for soy-based infant formula products.

Danone does not support reducing the aluminium maximum level (ML) for soy-based infant formula products from 0.1 mg/100 mL to 0.05 mg/100 mL [1 mg/kg to 0.5 mg/kg].

The following shows a comparison of recommended maximum aluminium levels:

Product	Current FSANZ Max	P1028 Change	Food Safety Recommendation (JEFCA)
Soy Based	7.0mg/kg as sold = 1mg/kg as consumed	3.5mg/kg as sold = 0.5mg/kg as consumed	2mg/kg bw/week = 0.28 mg/kg bw/day ≈ 7mg/kg as sold ≈ 1mg/kg as consumed WHO | JECFA
Milk Based	3.5mg/kg as sold = 0.5mg/kg as consumed		

NUTRIENT COMPOSITION FOR INFANT FORMULA PRODUCTS (SECTION 7 CFS2 AND SD2)

Danone supports most of the proposed requirements nutrient composition for infant formula products proposed in CFS2.

Danone fully supports the INC submission including its recommendations for some nutrients. These include proposed treatment of carbohydrate source and Docosahexaenoic acid (DHA) for infant formula products and vitamin D for follow-on formula. Information to support the use of Guidance Upper Levels is provided below.

Guidance Upper Levels

Danone supports change from the 'Guidance Requirements' to 'Guidance Upper Levels (GUL)' and the definition.

It is important that enforcement agencies understand the difference between a maximum and a GUL.

Infant Formula (Part B)

Carbohydrate sources

Danone supports the prohibition of the presence of added fructose and or/added sucrose in infant and follow-on formula except for formulas manufactured with partially hydrolysed protein. However, Danone fully supports the INC position and has some concerns regarding the incidental presence fructose and sucrose. Residual fructose at small levels may be "added" as part of the inulin-type fructans. Danone recommends that FSANZ clarify that these would not be considered as carbohydrate sources and therefore continue to be permitted to be used.

Docosahexaenoic Acid (DHA)

Danone does not support a GUL of 7mg/100kJ is for DHA.

Danone fully supports the INC submission but recommends a maximum of 12mg/100kJ which is within the range currently permitted and is reported in breast milk and aligns with the EU maximum permitted level.

Follow-on Formula (Part C)

Follow-on Formula Vitamin D Maximum

Danone does not support a maximum vitamin D level of 0.63 µg /100kJ for follow-on formula. This does not reflect the best scientific evidence available today.

Danone fully supports the INC submission and recommends that FSANZ align with the Codex and EU Vitamin D maximum of 0.72µg/100kJ for follow-on formula

The National Health and Medical Research Council (NHMRC) AI (Adequate Intake) for vitamin D is outdated and does not reflect the most up to date and best scientific evidence available today. This is why it does not align internationally, despite evidence that the incidence of vitamin D deficiency is similar to overseas markets.

Special Medical Purpose Products for infants (Part D)

Danone supports FSANZ's position on the composition of SMPPi as described in CFS2.

Danone supports the INC position on compostion of SMPPi.

The proposed draft variation promotes international harmonisation of regulations and as such, reduces a risk of a trade barrier from occurring. Most manufacturing of SMPPi occurs outside ANZ. These sites are highly specialised in manufacturing product for specific conditions and only manufacture in small quantities due to the rarity of some of the conditions.

Danone supports FSANZ's proposal in the proposed draft variation to allow the composition of SMPPi products to deviate from the specific compositional requirements for infant formula products, where required to address the product's special medical purpose. Deviations from the composition requirements would also be permitted where it would otherwise prevent the sale of a product.

SMPPi must be safe, beneficial and effective for the infants for whom they are intended, based on generally accepted scientific data. Infants cannot be restricted from accessing the most up to-date and efficacious products for their infant's specific condition and the draft variation recognises this. Danone supports FSANZ for including the same provisions on nutritive substances and novel foods as for Standard 2.9.5 on Food for Special Medical Purposes. These products are predominantly regulated under standards for FSMP in other markets.

The vast majority of Danone's SMPPi are imported from the EU where they must meet the requirements of Commission Delegated Regulation (EU) 2016/128 on the specific compositional and information requirements for FSMP[Regulation (EU) 2016/128]. This regulation requires review of the evidence and use of the product by the European Food Safety Authority (EFSA) under Article 3. Hence, a thorough assessment of the products composition and safety for its intended use has been recognised by an international regulatory body.

The permissions proposed in the draft variation recognises a continuous supply of SMPPi is critical for the provision of product for the dietary management of infants with conditions, diseases or disorders. For many conditions, the number of infants requiring a product may only be in the tens in Australia and/or New Zealand. Therefore, it is not feasible to tailor the composition of product specifically to Australian and New Zealand requirements. In some instances where an infant has a rare condition, a single product available in Australia or New Zealand may be the infant's sole source of nutrition.

In SD4, FSANZ state in response to a submitter's comment that: *FSANZ does not expect that reformulation of SMPPi will be required, therefore PBS re-registration will not be required.*

Permissions for the nutritional composition of SMPPi must be kept flexible as otherwise it will impact PBS and Pharmac registrations. For PBS specifically, any change to formulation requires a Committee Secretariat submission. It would be a costly and lengthy process to do a large number of these submissions, purely due to a regulatory change. This may impact supply of these products and could also lead to manufacturers assessing the viability of retaining supply of these products in Australia. Pharmac has a different process, but nonetheless Danone would expect a similar outcome as detailed above for PBS.

LABELLING FOR INFANT FORMULA PRODUCTS (SD3)

Safety-related labelling requirements

Danone supports most of the safety-related labelling requirements. However, Danone wishes to raise concerns regarding the proposed prescription of statements only appearing on front of pack, and in particular the restriction on the protein source statement.

Danone fully supports the INC submission and the recommendations discussed in their submission. However, Danone has specific concerns relating that restriction of statements to the front of pack, which may cause confusion. Allowing for information reference on back of pack is not promotional in nature but provides essential factual information to the consumer. Furthermore, these restrictions are not aligned with international regulations.

Danone does not support restricting reference to the protein source statement and staging information to the front of pack only. There is no scientific evidence to suggest that consumers are confused or unaware of what type of protein or staged product they are buying.

Danone recommends that these be permitted elsewhere on the packaging. Issues relating to this restriction will be discussed further in the following section.

New provision of information

Danone does not support many of FSANZ's proposed draft variation on provision of information labelling.

Danone fully supports the INC position and provides further details relating to the following areas of concern:

- prohibition in NIS on use of common terms, acronyms/abbreviations and additional information
- over prescription of statements only appearing on front of pack
- prohibitions of reference to ingredient accept in ingredients list.
- Clarification on use of "information" in relation to prohibitions.

The importance of consumers being provided with complete and accurate information on which to base their purchasing decisions is paramount, and is supported by the prohibitions against false, misleading or deceptive conduct consumer embedded in the Australian Consumer Law within the Competition and Consumer Act 2010 (the ACL).

s18 of the ACL creates a general prohibition on businesses engaging in *misleading or deceptive conduct or conduct which is likely to mislead or deceive*. This general prohibition is reinforced by specific prohibitions against false or misleading representations about goods and services which are set out in Chapter 3, Part 3-1, Division 1 of the ACL.

Effectively this means that when selling a product:

- truthful and accurate information regarding matters such as the standard, quality, composition, performance characteristics, uses or benefits of the product (ss18 (a) and (g) of the ACL) is to be provided;
- relevant information is not to be omitted; and
- false impressions are not to be created.

For products such as infant formula products, the amount, and even more so, the quality of information the caregiver will look to, is critical. Attributes such as the quality and performance characteristics of ingredients, the infant for whom the product was created or those who should not consume the product, and general suitability and the intended purpose of the product, are all key.

Prohibition in NIS on use of common terms, acronyms/abbreviations and additional information

Restrictions on the use of common terms, acronyms/abbreviations and additional information does not allow manufacturers to provide information to consumers. This restriction does not align with international labelling requirements.

Danone note that FSANZ has provided the following justification for using folate over folic acid: *caregivers are more likely to be familiar with the term 'folate' than folic acid*, without providing evidence. This means that FSANZ acknowledges that the term which is more familiar to consumers should prevail over a technical term. This also contradicts the restriction place on common terms, acronyms/abbreviations. Despite consumers having a greater understanding of these, FSANZ is not permitting them. Information directed to consumers should be understandable and have regard to the target market. Consumers cannot be expected to understand or familiarise with highly technical scientific descriptions.

The use of abbreviations and acronyms is important for the legibility of the NIS. Having regard to the overall look of the entire NIS, the use of some long nutrient names can mean that some shorter nutrient names will appear far away from the level in the NIS. Making it difficult to consider at a glance.

Danone recommends that FSANZ allow familiar and commonly used abbreviations and acronyms in the NIS. Such as those outlined INC's submission, e.g. DHA, EPA, ARA.

As raised in the novel foods and nutritive substances section of this submission, Danone again raise concerns regarding the labelling of nutritive substances on infant formula products during the assessment of the application. In order not to stifle innovation, consideration needs to be given to how to appropriately label these on infant formula products. To assess the value of making a pre-market assessment, manufacturers would need to understand the possibility of using consumer friendly and commonly used terms on the label. Danone therefore recommends that FSANZ provides clear guidance on how novel foods and nutritive substances will be labelled on infant formula products.

Over prescription of statements only appearing on front of pack

As stated in the safety-related labelling requirements section, Danone does not support restriction of terms to front of pack only.

Danone recommends that FSANZ remove the over prescription to not only allow for the following statements on front of pack:

- Protein source statement
- Lactose free or low lactose
- Partially hydrolysed protein

- Stage labelling

The prescription of the location of these statements is not consistent with international standards. The statements are not promotional in nature but, rather, provide valuable information to consumers to enable them to make informed decisions about the products.

Prohibitions of reference to ingredient except in ingredients list.

Danone does not support the restriction of reference to ingredients except in ingredients list.

Danone values its responsibility to accurately describe the product ingredients and their performance characteristics to consumers. Omitting this relevant information, or highlighting key ingredients or purposes of the product, is considered misleading.

This restriction does not align to international standards, where, including EU and Codex, restrictions are made on nutrition content and health claims only. **Danone supports** this restriction, however further restrictions on other statements such as reference to ingredients go beyond this restriction. The justification of this is unclear and has significant unintended consequences which are stated earlier in this submission.

