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# SUBMISSION ON PROPOSAL P1028 - Infant Formula

The Department of Health Western Australia (DOH) would like to thank Food Standards Australia New Zealand (FSANZ) for seeking comment on Proposal P1028 – Consultation paper.

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 infant health and safety are the pivotal drivers for all decision making relating to regulatory changes to infant formula composition, labelling and representation. The DOH further considers issues relating to the marketing of infant formula are of great importance, in light of the current unprecedented global transition to diets higher in milk based infant formulas.[(1)]

This submission has been prepared by the Food Unit located within the Environmental Health Directorate of the DOH. Comments in response to specific questions and preliminary views raised in the Proposal P1028 consultation paper are detailed below. Please note that due to time constraints, the DOH has not addressed all of the submission questions and there may be responses and approaches provided for the completed sections that could also be applicable to the unanswered submission questions.

**Q1.1 All Supporting Document 1 (SD 1)**
For all views presented in this SD, do you agree with FSANZ's preliminary view?
If so, indicate this in your submission and provide your reasons where appropriate.
If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

1. In general, the DOH suggests more consideration of the most recent evidence contained in the scientific opinion paper of the European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies (EFSA NDA) is required. In particular, the following recommendations that the compositional requirements for nutrients and substances should only be added to infant formula in amounts that serve a nutritional function or other benefit; and should not place a burden on the infant's metabolism or other physiological functions.
    - Minimum levels of nutrients should be used as target values, as there is no need to provide values in excess of the target value
    - Maximum levels should be regarded as upper limits as provision of excess nutrients may overload an infant's ability to excrete the nutrients i.e. excessive renal solute load.

    Based on these recommendations, along with the understanding that industry may utilise the practice of overages, DOH considers it is necessary to gather **further information** on the level of nutrients maximally present, such as at the beginning of the infant formula shelf-life, to further inform decision making.
2. The DOH continues to support the approach that if the evidence is strong enough to warrant the inclusion of a substance, for example (long chain polyunsaturated fatty acids such as DHA) in the **premium infant formula** product then it should be incorporated into the **standard infant formula**.
3. The DOH considers pre-market approval is required for any new ingredient/substance, including new sources of an ingredient/substance, as **safety is paramount** and the precautionary principle should be applied. The DOH considers that the level of evidence needs to be robust and substantial to support changes to standards regulating additions of any substance to food designed for infants. Criteria for assessing the totality of evidence should be according to an agreed internationally recognised approach and the review of evidence should follow a fully transparent model for evidence and expert opinion as the norm. Substances where there is no substantiated benefit to the normal growth and development of infants should not be permitted for addition to infant formula. The safety assessments should include allergenicity/immune response and immature gut permeability; along with the impact of a substance on other nutrients in the infant formula.[2] The emergence of potential epigenetic effects of early nutrition in the developing infant that impact on health in later life also requires consideration.[3, 4]

**Q1.2 (Section 2.2)**
Which of the following options to amend the definition (b) of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula?
(1) "satisfies by itself the nutritional requirements of infants less than 6 months of age"
(2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding "

(3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of infants from 6 months of age
(4) no change

The DOH supports a combination of Options 3 and Option 2, with the addition of the term "**around** 6 months of age", namely: "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding as part of a progressively diversified diet of infants from **around** 6 months of age.

**Section 3: Protein**

**Q1.3 (Section 3.1)**
Do you support a higher minimum of 0.5 g/100 kJ for infant formula based on isolated soy protein? Please provide your rationale?

The DOH supports the higher minimum level of 0.5 g/100 kJ for infant formula based on isolated soy protein, due to the differences in bioavailability and amino acid composition.

Additional comments: Section 3
The DOH **supports** the view that the source of protein needs to be specified, as this would permit new sources of protein in infant formula without undergoing premarket approval. Refer to point 3 of the DOH response to Q1.1 for the rationale to support this position.

