Comments from the Victorian Department of Health and the Victorian Department of Energy, Environment and Climate Action.

Due date of submission – 7 July 2023

The Victorian Departments of Health and Energy, Environment and Climate Action including relevant portfolio agencies (the departments) welcome the opportunity to provide comment on the 2nd Call for Submissions (CFS) for Proposal P1028 – Infant Formula.

The departments recognise breastfeeding is the recommended way of feeding infants and is associated with improved health outcomes for both mother and baby. Where infants are not breastfed, infant formula is the only suitable substitute. Ministerial expectations for these products are set out in the Ministerial Policy Guideline on the Regulation of Infant Formula Products (the policy guideline). The policy guideline recognises the vulnerability of infants, their reliance on infant formula as the sole or principal source of nutrition, and the need for commensurate requirements in relation to the composition, labelling and promotion of infant formula products.

Recognising the extensive consultation to date and the response of Food Standards Australia New Zealand (FSANZ) to previous stakeholder submissions, comments are limited to matters where FSANZ has proposed a new or revised approach since the 1st CFS, or where the departments hold significant concerns in relation to infant health and safety, regulatory clarity or alignment with ministerial expectations. Where the departments have not made comment, our position remains unchanged from comments submitted to previous statutory and non-statutory consultations. This includes in relation to nutrient composition, food additive permissions, contaminant limits and approach to optional ingredients.

The departments recognise the extensive history and considerable work that has been conducted as part of P1028 to lead to the proposed draft variations presented in the 2nd CFS. We thank FSANZ and all those involved in achieving this significant milestone. We are committed to resolving any outstanding concerns to enable the smooth progression of the proposal and welcome further discussion as required.

Overview of comments to the 2nd CFS

Table 1 summarises the departments' comments to key issues raised in relation to the 2nd CFS. Further detail is provided in subsequent sections.

Section	Comments
Regulatory framework	<u>'Low risk' infant formula products</u> • Agree that partially hydrolysed infant formula should be classified as a general purpose infant formula product but suggest further consideration is required of labelling restrictions to prevention inappropriate representation as pseudo-medical products. • Do not support the categorisation of 'low lactose' and 'lactose-free' as 'low risk' general purpose infant formula products as it would create a dual regulatory pathway. Consider these products should only be regulated as Special Medical Purpose Product for infants (SMPPi). <u>SMPPi</u> • Support capturing SMPPi within the definition of an infant formula product. • Consider the SMPPi definition requires refinement to ensure only true medical products are captured. <u>Human milk fortifiers and supplementary products</u>

	• Support excluding fortifiers and supplementary products from the scope of the Proposal.
Novel foods and nutritive substances	• Suggest a clause should be added to Standard 2.9.1 to clarify that substances must not be added to infant formula products unless expressly permitted. • Do not support the total exemption from novel food restrictions for SMPPi. Suggest placing some restrictions on the exemption that requires novel substances to have been approved by an equivalent government or scientific authority.
Lactic acid producing microorganisms (LAM)	• Do not support the proposed approach to retain the existing blanket permission for LAM. • Consider the permission should be clarified that LAM may only be added for acidification purposes to provide regulatory clarity.
Labelling	<u>Nutrition Information Statement (NIS) – Additional</u> • Support the required NIS format but suggest changes to drafting in relation to the 'additional' section to ensure all voluntary substances are included. <u>Stage labelling and proxy advertising</u> • Support the proposed approach but suggest the drafting in relation to the age statement is amended to provide clarity that infant formula is suitable and recommended from birth to 12 months. <u>Product differentiation</u> • Support the intention but suggest changes to the drafting aligned with Codex and EU regulations to improve clarity and enforceability. <u>SMPPi – labelling exemptions</u> • Do not support exemption from the requirement to label name and address of supplier. <u>SMPPi – labelling of medical purpose</u> • Support in principle but suggest drafting should be amended to prevent the statement being represented as a health or therapeutic claim.
Costs and benefits	• Interested in the further break even analysis that will be conducted by FSANZ as this information will be critical in ministerial decision-making.
Transition period	• Suggest a three year transition period with stock in trade allowance would provide an equivalent total transition timeframe whilst enabling earlier transition where product sales are higher.