Clarification on use of "information" in relation to prohibitions

Danone does not support the reference to "information" in 2.9.1-29(2) including all prohibitions in 2.9.1-29(1).

The CFS2 only discusses the intent to restrict "a name, a number, a picture, an image, a word words" in relation to another product.

Danone fully support the recommendation by INC that the drafting should reflect this intent and therefore 2.9.1-29(2) should clearly only relate to 2.9.1-29(1) (c).

New labelling requirements for SMPPi

Danone supports most of FSANZ's proposed draft variation on labelling for SMPPi.

Danone is aligned with the INC submission on labelling requirements for SMPPi.

Danone acknowledges that FSANZ has proposed flexible labelling requirements for SMPPi as described in CFS2.

However, there are aspects to the proposed labelling that may inadvertently create an unintended trade barrier for the import of these products. Danone does not support FSANZ's proposals for the following:

- Nutrient modifications
- Prohibited representations
- Warning statements
- Nutrition information statement

It is imperative that this does not preclude or restrict the label from providing information on the properties and characteristics that make a product suitable for a specific condition.

Nutrient modifications

Danone agrees that there is a need to provide information on the nutritional content of an SMPPi and supports a requirement for the label to include a statement describing the properties or characteristics which make the food appropriate for the medical purpose on the label.

The key issue is that the baseline composition for an infant formula product, as proposed in the draft variation, varies from other international regulations including Codex and the EU. For example, the iron level of an SMPPi may be 0.1mg/100kJ which will vary from the composition criteria in Standard 2.9.1 and Schedule 29, however, this level is within the composition criteria of credible international regulations, specifically, the EU and Codex. For this reason, iron will not be called out as a nutritional modification on the label.

Therefore, mandating the proposed provisions in the draft variation under 2.9.1-38 (g) (ii) will cause a trade barrier for importing some SMPPi. For highly specialised products, ANZ often share a label with EU countries, due to the small number of individuals who require the product. There is simply not enough supply to warrant a label tailored to the requirements of ANZ. If restrictions are put in place so that the label is non-compliant, it is likely that the product will no longer be supplied.

If there is any delay in importing these products due to questions raised by authorities, it could have a direct impact on infant health as there are some instances where one product is the sole source of nutrition for the dietary management of a condition.

Furthermore, for products such as pre-term formulas, there will be a significant number of nutrients, primarily vitamins and minerals, that vary from the compositional requirements of section 2.9.1-32. These modifications are due to the requirements of the condition and are backed by scientific evidence that supports their usage at certain levels. For example, formulations will be based on The European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPHGAN) guidelines (Embleton et al., 2022) in addition to the relevant infant formula regulation, rather than purely based on compositional criteria of standard infant formula products.

Danone recommends that FSANZ adopts flexibility in labelling for nutritional modifications of vitamins and minerals specifically. All nutrient modifications can be made available through other resources, particularly to healthcare professionals.

For products such as pre-term formulas, there will be a significant number of nutrients which vary from the compositional requirements of section 2.9.1-32. These modifications are due to the requirements of the condition and are backed by scientific evidence that supports their usage at certain levels. For example, formulations will be based on ESPHGAN guidelines in addition to the compositional criteria of infant formula products.

Prohibited representations

FSANZ has listed the prohibited representations applicable to SMPPi in 2.9.1-35 of the draft variation. Danone notes that this is a reversal of its position of CFS1, where it proposed that prohibited representations would not apply to SMPPi.

Danone supports the introduction of some restrictions on labelling for SMPPi. However, strongly recommends that the prohibited representations are aligned with international regulation, e.g. Article 8 of Regulation (EU) 2016/128 and certainly not be more restrictive. This is to prevent any unintended trade barrier for importing SMPPi products.

It is imperative that the restriction on nutrition claims and health claims does not preclude or restrict the label of an SMPPi from providing information on the properties and/or characteristics that make a product suitable for a specific condition to the disease, disorder or medical condition for the dietary management of which the product is intended. SMPPi are primarily used or discussed in a healthcare setting where the HCP can discuss the label of an SMPPi with a caregiver.

It is critical that SMPPi retain flexibility in permissions on labelling, to allow for imported products to meet relevant international regulations and prevent any potential trade barriers. Any risk to preventing or delaying import of highly specialised products only puts the infant at risk. There is no viable option to import the majority of these products, other than to share a label with other markets.

Danone does not support the inclusion of the following prohibited representation in 2.9.1-35 of the draft variation on information relating to another food.

Danone does not promote or recommend other products to caregivers and patients on the label, there are instances where it is imperative that there is a generic mention of other categories of product for safety reasons. For example, a label may include a reference that the product should only be taken in combination with a hypoallergenic product or human milk, to ensure adequate nutrition or may refer to specific sources of nutrients generically. To not include this information is a safety risk.

Warning statements

Danone reiterates the INC position on the minimum size of type for warning statements. Under Standard 1.2.1-25 it is 1.5mm but under Regulation (EC) 609/2013 it is 1.2mm. There must be flexibility for imported SMPPi to have warning statements that are compliant with EU Regulations to ensure the continued availability of highly specialised products.

It is imperative that the draft Variation under 2.9.1-38 (2) (b) does not mandate what mandatory declaration must state in relation to Standard 1.2.3. This is because of differences in what must be included in mandatory declarations between FSANZ and other major international regulatory requirements.

Nutrition information statement

Danone supports the INC recommendation on amendments to the nutrition information statement for SMPPi. As a large number of SMPPi share labels with other markets there are limitations to 2.9.1-41 of the draft variation.

The drafting for the nutrition information statement for SMPPi must align with relevant major international regulations, particularly Codex and the Regulation (EU) 2016/128 so as to not create an unintended trade barrier.

FSANZ ACT ASSESSMENT REQUIREMENTS (Section 10 CFS2 and SD4)

Section Summary

Danone has the strong view that the impact of the proposal on its own operations in ANZ and those of other infant formula manufacturers will be substantial. As seen in other markets, the proposed changes will cause loss of domestic and export revenue for the entire industry, which can potentially cause the industry to scale down and/or exit operations in ANZ.

The following sections detail why Danone:

- **Disagrees** that some of the proposed variations to Standard 2.9.1 are improvements to the interpretation and enforceability of the infant formula product standard.
- **Disagrees** with some of the proposed variations to Standard 2.9.1 on the basis that they will lead to unintended and irreversible adverse consequences for consumers, industry, and government.
- **Disagrees** with the cost and benefits analysis conclusion reached by FSANZ.
- **Disagrees** that FSANZ has met its obligations under section 59(2) of the FSANZ Act 1991 when assessing the proposal and, in that regard, Danone has provided additional information that FSANZ must consider for it to fulfil its section 59(2) FSANZ Act 1991 obligations.
- **Recommends** a reassessment of the proposal by FSANZ to include consideration of matters highlighted in this response.

Danone believes that unless the proposal is amended, the following will result:

- less players in the industry, which would substantially lessen competition and adversely reduce the essence of choice of product, which is currently available to consumers.
- direct job losses for industry employees and employees of business providing goods and services to the industry in ANZ, including dairy farmers.
- loss of industry investment and industry driven opportunities for businesses, graduates, and communities in ANZ.
- loss of income tax and GST revenue for the government from this primary industry.
- loss of or impairment of intellectual property including secret recipes, trademarks, patents, brands, technologies, and innovations that could have continued to enable ANZ to compete globally by leveraging the competitive advantage that this type of property provides.
- loss of discretionary investment by industry into social and environmental initiatives in ANZ.
- loss of access to the most up to date science leveraging global and local research and development initiatives and talent that could have been applied to infant formula products, but also to the wider infant formula manufacturing and dairying industry of ANZ.

The list above is not exhaustive. Further detail is provided in that sections that follow.

Assessment of the proposal under the FSANZ Act

Danone does not agree with FSANZ's assessment that the costs it has identified, that would arise from these proposed amendments, will not outweigh the direct or indirect benefits of those proposed amendments.

Danone provides additional information and other relevant matters that FSANZ must consider to enable it to assess the proposal as required by section 59(2) of the FSANZ Act 1991.

Development of a Decision RIS

Danone recommends that FSANZ incorporate the matters covered here in the preparation of a Decision Regulation Impact Statement (DRIS).

Danone recommends the careful consideration of potentially irreversible and unintended consequences that would arise if the proposed amendments are not considered alongside the information and submission detailed in the SD4 Response.

While Danone does not agree with the unintended consequences that arise from the current standard as highlighted in the SD4 Response, it views that the current standard for infant formula products are, overall, functioning adequately. The proposal will result in further unintended consequences which should be highlighted in the DRIS.

Balancing Regulation and Innovation

Danone agrees with FSANZ's statement at paragraph 1.1 of the 2nd Call for Submissions –Proposal P1028, that: *Infant formula products are specifically regulated through Standard 2.9.1 and Schedule 29 of the Australia New Zealand Food Standards Code (the Code) and have the most prescriptive requirements of any food category in the Code. Other standards in the Code also contain provisions for infant formula products, such as those relating to definitions, food additives, contaminants, labelling, novel foods and microbiological limits*.

However, FSANZ must ensure that the correct balance is struck between regulation and innovation. FSANZ should be well aware of this requirement after commissioning a report which considered innovation in manufactured food and infant formula sectors (Kollmann et. Al, 2021). The Kollmann report highlighted the need for: strict regulatory regimes are an important protectant of consumers, however they acknowledge that regimes should not be: o*verly restrictive such that it limits the innovation of safe and suitable ideas. We consider infant formula to demonstrate the tension between regulation and innovation*. Danone recommends that FSANZ should consider this balance when reassessing the proposal.

Innovation is defined as: *the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations* (OECD, 2055). Innovation is imperative for ensuring companies success in creating and maintaining market share. Companies must innovation to maintain competitiveness. To remain competitive: in the international infant formula market ANZ must foster an innovative industry (Kollmann et al., 2021).

"Breast is Best", but if not possible, "Fed is Best"

Danone does not agree that with FSANZ's heading in SD4 that: *population health benefits from promoting breast milk, rather than substitutes*. Breast milk and infant formula products are needed to serve the needs of different categories of infants. The heading implies that no population health benefits will result in substitutes. This is not correct and inconsistent with FSANZ's own stated views.

