Submission – Consultation Paper 3 - Regulatory framework and definitions

Proposal P1028 – Infant Formula

Comments from Public Health Services, Department of Health, Tasmania,
20 October 2021

Public Health Services, Department of Health, Tasmania (PHS) appreciates the opportunity to comment on Proposal P1028 – Infant Formula, Consultation Paper 3.

PHS recognises that breastfeeding is the normal and recommended way to feed an infant. For infants that rely on infant formula as the sole or principal source of nutrition up to 12 months of age, regulation is essential to ensure infant formula remains safe and that its nutrient composition supports normal growth and development.

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

There are a number of general comments that PHS would like FSANZ to consider as well as more detailed responses to questions and proposed approach of FSANZ throughout the consultation paper.

General questions

- **How effective do you believe the current regulatory measures for IFPSDU are? How could they be made more effective? If you think the requirements should be changed to better manage risk, please explain how and why. Please provide supporting detail and data, where available**.

The current regulatory measures for IFPSDU have ensured that very specialised formulas that are produced overseas are available in Australia enabling clinical dietitians in Tasmania to use these products effectively with their patients.

However, concern remains on the creep of these 'specialised formulas' into the mainstream market. Some studies on special purpose formulas for 'transient gastrointestinal conditions' such as colic and reflux have highlighted concerns regarding the marketing of these products for generally healthy infants. Mothers are persuaded by the credibility of this advertising and the use of language that sounds scientific or technical. There is the belief that these infant

formulas can treat common aliments or resolve inconvenient but normal infant behaviours[i]. The risk is that these formulas may be perceived as an alternative to breastfeeding in addition to an economic cost associated with a higher price for these modified formulas[ii]. Examples illustrated in these studies include the low lactose containing infant formulas for colic[iii] where there is limited scientific evidence that these work for mild to moderate colic conditions.

Restricting access to these products and redefining them as an Infant Formula for Special Medical Purposes that can only be used under medical supervision would ensure better health outcomes for all infants. Infant would receive a more thorough medical diagnosis and reduce parental anxiety associated with constantly changing formulas to address symptoms such as excessive crying that may be better addressed through other strategies.

- **Do you consider that the options proposed in this paper will ensure that IFPSMP are safe, suitable and meet the nutritional requirements of the infants for whom they are intended? If not, please explain why and provide supporting data and detail, where available.**

PHS supports many of the changes outlined in this paper and considers the move to Infant Formula Products for Special Medical Purposes (IFPSMP) an important step to separate these products from standard infant formula and follow on formula.

However, the definitions may require further consideration to ensure they clearly articulate that IFPSMP are safe, beneficial, and effective in meeting the specific nutritional requirements for the infant for whom they are intended based on accepted scientific data. This is in line with the EU 2016/128[iv] requirements for food for special medical purposes. All definitional elements are required to ensure that products as described above are not provided to infants without sufficient scientific evidence that they are effective in managing medical conditions where dietary changes such as modifications to infant formula is required.

- **How effective do you believe the options proposed for IFPSMP will be? How could they be made more effective? Do they place an unreasonable cost burden on industry to achieve and/or maintain compliance? Please provide supporting detail and data, where available.**

PHS generally supports the simplification of the standard and the one category for IFPSMP. However, this will only be effective if all definitional elements outlined in the paper are included. This includes that IFPSMP are

- Specially formulated (based on scientific evidence) for the dietary management of infants who have a special medically determined nutrient requirement or have limited or impaired capacity to take, digest, absorb, metabolise other IFP or excrete the metabolites of other IFPs or whose dietary management cannot be completely achieved without the use of IFPSMP AND
- Must be used under medical supervision

This also needs to include restrictions on the labelling, presentation, advertising and promotional and commercial practices to reduce consumer confusion and ensure these products are only used for special medical purposes. This should extend to ensure these products do not include pictures of infants, or other pictures or text which may idealise the use of these products.

2. Novel Foods and Nutritive Substances

2.1 Pre-market assessment requirements

PHS does not support FSANZ proposed approach to not consider novel foods and nutritive substances under P1028.

PHS supported FSANZs view in 2016 that IFP should be excluded from P1024 - nutritive substances and novel foods and assessed under P1028 as infants are a vulnerable population group and a greater level of risk assessment needs to be applied to these products, that may not be as relevant to general purpose foods.

As stated by FSANZ in 2016 consultation report the intent of the Code is that pre-market approval is required for all nutritive substances and novel foods for use in infant formula. This is reinforced by the *Ministerial Policy Guideline on Infant Formula Products* where it clearly states that pre-market assessment is required for infant formula and follow-on formula that:

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

ii. *has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.*

As noted by FSANZ in 2016 there is differing interpretations in the Code on whether substances that are naturally present in an ingredient of infant formula products require pre-market assessment. PHS supports the Code being clearer in this to mean that any substance would require pre-market assessment if a different form/structure is used, or a different technology or technique is used or if a different level of these substances was added to IFPs.

Clarifying what is a nutritive substance cannot wait until P1024 is underway as infant formula regulation has already taken a significant amount of time and P1024 is currently delayed. This added delay of not addressing novel foods and nutritive substance under P1028 will likely cause concern for both industry and food ministers and may undermine the safety of infant formula products.

