Proposal 1028
Infant Formula – NSW Submission

Major Procedure – 2nd Call for Submissions

Summary

Breastfeeding is the recommended way to feed an infant. In the situation where breastfeeding is not possible, it is desirable to have products with composition closer to human milk, except in the rare cases where this is not medically indicated.

NSW appreciates the opportunity to comment on Proposal 1028 (P1028) Infant Formula – the 2nd Call for Submissions (CFS). NSW congratulates FSANZ on the progress of this work to date and for providing draft variations to the Australia New Zealand Food Standard Code (the Code) for stakeholder consideration. This submission does not represent a NSW Government position, which will be a matter for the NSW Government should notification be made by the FSANZ Board to the Food Ministers' Meeting.

NSW recognises the extensive resource commitment by FSANZ in bringing this CFS together and supports amendment of Standard 2.9.1 of the Code to reflect the current infant formula product (IFP) market. In achieving this purpose, the principal purpose of Standard 2.9.1 in protecting infant health and safety must be retained. NSW also views P1028 as an opportunity to add regulatory clarity to the IFP market.

NSW offers specific comments in a broad range of issues considered by this CFS and offers solutions where applicable.

NSW considers the following elements in this CFS require further clarity or resolution before the production of an approval report for P1028.

- Pre-market safety assessment requirements for SMPPi
- Pre-market safety assessment requirements for general IFP
- Prescribed name for SMPPi
- Partially hydrolysed protein formulas
- Lactose free and low lactose formulas
- Lactic acid producing microorganisms (LAM)
- Product differentiation
- Stage labelling and age labelling
- Prohibited representations
- Claims

For each identified issue, suggestions are proposed to address the identified concern.

Pre-market safety assessment requirements for SMPPi

(Proposed draft paragraph 2.9.1—30(a) and subsection 2.9.1—32(2))

NSW is concerned the width of permission granted by draft paragraph 2.9.1—30(a) in excluding prohibitions on nutritive substances and novel foods unless expressly permitted for Special Medical Purpose Product for infants (SMPPi) is too broad and may pose risks to infant health by opening permission to add any substance to SMPPi without pre-market approval.

NSW appreciates the sentiment of what this draft modification is aiming to achieve in balancing international innovation with domestic controls but suggests it is tightened or completely removed. In its current form, NSW contends it is an open permission to add any new substance to SMPPi without any pre-market safety assessment by a competent regulatory authority. This could result in Australia and New Zealand infants becoming exposed to new product substances that are not available for sale in any other market. NSW does not consider this consistent with advice provided in the Ministerial Policy Guideline for the regulation of infant formula products (MPGI), where pre-market safety assessment is required by the Authority (FSANZ).

NSW is also not supportive of the proposed draft subsection 2.9.1—32(2)(b) that allows compositional deviation in SMPPi *to the extent that a variation from a maximum or minimum amount:*

(a) is required for a particular medical purpose; ***or***
(b) ***would otherwise prevent the sale of the food.***

The proposed wording of paragraph (b) listed in parallel to (a) with the word 'or' offers an open permission for compositional deviation in SMPPi regardless of the purpose of variation or the approval/safety assessment status of the new substance. This again is a broad permission where Australian and New Zealand infants might be exposed to new product innovations that have not been subject to pre-market safety assessment by a competent regulatory authority, regardless of the country of manufacture.

Jurisdictions have responsibility to enforce the Code. Should a safety issue arise in relation to a new substance used in SMPPi, food recalls would need to be initiated. In the absence of a specific prohibition clause in the Code on the addition of new substances without pre-market safety assessment and express approval in the Code, jurisdictions would need to rely on unsafe/unsuitable food provisions in State Food Acts to trigger a food recall. This is a significant and unusual shift in the burden of proof required to recall IFP from the market considering infants are a highly vulnerable sub-population. NSW considers this shift is not consistent with the MPGI.

Given the inherent risk of new nutritive substances and novel foods in IFP plus permission for SMPPi to deviate from the regulated baseline compositional requirements for IFP, the proposed open exemption from pre-market safety assessment requirements for SMPPi creates significant doubt on the safety of new substances before they may be released onto the IFP market. NSW contends that the breadth of open permission created by draft paragraphs 2.9.1—30(a) and 2.9.1—32(2)(b) does not protect infant health and safety and goes beyond the desired intent of ensuring that imported, essential clinical formulas remain available in Australia and New Zealand.

Specific Policy Principles i) and j) of the MPGI state:

- infants that need SMPPi are '*an even more vulnerable population than infants generally*', and

- '*Policy principles relating to the pre-market assessment of substances without a history of safe use in infant formula (i)-(j) may apply to infant formula products for special dietary uses at the discretion of the Authority*.

Complete removal of pre-market safety assessment is not exercising discretion. The intent of this clause is to apply a flexible and risk-based approach to this area of IFP regulation.

NSW proposes alternative wording for consideration to draft paragraphs 2.9.1—30(a) and subsection 2.9.1—32(2) to resolve the above-mentioned issues. One consequential amendment is also proposed for use of new substances in SMPPi:

- **Remove 2.9.1—30(a)**, or alternatively **add the proposed words or words to this effect (in red) to the end of current drafting for 2.9.1—30(a)** (to ensure availability of imported valid SMPPi products to Australian and New Zealand infants that need them)
  The following provisions do not apply to SMPPi
  'paragraphs 1.1.1—10(6)(b) (foods used as nutritive substances) and 1.1.1—10(6)(f) (novel foods) where the nutritive substance or novel food is deemed medically necessary for the dietary management of the relevant condition or has been subject to an equivalent rigorous assessment for safety and suitability by an overseas regulatory authority.'

  and

- **Delete 2.9.1—32(2)(a) 'or' and (b)**, or alternatively **add the proposed words or words to this effect (in red) to the end of current drafting for 2.9.1—32(2)(b)**
  'would otherwise prevent the sale of the food, where that substance has been subject to an equivalent rigorous assessment for safety and suitability by an overseas regulatory authority.'

  and

- **Add SMPPi to 1.5.1—2(2)** so that use as a food represented as SMPPi does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section.

Pre-market safety assessment requirements for general IFP
(Proposed draft section 2.9.1—5)

NSW notes that FSANZ maintains its position to consider the broader role of nutritive substances and novel foods as part of Proposal 1024 (Revision of the Regulation of Nutritive Substances and Novel Foods). However, as this proposal is on hold pending the FSANZ Act Review, NSW re-iterates its preference for novel foods and nutritive substances to be subject to pre-market safety assessment and express approval in the Code.

NSW suggests the proposed draft paragraph 2.9.1—30(a) is inconsistent with the Specific Policy Principle i) of MPGI as this states pre-market assessment should be required for **any** new substance. This principle of pre-market safety assessment was a key part of the MPGI prepared to assist FSANZ undertake P1028. Omission of this

principle in the draft variation represents a significant shift in regulatory responsibilities for a highly, vulnerable sub-population. NSW re-iterates its support for pre-market safety assessment for **any** new substance added to IFP, regardless of the purpose of addition.