Paragraph 1.1 of the 2nd Call for Submissions – Proposal P1028, FSANZ states that: *[a]lthough breastfeeding is the recommended way to feed infants, a safe and nutritious substitute for breast milk is needed for infants who are not breastfed. Infant formula products are the only safe and suitable alternative to breast milk*.

Danone acknowledges that the WHO Code recommends various requirements and restrictions for the marketing and distribution of breast milk substitutes for industry and health care workers. This includes restrictions on infant formula being advertised or otherwise promoted to the public, and that health care providers should not be given free or subsidised supplies of these products and must not promote these products

Danone and other industry counterparts already comply with the requirements of the WHO Code. Danone shares the WHO's view on the importance of infant nutrition and the goal to improve it at scale. However, Danone does not discriminate between the needs of infants who are breastfed or infants who are fed infant formula products.

Danone agrees that 'breast is best,' when breastfeeding is possible. But when this is not possible, Danone reverts to its belief that 'fed is best'. Danone wants to ensure that infants are fed and submits that not all infants have access to breast milk.

After breast milk, Danone prefers that infants are fed infant formula products that are produced with ingredients and techniques that incorporate the most up to date scientific innovations. Danone's unwavering view is that continued innovation in infant formula products is needed so that the substitute produced is as close to breast milk as possible.

Danone and other industry counterparts also adhere to the marketing requirements of the MAIF Agreement, the INCCoP in NZ, and the Danone Policy for Marketing of Breast-Milk Substitutes. Under these, Danone does not promote and advertise infant formula products.

Danone acknowledges the view that marketing is restricted in order to encourage breastfeeding as much as possible. However, FSANZ must acknowledge that the marketing of infant formula products is not the sole or main cause of prevention or cessation of breastfeeding.

Research in Australia commissioned by Danone and conducted by Ipsos in August 2019 show that mothers have multiple reasons to start, stop, and/or not start breastfeeding being reasons which are not scientifically linked to the marketing of infant formula. In particular:

The top 5 reasons to start breastfeeding were[1]:

- breast milk is better for my child's immunity
- breast milk is more nutritious for my child
- emotional connection I create with my baby

[1] Ipsos, Consumer Journey, N=548, those who have breastfed (ever). August 2019 research commissioned by Danone in AU.

- breast milk is more natural and therefore better
- formula is too expensive

The top 5 reasons to stop breastfeeding were[2]:

- my breast milk supply dwindled already
- baby did not seem fully fed/satiated
- I went back to work
- I didn't want to do it anymore
- I moved my baby to cow's milk

The top 5 barriers to start breastfeeding were[3]:

- it was painful
- I did not have enough milk supply
- I had health concerns that prevented me from breastfeeding
- my baby had a hard time sucking my breasts
- I am uncomfortable with the idea of breastfeeding

The above results show that the matters that drive breastfeeding were for either physiological/physical (mother or infant), psychological, and/or socioeconomic reasons. Women and infants unable to breastfeed and be breastfed should not be disadvantaged because they choose infant formula products.

As an aside, it is important to note that the median age of women giving birth is around 30 to 31 years old. See below.[4]

2 Ipsos, Consumer Journey, N=275, those who stopped breastfeeding. August 2019 research commissioned by Danone in AU.

[3] Ipsos, Consumer Journey, N=55, those who never breastfed (ever), August 2019 research commissioned by Danone in AU.

[4] Retrieved from: health-and-independence-report-2021-nov22.docx (live.com)

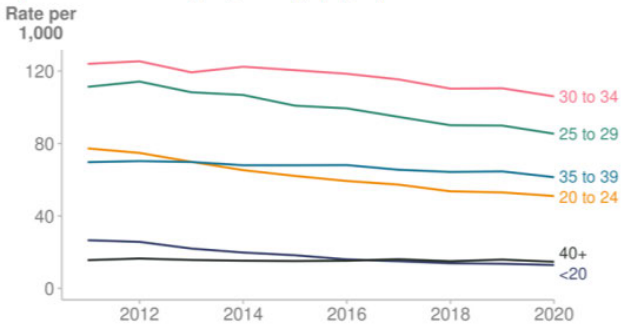
Changing demographics

In 2021, the median age of New Zealand women giving birth was 31.0 years. The median age has remained at around 30 years of age since 1999 (Stats NZ 2022a). This compares to around 25 years in the 1970s.

Over half (58%) of births in 2021 were to mothers aged 30 years or older, up from 48% in 2000.

Age-specific fertility (or birth) rates measure the number of live births that 1,000 women in a particular age group have in a given period (usually a year). Over the past 10 years (2020 compared with 2011), birth rates have dropped for every age group of women, except for those over 40 (Stats NZ 2022a, Figure 1).

Figure 1: Rate of women giving birth, by age group, 2011–2020



Source: Ministry of Health (2022o)

Birth rates remain higher for Māori and Pacific peoples than the Asian and European/other ethnic groups (Ministry of Health 2022o). However, there has been a steeper decline in birth rates for Māori and Pacific peoples over the past 10 years, which means that the gap in birth rates between ethnic groups is starting to close.

Source: Ministry of Health (2022)

If these women choose to have children, as well as return to work or study, then as part of their transition back to work or study, it is likely that some of these women will choose infant formula products to supplement their breast milk. The Growing Up in New Zealand Study found that only 30 percent of parents were still on leave when their baby was nine months old; returning to work or study was the main reason for the children being looked after by someone other than their parents (Key Findings, Growing Up in New Zealand). At nine months an infant requires a principal liquid source of nourishment as part of a progressively diversified diet. Women and their infants should not be disadvantaged if they opt to include infant formula products in their infant's diet.

The youngest median age for mothers was 30.4 and 30.6 years in the Northern Territory and Tasmania respectively (ABS, 2022a).

Median age of parents

The oldest median ages for mothers and fathers were in:

- the Australian Capital Territory (32.6 years for mothers and 34.4 years for fathers)
- Victoria (32.4 years for mothers and 34.2 years for fathers).

The youngest median age for mothers was in:

- the Northern Territory (30.4 years)
- Tasmania (30.6 years).

The youngest median age for fathers was in:

- Tasmania (32.4 years)
- Queensland (32.8 years).

The information above relates to caregivers who are mothers, but it is also important to note that there are diverse feeding practices which apply. These include families where the birth mother may not be responsible for infant care and feeding, including, but not limited to, intergenerational families, adoptive families, surrogate families, LGBTQIA+ families, and/or temporary caregivers. These situations recognise that the feeding responsibility may not necessarily fall on the birth mother and that in some instances, shared feeding occurs. All caregivers and infants should not be disadvantaged because they use and are fed infant formula products respectively.

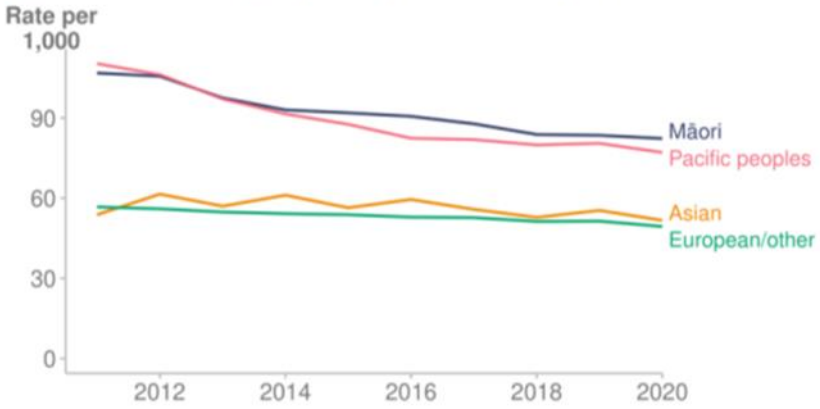
In NZ, it is important to note the ethnic groups that have given birth. Māori, Pacific, and Asian ethnic groups historically and traditionally share child rearing responsibilities. The homes in which these infants live are often multi-generational and it is common for the caregiver to be someone other than the birth mother at any given time. See below:[5]

[5] Sourced from: health-and-independence-report-2021-nov22.docx (live.com)

Figure 2 shows the change in rates of women giving birth by ethnic group between 2011 and 2020. It sets out the following decreases over that time:

- Māori: 106.8 births per 1,000 women in 2011, compared with 82.3 births per 1,000 in 2020
- Pacific peoples: 110.3 births per 1,000 women in 2011, compared with 77.1 per 1,000 in 2020
- Asian people: 53.8 births per 1,000 women in 2011, compared with 51.7 per 1,000 in 2020
- European/other people: 56.7 births per 1,000 women in 2011, compared with 49.4 per 1,000 in 2020.

Figure 2: Rate of women giving birth, by prioritised ethnic group, 2011–2020



Source: Ministry of Health (2022o)

Source: Ministry of Health (2022)

For the above reasons, caregivers may choose combination feeding or infant products alone.

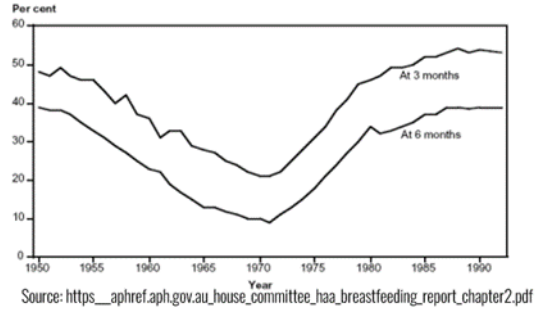
Research in Australia commissioned by Danone and conducted by Ipsos in August 2019 also indicate that caregivers use both breast milk and infant formula for the following top 5 reasons[6]:

- I didn't have enough breast milk
- Breast milk alone did not satisfy my baby
- To enable other people than the baby's mother to share in feeding process i.e., give a bottle
- I was/I am sometimes unable to breastfeed
- I combined the benefits of both breast milk and infant formula

Breastfeeding rates have remained consistent since the establishment of the MAIF Agreement. Data published by the Australian Bureau of Statistics and House of Representatives Standing Committee on the Health and Ageing show the number of exclusively breastfed infants at 6 months has remained steady since the early 1990s, when the Agreement was first implemented, until the last reported data in 2021 (ABS, 2022b).

[6] Ipsos, Consumer Journey, N=217, those who used both breast milk and infant formula, August 2019 research commissioned by Danone in AU.

