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7 July 2023

Submission – 2nd Call for submissions
Proposal P1028 – Infant Formula

Public Health Services, Department of Health, Tasmania (PHS) appreciates the opportunity to comment on Proposal P1028 – Infant Formula Second Call for Submissions.

PHS recognises that breastfeeding is the normal and recommended way to feed an infant. For infants that rely on infant formula as the sole or principal source of nutrition up to 12 months of age, regulation is essential to ensure infant formula remains safe and that its nutrient composition supports normal growth and development. It is for this reason that Standard 2.9.1 should be one of the most prescriptive standards in the Food Standards Code.

Regulation of infant formula must also ensure that labelling and advertising of infant formula products does not undermine the promotion of breastfeeding. This is consistent with the World Health Organisation (1981) *International Code of Marketing of Breast Milk Substitutes*.

The *Ministerial Policy Guideline on the Regulation of Infant Formula Products* clearly states that a greater level of risk needs to be managed and that the regulatory framework should include requirements commensurate with this level of risk for the composition, labelling, advertising, and promotion of infant formula products. PHS remains committed to this Ministerial Policy Guideline.

PHS has provided seven submissions on the review of infant formula regulations since 2012. Whilst a number of FSANZ proposed changes are supported by PHS there are a number of areas that have consistently not been resolved:

- Reviewing the scientific evidence for optional ingredients and considering a regulatory framework on how this can be addressed
- Failure to address areas of regulatory uncertainty regarding pre-market assessment by not including the review of novel foods and nutritive substances as part of P1028.

2. Regulatory Framework

PHS does not support FSANZ proposed approach in full and remains concerned with the inclusion of nutritionally complete infant formula products with a modified formulation (partially hydrolysed protein and/or low lactose/lactose free) included in Category 1 – Infant Formula Products.

Whilst PHS acknowledges that Category 1 Infant formula products cannot include nutrition content claims or health claims there is currently no mechanism in the Code to address trademark terms and names which can act as a pseudo claims. These inadvertently promote these modified formulas to aid with sleeping, crying, or unsettled behaviour. Examples include 'sweet dreams', 'HAPPi day', 'HAPPI night', 'Sensitive' and 'Comfort'.

Partially hydrolysed infant formula

FSANZ notes in Supporting Document 2 (2022) that partially hydrolysed formula in the prevention of allergies is not supported by the majority of stakeholders and current infant feeding guidelines. This is also supported by systematic reviews where they found 'no evidence that hydrolysed formula prevents eczema or milk allergy' (Munblit et al., 2020); further supported by *ASCIA Guidelines: Infant Feeding and Allergy Prevention* (2020) and consultation with clinical experts in Tasmania.

Whilst there is no evidence that these products are unsafe, current practice of marketing these products for managing colic, regurgitation and constipation can undermine breastfeeding. The WHO report (WHO 2022) highlights there has been a rise in 'pain point' marketing of infant formula products. This is a strategy that aims to raise awareness of a problem or convince potential customers that they have a problem which can be solved by purchasing a product. It is often linked to common infant behaviours such as colic, reflux and crying that may be better addressed through other strategies (WHO 2022). There is also the risk that the marketing of these products may cause harm by delaying appropriate investigations of treatment for underlying medical conditions (Munblit et al 2020).

Whilst PHS remains concerned with partially hydrolysed infant formula remaining on the market for no functional purpose, the restriction in claims as a result of its inclusion as a standard formula, go some way to alleviating this issue.

Lactose free/low lactose infant formula

PHS considers low lactose/lactose free infant formula is better placed as a special medical purpose product for infants (SMPPi). These products, if required, are for a medical purpose including primary lactose intolerance (rare in infancy), galactosemia (rare genetic condition) and secondary lactose intolerance (transient condition as a result of gut injury and should be under medical supervision if prolonged diarrhoea).

The use of low lactose/lactose free formulas for healthy infants is not warranted and the marketing of these products to reduce fussiness, crying, reflux and discomfort in infants undermines breastfeeding and should be restricted.

In addition, lactose makes up the largest provision of carbohydrate energy in breastmilk and replacing this with other carbohydrate sources for no reason moves away from the composition of breastmilk. There is some evidence that low lactose formulae are associated with later onset obesity which may be attributed to the greater sweetness of glucose and other sugars compared to lactose or metabolic effects as a result of higher gylcemic index and rapid digestion (Anderson et al.,2022).