2.2 Novel Foods – Schedule 25

PHS supports FSANZ proposed approach to add the conditions in Table 5 to novel foods listed in Schedule 25.

3. Specialised infant formula products

3.1 Approaches to regulation of IFPSDU

PHS supports FSANZ proposed approach to retain the regulation of IFPSDU in Standard 2.9.1 for the reasons outlined by FSANZ. Standard 2.9.1 also contains regulation around the labelling and packaging requirements of infant formula products which is an important consideration for these products to ensure they do not undermine breastfeeding.

3.2 Human milk fortifier and pre-term supplementary products

PHS considers that HMF could be regulated under either Standard 2.9.1 or Standard 2.9.5 with either option requiring additional work.

If HMF are regulated under Standard 2.9.5 PHS does not support delaying the review of which provisions within Standard 2.9.1 are relevant to HMF. Until careful consideration is given to this issue it will remain unclear if there are any issues with regulating these products under this Standard. Delaying the review of HMF will also add greater uncertainty for industry and regulators if it is not introduced at the same time as Standard 2.9.1 is finalised.

If it remains within Standard 2.9.1 the only real change will be to the definition of infant formula products as HMF are not the sole or principal source of nutrition. This may be simpler and reduce complexity by not having to duplicate regulations between two standards.

4. Definitions

4.1 Definition of Infant Formula Products

PHS supports in principle FSANZ approach to modify the current definition if Infant Formula Products if the compositional requirements for general IF and FOF are applied.

4.2 Definition of Infant Formula

PHS does not support FSANZ proposed definition of infant formula. The key reasons include:

- there is no mention of base ingredients that were taken out of the definition of IFP. It states on page 19 this will be included in the compositional requirements of IF and FOF.
- The definition as it currently stands suggests that after 6 months IF will no longer satisfy the nutritional requirements of infants. This implies that infants should swap to FOF. The NH&MRC Infant Feeding Guidelines clearly state that '*the use of 'follow-on formula' for infants aged 6-12 months is not considered necessary and no studies have shown advantages over using 'infant formula'*

PHS supports the definition – Infant formula

(a) Is represented as a breast milk substitute for infants
(b) Is a product based on milk or other edible food constituent of animal or plant origin
(c) Satisfies by itself the nutritional requirements of infants under the age of 6 months and as part of a progressively diversified diet from around 6 months of age.

This ensures that IF is still seen as the main source of nutrition for infants after 6 months of age until 12 months of age.

5 Regulatory framework for IFPSDU

5.2 Option for regulatory framework

PHS supports FSANZ proposed approach to discontinue with Option 4 (four subcategories). PHS supports the creation of one category defined as Infant Formula for Special Medical Purposes (IFPSMP). Subcategories should only be established if specific regulation beyond that set out for Division 4 is needed.

5.3 Principles for purpose, composition, use and sale of IFPSDU

A clear framework with guiding principles needs to be developed for purpose, composition, use and sale of IFPSDU. These guiding principles need to clearly support the protection of breastfeeding and ensure that IFPSDU are not inappropriately used for healthy infants. PHS supports the terminology - Infant Formula Products for Special Medical Purposes (IFPSMP)

5.3.4 Proposed consolidated principles – purpose, composition, use, sale

PHS supports FSANZ proposed principles for IFPSMP with modifications highlighted in **BOLD**: IFPSMP:

- serve as a sole or principal source of nourishment **for infants when a diagnosed medical condition requires dietary management that cannot be achieved through breastmilk or infant formula alone.**
- serve as a substitute for human milk, and replacement for infant formula **from birth to 12 months** and**/or** follow on formula **from 6 to 12 months.**
- are formulated for infants with a specific disease, disorder or medical condition
- are intended to meet an infant's nutritional requirements to support growth and development
- are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended **medical** purpose
- have a nutrient composition that reflects that of IF or FOF except where necessary to meet the intended purpose of the IFPSMP
- are intended for use under **medical supervision to manage the risks to infant's growth and development**
- are subject to a restriction on sale.
- **Are subject to restrictions on the labelling, presentation, advertising and promotional and commercial practices to ensure these products are only used for special medical purposes.**

PHS supports all these principles being included and that each principle cannot be considered in isolation.

5.4 Name and definition of IFPSDU

PHS supports FSANZ proposed approach to rename Division 4 as Infant Formula Products for Special Medical Purposes. PHS considers that all definitional elements need to be included and supports the following additions in **BOLD**:

IFPSMP

- serves as a substitute for human milk, and replacement of IF and/**or** FOF **AND**
- is specially formulated to be **safe, beneficial, and effective** for the dietary management of infants based on appropriate scientific evidence **AND**
- is for infants:
    - who have special medically determined nutrient requirements or
    - who have limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolites of other IFPs and
    - whose dietary management cannot be completely achieved without the use of IFPSMP **AND**
- is a food that must be used under medical supervision.