Mothers fully breastfeeding at three and six months, Victoria, 1950-1992



Source: https__aphref.aph.gov.au_house_committee_haa_breastfeeding_report_chapter2.pdf

Source: ABS (2022b)

Breastfeeding in Australia Statistics 2020 – 21

- Most (95.9%) children aged 0-3 years received breast milk
- One in three (35.4%) were exclusively breastfed to 6 months

Findings based on research commissioned by the Infant Nutrition Council, ANZ with Pragmatic Research & Advisory indicate that only 6% of parents thought that marketing formulated supplementary foods for young children (FSFYC) might discourage breastfeeding.

This research also showed that 76% of parents need all the information about options for feeding readily available to them so they can make decisions about what is best for their child. This highlights the need to provide information about products readily available, like on the label, to ensure caregivers to make decisions on what to feed their child (Pragmatic Research & Advisory, 2022)

Assessing the Proposal

FSANZ must consider the following to ensure that it meets its obligations under section 59(2) of the FSANZ Act 1991:

- Section 59(2)(a) requires a consideration of costs and benefits.
- Section 59(2)(d) requires a consideration of any other relevant matters, which includes, but is not limited to, the requirements of sections 9(1)(b)(i), 9(1)(b)(ii), 18 of the FSANZ Act 1991, and section 397(2) of the Food Act 2014 (NZ).

Costs and Benefits

Section 59(2)(a) of the FSANZ Act 1991 imposes an obligation that FSANZ must ensure that the appropriate benefits are weighed against all relevant costs when considering whether the proposal results in a net benefit. Danone submits that:

a. Neither costs nor benefits are defined in the FSANZ Act 1991 so, as proper statutory interpretation requires, words have to be understood in context of the entire statute. Having regard to section 9(1)(b), which sets out that the operation of the Act is to ensure that trade and commerce by corporations is efficient and profitable, it can be concluded that 'costs' in section 59(2)(a) encompasses the costs and losses incurred by those corporations, including loss of profits.
b. There is no wording of limitation attached to the word 'costs' so, having regard to the preceding paragraph, it includes all types and forms of costs, which can be in the form of losses, including direct loss of sales, re-labelling costs, loss of profits, loss of opportunity and loss of market share. In addition, any undesired effect or consequent of reforms would be considered a 'cost'.

c. The concept of 'efficiency' in section 9(1)(b) connotes that any changes or reforms should be achieved with minimal expense or loss. This suggests that, not only do the benefits have to outweigh the costs (which includes broad losses) but, in addition, the benefits have to justify the costs (which includes broad losses). This means that, even if the benefits do outweigh the costs, the expenditure of those costs must still be justified, having regard to its impact on the corporation's efficiency and profitability.

Danone acknowledges that FSANZ has attempted to highlight in Table 5-1 the main groups likely to be affected by the proposed regulation and the main potential impacts on these groups. However, due to information gaps, FSANZ has not highlighted all the appropriate direct and indirect costs and benefits in its analysis. Danone provides commentary and additional information that FSANZ should regard in assessing the proposal pursuant to section 59(2)(a) FSANZ Act 1991 requirements in the sections below.

It is important to note that Danone's view is based on the following:

- Danone ANZ is part of a multi-national company that supplies infant formula products all over the world.
- Danone heavily invests in research and development to continuously improve its offerings.
- Danone has experience in navigating food standards and regulatory requirements across multiple jurisdictions.
- Danone in NZ manufactures for both the domestic (ANZ) and export markets.
- Danone ANZ make and sell products that meet ANZ consumer, government, legal and regulatory requirements.
- Danone ANZ is also required to meet consumer, government, legal and regulatory requirements for each of its export markets.
- Danone NZ supply point is one of many supply points in the Danone supply network.
- Danone European supply points are in direct competition with Danone NZ supply point in export markets.

It is also important to note that ANZ industry is currently positioned to take advantage of major importing markets, especially China, Vietnam and South Korea (Kollmann, et al., 2021). This only remains true if there are no technical barriers that would prevent market access. **Danone recommends** that FSANZ take into account the loss of opportunity that would occur if ANZ industry is faced with technical barriers due to its proposal.

Table 5 1 Major potential impacts by social group

Social group	Potential Impact	Notes on potential impact	Danone comments based on proposed changes to the Standard under P1028
Infant formula consumers	Benefits	Health improvements due to higher quality formula that better meets infants' development needs	Danone agrees that higher quality formula is desirable. However, there are unintended adverse consequences detailed in the sections below that may lead to less innovation in ANZ infant formula products resulting in lesser quality formula in ANZ in comparison to

			formula accessible and available in other countries. Industry should be supported in continued innovation to help to close *the health and development gaps between breastfed and infant formula-fed infants* (Kollmann, et al. 2021).
		Long term potentially lower cost formula	Danone agrees that industry players may use price competition to differentiate its products if they are unable to differentiate their products in other ways e.g. functional aspects on labels. Danone disagrees that this may apply in the long term. The proposed changes may lead to the commoditisation of infant formula products when industry loses the incentive to innovate and differentiate. This sentiment is echoed by Kollmann et al (2021) who states: *without keeping abreast of the international frontier for product quality, we will become known for belonging to the cheap, low-quality end of the market*. Without the ability to differentiate, industry players are likely to resort to price competition. This may lead to short term decreases in price if industry chooses to absorb the increased costs of change in return for market share gains or retention. Over time, this commoditisation may lead to increases in price in the long term, as industry adjusts to each other's pricing strategies. This might lead to incidents of anti-competitive behaviour such as price gouging or cartel conduct, such as observed in other commoditised trade, such as petrol.

		Improved ability to compare and choose products	Danone does not agree that the proposal will enable improved comparison. The proposal contains labelling constraints that will reduce the information available on pack and will make it more difficult for consumers to understand the differences between formulas e.g. removal of well understood commonly used terms, such as, probiotics and DHA; conversion of layman's terms to their scientific equivalent; removal of signifiers of quality and content currently permitted, such as, 'made with New Zealand/ Australian milk'. This could prove misleading to some consumers who may not be able to make an informed decision of purchase. Existing constraints in shelf space in pharmacy channels will mean that most pharmacies will not have the capacity to stock all products e.g. SMPPi for gastrointestinal conditions and feeding problems. This will reduce consumers ability to compare products.
		Better advice at point of sale for specialised products which could result in both improved health outcomes and unnecessary costs being avoided if advised specialised formula is not desirable or needed	Danone agrees that if caregivers can access advice from HCPs at the point of sale of specialised products, then this would assist in improving health outcomes and avoiding unnecessary costs if the specialised formula is not desirable or needed. However, Danone disagrees with the assumption that better advice would be available at the point of sale for specialised products. From discussions with FSANZ, it is clear that there has not been extensive consultation with the pharmacy channel. A move to the pharmacy channel for these products will result in some caregivers not having access to

			these products if they are in remote or rural areas. In some pharmacies, staff at the point of sale are not necessarily HCPs. In bigger pharmacy chains, consumers have little engagement with pharmacists and are likely to speak, if at all, to retail or floor staff. Further details on the challenges to SMPPi channel changes have been discussed in previous sections and more comment is provided below.
		Clearer instructions on product labels leading to reduced risk	Danone agrees that this is a benefit.
			Danone does not agree that the above captures all the benefits. Another benefit for consumers is that if it is unable to source products locally which do not meet their requirements e.g. due to functional aspects unavailable in domestically available formulas, then they may turn to international sources of these products. They are likely to do so using online channels which increases the convenience and provides greater accessibility. Danone notes that this will potentially circumvent FSANZ's stated benefit that the consumer will get better advice at point of sale if there is no opportunity on the online channel to get advice. This could lead to poorer health outcomes and unnecessary costs for consumers. Danone notes that FSANZ mentioned the use of online disclaimers at point of order and at point of sale could be used to mitigate this gap. However, the majority of consumers do not necessarily read these disclaimers and 'click through' to purchase the product if they determine that it meets their needs. In an online channel, this does not necessarily come with the

			specialised advice desired by FSANZ in its proposal.
	Costs	Restricted sales of specialised formula may cause some inconvenience	Danone does not agree with this statement. Restricted sales may result in loss of availability and accessibility to specialised formula. The pharmacy channel is unlike the grocery channel. It does not have the same logistics and warehousing support that grocery channels have since the latter is well set up and experienced in dealing with the needs of consumers requiring Fast Moving Consumer Goods (FMCGs). The shelf space in the grocery chain allows for more products and more competition. This provides better choice and availability for consumers because there is more stock and more variants for a specific condition, to choose from. However, a move away from the grocery channel will mean less availability, less choice, likely higher prices and less access. These unintended consequences have not been captured by FSANZ in its impact analysis.
		Short term price increases are possible	Danone agrees that it is possible that the extensive changes that are required by the proposal will lead to increased costs for industry that may lead to an increase in prices. However, Danone disagrees that this may be in the short term. The proposed changes may lead to the commoditisation of infant formula products when industry loses the incentive to innovate and differentiate. Without the ability to differentiate, industry players are likely to resort to price competition. This may lead to decreases in price in the short term if industry chooses to absorb the

			increased costs of change in return for market share gains or retention. Over time, this commoditisation may lead to increases in price in the long term, as industry adjusts to each other's pricing strategies. This might lead to incidents of anti-competitive behaviour such as price gouging or cartel conduct, such as observed in other commoditised trade such as petrol.
			Danone does not agree that these are all the costs that will arise for infant formula consumers.
Infant formula industry: Base powder manufacturers	Benefits	Improved harmonisation increasing cost efficiencies of manufacturing	Danone agree that if improved harmonisation was the outcome of the proposal, then this would increase the cost efficiencies of manufacturing. The current standard already prevents the ability to harmonise due to deviations from composition requirements acceptable in other geographies. For example, HMOs are accepted and used in infant formula and follow-on formula in international markets, and they are added into infant formula products where industry is able to communicate that its products contain HMOs using this commonly used term. ANZ is out of step with this permission. Danone does not agree that the proposal leads to increased harmonisation for all inputs into base powders. For example, changes to aluminium levels in soy-based formula proposed are out of step with international standards. This change creates a technical barrier that means that it would be impossible for industry to meet this proposed tighter requirement due to the natural variation of aluminium levels in soy ingredients.