By placing these products in SMPPi, infants will consume these only when considered medically necessary and not because of the perception that lactose is associated with gastrointestinal discomfort. By including these in SMPPi they can only be labelled with a specific medical purpose and according to *the Policy Guideline on the Regulation of Infant Formula Products*, specific policy principle (p) states – *the composition of infant formula products for special dietary uses should be based on appropriate scientific evidence*. This will reduce the use of pseudo claims mentioned previously.

3. Definitions

PHS supports the definition of Infant Formula with the following additions:

Infant formula means an infant formula product that:

- *a. is represented as a breast milk substitute for infants; and*
- ***b.*** *satisfies by itself the nutritional requirements of infants under the age of 6 months* ***and as part of a diversified diet from 6 months of age.***

Whilst PHS acknowledges that the definition of an infant means a person under the age of 12 months, the definition as it currently stands implies that after 6 months infant formula will no longer satisfy the nutritional requirements of infants. The NH&MRC Infant Feeding Guidelines (2012) clearly states that '*the use of follow-on formula for infants aged 6-12months is not considered necessary and no studies have shown advantages over using infant formula*'.

PHS supports the definition of SMPPi with the following additions:
A Special Medical Purpose Product for infants means an infant formula product that is

a. represented as being:
    i. 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 principle 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; and
d. are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended medical purpose

PHS strongly supports the categorisation of products as SMPPi to be based on scientific evidence. This approach not only protects vulnerable infants, but also protects breastfeeding by caregivers not persuaded that a certain formula can treat common ailments or resolve inconvenient but normal infant behaviour such as unsettled babies. It needs to be clearly stated that the intended purpose be specified as a medical purpose and that it clearly needs to demonstrate efficacy of the product in accordance with the intended purpose.

4. Novel Foods and Nutritive Substances

Pre-market assessment requirements

As stated in previous submissions, PHS does not support FSANZ proposed approach to not consider novel foods and nutritive substances under P1028 and instead consider these as part of P1024. As FSANZ states, pre-market assessment would always be required for substances added to infant formula products and that a risk proportionate framework will not by-pass these pre-market assessment requirements. With this in mind, it is unclear why P1028 does not clarify outstanding issues with what substances require pre-market assessment in Standard 2.9.1 to reduce existing ambiguities in the Code. These small changes are unlikely to impact P1024.

Whilst P1025 Code Revision in Standard 1.1.2 -12 may have addressed some of the issues on what substances require pre-market assessment, it has not addressed all. For example, alpha – lactalbumin, naturally present in milk (whey) protein requires pre-market assessment as a result of -

> *'any substance (other than an inulin-type fructan, a galacto-oligosaccharide or a substance normally consumed as a food) that has been concentrated, refined or synthesised, to achieve a nutritional purpose when added to a food' (Standard 1.1.2 -12)*

This clarification ensures that any macronutrient that is naturally present in milk cannot be automatically assumed to be safe when added back to infant formula product if it has been concentrated, refined, or synthesised to achieve a nutritional purpose.

However, PHS is unclear if a bioactive component such as a probiotic may or may not be captured under the definitions currently in the Code and needs further clarification as part of P1028. A probiotic by definition is a 'live microorganism which when administered in adequate amounts confer a health benefit on the host' (Ebner et al., 2014). Another

substance, postbiotic are 'compounds produced by microorganism and released from food components or microbial constitutes, when administered in adequate amounts to promote health and wellbeing' (Salminen et al., 2020). These bioactive compounds are a growing area of research in infant formula products, and it is essential that these are captured to include pre-market assessment. It is ambiguous whether these substances are captured under the current definition of a nutritive substance as technically they do not achieve a 'nutritional purpose' when added to food but a 'health effect'. Whilst FSANZ notes that evidence from Industry suggests they continue to seek pre-market assessment for these substances added to infant formula products, therefore providing evidence that the current regulation is clear and functioning effectively, there is still a level of ambiguity. As a result, there is no guarantee that this will function effectively in the future.

The *Ministerial Policy Guideline on the Regulation of Infant Formula Products* clearly states that **any substance** would require pre-market assessment if a different form/structure is used, or a different technology or technique is used or if a different level of these substances was added to Infant Formula Products. *The Ministerial Policy Guideline on the Regulation of Infant Formula Products* is clear on this as it states '*pre-market assessment should be required for **any substance** proposed to be used in infant formula and follow-on formula that*:

i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or

ii. 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.