**Section 4: Fat**

**Q1.4 Section 4.3**
Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale.

**No**. The DOH considers that infant formula should be aligned with LA levels found in breastmilk, and established adequate infant intakes. The DOH supports consideration of the EFSA scientific opinion, and the minimum and maximum levels set in EU regulation EU 2016/127.

**Q1.5 Section 4.5**
What issues, if any, do you have with the current approach to regulation of the source of fat in infant formula? Please provide your rationale

The DOH considers that fat in infant formula should be aligned with levels found in breastmilk, and established adequate infant intakes. The DOH notes that the EFSA recommended the addition of docosapentanoic acid (DHA) to infant formula at a

minimum level of 4.8 mg/ 100 kJ and maximum level of 12 mg/ 100kJ. The DOH supports consideration of the EFSA NDA scientific opinion, and the minimum and maximum levels set in EU regulation EU 2016/127. The DOH also supports reviewing the current scientific evidence relating to benefits and adverse effects.[5]
The DOH notes that where evidence is strong enough to warrant the inclusion of a substance, for example (long chain polyunsaturated fatty acids such as DHA) in the **premium infant formula** product then it should be incorporated into the **standard infant formula**.
The DOH notes that current supplementary sources of fatty acids (i.e. DHA) for use in infant formula are specifically produced from different oils: fish oil, egg yolk, or oil isolated from specific algae or fungi. The DOH supports pre-market approval of new sources of oils. Refer to point 3 of the DOH response to Q1.1 for the rationale to support this position.

**Q1.6 Section 4.6.5**
What amount of lecithin is used in infant formula for technological purposes?

No Comment.

Additional comments: Section 4

1. **Trans-fatty acids (TFAs)**
   The DOH supports FSANZ's preliminary view to lower the maximum proportion of trans fatty acids to < 3%. This aligns with the EFSA NDA scientific opinion.
2. **Phospholipids**
   The DOH supports the FSANZ's preliminary view that the amount of phospholipid in infant formula should not exceed the amount that is naturally occurring in breast or cow's milk, based on a lack of evidence to support both the safety and functionally benefit of using phospholipids as a source of LC-PUFA.
3. **Medium chain triglycerides (MCTs)**
   The DOH supports the FSANZ's preliminary view that the current limitations on MCTs in Standard 2.9.1 remain based on FSANZ's rational that they do not pose a risk to infants, and there is no apparent benefit from permitting MCTs in infant formula.

**Section 5. Carbohydrates**

**Q1.7 Section 5.1**
Should the concept of dietary fibre or its prescribed methods of analysis apply to infant formula?

No comment.

**Q1.8 Section 5.3**

What issues, if any, do you have with the current approach to regulation of the source of carbohydrate in infant formula? Please provide your rationale.

1. Sucrose, glucose and fructose.
   - The DOH notes that addition of sucrose, glucose and fructose to speciality formulae is outside the scope of P1028, and will require consideration in a separate process.
   - The DOH **does not** support FSANZ's preliminary view to maintain current provisions in Standard 2.9.1, based on the following:
     - FSANZ's approach does not align with EU regulations on infant formula, and Codex STAN 72-1981.
     - The EFSA NDA opinion supports the position that sucrose, glucose and fructose **should not** be included in **standard infant formula**. This opinion is based on sucrose and fructose not being better sources of carbohydrate than lactose, the potential harm to infants with fructose intolerance and glucose is not suitable due to the impact on blood sugar levels and increased osmolality of the formula.

The DOH suggests review of the ESFA NDA approach, and supports consideration of not permitting the addition of sucrose, glucose and fructose in **standard infant formula**.

2. Non digestible oligosaccharides
   It is currently unclear what proven physiological benefits of added fructo-oligosaccharides and galacto-oligosaccharides have been established. The DOH notes the following ESFA NDA statement extract from their review of the evidence of physiological effects of the addition of non-digestible oligosaccharides in infant formula:

   *"On the basis of the data available and in consideration of the modest quality of the available studies the Panel considers that there is insufficient evidence for beneficial effects on infant health of the non-digestible oligosaccharides that have been tested to date in RCTs when added to IF or FOF."*[6]p37

**Section 7: Micronutrient composition**

**Q1.9 Section 7.2.1**
Should the minimum folate requirement include or exclude the contribution of naturally occurring folate? Please provide your rationale.