			Imposing this specification requirement on soy ingredients suppliers means that it can neither meet the specification or if it is able to meet the specification, this will come at a greater cost for ANZ industry because it is a deviation from normal specifications accepted by other international infant formula manufacturers. It is also important to note that if finished goods competition in domestic and export markets decline due to the proposal, consequently, less finished goods will be manufactured. Less base powder will be needed. Less input products and services associated with base powder production will be needed. The reduction of input products will lead to decrease in volumes needed. Where the reduction in volumes mean that minimum order quantities of input products are not met, base powder manufacturers may no longer have access to these products or may have to pay a premium for continued supply. This increases the costs of goods. Increases in prices may be passed on to the finished goods, which may then be passed on to consumers. Finished goods manufacturers may see a reduction in revenue which could lead to reduced demands for base powder manufacturers. With reduced demand to be balanced against increasing costs, base powder manufacturers will be faced with the challenging of finding efficiencies which could ultimately lead to job losses to fund costs savings. Those who cannot adjust to these pressures may cease to operate locally by moving its operations offshore where it has that option or cease operations entirely.

			Ultimately, this leads finished goods manufacturers with a new problem of having to source base powder from other manufacturers.
	Costs	Reformulation costs	Danone agrees that reformulation costs will apply but disagrees with the magnitude of these costs in the sections below.
		Potential additional manufacturing cost to reduce contaminants	Commentary above on improved harmonisation equally applies to this section.
			Danone does not agree that these are all the costs that will arise for base powder manufacturers. These are further detailed in the sections below.
Infant formula industry: Finished product manufacturers	Benefits	Improved cost efficiencies due to greater international harmonisation, improved regulatory certainty	Danone disagrees that cost efficiencies will result for the same reason that cost efficiencies will not result for base powder manufacturers. The same arguments apply here. Danone disagrees that greater international harmonisation will be achieved by the proposal as noted in the soy-based formula example provided earlier. In addition, there would be no cost efficiencies if the proposal leads to the relocation, exit or downsizing of finished goods manufacturers operations locally.
	Costs	Reformulation costs, relabelling costs	Danone agrees that there will be reformulation and relabelling costs but disagrees with the magnitude of these costs in the sections below.
			Danone does not agree that these are all the costs that will arise for finished product manufacturers. These are further detailed in the sections below.
General retailers (supermarkets)	Benefits	Potential lower cost of goods	Danone agrees with this benefit.

	Costs	Loss of sales for specialised formula	Danone agrees with this cost.
			Danone does not agree that these are all the costs that will arise for general retailers. Retailers may experience further losses in revenue if it is unable to offer the current range of infant formula products currently permitted under the existing standard. Loss of SKUs on shelf may drive consumers to source products online. Once online, consumers may choose to purchase products from international retailers rather than local retailers, leading to loss in revenue for the latter.
Other retail (pharmacists, etc)	Benefits	Increased sales (specialised formula), lower cost of goods	Danone agrees that other retail will benefit from increased sales with the shift in channel away from the grocery channel. Danone does not agree that there will be a lower cost of goods for other retail if they are being supplied by industry. It is unclear why FSANZ believes that lower costs of goods would result as a benefit for other retail.
			Danone does not agree that there are no costs for other retail. If specialised formula sales are driven to this channel, then the channel will need to adjust its business model or increase investment to adjust to increased demand. Channel changes that may be required include logistics and warehousing that have not been needed before. If this channel is unable to fulfil this demand, this may drive consumers to source products online. Once online, consumers may choose to purchase products from international retailers rather than local retailers, leading to loss in revenue for the latter. Alternatively, other retail may opt to create or grow its online presence to

			compensate. This is another added cost.
Government	Benefits	Improved ability to enforce Standard, savings in health care expenses	Danone does not agree that Governments will have an improved ability to enforce the Standard because there will still be continued diversity in enforcement regimes and approaches. Danone does not agree that there will be savings in health care expenses due to: ○ Savings in health care expenses require Government to first address systemic issues in the healthcare system that impact access, availability, and affordability for caregivers. ○ Loss of GST and income tax from domestic and export sales revenue for the Government to apply to its portfolio of work which include health and wellbeing initiatives. ○ Delayed economic recovery for ANZ post-covid if the export market for dairy products further shrink due to the infant formula market shrinking. ○ Reduction in innovation leading to little or no further improvement in infant formula product available domestically. ○ Reduction in competition in industry reducing the choice available for consumers and lack of access to products that meet tailored needs. ○ Potential shifts on to online retail channels, where caregivers may not gain the benefit of specialised advice. ○ Job losses for industry and its supply chain negatively impact socio-economic wellbeing of

			individuals leading to reduction in incomes and poorer quality of life. ○ Reduction in social and environmental programmes driven by industry disadvantages communities and the individuals in it as their access to socially beneficial programmes reduce/disappear and measures to improve the environment around them receive less funding and know-how. ○ Increased strain on dairy farmers as earnings reduce and shifts are forced upon them due to possible herd changes (e.g. inability to differentiate A2 milk on label). Note that it takes 3 milk seasons to convert A1 dairy herds to A2 dairy herds. A2 milk supply commands a premium. Conversion back to A1 milk will mean increased cost and loss of revenue for dairy farmers. ○ Lack of easy-to-understand information on label driving poor consumer choice.
	Costs	Adapting to new Standard	Danone agrees that there will be a cost to Government adapting to the new Standard.
			Danone does not agree that this will be all the costs to Government. In the sections above and below, Danone details the value of the infant formula industry trade to Government. The infant formula industry brings in sizeable revenue into ANZ, largely from export markets. ANZ has been able to 'punch above its weight' in recent times due to its ability to quickly mobilise to respond to global needs. In the infant formula products space, ANZ was able to step in to supply products to China off the back of the

			2008 melamine scandal. ANZ industry gained a reputation of consistently being able to supply high quality infant formula to the China market that eventually spread throughout the Asia region. This led to phenomenal gains for ANZ industry, but also to ANZ dairy. More recently, ANZ industry was only a few global players allowed in by the US FDA to assist during the Abbott infant formula crisis. If industry were not efficient and able to continue to produce high quality products, then it would not have been able to take advantage of this opportunity. Undoubtedly, this resulted in diplomatic gains for the Government. NZ MPI recognises dairy as a primary industry and looks to its continued ability to drive NZ out of the economic challenges post-covid and NZ's technical recession. This is of the back of continued expected performance in our export markets. The labelling and composition constraints proposed will reduce the ability for industry to differentiate its products. Without the ability to differentiate its products, the incentive to innovate disappears. For industry, the reduction in ability to gain a return on investment on current and proposed research and development activities will mean that these activities will be dramatically scaled down. There is a loss in opportunity domestically and globally because if there is a lack of incentive and investment to continue to improve, the lesser the potential number of scientific discoveries that will be made. This is not only a loss to the industry, but to the consumers who could have benefited from these discoveries.

			The products that will be available for caregivers and infants will no longer be able to take the benefit of the most recent scientific discoveries. These can lead to poorer health outcomes for infants and caregiver as they do not have access to improved products available to their overseas peers. For Government, the regulatory technical barriers create a reputation that local conditions for infant formula product research and development have ceased to exist. This will drive investment by innovative firms in ANZ to other offshore locations because the conditions for trade and innovation are not optimised, let alone, efficient. The conditions that the proposal will create will negatively impact or remove the ability of Government to continue to receive the benefit of the following if the industry ceases to be efficient, competitive, and profitable: ○ economic gains (income taxes and GST), ○ social gains (B Corp organisations in NZ such as Danone[7]), ○ environmental gains (Danone biomass boiler[8] and Danone/ Synlait/ AgResearch regenerative soil health project[9]) ○ export revenue ○ strong dairy sector ○ strong R&D sector

[7] See: Danone Oceania joins B Corp (dairyreporter.com)
[8] See: Plant's biomass boiler beginning operation | Otago Daily Times Online News (odt.co.nz)
[9] See: Danone teams up to enhance soil health in New Zealand - Dairy Global

Other Relevant Matters

Danone submits that FSANZ should consider amend the proposal in response to the submissions made by Danone on the following 'other relevant matters' under section 59(2) of the FSANZ Act.

Other Relevant Matters	Danone comments
Sections 9(1)(b)(i) and 9(1)(b)(ii) of the FSANZ Act 1991	Danone submits that the labelling requirements in the proposal result in further technical barriers to trade and commerce in domestic and export markets (section 9(1)(b)(i-ii) FSANZ Act 1991). e.g. In NZ, if unable to meet FSANZ Code, then unless exemptions are granted through parliamentary gazetting of each variation, then we cannot add information to labels that are allowed to appear on labels if imported from countries other than NZ. In contrast, Australia is still able to export product that meet importing country requirements without seeking exemptions. Industry there does not have to seek exemptions if it seeks to deviate from the FSANZ Code. However, ANZ's biggest market, China, requires compliance with local regulations, effectively forcing compliance with FSANZ Code. e.g. China Cross Border Ecommerce channel.
Section 18(1) of the FSANZ Act 1991 sections:	
(a) the protection of public health and safety; and	Danone submits that the labelling requirements in the proposal do not further protect public health and safety (section 18(1)(a) FSANZ Act 1991), but on the contrary, impairs it if industry chooses to stop innovating due to a lack of return on investment because it is unable to communicate its innovations to the public. It is commonly acknowledged that: i*nnovation can influence export performance through various channels*, one of which: *being closer to what the foreign customers demand* (Kollman et al., 2021). If industry deletes infant formula product SKUs because they will no longer be compliant or profitable to produce, then this reduces choice for consumers. If industry cannot hold on to its R&D talent due to these constraints, then there are opportunities lost to retain their potential contributions for ANZ industry, which means that innovative products won't be produced or available locally for consumers. At worst, industry may be forced to exit the ANZ market because it is no longer commercially viable.
(b) the provision of adequate information relating to food to enable consumers to make informed choices; and	Danone submits that the labelling requirements in the proposal will impair the provision of adequate information relating to infant formula products to enable to caregivers to make informed choices (section 3 (c) and 18(1)(b) of the FSANZ Act 1991). e.g., no longer able to use commonly understood acronyms such as DHA; no longer able to reference ingredients such as probiotics, A2 milk, or made from milk from NZ
(c) the prevention of misleading or deceptive conduct.	Danone submits that the labelling requirements in the proposal may actually lead to misleading or deceptive conduct and/or a decrease in the promotion of fair trading in food (section 18(1)(c) and section 18(2)(d) FSANZ Act 1991).