Table 1: Summary of key comments from the Victorian Departments of Health and Energy, Environment and Climate Action to Proposal P1028 2nd CFS

Regulatory framework

The departments largely support FSANZ's proposed regulatory framework but believe some areas require reconsideration to ensure labelling and access controls are consistent with, and support, appropriate use. These areas are discussed below.

Labelling and classification of 'low risk' infant formula products

Consistent with the 1st CFS, FSANZ is proposing that 'low risk' infant formula products with compositional modifications relating only to partially hydrolysed protein or low lactose/lactose-free are classified as general purpose infant formula products.

The departments continue to support classifying infant formula based on partially hydrolysed protein as a general purpose infant formula and not a SMPPi on the basis that there is no evidence to support their use in the dietary management of medical conditions in infants and they are not recommended by medical professionals. The Australasian Society of Clinical Immunology and Allergy (ASCIA) do not recommend using partially hydrolysed formula for dietary management of allergy [1,2]. Additionally, there is a lack of robust evidence for other purported benefits of partially hydrolysed infant formulas such as reducing infantile colic[3,4] and preventing eczema, food allergy, asthma or allergic rhinitis[5].

Despite the lack of evidence for benefit, partially hydrolysed formulas are commonly represented as a medical-type product through positioning as a solution to what is otherwise common transient infant behaviours (e.g., colic, reflux, frequent waking). This presentation is referred to as pain-point marketing and have been identified by the World Health Organization as a growing issue that has the potential to undermine maternal breastfeeding confidence and result in unnecessary transition to formula feeding[6].

To protect continued breastfeeding, regulation must adequately prevent modified formulas from being represented as a solution to common infant problems through suggestive labelling such as 'colic'. The proposed restriction on labelling that permits only the words 'partially hydrolysed' in the name of the food and the statement of ingredients goes some way to ensure appropriate presentation of these formulas. However, the departments remain concerned the intentions of the Code in ensuring appropriate presentation of these products will be undermined if the suggestive labelling is trademarked. It is noted that FSANZ intends to liaise with IP Australia and the Intellectual Property Office of New Zealand (IPONZ) to ensure they are aware of the intent of the changes to Standard 2.9.1—24 (prohibited representations). It would be opportune to also revisit and reiterate prohibitions on health claims under Standard 1.2.7 for infant formula products during these discussions.

While the departments previously also supported capturing lactose-free and low lactose products as general purpose infant formula, the additional information provided in the 2nd CFS related to the statement of medical purpose required for SMPPi has highlighted potential issues with the proposed approach. **The departments are concerned that the proposed regulatory framework will create a dual pathway for lactose-free products as both general purpose infant formula and a SMPPi**. Although uncommon in infants, congenital lactose intolerance and galactosaemia are medical

[1] D'Auria, E., Salvatore, S., Acunzo, M., Peroni, D., Pendezza, E., Di Profio, E., Fiore, G., Zuccotti, G.V. and Verduci, E., 2021. Hydrolysed formulas in the management of cow's milk allergy: new insights, pitfalls and tips. *Nutrients*, *13*(8), p.2762.
[2] Joshi, P.A., Smith, J., Vale, S. and Campbell, D.E., 2019. The Australasian Society of Clinical Immunology and Allergy infant feeding for allergy prevention guidelines. Medical Journal of Australia, 210(2), pp.89-93.
[3] https://www.schn.health.nsw.gov.au/files/factsheets/infant_formula-en.pdf
[4] Gordon, M., Biagioli, E., Sorrenti, M., Lingua, C., Moja, L., Banks, S.S., Ceratto, S. and Savino, F., 2018. Dietary modifications for infantile colic. *Cochrane Database of Systematic Reviews*, (10).
[5] Boyle, R.J., Ierodiakonou, D., Khan, T., Chivinge, J., Robinson, Z., Geoghegan, N., Jarrold, K., Afxentiou, T., Reeves, T., Cunha, S. and Trivella, M., 2016. Hydrolysed formula and risk of allergic or autoimmune disease: systematic review and meta-analysis. *bmj*, *352*.
[6] https://www.who.int/news-room/commentaries/detail/it-s-time-to-stop-infant-formula-marketing-practices-that-endanger-our-children

