Government of **Western Australia**
Department of **Health**

Food Standards Australia New Zealand
Submissions
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Dear FSANZ Submissions

PROPOSAL P1028 – INFANT FORMULA

Thank you for providing the Department of Health (DOH) Western Australia with the opportunity to provide comment on this 2nd Call for Submissions on Proposal P1028 – Infant Formula. The department acknowledges the significant amount of work undertaken by the project team at FSANZ in the review of this standard.

The structure of this response is as follows:

General Points for Consideration
This section outlines general items relevant to P1028 and the Australia and New Zealand Food Regulation Ministerial Council Policy Guidelines for the Regulation of Infant Formula Products.

Overview DOH WA Responses
This section provides a summary table of the DOH WA responses to P1028.

Comments specific to: Document 2nd Call for Submissions (2nd CFS) Proposal P1028
This section provides greater detail and rationale for all summary table responses for the 2nd CFS document. All numbering used reflects that of the 2nd CFS.

Comments specific to: Supporting Doc 2 Nutrient composition for Infant Formula Products
This section provides greater detail and rationale for all summary table responses for Supporting Document 2 (SD2). All numbering used reflects that of SD2.

Comments specific to: Supporting Doc 3. Labelling for Infant Formula Products
This section provides greater detail and rationale for all summary table responses for Supporting Document 3 (SD3). All numbering used reflects that of SD3.

General Points for Consideration

Independent Expert Working Group – The work required to undertake this review is extensive and requires a high level of technical expertise. The establishment of an independent expert working group although not currently permitted under the FSANZ Act would have greatly assisted FSANZ in examining the evidence and providing recommendations to the review. Newborn babies and developing infants are our most

vulnerable population group, with new research knowledge emphasising the importance of early nutrition in every aspect of their development. Clinical studies to investigate dietary levels of nutrient intake for infants are impractical and thus careful consideration of the scientific literature together with an in-depth understanding of human milk composition and pre-clinical studies is needed to provide guidance and inform recommendations. Although very experienced in their roles, it is unreasonable to assume that this level of expertise exists amongst jurisdictional officers.

The establishment of an independent expert group would have supported this review in terms of providing an unbiased and expert critical review of the evidence. Further consideration of potential mechanisms to explore the establishment of such expert groups in future could be considered as part of the FSANZ Act review.

Australian Expertise – Following on from the advantage on an independent expert working group is the recognition of the work done by Australian researchers in internationally setting standards for Australian national policy that influences infant feeding on an international scale. (Binns 2018, Geddes, Gridneva et al. 2021) Given this strong legacy as a world leader in infant feeding research it is important that we continue to lead the world in ensuring that regulations to protect infants who are receiving products that replace breastmilk are true to the evidence base and reflect only the latest scientific research.

Level of Evidence – Breastmilk provides the optimum nutrition for the first six months of infant life and provides the gold standard reference for the formulation of infant formula however "*it is also important to consider that an identical intake level of substrate in infant formula as observed in human milk does not by itself ensure safety and suitability"* (Carlson, Schipper et al. 2021)(p2087).

Making decisions regarding a vulnerable population where there has been no evidence of harm or no new studies, is not a paradigm for making ethical or food safety decisions. The permission to allow sheep milk as a protein source where this does not have an established history of use in infant formula products is an example and if presented to a human ethics review committee for a research trial would undergo a high level of scrutiny. Irrespective, there are several proposed changes being ushered in by FSANZ throughout the 2nd CFS and supporting documents of P1028 with the rationale for change being based on *"no new evidence has been provided within the 1st CFS".* In these instances, it would have been prudent for FSANZ to conduct a review of all the existing evidence and/or await new evidence before making changes.

Regulatory Concern – The DOH WA has referred to infant formula products throughout this document to collectively refer to infant formula and follow on formula given infant formula can be provided from birth – 12 months and follow on formula is an unnecessary product.

Confidential Commercial Information – Section 114 of the FSANZ Act is acknowledged however the provision of '*confidential information given to FSANZ provided an exposure estimate for trehalose when present in infant formula products as a cryo-preservative for LAM*' (2nd CFS, p27) exhibits a lack of transparency and does not instil confidence in the decision-making processes surrounding the protection of vulnerable infants.

Taxonomy – Of note, throughout the document breastmilk is written as two words, whereas breastfeeding and breastfed are written as one whole word. In an effort to reflect the wholistic nature and optimum source of nutrition, FSANZ could consider the use of the word 'breastmilk' as one word, which is current best practice in most peer review journals. Similarly, the method of infant feeding using infant formula, which is

well known not to be a complete nutritive substance, is presented as a hyphenated word; 'formula-fed', and once again it would be preferential to demonstrate the incompleteness of this by presenting it as 'formula fed'.

