Queensland Government

Queensland Health

[redacted]

7 July 2023

Standards Management Officer
Food Standards Australia New Zealand
PO Box 5423
Kingston ACT 2604

Dear Sir / Madam

Submission – Proposal P1028—Infant formula – 2nd Call for Submissions

Thank you for the opportunity to provide a submission on the *2nd Call for Submissions (CFS) – Infant Formula* for Proposal P1028, regarding whether the proposed regulatory approach and the related proposed draft variations should be approved, amended, or rejected.

This submission was prepared with input from health professionals from the following areas of Queensland Health: Queensland Children's Hospital, Health and Wellbeing Queensland, Prevention Strategy Branch and Food Safety Standards and Regulation Unit. As such it includes expert advice related to clinical paediatric dietetics, health promotion, public health nutrition, and food regulation and enforcement. The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government should notification be made by the FSANZ Board to the Food Ministers' Meeting.

The Queensland Government remains committed to protecting, promoting, and supporting breastfeeding and optimal infant nutrition. It is also recognised that infant formula and other breastmilk substitutes have a legitimate role to play in circumstances where an infant cannot be breastfed. The Department continues to support the *Ministerial Policy Guideline on the Regulation of Infant Formula Products,* which recognises there is a greater level of risk for infants. In line with FSANZ's primary objective of protecting public health and safety, it is important that P1028's primary objective is to ensure infant formula is safe for infants to consume, has a nutrient composition that supports expected growth and development, particularly when it is an infant's sole source of nutrition (i.e. from birth to around 6 months), and improves health outcomes of formula-fed infants. Whilst alignment of Australian and New Zealand standards with international regulations is important, the health and safety of infants must be the priority. Therefore, whilst industry innovation should be facilitated by regulations, this must advance the health incomes of formula fed infants closer to breast fed infant health outcomes. Broad innovation by industry which does not positively influence a reduction of adverse health effects in formula fed infants, may lead to the promotion of unnecessary consumption of infant formula products (IFP) with resultant negative impacts on breastfeeding rates.

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2nd Call for submissions – Proposal P1028

FSANZ throughout the 2nd CFS refer to Infant Formula Products having nutrient composition to support **normal** growth and development. However only human breastmilk supports normal growth and development of human infants. Different growth trajectories are experienced by infants fed artificial baby milks in comparison to human breastmilk-fed infants and these different growth trajectories are widely accepted and well documented. It is proposed that the wording throughout the 2nd CFS, and later documents such as the approval report, is amended to 'expected growth and development' to replace 'normal growth and development' (Centers for Disease Control and Prevention, 2022).

Section 2 – Regulatory Framework

Modified Formulas

Concern is again raised regarding the proposed inclusion of products which have been compositionally modified to be either low lactose or lactose free or contain partially hydrolysed protein as IFP. This proposal has been put forward on the basis that these formulas are modified for dietary conditions and are otherwise deemed safe for use by healthy infants. Whilst the basis provided is not incorrect, the following issues should be considered:

- ***Low lactose and lactose free products***. Human breastmilk is high in lactose and healthy infants produce sufficient enzyme lactase to digest lactose. Primary lactose intolerance is an extremely rare genetic condition that is incompatible with normal life without medical intervention. Secondary lactose intolerance occurs when the enzyme lactase is compromised by illness and/or disease such as in gastroenteritis; food intolerance or allergy; parasitic infection; coeliac disease and / or following bowel surgery. Therefore, if an infant is exhibiting lactose intolerance behaviours, medical assessment and treatment for the underlying cause is warranted. Classifying low/no lactose formulas as IFP and thereby enabling these products to be available without medical advice places the infant at risk of untreated medical conditions and associated adverse health outcomes (Hammer & Hogenauer, 2022; Di Costanzo & Canani, 2018).

