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SUBMISSION ON PROPOSAL P1028 –
Regulation of infant formula products for special dietary uses

The Department of Health Western Australia (DOH) would like to thank Food Standards Australia New Zealand (FSANZ) for seeking comment on Proposal P1028 – consultation paper – Regulation of infant formula products for special dietary use (IFPSDU). This submission has been prepared by the Food Unit, Environmental Health Directorate, with input from specialist paediatric clinical dietitians practicing at Princess Margaret Hospital (PMH), Child and Adolescent Health Services. Comments in response to questions and preliminary views raised in the Proposal P1028 consultation paper are detailed below.

General statements in response to questions raised in the submission paper

The DOH notes that currently Standard 2.9.1 – Infant Formula Products of the Australia New Zealand Food Standards Code (the Code) regulates the following infant formula products:

- infant formula (for infants aged 0 - <12 months)
- follow-on formula (for infants aged from 6 – < 12 months)
- infant formula products for special dietary use (for infants aged 0 - < 12 months)

The DOH supports infant formula products for special purposes regulations that provide an appropriate regulatory platform to ensure a consistent supply of IFPSDU with proven efficacy, whilst ensuring that they appropriately reflect the Ministerial Policy Guideline – Regulation of Infant Formula Products. Ensuring appropriateness of regulations relating to specialised infant formula products is of highest importance given that these products are specifically formulated for highly vulnerable infants whose nutritional needs differ from healthy infants because of a medical condition.

- Infant health and safety are the pivotal drivers for all decision making relating to infant formula composition, labelling and representation. Infants requiring IFPSDU are the particularly vulnerable population group, even compared to other infants.

As such, regulation of the IFPSDU, including from an access and representation perspective, should be consistent, appropriate and proportionate to risks.

- Issues relating to the marketing of infant formula are of great importance, in light of the current unprecedented global transition to diets higher in milk based infant formulas.[1]
- The DOH supports industry innovation in the provision of special formula for medical purpose that are based on robust scientific evidence.
- The DOH considers that pre-market assessment of any new nutritive substance and/or bioactive substance is required to ensure the substance is safe, beneficial and/or effective in managing the specific medically determined condition.

Question 2: What are the advantages and/or disadvantages of these options, in particular creating an 'infant formula product for special medical purposes' subcategory? If you support creation of a separate category for IFPSMP, should products developed for pre-term and low birthweight infants be included or retained as a separate subcategory? Please provide your rationale.

Question 4: If you support including a subcategory definition for IFPSMP in the Code, is the proposed definition of IFPSMP appropriate; if not, what should it say?

The options raised by FSANZ in their consultation paper (2017) are as follows:

> *1. Delete the current subcategories in Division 4 and merge them into one IFPSDU Division. This option deals with gaps and overlaps but may not improve the regulatory clarity if specific requirements for the various subcategories are retained. As noted above, some highly specialised products may pose a risk if consumed regularly by a healthy infant. This option would not assist in differentiating products to manage that risk.*
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> *2. Retain the three present subcategories and narrow their scope based on product use, highly specialised nature and risk. This could potentially transfer products for transient gastroenterological conditions or the partially hydrolysed protein formula into general infant formula based on the low risk to a healthy infant from consumption of these products. The 'high risk' specialised products could then be more easily differentiated from general infant formula.*
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> *3. Divide the second subcategory 'products for metabolic, immunological, renal, hepatic and malabsorptive conditions' to better reflect the range of products on the market. This approach creates a new subcategory of infant formula products for special medical purposes (IFPSMP) within the IFPSDU Division, which was suggested by some submitters in 2012. The approach aims to more clearly capture these highly specialised products in order to provide an appropriate level of compositional flexibility and labelling consistent with their risk. Figure 1 shows a possible approach that arranges the Division into four product subcategories.*

[1] Baker P, Smith J, Salmon L, Friel S, Kent G, Iellamo A, Dadhich JP, Renfrew MJ. Global trends and patterns of commercial milk-based formula sales: is an unprecedented infant and young child feeding transition underway?. Public Health Nutrition. 2016 Oct;19(14):2540-50.

Of the options provided, the DOH **supports option 1,** as these infant formula products are highly specialised, and restricted to where breast feeding and the standard formula products are not suitable and/or should not be used. All of the specialised IFPSDU should provide valid dietary management of specific and specified medically determined conditions **under medical supervision**. Using a single category approach with products, described as being specifically designed for **medical purposes** may assist with discouraging inappropriate marketing to healthy infants, both breast fed and standard infant formula fed infants. In addition, a requirement for these products to be scientifically evidence based should be included in the standard, as this would be consistent with the Ministerial Policy Guideline and EU regulations that state products should be "safe, beneficial, and effective for the persons for whom they are intended on the basis of generally accepted data". All IFPSDU should require a statement on the label that specifies:

- Is suitable for the specific and medically determined condition
- Is not suitable for general use and should be used under medical supervision
- the nutritional modifications which have been made to the product

Conversely, the DOH does **not** support options 2 or 3. The sub divisions are not mutually exclusive, and are not risk based. DOH considers this has the potential to create confusion and misunderstanding, and it is not appropriate for any special purpose formula to be categorised under a general infant formulas as this would continue unlimited access to these product. For example:

- The products for special dietary use based on a protein substitute include partially hydrolysed protein formula, extensively hydrolysed protein formula and amino acid based formulas which all have very different evidence base and clinical use. Amino acid formulas are required for management of infants diagnosed with an anaphylaxis allergy to cow's milk protein, which is a **serious** medical condition (IgE mediated immune system response) i.e. a 'special medical purpose'. However it is categorised with partially hydrolysed infant formula products that are described by FSANZ as 'less specialised', and which are not recommended by paediatric allergists for the prevention of allergic disease[2].
- Lactose free formula is necessary for management of primary and secondary lactose intolerance; however this access should require medical supervision to prevent continued unnecessary avoidance of lactose as an infant, and continuation into later childhood and adulthood.