	Forcing the use of scientific nomenclature to describe LAM in the ingredient list only will be confusing for consumers who may use search engines to find inaccurate information if industry is unable to communicate on this. Statements about LAM without being able to state the level of cfu that make them effective may mean that some industry participants may add a sprinkle of these microorganisms and reference them in the ingredient list of formula without disclaiming that a certain minimum amount of cfu are required to make them effective.

Other Relevant Matters	Danone comments
Section 18(2) FSANZ Act sections:	
(a) the need for standards to be based on risk analysis using the best available scientific evidence;	Danone submits that labelling requirements in the proposal mean that the latest science may not be available in the ANZ market as regulations create conditions that impair trade. Innovations that have been devised to achieve the normal growth and development of exclusively breastfed infants may not be available to ANZ infants if the market participant who has proprietary rights in the innovation chooses to exit the ANZ market. Continuous research and innovation are costly and requires a path to a return on investment. If the latter is severely impaired in the ANZ market, then the incentive to invest in R&D activities evaporate.
(b) the promotion of consistency between domestic and international food standards;	Danone submits that the labelling requirements in the proposal are inconsistent with claim restrictions that apply in other international standards, despite the fact that there are no grounds upon which ANZ should depart from aligning with these standards. departure from aligning with these international standards (section 18(2)(b) FSANZ Act 1991). For example, the addition of ingredient statement restrictions when international standards only prohibit nutrient and health claims, including: Codex STAN CXS 72-1981 which only restricts nutrition and health claims for foods for infants except where specifically provided for in relevant codex standards or national legislation; WHO Code WHA58.32 resolutions adopted subsequent to the WHO code also only references restrictions on nutrition and health claims for breastmilk substitutes, unless national/ regional legislation allows. If ingredient-based claims were an issue, then this restriction would be explicitly included in Codex and the WHO code which it is not; and EU 2016/127 restricts nutrition and health claims on infant formula but allows them on follow-on formula.
(c) the desirability of an efficient and internationally competitive food industry;	Danone submits that the labelling requirements in the proposal negatively impact the ability to have an efficient and internationally competitive infant formula product industry, resulting in reduction in opportunities and/or increased costs of operations for industry, an inability to inform consumers of innovations in infant formula products which disincentivises investment in R&D, and deprives consumers the ability to access infant formula product which benefits from innovation that will continue to be available outside ANZ (section 18(2)(c) FSANZ Act 1991).
(d) the promotion of fair trading in food;	Danone submits that the labelling requirements in the proposal may actually lead to misleading or deceptive conduct and/or a decreased in the promotion of fair trading in food (section 18(1)(c) and section 18(2)(d) FSANZ Act 1991). For example, if a2 Milk Company can be the only one that can reference A2 because it is in its trademark/ brand name, then the proposed changes would confer an unfair advantage to a2 Milk Company. As mentioned above, forcing the use of scientific nomenclature to describe LAMs in the ingredient list only will be confusing for consumers who may use search engines to

	find inaccurate information if industry is unable to communicate on this. Statements about LAM without being able to state level of cfus that make them effective may mean that some industry participants may add a 'sprinkle' of these microorganisms and make a statement that they are in the formula without disclaiming that acertain minimum amount of cfus are required to make them effective
(e) any written policy guidelines formulated by the Forum on Food Regulation for the purposes of this paragraph and notified to the Authority.	Danone supports that P1028 CFS2 meets Policy Guideline for the Regulation of Infant Formula Products [The Policy Guideline] apart from in the following instances: Restriction on sale • Danone is not aware of any evidence that the restriction on sale is for the protection of public health and safety. There is no known miss use of these products and the full extent on the implication of the proposal to restrict access and availability of products has not been quantified. • Furthermore, Danone asks FSANZ to conduct a risk analysis on the change to accessibility and availability on the restriction of sale of SMPPi, to ensure products are remain accessible and available to formula-fed infants diagnosed with specific conditions. Labelling • The proposal limits the objective to provide adequate information relating to the food to enable consumers to make informed choices o It is vital that labelling requirements in the regulation allow all infant formula products including infant formula, follow-on formula and SMPPi allow for sufficient provision of information to ensure consumers – which in this case are also caregivers – to make an informed choice. • The proposal limits the consistency between domestic and international food standards by further restricting the ability of products manufactured in ANZ to provide information to consumers. • This, in itself, lessens the desirability of an efficient and internationally competitive food industry. Composition and Food Technology • Danone is supportive of more consistency in composition and food technology between domestic and international food standards and is appreciative of FSANZ's work on this. • However, for contaminants, FSANZ should take note of the update scientific evidence and reference to JECFA in its risk analysis for aluminium in soy-based infant formula products specifically. Innovation and competitive food industry • It is vital that the ability to innovate remains. If the composition of infant formula products in ANZ has an objective to achieve a health outcome for formula-fed infants that is as close as possible to the health outcome of

	populations of exclusively breastfed infants, then regulation must allow for innovation. The innovation stems primarily from research on human milk and its components. • The regulatory environment must enable innovation that benefits those infants who need infant formula products. This in itself promotes the desirability of an efficient and internationally competitive food industry whilst also protecting public health and safety. *Encouraging an innovative food sector will enable ANZ to compete on the world stage* (Kollmann, et al, 2021). • Danone is supportive of breastfeeding being the recommended way to feed an infant and this information should be on all products, where it applies. Acknowledging, there are some highly specialised SMPPi used for the management of rare conditions where this may not be the case. • National nutrition policies and guidelines of ANZ recognize the importance of infant formula in instances where the infant is not solely breastfed. Breast milk or infant formula remains the most important nutrient source for the first year of life. Danone recommends that the Policy Guideline is updated to reflect the change to Category two and the introduction of Special Medical Purpose Products for infants (SMPPi).
Section 397(2) of the Food Act 2014 (NZ) sections:	
(b)the desirability of avoiding unnecessary restrictions on trade:	In the sections above and below, Danone detail reasons why the proposal will create additional unjustified technical barriers. Currently, NZ industry has to apply for exemptions under the Food Act 2014 in order to continue to manufacture and export product that does not conform to the requirements of the FSANZ Code even if the importing country does not require compliance with the FSANZ Code. Exemption applications are costly, time consuming, and complex. There are no guarantees that exemption requests will result in an ability to export, even if there is proof provided that the same class of formula made in other countries already exist on importing country's shelves. NZ Ministry for Primary Industries has previously ruled against providing exemptions to the FSANZ Code even if the importing market permits the activity that would be non-compliant to FSANZ. This applies even if the NZ manufacturer is making product exclusively for that export market. For example, the ANZ industry cannot make statements about HMOs on pack, whereas its overseas competition can. Even if ANZ industry manufactures the product solely for the export market, NZ MPI has previously ruled against issuing an exemption to allow deviation from the FSANZ Code. This is despite the fact that it is provided examples of products with HMOs on labels from overseas competition.

	This impacts NZ disproportionately because Australia does not have the same restrictive export regime. By law, export products coming out of Australia can deviate from the FSANZ Code. Even if the export regime between NZ and Australia were aligned, the fact that key markets such as China use daigou channels means that anything that makes the domestic product less attractive, leads to export losses. Chinese consumers choose highly functional products with the latest scientific innovations. Infant formula products sold in domestic channels have been viewed as desirable because they signify a higher level of quality and rigour in production. Chinese consumers trust that domestic products are safe because they are chosen by ANZ caregivers and consumed by ANZ infants. Historically, Chinese consumers placed less trust on its own locally manufactured formula. Where the proposal disincentivizes innovation and diversification, the product on domestic shelf becomes less desirable to these Chinese consumers. Demand via daigou channels who export these domestic products directly to Chinese consumers will markedly decrease. This will have a huge impact on revenue derived from export. In contrast, local Chinese shelves will continue to receive products from other overseas infant formula manufacturers with functional statements showcasing continued innovation. The same cannot be said about products exported directly by infant formula manufacturers in ANZ or indirectly by daigous from domestic stock due to the constraints imposed on labelling by the proposal. This will further reduce export demand for products from ANZ.
(c)the desirability of maintaining consistency between the adopted joint food standards and those standards that apply internationally:	In the sections above and the sections below, Danone detail inconsistencies between the proposed standard and international standards that are not warranted by local conditions. These inconsistencies create an environment where industry in ANZ are subject to greater technical barriers than those of its competitors, especially in global markets.
(e)any other matters that the Minister considers relevant.	**NZ LAW** FSANZ should consider that in assessing whether to adopt a joint standard, the NZ Minister will consider overarching obligations under other NZ legislation and regulations as relevant matters. In previous sections, Danone highlighted the reasons why infants may need to be fed infant formula products. Different feeding situations arise due to the diversity of caregivers and infants and their individual circumstances. Physical, physiological, mental, economical, and social drivers all influence infant's feeding regimes. While Danone unequivocally agrees and promotes that breast milk is best, it believes that in some instances where breastfeeding is not physically possible, that 'fed is best'. The NZ Bill of Rights 1990 clause 19 states that: *everyone has the right to freedom from discrimination on the grounds of discrimination in the Human Rights Act 1993*. The NZ Human Rights Act 1993 makes discrimination unlawful in NZ. Prohibited grounds of discrimination include sex, marital status, religious belief, ethical belief, race, ethnic or

national origins, disability including physical or psychiatric illness, age, political opinion, family status, employment status, and sexual orientation. Each of these characteristics and identifiers represents the different types of caregivers that may choose infant formula products.

For example (and with due respect and sensitivity), the following groups may not be able to breastfeed:

- Male same-sex couples;
- Elder women
- Disabled women
- Women with health conditions that prevent breastfeeding, or contaminate milk
- Parents who have infants that cannot latch to the breast
- Parents who have infants that require additional nutrients above and beyond breast milk, as a result of a medical condition
- Women who are displaced from their infant (i.e. live separately, incarceration, custody arrangements ordered by Courts or where children are in daycare)

Caregivers in NZ and their infants should have a continued right of access to infant formula product regardless of their status or circumstances. These individuals should have the continued right to access infant formula products available to its overseas peers. Equally, they should have the ability to make informed choices and they should be able to benefit from science led innovations that would improve their health outcomes. Whilst breast milk is best and preferred, for some it is not an option, so there needs to be a safe and suitable alternative to breast milk for those people.

