Proposal 1028
Infant Formula – NSW Submission

Major Procedure

Summary

NSW appreciates the opportunity to comment on Proposal 1028 Infant Formula – 1st Call for Submissions. NSW acknowledges the extensive work undertaken by FSANZ in bringing the 1st call for submissions together as it unites five previous consultation documents.

NSW recognises the challenge in undertaking this review to balance: i) infant health and safety, ii) innovation, iii) international market access and iv) certainty for medical professionals and care-givers.

NSW acknowledges that breastfeeding is the normal and recommended way to feed an infant. Where infant formula products are the sole or principal source of nutrition, regulation has a role. In Australia and New Zealand regulation of infant formula products is guided by the expectations of Ministers (the Food Ministers' Meeting). These are articulated in the Ministerial Policy Guideline – *Regulation of Infant formula products* (MPGI).

Guided by the MPGI, NSW favours retention of a prescriptive approach to Standard 2.9.1 as it services a very vulnerable sub-population (0-12 months).
Infants, as a specifically vulnerable population group, have a greater level of risk compared to other population groups. Protection of infant health and safety and the prevention of misleading and deceptive conduct must always have primacy in the review of Standard 2.9.1 as a legal document.

NSW is concerned that the proposal introduces the category 'Special Medical Purpose Products for Infants' within Standard 2.9.1 as the MGPI relates solely to 'Infant formula products'. The MPGI is clear that variation to the baseline of 'Infant Formula Products' for appropriate medical reasons still falls within the purview of 'Infant formula product'. Creation of a separate product category within Standard 2.9.1 is inconsistent with the MPGI. NSW has enforcement concerns with this proposed category of 'SMPPi'.

NSW also offers comments on the modified general infant formula category, the proposal to collapse novel foods and nutritive substances into Proposal 1024, and the supporting documents provided with the 1st call for submissions.

1st Call for submissions: Consultation paper

Regulatory framework and definition

i) Categories within Standard 2.9.1 – SMPPi is not 'infant formula'

NSW has expressed its consistent position to support two categories of Infant Formula Product (IFP) in Standard 2.9.1, general IFP for a normal, healthy infant and IFP for special medical purposes (SMP) following advice of a medical professional and intended for use under medical supervision. NSW considers this position is consistent with the MPGI in its reference to IFP and IFP for Special Dietary Use (SDU).

NSW notes that both IFP product categories are under the same umbrella of 'infant formula' in Standard 2.9.1, to ensure that general requirements of Standard 2.9.1 (e.g. prescribed name, prohibited representations) apply to all 'infant formula' labelling products.

Creation of a Special Medical Purpose Products for Infants (SMPPi) breaks this link. and proposes Standard 2.9.1 contain two product categories with different rules applying to each category. This is considered inconsistent with the policy principles of the MPGI.

This can be addressed by amending the SMPPi product category to IFP for Special Medical Purposes (IFPSMP). As IFPSMP is a sub-category of infant formula general rules are consistently applied across the IFP product category (e.g. prescribed name, pre-market safety assessment, nutritive substances and novel foods and prohibited representations). NSW agrees that IFPSMP should be permitted to vary the composition of the formula to address the special medical purpose for which they are prepared (noting this permission already exists for the sub-category of IFPSDU).

NSW chief concerns with the sub-category of SMPPi as proposed in the 1st CFS:

- It is not infant formula, SMPPi is a separate product category to infant formula.

- 'Generally accepted scientific data' does not provide an adequate level of certainty for jurisdictions to enforce. Jurisdictions require a level of evidence for SMP that is clear, un-ambiguous and unequivocal. 'Generally accepted scientific data' is arguably a vague, ambiguous and contestable benchmark.

- Segregation of mandatory pre-market safety assessment for additional nutritive substances, food additives etc in SMPPi from substances added for the SMP of the product on the basis of 'generally accepted scientific data' creates a loophole for marketers potentially to subvert pre-market safety assessment processes in the Australia New Zealand Food Standards Code for IFP. This is not acceptable to NSW and is inconsistent with the MPGI.

- 'Generally accepted scientific data' provides a means for formulas on the current market sold as IFPSDU, that are the subject of concern in the 1st CFS (e.g. 'anti-reflux', 'colic' formulas: pg 22 of SD3), to re-label as SMPPi with no product re-formulation. It would then become a matter for jurisdictions to enforce post-market. This is not an acceptable entry threshold for very high-

risk foods developed for a very high-risk sub-population. This is inconsistent with the MPGI. It may also lead to the development of products for infant consumption that reflect consumer demand rather than specific medical purposes.

- The absence of a prescribed name for these specific products may provide challenges for health professionals in identifying a specific product.

The onus of certainty must be placed on the company marketing the 'special' IFP that it is sufficiently robust to withstand scrutiny from industry competitors and health professionals on its special medical purpose. With this onus verified prior to the marketing of the product. The proposed SMPPi category allows a company to market a 'SMP' with no pre-market independent verification, on the proviso that it holds evidence to a degree of 'generally accepted scientific data'. Inquiry as to the effectiveness of the SMP becomes a post-market concern for jurisdictions. NSW objects to this proposition on the basis it is inconsistent with the MPGI due to policy principles i) and j). '*The Authority (FSANZ) is advised to take particular caution where links are less clear'*. NSW does not understand how the Authority (FSANZ) is discharging this caution if it is proposing that assessment of medical benefit is only independently verified post-market. NSW suggests the proposed process shifts assessment from a single, independent, national point to many (jurisdictional enforcement agencies), which could create regulatory uncertainty and inconsistency.

