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 Western Australia (DOH) with the opportunity to provide input into this consultation. Please find the DOH's comments in response to Proposal P1028 Infant formula – Consultation paper – Call for Submissions (CFS). The DOH commends Food Standards Australia New Zealand (FSANZ) for undertaking this important Australia New Zealand Food Standards Code (the Code) body of work on infant formula products.

Overall Summary:

The DOH acknowledges that breast feeding is the normal and recommended way of feeding infants. Where an infant is not breastfed or is partially breastfed, commercial infant formulas are the alternative source of essential nutrition required for growth and development. The DOH considers that protecting infant health and safety are the pivotal drivers for all decision making concerning regulatory changes to infant formula composition, labelling and representation. Given the high vulnerability of infants, including sick and immature infants, the DOH notes that where there is a lack of evidence, a precautionary approach is warranted. The DOH is committed to protection, promotion and support of breastfeeding, and notes the marketing of infant formula continues to be an ongoing issue for food regulators.

The DOH considers breast milk as the primary reference for determining compositional requirements of infant formula products; and that comparison of breast milk from Australian and New Zealand mothers should be the specific primary reference where available.

The DOH also highlights the importance of FSANZ having regard to the current Ministerial Policy Guideline – Regulation of Infant Formula Products (Ministerial Policy Guideline which states:

> *"It is recognised that breastfeeding is the normal and recommended way to feed an infant and that the regulation of breastmilk substitutes, such as infant formula, has implications for health outcomes for all infants, formula-fed and breastfed. Infants are a vulnerable population group because they have immature immune systems and organs and are dependent on adults for feeding. For some infants, infant formula products may be the sole or principal source of nutrition. For these reasons there is a greater level of risk to be managed compared to other population groups. The regulatory framework for infant formula products should include requirements commensurate with this level of risk for the composition, labelling, advertising and promotion of infant formula products"*

In addition to the mandate of protecting the health and safety of vulnerable infants, having well-designed and evidence-based regulation and supply of infant formula products will support the integrity, innovation and competitiveness of infant formula industries now and into the future. The recent infant formula supply issues in the US further highlights the importance of Australia and New Zealand maintaining trust in its reputation for high nutritional quality and safety standards for products which are fit for purpose.

Whilst the importance of infant formula products as essential products is acknowledged, the DOH supports the regulation of these products in a manner which 1) places the health and development of vulnerable infants as the central and primary focus to any regulatory decision making; 2) does not adversely impact breast feeding rates; 3) meets the optimal needs of Australian and New Zealand formula fed infants; 4) recognises that due to an infant's immature body system, it is essential to ensure infants are not burdened with unnecessary substances in infant formula.

Comments in response to the Call for Submissions consultation paper (below), are underpinned by the intent of the Ministerial Policy Guideline and that regulation of infant formula has potential health impacts for all infants, formula-fed and breastfed.

Section 2. Regulatory framework

The DOH notes that infant formula is currently regulated under Standard 2.9.1 – Infant Formula Products and Schedule 29 – Special Purpose Foods in the Australia New Zealand Food Standards Code (the Code). Other standards in the Code also contain provisions related to safety and food technology for infant formula, such as Standards 1.3.1 – Food Additives and 1.4.1 – Contaminants and Natural Toxicants.
The DOH notes FSANZ preferred option in Section 2.5 where *Infant formula products* are proposed to include the following (Box 1):

Box 1.

Infant formula products are proposed to include the following:

1. Nutritionally complete infant formula products with a standard nutrient formulation which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for infants.
2. Nutritionally complete infant formula products with a modified formulation relating only to partially hydrolysed protein and/or low lactose/lactose free which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for infants.

Special medical purpose products for infants are proposed to be:

1. Nutritionally complete with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, when used under medical supervision in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the infants for whom it is intended
2. Nutritionally incomplete with a nutrient-adapted formulation specific for a disease, disorder or medical condition that is supplementary and is not suitable to be used as the sole source of nourishment.

The DOH **supports** the approach of a separate category for Special Medical Purpose Products for infants (SMPPi) which are formulated (and substantiated by generally accepted scientific evidence) to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition. The supply of infant formula for these medical conditions is essential and access retained under suitable medical supervision control.

The DOH, at this time, **does not support** FSANZ's suggested new approach to the regulatory framework for a subsection for infant formula products which are modified (Nutritionally complete infant formula products with a modified formulation relating only to partially hydrolysed protein and/or low lactose/lactose free which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for infants). The DOH highlights:

- Given the known drain on parental and carers resources during this life stage, it is essential that those purchasing and preparing the formula products are provided with sufficient and appropriate information to easily choose safe and nutritionally based formula (formulated based on generally recognised scientific evidence).
- It is important to consider whether the infant formula products standards may medicalise normal infant developmental age and stage behaviour / responses to feeding. Marketing of transient gastrointestinal infant formula for infants (e.g. for colic, anti-reflux, crying) and others (e.g. hungrier baby, comfort formula, good night milk) where there is a lack of generally recognised scientific evidence base

may be problematic. Conversely, in the instance where there is a medical problem, there may be a potential for parents and/or carers to try and persist with these types of formula without seeking timely medical review.

- Concerns related to infant formula marketing continue and have been raised recently by the World Health Organization[1], and as such, it is an important opportunity to review and ensure the new regulatory framework is robust, evidence based and fit for purpose.