These rights will diminish if:

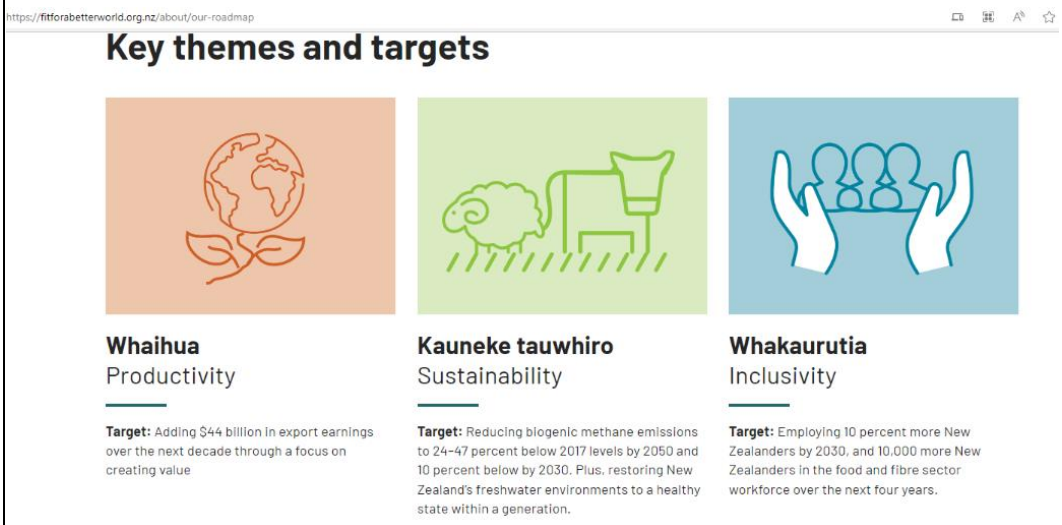
- They are unable to freely understand the products they are buying.
- Manufacturers are not able to educate these groups, or highlight key features of products which may be suitable for their infants.
- Particular SKUs of infant formula disappear e.g. plant-based milks.
- They cannot access pharmacies to buy SMPPi.
- Scientific innovations in infant formula products available offshore are not readily available to them because industry stops innovating locally.

These rights will disappear if infant formula product that they grew up with and trusted over the years disappear from shelves if the industry that used to make them moves operations offshore.

FIT FOR A BETTER WORLD

New Zealand has a roadmap which lays out the Government's plant for rebuilding a better economy over the next 10 years. This is known as the Fit for a Better World roadmap. Its aims are to: *brings together actions, investment, and resources that will*

work together to accelerate the transformation we need. It spans all of the food and fibres sector and brings together significant opportunities to add value across the agriculture, horticulture, fisheries and marine, and forestry sectors.[10]



The infant formula industry is a key contributor to ensure that the roadmap's three targets of productivity, sustainability, and inclusivity. Specifically contributing to key targets in export earnings; engaging its dairy farmer suppliers to work towards reduction of methane emissions; providing meaningful employment and opportunities to employees.

Danone is a key contributor to the above in NZ. Danone ANZ contributes to export earnings in NZ due to both its exports of infant formula products and base powder. Danone has announced an ambitious plan to reduce its methane emissions.[11] Danone will leverage ideas and methods from its global network to action this plan. Danone brings in globally skilled migrants into New Zealand and employs local talent in its North and South Island locations, which includes graduates locally and globally.

MPI STRATEGIC INTENTIONS

NZ's infant formula industry forms a vital part of the NZ dairy sector. Dairy is a key driver for the NZ economy. FSANZ should consider how the proposal impacts this contribution.[12]

[10] Our roadmap | Fit for a Better World and Fit for a Better World: Accelerating our economic potential – 2020 roadmap
[11] Danone announces an ambitious plan to reduce its methane emissions
[12] 48589-Strategic-Intentions-2021-2025 (mpi.govt.nz)

LIST OF QUESTIONS FROM FSANZ

Question 1: Have all major impacts of the proposed changes to the Standard been identified? Please provide evidence (data, studies or other information) to support the inclusion and magnitude of other impacts.

No. Additional impacts are detailed above and below.

The current standard and the proposed changes result in the following:

- existing differences in labelling and composition requirements in the current infant formula standard and export country regulations act as technical barriers for export of ANZ infant formula products;
- compliance with labelling and composition requirements in the current infant formula standard by ANZ manufacturers and exporters mean that ANZ infant formula products are less competitive in global markets, where it competes directly with infant formula products from jurisdictions with [less prescriptive and less restrictive] composition and labelling regulations;
- proposed changes to labelling requirements in the current infant formula standard will further increase the technical barriers for export of ANZ infant formula products;
- compliance with the proposed labelling changes will further negatively impact the ability of ANZ manufacturers and exporters to compete in global markets;
- proposed changes to composition requirements in the current infant formula standard, where not aligned with other jurisdictions, will have an impact on volumes and consequently prices payable for imported inputs into infant formula;
- consequently, further technical barriers to trade impact ANZ manufacturers ability to compete in both domestic and export markets reducing the efficiency and international competitiveness of the ANZ infant formula market industry;
- reduction in competitiveness will result in losses to ANZ infant formula market industry, which may result in the following:
    - Industry may choose to reduce the range and number of infant formula market SKUs available for the domestic and export market, thereby reducing the choice available to the consumer.
    - Industry is naturally incentivised to retain its competitive advantage by producing improved and innovative products. Industry may halt any planned or in progress research and development activity, thereby reducing science led innovation in infant formula products available to the consumer. Where industry research and development in infant formula products is consistently driven by the need to match the benefits of breast milk, halting this innovation for ANZ infant formula products means that consumers of ANZ infant formula products will not have the opportunity to receive the benefits of these improvements.
    - Industry may reduce or halt investment in social and environmental initiatives within its operating geographies which will negatively impact local communities and impact the ability of ANZ governments to meet its environmental global obligations e.g. carbon and methane emissions.

- Industry may downsize its operations in the short term to adjust to reduced demand.
- Alternatively, industry participants may choose to relocate operations in its entirety.

There will be both direct and indirect losses.

In particular:

- This will lead to direct losses of jobs in ANZ infant formula industry, as well as, losses for goods and services businesses that are engaged by the industry.
- Job losses will impact the consumers and the community within which these businesses operate.
- Job and businesses loss will add further economic strain which lead to poorer health and wellbeing outcomes for individuals and families impacted.
- Government will lose associated income tax and goods and services tax revenue.
- Export revenue into ANZ will decrease which further exacerbates the effects of technical recession and cost of living pressures.
- Industry investment in ANZ will decrease. Government, consumers, and communities will lose opportunities that arise from industry choosing to operate in their geographies as this investment relocates offshore and/or ceases.

SMPPi

Section 2.0 on Framework provides further supporting information on the impact of the proposed restriction on sale on health, accessibility, availability and supply chain. This is supported by the findings of the IQVIA researched commissioned by the INC on the proposed restriction on sale.

This proposal has not fully captured the magnitude of the proposed restriction on sale. It has not fully quantified the impact to the accessibility and availability of all SMPPi products but specifically those currently available in the grocery retail channel. The proposal has also not provided evidence of a thorough review of the suitability of the pharmacy sector to ensure there is capacity for this change to occur without any unintended consequences.

Question 2: Do you have any information that can be used to quantify the value of any of the health benefits identified in this impact analysis?

No. However, FSANZ should consider that: *Many complex factors combine to affect the health of people and communities* (World Health Organization 2017). These determinants of health include[13]:

- socioeconomic factors (income, employment status, housing and education)
- the physical environment
- individual characteristics and behaviours.

Socioeconomic deprivation

Higher income and social status are linked to better health. The greater the gap between the richest and poorest people, the greater the differences in health (World Health Organization 2017).

The New Zealand Deprivation Index is an area-based measure of socioeconomic deprivation in NZ. It measures the level of deprivation for people in each small area based on 9 census variables (Atkinson et al 2019). Deprivation is strongly linked to health outcomes (Ministry of Health 2002). Figure 7 below shows Māori and Pacific peoples are overrepresented in the most deprived areas (Atkinson et al 2021).

Danone submits that the above determinants of health are important to consider when the proposal has unintended consequences that leads to losses that affect the socioeconomic factors, the physical environment, and the individual characteristics and behaviours of consumers. In particular:

- Job losses in the industry and associated industries will lead to economic stress which leads to social stress for those impacted. Communities concerned will suffer as opportunities dry up in the wake of industry downscaling or exiting ANZ. Reduction in industry revenues will flow into reduction in income and employment status for individuals, further impacting those individuals, their families, and their communities.
- Industry driven initiatives to improve the environment and capital expenditure investment into industry locations will reduce or cease which will impact the physical environment. This will impair health of local communities.
- The decrease in availability and accessibility of high quality formula improved with the latest scientific innovations will put a physical and mental strain on caregivers, as their infant's physical wellbeing is put at risk.

[13] From: health-and-independence-report-2021-nov22.docx (live.com) Factors contributing to health loss

Question 3: Do you have any evidence that can be used to quantify the unquantified costs to industry presented in this analysis?

See above sections.

Question 4: Have all the major impacts on government been identified?

Refer to the detailed sections on the impacts on government above.

Question 5: Do you have any information that could be used to quantify any of the impacts on government?

Government would also be impacted by the reduction in economic burden associated with innovation within the infant formula industry (Kollmann et al., 2021).

It has been estimated that a one deviation fall in innovation by the Australian dairy industry equates to AUD27.5 million in dairy exports of approximately 1.4% of annual diary exports in Australian. Similar decline the NZ exports would be a NZD234.6 million a year (Kollmann et al, 2021).

New Zealand

For NZ, in the year to the end of March 2023, the value of infant formula products[14], exports from NZ were NZ$1.93 billion, sourced from DCANZ's website NZ Dairy Industry | Dairy Farming in NZ | DCANZ [15]

In the year to March 2020, NZ exported NZ$19.7 billion of dairy products, which supported NZ$10.2 billion of direct value add to the NZ economy. Dairy is NZ's largest value-added contributor by far. In 30 years, dairy exports have grown from just over NZ$2 billion per year to almost $20 billion.

