Proposal 1028 Infant formula
Consultation paper 3 – Regulatory framework and definitions

Summary

NSW appreciates the opportunity to comment on Proposal 1028 Infant Formula – Consultation paper 3 (CP 3) Regulatory framework and definitions. Due to the on-going impact of the COVID-19 pandemic and the heavy NSW investment in response, it has not been possible to undertake the required level of consultation on the range of issues considered by CP 3, particularly with clinical stakeholders which remain a significant gap. However, NSW offers the following high-level summary comments that are expanded upon further:

- Collapsing consideration of nutritive substances and novel foods for infant formula products (IFP) into *Proposal 1024 Review of Nutritive Substances and Novel Foods* (P 1024) must preserve the existing policy position that such substances are subject to pre-market safety assessment prior to addition to IFP. The Ministerial Policy Guideline for Regulation of Infant Formula[1] (the Guideline) advises these substances should be subject to pre-market safety assessment prior to addition.

- NSW considers that further consultation with Paediatric Specialists is required before a view on moving human milk fortifiers to Standard 2.9.5 Foods for Special Medical Purposes can be supported. There are also possible policy considerations around access by non-target markets (for example, bodybuilders[2]) to investigate and manage.

- The proposal of merging Special Dietary Use (SDU) products into a broader category of Special Medical Purposes requires significantly more detail before NSW can offer a position. Key information gaps include evidence keeping requirements for determination of an infant formula product (IFP) as an infant formula product for special medical purposes (IFPSMP), whether this would be managed pre- or post-market, and the possible use of special medical purposes (SMP) labelling provisions to make claims on IFP. All IFP are prohibited from making nutrition content and health claims; the FSANZ proposal to use SMP provisions for IFPSMP could inadvertently provide a means for products regulated by Standard 2.9.1 of the Code to carry nutrition and health claims.

- NSW is of the view that addressing issues related to molybdenum/chromium, medium chain triglycerides and low lactose formulas requires effective engagement with the appropriate clinical expertise, which has been limited at this time. However, NSW shares the concerns raised by other jurisdictions and stakeholders about the potential impacts on continuation of breastfeeding of low-lactose and lactose-free formulas if these were considered as standard infant formula and readily available in

[1] Infant formula
[2] https://www.menshealth.com/fitness/a19530877/human-breast-milk-and-bodybuilding/

supermarkets, and provides some specific comments on molybdenum/chromium and medium chain triglycerides, below.

- Consultation with clinicians has been severely limited due to the impacts of Covid-19 on the health system; targeted and structured consultation with these groups is needed to effectively progress the review of infant formula, and NSW strongly urges FSANZ to undertake targeted and facilitated consultation with this these clinicians once this is possible.

- The lack of a prescribed name for IFPSMP. NSW cannot provide an opinion or a firm position on this proposal due to its link to the evidence keeping provisions required to substantiate use of SMP as a class of IFP. NSW understands that FSANZ will expand on this in the 1st call for submissions for P 1028. However, the proposal to not make IFPSMP a prescribed name coupled with undefined evidence-keeping provisions for the use of SMP as a class of IFP raises concerns that the rigidity of the SMP category may not be sufficiently robust to address some concerns with the current use of Special Dietary Use (SDU) as a class of IFP. The current SDU category captures pre-term formulas but also formulas developed to assist in the dietary management of transient conditions of colic and reflux. In general, NSW's view is that FSANZ should retain the prescribed name "Infant formula" and "Infant formula for medical purpose" on labels to ensure parents and health professionals can distinguish these formulas clearly. This would also assist industry understand what is standard 'infant formula' and what is IFPSMP.

- NSW supports FSANZ proposed approach to requiring infant formula products for special medical purpose (including low-lactose and lactose-free formulae, as noted above) only be available for sale from pharmacy/ medical institution under medical supervision. Consideration will need to be given to appropriate online pharmacy sales especially in rural and regional areas.

- NSW supports the retention of the 'Breastmilk is best' statement on all infant formula, including on IFPSMP.

The above points are expanded below.

Novel Foods and Nutritive Substances

In its 2017 and 2016 submissions to Proposal 1028, NSW supported retention of nutritive substances and novel foods for Infant formula products within the scope of Proposal 1028 due to the increased vulnerability of infants as a sub-population in general but also due to specific advice provided by the Guideline. The Guideline advises that such substances are 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 provides clear direction that such substances should be subject to pre-market safety assessment prior to legal addition to infant formula products. In raising the proposal to shift consideration of these substances to P 1024, FSANZ should acknowledge the clear advice of the Guideline for pre-market safety assessment for these substances.