conditions which pose specific nutritional requirements and require the use of lactose-free formula. Thus, lactose-free formula appears to meet the definition of a SMPPi. If a lactose-free formula was sold as a SMPPi, the product would be required to be labelled with a statement of the medical purpose (lactose intolerance), thereby enabling the same or similar products to be on the market labelled as both 'lactose-free' and for 'lactose intolerance. This could create confusion among caregivers if a seemingly similar products are presented and labelled differently (for example, with or without guidance on use under medical supervision**). The departments consider that lactose-free and low lactose formula should only be permitted to be classified as SMPPi** as this would align with their primary medical purpose and remove any caregiver or regulatory confusion. Accordingly, **the departments do not support the provisions for lactose free and low lactose formula proposed in the 2nd CFS**.

SMPPi

FSANZ has revised the proposed regulatory framework from the 1st CFS such that SMPPi will be captured as a subcategory of infant formula products (rather than a parallel separate category to infant formula products). The departments support this approach which will ensure all relevant general infant formula provisions are applied to SMPPi. We note this is also consistent with the scope of the policy guideline.

FSANZ has also revised the definition for SMPPi, keeping most elements from the definition presented in the 1st CFS (except the reference to partial feeding) but rearranging the various components. The proposed definition now reads:

> ***special medical purpose product for infants*** *means an infant formula product that is:*
> *(a) represented as being:*
> *(j) specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and*
> *(ii) suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and*
> *(iii) for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and*
> *(b) intended to be used under medical supervision; and*
> *(c) not suitable for general use.*

The departments are concerns that bringing 'represented as being' to the start of the definition weakens the capture of true evidence-based medical products. Whereas the definition previously stated:

> *'**special medical purpose product for infants** means a food that is:*
>
> *a. specially formulated for the dietary management of infants….'*

The revised definition means a SMPPi only needs to be represented as being formulated for the dietary management of infants, thereby bringing into question whether products under this category need to demonstrate an effective role in the dietary management of infants.

It is critical that the SMPPi definition only incorporates products that are scientifically proven to be necessary for infant nutrition given the regulatory flexibilities that are proposed for this category on

the basis that they are specialised, predominantly imported products, for which continued supply may be critical for infant health. Without adequate controls, there is a risk that products may be represented as a SMPPi in order to access novel food permissions without proper scrutiny or evidence for benefit. As noted earlier, it is also important that pseudo-medical products that claim to resolve transient infant problems are not represented as SMPPi as this could undermine maternal breastfeeding efforts. We note that the primary draft variation will pose restrictions on places of sale for SMPPi to discourage inappropriate use without proper guidance from a health professional. However, given the ubiquity and accessibility of pharmacies, including online stores, these access restrictions cannot be relied on entirely and the Code must also act to prevent inappropriate representation.

The departments suggest the phrase *'represented as'* creates a circular definition where the proposed labelling provisions for SMPPi cause the product to meet the represented criteria. For example, a SMPPi is required to be labelled with a statement of the medical purpose, therefore, by virtue of complying with the Code, the product will be represented as being for the dietary management of a medically diagnosed disease, disorder or condition of an infant. We also note subsection 2.9.1 – 33 requires that a food may only be represented as a SMPPi if it complies with the requirements for SMPPi outlined in Division 4. This suggests SMPPi and products represented as SMPPi are one and the same, and there is no need to specifically identify products represented as SMPPi in the definition.