Incorrect Presentation of Information – In section 2.3.4 the information presented regarding low lactose or lactose free formulas was incorrect and the use of these formulas was not commensurate with the specified condition of cow's milk protein intolerance.

Overview DOH WA Responses

The following table outlines the DOH WA response to the individual proposals outlined by FSANZ in the 2nd CFS and supporting documents. DOH WA has not addressed all areas requiring a response and has focussed on those of greatest concern where this is a proposed change to the standard and/or where DOH WA have previously made comment.

FSANZ Proposal	**Department of Health WA Response**
2nd Call for Submissions Document	
2.3.4 Composition: low lactose or lactose free	**Does not support** the availability of lactose free and low lactose products as general infant formulae. These modified formulae should be included in the SMPPi category.
6.1 Food additives	**Does support** the proposal to remove carry-over permissions for food additives.
11.1 Transitional arrangements	**Does not support** a five year transitional period.
Supporting Document 2. Nutrient Composition	
Guidance Upper Levels (p13)	**Does not support** GULs being exceeded due to high or variable contents in nutrients of infant formula products.
4. Macronutrients Table 4 (p18)	
Linoleic Acid	**Does not support** the proposal for a minimum of 90mg/100kJ of linoleic acid; and maximum of 330mg/100kJ.
4.1 Carbohydrate Source	**Does not support** Draft Standard 2.9.1 Division 2, 2.9.1-5 that does not prescribe a specification for type and amount of carbohydrate to be included in infant formula products.
4.4 Protein Source	**Does support** the proposal for the Standard to clearly state the protein sources that have undergone pre-market assessment and are permitted in infant formula products (including special medical purpose products).

	Does not support the introduction of sheep milk as a permitted protein source without further regulatory investigations.
4.5 Docosahexaenoic Acid (DHA)	**Does not support** the retention of the voluntary permission for DHA in infant formula products.
5. Micronutrients Table 5 (p36)	
Vitamin C	**Does not support** the proposed Vitamin C range of 1.7 to 17 mg/100 kJ in infant formula products.
5.1 Vitamin A	**Does not support** the proposed Vitamin A range of 14 – 43ug RE/100kJ in infant formula products.
5.1 Vitamin B12	**Does not support** the proposed Vitamin B12 GUL of 0.36ug/100kJ in infant formula products.
5.4 Niacin	**Does support** the proposed Niacin range of 70 – (GUL) 359ug/100kJ in infant formula products.
5.7 Iron	**Does not support** the proposed iron range of 0.2 – 0.5mg/100kJ in infant formula products.
7. Nutritive Substances Table 7 (p59)	
Taurine	**Does not support** the retention of the voluntary permission for Taurine in infant formula products.
Nucleotides	**Does not support** the retention of the voluntary permission for nucleotides in infant formula products.
Lutein	**Does not support** the retention of the voluntary permission for Lutein in infant formula products.
Supporting Doc 3. Labelling for Infant Formula Products	
Specific labelling requirements in Standard 2.9.1- Warning Statement *Breast milk is best for babies*	**Does support** retaining the statement *breast milk is best for babies but changing this to reflect best practice word use of '**breastmilk**' is best for babies.*
Table 2. (piii) & 5. (p25)	**Does not support** the optional format of Draft Standard 2.9.1 – 24 that does not require a statement of ingredients listed in descending order of ingoing weight.
Table 2. (piii) 9.5 Stage labelling (p61)	**Does not support** stage labelling and encourages alignment with the WHO International Code for the Marketing of Breastmilk Substitutes by having manufacturers use ***age***_labelling instead.
10. Therapeutic claims	**Does support** nutrition content, health, and therapeutic claims to ***not*** be permitted on SMPPi.

Comments specific to:
Document 2nd Call for Submissions Proposal P1028

1.2 Reasons for preparing the Proposal (page 5, paragraph 1)
The DOH WA notes in the 2nd CFS, the scope to consider the application of the Ministerial Policy Guideline on the Regulation of Infant Formula Products when clarifying some standards. With regard to this point, DOH WA brings to the attention of FSANZ the April 4, 2023 FMM and the consensus for the convening of *a FRSC working group to examine the evidence required to substantiate whether an infant formula product has a beneficial role in the normal growth and development of infants including considering the cumulative effects*.

Dot point 2, paragraph 3
The reason for the revised standard is outlined as follows:

- require adequate information to ensure their safe preparation and use, and enable parents/carers to make an informed choice

The ability of parents to make informed choices is paramount and should be listed as a separate dot point to highlight this importance.