This definition ensures that **any substance**, not just a vitamin, mineral, food additive or nutritive substance requires pre-market assessment. Inclusion of a clause in 2.9.1 that states 'substances must not be added to infant formula products unless expressly permitted' would reduce this ambiguity for both regulators and industry.

Novel Foods

PHS supports amendment to section 1.5.1-3 to state that novel foods must not be added to infant formula products unless express permission is stated in the table S25-2.

PHS also supported FSANZ previous position in Consultation Paper 3 (2021) where the conditions for novel foods included infant formula products in addition to foods for infants (2.9.2) and formulated supplementary foods for young children (FSFYC) (2.9.4). Whilst PHS acknowledges these regulations are out of scope for P1028, in 2021 FSANZ reviewed the exposure assessment to determine which novel foods did not include infants and young children less than 2 years and concluded that infant foods and FSFYC should also be included along with infant formula products. Amending Schedule 25 without the addition of infant foods and FSFYC exacerbates the current ambiguity and inefficiencies within the food regulatory system and poses a level of risk to infants.

Trehalose

As stated by FSANZ in the first call for submissions (April 2022) the original assessment of trehalose was to restrict its use in infant formula, infant foods and FSFYC. At the time of trehalose assessment (2003) dietary exposure was not undertaken on children under 2 years and therefore you could argue its permission in infant formula products was not considered.

In the second call for submissions FSANZ have provided additional data on the safety in this age group. If Trehalose is to be approved in infant formula PHS supports FSANZ's condition statement that its use by restricted to a cryo-preservative purpose (and noy as a carbohydrate source).

5. L(+) Lactic acid producing microorganisms (LAM)

PHS supported FSANZ position in the first CFS to retain the existing permissions for addition of LAM for acidification purposes only. PHS does not support LAM being added for a probiotic function when it has not undergone pre-market assessment. This not only undermines the *Ministerial Policy Guideline on the Regulation of Infant Formula* but also poses a risk to infants. There have been case reports of sepsis and infections in infants with underlying clinical complications including pre-term, low birth weight and immune-compromised infants. FSANZ states 'due to a lack of sufficient data on infectivity and exposure, FSANZ was unable to assess the level of risk in these circumstances' but FSANZ concluded for healthy fully term infants LAM poses no to public health and safety.

As stated by FSANZ, LAM have not been assessed for their beneficial health effects in infant formula products and therefore existing conditions does not include the addition of LAM for a novel food or nutritive substance. However, we know from their addition in toddler milks that they are being promoted as probiotics, with a number of companies promoting their addition as a probiotic in the ingredients list in infant formula and follow-on formula (see figure 1). Even if words prohibiting the use of LAM as a probiotic are included in the proposed changes to 2.9.1, cross-promotion of stage 3 (toddler milks) will still continue.


Organic **Lactose**, Organic Vegetable Oil Blend (High Oleic Sunflower, Coconut, **Soy**, Canola), Organic **Whole Milk** Powder, Organic **Whey Protein** Concentrate, Organic **Skim Milk** Powder, Organic Galacto-Oligosaccharide (**GOS**), Emulsifier (**Soy** Lecithin), Docosahexaenoic Acid (**DHA**, from Algae), Arachidonic Acid (**ARA**), **Probiotic** Bifidobacterium longum BB536.

Figure 1: Stage 1 (infant formula product) highlighting the use of probiotics.

FSANZ have outlined that restricting the existing permissions for acidification has the potential to disrupt the market; consideration of a bulk application process of existing LAM currently permitted during the transition period may reduce this impact. This would be

consistent with the policy guideline and enable a thorough risk assessment to be undertaken, including a review of the evidence for a substantiated beneficial role in the normal growth and development of infants.

7. Nutrient composition for Infant Formula Products (SD2)

Carbohydrate source - PHS supports FSANZ approach to carbohydrate source and the additional clarification that sucrose and fructose can only be added to partially hydrolysed infant formula.

Protein source – PHS supports prescribing protein source to increase regulatory clarity and the wording change to include '*of one or more of these specified proteins'* to better infer the intent of this regulatory decision. PHS supports pre-market assessment of sources outside those specified as this aligns with the *Ministerial Policy Guideline on the Regulation of Infant Formula Products* in protecting public health and safety of infants

The rationale for the inclusion of sheep's milk appears sound, however this has not undergone a pre-market assessment and therefore potentially undermines the policy guideline. Consideration of an application to FSANZ to assess the use of sheep's milk protein may be warranted.