The departments recommend removing the phrase 'represented as' and including additional wording to make clear only evidence-based medical products are included, as proposed below:

> **special medical purpose product for infants** means an infant formula product that is:
> (a) specially formulated:
> i. for the **effective** dietary management of infants who have medically **diagnosed** nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and
> ii. whose dietary management cannot be completely achieved without the use of the food; and
> iii. to constitute either the sole or principal liquid source of nourishment
> (b) intended to be used under medical supervision; and
> (c) not suitable for general use.

Human milk fortifiers and supplementary products

In revising the regulatory framework for SMPPi, FSANZ has removed partial sources of nourishment such as fortifiers and supplementary products as they would not meet the definition of an infant formula product, which are by definition complete nutritional products. It is noted that the inclusion of supplementary products would increase the scope of P1028 and potentially further delay implementation. **The departments consider excluding supplementary products from P1028 is preferable to delaying amendment to Standard 2.9.1**, particularly given the current regulation of supplementary products are generally functioning effectively. The departments support FSANZ's position on the scope of P1028 as detailed in the 2nd CFS.

Novel foods and nutritive substances

The departments recognise the benefits and efficiencies associated with reviewing permissions for novel foods and nutritive substances in infant formula as part of the wider review under P1024, particularly where changes to definitions are to be considered. However, given Proposal P1024 remains on hold without clear timeframes for recommencement or finalisation, the departments are uncomfortable that ministerial policy direction in relation to novel food and nutritive substances will not be achieved under Proposal P1028. The Policy Guideline states *'Pre-market assessment… should be required for **any substance** proposed to be used in infant formula or follow-on formula..'.* Currently, the Code prohibits the addition of novel foods and substances used as a food additive, nutritive substance or processing aid unless expressly permitted. The departments consider the Code does not completely fulfill the objective of the policy guideline and leaves potential gaps for substances which may not fall within the current distinct categories. While we recognise several recent applications for the addition of substances to infant formula indicates industry are seeking appropriate pre-market assessment, this does not guarantee certainty for the future.

To provide clarity for industry and regulators and ensure alignment with the policy guideline, **the departments suggest a clause should be added that states a substance must not be added to infant formula products unless expressly permitted**. This could be placed under Division 2 Compositional requirement for infant formula and follow-on formula, with additional clarification under Division 4 that the paragraph does not apply to SMPPi. These provisions could later be reviewed and if necessary repealed under Proposal P1024.

In addition, the departments are concerned with the proposed excluded provisions for nutritive substances and novel foods for SMPPi. FSANZ has proposed that paragraphs 1.1.1—10(6)(b) (foods used as nutritive substances) and 1.1.1—10(6)(f) (novel foods) will not apply to SMPPi, in effect removing pre-market assessment requirements. While we recognise lengthy pre-market assessment may limit expedient SMPPi access, the departments do not support the current approach which removes all regulatory scrutiny and safety assessment. **We are particularly concerned that novel emerging technologies or substances, such as cell-based human milk fortifier, could be positioned as SMPPi and subsequently bypass appropriate pre-market assessment**.

The departments suggest the following additional caveats to the proposed drafting of clause 2.9.1-30 (a) may provide a more balanced approach between market flexibility and safety assurance:

1) specify the exemption may only be applied where the substance is required for the medical purpose or would otherwise prohibit access; and
2) require regulatory approval by at least one appropriate scientific or government authority

Lactic Acid producing Microorganisms

At the 1st CFS, FSANZ proposed to clarify, in line with the original intent, that L(+) lactic acid producing microorganisms (LAM) may only be added to infant formula products for acidification purposes. FSANZ has since revised this position and instead proposes to retain the existing blanket permission for LAM based on:

1) No safety concerns;
2) Long history of use in infant formula products currently on market;
3) Alignment with Codex; and

4) Removal of permission would cause large reformulation cost to industry, loss of products from the market and potentially a large influx of applications to FSANZ seeking permission to add LAM to infant formula products (where current use is not for acidification purposes).