2.3.4 Composition: low lactose or lactose free (page 15)

- DOH WA does not support the availability of low lactose & lactose free products as general infant formulae. These modified formulae should be included in the SMPPi category.

The DOH WA does not support (as per the DOH WA submission in the 1st CFS) the availability of lactose free products on the open market, and after further examination extends this to include low lactose products. **These infant formula products should be considered SMPPi for the reasons summarised and detailed below**.

In summary:

- concerns about safety and growth in infancy should not be restricted to insufficient weight gain,
- the removal of a whole macronutrient source of energy cannot be considered ethical or safe for vulnerable infants.
- low lactose and lactose free formulas should be included in the SMPPi category given
    - the need to seek advice from a health professional before introducing a SMPPi can effectively positively prolong breastfeeding duration,
    - there are minimal long-term longitudinal studies regularly being conducted on the growth and development outcomes of infants fed low lactose/lactose free formula.
- the potential that Australia's increasing infant obesity rates need to be considered in the context of increasing use of low lactose & lactose free formulas (or indeed all formula feeding).(Rito, Buoncristiano et al. 2019)
- good longitudinal research in formula fed infants which investigates outcomes other than safety and growth insufficiency are rare and decisions made in the absence of this evidence are not justified and not without long term consequence or government liability.
- the lack of parent capacity to clearly interpret and identify the correct age for stage infant formula has serious implications for infant health and including low

lactose & lactose free formulas as SMPPi will help reduce any unintentional risk to infants.

- Specialised formulas attract a higher price and if included in the general category of formulas parents may inadvertently being paying for a formula that is not only costly but unnecessary.

Extended Rationale of Summary Points

The importance of lactose

It is common knowledge that the formulation of infant formula is founded on the concept of mimicking breastmilk as closely as possible. It makes no sense then that when formulating infant formula to be as close as possible to breastmilk, to remove lactose, the carbohydrate source making up the largest provision of carbohydrate energy of the three macronutrients (40%). See Table 1 below.

Table 1. The Macro-Nutrient Content of Milk from Domestic, Laboratory and Aquatic Mammals Compared to Human Milk.

Milk Composition (g/L)			
Mammal	Lactose	Protein	Fat
Women	70	8	41
Horse	62	19	13
Pig	55	56	83
Cow	48	32	37
Goat	41	29	38
Sheep	48	55	74
Dog (she-wolf)	38	75	95
Rabbit	22	103	151
Harp Seal	1	87	422

Compositional data table comparing mammalian milks excerpt from: (Hale and Hartmann 2007).

Carbohydrates make up the greatest amount of content in human breastmilk and lactose is the most prominent as infants have not yet developed the gastrointestinal tract to ingest glucose and possibly other carbohydrates.(Kim and Yi 2020) There are many **known** integral health functions of lactose in breastmilk including supporting intrinsic immunity, the significant neurological development of the infant brain, of which the majority of growth (75%) occurs after birth and the augmentation of the gut microbiome.(Hale and Hartmann 2007, Cederlund, Kai-Larsen et al. 2013, Romero-Velarde, Delgado-Franco et al. 2019)

The importance of including lactose in formula cannot be overlooked, and the opportunity for all formula fed infants to have the ability to obtain optimal growth outcomes (without receiving breastmilk) should be protected by including low lactose & lactose free formula in the SMPPi category. In addition, lactose in formula promotes calcium absorption, has a prebiotic action, appears to promote a faecal microbiome and metabolome closer to that of breastfed infants, and promotes adaptive metabolic response.(Sherman, Anderson et al. 2015) (*secondary source reference*)

Lactose intolerance

Lactose is readily digested in almost all infants as lactose intolerance (down regulation of lactase expression) is rare as primary lactose[1] intolerance occurs in most humans post weaning. Secondary lactose intolerance is also rare and results from a loss of

[1] Primary lactose is sometimes referred to as primary hypolactasia and primary lactase deficiency.

lactase activity due to intestinal injury (e.g. viral gastroenteritis, coeliac disease).(Kim and Yi 2020, BMJ Publishing Group 2022)

Both conditions for lactose intolerance are aetiologically rare in infants and demonstrate the need to have low lactose & lactose free formulas included in the SMPPi category to ensure that removal of the most predominant carbohydrate found in breastmilk, is not mistakenly implemented. All best practice management recommendations highlight that the temporary replacement of lactose by other carbohydrates is only justified in cases of severe intolerance symptoms, if the condition is then, a true expression of lactase deficiency.(Romero-Velarde, Delgado-Franco et al. 2019, BMJ Publishing Group 2022)

Two further categories of lactose intolerance include congenital lactose intolerance, which is extremely rare and occurs in infants from birth, of which survival is impossible without lactose-free feeding. Developmental lactose intolerance occurs in preterm infants of less than 34 weeks gestation due to underdevelopment of the lactase enzyme and oral lactase supplementation is considered a first line of treatment.(BMJ Publishing Group 2022)

In short, there is no justification for the low lactose & lactose free infant formula to be generally available and it is clearly indicated that these formulas should be for medical purposes only, managed by a qualified health professional, and most often for a limited time period.