- ***Partially hydrolysed protein***. It is proposed that differentiating partially hydrolysed protein formulas as IFP and extensively hydrolysed protein products as Special Medical Purpose Products for infants (SMPPi) requires criteria defining when a partially hydrolysed product becomes extensively hydrolysed, and delineation of how this would be regulated. As there is no evidence (that we are aware of) that partially hydrolysed formula is suitable to treat or manage any medical/health condition, and a healthy infant would have no requirement for this type of formula, questions arise regarding the need for this product at all. However, should it be determined that partially hydrolysed formulas remain a permitted product, subject to provision of clear criteria and definitions of partially vs. extensively hydrolysis, it is considered suitable to list partially hydrolysed in the IFP category and extensively hydrolysed protein products as SMPPi.

Permitting the production and sale of IFP for 'transient digestive problems or illnesses' and then labelling them with terms such as 'partially hydrolysed', requires a parent or carer to have detailed nutritional knowledge to understand both the need for, and appropriate use of, such products. Thus, these terms have little use in aiding informed choice as they are supposedly intended and are more likely to be used as a 'blind them with science' marketing tool. Further, the rationale for prohibiting such terms for use in follow-on formulas, but not infant formulas does not make sense and seems to imply that parents of infants up to the age of 6 months are expected to have greater nutritional knowledge than those of infants 6-12 months. In addition, labels such as 'low lactose' and 'lactose free' could easily be considered nutrient content claims (lactose being part of the nutritional composition of milk) which FSANZ has acknowledged are prohibited on IFP.

FSANZ has advised that formulas for 'transient' gastrointestinal conditions will need to be repositioned within the SSMPi category and this may eventually lead to them disappearing from the marketplace. The issue with this is that these "pseudo" medical formulas will be able to be sold without the 'breast milk is best' statement on them should manufacturers persist with creating such products. The World Health Organization International Code of Marketing of Breast-milk Substitutes (WHO Code) (1981) explicitly states that IFP labels should explain the benefits of breastfeeding. As a signatory to the WHO Code, Australia committed to complying with its requirements. Omitting the 'breast milk is best' statement contradicts this commitment.

2.3.4 Composition: low lactose or lactose free

It should be noted that page 15 of the 2nd CFS document indicates that low-lactose or lactose-free formulas are intended for infants with cows' milk protein intolerance. It is recommended that this section is reviewed. Low lactose or lactose-free formulas are intended for infants indicating lactose intolerance or malabsorption, not cows' milk protein intolerance. Lactose (carbohydrate) and protein are different macronutrients. This incorrect information confuses cow's milk protein intolerance with lactose intolerance and demonstrates the ease at which confusion can occur. This distinction needs to be clear on product labelling. It is suggested in addition to the labelling requirements set out in section 2.9.1-21, there be an additional requirement to include the statement 'not suitable for use in infants with cow's milk protein allergy'.

Section 3 – Definitions

3.2 Definition for SMPPi

The proposed definition for SMPPi including 'suitable to constitute either the sole or principal liquid source of nourishment' is not appropriate for all SMPPi. For some infants the SMPPi may make up anywhere between 20-100% of their nutritional requirements e.g., a Phenylketonuria (PKU) infant formula prescription is based on the infant's blood phenylalanine levels and will never be the sole or principal liquid source. It is suggested an alternative statement should be included that states: '*OR suitable for partial feeding when specifically required for the child's medical condition.'*

Section 4 – Novel foods and Nutritive Substances

4.1 Pre-market assessment requirements

Queensland Health remains concerned that the existing and proposed requirements for novel foods and nutritive substances are insufficient to require the premarket assessment of all substances added to infant formula.

It appears the current framework for novel foods, nutritive substances and food additives does not prevent a 'traditional food' or substance derived from a traditional food being used in an IFP, if it is not used as a nutritive substance or as a food additive. Other purposes could include technological functions, physiological functions, medical purposes, and prebiotic and probiotic purposes. That is, if any foods or substances used in an IFP are 'traditional' (regarding Standard 1.5.1), they are outside the scope of requirements for Standard 1.5.1.

It could be argued that substances found in foods traditional to Australia and New Zealand are not traditional in breast milk or past IFP. However, from an assessment perspective, the definition of 'non-traditional' (defined in Standard 1.1.2—8 and used Standard 1.5.1) is problematic because:

- No distinction is made about the population group, that is, a substance may be traditional in the general population but not for infants. A substance safe for the general population may not be safe for infants considering the infant formula may be the sole source of nutrition and infants may be too immature to safely consume the substance.