NZ produces approximately 21 billion litres of milk every year. That is approximately 3% of the world milk production or a milk volume equivalent for two and a half serves of dairy per day for 90 million people. Being the world's 8th largest milk producer with a population of just five million, we export over 95% of the milk produced in NZ, to more than 130 different countries worldwide.

NZ gross exports of dairy products is valued at over NZD 16.8 billion (Kollmann, et al., 2021).

Australia

An estimated 30% of milk produced is exported, equating too AUD2.7 billion of exports (Kollmann, et al, 2021).

Data provided by INC Trade & Market Access indicates that:

> Australia's IMF export figures are 2021 A$414m.
> Austrade has China receiving 90% of Australian IMF exports

[14] Search using HS code 1901.10.

[15] NZ Dairy Industry | Dairy Farming in New Zealand | DCANZ

References

Atkinson J, Crampton P, Salmond C. (2021) NZDep2018 analysis of census 2018 variables – Overall (New Zealand). http://hdl.handle.net/10523/12052.

Atkinson J, Salmond C, Crampton P. (2019) NZDep2018 Index of Deprivation. www.otago.ac.nz/wellington/otago823833.pdf

Australian Bureau of Statistics (ABS)(2022a). National, state and territory population. Available online at National, state and territory population, December 2022 | Australian Bureau of Statistics (abs.gov.au)

Australian Bureau of Statistics (ABS)(2022b). Breastfeeding, 2020-21 financial year. Available online at Breastfeeding, 2020-21 financial year | Australian Bureau of Statistics (abs.gov.au)

Australian Bureau of Statistics (ABS)(2022c). Annual live births. Available online at https://www.abs.gov.au/statistics/people/population/births-australia/latest-release

Australian Institute of Health And Welfare (2011). The Australian National Infant Feeding Survey 2010-2011. Available online at https://www.aihw.gov.au/reports/mothers-babies/2010-australian-national-infant-feeding-survey/summary

Anand, K.J., Runeson, B. and Jacobson, B. (2004) "Gastric suction at birth associated with long-term risk for functional intestinal disorders in later life," The Journal of Pediatrics, 144(4): 449-454.

ASCIA (2022) Cow's Milk (Dairy) Allergy. https://allergy.org.au/images/ASCIA_PCC_Cows_milk_dairy_allergy_2022.12.pdf

Barreau, F., Ferrier, L., Fioramonti, J. and Bueno, L. (2007) "New insights in the etiology and pathophysiology of irritable bowel syndrome: contribution of neonatal stress models," Pediatric Research, 62(3): 240-245.

Baudon, J.J. (2009) "Gastroesophageal reflux in infants: myths and realities," Archives de Pediatrie: Organe Officiel de la Societe Francaise de Pediatrie, 16(5): 468-473.

Belitsi, S.T., Mathew, A.V. and James, M. (2015) "G364 (P) Management of gastroesophageal reflux in infants: current practice of diagnosis and treatment in a UK district general hospital," Archives of Disease in Childhood, 100(Suppl 3): A149.

Benninga, M.A., Faure, C., Hyman, P.E., St James Roberts, I., Schechter, N.L. and Nurko, S. (2016) "Childhood Functional Gastrointestinal Disorders: Neonate/Toddler," Gastroenterology, 150: 1443–1455.

Bonilla, S. and Saps, M. (2013) "Early life events predispose the onset of childhood functional gastrointestinal disorders," Revista de Gastroenterología de México, 78(2): 82-91.

Buts, J.P., Barudi, C. and Otte, J.B. (1987) "Double-blind controlled study on the efficacy of sodium alginate (Gaviscon) in reducing gastroesophageal reflux assessed by 24h continuous pH monitoring in infants and children," European Journal of Pediatrics, 146: 156-158.

Council for Responsible Nutrition and the International Probiotics Association (2021) Best practices for probiotics in dietary supplements. https://www.crnusa.org/regulation-legislation/self-regulation/best-practices-probiotics

Del Buono, R., Wenzl, T.G., Ball, G., Keady, S. and Thomson, M. (2005) "Effect of Gaviscon Infant on gastro-oesophageal reflux in infants assessed by combined intraluminal impedance/pH," Archives of Disease in Childhood, 90(5): 460-463.

Douglas, P.S. (2013) "Diagnosing gastro-oesophageal reflux disease or lactose intolerance in babies who cry a lot in the first few months overlooks feeding problems," Journal of Paediatrics and Child Health, 49(4): E252-E256.

Dykes, F., Richardson-Foster, H., Crossland, N., & Thomson, G. (2012). 'Dancing on a thin line': Evaluation of an infant feeding information team to implement the WHO code of marketing of breast-milk substitutes. *Midwifery*, *28*(6), 765–771. Available online at https://doi.org/10.1016/j.midw.2011.08.012

EFSA Panel on Dietetic Products, Nutrition and Allergies (2015) "Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013," EFSA Journal, 13(11): 4300-4323.

EFSA (2015) Scientific Opinion on the re-evaluation of tocopherol-rich extract (E 306), α-tocopherol (E 307), γ-tocopherol (E 308) and δ-tocopherol (E 309) as food additives. EFSA Panel on Food additives and Nutrient Sources added to Food (ANS). EFSA Journal 13(9):4247, 118 pp. doi:10.2903/j.efsa.2015.4247

Embleton ND, et al. Enteral Nutrition in Preterm Infants (2022): A Position Paper From the ESPGHAN Committee on Nutrition and Invited Experts. J Pediatr Gastroenterol Nutr. 2023 Feb 1;76(2):248-268.

European Commission (2011) Food and Feed Information Portal Version 1.2 Food additives Alpha-tocopherol https://ec.europa.eu/food/food-feed-portal/screen/food-additives/search/details/POL-FAD-IMPORT-3082. Accessed June 2023

FSANZ (2021) Supporting Document 4 – Consumer research. 2021 Consultation Paper 1. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

FSANZ (2022) Attachment to Supporting Document 3 – Consumer research on infant formula labelling. 1st Call for Submissions. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

Growing Up in New Zealand, Key Findings. https://www.growingup.co.nz/key-findings-0 (accessed July 2023)

Hua, S., Peters, R.L., Allen, K.J., Dharmage, S.C., Tang, M.L., Wake, M., Foskey, R. and Heine, R.G. (2015) "Medical intervention in parent-reported infant gastro-oesophageal reflux: A population-based study," Journal of Paediatrics and Child Health, 51(5): 515-523.

Indrio, F., Di Mauro, A., Riezzo, G., Cavallo, L. and Francavilla, R. (2015) "Infantile colic, regurgitation, and constipation: an early traumatic insult in the development of functional gastrointestinal disorders in children?" European Journal of Pediatrics, 174(6): 841-842.

JECFA (2011) Evaluation of the Joint FAO/WHO Expert Committee on Food Additives: Aluminium https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/298. Accessed June 2023

Jigsaw (2015). *Informed choice for consumers [CONFIDENTIAL]*. Commissioned by Infant Nutrition Council. Australia.

Kollmann, T., Palangkaraya, A., Webster, E. (2021). Innovation in manufactured food and infant formula sectors. The Centre for transformative Innovation, Swinburne University of Technology. https://www.foodstandards.gov.au/code/applications/Documents/A1155%20Review%20SD5%20Innovation%20in%20manufactured%20food%20and%20infant%20formula%20sectors.pdf

Miller, S. (1999) "Comparison of the Efficacy and Safety of a New Aluminium-free Paediatric Alginate Preparation and Placebo in Infants with Recurrent Gastro-esophageal Reflux," Current Medical Research and Opinion, 15(3): 160-168.

Ministry of Health. (2022). Health and Independence Report 2021: The Director-General of Health's Annual Report on the State of Public Health. Wellington: Ministry of Health. https://www.health.govt.nz/system/files/documents/publications/health-and-independence-report-2021-nov22.pdf

NICE, NICE Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people. Available at: www.nice.org.uk/guidance/ng1 (accessed July 2023), 2015, updated 2019..

OECD (2005) 'Guidelines for Collecting and Interpreting Innovation Data', Organisation for Economic Co-operation and Development and Eurostat, Paris.

Partty, A., Kalliomaki, M., Salminen, S. and Isolauri, E. (2013) "Infant distress and development of functional gastrointestinal disorders in childhood: is there a connection?" JAMA Pediatrics, 167(10): 977-978.

Pragmatic Research & Advisory (2022) Parents have their say about feeding infants and toddlers, https://www.infantnutritioncouncil.com/wp-content/uploads/2022/06/Parents-have-their-say.pdf

Rosen, R., Vandenplas, Y., Singendonk, M., Cabana, M., DiLorenzo, C., Gottrand, F., Gupta, S., Langendam, M., Staiano, A., Thapar, N., Tipnis, N. and Tabbers, M. (2018) "Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition," Journal of Pediatric Gastroenterology and Nutrition, 66(3):516-554.

Saps, M. and Di Lorenzo, C. (2009) "Pharmacotherapy for functional gastrointestinal disorders in children," Journal of Pediatric Gastroenterology and Nutrition, 48: S101-S103.

Statistics New Zealand (2022). Births and Deaths. Available online at https://www.stats.govt.nz/topics/births-and-deaths

Vandenplas, Y., Abkari, A., Bellaiche, M., Benninga, M., Chouraqui, J.P., Cokura, 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. and Thapar, N. (2015a) "Prevalence and Health Outcomes of Functional Gastrointestinal Symptoms in Infants From Birth to 12 Months of Age," Journal of Pediatric Gastroenterology and Nutrition, 61(5): 531-537.

Vandenplas, Y., Alarcon, P., Alliet, P., De Greef, E., De Ronne, N., Hoffman, I., Van Winckel, M. and Hauser, B. (2015b) "Algorithms for managing infant constipation, colic, regurgitation and cow's milk allergy in formula-fed infants," Acta Paediatrica, 104(5): 449-457.

Vandenplas Y, Hauser B, Salvatore S. (2019) Functional Gastrointestinal Disorders in Infancy: Impact on the Health of the Infant and Family. Pediatr Gastroenterol Hepatol Nutr.;22(3):207-216.

World Health Organization. (2017). Determinants of health. https://www.who.int/news-room/questions-and-answers/item/determinants-of-health