Unwarranted removal of lactose from the infant diet

In recent years, there has been an increase in the use of reduced lactose free or low lactose formulas, even in healthy infants and young children who fully express the lactase enzyme. Misdiagnosis of childhood functional disorders, difficulties in infant behaviour related to apparent formula/breastmilk intolerance, combined with the level of distress parents perceive in these situations, and the readily availability of formulas devoid of lactose that can be purchased without health professional support ease the introduction of these formulas.(Polack, Khan et al. 1999, Romero-Velarde, Delgado-Franco et al. 2019)

Interestingly, a randomised control trial that investigated the role of lactose-free (LF milk) or soy-based lactose free (LF Soy) and milk based lactose- containing (control) milk formulas in alleviating the common fussiness, crying and need for attention often experienced by new born infants, found no effect on these behaviours. After 14 days with the study formula as the sole source of nutrition, there were no significant differences among the three formulas in reducing caregivers' reports of difficult infant behaviours and caregivers' distress.(Sherman, Anderson et al. 2015)

There are numerous studies citing mother and medical indication for soy based formulas on the basis of occasional symptoms or personal preference. This is further supported by a 2012 report outlining that lactose free formula accounted for approximately 7% of worldwide, and 19% of USA formula sales, despite a lack of evidence for widespread lactose intolerance (reference unavailable*; Nielsen Global Track and Global Snapshot, Nielsen Company 2012).*

Burgeoning childhood obesity; a relationship with low lactose infant formula?

It is important to consider implications of the removal of lactose from the infant diet particularly when this is the most abundant source of energy in breastmilk and the large volumes of formula consumed in relation to infant body weight. Typically this is between 150-200ml/kg/day for a young infant solely receiving infant formula which is equal to approximately 11 – 14L/day for a 70kg adult.(Munblit, Crawley et al. 2020)

Lactose is required for numerous important health outcomes in the human infant beyond provision of energy, both in the short term and long term. Primarily it is an energy source that unlike any other carbohydrates, doesn't elicit a feedback response due to its lack of sweetness. In essence, lactose does not set infants up for a long-term craving of sweet food. It is the least cariogenic of all fermentable sugars and possesses a low glycaemic index.(Romero-Velarde, Delgado-Franco et al. 2019) Numerous other physiological roles for lactose exist but outlining them is beyond the scope of this response, however of interest is emerging research which potentially indicates a relationship between low lactose & lactose free formula and increasing obesity rates.

A recent study of 15,246 infants enrolled in in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) of the United States investigated whether glucose-based lactose-reduced infant formula made with corn syrup[2] solids (CSSF) is associated with increased obesity risk compared with non-CSSFs that are lactose based. Uniquely this robust study looked at children introduced to formula upon breastfeeding cessation at three months, the introduction of cows milk based formula through 12 months and in their final year of WIC eligibility at age four years. Obesity risk was higher at age two years among children with any CSSF issuance (RR: 1.10; 95% CI: 1.02, 1.20) than children with no CSSF issuance. This risk attenuated slightly but remained significant through to age four years (RR: 1.07; 95% CI: 1.01,1.14), independent of maternal weight status, total formula issued and breastfeeding duration, and were not modified by child race or sex. Obesity risk increased slightly with each additional month of CSSF exposure, reaching 16% higher risk (RR: 1.16; 95% CI: 1.05, 1.28) at age two years for children with 12 months of CSSF.(Anderson, Whaley et al. 2022)

Proposed hypotheses for this increase in obesity in infants fed low lactose formula include

- an effect on the characteristics of the infant gut microbiome, including alpha diversity which have also been associated with rapid growth during the first year of life, a known risk factor for obesity,
- the CSSFs contributing to rapid weight gain in early infancy that predisposes infant to later risk of obesity,
- CSSFs leading to altered and undesirable metabolic programming through a higher glycaemic index compared with other formulas, and
- CSSFs assisting in the developing learned preference for intense sweetness greater than lactose and growing desire for foods and beverages with added sugars into childhood.(Anderson, Whaley et al. 2022)

Given that the benefit of the formula change to low lactose & lactose free is ever rarely formally challenged, as the infant grows it is likely they will be introduced to follow on milks and toddler milks that are lactose free, and no doubt a diet devoid of dairy. Unwittingly and without purpose, a dietary preference is transmitted to the infant that can have long lasting lifetime negative nutrition and growth effects.

