Queensland Government

Queensland Health

[redacted]

17 June 2022

Standards Management Officer
Food Standards Australia New Zealand
PO Box 5423
Kingston ACT 2604

Dear Sir / Madam

Submission – Proposal P1028—Infant formula – 1st Call for Submissions

Thank you for the opportunity to provide a submission on the *1st Call for Submissions (CFS) – Infant Formula* for Proposal P1028. The responses below are indicated with reference to their respective CFS document - Proposal P1028 and the supporting documents.

This submission was prepared with input from health professionals from Children's Health Queensland Hospital and Health Service, Health and Wellbeing Queensland, Preventive Health Branch and Food Safety Standards and Regulation. The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government should notification be made by the FSANZ Board to the Food Ministers' Meeting.

The Queensland Government remains committed to protecting, promoting, and supporting breastfeeding and optimal infant nutrition. It is also recognised that infant formula and other breastmilk substitutes have a legitimate role to play in circumstances where an infant cannot be breastfed. The Department continues to support the *Ministerial Policy Guideline on the Regulation of Infant Formula Products,* which recognises there is a greater level of risk for infants. In line with FSANZ's primary objective of protecting public health and safety, it is important that P1028's primary objective is to ensure infant formula is safe for infants to consume, has a nutrient composition that supports expected growth and development, particularly when it is an infant's sole source of nutrition (i.e. from birth to around 6 months), and improves health outcomes of formula-fed infants. Whilst alignment of Australian and New Zealand standards with international regulations is important, the health and safety of infants must be the priority. Therefore, whilst industry innovation should be facilitated by regulations, this must advance the health incomes of formula fed infants closer to breast fed infant health outcomes. Broad innovation by industry which does not positively influence a reduction of adverse health effects in formula fed infants, may lead to the promotion of unnecessary consumption of infant formula products (IFP) with resultant negative impacts on breastfeeding rates.

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Call for submissions – Proposal P1028

FSANZ throughout the CFS refer to Infant Formula Products having nutrient composition to support **normal** growth and development. However only human breastmilk supports normal growth and development of human infants. Different growth trajectories are experienced by infants fed artificial baby milks in comparison to human breastmilk-fed infants and these different growth trajectories are widely accepted and well documented. It is proposed that the wording throughout the CFS is amended to 'expected growth and development' to replace 'normal growth and development' (Centers for Disease Control and Prevention (2022). Breastfeeding as the Norm for Infant Feeding. Retrieved from https://www.cdc.gov/nccdphp/dnpao/growthcharts/who/breastfeeding/index.htm)

Section 2 – Regulatory Framework

As IFP are not regular commercial foods, when establishing a new regulatory framework, consideration is needed to ensure products are as safe as possible, are designed to meet infant requirements and feeding guidelines, and they only deviate where it is necessary to manage a valid medical condition where breastmilk or standard formula cannot be used.

2.4.2 Modified infant formula products

The use of a subcategory that modifies protein and/or lactose free/low lactose content could be beneficial only if modified protein refers to partial hydrolysis of one or more of the proteins on which infant formula is normally based.

2.4.3 Special Medical Purpose Products for infants (SMPPi)

Health professionals agree regarding the proposed new category – SMPPi and for this to include nutritionally complete nutrient-adapted formulation specific for a disease, disorder or medical condition.

2.4.4 Human milk fortifiers and pre-term supplementary products

It is considered that SMPPi could include nutritionally incomplete, i.e. supplementary feeds such as human milk fortifiers and not used as a sole source of nourishment.

2.5 Preferred option

Health professionals do not support the proposal for IFP to include those products that have a modification in the hydrolysis of the lactose component. As there is no evidence that partially hydrolysed formula is suitable to treat or manage any medical/health condition, consideration may be required for the need for this product at all. However should it be determined that partially hydrolysed formulas remain a permitted product, subject to provision of clear criteria and definitions of partially vs. extensively hydrolysis, health professionals support listing of partially hydrolysed in the IFP and extensively hydrolysed protein products as SMPPi. Further, it is agreed that required changes to standard 2.9.1, including removing the Infant Formula Products for Special Dietary purposes categorisation and current associated sub-categories are appropriate.