NSW proposes the following definition for IFP for SMP:

Infant Formula Product for Special Medical Purposes means an infant formula product that is:

i) specially formulated for the dietary management of infants who have **medically determined** nutrient requirements; including 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 medically be achieved** without use of the food; and
iii) intended for use under **medical supervision**; and
iv) represented as being for the dietary management of a **medically diagnosed** disease, disorder or **medically diagnosed condition** in an infant; and
v) may be provided to **medically diagnosed** infants by way of exclusive or partial feeding.

Standard 2.9.1-17:
add c) Infant formula product for Special Medical Purposes.

This definition places *'medical determination'* as the pre-requisite entry requirement to the SMP category. Addition of *'cannot medically be achieved'* places the onus on the manufacturer to be confident the product will provide adequate dietary management for the medically diagnosed matter, prior to marketing. This pre-market requirement aligns with the need to ensure these formulas cannot be accessed by caregivers of healthy infants, as access is only permissible following professional medical diagnosis. This will also assist in providing clear access for recognised SMP to the Pharmaceutical Benefits Scheme (PBS). This is important to ensure care-givers can cost-recover money spent on these special formulas as the range of cost is from $40 - $80 per 400-500g can.

NSW considers decision to continue to feed a developing child IFPSMP beyond the age of 12 months lies with the relevant medical practitioner and is a discretionary matter for the practitioner to advise on a case-by-case basis. NSW considers this is not a 'standards' matters for the IFPSMP category as Standard 2.9.1 is solely concerned with infants (defined in Standard 1.1.2 to mean a person under the age of 12 months). NSW chief concern with the FSANZ proposal to permit labelling to advise on possible consumption past 12 months is blurring lines between Standards 2.9.1 (infants – a person under the age of 12 months) and Standard 2.9.3 (formulated supplementary foods for young children aged 1 to 3 years).

The intent in proposing the IFPSMP is to **protect** those products of agreed medical need. Factors composing 'medical determination' for a specific IFPSMP could be resolved by an independent expert panel of paediatric medical consultants. Only products unanimously supported by the independent panel would be permitted to label as IFPSMP and be offered the protection of the prescribed IFPSMP name. A positive list of 'approved IFPSMP' could be developed as a Code of Practice that sits beside Standard 2.9.1 as a reference point for medical practitioners in selecting a product of appropriate composition and function for a diagnosed medical disease, disorder or condition. Additions to the list could be expediently considered by the independent expert panel without requiring activation of the entire standards amendment process of the FSANZ Act. NSW understands that an expert panel already assists in advising the Therapeutic Goods Administration (TGA) of appropriate special medical formula for listing on the PBS scheme. The independent expert panel concept for IFPSMP is merely extending this level of assurance to the 'food' side of the food medicine interface.

Protection for the IFPSMP category could be provided by placing an express offence into Standard 2.9.1 for a product to determine itself to be IFPSMP without being listed on the positive list (Code of Practice).

The explanatory statement for IFPSMP could outline the range of conditions already known to warrant production of existing SMP infant formula products as described on pg 7 of SD4. This would guide innovators as to the type of evidence required to support an IFPSMP application to the expert panel:

- Extensively protein hydrolysed formulas – allergy treatment and management
- Pre-term formulas – lower maximum level of aluminium and medium chain triglyceride (MCT) content (higher water solubility and more absorbed by pre-term infants).
- Formulas developed to manage renal, hepatic and medically diagnosed allergy and immunological conditions.
- L-amino acid based and elemental formulas – medically diagnosed disorders related to infant capacity to digest food.

NSW proposes the independent expert panel to FSANZ as a means of reviewing potential entrants to the SMP category for IFP as this category of infant formula is not standard and is not a standard food for special medical purpose assessment matter. NSW understands this is also FSANZ understanding of infant formula due to the below statement in the draft assessment report for Proposal 242 – Foods for Special Medical Purposes (page 8):

'Additionally, due to the complexity of the issues involved with the regulation of specialised infant formula products, these products are also excluded from the scope of this Proposal'.

Supplementary products to SMP infant formula products (e.g. bovine milk fortifiers) may then be regulated as either i) *Standard 2.9.1a – Supplementary foods for infants with medically determined needs* or ii) Regulated as therapeutic goods. The option of regulating these products as therapeutic goods is raised as they are:

i) provided at the express request of a medical practitioner for treatment of a medically diagnosed matter,
ii) other supplements to foods are also regulated as therapeutic goods (e.g. supplement capsules). Clearly capsule form is not practical for the population 0-12 months; hence the form of the supplement will nearly always be liquid.

FSANZ is requested to explore these 2 options for supplementary products for infants with medically determined needs that are not infant formula.

There may also be merit in considering additional regulatory controls at the point of consumer supply for IFPSMP products to that proposed in the 1st CFS. NSW supports the notion that SMP formulas should be restricted to chemists/majority sellers. However given the increased risk associated with inadvertent supply of a SMP formula to an un-informed but well-meaning caregiver (e.g. internet purchase), suggests, that at a minimum, controls akin to Schedule 3 (Poisons Standards) apply to IFPSMP. Schedule 3 controls would ensure that a conversation is held between a pharmacist and a potential care-giver before a IFPSMP may be purchased. NSW understands that highly medicalised formulas are already schedule 4 products (prescription from a doctor required before product is supplied) so no change is required for access to these products.

ii) Subcategory "Modified infant formula products"

NSW requires further information from FSANZ to understand how the proposed subcategory "Modified infant formula products" within the general IFP category is not creating a third IFP category, specifically for partially hydrolysed formulas.