The DOH **supports** the requirement to include naturally occurring folate given 40% of the folate in infant formula is inherent in the ingredients used in infant formula.

**Q1.10 Section 7.2.1**

If you consider minimum folate requirement should include natural folate, should dietary folate equivalents (DFE) be applied? Please provide a rationale in support of your view.

The DOH **supports** the use of DFE terminology. The rationale for this includes being aligned with EU regulations and the EFSA NDA scientific opinion; and excluding naturally occurring folate does not reflect the folate content of the infant formula.

**Q1.11 Section 7.3.2**
Is it appropriate to amend the maximum phosphorus amount in Standard 2.9.1 to a GUL and align with the lower minimum Ca:P ratio? Please provide a rationale in support of your view.

1. At this time, the DOH **does not** support replacing the maximum levels with GUL, based on the finding of infant formula implicated in hypocalcaemia cases;[7] and considers that a review of the literature may assist to inform this issue.
2. The DOH **supports** the approach to maintain the lower minimum Ca:P ratio based on alignment with Codex STAN 72-1981 and EU regulation EU 2016/17.

Additional comment: Section 7.3.2 Phosphorus
The DOH views that the approach of setting separate minimum and maximum levels for soy based infant formula in line with the approach of EU regulations has merit, and warrants further consideration.

**Q1.12 Section 7.3.2.1**
Should the GUL amount for vitamin C be increased to 17 mg/100 kJ? If not, is the current GUL in Standard 2.9.1 appropriate? Please provide a rationale in support of your view.

At this time, the DOH **does not support** increasing the GUL amount for vitamin C to 17 mg/ 100 kJ. The DOH suggests further consideration of the GUL is warranted to ensure there is no potential for these levels to exceed an infant's ability to process excess vitamin C.

Additional comments: Section 7.3.2.1
The DOH **supports** FSANZ's view to align the minimum level of vitamin C of 2.5 mg/ 100 kJ based on alignment with similar levels in breastmilk.

**Q1.13 Section 7.3.3.2**
Do you support retaining the current minimum and maximum amount of iron required in infant formula? Please provide your rationale.

1. Minimum level:
   **No**. The DOH **does not** support FSANZ's preliminary view at this time. The DOH

notes that FSANZ's preliminary view is to maintain a minimum level of iron that does not align with the levels of iron in breastmilk (accounting for differences in bioavailability). The Ministerial Policy Guideline on the Regulation of Infant Formula Products states that breastmilk is the primary reference. It is unclear as to the justification to retain a higher minimum level of iron in infant formula; and it is of concern that the approach is being taken to treat iron deficiency. The DOH considers that if there is a significant problem (i.e. iron deficiency in infants), then a full review is warranted to comprehensively identify the issues and causal factors, along with the development of an appropriate public health strategy. The DOH supports further investigation/consideration of the evidence including the recent ESFA NDA report, and the ESPGHAN Committee on Nutrition to inform the decision making process.

2. Maximum level:
   The DOH notes that the proposed maximum level for iron is higher than the EU regulation 2016/127. In light of this, the DOH **supports** further consideration of the approach taken in Europe and by the EFSA NDA on maximum iron levels, to inform decision making.

Additional comments: Section 7.3.3.2

The DOH **supports** a higher level of iron for soy based infant formula, on the basis of the reduced bioavailability due to the presence of inhibitors (phytic acid).

**Q1.14 Section 7.3.3.3**
Do you support raising the minimum and maximum amount of selenium required in infant formula? Please provide your rationale.