Formula choice

Australian research clearly highlights the need for modified infant formulas to be included in the SMPPi category as evidenced by a study of 153 parents who were fully

[2] Corn syrup is made from the starch of corn and contains varying amounts of glucose, maltose and higher oligosaccharides, depending on the grade. It is the staple ingredient in the US used to prevent crystallisation and to sweeten many foods. In Australia the equivalent is cane sugar.

or partially feeding (i.e. still providing breastmilk) infants 0-6 months of age and reported the formula tin as the most cited source of information or advice for choosing a type of infant formula (96.6%).(Appleton, Russell et al. 2022)

Despite 79.2% of parents receiving information or advice about formula feeding from a health professional, only 18.9% received advice before starting formula. The parents who were mixed feeding (breastmilk and formula) had 3.8 times higher odds of getting any advice before the introduction of formula than those who were full formula feeding. Parents who did get advice before starting formula were more likely to introduce formula later than those who did not get advice. Over 50% used a specialised infant formula.

This study from Australia highlights the importance of getting advice before purchasing a formula that is readily available and potentially associated with poorer infant development outcomes. The ready availability of low lactose & lactose free formulas will afford an easy path to purchasing a specialised infant formula which can unwittingly lead to a shortened breastfeeding duration, the unnecessary avoidance of nutrients (i.e. lactose), and the potential for unknown long term problems, with that of obesity currently being investigated as one of them.

P1028 Attachment 1 - *Rapid Systematic Evidence Summary on Infant Formula Stage Labelling* and *Proxy Advertising Supporting Document 3* (*Labelling for Infant Formula Products*) together with previous work financially supported by FSANZ (Malek, Fowler et al. 2019) clearly outlines a lack of parent understanding of stage labels leading to inappropriate formula choice for age. It is questioned in Attachment 1 (page 9) if stage labelling is usurping breastmilk and if greater education from health professionals is required to prevent the use of later stage products when not required. Both issues identify serious public health nutrition issues that will clearly impact short- and long-term infant health if regulatory controls (marketing and labelling of infant & follow on formula) are not enacted.

6.1 Food Additives

- DOH WA does support the FSANZ proposal to remove the carry-over permissions for food additives.

11.1 Transitional arrangements

- DOH WA does not support the five year transitional period

DOH WA does not support the five year transitional period especially given that infant formula has a use by date of approximately 12 months since the date of manufacture and therefore a high product turnover.

Comments specific to:
Supporting Doc 2 Nutrient composition for Infant Formula Products

3.2 Guidance Upper Limits

- DOH WA does not support GULs being exceeded due to high or variable contents in nutrients of infant formula/and or follow on formula.

To ensure infant safety, how will GULs be monitored for compliance so that nutrient content levels are not regularly exceeding GULs and for no apparent reason? The inclusion of unnecessary amounts of components, may put a burden on metabolic and other physiological functions of the infant and will reduce the margin of safety. These maximum values should be based on available scientific data on infants' requirements and the absence of adverse effects.

Part B Infant Formula
4. Macronutrients
Table 4 – Macronutrients: Summary of submitter comments and FSANZ response

Linoleic Acid (LA)(p18)

- DOH WA does not support the proposal for a minimum of 90mg/100kJ of linoleic acid; and maximum of 330mg/100kJ

In the 1st CFS, DOH WA expressed opposition to the introduction of a minimum level considerably lower than the average for Australian and New Zealand breastmilk levels and not reflective of the most recent EU (2016/27 Annex I&II) revision. Similarly, DOH WA expressed concern regarding the proposed maximum level of 330 mg/100 kJ which is higher than the maximum found in breastmilk and in EU regulations and requested a rationale for the proposal of these by FSANZ.

Not included in the *July 2021 SD1: Nutrition Assessment* and *April 2022 SD2 Nutrient composition for infant formula products* documents was the review of available evidence on the effects of linoleic acid in an infant diet on infant health outcomes in relation to the recently adapted changes in regulations for the addition of linoleic acid (LA) to infant formula.(Carlson, Schipper et al. 2021) Despite being industry funded (Danone Nutricia Research) the review provided a comprehensive overview of the outcomes of crossing recognised lower or upper levels of LA in infant formula which could increase the risk of negative short and long term consequences. Observational studies presented in the review demonstrated an association between high LA in breastmilk with poor neurocognitive outcomes, excessive weight gain and obesity risk, and an increased risk for atopic eczema and allergic responses.