The departments **do not support the proposed approach to retain the existing blanket permission for LAM** on the basis that it is inconsistent with the intent of the policy guideline, and would leave regulatory ambiguities previously raised by stakeholders unresolved.

FSANZ notes in the 2nd CFS that LAM added for a probiotic purpose would constitute a substance that is being added to achieve a nutritive purpose, and accordingly would require pre-market assessment. However, due to the unspecific nature of the LAM permission, the purpose of addition to infant formula products and whether it is as a nutritive substance may be contested. This is because it could be argued that LAM present in infant formula is not performing a nutritive purpose if the substance is not listed in the NIS (which is current practice among market products). While LAM are not being declared as a nutritive substance on stage 1 and 2 product labels, it is commonplace for the stage 3 product of the same product line to label the exact same LAM strain in the NIS and on the front of pack as a probiotic. We have also identified products where LAM are not represented as being used for a nutritional purpose on the label but are promoted as containing probiotics in product information targeted at healthcare professionals. Thus, it appears LAM are being added for a probiotic purpose but are intentionally not being represented as such in infant formula labels to avoid pre-market assessment requirements. This undermines nutritive substance permissions in the Code and the intent of the policy guideline which states that all substances added to infant formula should undergo pre-market assessment and should demonstrate a beneficial effect in infant growth and development.

The departments strongly consider clarifying that LAM may only be added for acidification purposes would remove any ambiguity or loophole regarding nutritive substance permissions. While it is recognised that this would impact a number of products currently on the market, the departments disagree that it would cause a large reformulation cost to industry or loss of products from the market. As noted above, current LAM addition appears to be for a probiotic purpose. Probiotics are generally added at very small ingoing amounts and do not perform a technical function. Accordingly, reformulation should involve a relatively simple removal and replacement with a main ingredient such as milk solids. This would not require shelf life testing and should be achievable within the proposed transition period to ensure compliant and continued supply. Without specifying the intended purpose for the LAM permission, new LAM strains will be permitted in the absence of a pre-market assessment in opposition to the intent of the policy guideline.

Labelling

Nutrition Information Statement (NIS) - Additional

The departments support the required NIS which will simplify and standardise nutritional information. However, we consider changes are required to the proposed format to clearly separate mandatory from voluntary substances. We suggest docosahexaenoic acid is removed from the indent under ‘Long chain polyunsaturated fatty acids’ and the clause under ‘Additional’ is amended with the addition below in bold to ensure, consistent with its voluntary permission, docosahexaenoic acid is captured under ‘Additional’.

*(insert any other substance used as a nutritive substance; **or novel food**; or inulin-type fructans and / or galacto-oligosaccharides, to be declared)*

Stage labelling and proxy advertising

The departments support FSANZ's proposed approach to stage labelling and proxy advertising, including:

- permitting the numbers '1' and '2' be displayed on the front of pack for infant formula and follow-on formula respectively
- requiring co-location of an age statement where stage information is displayed
- Prohibiting stage information elsewhere on the label

The departments **strongly support the co-location of stage and age information** to prevent any potential misunderstanding regarding stage labelling. However, the departments do not consider the proposed drafting in relation to age statement is sufficient to ensure labelling consistency and prevent caregiver confusion. The proposed drafting for the age statement for infant formula states:

(a) for infant formula—the infant formula may be used from birth;

Current practice for 'stage 1' age labelling varies between market products, with some labelling *'from birth'* and others stating *'from birth to 6 months'*. Both approaches would be compliant with the proposed drafting but would not provide consistent advice to caregivers. The departments suggest **the subclause is amended to provide clarity that infant formula is suitable and recommended from birth to 12 months**.