Allowing new substances in IFP without pre-market assessment risks infant health and safety. For infants as '*a vulnerable population group*' with '*greater level of risk to be managed compared to other population groups*' as advised in MPGI, NSW suggests this issue should be addressed by FSANZ ahead of preparing the approval report.

NSW proposes the following amendment to the proposed draft variation to the Code, noting these words reflect those in the MPGI approved by food ministers:

- **Add the following, or words to this effect, provision to 2.9.1—5** (in red) at the end of the current draft**:**

  (4) 'Pre-market assessment is required for any substance proposed to be used in infant formula and follow-on formula that:
  (a) does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or
  (b) has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology'.

Prescribed name for SMPPi
(Division 4 of the proposed draft)

NSW supports restriction of sale on SMPPi in the proposed draft paragraph 2.9.1—31 to mirror restrictions applied to Food for Special Medical Purposes (FSMP) regulated under Standard 2.9.5 of the Code.

NSW suggests **adding prescribed name for SMPPi to 2.9.1—33, with flexibility** in elements to allow continuous import of *necessary* clinical products, in line with Codex as below:
*'"Special medical purpose product for infants" is the *prescribed name for special medical purpose product for infants. Where this requirement would prevent the sale of an imported product, an alternative name indicating the nature as a special medical purpose product for infants is permitted.'*

Partially hydrolysed protein formulas
(Proposed draft subsection 2.9.1—20(2) and paragraph 2.9.1—29(1)(l))

Further to its submission to the 1st Call for Submission for P1028, NSW does not support the new special labelling requirements to declare the presence of partially hydrolysed protein on the front of package of infant formula.

NSW contends there is no clear scope and sufficient justification for this labelling provision that will assist consumers make more informed decisions. The role and functional purpose of partially hydrolysed protein in standard IFP has not been clearly defined in this CFS or in the 1st CFS for P1028:

- The draft paragraphs provide no definition of *'partially hydrolysed protein'* – FSANZ further informs there is a lack of international consensus on an agreed definition for partial hydrolysis (2nd CFS document pg65). Given this lack of clarity it is not possible to define the purpose of this process when applied to standard IFP.
- No clear purpose/function of partial hydrolysed protein in general IFP is provided in 2nd CFS or supporting documents. NSW proposes that a role and purpose of what partial hydrolysis achieves is a pre-requisite to inclusion of specific labelling requirements within Standard 2.9.1.

Furthermore, there is a risk the presence of this information on the front of the package could function as an implied claim to a consumer, with carers assuming some benefit or purpose associated with partially hydrolysed proteins. This is inconsistent with Specific Policy Principle n) of MPGI that prohibits nutrition and health claims on IFP.

NSW further contends that specific references to 'partial hydrolysis' on standard IFP labelling will present enforcement complications. The absence of a definition of 'partial hydrolysis' as a process applied to standard IFP to 'extensive hydrolysis' applied to SMPPi leaves the point of sale as the clear point of product segregation for enforcement agencies. This will invite contention of when and where the difference between the two processes applies and will result in jurisdictions examining labelling (food additives listed, protein sources listed – 2nd CFS pg 15) to make determinations between the 2 product categories rather than composition and processing parameters. This is a sub-optimal outcome for consumers.

NSW proposes the following amendment to the proposed draft:

- **Remove 2.9.1—20(2)** to not allow the special labelling front-of-package requirement for partially hydrolysed protein, and
- **Remove 2.9.1—29(1)(l)(ii)** to allow information regarding partially hydrolysed protein only in a statement of ingredients and nowhere else.

NSW understands that the use of partially hydrolysed protein in general IFP is compliant to the baseline compositional requirement (as in the proposed draft paragraph 2.9.1—6(1)(e)). Therefore general IFP can still contain partial hydrolysed proteins but reference to the presence of partially hydrolysed protein should be limited to a statement of ingredients. NSW considers the information on partially hydrolysed protein should not be on Nutrition Information Statement (NIS) without a clear definition on what 'partial hydrolysis' means.

NSW also agrees that partially hydrolysed protein may be used in SMPPi together with other compositional modifications to serve a particular medical purpose if valid justification to meet the SMPPi definition is available.
The views of paediatric dietitians on the issue of partial hydrolysis were sought. Feedback advised they do not recommend partially hydrolysed infant formulas to treat medical conditions and acknowledged that these formulas do not reduce the risk of allergy. The National Allergy Council (partnership with ASCIA and Allergy and Anaphylaxis Australia) do not recommend partially hydrolysed formulas for the treatment of allergies.

NSW supports the position of the National Allergy Council (ASCIA) to recommend an advisory statement on partially hydrolysed products that these are not recommended for allergy prevention or treatment.

Lactose free and low lactose formulas
(Proposed draft sections 2.9.1—14 and 2.9.1—21)

NSW considers that it is more appropriate to regulate IFP represented as lactose free and low lactose as SMPPi, because they meet the SMPPi definition well in that:

- lactose modified formulas are used for dietary management of infants with some medically-diagnosed conditions such as cow's milk protein intolerance (non IgE mediated), gastroenteritis, coeliac disease, Crohns disease; and
- the dietary management cannot medically be achieved without the use of lactose modified products; and
- it is common to see lactose modified products represented as formulated for dietary management of these conditions.

NSW supports FSANZ's proposal not to permit representation as lactose free and low lactose for follow-on formula.

Also NSW notes the proposed SMPPi regulation does not prevent lactose modified products from being represented as SMPPi.

However, with the proposed special labelling requirement for lactose modified infant formula, the proposed draft sections 2.9.1-14 and 2.9.1-21 allows industry a choice of marketing their lactose modified product either as 1) SMPPi, 2) general infant formula represented as lactose free or low lactose, or 3) general IFP NOT represented as lactose free or low lactose.

This may result in a confusing situation that an identical lactose modified product may be sold with three different representations with different labelling requirements as shown in the table below:

Representation	**1 — SMPPi**	**2 — Lactose free/low lactose infant formula**	**3 — General IFP**
Mention to lactose modification	**Yes**. Wording or location not prescribed. Mandatory statement describing the properties or characteristics which make the food appropriate for the medical purpose (2.9.1—38(1)(d))	**Yes**. Wording and location prescribed. • Mandatory front-of-package statement 'low lactose' / 'lactose free' included in the name of the food (i.e. 'infant formula')(2.9.1—21) • Mandatory Lactose and galactose content information in the NIS (S29—10)	**No**. Prohibited (2.9.1—29(1)(m))
Mention to conditions	**Yes**. Mandatory statement indicating the medical purpose of the food (2.9.1—38(1)(c)) Health claims prohibited (1.2.7—4)	**No**. Health claims prohibited (1.2.7—4)	**No**. Health claims prohibited (1.2.7—4)
Other relevant labelling requirements	• Name of the food not prescribed • The food must be used under medical supervision (2.9.1—38(1)(a)) • If applicable any precautions and	• Mandatory front-of-package age statement (2.9.1—22(2)) • Prescribed name (2.9.1—16)	• Mandatory front-of-package age statement (2.9.1—22(2)) • Prescribed name (2.9.1—16)

	contradictions (2.9.1—38(1)(b)) • If applicable intended age group (2.9.1—38(1)(e))		
Restriction of sale	**Yes** (2.9.1—31)	**No**	**No**

Although SMPPi is subject to restriction of sale, it is possible to have all the three representations in the same chemist, possibly presented side by side on the shelf. In this case the difference in the labelling may cause consumer confusion and lead to the purchase of a modified product without informed medical advice.