- A history of consumption does not mean it has a history of safe consumption. For example, under the current requirements, it may be possible to add alcohol (when not used as an additive or processing aid) to IFP.

Concern is also raised about the lack of restrictions on the addition of probiotic microorganisms to IFP. The current and proposed requirements do not appear to prevent the addition of microorganisms for a probiotic purpose. However, it is acknowledged that there are restrictions on labelling and claims unless approved as a novel food or nutritive substance through the application process. If a probiotic meets the definition of a non-traditional food, then the novel food requirements could potentially be applied. However, if the probiotic has a tradition of use, e.g. in the general population, then the current drafting of the novel food requirements would be difficult to apply for the reasons discussed above.

If the requirements for novel foods in the Code are going to be relied upon to ensure any substance added to infant formula products undergoes premarket assessment and approval before use in an IFP (that are not being used as a nutritive substance, food additive or processing aid), then the definitions of novel food and non-traditional food need to be amended to close the loopholes discussed. FSANZ has previously argued that this should be considered as part of the review of novel food requirements. However, we remain concerned about the delays to the P1024 review and think it appropriate for this to be considered as part of P1028 regarding infant formula products.

Section 7 – Nutrient Composition for Infant Formula Products (SD2)

Part B Infant Formula

4.1 Carbohydrate Source

Added sugar content in foods and beverages continues to be of concern in relation to the prevention and control of unhealthy weight gain and dental caries (WHO, 2015). It is therefore reasonable to include a minimum and maximum carbohydrate content in the nutrient composition for infant formula products. As there is a minimum and maximum energy content, logically the carbohydrate content could be calculated from the minimum and maximum protein and fat contents. Also, there is a specification that sucrose or fructose should not be added (unless as the consequence of hydrolysis) so it is assumed lactose would be the main carbohydrate content, however this needs to be clarified.

4.4 Protein Source

We note that some of the plant-based products may contain sources of contaminants including aflatoxins and other metals. It is noted that no maximum level has been established for arsenic, rather monitoring and review of rice that may be used as an ingredient in infant formula will be undertaken. Should there be a new application made to FSANZ with regards to a new protein source to be used in IFP (including rice but not excluding other sources), there may be a need for assessment of contaminants that could be a higher health risk in these proposed products.

The concern regarding inorganic arsenic in rice-based formulas also applies to cadmium and is presumably based on the findings summarised in Ljung *et al* (2001) and Concha *et al* (2013). Noting the latter's conclusion, "cadmium uptake is probably higher in children compared to adults, and it may be discussed if the (EFSA, sic.) TDI covers all potential health effects associated with cadmium exposure restricted to early life." It is also noted testing for these metals (Pb, IAs, Cd) in IFP metals testing is not excessively costly for a bulk product at approximately $120-160 AUD per sample.

Further, ultra-processed foods (UPFs) are increasingly found to be associated with adverse health outcomes including overweight, obesity, diabetes and cardiovascular diseases, cancer, gastrointestinal diseases, depression, and all-cause mortality (Elizabeth et al., 2020). Infant formula products are by nature UPFs with protein sources such as soy isolates, and protein source combinations such as rice and pea extracts which may require added amino acids to provide the full

complement of essential amino acids to achieve nutritional adequacy for the developing infant. It is therefore recommended that any current and future applications for protein sources as ingredients in IFP should be extended to consider the manufacture and treatment of ingredients, to minimise UPF content as much as practicable. For example, soy-based formulas derived from whole soybeans are nutritionally superior and less processed than isolates.

Currently there are IFP for sale in Australia with alternative protein sources (pea protein and rice protein) and there will be no provisions for the inclusion of such alternative protein sources in IFP as they will be excluded under the proposed code. Queensland's position is that pre-market evaluation for any alternative protein source is required to ensure sufficient evidence regarding safety and efficacy. There appears to be limited evidence regarding the suitability of pea protein as a primary protein source for infants.

Part D Special Medical Purpose Products for infants

Standard 2.9.1—30 identifies that SMPPi must contain the substances listed in Schedule 29—5 however, deviation is required should variation be required for a particular medical purpose.