**Q1.15 Section 7.3.3.3**
Do you support moving the maximum amount to a GUL? Please provide your rationale.

1. Minimum level:
   **No**. Providing a level of selenium that is higher than contained in breastmilk (based on a selenium sufficient population) has the **potential to risk** infant formula being viewed as a superior source than breastmilk. The DOH **supports** setting the minimum level for selenium at the level of breastmilk from an Australian breastfeeding population that have adequate selenium status. Further to this, if there is a known issue of selenium deficiency in specific sub-groups in the Australian population, then public health initiatives to address should further be considered.
2. Maximum level:

   **No**. As raised in FSANZ's nutritional assessment, the maximum selenium level set in the US based on their review of the evidence (Final Rule) including evidence from the Institute of Medicine 2000 is halfway between the levels

specified in Codex STAN 72-1981 and Standard 2.9.1. The Codex STAN 72-1981 was based on a history of safe use of selenium and not scientific data. At this time, the DOH supports setting a maximum level of selenium to achieve intakes less than the current UL of 45 µg/ day. The DOH **supports** further consideration of retaining the mandatory requirement of a maximum level for selenium.

**Additional comments: Section 7**

The DOH notes the EFSA NDA recommendation on the importance of not exceeding maximum levels of substances in infant formula based on the potential burden on an infants' system. The DOH supports **further information** to be gathered on industry exceedance of maximum levels to inform this current decision making process. Refer to point 1 of this DOH response to Q1.1 for further elucidation of the rationale to support this position.

**Supporting document 2: Safety and Food Technology**

**Q3.1 SD 3 Section 2.1**
Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position.

The DOH **supports** the approach that all substances should require a pre-market assessment. Refer to point 3 of the DOH response to Q1.1 for the rationale to support this position.

**Supporting document 3: Provision of information**

**Q3.1 SD 3 Section 2.1**
Should claims about specific ingredients be permitted on packaged formula? If no, then why not?
If yes, then how should they be regulated?

**No.** The DOH **supports** the approach of infant formula labelling being fully consistent with wording and intent of the Ministerial Policy Guideline-Regulation of Infant Formula Products specific policy principles (l) and (n). Claims on infant formula whether nutrition content or health claims should remain as being not permitted.

The implied nature of **nutrition content claims cloaked as ingredient claims** and health claims associated with infant formula products are a significant concern for the DOH. The DOH considers that where a claim about an ingredient such as contains 'fish oil' or 'prebiotics' is made, it is a **nutrition content claim, and as such, is not permitted**. The DOH considers that ingredient claims are covered by the definitions contained in Standard 1.2.7 and 1.2.8 of the Code.

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|---|---|
| Standard 1.2.7 Nutrition, health and other claims | ***nutrition content claim*** *means a claim about –*<br>*(a) the presence or absence of –*<br>*(i) a biologically active substance*<br>(ii) dietary fibre; or<br>(iii) energy; or<br>(iv) minerals; or<br>(v) potassium; or<br>(vi) protein; or<br>(vii) carbohydrate; or<br>(viii) fat; or<br>(ix) the components of any one of protein, carbohydrate or fat; or<br>(x) salt; or<br>(xi) sodium; or<br>(xii) vitamins; or |
| Standard 1.2.8 Nutrition information requirements | **biologically active substance** means a substance, other than a nutrient, with which health effects are associated |

The ancillary information available at the point of sale can mislead parents. For example, parents and future mothers may perceive that some infant formula products are better than breastmilk due to the marketing/advertising of the (special) ingredients these contain. **Ensuring that infant formula products are not seen to be better than breastmilk is an important public health issue**. The use of claims by industry takes the focus off breastfeeding as the ideal source of nutrients for infants, and is not conducive to the promotion of breastfeeding in the community.

Thank you for considering the above comments. Should you wish to discuss any of these comments please do not hesitate to contact Ms Catrina McStay on (08) 9388 4908 or e-mail Catrina.Mcstay@health.wa.gov.au.

Yours sincerely

[redacted]

[redacted]

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