Section 3 – Definitions

3.4.1 Soy-based infant formula

Health professionals agree with the proposed removal of the definition for 'soy-based infant formula' from standard 2.9.1.

3.4.2 Pre-term formula

Health professionals agree regarding the removal of the definition for 'pre-term' from standard 2.9.1.

Section 4 – Novel foods and Nutritive Substances

4.1 Pre-market assessment requirements

Concern is raised about the proposal to defer consideration of requirements to permit new novel foods and nutritive substances in IFP to the broader review of the Food Standard Code provisions applicable to all foods. The regulatory framework for novel foods and nutritive substances for general foods should not be applied to IFP due to the inherent risks and vulnerability of infants. Premarket assessment of novel foods and nutritive substances used in IFP should be managed within Standard 2.9.1 (Infant Formula Products) and not Standard 1.5.1 (Novel Foods) for the following reasons.

- IFP may be the sole or main source of nutrition and require a higher level of evidence of their safety under the Ministerial Policy Guideline *Regulation of Infant Formula Products*.

- There is ambiguity in Standards 1.5.1 in relation to tradition of use. The assumption of traditional use is that food traditional in Australia and New Zealand is safe. This is not necessarily always true, and an unsuitable way of ruling out certain food that may require premarket assessment. This does not appear to be an appropriate screening tool for IFP, which may be the sole source of nutrition for infants, and because infants are a vulnerable population group.

- Premarket assessment should be required of all nutritive substances, novel foods and novel substances added to IFP due to the higher risk they may present to infants considering IFP may be the sole source of nutrition and infants are a vulnerable population group.

- Standard 1.5.1 does not make a distinction in relation to non-traditional food for infants, that is, the requirements are for food in general and do not consider the special needs of infants.

- The conditions for accepting a novel food into the Food Standards Code under Standard 1.5.1 do not consider whether it has a substantial beneficial role or technological role. However, this is a requirement that FSANZ must consider in standards development under Policy principle j of the Ministerial Policy Guideline *Regulation of Infant Formula Products,* which states '*Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants, children, or a technological role, taking into account, where relevant, the levels of comparable substances in breastmilk…*'

- Standard 1.5.1 has been difficult to apply and enforce in practice regarding determining if a food is novel and requires a safety assessment. The Advisory Committee on Novel Foods just provides an opinion. It is up to jurisdictional enforcement officers to enforce. If a matter was to proceed to a defended prosecution, it is up to the enforcement agency to argue why it is non-traditional and requires a safety assessment. This requires appropriate expert witnesses, is expensive and carries a higher risk of prosecutorial failure.

- Deferring consideration of the addition of novel foods to IFP to the review of the Novel Foods standard (P1024) risks delaying the completion of this aspect of the review of IFP as work on P1024 is currently on hold.

4.2 Novel foods – Schedule 25

- It is considered that clarification is needed regarding the circumstance where current novel food provisions do not apply to IFP unless expressly permitted.

- Health professionals agree with the proposal to restrict the following substances from use in IFP: A-cyclodextrin, Y-cyclodextrin, diacylglycerol oil, isomaltulose, D-tagatose and trehalose.

Section 5 – Safety and Food Technology (SD1)

Consideration may need to be given to including an assessment of the microbiological risks associated with ready-to-feed infant formula and follow-on formula products and whether there is a need to prescribe microbiological limits in the Food Standards Code. Ready-to-feed infant formula and follow-on formula products are currently on the market but the current microbiological requirements in Schedule 27 apply only to powdered infant formula and powdered follow-on formula. It is understood their use in Australia may currently be mainly limited to hospital settings. However, they are sold directly to consumers overseas, for example by Target and Walmart in the USA and via online stores. When conducting a web search of 'ready to feed infant formula' examples of such products were easily found. With the industry trend to marketing convenience food products, it would be surprising if such products do not become more readily available to the public in Australia. It is important to help future-proof requirements as part of Proposal P1028. Prescribing safety related microbial limits is important because infants are a vulnerable population and because it also provides greater regulatory certainty.