Without going into detail, the review article outlines the complex interplay between the intakes of n-6 and n-3 Fatty Acids (FA) on circulating Docashexanoic Acid (DHA) levels, which is not just a direct result of the LA/α-LA ratio but also depends on the total preformed dietary Polyunsaturated FA (PUFA) provided.

In light of this review and the considerable complexity of determining required levels of fatty acids infant formula, it would be prudent for FSANZ to reconsider the proposed minimum and maximum LA levels.

4.1 Carbohydrate source (and level Not Specified [NS])

- DOH WA does not support Draft Standard 2.9.1 Division 2, 2.9.1-5 that does not prescribe a specification for type and amount of carbohydrate to be included in infant formula
- DOH WA requests the introduction of specific carbohydrate source(s) and amount.

Given lactose is the major contributing source of carbohydrate and carbohydrate contributes ~40% of the energy in breastmilk, not setting a level and type for carbohydrate is potentially a health risk for infants and an accountability risk for the government. Although alignment should not be a guiding principle it is important to note that both Codex and European Food Safety Authority (EFSA) have strict recommendations for the types of carbohydrate provided in infant and follow on formula.

On page 23, it is noted that *"The amount of carbohydrate within infant formula products, regulated by Standard 2.9.1, is self-limiting and dependant on the energy, protein and fat content of the product. Considering this, infant formula would not have a*

"high content" of glucose. There are also directions for use on the label and infant feeding guidelines to mitigate the risk of cariogenic health consequences."

However, given the rise of obesity in young children, setting a guideline for carbohydrate amount and type will minimise any variations to the incorporation of free sugars, including glucose. A growing body of research clearly indicates detrimental short- and long-term health effects due to providing high GI carbohydrates early in life. Replacement of lactose with glucose polymers can possibly lead to a change in intestinal microbioata and reduced calcium absorption resulting in an initial poor nutritional status and a long-term link to chronic disease. There is still considerable research required to elucidate the effects of lactose-containing or lactose-free formula on insulin and glucose levels, and the relevance of early exposure to these on childhood metabolic programming and exposure to sweet high GI food products.(Romero-Velarde, Delgado-Franco et al. 2019) Robust, long term longitudinal cohort studies that follow infants throughout these early years are expensive, draining on participants and therefore rare. It is only with more of these studies that long term implications of removing important nutrient groups and/or nutrients becomes apparent and provide much needed evidence for policy makers.(Anderson, Whaley et al. 2022)

A suggestion of a minimum standards for carbohydrate and lactose concentrations in infant formula must be included in the regulations (reference limit, lactose >53.6g/L).(Boss, Gardner et al. 2018)

4.4 Protein source

- DOH WA supports the proposal for prescribing the protein sources that have undergone pre-market assessment and are permitted in infant formula products (including special medical purpose products).
- DOH WA does not support the introduction of sheep milk as a permitted protein source without further regulatory investigations.

There is considerable support from FSANZ to include sheep milk as a protein source in infant formula products with the decision based on the equivalent composition of sheep, cow and goats milks but not with breastmilk (p 29). However, further investigation of the protein fraction of mature milk from sheep indicates that it is quite a long stretch to suggest that human milk and sheep milk are comparable.(Claeys, Verraes et al. 2014) In Table 3 of the paper by Claeys et al (2014) it is quite clear there are considerable differences between sheep and human milk and that differences between species seem most likely related to differences in total protein content. In the words of the late Professor Peter Hartmann[3] "*We should be riding the cows and milking the horses"* in reference to the closest source of milk resembling breastmilk for infants.

The DOH WA acknowledges the importance of facilitating trade and innovation however as the department has stated in previous submissions, the Western Australia Department of Health continues to strongly advocate that the priority goal of the FSANZ Act must remain public health and that other goals such as trade should be subordinate to public health. It is unclear if the introduction of sheep milk has undergone any premarket assessment. Similarly, long term studies of infants fed on

[3] https://www.uwa.edu.au/news/article/2021/august/remembering-the-exceptional-work-and-life-of-emeritus-professor-peter-hartmann

sheep milk would be highly desirable given the Good Clinical Practice and ethical requirements of such an investigation.

4.5 Docosahexaenoic Acid (DHA)

- DOH WA does not support the retention of the voluntary permission for DHA in infant formula products.

In the 1st CFS, DOH WA requested a review of the evidence on DHA as an essential/partially essential nutrient and whether it should be made mandatory and, in this submission, have chosen **not to** support the voluntary permission for DHA. Breastmilk is the only source of DHA for newborn infants until the introduction of solids. For this reason, infants receiving infant formulas must receive adequate amounts of DHA to cover their nutritional requirements. The most recent guidelines EU (2016/27 Annex I&II) revision by the European Food Safety Authority (EFSA) (2016) recommend that infant formulas and follow on formulas must contain a minimum (and maximum) level of DHA and it would be timely for FSANZ to consider a review of evidence on whether DHA is an essential/partially essential nutrient, and as such, whether these ingredients should be mandatory.