FSANZ should also acknowledge the element of a 'substantiated beneficial role' proposed for these substances provided by the Guideline, that is arguably a unique requirement for the pre-market safety assessment and approval of nutritive

substances and novel foods that is not required for the addition of these substances to foods for the general population.

FSANZ should also preserve the additional element of the Guideline for establishment of an expert panel for substances requiring pre-market safety assessment for infant formula products, where the levels of evidence for a 'substantiated beneficial role' are less clear. How this will be incorporated into P 1024 as a unique element of novel foods and nutritive substances for infant formula substances in not clear to NSW. Clarity from FSANZ on how the unique elements of the Guidelines will be carried over to P 1024 is requested in the 1st call for submissions should FSANZ continue to pursue the proposal to merge all nutritive substances and novel foods into P 1024.

NSW further considers the following policy principles of the Guideline explicitly apply to the consideration of nutritive substances and novel foods in infant formula products:

Specific Policy Principles – Composition
d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.
i) Pre-market assessment should be required for any substance proposed to be used in infant formula that:

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

Additional Policy Guidance
Expert Group
FSANZ should consider establishing an independent scientific expert group that may provide advice prior to pre-market assessment, based on scientific criteria established by the Authority, on whether:
i) a substance proposed to be added to infant formula products has a history of safe use in infant formula or follow-on formula in Australia and New Zealand; and
ii) there is evidence available that the substance has a substantiated beneficial role in the normal growth and development of infants or children.

NSW notes that amendments to the definition of 'nutritive substance' provided by Proposal 1025 – Code revision, in that substances naturally contained as a component of other existing ingredients in a food, if added to foods at levels well in excess levels found naturally, are nutritive substances (when added to fulfil a nutritive purpose). This provides the necessary clarity for FSANZ to consider and advise on some of the milk protein fractions that are added to some infant formulas (e.g. Lactoferrin) where the levels added appear to exceed those found in naturally occurring ingredients of infant formula. Do they serve a nutritional purpose, or 'substantiated beneficial effect' that warrants their inclusion as specific ingredients in and of themselves? NSW suggests that FSANZ should use the opportunity of Proposal 1028 to clarify the regulatory identity of such substances when added to standard infant formulas.

Specific substances other than nutritive substances and novel foods

NSW has been able to undertake only minimal consultation with clinicians on these issues and has the following comments to offer as a result.

Chromium and molybdenum: both have recommended Adequate Intakes for infants in Australasia, so it is appropriate that these are added within recommended amounts to infant formula that otherwise do not contain them, particularly given the formula may well be the sole source of nutrition for the infant. While information on deficiency is limited for both of these nutrients, it has been documented in long-term parenteral nutrition not in adults and is recommended as a component of parenteral nutrition solutions.

Medium Chain Triglycerides (MCTs): NSW supports requirements be retained for specific malabsorption or metabolic conditions, with addition only permitted where necessary to manage a specified condition.
MCTs are saturated fats; breast milk contains a small component of MCTs. Formula for special medical purposes should be modified specifically to meet the need of the condition they are used for, for example, there is no benefit for an infant with phenylketonuria to have MCT in their formula compared to the fats used in standard formula. Unless the evidence supports MCTs as a beneficial addition to all standard IFP there is no rationale for it to be included in all IFPSMP.

Regulatory framework

In its 2017 submission NSW suggested that FSANZ apply the term 'medically determined' to the definition of Infant Formula Product for Special Medical Purpose (IFPSMP) in order to remove the ambiguity between the place of standard Infant Formula Product (IFP) in the market and its access and specifically formulated products for manage a defined medical condition.

NSW suggests that FSANZ re-consider the proposed definition provided in CP 3 as it only requires medical supervision *after* it has been supplied. A key concern with the construction of the current Special Dietary Use category is IFP requiring medical prescription are grouped in the same category as products that purport to assist in the management of transient conditions (reflux). Consultation with a medical doctor for the treatment of conditions such as chronic reflux in an infant is important to ensure that any underlying medical condition is appropriately diagnosed and treated effectively.

NSW proposes that FSANZ re-consider the following definition for IFPSMP:

Infant formula product for special medical purposes means an infant formula product that is specifically formulated:

(a) for infants who have ***medically determined***:
    (i) nutrient requirements, or
    (ii) limited or impaired capacity to take, digest, absorb, metabolise, or excrete food including another type of infant formula product, or certain nutrients contained therein, and
(b) To be used under medical supervision.

NSW suggests the addition of 'medically determined' resolves the concern with the potential ambiguity that sits in the interface of standard IFP and IFPSDU or IFPSMP. This will assist consumers, industry and regulators as a product labelled as IFPSMP will need to be developed for the dietary management of a medically diagnosed condition.