5.2 Contaminants

5.2.2 Arsenic and Lead and 5.2.3 Cadmium

- Microbiology experts agree with the revised ML for lead from 20 to 10 mg/L, noting this corresponds with EU Commission Regulation (EC) No 2021/1317, but recommends *some* inorganic arsenic (iAs; sum of As [III] + AS [V]) and cadmium (Cd) ML criterion be provided in the Code. Specifically in relation to iAs in rice-based, e.g. hydrolysed rice protein, IFP, which have been found to be at higher risk of iAs contamination than cow's milk or other grain-based infant formulas (see Arcella et al. 2021)

  This is due to:

  (a) the reported elevated iAs-associated risk linked with rice-based products,

  (b) their market introduction as alternatives for infants with bovine milk protein allergy,

  (c) potential arsenic and cadmium developmental neurotoxicity and carcinogenicity, and the potential for Cd nephrotoxicity, growth retardation, impaired child development, bone demineralization and fractures, reproductive impairment, and diabetes,

  (d) *potential* non-monotonic effects (increased toxicity at lower doses), and Cd's considerable *in vivo* half-life (ca. ≥ 15 years.)

- The concern regarding inorganic As in rice-based formulas also applies to Cd, and is presumably based on the findings summarised in Ljung *et al* (2001) and Concha *et al* (2013). Noting the latter's conclusion, "cadmium uptake is probably higher in children compared to adults, and it may be discussed if the (EFSA, sic.) TDI covers all potential health effects associated with cadmium exposure restricted to early-life." Noting testing for these metals

(Pb, IAs, Cd) in infant formula metals testing is not excessively costly for a bulk product at approximately $120-160 AUD/sample.

- Therefore, it is recommended that adopting a Cd ML based on EU Commission Regulation (EU) No 2021/1323 of 40 mg/kg wet weight for processed cereal-based foods and baby foods for infants and young children (see 3.2.16.18.) for rice-based, or rice-ingredient-containing infant formulas. A 100 mg/kg (wet weight) iAs ML (as consumed) for infant formula, follow on formula and SMPPi is suggested. This strikes a balance between with the Codex recognition of the increased iAS risk presented by rice-based foods and 200 mg/kg ML, and the USFDA 2021 *Baby Food Safety Act* infant rice formula proposed 10 mg/kg ML for infant and toddler food (except cereal) and 15 mg/kg ML for infant and toddler food that is cereal.

5.3 MLs for infant formula in dry powder form or as consumed

- Microbiology experts concur with FSANZ' preferred option to change contaminant ML measurand units from ppm (mg/kg) as dry powder to "as consumed". However, the associated measurand units proposed (mg/kg, weight/weight [wt/wt]) are presumably based on a solid, while units for liquids are generally ppm in mg/L (wt/volume) unless (a) a density or dilution factor (with or without mass-volume displacement correction) is applied to convert wt/vol to wt/wt, (b) a density of 1 kg/L is assumed, or (c) "wet weight" is used as a unit qualifier. The latter is the approach used in Commission Regulation (EU) No 2021/1323 (see 3.2.16.) References within Proposal P1028 materials are also inconsistent. For example, SD1 Table 2 *preferred approach for lead* states, "Lower ML from 0.02 mg/L to 0.01 mg/L in IFP and apply to infant formula on a ready-to-feed basis." while SD1 5.3.3 states, "FSANZ's preferred option is to proceed with the FSANZ 2021 CP1 approach, which is to apply MLs that are established for infant formula to an 'as consumed' form in mg/kg." The first cited as wt/vol, and second wt/wt. As exposure dose of an "as consumed" reconstituted product in liquid form is generally based on volume consumed, ML units of wt/vol would simplify exposure and compliance. If wt/wt (mg/kg) units for "as consumed" liquid infant formula/follow-on products is adopted, the applicable qualifier, e.g. wt/vol to wt/wt conversion criteria, "wet weight" designation, etc., must be described.

- It is noted that the limit for Aluminium (Al) in Standard 2.9.1-8 is expressed in mg/100 ml as consumed, rather than mg/L or mg/kg or mg/kg as for other Schedule 19 MLs. It is recommended that the Al MLs be made consistent with schedule 19 by normalisation to units of mg/L (or mg/kg wet weight.)