NSW understands the FSANZ proposal in the 1st CFS is to create two product categories within Standard 2.9.1 to address the ambiguities associated with the current two category structure of IFP and IFPSDU.

The 'modified IFP' category to account for 'low lactose', 'lactose free' and 'partially hydrolysed' formulas needs specific definitions to provide the appropriate legal clarity for where these products may differ from standard IFP compositional requirements and where they cannot.

NSW notes 'low lactose' and 'lactose free' IFP have definitions in the 1st CFS and assumes that it is only the lactose component of these formulas that deviates from the standard IFP baseline. Given this certainty for lactose, NSW does not understand why 'partial hydrolysis' for proteins is not provided with a definition. The lack of a definition creates ambiguity between 'partial hydrolysis' as a standard IFP from 'extensive hydrolysis' as a SMP product. A definition of 'partial hydrolysis' further provides regulators with something clear to analytically separate standard IFP from SMP products. This would be very useful in undertaking compliance operations as it is an

additional verification point to measure on top of verifying the accuracy of product labelling.

NSW further does not understand the functional purpose of 'partial hydrolysis' of proteins in standard IFP. FSANZ commentary in the 1st CFS (pg 28) provides that 'partial hydrolysis' is not efficacious in the management of medically diagnosed allergy. What is lacking is a clear purpose for the partial hydrolysis of proteins in standard IFP.

In the 2nd CFS, NSW would like further commentary from FSANZ on the following:

- The functional purpose of 'partial hydrolysis' of proteins in standard IFP. It is assumed that it is not medical, as it would otherwise be considered a SMPPi. Extensively hydrolysed protein formulas are medically recognised as appropriate for treating infants with diagnosed medical conditions (allergy). NSW is unclear on the purpose of 'partial hydrolysis' especially when the Australasian Society of Clinical Immunology and Allergy state that partial or extensively hydrolysed formulas should not be used in allergy prevention[1] and partial hydrolysed formulas are not suitable for infant allergy management.[2]

- Definition of 'partial hydrolysis' - so it may be clearly established as a standard IFP and not as a SMP product. Reliance on examination of product labels for food additive declarations (e.g. thickeners) is not an effective means of product separation for care-givers. NSW is concerned that the absence of a definition of 'partial hydrolysis' (as a standard IFP) provides opportunity for current IFPSDU of concern to re-label as SMPPi, with no re-formulation and self-determine a medical purpose. It will become a post-market enforcement matter for jurisdictions to determine what is appropriate hydrolysis to constitute an unequivocal medical purpose from a contestable, self-proclaimed medical purpose.

- The *'substantiated beneficial role in the normal growth and development of infants, or a technological role[3]'* played by partial hydrolysis as a general IFP. Safety of these products was discussed in SD2 but NSW is unclear of what 'special dietary use' is fulfilled by these partial hydrolysed products.

NSW considers this request is appropriate as the MPGI provides for SDU products:

'These infants have special dietary or medical needs and are an even more vulnerable population group than infants generally. The diet of these infants is usually managed under the supervision of a medical specialist or paediatric dietitian'.

Clarity in the specific dietary/medical purpose of 'partial hydrolysis' of proteins can then assist care-givers and medical practitioners make appropriate choices in referring specific products should feeding by breast milk not be possible/practicable. Although a NSW senior paediatric dietitian consulted in preparing this submission was of the view dietitians would not recommend partially hydrolysed products.

[1] https://www.allergy.org.au/hp/papers/infant-feeding-and-allergy-prevention
[2] https://www.allergy.org.au/patients/food-allergy/cows-milk-dairy-allergy
[3] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/56968B08A431CFE3CA25801B00117E7A/$File/Forum-Policy%20Guideline-Regulation%20of%20Infant%20Formula%20Products.pdf

Low lactose and lactose free formulas

NSW suggests that low lactose and lactose free formulas should be accompanied by an advisory statement to inform care-givers that such IFP should only be purchased following medical diagnosis of a lactose susceptibility/intolerance. Health professionals may recommend low lactose for transient gut conditions but it would not be required permanently and breast-fed babies with transient gut conditions would still remain on breast milk despite the lactose content of breast milk. Care-givers should not self-determine need for low-lactose formulas. Lactose is a very common carbohydrate in mammalian milks (including human). A shift away from lactose as a carbohydrate source for an infant is a matter requiring medical diagnosis, especially where the IFP becomes the sole source of nutrition for a growing infant. NSW paediatric dietitians report that lactose assists with absorption of minerals (calcium, magnesium and manganese), provides a source of galactose for liver glycogen production, and positively impacts the gut microbiome. NSW considers this advisory statement would assist caregivers make informed choices as low lactose and lactose free formulas should not be purchased by consumers in the absence of medical advice or given to healthy babies due to the health risks of avoiding lactose unnecessarily. These formulas are not low risk to a healthy infant. Given the need for medical advice as a pre-cursor to purchase there may also be merit in moving these products to a SMP category of IFP.

NSW Child & Family Health Clinical Nurse Consultants (CFH CNC) network was consulted and they feel there has been an anecdotal increase in the use of 'colic', 'low lactose and 'reflux' formulas but have no qualitative evidence. Parents change to these formulas, without seeking advice from a health professional, if they feel their infant is unsettled due to being “colicky” or having reflux or regurgitating after a feed.