The DOH notes that an independent expert advisory group review of the evidence for the modified formula products category and its use in the dietary management of a transient gastrointestinal condition would assist in strengthening the rationale to support decision making.

Section 6: Nutrient Composition

The DOH strongly supports infant formula products standards which provide optimal nutrition based on current and generally accepted scientifically substantiated evidence. Given the importance of getting this new food standard right, the DOH seeks clarification from FSANZ on the rationale and scientific evidence base for some nutrients (refer to Table 1). The DOH suggests FSANZ consider establishing an independent expert group to provide additional expert advice and help to critically review the evidence.

Table 1.

Nutrient	CFS – FSANZ position	DOH comments
Vitamin A (Retinol equivalent - RE)	14 to 43 µg RE/100 kJ in both infant formula and follow on formula.	Consider a review of the evidence on the maximum levels of RE, given there is potential confusion on the maximum levels in breastmilk that FSANZ have referenced in the CFS; that the recent EU evidence review set the EU maximum of 27.2 µg RE/100 kJ. Query whether there may be potential to exceed the UL set by the NHMRC (at 43 µg RE/100 kJ) for infants in the age range of 6 to 12 months. UL should be conservative for Vitamin A. Also, a review of FSANZ's preferred approach to exclude β-carotene from the vitamin A calculation, while retaining the permission for β-carotene as a permitted form of vitamin A in section S29–7 and provision of the justification for its addition to infant formula, and also clarify whether it creates the potential to mislead by permitting it as a form of vitamin A, but not including it in the calculation.

[1] Clark H and Ghebreyesus TR. 2022. World Health Organization. It's time to stop infant formula marketing practices that endanger our children (who.int) (extract) "**Pain point marketing** is considered to be 'A common but often subtle marketing scheme that aims to convince potential customers that they have a problem which can be solved by purchasing a product'. There has been a rise in marketing for 'specialized' and 'comfort' milks that make bold claims to solve common infant ailments and behaviours such as colic, reflux and crying, despite insufficient evidence that they are effective."

Niacin	70 – 360 µg /100 kJ in both infant formula and follow on formula.	Consider a review of the evidence to justify reducing the minimum levels of niacin from 130 µg /100 kJ to 70 µg /100 kJ, given that the EFSA concluded 2 mg/day was required to meet the infant needs (used to inform EU minimum level of 100 µg /100 kJ), and matching levels in breastmilk.
Iron	0.2 to 0.5 mg/100 kJ in both infant formula and follow on formula.	Consider a review of the evidence on the minimum and maximum levels of iron given there may be potential for some infants to reach excess iron intakes, noting that the EFSA recommends lower minimum of 0.14 mg/100 kJ and a maximum of 0.31 mg/100 kJ
Vitamin C	1.7 to 17 mg/100 kJ in both infant formula and follow on formula.	Consider a review of the evidence on the minimum and maximum levels based on infant needs and for consistency in approach regarding the impact of shelf life losses, scurvy risk safety factor, and the Codex minimum of 2.5 mg/100 kJ. Also consider reviewing the current proposed high maximum of 17 mg /100 kJ in comparison to maximum level set by EU of 7.2 mg/100 kJ, from perspective of the principle of avoiding unnecessary excesses of substances in infant formula and taking into account risk of nutrient interactions.
Vitamin B12	0.025 to 0.36 µg /100 kJ in both infant formula and follow on formula.	Consider a review of the evidence on both the minimum and the maximum levels of B12 to confirm the evidence for infant health including from the perspective of breastmilk levels of B12; and the principle of avoiding unnecessary excesses of substances in infant formula (maximum level).
Linoleic acid	90 to 330 mg/100 kJ in both infant formula and follow on formula.	Consider review of the evidence on the minimum and maximum levels based on the needs for infant health and safety, and minimum and maximum breastmilk levels in a representative population. The DOH notes there is some confusion regarding the rationale for both the minimum and maximum levels for FSANZ preferred positions; and it is unclear on what basis FSANZ has chosen a minimum level of 90 mg/ 100 kJ. 1) the minimum level considerably lower than the average for Australian and New Zealand breast milk levels, is not reflective of the levels in infant formula on the market (146 – 267 mg/100 kJ); appears to be inconsistent with FSANZ's conclusion that "*the risk of harm to infants' health due to inadequate LA or ALA intake would be low if FSANZ adopted a minimum LA amount between 110 and 140 mg/100 kJ*." and FSANZ's position that the Codex minimum of 70mg/100kJ is not a suitable level. 2) the maximum level of 330 mg/100 kJ is higher than the maximum found in breastmilk

		(300 mg/ 100 kJ) and the purpose of increasing this maximum level is unclear. The review could consider a range of 120-300 mg/100 kJ, as this would be consistent with the EU levels, given that alignment with Codex levels is not suitable.
DHA, lutein, taurine, nucleotides	FSANZ preferred position is for these optional ingredients should be remain optional	Consider a review of evidence on whether these are essential / partially essential nutrients, and as such, whether these ingredients should be mandatory.

Section 7. Labelling

The DOH considers that, in addition to having category clarity for those purchasing the infant formula for their infant, it is important for regulators to be able clearly identify what product category a product fall in for compliance and enforcement purposes. Requiring prescribed names for SMPPi would also assist in providing this clarity.

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

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