5.4 L (+) Lactic acid producing microorganisms

Addition for acidification purposes

- While it is recognised that a principal function of LAM addition (or growth promotion of naturally occurring saprophytic LAM) is *L*(+) lactic acid production with associated beneficial food quality and preservative impacts, principal LAM function(s) may alternatively or additionally include "fermentation" (currently suggested as primarily for the purpose of *L*(+) lactic acid production), competitive inhibition of pathogens and spoilage organisms, and their inhibition mediated via bacteriocin production. Should the principal intended (potentially beneficial) function of an added LAM be other than lactic acid-mediated production, but not as a probiotic *per se*, this may create a circumstance where these common, non-probiotic purposes might not be permitted. FSANZ has clarified that addition of microorganisms for intended probiotic purposes would represent a novel food under Code Section 1.5.1, requiring pre-market safety assessment.

- As the non-probiotic functions of LAM fermentation, *L*(+) lactic acid production, competitive inhibition and bacteriocin production are food safety and quality preventative/preservative, it is recommended FSANZ LAM permission either qualify LAM addition for the purposes of fermentation and/or preservation/food safety or similar, rather than restricting to *L*(+) lactic acid production exclusively.

Definition of ferment/fermentation

- Related to the above is a lack of clear Code definition of the term *ferment* (and *fermentation*) in the Code. These terms occur in section 1.1.2 *Definitions used throughout the Code* 17 and 12 times, respectively. This includes use of these terms intrinsic to delineating the meaning of the terms being defined, e.g. "*fermented* milk means a food obtained by *fermentation* of milk…, and where some specific characteristics of a *particular fermentation type* are cited, e.g. "…*fermentation* is described or products derived from milk, where the *fermentation* involves the action of microorganisms and results in coagulation and a reduction in pH." The lack of a general definition of ferment/fermentation where these terms are used without qualification within 1.1.2 definitions, or elsewhere throughout the Code can lead to different interpretations as the term is one with substantially different interpretations and definitions amongst different disciplines and operations. It is recommended that as part of P1028, definition of the term(s) ferment and/or fermentation are included in Code section 1.1.2 by amendment. This will clarify the types and purposes of Code permitted fermentation(s). This includes the present proposed Proposal P1028 permissions related to purpose(s) of LAM addition.

It would be appreciated that consideration be given to a proposal to clarify the permission that only non-pathogenic or non-toxigenic microorganisms may be used.

FSANZ query 1: Does the current permission for L(+) lactic acid producing microorganisms need to be clarified? For example, some L(+) lactic acid producing microorganisms are pathogenic.

- While it is believed the current permission might benefit from clarification with respect to the status of some *L*(+) lactic acid producing microorganisms (LAM, the vast majority of which are lactic acid bacteria [LAB]) as *potentially opportunistic pathogens*, the terms "pathogenic" and/or "toxigenic" would need clear and unambiguous definition to avoid potential misinterpretation. As indicated via FSANZ review of the scientific literature, currently available scientific evidence suggests microorganisms of reported human clinical LAB infections (bacteraemia; infectious endocarditis; meningitis; urinary tract-, chest-, and digestive tract-infections) are opportunistic rather than frank pathogens. LAB clinical infection (except for enterococci – see below) is very rare compared to other bacterial pathogens, with cases almost entirely associated with individuals with an underlying debility or condition such as immune system dysfunction/suppression, tissue barrier damage, and/or undergoing antibiotic treatment which eliminates competing flora. Additionally, LAM are common human commensal organisms, with most reported human cases of infection appearing to have been caused by these flora rather than that from LAB-containing foods (Adams, M [1999] *J Biotechnol* 68:171-178; Kubiszewska et al. [2014] Postepy *Hig NMed Dows* 68:1325-1334.)