The CFH CNC network find parents change formula multiple times in a short time period when their infant maybe displaying normal developmental behaviours that they don't understand. The CFH CNC network supports carers to seek health professional advice regarding changing formulas including those labelled 'colic', 'low lactose' or 'reflux'

iii) *Nutritive Substances and Novel Foods*

NSW disagrees with the proposal to collapse nutritive substances and novel foods for IFP with general foods under Proposal 1024. This objection is made more pertinent with the proposal that substances added to SMPPi for ‘medical purpose’ do not require pre-market safety assessment, whereas ‘nutritive substances’ would. This is akin to a self-substantiation pathway for IFP and is wildly out of step with the MPGI and its advice *‘there is a greater level of risk to be managed compared to other population groups’*.

Policy Principles i) and j) provide that the Authority (FSANZ) should undertake pre-market assessment and determine that any substance to be added to infant formula achieves benefit for the target population (infants less than 12 months) and *‘particular caution should be applied by the Authority where such links are less clear’.*

NSW cannot reconcile how the SMPPi proposal (with its self-substantiation pathway for a special medical purpose) aligns with, nor has regard for, the content of the MPGI.

The MPGI advises *any* substance to be added to infant formula is subject to pre-market safety assessment where there is no history of safe use in Australia and New Zealand, or for substances with a safe history of use that are produced, or have different forms or structures, to those with known safety profiles.

NSW considers this advice in the MPGI provides clear direction that *all* substances to be added to infant formula should be subject to pre-market safety assessment.

In raising the proposal to shift consideration of novel foods and nutritive substances for infants to Proposal 1024, FSANZ should acknowledge the element of a '*substantiated beneficial role'* described for these substances in the MPGI. This is arguably a unique requirement for the pre-market safety assessment and approval of nutritive substances and novel foods for infants that is not required for the addition of these substances to foods for the general population.

FSANZ need also to give regard to the role of expert panels for substances requiring pre-market safety assessment for infant formula products, where the levels of evidence for a 'substantiated beneficial role' are less clear.

FSANZ' consumer understanding study of nutritive substances gathered in SD3 provides evidence that consumers do not understand what is required to be in infant formulas and use the ingredient list to compare products *'if they believe their infant has specific nutritional requirements or health concerns' – allergies or intolerances'* (pg 6 of SD3).

This is evidence of care-giver self-diagnosis of medical conditions associated with their infants. NSW suggests this is a role for a medical practitioner. However given this existing trend, the role of the MPGI in advising on a *'substantiated beneficial role'* for novel foods and nutritive substances added to IFP becomes very important as it can act as a safeguard to misleading representations on infant formula. This is unique to IFP, and in conjunction with advice to establish expert panels where links are less clear, is sound reason to consider novel foods and nutritive substances under Proposal 1028 as the MPGI clearly advises they are a separate category to general foods *('there is a greater level of risk to be managed compared to other population groups'*).

Supporting document 1

Food Additives

NSW supports the 3-principle framework FSANZ has developed to guide its assessment of food additive permissions in the 1st CFS. NSW further notes some harmonisation with international regulations (e.g. EU, Codex) is necessary to ensure the viability of supply into the Australian market and ensure supply is adequately guarded from supply chain shocks (i.e. Abbott Nutrition closure in USA, COVID-19). Concerning the specific matters described in SD1, NSW offers the following comments:

- Prohibition on addition of food additives by carry over unless the additive has an explicit permission in the Code is supported. This is aligned with the MPGI that provides for pre-market safety assessment of all additives in IFP.

- NSW notes stakeholder concerns that further investigation is required into the safety and efficacy of thickeners marketed as 'anti-reflux'. NSW further notes FSANZ statement that food additives must serve an appropriate technological purpose to support their addition to IFP. Given this concern, NSW requests further advice from FSANZ on the efficacy of these substances in achieving an 'anti-reflux' purpose as it seems there may not be 'generally accepted scientific data' for this claimed effect.

- The technological purpose served by citric and fatty acid esters of glycerol (472c) in standard IFP. NSW notes that standard IFP is currently not permitted to contain citric and fatty acid esters of glycerol. Extension of the permission from IFPSDU to standard IFP needs to define an appropriate technological function in standard IFP.

- Clarity is sought from FSANZ on the current state of Starch Sodium Octenylsuccinate as an additive for IFPSDU in the Code. NSW does see a listing for this substance in Schedule 15 of the Code under IFPSDU and does not understand FSANZ statement 'no changes to the Code are required' (pg 28 of SD1) with regard to this additive.

- Justification for the continued addition of Locust Bean Gum to standard IFP at a limit of 1000mg/L and to a limit of 5,000mg/L in SMP products (for alleviation of reflux). FSANZ has cited stakeholder concern as to the safety and efficacy of thickeners marketed as 'anti-reflux' (pg 26 of SD1). NSW assumes this includes Locust Bean Gum, given the equivocal nature of science surrounding this claimed technological effect. NSW is concerned that Locust Bean Gum may not be adequately achieving its technological function as a food additive.

- Data in support of the claimed technological purpose (effect) for pectin concerning gastrointestinal disorders, given it has no current permission in the Code as a food additive in IFP and FSANZ is proposing a limit of 5000mg/L for SMP products (for treating gastro-intestinal disorders).

- Data in support of the claimed technological purpose (effect) and safety assessment for Xanthan Gum at 1200mg/L, given it has no permission in the Code for IFP. NSW seeks this information given that JECFA has assessed Xanthan Gum as safe at 1000mg/L. NSW also seeks to understand the technological effect in SMP products as it is cited as suitable for infants with impairment of the GI tract, protein malabsorption or inborn errors of metabolism. NSW also seeks advice on the placement of such products – should they be considered IFPSMP?