NSW is concerned the special labelling requirement for lactose modified infant formula (representation 2 in the above table) will make the market unnecessarily complicated. Also the special front-of-package labelling 'lactose free' or 'low lactose' on general infant formula is a kind of information typically deemed as nutrition content claims. This is inconsistent with the Specific Policy Principle n) of MPGI.

NSW favours simple and clear two categories under IFP: general IFP or SMPPi. If a product is formulated for special medical purpose (and meets all the SMPPi definition), it should be SMPPi. Otherwise it should be general IFP with no mention to claims or conditions permitted. NSW believes this is in line with FSANZ's intention of P1028 to improve regulatory clarity and reduce consumer confusion.

NSW suggests permitting lactose-related product representation only in the SMPPi category by amending the proposed draft as follows or words to this effect:

- **Move compositional requirements for low lactose and lactose free from 2.9.1—14(1)(2) to Division 4**
- **Remove 2.9.1—14(3)**
- **Remove 2.9.1—21** to allow representation as low lactose and lactose free only for SMPPi
- **Remove lactose and galactose content information and related note from NIS in S29—10** to make the declaration of lactose-related modification only available for SMPPi

This will significantly improve product differentiation between general IFP and SMPPi.

NSW understands that lactose free products will still exist as general IFP (i.e. representation 3 in the example above). An example is soy-based IFP. However representation as lactose free formula and any special labelling related to lactose modification should be prohibited on general IFP.

The views of NSW paediatricians, paediatric dietitians, and representatives of midwives and child and family health nurses were sought. Overall the majority agreed regulation of no/low lactose formulas should be as SMPPi. Paediatric dietitians noted these formulas are used to treat specific conditions such as congenital lactase deficiency (very rare), and are used temporarily following gastroenteritis, Coeliac Disease and Crohns Disease while the gut recovers. They were clear to point out that these formulas are not recommended for perceived 'lactose intolerance' to manage colic, reflux and unsettled babies – normal infant development behaviours. They support consultation with a health professional prior to using these formulas and restricting sale to pharmacy only. No/ Low lactose formulas are not suitable for the

treatment of cow's milk protein allergy as these formulas may still be based on cow's milk protein ingredients.

Lactic acid producing microorganisms (LAM)
(Proposed draft section 2.9.1—11)

While acknowledging that LAM have been used in IFP for a number of years, NSW requests that FSANZ clarify the risk assessment process used to justify retention of the current existing unrestricted permission to add LAM to IFP.

In 2021 CP1 SD2, FSANZ identified case reports of sepsis and bloodstream infections in infants with underlying clinical complications (including pre-term, low birth weight and immuno-compromised infants) associated with dietary supplementation with non-pathogenic L- and DL-lactic acid producing bacteria. Given infants with these underlying conditions are frequently fed standard formulas (that may be fortified) rather than SMPPi, FSANZ's risk assessment indicates there is a safety concern with this unrestricted permission. FSANZ concluded '*safety should be assessed on a case-by-case basis, prior to addition to infant formula products, to provide assurance of public health and safety* (pg39)'.

The proposed broad permission for addition of any LAM is not consistent with FSANZ's own assessment based on best available scientific evidence if not qualified with appropriate criterion to address the previously identified risk. NSW is concerned that an unqualified permission could lead to infant health and safety concerns.

Regardless of FSANZ's anticipation that industry will not use probiotics that have not been assessed through a pre-market process as they will not be able to highlight them on the NIS, the proposed retention of broad permission to add all LAM without any caveats is not consistent with the Specific Policy Principles i) and j) of MPGI on pre-market safety assessment of new substances.

NSW is concerned the current proposed open permission for LAM could result in Australian and New Zealand infants being exposed to more lenient standards than Codex, the EU, US and China.

To address the problems, NSW supports clarification in the Code that L-Lactic acid producing microorganism may be added as an ingredient for acidification reasons (as proposed in the 1st CFS), and L-Lactic acid producing microorganism added for these purposes may not be listed in the NIS. This could be supported by additional drafting clarifying that L-Lactic acid producing microorganisms added to IFP or SMPPi for nutritional purposes is a nutritive substance and needs to be included in the table to Schedule 29-7 or Schedule 29-8. If the proposed five-year transition period is considered insufficient to assess LAM being used as probiotics, other options to avoid an open permission in IFP include applying a longer transition period for LAM, or a rapid review by FSANZ of overseas regulators' assessments that have considered specific strains (e.g. US and China). FSANZ already has conducted rapid review of some substances (e.g. trehalose) for use in IFP under P1028. This will ensure the safety and functional purpose of LAM is clarified in IFP, and allow listing of appropriate strains in the NIS, aligned with their nutritive purpose.

NSW proposes amending the proposed draft as below:

- **Amend 2.9.1—11** as follows or words to this effect (in red):

'L(+) lactic acid producing microorganisms may be added to infant formula and follow-on formula:.

(1) if the L(+) lactic acid producing microorganism is added as an ingredient for acidification purposes; or

(2) if the L(+) lactic acid producing microorganism is listed in the table to sections S29—7 and S29—8'

(3) L(+) lactic acid producing microorganisms added according to subsection (1) may not be listed in the NIS.

(4) L(+) lactic acid producing microorganisms listed in the table to sections S29-7 and S29-8 may be listed in the NIS.

Product differentiation

(Proposed draft subsection 2.9.1—15(2) and section 2.9.1—33)

NSW supports prescribing location of the name of the food (i.e. prescribed name 'infant formula' or 'follow-on formula') on the front of a package in the proposed draft section 2.9.1—19.

NSW also supports FSANZ's intention to add new provisions in the proposed draft section 2.9.1—15 to require improved product differentiation on label. However, NSW proposes further clarity in drafting to achieve the intent discussed in SD3 section 9.6.