- The enterococci (principally *E. faecalis* and *E. faecium*) LAB are *generally* more successful opportunistic pathogens within the LAM, are present as a substantial portion of normal human flora (particularly gastrointestinal) and are generally present in a number of traditional fermented foods such as traditional cheeses and sausages, as well as causing processed meat spoilage. Principal enterococcal risks associated with potential food safety and pathogenicity relate to their ability to act as reservoirs for virulence traits and/or antimicrobial resistance (AMR) rather than as frank-pathogen causative agents of foodborne illness. Such

virulence and AMR traits may be intrinsic and/or acquired through *in vivo* genetic exchange (typically conjugative) and/or mutation. However, they do not confer general foodborne pathogenicity to immunocompetent individuals. Human health risk assessment of enterococci is complicated by a lack of knowledge regarding types and combinations of virulence factors conferring pathogenic potential. Enterococcal production of biogenic amines in foods may lead to foodborne intoxication. However, experimental evidence to date does not definitely support confirmation enterococci as causative agents of foodborne illness. While enterococci are among the most commonly isolated organisms from nosocomial urinary tract and wound infections, they are overall considered low virulence, opportunistic pathogens. *Enterococcus* sp. strains lacking virulence or antimicrobial traits introduction to the human gastrointestinal tract via food and probiotics presents negligeable risk to immunocompetent individuals (Adams 1999; Franz et al. 2003; Oprea and Zervos 2007; Kayser 2003). For example, as cited by FSANZ, *E. faecium* strain SF68 – which lacks enterococcal virulence factors – is used probiotically in pharmaceutical preparations to treat intestinal tract disorders. Whether infants or those consuming follow-on formula are classified as immunocompetent for the purposes of classification of LAM as potentially opportunistically pathogenic creates additional uncertainty regarding interpretation of permissions citing "pathogenicity" *per se* as a criterion.

- LAM/LAB-associated foodborne microbiological risks appear largely secondary, i.e. associated with potential harbouring and transfer/amplification of virulence and/or AMR traits within in-food or *in vivo* LAM populations rather than frank pathogenicity in those consuming respective LAM containing product. Therefore, a specific requirement that added LAM must be non-pathogenic (and/or non-toxigenic) *could* add clarity, strengthen requirements and minimise risk. But only if specific criteria defining "non-pathogenic" is also provided.

- Use of spore-forming LAM is more common in industrial fermentation for production of bulk short chain acids. Nonetheless, their potential for increasing use in foods is recognised, as well as the increased risk of toxin production associated with these genera. However, the range of recognized human toxins associated with the spore forming bacteria is not excessive, and more easily defined than factors conferring potential enterococci pathogenicity. Therefore, it is suggested the Code be amended to include a requirement spore-forming bacteria addition for purposes as delineated above (see *Addition for acidification purposes*) be demonstrated as not producing such toxins and/or below specified maximum levels in the respective food to which they are added.

FSANZ query 2: *Do these need to be explicitly excluded or is the base 'safe and suitable' requirement considered sufficient to manage this risk?*

- Microbiology experts recognise the potential for use of LAM with potentially pathogenic traits or toxin production outside the requirements for pre-market assessment of those added for prebiotic purposes. However, if a clear and unambiguous criteria-based definition of "non-pathogenic", and delineation of requirements regarding spore-former toxin production are provided, the permission may be amended to state that only non-pathogenic or non-toxigenic microorganisms may be used. Otherwise, in the absence of such criteria, the base 'safe and suitable' requirement is considered sufficient to manage associated risks.

- Microbiology experts recommend against the designation of specific taxonomic groups of LAMs or spore-forming bacteria due to the evolving nature of bacterial phylogeny related to these organisms (particularly genus *Lactobacillus* - see Zheng et al. 2020 *Int J System Evol Biol* 70:2782-2858), and the proposed application of a functional (production of *L*[+] lactic acid, pathogenicity/toxicity) rather than taxonomic classification.

Attachment 1 – Microbiological safety of powdered infant formula: Effect of water temperature on risk.

- FSANZ's risk assessment considered valid temperature parameters and it is agreed that there is no apparent elevated disease risk to infants presented by the plausible conditions modelled using the JEMRA risk assessment model for *C. sakazakii* in powdered infant formula. Risk may also arise from use of inappropriately sanitised feeding apparatus or disinfected water. However, it is understood that this is outside the scope of FSANZ P1028 remit.