- NSW requests advice from FSANZ on the EFSA re-evaluation of Guar Gum for use in SMP products (proposed limit 10,000 mg/L) as this is seeking toxicological data to assess safety in infants under 16 weeks.

- Evidence of safety and justification of technological purpose is requested on the proposal to permit Sodium Alginate in SMP products, given it has no permission in the Code for use in IFP.

- NSW supports FSANZ decision to not permit sodium carboxymethylcellulose in any food regulated by Standard 2.9.1.

- Additional evidence is requested on the safety and technological function of sucrose esters of fatty acids, given there is no current permission in the Code for the use of these compounds in IFP. FSANZ has noted the lack of safety assessment for these compounds in infants of less than 16 weeks. NSW also notes the EFSA is currently assessing safety in infants of less than 16 weeks of age, noting that infants of this age were not considered in its 2018 EFSA risk assessment of this substance.

- NSW supports FSANZ proposal to remove Diacyltartaric and fatty acids esters of glycerol from food additive permissions for IFP in the Code.

Contaminants

NSW offers the following comments on contaminants:

- NSW notes the lack of evidence in support of an ML in the Code (pg 51-55 of SD1) for IFP for Cadmium, Aflatoxin B1 and M1, Ochratoxin A, Polycyclic Aromatic Hydrocarbons, Perchlorate. Chloropropanol, glycidol and their esters. However, this might raise concerns and public perception that Australia might become a port of IFP rejected by other nations where MLs exist.

L-Lactic Acid producing microorganisms

- NSW supports the notion from FSANZ that addition of L-Lactic Acid producing microorganisms for prebiotic purposes would require a pre-market safety assessment, as this is a novel food/possible nutritive substance.

- NSW supports the clarification in the Code that L-Lactic Acid producing microorganisms may be added for acidification reasons.

- NSW does not support FSANZ notion that addition of L-Lactic Acid producing microorganisms to SMP products for prebiotic purposes would not require pre-market safety assessment. This is the same function as addition to standard IFP where pre-market safety assessment is required. NSW suggests that FSANZ correct this in the 2nd CFS as this presents a means for subversion of pre-market safety assessment requirements in Standard 2.9.1. Such an outcome is not consistent with the MPGI.

Labelling

- NSW supports original proposal for warning statement *'Do not add anything or change proportions of powder except on medical advice'*. This sentence is very clear to care-givers that nothing should not be added (or taken away) from the preparation of IFP. NSW supports retention of this sentence as a warning statement so it carries the appropriate weight. NSW is concerned that moving such information to preparation instructions (unless bolded and underlined) will not carry equivalent weight to a warning statement. IFP as a sole source of nutrition for an infant must be prepared as instructed, as a safety matter.

- NSW supports retention of prescribed name for IFP and follow-on formula, as well as prohibited representations on IFP. NSW further supports retention of the existing prohibition on nutrition, health and related claims on infant formula.

- NSW supports use of the 'protein source' statement on IFP and not statements on protein fractions.

Supporting document 2

Composition

NSW offers the following comments on the composition of IFP and SMP products:

- NSW assumes that continuity of supply is an influencing factor in the proposal to maintain Codex values for protein range rather than adopt lower EU values.

- NSW agrees with FSANZ's approach to prescribe protein sources for use in IFP with the view that non-listed sources would require pre-market safety assessment before they could be included in the Code.

- NSW further agrees with FSANZ that protein fractions that are synthesised, extracted and/or concentrated above their background levels in existing ingredients in IFP as nutritive substances that require pre- market safety assessment. An example is lactoferrin, currently subject of Application 1253.

- Regarding linolenic acid, NSW does not understand why FSANZ has concluded that maintaining current minimum linolenic acid levels in the Code is appropriate for Australian infants. Values in breast milk align more with minimum levels in the EU rather than Codex. NSW requests further information from FSANZ to more clearly explain why it is proposed to retain sub-optimal minimum levels in IFP when contemporary science provides higher minimum values.

- NSW notes the points on page 18 of SD2 concerning the status of substances added voluntarily to IFP, examples include DHA, ARA and EPA. NSW concurs with FSANZ conclusions on these substances however suggests that data should be invited from industry submitters on the purpose of addition of these substances so the MPGI statement concerning efficacy may be addressed.

- NSW requests further comment from FSANZ to consider the duration of time an ingredient can maintain a voluntary addition status before it is reviewed for efficacy. This would assist in maintaining the best possible IFP on the market as close to breast milk as possible. As such a review could inform on the need to possibly consider mandatory addition of the substance to IFP so all bottle-fed babies have access to formula as close to breast milk, or provide a statement to care-givers on the substance that it is not required to be present in IFP, but added voluntarily by the manufacturer. Examples of such substances include DHA, ARA, EPA and lutein.

- NSW notes comments provided by submitters concerning a 5-year review on the efficacy of optional ingredients added to IFP. NSW is not opposed to this review but seeks further information on desired outcomes, i.e. does a review constitute re-prosecution of the permission to add the substance? Does it lead to consideration of possible mandatory fortification? NSW is unclear of the desired outcomes of this proposed review (pg 38 of SD2).

- NSW supports FSANZ proposal to maintain current restrictions on medium chain triglyceride (MCT). These substances are intentionally added to pre-term formulas and should have permissions aligned with their functional purpose in these SMP formulas.