Product differentiation

The departments support introducing provisions that require clear differentiation between infant formula, follow-on formula and other formula products for young children. In particular, we note distinction between infant formula and 'stage 3' products (commonly known as toddler milks) has several benefits, including:

- reducing the risk of toddler milk being provided to infants either accidently due to the similar appearance or intentionally as a result of caregiver's believing the products are similar enough to act as a replacement in times of product shortages or financial hardship (noting toddler milks are generally cheaper than infant formula and follow-on formula)
- ensuring claims on toddler milks are not interpreted as applying to infant and/or follow-on formula, which may discourage breastfeeding efforts.

We also note clarifying product differentiation requirements would be aligned with European Union regulations and the Codex Draft Standard for Follow-up Formula for Older Infants (FuFOI). While we support the intention, we consider the proposed drafting may not provide enough clarity for industry and regulators. Under the draft amendments, subsection 2.9.1 – 15(2) states:

2) A food represented as infant formula or follow-on formula must not be also represented as another food.

Example A food represented as infant formula must not be also represented as, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.

The departments believe the clause as currently drafted is unenforceable as it is not clear what would constitute infant formula or follow-on formula being represented as another food. For example, does a shared brand name indicate a food is represented as infant formula? How similar does the imagery or colours on labels have to be to consider infant formula being represented as another food? **We suggest, consistent with EU and Codex, a more descriptive clause is included that notes the intention of avoiding confusion between infant formula, follow-on formula and other related products relative to the text, images and colours used**.

SMPPi – labelling exemptions

The departments recognise the need for modified labelling requirements for SMPPI due to their specialised nature and predominant production outside of Australia. While we generally support the proposed modified labelling requirements, **we do not support the exemption for SMPPi from providing the name and address of the supplier**. This information provides a clear and immediate point of contact in cases of food safety incidents that require products to be recalled. The absence of supplier information could delay recall activities thereby increasing the risk of further infant harm. The departments do not consider that the cost of over stickering supplier information outweighs the potential risks to infants posed by delayed recall, particularly given product volumes are likely to be modest due to their specialised nature. The departments recommend the name and address of the supplier is provided on SMPPi.

SMPPi - labelling purpose of medical purpose

The departments support the proposed requirement for SMPPi to be labelled with a statement indicating the medical purpose of the food to ensure the medical nature and purpose of the product is clear. However, **we are concerned that the proposed drafting is not prescriptive enough to prevent the statement from being presented as a health or therapeutic claim** which could create regulatory uncertainty and undermine current health claim prohibitions**.** The proposed draft variation outlines the required statement as:

> *(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated*

The draft variation should prohibit non-relevant information from being incorporated into the statement that may serve to inappropriately promote the product. FSANZ may also consider aligning with the approach in the European Commission Delegated Regulation (EU) 2016/128 on Foods for Special Medical Purposes, which is more specific and requires *'the statement 'For the dietary management of …' where the blank shall be filled in with the disease, disorder or medical condition for which the product is intended*'. The departments recommend the labelling provision makes it clear that while the statement may reference a disease, disorder or medical condition, it must not indicate a therapeutic benefit.

Costs and benefits

The economic assessment of Supporting Document 4 identified in order to break-even, a benefit of approximately $27 AUD per infant would need to be realised. FSANZ anticipates this will be achieved

but noted an improved analysis will be conducted, based on comments to the 2nd CFS, and incorporated into the Decision RIS provided to Ministers. The departments are very interested to consider these further detailed analyses as they become available in order to support informed ministerial decision-making.

Transition period

The departments appreciate the scale of proposed changes and the need for a commensurate transition period. However, we are concerned that the proposed five year transition will create an unnecessarily extended period of regulatory cross-over and may cause confusion or uncertainty among caregivers, medical professionals and regulators. In addition, there may be significant advancements in infant formula products over this time where the revised standard is no longer fit for purpose by the time it takes full effect. **The departments suggest a shorter transition period of three years in conjunction with stock in trade provisions** would effectively provide the same five year transition period (noting shelf life of infant formula may be up to 24 months) but with opportunity for earlier transition where sales volumes are higher and products are sold through sooner.