As FSANZ identified in the 2nd CFS SD3, one of the problems cited for feeding infants an inappropriate product lies with the similarity between package designs in a company's product range. Simply put, consumers purchasing products quickly can make honest mistakes in product selection as products suitable for different age groups look very similar (i.e. 0-6 months compared to 6-12 months). FSANZ survey work found that 73% of products used colours to differentiate between different product ranges of IFP made by a certain manufacturer. However, these differences simply refer to minor differences (for example identical tin colour and branding with only stage numbers in different colours). This can result in an inappropriate product being purchased and inadvertently being fed to an infant.

NSW suggests more prominent differences are required in label design to clearly separate age specific products within a manufacturers portfolio. NSW suggests the proposed drafting for *2.9.1.-15(2) A food represented as infant formula or follow on formula must not be also represented as another food* does not provide sufficient clarity for enforcement purposes.

To improve clarity and better reflect the intention, NSW proposes re-wording of the proposed draft or words to this effect (in red) to be more consistent with the EU Regulation:

Amend 2.9.1—15(2) *A food represented as infant formula or follow-on formula must be designed in such a way that it avoids any risk of confusion between infant formula and follow-on formula and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used.*

- **Add the provision to 2.9.1—33** as below or words to this effect (in red) so that appropriate product differentiation requirement will also apply to SMPPi.
  'A food represented as a special medical purpose product for infants must be designed in such a way that it avoids any risk of confusion between infant

formula and SMPPi and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used.

Stage labelling and age labelling
(Proposed draft sections 2.9.1—22 and 2.9.1—28)

NSW does not support the draft provision to permit the use of stage labelling for infant formula and follow-on formula. Although prevalent in the current market, stage labelling practice is only one way to inform consumers of the product identity. FSANZ's evidence shows that age labelling is best used, and that carers need to use age labelling to interpret stage labelling.

Page 6 of Attachment 1 to 2nd CFS SD3 provides some evidence suggesting that while stage labelling on IFP may be used by some care-givers to differentiate between formula products, age labelling was viewed as the most important label element for product differentiation.

NSW reiterates its concern about potential negative impacts of stage labelling, such as misinterpretation of the function of stage labelling (as identified in 2nd CFS SD3 pg 62). In particular, providing the incorrect impression that carers should progress through all labelled stages. Recent reviews[1] have also identified negative impacts of stage labelling including the unnecessary use of products and the use of the older stages as ways to circumvent marketing and claims restrictions on infant formula products.

Typical marketing practice suggests:
- Stage 1: infant formula for infants from birth to 6 months of age,
- Stage 2: follow-on formula from 6 to 12 months of age,
- Stage 3: toddler milk for 1 – 3 years of age
- Stage 4: for 3 years old onwards

There are also Stage 5 products marketed overseas for children from 6 years old.

This marketing practice is problematic from multiple aspects, including:
- Evidence supporting the need to transition from 'stage 1' products (0-6 months) to 'stage 2' products (6-12 months) is limited. By definition infant formula product is a breast milk substitute for infants (defined as persons under the age of 12 months). Representatives of midwives and child and family health nurses support labelling which clearly indicates that there is no need to transition to 'Stage 2' follow on formulas at age 6 months.
- There is no need to progress from follow-on formula to Stage 3 and 4 formulas. Australian Dietary Guidelines recommends '*A wide variety of different coloured, textured and tasting vegetables and fruit, both fresh and cooked*' for children

[1] World Health Organization and the United Nations Children's Fund (UNICEF) 2022. How the marketing of formula milk influences our decisions on infant feeding. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF), Licence: CC BY-NC-SA 3.0 IGO and
The Lancet Breastfeeding 2023 series https://www.thelancet.com/series/Breastfeeding-2023, in particular:
Rollins et al. Marketing of commercial milk formula: a system to capture parents, communities, science, and policy. The Lancet. February 7, 2023
Baker et al. The political economy of infant and young child feeding: confronting corporate power, overcoming structural barriers, and accelerating progress. The Lancet. February 7, 2023

above the age of 1 year. Young children aged 1 year old do not usually require a nutritional supplement and the feeding of unnecessary energy could promote overweight and obesity[2][3][4].

Government jurisdictions and public health stakeholders have repeatedly raised the issue of stage labelling, and the need for it to be addressed, since the first consultation paper in 2012. NSW is concerned that addressing these by explicitly permitting the numbers '1' and '2' for IFP entrenches this marketing practice and provides more incentive to care-givers to progress through the stages, particularly from 'stage 2' (follow-on formula) to 'stage 3' (formulated supplementary foods for young children) where evidence supporting this extension is limited. NSW is concerned that legislating staged related numbering practices in the Code provides further incentive for line marketing practices, e.g. use of nutrition content and/or health claims on Stage 3 and 4 labelled formulas on ingredients that are also present in infant formula products. Consumers can mistake toddler milks bearing such claims as extending to IFP. Published literature[5][6][7][8] demonstrating use of line marketing practices to circumvent prohibition of advertisement and nutrition content/health claims on IFP is cited for FSANZ information as evidence of these risks. NSW considers such practices as inconsistent with the Specific Policy Principle n) ii of MPGI. Unlike Stage 3 or 4 formulas, IFP is the only available substitute for breast milk and an essential milk for non-breastfed infants. To protect breastfeeding rates, IFP should not be advertised or have health claims either directly or indirectly.

FSANZ has noted that industry support retaining stage labelling and that the Marketing in Australia of Infant Formulas (MAIF) committee issued guidance in 2020[9] stating it was appropriate to use stage labelling on labels of IFP. Given the labelling of IFP is under current review (MAIF) and this specific issue was raised as a concern, it is arguably inappropriate to propose amendments to the Code concerning stage labelling until a clear conclusion is determined.

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[2] Appleton J, Russell CG, Laws R, Fowler C, Campbell K, Denney-Wilson E. Infant formula feeding practices associated with rapid weight gain: A systematic review. Matern Child Nutr. 2018 Jul;14(3):e12602. doi: 10.1111/mcn.12602. Epub 2018 Apr 14. PMID: 29655200; PMCID: PMC6866175.

[3] Koletzko B, von Kries R, Monasterolo RC, Subías JE, Scaglioni S, Giovannini M, Beyer J, Demmelmair H, Anton B, Gruszfeld D, Dobrzanska A, Sengier A, Langhendries JP, Cachera MF, Grote V; European Childhood Obesity Trial Study Group. Infant feeding and later obesity risk. Adv Exp Med Biol. 2009;646:15-29. doi: 10.1007/978-1-4020-9173-5_2. PMID: 19536659.

[4] Azad MB, Vehling L, Chan D, Klopp A, Nickel NC, McGavock JM, Becker AB, Mandhane PJ, Turvey SE, Moraes TJ, Taylor MS, Lefebvre DL, Sears MR, Subbarao P; CHILD Study Investigators. Infant Feeding and Weight Gain: Separating Breast Milk From Breastfeeding and Formula From Food. Pediatrics. 2018 Oct;142(4):e20181092. doi: 10.1542/peds.2018-1092. PMID: 30249624.