- Carbohydrate source, NSW requests further discussion from FSANZ on the exclusion of glucose from the adoption of limits for other mono and disaccharides in IFP. It appears that alignment with Codex is the predominant influence on this decision rather than a consideration of potential risk. NSW sought advice from Professor Woosung Sohn, Dental Public Health specialist, Chair of Population Oral Health for Centre for Oral Health NSW Ministry of Health, and from the University of Sydney previously conducting research on the cariogenicity of sugars. Professor Sohn supported the limits on sucrose and fructose contents in infant formula given the link between the sugars intake and dental caries, obesity, and other metabolic disorders. NSW notes glucose is not currently included in the list of sugars for restrictions. Professor Sohn reported although glucose is not as highly cariogenic as sucrose, a high content of, and prolonged exposure to glucose is still cariogenic. Consideration should be given to including glucose in the carbohydrate source list.

- NSW requests further information from FSANZ on whether beta-carotene is used in the calculation of Vitamin A values in other foods. The decision to exclude beta-carotene from Vitamin A calculations for IFP could lead to discrepancies in the application of the Code to foods. Beta-carotene should either be included in the total vitamin A calculation or excluded from IFP.

- NSW requests further discussion from FSANZ on its decision to maintain minimum levels of choline in IFP aligned with Codex and not the EU, given that EU levels are more aligned with breast milk choline values.

- Minimum levels of inositol in IFP currently in the Code are cited as being below those in breast milk (pg 37 of SD2). Given changes made by the EU to increase minimum inositol levels to be more comparable with breast milk, NSW requests further information to explain why minimum levels of inositol, lower than breast milk, are supported.

- NSW requests further information from FSANZ on minimum levels of nucleotides in IFP required to achieve the desired functional purpose. NSW does not object to the removal of minimum requirements for these substances provided an understanding is achieved on what dose is required to attain a functional purpose. NSW suggests this information is necessary as pg 12 of SD3) provides evidence that care-givers use the Nutrition Information Statement (NIS) to make product comparisons. Consumers need to have assurances that minimal levels of optional ingredients permitted in IFP will achieve a functional purpose.

- NSW does not support removal of the Potential Renal Solute Load (PRSL) from Standard 2.9.1 as paediatric dietitians use this information for specific medical conditions and finding this information is difficult and time consuming thus prefer to retain on the label. While a mandatory requirement for this information may create a trade barrier, NSW supports provision that state the PRSL should be included on labels where possible.

- NSW requests further explanation from FSANZ as to why it is desired to adopt the Codex range for Zinc when its own modelling has concluded potential exceedances of the upper limits (pg 47 of SD2). Adoption of the EU 2016/127 regulations would seem to provide a better infant outcome.

- NSW requests information from FSANZ on the functional purpose of Choline in follow-on-formula (pg 51of SD2) given the EFSA recommendation there is no need to add choline to follow-on-formula. NSW requests this information as it is unclear why Choline is being added (is it serving a technological or nutritional purpose?), given choline can be obtained through complementary foods from around 6 months of age.

- NSW requests information from FSANZ on the justification for addition of myo-inositol to follow-on-formula (6-12 months of age) (pg 51 of SD2) as EFSA has suggested it can be synthesised endogenously and provided by other foods in the complementary diet from around 6 months of age.

- NSW requests information from FSANZ on the purpose of L-carnitine in follow-on-formula (pg 51 of SD2) as it is not specified in Codex and the EU. EFSA has further noted that it should not be mandatory in follow-on-formulas due to the addition of other complementary foods from around 6 months of age and endogenous synthesis.

Supporting document 3

NSW offers the following comments on labelling matters provided in SD3.

- NSW supports the proposal from FSANZ to mandate the format of the Nutrition Information Statement (NIS) as provided by Schedule 29 -10(3). NSW Child & Family Health Clinical Nurse Consultant (CFH CNC) network have noted that some parents and carers:
    - compare formulas by reading nutrition information
    - others find claims on the front of formula cans such as 'gold' or 'platinum' are unfortunately more important than nutrition information.

- NSW further supports use of ‘additional’ to collapse optional substances (e.g nutritive substances, galacto-oligosaccharides etc) under one common heading. Use of various terms ‘probiotics’, ‘prebiotics’ are likely to have limited understanding with care-givers. NSW suggests these ingredients should be listed in order from highest to lowest amount.

- NSW supports use of per 100ml as re-constituted in the NIS as this provides care-givers with a consistent basis for product comparison.

- NSW supports retention of the requirements for one scoop to be declared and the proportion of powder or concentrate to re-constitute the formula according to directions to be declared and for this information to be provided in the NIS.

- NSW seeks further information of the care-giver benefit provided by the proposal to permit whey:casein ratios and alpha-lactalbumin to be declared on IFP labels. NSW requests this information as health professionals are already

using it to advise care-givers on specific products when necessary. NSW is concerned that without some sentiment of care-giver benefit provided by the proposal it could give rise to self-diagnosis of medical conditions that ought to be referred to a medical practitioner for professional advice.

- NSW supports the notion that 'anti-reflux' and 'colic' will not be permitted on standard IFP. NSW suggests these terms could be added to 'prohibited representations for standard IFP to ensure exclusion from the standard IFP market.

- NSW supports retention of prohibited representations (e.g. HMO) on standard IFP. NSW notes consumer sentiments on claims made on infant formula 'considered them to be marketing tactics unsupported by evidence' (pg 25 of SD3).

- NSW supports maintenance of the existing prohibition of nutrition, health and related claims on IFP.