PHS is concerned that allowing sheep's milk without a pre-market assessment opens the gate for other products such as rice and pea protein infant formulas that are already on the market. This would not be consistent with the *Ministerial Policy Guideline on the Regulation of Infant Formula Products.*

Docosahexaenoic Acid (DHA) – PHS does not support FSANZ view that optional ingredients such as LC-PUFA's should not be reviewed. The rationale outlined by FSANZ includes (1) a long standing permission and no sound evidence of safety concerns, (2) consistency with international regulations, (3) no lack of regulatory certainty and (4) assessment against the *Ministerial Policy Guidelines on the Regulation of Infant Formula* only applies to new ingredients or substances.

The EU has recently mandated DHA on the basis that (1) DHA is an essential structural component of the nervous tissue and retina and is involved in normal brain and visual development; (2) the developing brain has to accumulate large amounts of DHA in the first two years of life; (3) although DHA can be synthesised from ALA, the intake of pre-formed DHA results in erythrocyte DHA status more closely resembling that of a breast fed infant than ALA alone; and (4) although there is no convincing evidence beyond infancy there is a lack of long term follow up data. Based on these factors combined ESFA supported pre-formed DHA to be mandatory in infant formula (ESFA 2014). With the EU now mandating DHA, FSANZ is no longer consistent with all international regulations.

The food regulatory system needs to include a mechanism where optional ingredients can be reviewed after a certain number of years to ensure these ingredients do not remain

'optional' for more than 20 years. Evidence should have accumulated over this length of time to either accept or revoke DHA inclusion in infant formula. PHS would like to understand what mechanism FSANZ will put in place to review the evidence of these long standing voluntary permissions.

Continuing to allow DHA to remain an optional ingredient increases inequity in infant formula products as many of these products are sold at a higher premium. If it is deemed that there is no need for pre-formed DHA, then retaining the permission could be considered misleading. If it is deemed that pre-formed DHA should be included in all infant formulas, then this would create a level playing field and ensure all consumers can obtain the benefits irrespective of purchasing standard formula or a premium one.

Nucleotides, Taurine and Lutein – PHS does not support maintaining indefinite optional status of nucleotides, taurine and lutein. In 2021 PHS requested that FSANZ review all optional/voluntary ingredients as part of the review as many of these substances have been added to infant formula for up to 20 years without a review. This request has not been addressed in the current Call for Submissions.

Whilst PHS understands that optional ingredients have been permitted in the Code to enable industry to innovate and improve outcomes for formula-fed infants, remaining optional for up to 20 years is not in line with protecting the health and safety of all infants. If these substances have a substantiated beneficial role in normal growth and development, by keeping them optional, many infants are missing out on key nutrients. Alternatively, there may be consumers purchasing infant formula, (often at a premium price), because it contains an optional ingredient that may not have a substantiated beneficial role in growth and development.

Standard 2.9.1 currently has no mechanism to enable these substances to be:

1) added to **all** infant formula products once there is evidence that the ingredient has a substantiated beneficial role in the normal growth and development of infants, OR

2) there is not enough evidence that they have a substantiated role in normal growth and development and therefore their permission should be revoked.

PHS requests that FSANZ consider a mechanism to review the evidence after a specific timeframe (e.g., 5 years after gazettal) to ensure any future optional ingredients are either added to all infant formula or revoked. FSANZ notes that both Codex and EU regulations do not have specific permissions for lutein in infant formula or follow-on formula.

Special Medical Purpose Products for infants (SMPPi)

PHS remains concerned about the lack of pre-market assessment of new substances added to SMPPi that have not been added for a special medical purpose. FSANZ states the substances permitted internationally should have previously undergone rigorous assessment. This needs to be captured in the standard or another mechanism established to ensure the

protection of vulnerable infants. The inclusion of additional wording in the draft standard may reduce the risk of SMPPi being used to bypass new substances requiring pre-market assessment.

Consideration of a clause in 2.9.1-30 such that the exemptions in the draft 2.9.1-30 (a) only apply where (1) the substance is required for a medical purpose; or (2) would otherwise prevent the sale of the food; **and** (3) that the substance has undergone a rigorous assessment by at least one regulatory authority equivalent to FSANZ.