5. Micronutrients

Table 5 – Micronutrients: Summary of submitter comments and FSANZ response

5.1 Vitamin A

- DOH WA does not support the proposed Vitamin A range of 14 – 43ug RE/100kJ in both infant formula products.

In the 1st CFS, DOH WA opposed the proposed Vitamin A range of 14 – 43ug RE/100kJ based on the most recent EU maximum of 27.2 ug RE/100kJ and the potential for the proposed level to exceed the UL set by the NHMRC for infants in the age range of 6 – 12 months. DOH WA continues to oppose the range proposed in the 2nd CFS.

5.2 Vit B12

- DOH WA does not support the proposed Vitamin B12 GUL of 0.36ug/100kJ in infant formula products.

DOH WA continues to oppose the upper GUL for Vitamin B12 based on the fact that it does not reflect the gold standard of levels found in breastmilk and introduces an unnecessary level of unnecessary substances into the infant's system.

5.4 Niacin

- DOH WA does support the proposed Niacin range of 70 – (GUL) 359ug/100kJ in infant formula products.

5.7 Iron

- DOH WA does not support the proposed iron range of 0.2 – 0.5mg/100kJ in infant formula products.

DOH WA acknowledges the complexity of determining a required and safe level of iron to be provided in infant formula and recognise the importance of getting this right in order to support optimum infant growth, neurological development and immunity. It is unclear why FSANZ has not looked to our national research authority when considering setting the level for this mineral (and other nutrients) and incorporated the evidence from the NHMRC Nutrient Reference Values (NRVs). DOH WA has concerns regarding the potential for excess iron intakes and the associated negative health consequences.

Vitamin C

- DOH WA does not support the proposed Vitamin C range of 1.7 to 17 mg/100 kJ in both infant formula products.

DOH WA continues to oppose the proposed minimum which is lower than potential infant needs and the Codex minimum of 2.5mg/100kJ. It also continues to oppose the high maximum of 17mg/100kJ in comparison with other international standards and questions the principle of avoiding unnecessary excesses of substances in infant formula.

7.1 Taurine

- DOH WA does not support the retention of the voluntary permission for taurine in infant formula products.

In the 1st CFS, DOH WA requested a review of the evidence on taurine as an essential/partially essential nutrient and whether it should be made mandatory and, in this submission, have chosen **not to** support the voluntary permission for taurine. Breastmilk is the only source of taurine for newborn infants until the introduction of solids and in a recent review, a possible relationship between limited taurine levels during infant development could increase the risk of chronic diseases during adulthood was purported. It was also noted that the addition of taurine to infant formula was carried out in an absence of scientific evidence and that further research would help elucidate the benefits of taurine in infant development and supports it considered addition to infant formula.(Tochitani 2022)

Nucleotides

- DOH WA does not support the retention of the voluntary permission for nucleotides in infant formula products.

Subsequent to the *July 2021 SD1: Nutrition Assessment* and *April 2022 SD2 Nutrient composition for infant formula products* documents is a review by Hodgkinson, Wall et al. (2022) that outlines the function and concentration of nucleotides in human breastmilk. The review clearly outlines continued gaps in knowledge regarding nucleotides but identifies that the addition of monomeric nucleotides to infant formula, which supplements the already present levels of total potentially available nucleotide in IF, may contribute to biological activities including immune function, lipid metabolism, intestinal function and iron adsorption.

Lutein

- DOH WA does not support the retention of the voluntary permission for lutein in infant formula products.

In the 1st CFS, DOH WA requested a review of the evidence on lutein as an essential/partially essential nutrient and whether it should be made mandatory and, in this submission, have chosen **not to** support the voluntary permission for lutein. Since the *July 2021 SD1: Nutrition Assessment* and *April 2022 SD2 Nutrient composition for infant formula products* documents a systematic review by Zaidi, Stroh et al. (2022) has conclusively indicated the presence of lutein as a carotenoid present in breastmilk. As breastmilk is the only source of lutein for newborn infants until the introduction of solids and plays a probable role in cognitive and visual development, the DOH WA does not support the retention of the voluntary permission for lutein in infant formula products. It is timely, that as the NHMRC undertakes a phased review of NRVs that lutein is included and adopted more widely.