- NSW suggests FSANZ await the results of the Commonwealth Department of Health review of the MAIF agreement given ACCC concerns on the undermining of factors relevant to IFP through marketing of toddler milks. This may have relevance for future consideration of permitted marketing practices for other standards. NSW notes this is not in scope of Proposal 1028.

- NSW suggests that line marketing practices would be significantly improved by preventing any representation or allowing similar branding for pregnancy formulas, infant formula, follow on formulas, toddler milks and junior milks (noted out of P1028 scope). In addition parents and carers should not be misled that follow on formulas are a natural progression. The use of numbers or words on infant formula indicating a sequential or progressive feeding regimen that use 'stage' or 'step' or any words or numbers having the same or similar effect should be prohibited. NSW considers this appropriate as standard infant formula is for 0–12-month infants and the NHMRC Guideline[4] for Infant feeding guidelines inform that toddler milks are not necessary *'From 12 months of age and beyond, toddlers should be consuming family foods consistent with the Australian Dietary Guidelines. Special complementary foods or milks for toddlers are not required for healthy children'.*

  NSW CFH CNC network have noted parents and carers:
  - can get confused and believe they have to use every stage of formula e.g. parents feel obligated to use 'toddler' formula as it is marketed as 'everything your toddler needs'
  - have bought the wrong stage formula due to formula brand cans being similar in appearance.

- Parents and carers are not the only ones to make these mistakes. A NSW senior paediatric dietitian recalled many years ago that a brand of SMP formula range were all labelled similarly and this resulted in a health professional providing the wrong formula as the can designs were not distinctly identifiable. The dietitian worked with the company to redesign the label artwork and brand naming

[4] https://www.nhmrc.gov.au/about-us/publications/infant-feeding-guidelines-information-health-workers#block-views-block-file-attachments-content-block-1

conventions to ensure each formula could be identified with ease and the risk of an infant being given the wrong formula prevented.

- NSW queries if FSANZ has approached IP Australia on the intent of some areas of Proposal 1028 so it is pro-actively aware of some identified concerns with current marketing practices of some IFP (e.g. trademarked names using terms 'colic', 'anti-reflux').

- NSW considers that the directions for preparation and use should inform to discard unfinished formula 'within one hour' from the commencement of a feed and not 2 hours as proposed by FSANZ. NSW Health facilities provide advice to parents and carers based on the NHMRC Australian Infant Feeding Guidelines[5] (2012) - which recommends discarding of any formula that has been at room temperature for longer than 1 hour. NSW supports adoption of NMHRC guidelines in this area. NSW offers this advice to FSANZ as a MPGI informs *'regulation of infant formula products should not be inconsistent with the national nutrition policies of Australia relevant to infant feeding'*.

- NSW CFH CNC network have noted in their experience many parents and carers would consider that the formula does not have to be discarded until 2 hours after the feed has finished. With the potential risk that formula would be reoffered 3 -4 hours after it was prepared.

- NSW further suggests an additional warning statement for IFP labels:

  "Putting your baby to bed with a bottle unsupervised can cause tooth decay and risk ear infections".

NSW offers the below information as evidence.

Risk of dental caries with bottle feeding

Some of the major contributing factors to dental caries in children are poor dietary and oral hygiene practices. Young children may be more likely to be admitted to hospital because dental procedures may be difficult to perform in outpatient or community settings at this age. Dental caries continues to be a reason for treatment in hospital under general anaesthetic. In NSW in 2019/20 removal or restoration of teeth for dental caries in children was higher for children aged 0-4 years and particularly aboriginal children of this age group (See table 1 overpage)[6]. In 2019/20 better dental health practices may have prevented 369 per 100,000 hospitalisations for dental conditions for children aged 0-4 years. Compared to 208 per 100,000 for the general population.[7]

Table 1:

[5] https://www.nhmrc.gov.au/about-us/publications/infant-feeding-guidelines-information-health-workers#block-views-block-file-attachments-content-block-1

[6] NSW Government Health Stats NSW **Removal and restoration of teeth for dental caries** by Age (years) and Aboriginality https://www.healthstats.nsw.gov.au/#/indicator?name=-ora-cariesteeth-proc-hos&location=NSW&view=Trend&measure=DSTRate&groups=Aboriginality,Age%20(years)&compare=Age%20(years),Aboriginality&filter=Age%20(years),All%20ages,0-4%20years&filter=Aboriginality,Total,Aboriginal

[7] NSW Government Health Stats NSW **Potentially preventable hospitalisations: Conditions** Dental conditions for 2019/20 by Age (years) https://www.healthstats.nsw.gov.au/#/indicator?name=-pph-cond-hos&location=NSW&view=BarHorizontal&measure=DSTRate&groups=Period,Condition,Age%20(years)&compare=Condition,Period,Age%20(years)&filter=Period,19/20&filter=Condition,Dental%20conditions&filter=Age%20(years),All%20ages,0-4%20years

Dental condition	0-4 years (rate per 100,000 all children)	0-4 years (rate per 100,000 Aboriginal children)	All ages (rate per 100,000)
Removal and restoration of teeth for dental caries (2019/20)	289	376	104
Potentially preventable hospitalisations for dental conditions (2019/20)	369	n/a	208

One of the risks for dental caries in this age group is not supervising, propping up or putting an infant or toddler to bed with a bottle of formula or milk where formula or milk may remain in contact with teeth for prolonged periods of time.[8]

Warning of tooth decay is consistent with the NSW Health My Personal Health record given to all parents/carers on the birth of a child in NSW.[9]

Risk of ear infections with bottle feeding

Health professionals also noted that in addition to tooth decay risks infant formula increases the risk of ear infections.[10] This may be because reclined feeding may also increase the risk of milk flowing into the ear cavity causing ear infection.