There is no reference to the fact that other components of SMPPi may require modification (for example energy, protein, amino acids, fatty acids) for the management of the medical condition the product is indicated for (which may include amino acid profile for metabolic disease, fat profile for chylothorax) or all nutrients for malnutrition. Explicit inclusion of the requirement for SMPPi products to meet the baseline composition of all nutrients included in Schedule 29 and Division 2 is needed and that variation may be required across any component.

Queensland additionally seeks clarification regarding what processes will be established to ensure that products listed under the SMPPi category are and have demonstrated efficacy and safety for use with the medical condition they are proposed for. Any modifications made to IFP must be necessary and evidence-based for the medical condition they are proposed for, particularly for IFP available for purchase over the counter and not on prescription. Without regulation, the SMPPi category will be susceptible to any IFP claiming benefit for any condition and without limitation.

Section 8 - Labelling for Infant Formula Products (SD3)

It is noted that there are amendments being considered regarding the labelling of products and that although changes are positive, they will not fully address the current marketing and advertising practices of manufacturers. However, Queensland also notes that labelling issues are being considered in the current Review of the 1992 Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF) (Australian Government Department of Health and Aged Care, 2023). MAIF is Australia's voluntary and industry-regulated response to the WHO Code. It is well documented that US$55 billion industry investment in marketing IFP (WHO UNICEF, 2022) can harm children (Nestle, 2023), drives over-consumption of infant formula, discourages breastfeeding, undermines women's confidence, and exploits parent and caregiver's instinct to provide what is best for their children (WHO UNICEF, 2022). MAIF does not enact the WHO Code as law and consequently has been ineffective in restricting inappropriate advertising on infant formula. This is evidenced by outcomes published by the MAIF Complaints Committee (Australian Government Department of Health and Aged Care, 2023). Further evidenced by the World Breastfeeding Trends Initiative Australia (WBTIA) report card (WBTIA, 2018), which allocated Australia 25.5 from a possible total score of 100 in its assessment of implementation of policies and programs from the Global Strategy for Infant and Young Child Feeding (WHO, 2003).

Labelling of IFP provides a mechanism and opportunity for advertising, including cross-promotion and proxy advertising. Considering FSANZ analysis found proxy advertising practices present on 52.4%

of IFP, and that as a signatory to the WHO Code, Australia has committed to protect, support and promote breastfeeding, it is vital that the MAIF review and outcomes be considered in parallel with P1028 to enable a robust update of marketing policy and further tightening and restriction of IFP marketing practices.

It is important to note, and is of concern, that while infant formula cannot be represented as another product, this is not the case for 'toddler milk'. Given toddler milks are often cheaper and on sale more often than IFP, with the current cost of living pressures, toddler milks may be inappropriately used for infants.

Labelling for provision of information about infant formula and follow on - formula (Part A)

For directions on preparation and use, FSANZ should consider the average literacy level in the community (about year 7 at school) and keep wording as simple as possible. For example, the proposed new warning statement "do not change proportions of the powder or concentrate or add other food except on medical advice" may be too complex for the average person to understand.

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

We are unaware of any evidence that partially hydrolysed formula is suitable to treat or manage any health or medical condition. Inclusion of these products under the SMPPi category will allow variation in labelling and this creates risk. It will also give the perception that these products are suitable for management of a clinical condition when they are simply a variation of a normal IFP, and a healthy infant would have no requirement for a partially hydrolysed protein artificial baby milk product. Therefore, reference to partially hydrolysed proteins in the statement of ingredients only is preferred.

A nutrient content claim or reference to partially hydrolysed formula should not be permitted elsewhere on the package, given partially hydrolysed formulas are not recommended by health professionals and generally accepted science does not support their use for infants. Emphasising this aspect would elevate this point of difference inferring it is important and of benefit to infants. There should also be no claims permitted that imply there is an associated physiological or health effect, such as one relating to digestion.