Comments specific to:
Supporting Doc 3. Labelling for Infant Formula Products

Table 1. Specific labelling requirements in Standard 2.9.1

- DOH WA does support retaining the statement breast milk is best for babies but changing this to reflect best practice taxonomy of using the word **'breastmilk'** is best for babies.

Table 2. and Table 5.

- DOH WA does not support the optional format Draft Standard 2.9.1 – 24 that does not require a statement of ingredients listed in descending order of ingoing weight.

The optional format of not listing vitamins and minerals in descending order does not align with Section 1.2.4-5 of the Food Standards Code, and makes it difficult to make comparisons between products by consumers which is also in conflict with the food regulation system objective of:

- help consumers make informed choices about food by making sure they have information they need and are not misled.

9.5. Stage Labelling

- DOH WA does not support stage labelling and encourages alignment with the WHO International Code for the Marketing of Breastmilk Substitutes by having manufacturers use age labelling instead.

It appears from P1028 Attachment 1 - *Rapid Systematic Evidence Summary on Infant Formula Stage Labelling* and *Proxy Advertising Supporting Document 3* (*Labelling for Infant Formula Products*) there is confusion with stage labelling that uses the numbers 1, 2 and 3 to indicate the stage of the infant the formula is relating to. Similarly, in section 9.5.2 Australian and New Zealand consumer evidence '*suggests that caregivers generally understand that each stage has a specific nutrient composition designed to meet the needs of children at a certain age*' (p62) however this is not the case and is misleading as both infant formula (0 – 6 months) and follow on formula (from 6 months) have virtually the same ingredients. This is outlined in the proposed nutrient composition table of the draft standard of the Code (See Table 7, 2nd CFS p35). To minimise caregiver confusion and align more closely with the WHO Code for the Marketing of Breastmilk (World Health Organization 1981) the DOH WA supports age labelling instead of stage labelling with an overall preference for the removal of follow on formula given it is not recommended by Australian national infant feeding guidelines and the lack of distinction between formula for infants aged under 12 months of age.

10. Therapeutic claims

- DOH WA supports nutrition content, health, and therapeutic claims to not be permitted on SMPPi.

It will be of significant regulatory importance to ensure the mandatory statements and declarations for SMPPi (2.9.1-38[c,d]) meet the need for the provision of the correct formula for the dietary management of a medically diagnosed disease, disorder, or condition and there that is a conclusive evidence base to support this mandatory statement.

For example, the Aptamil Gold+ label for Colic & Constipation outlines the formula which has partially hydrolysed cow's milk protein and contains ingredients (unclear

which) specifically designed for the dietary management of colic and constipation. Given colic and constipation are not on the same causal pathway poorly substantiated declarations, such as those on the Aptamil Gold+ imply an effective treatment but may in effect cause harm by delaying an appropriate diagnosis of an underlying condition.(Munblit, Crawley et al. 2020)

Labelling to Indicate the Medical Purpose of Low Lactose & Lactose Free Formula Included as SMPPi

As per the Draft variation to the standard in the ANZFS Code section 2.9.1-38 Mandatory statements and declarations— special medical purpose products for infants (2nd CFS p113) with regard to SMPPI a product must include:

> "(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated;
>
> (d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (c)"

It will need to be clear for low lactose & lactose free formulas included in the SMPPi category that these are not indicated for lactose intolerance and some overarching advisory will need to be considered given:

a. *Congenital lactose intolerance*: is a very rare autosomal recessive disorder that is characterised by the complete absence of the enzyme lactase with very poor prognosis. Infants with this disorder are extremely unwell from birth.
b. *Developmental lactose intolerance*: occurs in preterm babies of less than 34 weeks gestation and is a consequence of prematurity. Preterm infants should continue to receive breastmilk in all cases if available.
c. *Secondary lactose intolerance*: is a condition secondary to any form of gastrointestinal mucosal injury. Breastfed infants should continue to receive breastmilk in all cases.
d. *Primary lactose intolerance*: is the normal gradual reduction seen in lactase production during the progression to adulthood for about 70% of the world's population. Its presence depends on ethnicity, and is rare in populations with predominance of dairy foods in the diet (e.g. Northern Europeans). Reduced lactase production occurs from 2 years onwards and breastfed children should continue to receive breastmilk in all cases.(Boss, Gardner et al. 2018, Boss, Hartmann et al. 2020)

This information indicates that low lactose & lactose free formula are rarely required for an extended period and that only a small group of infants will require lactose free formula for an extended period. Correspondingly, there is no aetiological requirement for a low lactose infant formula and a transition to removing these defunct infant formulas from the food supply would be pioneering on behalf of FSANZ.

Thank you for considering the above comments. Should you wish to discuss any of these comments please do not hesitate to contact [redacted]

Yours sincerely,

[redacted]

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