[5] Romo-Palafox MJ, Pomeranz JL, Harris JL. Infant formula and toddler milk marketing and caregiver's provision to young children. Matern Child Nutr. 2020 Jul;16(3):e12962. doi: 10.1111/mcn.12962. Epub 2020 Mar 10. PMID: 32157807; PMCID: PMC7296786.

[6] Berry NJ, Jones SC, Iverson D. Relax, you're soaking in it: sources of information about infant formula. Breastfeeding Review. 2011;19(1):9–18.

[7] Cattaneo, A., et al., Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy. Archives of disease in childhood, 2014: p. archdischild-2014-306996.

[8] Richter APC, Duffy EW, Smith Taillie L, Harris JL, Pomeranz JL, Hall MG. The Impact of Toddler Milk Claims on Beliefs and Misperceptions: A Randomized Experiment with Parents of Young Children. J Acad Nutr Diet. 2022 Mar;122(3):533-540.e3. doi: 10.1016/j.jand.2021.08.101. Epub 2021 Aug 13. PMID: 34391941; PMCID: PMC8840993.

[9] https://www.health.gov.au/resources/publications/guidance-document-for-interpretation-of-the-maif-agreement-appropriate-age-range-on-infant-formula-labels-clauses-5a-and-9b?language=en

To address above-mentioned concerns NSW proposes that accurate age range is highlighted on the front of pack for infant formula and follow-on formula. The age statement should be the most prominent and visible for ease of product identification.

Namely:

- **Amend age labelling requirements in 2.9.1—22(2)** as below or words to this effect (in red) to mandate accurate indication of age suitable for infant formula and follow-on formula:
  (a) for infant formula—the infant formula may be used from birth to the age of 12 months; and
  (b) for follow-on formula—the follow-on formula may be used from the age of 6 months to the age of 12 months; and
  (c) for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months; and
  (d) for infant formula and follow-on formula—it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula

  and

- **Amend 2.9.1—22(3)** as below or words to this effect (in red) to mandate that the range of infant age suitable for infant formula and follow-on formula is highlighted in the front of package.
  'The statements required by paragraphs (2)(a) and (b) must appear in a prominent position on the front of the package of the product.'

Also, NSW proposes further amendments (2 proposals) to the Code.

NSW's preferred amendment is to **prohibit the stage labelling**:

- **Remove 2.9.1—28**

  and

- **Amend 2.9.1—29(1)(n)** as below or words to this effect (in red)
  'Sequential stage numbers or letters used to identify for consumers that the product is infant formula or follow-on formula. For the avoidance of doubt, aged-related descriptors (0-12 months, 6-12 months) are not prohibited representations.'

Alternatively, if stage labelling is not prohibited, NSW proposes **mandating the size of age labelling relative to the stage labelling** as well as the location:

- **Amend 2.9.1—28(2)** as below (in red):
  'A number used in accordance with subsection (1) must appear:
  (a) on the front of package of the product; and
  (b) immediately adjacent to and no more than the size of:
  (i) for infant formula–the statement required by paragraph 2.9.1—22(2)(a); and
  (ii) for follow-on formula–the statement required by paragraph 2.9.1—22(2)(b)

NSW supports the new provision in the proposed draft subsection 2.9.1—22(4) that clarifies that 2.9.1—22(3) does not prevent the age-related statements from appearing more than once on the label.

Prohibited representations
(Proposed draft sections 2.9.1—29 and 2.9.1—35)

NSW does not support exclusion of SMPPi from some of the current prohibited representations, namely:

- a picture that idealises the use of infant formula product (the current paragraph 2.9.1—24(1)(b))
- words claiming that the formula is suitable for all infants (the current paragraph 2.9.1—24(1)(d))
- information relating to the nutritional content of human milk (the current paragraph 2.9.1—24(1)(e))

FSANZ indicates that EU regulations include prohibitions consistent with or like the three above (2nd CFS SD3 pg 84). FSANZ states one of the major aims of P1028 is to align with international regulations where possible (2nd CFS document pg 2). Given there is no clear reason to remove above-mentioned prohibitions, NSW supports inclusion of these prohibited representations to ensure these aspects of the WHO International Code of Marketing of Breast-milk Substitutes[10] are appropriately applied to SMPPi. This is particularly important given the growing recognition that some "specialised" products such as colic/reflux formulas are marketed to manage normal infant behaviours and can impact on breastfeeding rates[1].

For consumers from culturally and linguistically diverse backgrounds or low literacy levels it is essential infant formula cans can be easily distinguished to prevent the wrong formula being purchased for a certain aged infant.

Specifically NSW proposes amending the proposed draft to:

- **Add the following three paragraphs to *2.9.1—35*:**
  (f) a picture that idealises the use of infant formula product
  (g) words claiming that the formula is suitable for all infants
  (h) information relating to the nutritional content of human milk

Claims
(Proposed draft sections 2.9.1—29, 2.9.1—35, 2.9.1—38 and 2.9.1—41)

Given that Specific Policy Principles n) of MPGI highlights the clear and effective prohibitions and restrictions on nutrient content, health, therapeutic and prophylactic claims in the Code for IFP, NSW reiterates the need to ensure prohibition of claims for IFP, including via trademarks or by means of abbreviations (such as HA for 'hypoallergic', AR for 'anti-reflux') as well as by way of line marketing (as discussed in *Stage labelling* above).

Specifically, NSW proposes amendment to:

- **Add the following paragraphs to 2.9.1—29**:
  (o) any abbreviation having the same or similar effect of nutrition content claims or health claims

[10] https://www.who.int/publications/i/item/9241541601

NSW requests improved clarity on the prohibition of claims for SMPPi. The proposed draft paragraph 2.9.1—30(b)(i) states Part 1.2 of Chapter 1 does not apply to SMPPi unless the contrary intention appears. Without explicit clarification in Standard 2.9.1 that Standard 1.2.7 applies to SMPPi, implication from the Note to 2.9.1—35 remains ambiguous. NSW considers this important as draft paragraph 2.9.1-38(c) permits statements informing on the medical condition the SMPPi has been developed to manage. NSW also informs that notes within the Standard are not enforceable and therefore proposes additional drafting to put the issue of claims beyond doubt.

Specifically, amendment is proposed to add:

- **following three paragraphs to 2.9.1—35**:
  (i) Nutrition content claims
  (j) Health claims
  (k) Therapeutic claims

Explicit prohibition of these claims for all IFP including SMPPi is appropriate and consistent with Specific Policy Principle n) of MPGI.

Furthermore, NSW considers the Code does not provide clarity on the difference between nutrition content/health claims and the required labelling information on SMPPi in relation to the medical purpose including mention to a disease, disorder or medical condition (the proposed draft paragraph 2.9.1—38(1)(c)) and the properties or characteristics for the medical purpose (the proposed draft paragraph 2.9.1—38(1)(d)).