- Section 5, reference hyperlink to "Paoli G, Hartnett E (2006) Overview of a risk assessment model for *Enterobacter sakazakii* in powdered infant formula www.who.int/foodsafety/publications/micro/RA_Overview.pdf" is non-functional. The correct reference should be either https://www.biosym.uzh.ch/modules/models/FAO_E_sakazakii/r_a_overview.pdf or more appropriately and comprehensively: https://www.who.int/publications/i/item/9241563311

Section 6 – Nutrient Composition (SD2)

6.3 Infant Formula Products

It is considered that protein source to be specified as only cows' milk protein, goat's milk protein, protein hydrolysates or one or more proteins normally used in infant formula and soy protein isolate. This does not inhibit innovation but protects the health and safety of infants by ensuring a pre-market assessment (safety, suitability and normal growth/development) of emerging plant-based proteins occurs.

Modified Formulas

Concern is raised regarding the proposed inclusion of products which have been compositionally modified to be either low lactose/lactose free or contain partially hydrolysed protein as IFP. This proposal has been put forward on the basis that these formulas are modified for dietary conditions and are otherwise deemed safe for use by healthy infants. Whilst the basis provided is not incorrect, the following issues are cause for concern:

- Low lactose / lactose free products: Human breastmilk is high in lactose and healthy infants produce sufficient enzyme lactase to digest lactose. Primary lactose intolerance is an extremely rare genetic condition that is incompatible with normal life without medical intervention. Secondary lactose intolerance occurs when the enzyme lactase is compromised by illness and/or disease such as in gastroenteritis; food intolerance or allergy; parasitic infection; coeliac disease and / or following bowel surgery. Therefore, if an infant is exhibiting lactose intolerance behaviours, medical assessment and treatment for the underlying cause is warranted. Classifying low/no lactose formulas as IFP and thereby enabling these products to be available without medical advice places the infant at risk of untreated medical conditions and associated adverse health outcomes. (References: Hammer HF, et al. Lactose intolerance: Clinical manifestations, diagnosis, and management. https://www.uptodate.com/contents/search. Di Costanzo M, et al. Lactose intolerance: Common misunderstandings. Annals of Nutrition & Metabolism. 2018; doi:10.1159/000493669)

- Partially hydrolysed protein: It is proposed that differentiating partially hydrolysed protein formulas as IFP and extensively hydrolysed protein products as SMPPi – requires criteria defining when a *partially hydrolysed* product becomes *extensively hydrolysed* and delineation of how this would be regulated. As there is no evidence that partially hydrolysed formula is suitable to treat or manage any medical/health condition, and a healthy infant

would have no requirement for this type of formula, questions arise regarding the need for this product at all. However should it be determined that partially hydrolysed formulas remain a permitted product, subject to provision of clear criteria and definitions of partially vs. extensively hydrolysis, consideration is requested regarding the listing of partially hydrolysed in the IFP category and extensively hydrolysed protein products as SMPPi.

Section 7 – Labelling

7.2 Provision of information (SD3)

Questions to submitters:

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

- *Agree regarding* the generic labelling requirements to apply to IFP. A requirement for the provision of nutrition information in a consistent manner enables parents/carers/ health professionals to easily compare nutrient profile between products, thereby facilitating informed choice.

- *Agree* to the maintenance of 100ml as reconstituted in preference to other labels (per 100g powder etc), as well as the prohibition of other base units of expression to ensure ease of comparison for parents.

- *Agree* regarding group of vitamins and minerals under subheadings as shown in Figure 1. This will enable consumers/caregivers to compare products with ease and reduce confusion (e.g. Beta-carotene or Vitamin A). FSANZ stakeholder surveys indicated most consumers use the nutrition information statement for comparison across products – consistent labelling is likely to further support caregivers and increase confidence in comparing products.

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

It is suggested that the subheadings 'Vitamins', 'Minerals' and 'Additional' are separated from macronutrient components of the NIS with the use of lines and bolded headings. This is to enable clear separation of vitamins minerals and additional ingredients enabling parents/carers/health professionals to easily compare nutrient profiles between different products and thereby facilitating informed decision making, especially if caregivers are looking for particular aspects in their IFP.