The inclusion of clause (3) that the substance has undergone a rigorous assessment by at least one regulatory authority equivalent to FSANZ could also be added to 2.9.1-32(2) to ensure that maximum and minimum amounts of nutrients are based on a rigorous scientific process too.

8. Labelling for Infant Formula Products (SD3)

Part A. Safety-related labelling for infant formula and follow-on formula

PHS supports FSANZ approach on:

- Directions for use and storage
- Date marking
- Storage instructions, warning labels and their legibility
- Age statements
- Prescribed name
- Statement of protein source and co-location with the name of the food

Whilst PHS notes FSANZ proposes to retain the words 'breast is best' PHS would like it noted that this is not contemporary health communication language and can be counterproductive in protecting breastfeeding. Research suggests that the 'breast is best' message idealises breastfeeding as optimal rather than the 'normal' way to feed infants (Berry 2009). PHS does support the intent of the statement that it is there to highlight the superiority of breastfeeding and suggests FSANZ consider undertaking additional research on more appropriate language to convey this message.

PHS supports FSANZ's proposed approach to retain the requirement for the label to state the specific source of the protein (i.e., cow's milk) and not the protein fractions (e.g., whey, casein). This will ensure that protein fractions cannot be used as a potential nutrition content claim.

PHS supports FSANZ's proposed approach to retain the requirement for the co-location of the protein source and the name of the product (Infant Formula) and requirement for it to be placed on the front-of-pack. This will reduce the safety risks for those with allergies but also reduces the risk of caregivers accidently choosing a product that is not suitable for infants (e.g., toddler milks).

PHS supports the use of age statements but considers the use of 0-6 months for infant formula misleading to caregivers as it suggests that the product is not suitable after 6 months. PHS supports the use of the words 'birth to 12 months' or 'from birth' as the only two suitable statements on infant formula.

Part B. Labelling for provision of information about infant formula and follow-on formula

PHS supports FSANZ approach on:

- Statement of Ingredients
- Allergen Declaration
- Labelling as 'genetically modified'
- Declaration of nutrition information – format
- Declaration of nutrition information – base units of expression
- Declaration of nutrition information – weight of one scoop

PHS supports FSANZ approach to group added vitamins and minerals under subheadings 'vitamins' and 'minerals' in the statement of ingredients. Whilst PHS considers mandating in descending order would provide greater assistance to caregivers to compare products, a prescribed Nutrition Information Statement (NIS) is likely to provide this additional information in a more readable format.

PHS supports FSANZ approach to prescribe the format of the NIS as FSANZ have highlighted that these proposed changes would assist caregivers to make product comparisons easier. Whilst PHS supports a flexible approach to formatting of the subheadings 'Vitamins', 'Minerals', 'Other nutrients', and 'Additional' in the NIS so that they are the same or larger than the nutrient name PHS request an additional comment in the standard.

To prevent the overemphasis of one heading over another PHS requests the inclusion of a clause in 2.9.1 to the effect that the format chosen in the NIS (e.g., lines, bolding, shading, font, or text size) for one heading is the same as all other headings to ensure all nutrients are equally identified.

PHS also supports this clause is relevant to the statement of ingredients as currently there is nothing preventing the overemphasis of one ingredient over another with many infant formula products bolding nutrients such as DHA ARA, GOS (refer to Figure 1, in Section 5). It will also reduce the confusion with the bolding of allergens that are required in the statement of ingredient. With a prescribed format of the NIS the practice of bolding in the statement of ingredients will not be necessary as caregivers can easily identify if the product contains certain ingredients. PHS supports the addition of wording in 2.9.1-24 to the effect that the format chosen for the statement of ingredients should be consistent for all ingredients with the exception of headings.

PHS remains concerned that macro-nutrient subgroups in the NIS may mislead consumers on the nutritional benefits by placing a disproportionate emphasis on these individual

components in infant formula. This is particularly the case for DHA where LC-PUFA's are used to market products as 'premium' when it is unclear if they have a substantiated beneficial effect to infants' growth and development.

PHS considers all voluntary ingredients should be considered under the heading of 'Additional', including novel foods and nutritive substances to ensure regulatory clarity. This would enhance caregiver and health professionals understanding of the NIS and future proof the NIS as new ingredients are added to infant formula and follow-on formula. Including voluntary ingredients in different sections of the NIS is confusing and potentially misleading. DHA would therefore be included under 'Additional' as would ingredients such as alpha lactoferrin. Amending the draft standard in 2.9.1-26 (3) and S29-10 to include 'novel food' would address this issue.