The FSANZ Rapid Systematic Evidence Summary of Infant Formula Stage Labelling and Proxy Advertising (SD3, Att. 1) found age labelling on infant formula products supports differentiation between formula products, and that stage labels are not always well understood. This summary also reported that stage labelling may encourage continuation of formula feeding beyond infancy and early childhood, this illustrates stage labelling as a powerful marketing tool. It is therefore recommended that stage labelling font be reduced to small font to minimize marketing impact, and age labelling font be enlarged, ensuring age labelling is the most prominent information source to guide selection of age-appropriate products.

Labelling for special medical purpose products for infants (Part C)

It is noted that labelling requirements that are proposed to <u>not</u> be applied to SMPPi products include the name and address of the supplier. The rationale for exemption for this requirement is questioned. Queensland is of the opinion that this information is important for product traceability in the case of food recalls, investigating complaints and foodborne illness cases, and for enforcement purposes. Without the name and address of distributors and importers, any recall action would require public health alerts/media releases which seems inappropriate for such a small specialised market. Medical facilities and hospitals would be able to locate this information in a timely manner however other sellers may not, resulting in a time-consuming process which may influence a speedy public health response. There may also be a potential for there to be multiple importers with pharmacies (as an example) potentially purchasing directly online from overseas. Incidentally, in the last two to three years these

products have been involved in recalls and evidence can be provided (should it be required) regarding these recalled products.

Furthermore, parents and caregivers should have easy access to name and address information, to enable direct line of inquiry on infant formula products purchased and provided to infants, and for transparency purposes. Provision of name and address information on outer packaging only as proposed in the 2nd Call for Submission, such as boxes that will be discarded by retailers, means that name and address information will usually not be available for parents and caregivers. Most SMPPi products should have ample space such as on the bottom or top of the container for the addition of the name and address of the supplier, which could be included by the application of a sticker, without the need for redesign of a label.

Additionally, it is argued that labelling requirements that are proposed to not be applied to SMPPi products such as 'directions for preparation and use', 'follow instructions exactly' and 'age related statements' are all still relevant and required on the labelling of SMPPi products. The directions for preparation and use on the product are utilised daily by paediatric clinical dietitians as a starting or reference point, when beginning to talk to parents and caregivers about the recipe required for their individual child. Although this almost always varies from the directions on the label, these directions are the reference point that these specialists use to then guide parents and caregivers to vary how they make their formula to their child's specific requirements.

The reality is that parents or caregivers caring for infants with some of these rare conditions would be getting considerable medical support from both specialist doctors and dietitians, whereas much of the population have less regular contact with the medical profession. This may need to be considered in the instance that there be a prescription written by a GP for these SMPPi products to be accessed through the Pharmaceutical Benefits Scheme. Written instructions for how these should be made up may not be provided by the GP and therefore when the prescription label is attached to the container, the generic instructions for preparation and use are still there as a safety fallback until there is hopefully contact with a dietitian who may provide a different recipe for that individual child.

An additional labelling requirement that is proposed to not be applied to SMPPi is the 'breast milk is best statement'. This labelling requirement is one that consulted Queensland Health experts have provided valid divergent comments on, and therefore both views are presented below for the consideration of FSANZ. It is acknowledged that the officers who have reviewed the 2nd CFS have varied skill sets, educational and work backgrounds, with expertise in areas of public health nutrition, environmental health and clinical paediatric dietetics. These experts feel very strongly with regards to this matter and therefore it is recommended that FSANZ consider both options presented.

From an expert paediatric clinical dietetic perspective reflecting on the requirements of individual infants and their parents and caregivers, Queensland Children's Hospital are aligned with the proposed changes in the 2nd CFS regarding the statement "breast milk is best" and that this should not apply to the SMPPi category. Highly specialised products in the SMPPi category are required for a minority of infants with complex medical conditions where exclusive breast feeding will be detrimental to the infant's health and development. In these circumstances the SMPPi is required to replace some or all breast milk (or infant formula) for an infant due to their medical condition. Failure to do this can result in severe complications including severe neurological impairment and even death.