Section 1.2.7— 2 provides definitions for the term ‘health claim’, ‘health effect’ and ‘high level health claim’ as below:

- health claim means a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect.

- health effect means an effect on the human body, including an effect on one or more of the following:

(a) a biochemical process or outcome;
(b) a physiological process or outcome;
(c) a functional process or outcome;
(d) growth and development;
(e) physical performance;
(f) mental performance;
(g) a disease, disorder or condition.

- high level health claim means a health claim that refers to a serious disease or a biomarker of a serious disease.

These definitions imply that health claims are potentially un-distinguishable from the required labelling information on SMPPi in that all can refer to diseases and conditions. NSW suggests that FSANZ could offer some guidance in the approval report on how permitted statements on SMPPi can be made in order to segregate legitimate statements from prohibited representations.

Other comments

NSW offers the following comments to the proposed draft:

Regulatory framework

Product categorisation as general IF/FOF or SMPPi

NSW is concerned that this proposed draft framework would offer industry the ability to re-label a product rather than re-formulate. NSW considers that formulas for transient gastrointestinal conditions do not fit the SMPPi definition. Dietary management of transient gastrointestinal conditions can medically be achieved without use of such products. Some conditions such as colic and reflux are medically diagnosed and provided therapeutic goods to manage (e.g. omeprazole).

Definitions
(Proposed draft section 2.9.1—3)

- *'SMPPi'*

  NSW supports the revised definition of SMPPi, that deleted an unenforceable term 'generally accepted scientific data' and that clarified the need for 'medical determination' as the pre-requisite entry requirement.

- *'responsible institution'*

  NSW does not support the proposed draft definition, because it contains irrelevant institutions such as hospice, aged care facility, disability facility and boarding schools. NSW understands that the proposed definition mirrors the one for FSMP, however, suggests tailoring the definition to suit the context where SMPPi may be sold.

  NSW **proposes following amendment** (in red):
  'in relation to special medical purpose food for infants, means a hospital, ~~hospice, aged care facility, disability facility,~~ prison, ~~boarding school~~ or similar institution that is responsible for the welfare of its patients or residents and provides food to them.'

- '*infant*'

  NSW **proposes highlighting this definition in section 2.9.1—3 as well**. Although the definition is provided section 1.1.2—2, this term is prevalent in Standard 2.9.1 and offers reference to other definitions (e.g. 'infant formula')

- '*soy-based formula'*

  NSW **proposes removing this definition**. This term is never used anywhere else in the proposed Standard 2.9.1. In 2nd CFS document pg22 FSANZ proposes to remove this definition.

- '*milk-based'*

  This term is ambiguous as to what milk is referred to. NSW suggests providing the definition or avoiding the use of this term. NSW suggests this term can be replaced with the reference to relevant proteins permitted in 2.9.1—6(1).

- *'nutrient'*

  The use of this term in the proposed draft section 2.9.1—26 may imply that this term refers to mandatory ingredients in the NIS as opposed to voluntary ingredients. Mandatory ingredients include nutritive substances such as vitamins, minerals and other essential substances required in S29—5 and S29—6.

  The use of the term 'nutrient' in the proposed draft subsection 2.9.1—29(3), together with 'a nutritive substance' does not provide clarity as to the difference between the two terms.

  NSW suggests defining the term or avoiding the use of this term in section 2.9.1—29. Subsection 2.9.1—29(3) (and paragraph 2.9.1—29(1)(i)) could refer to the NIS requirement in sections 2.9.1—25 and 2.9.1—26 as an alternative.

Novel foods and nutritive substances

Schedule 25 permissions
(Proposed draft section 1.5.1—3 and Schedule 25)

NSW supports FSANZ's proposal to improve regulatory clarity by prohibiting the use of novel foods for IFP unless explicitly permitted. This proposed change is consistent with the Specific Policy Principles i) and j) of MPGI.*Food Additives*

Removal of carry-over principle
(Proposed draft subsection 1.3.1—3(2))

NSW supports the proposed explicit prohibition of food additives in IFP by carry over unless explicitly permitted. This is consistent with the Specific Policy Principles i) of MPGI.

Food additive permissions
(Proposed draft S15—5)

- *Guar gum (412)*

  Although not yet available as of this submission, NSW suggests EFSA's re-evaluation regarding the safety of guar gum for infants below 16 weeks of age[11] should be considered if available before producing the approval report for P1028.

- *Xanthan gum (415)*

  NSW notes the latest EFSA's re-evaluation[12] that concluded the use of xanthan gum for infants below 16 weeks of age up to a concentration of 1,200 mg/L does not raise concerns.

[11] https://www.efsa.europa.eu/en/consultations/call/call-technical-and-toxicological-data-guar-gum-e-412-uses-foods
[12] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.7951

FSANZ's proposal to apply both Codex and EU MPL for xanthan gum in SMPPi creates possible regulatory uncertainty. The proposed conditions for the two MPLs may be confusing as extensively hydrolysed protein can be used for gastrointestinal and protein malabsorption issues.

- *Pectins (440)*

  NSW does not support the proposed MPL for pectins of 10,000 mg/L for follow-on formula, just for the sake of aligning with the current Codex draft permission. The 2nd CFS SD1 (pg 19) does not provide scientific evidence to support safety for the MPL.

  NSW notes the following risk assessment advice by the EU and JECFA:
  - JEFCA's assessment in 2016[13] and 2017 concluded exposures up to 2,000 mg/L did not raise health concerns but those at ≥ 5000mg/L (proposed level for SMPPi) were of concern.
  - In 2021 EFSA re-evaluated the safety of pectins[14] and recommended reducing the EU MPL down from 10,000 mg/L, pending a further re-evaluation. One of the concerns raised by EFSA was infants' exposure to methanol.

  FSANZ's risk assessment in 2021 CP1 SD1 concluded that a maximum use level of 2,000mg/L of pectin was not expected to result in adverse effects from methanol. It also noted it was only in use up to a maximum of 4,170 mg/L.

  FSANZ's proposal to adopt MPL for pectins in follow-on formula of 10,000 mg/L is not consistent with the results of safety assessments by FSANZ as well as international jurisdictions. This is not consistent with the Specific Policy Principle c) of MPGI and does not ensure protecting infant health and safety.

  NSW proposes deleting the permission of the use of pectins for follow-on formula, unless new evidence is provided to overturn the above-mentioned previous risk assessments.

- *Sucrose esters of fatty acids (473)*

  NSW notes that EFSA's re-evaluation[15] identified that sucrose esters of fatty acids are not being used in IFP and concluded that safety assessment is unable to be conducted.

  Codex does not permit the use of sucrose esters of fatty acids for IFP. The proposed permission of the use of sucrose esters of fatty acids for SMPPi is solely to align with the EU. As this substance is not being used in the EU absence of permission would not cause trade issues. NSW proposes removing the proposed permission for the use of sucrose esters of fatty acids.