PHS does not see any benefit of casein and whey ratio being included on the NIS. Health professionals have access to this information directly from manufacturers and therefore the need to include on the label is limited. Most caregivers are unlikely to understand the information and may lead to unnecessary purchasing decisions. It may also encourage new products with varying degrees of casein to whey but limited substantiation of the health effect of such changes to be developed and marketed. There is already significant on-line marketing of whey dominant formula being easier to digest and reduced risk of constipation.

Labelling of lactose free and low lactose formula

As stated previously, PHS supports lactose free and low lactose formula to be categorised as a SMPPi and as a result the labelling requirements for this category of infant formula products would be required.

PHS remains concerned with these products being categorised as an Infant Formula and readily available to all infants without scientific justification. The risk these products pose to breastfeeding rates has not been fully explored by FSANZ. Studies have shown that crying breastfed babies are provided lactose free formula despite the evidence that the problem of functional lactose overload is one of breastfeeding management, not the breastmilk itself (Douglas, 2013). In addition, studies in the US found that 55% of formula consumed is lactose reduced but only 7.5% of infants medically require this (Strzalkowski & Young, 2021). It is not fully understood what the metabolic implications of consuming low lactose or lactose free formula is on infant development considering lactose in the main carbohydrate in breastmilk (Strzalkowski & Young, 2021). Including these under Infant Formula and not SMPPi may have long term risks that are yet to be identified.

Labelling of partially hydrolysed formula

As previously stated, PHS remains concerned with these products remaining on the market with no functional purpose. As a result, PHS supports FSANZ position that prohibits claims that refer to conditions such as 'anti-reflux', 'colic' or 'constipation'.

PHS considers there is a lack of evidence on whether the inclusion of 'partially hydrolysed' as part of the protein source statement is beneficial to caregivers and whether in fact it may imply that it aids digestion. This is particularly the case if Trademark is not considered as part of P1028. Currently products that are partially hydrolysed use the words such as 'sensitive' and 'comfort' as part of their Trademark which implies these products have an advantage to aid digestion and reduce normal infant behaviour such as irritability, fussiness and crying.

If trademark is unable to be addressed as part of P1028, PHS supports the words 'partially hydrolysed' being placed at the back of the label in the statement of ingredients. This will still provide adequate information for either health care practitioners or caregivers on the correct formula to use whilst not being marketed as a nutrition content or health claim.

Prohibited representations

PHS supports FSANZ approach to maintain current regulation on prohibited representations and the new addition to the draft Standard (2.9.1-29) that a label on a package of infant formula must not refer to, among other things, follow-on formula, a SMPPi or a formulated supplementary food for young children.

If trademark is unable to be included as part of P1028, consideration of the additional prohibited representations in this standard is required to address pseudo claims that suggest the infant formula will help with 'unsettled' babies that could be considered normal infant behaviour. Words such as Sleepy time, Sensitive, Comfort, Sweet Dreams idealises infant formula as improving such behaviours. A clause under 2.9.1-29 that states a label must not contain: the words comfort, sensitive, settling or any word or words having that effect or suggesting it aids sleeping may assist in addressing pseudo claims and partly address issues associated with trademark.

Nutrition content and health claim prohibition

PHS continues to support FSANZs proposed approach to maintain existing prohibition on nutrition content and health claims on all infant formula products. *The Ministerial Policy Guideline on the Regulation of Infant Formula Products*, the WHO *International Code of Marketing of Breast Milk Substitutes* and regulatory developments internationally all support the restrictions of claims on these products. As stated under Article 9 of the WHO International Code of Marketing of Breast Milk Substitutes '*Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breastfeeding*'. Nutrition content claims and health claims on infant formula products would place a disproportionate emphasis on these individual components in infant formula. This may lead consumers in the belief that infant formula has an advantageous ingredient in it that breastmilk doesn't. Infant formula should not imply superiority over breastmilk by labelling their products with claims.

Nutrition claims do not enable consumers to make informed choice as the competing product, breastmilk is unable to advertise and market their true health benefits to the same extent as commercial ready made products on the shelves. The statement of ingredients and the NIS provides adequate information for caregivers.