Some examples include (noting there are many more than these below):

- An infant born with Phenylketonuria (PKU) will require a combination of PKU formula (SMPPi) and breast milk or infant formula for their medical treatment. Babies diagnosed with PKU require a short period of time (1-5 days) on PKU formula only to bring their blood phenylalanine levels down to a safe range to prevent potential damage to the brain. Following this period of PKU formula only, the proportion of PKU formula prescribed for the infant depends on their tolerance to phenylalanine (as protein in breastmilk). The PKU formula must be used in place of breast milk for between 20 and 100% of the infant's nutritional requirements or blood

phenylalanine levels will rise and tyrosine will fall resulting in neurological impairment, intellectual and physical disability.

- Some infants with renal disease will require a specialised formula with reduced electrolyte content to ensure stable blood levels. Exclusive breast feeding in these instances may result in seizures or coma and ultimately death. Breast milk may be suitable to be used in conjunction with the formula but is certainly not better than the SMPPi's.

- Even infants with severe cow's milk protein allergy may need a period without breast milk, during the initial period whilst maternal diet exclusion of milk is commenced. Breast milk expressed during the washout period cannot be used for the infant with allergy.

- Infants with a chylothorax (accumulation of chyle in the pleural cavity) require using an exclusive diet of an SMPPi low in long chain fat, high in medium chain fat such as Monogen or Lipistart. The prescribed period of time is usually 4-6 weeks and infants are not able to consume breastmilk or regular infant formula during this time.

- Infants born with long chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHADD) or symptomatic infants with very long chain acyl-CoA dehydrogenase deficiency (VLCADD) require a SMPPi as their sole source of nutrition until weaning onto solids commences. These children are unable to breastfeed and continue this formula past their first year of life.

Many parents become distressed at the concept that their breast milk is not suitable for their infant's sole source of nutrition. Any statement of "breast milk is best" on the SMPPi's label would be contradictory to medical advice. Therefore, clinicians suggest that the statement "breast milk is best" should not be applied to relevant SMPPi products, in particular to products requiring prescription by a medical professional.

The WHO Code (WHO,1981), states that 'Information on artificial feeding, including that on labels, should explain the benefits of breastfeeding and the costs and dangers associated with the unnecessary or improper use of infant formula and other breast-milk substitutes.' Although paediatric dietitians align with this WHO Code for standard infant formula and follow-on formula, this does not extend to products in the SMPPi category.

From a whole of population perspective, public health nutritionists from the Prevention Strategy Branch of Queensland Health, strongly refute the proposed labelling requirements that the statement 'breast milk is best' not be applied to SMPPi as whilst there are valid clinical requirements for an extremely small subset of the population with rare metabolic diseases; breastmilk is unequivocally and universally acknowledged as best for the vast majority of the human population. This team has further concerns, which include the possibility of industry seeking to reposition regular infant formula and follow-on formula in the SMPPi category, and thus not have to include the 'breast milk is best' statement.

Furthermore, Australia's application of the WHO Code is already extremely weak, evidenced by the World Breastfeeding Trends Initiative Australia (WBTIA) report card (WBTIA, 2018), which allocated Australia 25.5 from a possible total score of 100 in its assessment of implementation of policies and programs from the Global Strategy for Infant and Young Child Feeding (WHO, 2003). Taking a step further back and further weaking our response would not be well received by the public health community, both nationally and globally.

Queensland also submits the following labelling recommendations:

- Regarding Standard 2.9.1—22(5) *Directions for preparation and use* it is suggested:
  (a) each bottle **should** (not must) be prepared individually. Retaining current wording (should), otherwise this contradicts (b).
  (e) and (f) add 'or on the advice of a dietitian' after medical advice – this advice is more commonly provided by dietitians than medical doctors.
  (g) this item requires clarification, potentially add 'within 2 hours of preparing the formula'. Otherwise, this instruction may be incorrectly interpreted to mean within 2 hours of the infant stopping feeding.

- Regarding Standard 2.9.1—26 *Required form for the declaration of nutrition information* it is suggested the nutrition information statement should list nutrients in prescribed order to enable comparison between products by consumers and health professionals.