Macronutrient sub-group nutrients in the nutrition information statement

It is agreed in relation to the proposal to permit and prescribe wording and format of the voluntary listing of sub-group nutrients, and specifically limiting this permission to: whey and casein, and docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and arachidonic acid (ARA). Inclusion of these nutrients of interest would enable parents/carers/ health professionals to easily compare the nutrient profile of various IFP, thereby facilitating informed decision making. Limiting the permission to the stated sub-group nutrients avoids over-crowding of the NIS, which was identified as an issue for some caregivers in previous consultations.

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

There is no evidence that partially hydrolysed formula is suitable to treat or manage any health or medical condition. Inclusion of these products under the SMPPi category will allow variation in labelling and this creates risk. It will also give the perception that these products are suitable for management of a clinical condition when they are simply a variation of a normal infant formula and a healthy infant would have no requirement for a partially hydrolysed protein artificial baby milk product. Therefore, reference to partially hydrolysed proteins in the statement of ingredients only is supported.

A nutrient content claim or reference to partially hydrolysed formula should not be permitted elsewhere on the tin, given partially hydrolysed formulas are not recommended by health professionals and generally accepted science does not support their use for infants. Emphasising this aspect would elevate this point of difference inferring it is important and of benefit to infants. There should also be no claims permitted that imply there is an associated physiological or health effect, such as one relating to digestion.

Nutrition, health and ingredient claims

It is agreed that FSANZ's proposed approach to maintain existing prohibitions on nutrient content and health claims, and further to continue to only permit information about ingredients in the statement of ingredients (except for nutrients that are required to be declared in the Nutrition Information Statement) is appropriate. Content published on formula company websites may contain health claims that are not permitted to be listed on the product tin. It is recommended that this online content be subject to the same labelling requirements as the product tins to ensure caregivers are not misled about the quality or effectiveness of infant formula.

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

- Anecdotal clinical practical experience suggests many caregivers have a moderate-to-good understanding of the difference between formulas with regards to stage labelling. However, there is confusion that Stage 1 can be continued to be used until 12 months, with some caregivers expressing concern that they have not swapped over to the next stage.

- Stage 1 products should be clearly labelled as appropriate through to 12 months before cows' milk is a suitable drink. There is confusion as some products do state the 0–12-month range, some note 0-6months. This should be clearer and age ranges recommended in preference to stages.

- Stages can make it sound like a baby is developing well/normally or progressing, which can make caregivers feel as if their child/infant is behind if they have not moved onto a new 'stage' of formula.

- Stages can also undermine the importance of breastmilk. The research undertaken by Berry et al indicated that caregivers were not aware that breastmilk also adapted/changed as their baby grew/developed. This can make a 'stage' appear more appealing (Berry, N. J., Jones, S., & Iverson, D. (2010). It's all formula to me: women's understandings of toddler milk ads. Breastfeeding Review, 18(1), 21–30. "It's all formula to me: women's understandings of toddler milk ads" by Nina J. Berry, Sandra Jones et al. (uow.edu.au)).

- Health professionals support a *general age range* for formulas (0-12 months, 6 months + and 12 months +) in preference to stage range or names.

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

- Caregivers are influenced by follow-on formula advertising, which is utilised as a way of increasing brand association/familiarity.

- The use of advertising on an infant formula for follow-on formula or toddler milks should be prohibited as they are not necessary for health. They are intentionally marketed as a cheaper alternative, which can make them seem like attractive options. However, they are not necessary for much of the healthy infant/toddler population.

Section 9 – FSANZ Act assessment requirements

9.1.1 Considerations of costs and benefits

Questions

1. *To what extent do you agree with Food Standards Australia New Zealand (FSANZ) conclusion on benefits outweighing the costs?*

Consultation has occurred across Queensland agencies on this proposal, and it is considered that the benefits to Proposal P1028 outweigh the costs.

Should you require further information in relation to this matter, please contact Food Safety Standards and Regulation, Health Protection Branch, Department of Health on [redacted]

[redacted]