Claims about ingredients

PHS supports FSANZ preferred option to only permit information about ingredients in the statement of ingredients (except for ingredients such as nutritive substances that are required to be declared in the NIS). This needs to be clearly articulated in the drafting of the revised standard to include **any substance** in infant formula products to future proof the standard, including bioactive components.

FSANZ clearly highlighted that qualitative research suggests that the presence of ingredient claims can influence caregivers' perception of infant formula products, thereby making infant formula seem a close substitute for breastmilk. This has the undesirable effect of impacting on breastfeeding and ultimately the health and safety of infants.

Stage labelling, product differentiation and proxy advertising

PHS strongly supports addressing line marketing and proxy advertising to ensure infant formula and follow-on formula are distinctly different to any other product and is not cross promoted through the advertising of toddler milks (stage 3) or pregnancy milks or foods for young children.

PHS supports the use of age statements instead of the use of 1 for infant formula and 2 for follow-on formula. Continuing to allow numbers on infant formula products enables industry to continue to strategically market products together to 'normalise' their use and encourage caregivers to continue formula feeding beyond infancy and early childhood. The introduction of pregnancy formulas reinforces this staged approach before the infant is even born; a common marketing strategy to boost sales by establishing brand loyalty and familiarity. The use of stage labelling also adds confusion for products that are suitable from birth where a stage 2 follow-on formula is not necessary.

FSANZ's evidence highlighted that age labelling was viewed as the most important label element for product differentiation. If stage labelling is to remain, the inclusion of a clause that states that the age statement should be larger than the stage labelling information, would not only assist caregivers to choose the correct formula but reduce the impact of sequential and progressive feeding regimes.

As highlighted by FSANZ, products that did not change or made minimal change to colours and/or images were difficult to distinguish between infant formula products and toddler milks, regardless of how prominent the stage and/or age information was. This poses a public health and safety risk if infants consume the wrong formula for their age.

FSANZ have included in the draft Standard 2.9.1-15 (2) '*A food represented as infant formula or follow-on formula must not be also represented as another food*' as a means of addressing this. However, PHS considers this needs to be clearer to include design elements, as it could be argued that by simply stating the name (infant formula or follow-on formula) and age information that it is not represented as another food. Consideration of a statement similar to the EU that encompasses wording such as 'there must be a clear distinction between infant formula, follow-on formula and other food products including in the wording, pictorial representation or design and colours used in labelling, promotion and advertising'. This more clearly highlights that a number of changes to the design of the label are required to distinguish from another product and that it is more than just on the physical label.

PHS supports FSANZ on the removal of the practice of including numbers, text, statements, and images relating to other products on infant formula or follow-on formula and supports the draft Standard 2.9.1-29(1) (c) '*The label on a package of infant formula or follow-on formula must not contain: information relating to another product*'.

Part C. Labelling for Special Medical Purpose products for infants (SMPPi)

PHS supports FSANZ preferred options to apply the labelling requirements to SMPPi as listed:

- the requirement to label food as 'genetically modified' in section 1.5.2—4
- transportation outers (in subsection 2.9.5—8(4)
- mandatory labelling information in section 2.9.5—9
- a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

The labelling requirements that would not apply are:

- characterising ingredients and components in Standard 1.2.10

PHS supports the prohibition on therapeutic claims to SMPPi.

PHS supports the prohibitions outlined in 2.9.1 – 35 of the draft standard. This supports the Food Ministers Meeting that human milk oligosaccharides should not be permitted on the label of infant formula products including SMPPi.

PHS supports the mandatory statements and declarations in the draft standard 2.9.1 – 38 but is concerned about the degree to which the medical condition can be described under 2.9.1-38 (1) (c) and the properties or characteristics which make the food appropriate for the medical purpose (2.9.1-38 (1) (d).

For example, an infant formula currently on the market states for a medical purpose (Cow's Milk Protein Allergy) that '*X Brand is an infant formula that has been specifically formulated with protein sourced from rice. X is suitable for babies unable to tolerate formula containing cows milk*

protein or with a confirmed cow's milk protein allergy. Symptoms associated with cow's milk protein allergy can include but are not limited to an itchy rash, wheezing, irritability, crying and regurgitation'. This is beyond a simple statement indicating the medical purpose of the food and the properties that make it suitable for the condition. The inclusion of a clause in standard 2.9.1-38 to the effect that the medical purpose or characteristics that make the food appropriate must not describe the symptoms of the condition that could be attributed to other medical conditions would clarify the intent of mandatory statements and declarations for SMPPi.

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