NSW argues that provision of IFPSMP through pharmacies aligns with this specificity as evidence of a medically diagnosed condition will assist chemists in advising consumers of the need for an IFPSMP. Such advice could be provided online or face to face akin to the management to s3 substances, where a medical prescription is not required to access but consultation with a chemist is required as a purchase pre-requisite. This consultation extends to s3 products purchased over the internet from pharmacies.

NSW suggests the current definition proposed for IFPSMP will not resolve current concerns with the lack of clarity on difference between IFP and certain IFPSDU as it provides choice between a specifically determined medical condition, or limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolises of other IFPs. NSW argues that *limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolises of other IFPs* is a matter for determination by a medical professional and should therefore be captured by the pre-condition of professional medical determination as an entry to the category of IFPSMP.

NSW also suggests that a prescribed name should be applied to IFPSMP. This allows consumers, regulators and industry to clearly understand the pre-requisite conditions required to apply the name of IFPSMP, and also to clearly distinguish standard IFP from those required for the dietary management of a diagnosed medical condition. An alternative could be to include IFPSMP in 2.9.1-16 in that a food can only be represented as an IFPSMP if it complies with all elements of Standard 2.9.1 (including the amended definition for IFPSMP proposed by NSW).

NSW suggests such an approach is aligned with the Guideline as it has specific advice for IFPSDU:

*'For infants with **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**'.*

Management under the supervision of a medical specialist or paediatric dietitian implies that use of such specific products is in response to diagnosis of a specific medical condition or need in an infant by an appropriately qualified medical professional.

An example where the above proposed approach would work well are pre-term formulas. Pre-term products are highly specialised, generally available through neo-natal paediatrics, supplied where medically necessary and are used under the supervision of a medical professional. This is sufficient justification for such products to be considered IFPSMP when used in an in-patient setting for a pre-term infant prior to discharge and allow parents of such infants access to specialised formulas through pharmacies post-discharge and in accordance with professional medical advice.

Low Lactose formulas

NSW is concerned the proposal to shift low-lactose IFP from IFPSDU to general IFP may result in the inadvertent use of low-lactose formulas by mothers in the absence of professional medical advice warranting use of such products. NSW understands some temporary intolerance to lactose may occur in some infants following gastroenteritis.

NSW suggests that such products should remain as IFPSMP so that on-going use of low-lactose formulas is on the advice of a medical professional and not a self-diagnosis. 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.

Protein substitute formulas

A Cochrane review conducted to determine the ability of IFP containing hydrolysed proteins on preventing allergenic diseases in infants indicated equivocal evidence for a preventive effect. The extent of hydrolysis required to prevent the occurrence of allergic reaction appears a logical starting point for the consideration of such possible effects. NSW understand this is still under consideration and requests an update from FSANZ on this matter in the 1st call for submissions.

Labelling provisions for IFPSMP

FSMP labelling provisions 2.9.5-10(a) – (f)

NSW requests clarity from FSANZ in the 1st CFS for Proposal 1028 that incorporation of some labelling elements of Foods for Special Medical Purposes (FSMP) onto IFPSMP will not inadvertently result in the making of nutrition and health claims on IFP. NSW understands it is intended to use Standard 2.9.5-10(a) – (f) on IFPSMP in lieu of current labelling provisions for IFPSDU.

The Guideline specifically prohibits the making of nutrition and health claims on IFP. Standard 1.2.7 further prohibits the making of such claims on foods regulated by Standard 2.9.1. NSW affirms its on-going support for maintaining this prohibition to IFP and IFPSMP.

The requirement of Standard 2.9.5-10 (c) that a *statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated;* must be made on FSMP will need some explicit text in the explanatory memorandum for Proposal 1028 so a statement compliant with this requirement is not a nutrition or health claim.

This may also extend to Standard 2.9.5-10(d) that a *statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (c)*.

NSW considers this clarity is necessary as there are current FSMPs in the market targeted at children above the age of 1 and less than 10 that contain nutrition and health claims (*such products are not regulated by Standard 2.9.1 and so may be labelled with nutrition and health claims*).

Capacity to comply with US and EU regulations

Due to the very limited availability of FSMP internationally it seems sensible to permit ingredient listings in a manner compliant with EU or US regulations to be determined as compliant with Standard 1.2.4 of the Code.

'Breast is best' labelling exemption for all IFPSMP

NSW does not support the proposed exemption of all IFPSMP from the 'breast milk is best for babies', it is rare that breastmilk is not suitable for a baby, and in these cases the parents are aware they are feeding their baby under clear medical advice addressing a specific medical condition.

The use of infant formula products for special medical purposes beyond infancy

NSW considers it is not for the Code to prescribe medical practice and the need for use beyond 12 months is an individual medical decision which should be left to medical discretion and not canvassed on the label.

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.