We recommend the inclusion of a warning statement for infant formula labels that includes:

Putting your baby to bed with a bottle unsupervised can cause tooth decay and risk ear infections.

In a previous NSW P1028 submission we noted NSW based paediatric dietitians expressed concern that some parents take statements regarding the amount of formula an infant should drink quite literally. For example, if the product label says an infant should be drinking Xmls by a certain age and their infant does not do this on every feeding occasion, it causes worry. NSW would support a statement be included under the table of amounts such as:

"This is based on average needs and your baby's needs may be higher or lower; check with your healthcare professional for further advice if needed".
OR
"The formula amount for each feed is only an indication of what you baby may require - please seek assistance from your health professional"

[8] Cheng H, Chen R, Milosevic M, Rossiter C, Arora A, Denney-Wilson E. Interventions Targeting Bottle and Formula Feeding in the Prevention and Treatment of Early Childhood Caries, Overweight and Obesity: An Integrative Review. *Int J Environ Res Public Health*. 2021;18(23):12304. Published 2021 Nov 23. doi:10.3390/ijerph182312304 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8656950/
[9] NSW Health My Personal Health Record "Blue Book" 2017 https://www.health.nsw.gov.au/kidsfamilies/MCFhealth/Publications/blue-book-2017.pdf
[10] McNiel ME, Labbok MH, Abrahams SW. What are the risks associated with formula feeding? A re-analysis and review. *Birth*. 2010 Mar;37(1):50-8. doi: 10.1111/j.1523-536X.2009.00378.x. PMID: 20402722. https://pubmed.ncbi.nlm.nih.gov/20402722/

It would also be useful to co-locate the information re scoop and dilution rate to near this table as well.

NSW CFH CNC network also report similar findings that when feeding with formula:

- parents do get concerned if their infant doesn't consume the suggested amount on formula cans
- parents don't always consider if their infant has been born premature, small for gestational age or feeding frequently that they may need different amounts.
- there have been instances where parents overfeed their infants to align with amounts on the formula can.

Supporting document 4

NSW offers the following comments on SD4:

- NSW expresses significant concern with the notion that FSMP regulations applying to IFP should be sufficiently flexible to accommodate innovations in managing medical conditions without undertaking pre-market safety assessment. This has the effect of establishing a self-substantiation pathway for high-risk IFP (these products cannot be safely consumed by healthy infants).

- NSW argues that self-substantiation is not appropriate for IFP. Pre-market safety assessment should be required for all additional and/or new substances added to IFP consistent with existing provisions in the Code.

- NSW believes the self-substantiation process inappropriately shifts assessment from a single, independent, national point to many (jurisdictional enforcement agencies), which could create regulatory uncertainty and inconsistency.

- NSW asserts that even where the Code permits self-substantiation, it is not permitted for high-risk applications (e.g. high-level health claims). Such claims can only be permitted through express consideration by FSANZ. NSW refers FSANZ to its alternate proposal for the regulations of IFPSMP earlier in this submission.

- NSW contends the addition of a positive list of IFPSMP, overseen by an independent expert panel provides a flexible, yet independent means to ensure the desired protection for high-risk, low volume products manufactured internationally. The purpose of this list is to ensure continued supply of medically determined specialised IFP.

- NSW is concerned that removal of the definition of ‘pre-term formula’ from Standard 2.9.1 would not provide the means to appropriately tailor the maximum amount of aluminium (currently set at 0.02mg/100ml) and also guide medium chain triglyceride (MCT) permissions as these are shown to have high water solubility and are more easily absorbed by pre-term infants (pg 11 of SD4).

- NSW agrees that some elements of the FSMP labelling framework should be applied to IFPSMP, however the FSMP labelling framework should be customised to suit application to a very high-risk sub-population, and not the other way around. NSW concurs with FSANZ on the following matters:
    - A statement indicating the medical purpose of the food.

- A statement describing the properties or characteristics of the food which make it appropriate for the medical purpose.
- A statement that the food must be used under medical supervision.
- A statement highlighting any precautions or contraindications associated with consumption of the food.
- For products represented as sole source of nutrition the statement that the product is not for parenteral use and additional statements about nutritional modifications made to the product.

- NSW agrees the nutrition content, health and relation claims should be prohibited on the product.

- NSW disagrees with the proposal to exclude SMPPi from prohibited representations applicable to standard IFP. NSW sees this proposal from FSANZ as a loophole for HMO containing IFP to product shift to SMPPi (based on generally accepted scientific data) and label on the front of pack with 'HMO' labelling. This would be in direct contradiction to the decision of the majority of Food Ministers in considering Application 1155.

- NSW suggests prohibiting therapeutic claims on IFPSMP as is the case for FSMP.

- NSW is not supportive of the proposed exemption of SMPPi from the requirement for the name and business address of the supplier in section 1.2.2—4. This information on the label is important for product traceability especially in the case of food recalls. Currently this information is required for all IFP including IFPSDU. Considering high vulnerability of the infants who need these formulas, NSW does not see any rationale to exempt IFPSMP from this requirement.

In preparing this submission NSW consulted with a range of professionals: Medical Clinicians and Consultant Doctors, Clinical Nurse Consultants, Dentists, Specialist Paediatric Dietitians, Dietitians and Food Regulators (Compliance and food standards staff).

ENDS

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