PHS considers that each of these definitional elements need to be considered as a whole and that each element cannot be considered in isolation of other elements. This will reduce the number of infant formulas that have been produced in recent years where there is limited scientific evidence for their effectiveness such as partially hydrolysed formula for treatment of colic, or formulas that have been designed for 'hungry babies' or 'unsettled babies'. It will also ensure these products are under medical supervision.

5.5 Provisions for IFPSMP – composition

PHS supports drafting in Division 4 of the Food Standards Code that specifically addresses optional ingredients and pre-market approval. Currently the Code allows compositional deviation from the composition of IF to enable these specialised formula to meet the dietary management of infants with special medically determined nutrient requirements.

However, the Code remains unclear whether optional ingredients are permitted. The inclusion of optional ingredients that are not needed for the management of the intended condition should be prohibited. Infants are a vulnerable population group and those who are pre-term or with a specific dietary condition, disorder or disease are even more vulnerable. The inclusion of unnecessary ingredients can place a greater burden on immature kidneys.

The Code also remains ambiguous regarding what substances require pre-market assessment. The intent of the Code is that pre-market approval is required for all nutritive substances and novel foods for use in infant formula. This is also in line with the *Ministerial Policy Guideline on Infant Formula Products*. Pre-market assessment should be required for any substance that has not been approved in infant formula generally.

5.6 Provisions for IFPSMP – purpose, use and sale

PHS supports FSANZ proposed approach that scientific evidence to support the categorisation of products as IFPSMP is enshrined in regulation. As noted by FSANZ this is consistent with international regulations. PHS strongly supports this approach to not only protect vulnerable infants but also to protect breastfeeding by mothers not being persuaded that a certain formula can treat common aliments or resolve inconvenient but normal infant behaviour such as unsettled babies. It needs to be clearly stated that the intended purpose be specified as a medical purpose and that it clearly needs to demonstrate the efficacy of the product in accordance with the intended purpose.

5.6.2 Extension of use beyond infancy

PHS does not support including provisions for labelling a product beyond infancy. This is a clinical decision made on a case by case basis and is beyond the scope of the Code. The Code as it currently stands does not prohibit the use of IFPSMP beyond 12 months.

5.6.3 Lactose-free and low-lactose formulas

PHS does not support FSANZ preliminary view that IFPSMP does not apply to lactose free and low lactose formulas. If these products are making claims, then they need to be considered under IFPSMP.

5.6.4 Distribution and access

PHS supports FSANZ approach to have access restrictions for IFPSMP, similar to those in Standard 2.9.5. PHS recommends that FSANZ consider how the growth of on-line purchasing and large pharmacy outlets impacts on distribution and access. If this cannot be addressed there is even more reason to have stronger regulations in terms of labelling requirements.

5.7 Labelling of IFPSMP

PHS supports the following preliminary views of FSANZ with additional considerations in BOLD:

- to replace the labelling provisions for pre-term formula and IFPSDU for metabolic, immunological, renal, hepatic and malabsorptive conditions (except for lactose-free and low lactose formulas) with FSMP provisions in paragraphs 2.9.5—10(1)(a) to (f). **This needs to include all products categorised as IFPSMP not just those listed above. Also recommend that the statement of condition, disease or disorder for which the product has been formulated AND the nutritional modifications made be clearly stated on the back of the tin.**
- that replicating allergen declaration requirements and advisory and warning statements in subsections 2.9.5 —10(2) and (3) in Standard 2.9.1 for all infant formula products is unwarranted
- to adopt an approach consistent with section 2.9.5—11 for information relating to ingredients to be made in accordance with Standard 1.2.4 or information that complies with European or United States regulations. **This should be made in such a way that it does not permit nutrition or health claims to be made.**
- to adopt an approach consistent with section 2.9.5—12 for date marking information to be made either in accordance with Standard 1.2.5 or for the words 'Expiry date' or similar words to be used on the label.
- to extend the exemption from the 'breast milk is best' warning statement to all IFPSMP, **provided IFPSMP are clearly labelled with a prescribed name**
- extend the exemption from the statement about offering other foods in addition to IFPs to all IFPSMP **provided IFPSMP are clearly labelled with a prescribed name**
- the general directions for preparation and use requirements are appropriate for IFPSMP, and there are no additional, specific directions that should be mandated.

PHS does not support FSANZ preliminary view that prescribed name 'Infant formula' does not apply to IFPSMP, and that no overarching name should be prescribed for this category. Generic provisions in paragraph 1.2.2—2(1)(b) would apply to IFPSMP.

PHS supports a prescribed name '*Infant Formula for Special Medical Purposes*' located on the front of the pack. Permission to modify wording to permit alignment with international regulations form the EU could also be included.

References

[i] Berry N and Gribble K (2016) Health and nutrition content claims on websites advertising infant formula available in Australia: A content analysis. Maternal & Child Health 2016:1-8

[ii] Belmarich P. et al., (2015) A critical review of the marketing claims of infant formula products in the United States. Clinical Paediatrics (2015) 1-6

[iii] Abrams S.A (2015) Is it time to put a moratorium on new infant formulas that are not adequately investigated? The journal of Paediatrics 2015 Vol 166 (3).

[iv] COMMISSION DELEGATED REGULATION (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0128&from=IT