- *Lecithin (322)*

[13] http://apps.who.int/iris/bitstream/10665/250277/1/9789241210003-eng.pdf#page=46
[14] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6387
[15] https://www.efsa.europa.eu/en/efsajournal/pub/7961

NSW does not support retaining the current maximum limit of 5 g/L. NSW supports reducing the level to 1 g/L in line with the EU. EFSA's re-evaluation[16] concluded that the intake of lecithin up to 1 g/L does not raise safety concerns.

NSW notes the EU reduced the maximum level of lecithin in IFP from 5 to 1 g/L to better align with the level in human milk. This reduction was based on recommendation based on studies which claimed neurobehavioural effects in the offspring of rats fed high doses of lecithin.

NSW notes FSANZ's explanation in page 34-35 in the 2nd CFS SD2 that the level of lecithin will be regulated by the maximum limit of total phospholipids of 72 mg/100 kJ (I.e. 2 g/L). However, this does not provide safety assurance as to the use of lecithin above the level present in human milk. Also this is not consistent with the Specific Policy Principle h) of the MPGI.

Composition

Baseline composition for SMPPi
(Proposed draft section 2.9.1—32)

The proposed compositional requirements for SMPPi only refer to substances listed in S29—5 (i.e. vitamins, minerals, electrolytes and other essential substances). The proposed draft is silent about other nutrients, which creates ambiguity and allows unintended interpretation that there is no particular compositional requirement for SMPPi for nutrients not included in S29—5 (e.g. energy, protein and fat).

NSW proposes adding a clear provision in section 2.9.1—32 that requires SMPPi to comply with the baseline composition of infant formula (as shown in Table 1 in SD2 and proposed in Division 2 of the proposed draft Standard 2.9.1) except deviations permitted in subsection 2.9.1—32(2).

See below for an example of the amendment.

- **Add a new subsection 2.9.1—32(3) or words to this effect** :
  'Despite subsection (1), a special medical purpose product for infants must comply with the compositional requirements for infant formula in Division 2 of this Standard, unless compositional deviation is required for a particular medical purpose.'

Indefinite status of optional ingredients

FSANZ comments in page 8 of the 2nd CFS SD2 that FSANZ does not conduct a review to assess essentiality of optional ingredients as it is '*not general practice and is not evident for permissions within the Code'.*

Given the unique nature of IFP as the only available breast milk substitute and the sole or principal liquid source of nourishment for infants, NSW considers special consideration beyond '*general practice*' is needed for IFP regulation. The importance of special regulatory framework for IFP is highlighted in MPGI.

As the Specific Policy Principles d) to h) of MPGI require, all IFP must satisfy the nutritional requirements for the normal growth and development of infants. The

[16] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6266

comprehensive review of compositional requirements for IFP through P1028 should fully regard infants' nutritional requirements according to the best available scientific evidence.

NSW requested review of the status of optional substances as part of P1028 in its 1st CFS submission. FSANZ has decided to exclude this aspect from the scope of P1028.

NSW reiterates that optional ingredients (DHA, lutein) should be converted to mandatory if the best available scientific evidence shows essentiality of these ingredients for the normal growth and development of infants. Optional substances such as DHA and lutein have been permitted for voluntary use for number of years.

Another example is taurine. In page 67 of the 2nd CFS SD2 FSANZ states that:

- taurine is an amino acid found in breast milk and absent in cow's milk; and
- infants have little ability to synthesise their own taurine stores; and
- the removal of taurine's optional permission could pose risk to infant health.
- Despite this, FSANZ has proposed that taurine remain an optional ingredient and not be made available to all formula-fed infants.

NSW does not support inequity in the IFP market where those infants whose care-givers cannot afford premium formulas are prevented from accessing voluntary ingredients that may play an essential role for normal growth and development. This is not consistent with MPGI or with policies that promote equity such as Closing the Gap[17]. FSANZ has indicated previously that optional ingredients, and the associated exclusivity arrangements, foster innovation by allowing industry to recuperate research and development costs. The current framework for optional ingredients that allows indefinite voluntary permissions is not reflective of a system that seeks to better balance industry innovation and infant health such that optional ingredients are subject to regular reviews and mandated to ensure the benefits of research are made available to all formula fed infants.

Compositional requirements

- NSW agrees with the proposed changes in maximum level of energy of both infant formula and follow-on formula (from 2950kJ/L to 2930 kJ/L) and minimum protein content of follow-on formula (from 0.43 g/100 kJ to 0.38 g/100 kJ).

- NSW **suggests re-drafting section 2.9.1—5** to solve the issue of needing the term 'source of' as this term is typically seen as a nutrition content claim. Given nutrition content claims are prohibited for IFP the use of the term here is potentially confusing.

- *Methionine to cysteine ratio*
  (Proposed draft subsection 2.9.1—6 (5))

  NSW **proposes reflecting Codex and EU regulations** as below (in red). This will better protect infant safety by ensuring that infants receive appropriate levels of cysteine

[17] https://www.closingthegap.gov.au/

'Infant formula should aim to have a ratio of methionine to cysteine that is less than 2 to 1 and must have a ratio of methionine to cysteine of no more than 3 to 1.'

- *Protein content*
  (Proposed draft subsection 2.9.1—6 (2)(3))

  NSW does not support the proposed maximum protein content for both infant formula and follow-on formula, as the maximum level is associated with evidence of higher risk of obesity. NSW supports a lower maximum level, consistent with its *First 2000 Days of Life Framework*[18] which recognises the importance of reducing obesity.

  FSANZ has not addressed concerns raised previously that a level of 0.7g protein/100 kJ has been associated with significantly higher risk of obesity in childhood[19]. Another recent meta-analysis showed that infants fed formulas above 0.48g/ 100 kJ had faster growth rates than breastfed infants from 2 months of age and that, unlike breastmilk which reduces in protein content, formulas may provide 30% more protein than breastmilk[20]

  NSW **proposes reducing the maximum protein level to the EU levels of 0.6 g/100kJ**. This is more consistent with the Specific Policy Principle h) of MPGI that requires to use breastmilk as a primary reference for composition while facilitating trade by aligning with the EU level.

- *Vitamin A*
  (Proposed draft S29—5 and S29—6)

  NSW is not supportive of retaining the current maximum level (43 µg RE/100 kJ) which results in a mean daily intake that exceeds the UL set by NHMRC more than 15% (provides 937 µg RE/day compared to the UL of 600 µg RE/day). NSW **proposes adopting the lower EU maximum level** (27.2 µg RE/100 kJ, which provides a mean intake just under the UL of 593 µg RE/day).

- *Iodine*
  (Proposed draft S29—5 and S29—6)

  NSW is not supportive of the proposed maximum level of 14 µg /100 kJ that exceeds the UL set by the EU. NSW further does not support this maximum level being GUL that legally allows even higher iodine content.