- Regarding Standard 2.9.1—31 *Restrictions on the sale of special medical purposes products for infants* Queensland remains very concerned with the proposal to allow SMPPi to be purchased from pharmacies either off the shelf or online. This would mean that these products are able to be purchased without any medical or dietetic guidance or supervision. It may lead to inappropriate marketing of SMPPi, given their special medical purpose. FSANZ argue that it is not appropriate for SMPPi to be sold from supermarkets, however, some pharmacies are large and operate more like supermarkets and operate online stores, which can be popular with parents of infants.

  It is suggested for 2.9.1—31(1)(b) that removing 'pharmacy' and substituting 'pharmacist' may be more appropriate, so they could only be sold from a pharmacy by a pharmacist. Pharmacists already have a similar role to this with the sale of Schedule 3 drugs (pharmacist only medicines), which do not require a prescription and are only available for retail sale to the public from pharmacies and must be handed to the buyer by the pharmacist to ensure that the person purchasing the medication can receive professional advice about its use. Allowing sales only by pharmacists at pharmacies, may in practice mean that SMPPi products would need to be stored behind the counter or within the dispensary area.

  Restricting pharmacy sales to pharmacists would overcome several problems with unrestricted access from pharmacies as currently proposed by the 2nd CFS. It would:

  - allow the pharmacist to check if the SMPPi product is being purchased on medical or dietetic advice, allow advice to be provided prior to purchase on the safe use of the SMPPi product and caution against inappropriate or unsafe use, and provide an opportunity for the purchaser to be counselled to seek expert medical or dietetic advice if necessary
  - prevent online sales by pharmacies, which is inappropriate for the SMPPi category and beyond the intent of requiring some medical oversight
  - help prevent the development of infant formula products as SMPPi products to get around some restrictions on the composition and labelling of infant formula products and proposed restrictions on supermarket sales of SMPPi.

  Restricting pharmacy sales to pharmacists would require consultation with the Australian pharmacy profession and pharmacy industry, for example the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia on whether they could take on this role. If implemented, FSANZ could work with pharmacy profession and industry, and relevant tertiary

institutions on providing suitable information and guidance on the responsible supply of SMPPi.

Section 10 – FSANZ Act assessment requirements

10.1.1 Consideration of costs and benefits (SD4)

The breadth of firmly established and well understood health protective effects associated with breastfeeding and breastmilk, conferred to both mother and child across the life course, continues to only expand as emergent research further explores the complex biopsychosocial system of breastfeeding. (Pérez-Escamilla et al., 2023). Consequently, formula-fed infants require extra protection from any possible long-term health impacts.

Public health implications need to be placed more squarely at the forefront and considered as contributing to the overall cost to both community and government. The public health system comprises the most significant cost to governments in Australia. These costs will continue to increase with the increasing burden of chronic disease in the community. Currently, annual global losses in unrealised health and human development benefits associated with inadequate breastfeeding protection, promotion and support are currently estimated at US$341.3 billion (Pérez-Escamilla et al., 2023). Considered another way, median return on investment of public health investments is an estimated 4.1 to 1 and cost-benefit ratio 8.3 in high income countries (Masters et al, 2017). Consequently, all cost benefit analyses should incorporate as a standard component the cost burden of a proposal or standard to public health at both the community and government level.

Section 11 – Implementation

11.1 Transitional arrangements

Whilst it is appreciated that the regulatory changes proposed in this CFS are both complex and diverse, and we understand the concern regarding timeframes, a five-year transitional arrangement is viewed as too generous. In relation to customer certainty and comfortability, once the Code has been amended, parents and caregivers will want reassurance that they are purchasing a product that has been formulated to comply with the gazetted changes. As this is an important public health matter, Queensland recommends that a combined stock in trade and implementation period is no longer than three to four years. This time frame is provided with the consideration that most products have a two-year expiry date, and time will be required for manufacturers to reformulate IFP.

Further, with regards to the proposed transitional arrangements proposed by FSANZ, certain non-dairy infant formulas that are currently in the marketplace would continue to be able to be sold for up to five years. This period appears contradictory to the potential public health and safety risks discussed in the 2nd CFS related to amino acid profiles, allergens and contaminants and warrants a reduced implementation period for such higher risk products.

Should you require further information in relation to this matter, please contact Food Safety Standards and [redacted]

[redacted]