  NSW does not support the proposed minimum level of 2.4 µg /100 kJ with the concern that the total iodine intake from formula and water may not sufficiently achieve the NHMRC AI of 90 µg /day (a mean daily intake for infants will be 59-91µg /day, depending on water content). Given the majority of the Australian

[18] https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2019_008

[19] European Childhood Obesity Trial Study Group, Lower protein in infant formula is associated with lower weight up to age 2 y: a randomized clinical trial, The American Journal of Clinical Nutrition, Volume 89, Issue 6, June 2009, Pages 1836–1845, https://doi.org/10.3945/ajcn.2008.27091

[20] Ren Q, Li K, Sun H, Zheng C, Zhou Y, Lyu Y, Ye W, Shi H, Zhang W, Xu Y, Jiang S. The Association of Formula Protein Content and Growth in Early Infancy: A Systematic Review and Meta-Analysis. Nutrients. 2022 May 28;14(11):2255. doi: 10.3390/nu14112255. PMID: 35684055; PMCID: PMC9183142.

population is known to have endemic iodine deficiency due to low iodine water content, NSW **supports adopting the higher EU level** of 3.6 µg /100 kJ, which will provide 86-118 µg /day)

- *Linoleic acid (LA)*
  (Proposed draft paragraph 2.9.1—7(1)(ba))

  NSW does not support retaining the current minimum level of 90 mg/100kJ as it does not meet AI set by EFSA and is not consistent with FSANZ's own assessment.

  FSANZ's 2021 CP2 nutrition assessment concluded the risk of harm to infants' health due to inadequate LA intake would be low if FSANZ adopted a minimum LA amount between 110 and 140 mg/100 kJ.

  NSW **supports adopting the EU minimum level** of 120 mg/100kJ. This level will be in line with FSANZ's risk assessment.

- *Zinc*
  (Proposed draft S29—5 and S29—6)

  NSW does not support the proposed maximum level (GUL) of 0.36 mg/100 kJ that results in intakes almost double the UL for infants below 6 months old. NSW **supports adopting the lower EU level** of 0.24 mg /100 kJ.

- *Iron*
  (Proposed draft S29—5 and S29—6)

  NSW considers a **lower maximum iron level** of 0.31 mg/100 kJ, rather than 0.48 mg/100 kJ for animal milk-based infant formula, in line with the EU, better protects infant health and safety. NSW notes concerns raised by previous submitters that there is evidence that excess iron intake (at a lower level than the proposed maximum) in iron-replete infants is associated with poorer long term developmental outcomes, infection risk and status of trace minerals have not been addressed[21][22][23][24]

[21] Koletzko, B., et al., Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group. Journal of Pediatric Gastroenterology and Nutrition, 2005. 41(5): p. 584-599.

[22] Lozoff B, Castillo M, Clark KM, Smith JB. Iron-Fortified vs Low-Iron Infant Formula: Developmental Outcome at 10 Years. Arch Pediatr Adolesc Med. 2012;166(3):208–215. doi:10.1001/archpediatrics.2011.197

[23] Hare DJ, Cardoso BR, Szymlek-Gay EA, Biggs BA. Neurological effects of iron supplementation in infancy: finding the balance between health and harm in iron-replete infants. Lancet Child Adolesc Health. 2018 Feb;2(2):144-156. doi: 10.1016/S2352-4642(17)30159-1. Epub 2017 Dec 6. PMID: 30169236.

[24] Lönnerdal B, Excess iron intake as a factor in growth, infections, and development of infants and young children, The American Journal of Clinical Nutrition, Volume 106, Issue suppl_6, December 2017, Pages 1681S–1687S, https://doi.org/10.3945/ajcn.117.156042

NSW does not agree with the proposed higher minimum iron level for follow-on formula. There is no evidence demonstrating that iron content in breast milk increases after 6 months and therefore this is not consistent with the MPGI which states *h) The composition of breastmilk should be used as a primary reference for determining the composition of infant formula and follow-on formula.* NSW **suggests setting the same minimum iron level** of 0.14 mg/kJ for infant formula and follow-on formula. Shifting the primary reference for the composition of follow-on formula away from breastmilk to total nutritional requirements ignores the contribution of food after 6 months and moves follow-on formula away from being a breastmilk substitute, introduction of iron-containing solids at around 6 months of age provides an appropriate source of iron to an infant's diet.

Labelling requirements

Name and address of the supplier of SMPPi
(Proposed draft section 2.9.1—37)

NSW disagrees that the general labelling requirement 'name and address of the supplier' (see section 1.2.2—4) is exempt for SMPPi. NSW notes the proposed draft section 2.9.1—43 requires this information for transportation outer of SMPPi, however, considers this ineffective in case of recall. NSW **proposes including 'name and address of the supplier' in 2.9.1—37**.

Prescribed format of the NIS
(Proposed draft section 2.9.1—26 and S29—10)

NSW supports prescribing a format for the NIS. Prescribing the names and units of measurement for mandatory ingredients in the NIS would better assist consumers to compare products.

NSW proposes also prescribing the names and units of measurement for optional ingredients (e.g. HiMO's) that are permitted to be declared in the NIS under the subheading 'Additional'. The proposed draft has not provided clarity on this. Prescribing the names and units for all substances in the NIS will significantly improve product comparison and informed purchase decisions

Specifically NSW **proposes following amendment in 2.9.1—26(3)** or words to this effect (in red):
If the statement includes the average quantity of a permitted nutritive substance, an inulin-type fructan or a galacto-oligosaccharide, the average quantity must be included in the statement:

(a) under the subheading 'Additional'; and
(b) using the names as listed in S29—7 (for infant formula) or S29—8 (for follow-on formula); and
(c) expressed in micrograms or milligrams; and
(d) in the same format as specified in the table for that substance.

Prohibition on proxy marketing
(Proposed draft section 2.9.1—29)

NSW supports the new provision in the proposed draft paragraph 2.9.1—29(1)(c) with the new clarification in the proposed draft subsection 2.9.1—29(2) — prohibiting

reference to another food by means of a name, a number, a picture, an image, a word or words. NSW agrees that proxy marketing should be prohibited on the label of IFP.

Whilst we acknowledge toddler milks (stage 3) and pre-schooler milk (stage 4) are out of scope of P1028, NSW would encourage FSANZ to review Standard 2.9.3 to close the loop on proxy marketing of IFP on toddler/pre-schooler milk labels.

Applicability of advisory statements to SMPPi
(*Proposed draft paragraph 2.9.1—38(2)(a)*)

NSW queries what is the reason for applying part of items of the table to section S9—2 to SMPPi. Specifically NSW does not understand why advisory statements about bee pollen (Item 1), aspartame (contains phenylalanine) (Item 4), guarana (contains caffeine) (Item 6) and propolis (Item 9) are required, while advisory statements about quinine (Item 5), cola beverage (Item 8) and unpasteurised egg product (Item 10) and unpasteurised milk (Item 11) are not required.

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.

Dated as 7 July 2023