Specialist paediatric dietitians expressed interest in then further dividing this into two sub-categories:

1. Premature or low birthweight.
2. Other products for special medical purposes.

[2] Australasian Society of Clinical Immunology and Allergy. Infant feeding and allergy prevention. https://www.allergy.org.au/images/pcc/ASCIA_Guidelines_infant_feeding_and_allergy_prevention.pdf. Accessed Sept, 2017

Question 3: Do you support including a category definition for IFPSDU in the Code? Why or why not? Is the proposed definition of IFPSDU appropriate; if not, what should it say?

It is the DOH view that all IFPSDU should be for conditions that are medically-determined, medically supervised and based on appropriate scientific evidence in line with the Ministerial Policy Guideline. The DOH supports one overarching IFPSDU definition, and naming this group of products as 'infant formula products for special medical purposes'. The DOH does **not** support the proposed definition of IFPSDU, and proposes the following alternative definition:

> *Infant formula products for special medical purposes means an infant formula product that is specifically formulated:*
> *(a) for the exclusive or partial feeding of infants with a specific medically determined;*
> *i) limited or impaired capacity to digest, absorb, metabolise or excrete food, including other infant formula products, or*
> *ii) altered nutrient requirements, and*
> *b) is beneficial, and effective in the dietary management of the specific medically determined condition based on generally accepted scientific evidence, and*
> *(c) is to be used under medical supervision.*

Question 6: Is there a benefit to defining one or more of the following in the Code:
– Hypo-allergenic formula
– Partially hydrolysed formula
– Extensively hydrolysed formula
– Amino acid-based infant formula?
If yes, what are the benefits of including these definitions? And what should be the key elements of each definition?

The DOH notes these formulas, which vary greatly in composition, are designed by the manufacturers for a range of allergy related conditions. Any of these types of formula should clearly identify the specific condition that the formula is designed to manage (i.e the formula is not for general use, suitable for infants with the specific determined medical condition, under medical supervision); and specify the changes to the formula composition. As mentioned above, it is noted that partially hydrolysed infant formula products are not recommended by paediatric allergists for the prevention of allergic disease.

Specialist paediatric dietitians expressed concern that a formula may be defined as "hypoallergenic' when there is currently no evidence base on which to substantiate such a formula product. They have indicated should the efficacy of a particular nutrient composition be proven by scientific evidence that specifying the clinical indications and the nutritional composition modification are of key importance i.e a

statement of the specific condition targeted by the product and compositional modifications, including technical data on percentage of amino acids, peptide sizes (Daltons), modified fats such as medium chain triglycerides and modified carbohydrates (lactose free).

Question 7: Are there any issues with the current definition for pre-term products?

All special purpose formulas should clearly identify the specific medically determined condition that the formula is designed to manage (i.e the formula is not for general use, suitable for infants with the specific determined medical condition, under medical supervision); and specify the changes to the formula composition.

Question 8: What, if any, are the benefits of including age and weight parameters in the regulatory definition for pre-term products?

Specialist paediatric dietitians considered there was significant benefit in the inclusion of age and weight parameters in the regulatory definition for pre-term products, particularly given the lack of definitions, and that this approach would support correct usage. Current clinical practice at PMH is for the use of preterm formula or expressed breast milk (EBM) fortification with human milk fortifier for infants weighing <2kg that are born <37 weeks. The preterm formulas are ceased once 37 weeks are reached and infant weighing >2kg.

Question 10: Is there a need to prescribe a name for IFPSDU – what are the implications for subcategories?

Question 11: Is there a need to prescribe names for any the IFPSDU subcategories? If yes, what benefit would this provide?

The DOH supports a prescribed name for all IFPSDU. This prescribed name should be ‘infant formula for special medical purposes’. The specific condition that the formula is designed to manage should be clearly identified (i.e. the formula is not for general use, suitable for infants with the specific determined medical condition, under medical supervision); and specify the changes to the formula composition.

Question 10: What benefit, if any, would the inclusion of a specific requirement for any IFPSDU to be demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of intended infant subpopulation?

Given the vulnerability of this population group, the inclusion of a specific requirement for any IFPSDU to be demonstrated by generally accepted scientific data as being: safe, beneficial and effective in managing the specific medically determined dietary requirements of intended infant subpopulation, is an essential risk management

approach.

Question 25: To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?

Specialist paediatric dietitians advised current practice at PMH is that preterm infant formula is **not** prescribed for discharge. Pre-term formula use stops at discharge and standard formulas are used to fortify EBM, or increased strength standard infant formula recipes are given, for use under medical supervision.

Question 28: Are there any specific FSMP labelling requirements that should apply to all IFPSDU?

The DOH supports the following specific 'infant formula for special medical purposes' (FSMP) labelling requirements that should apply to all IFPSDU:

- The requirement for a prescribed name "Infant formula for special medical purposes" for all IFPSDU. The prescribed name should be placed on the front of the formula container.
- The requirement for a statement to the effect that this formula product:
    - is not for general use
    - is restricted for use under medical supervision
    - is formulated for a specific medically determined condition
    - specifies changes to the nutritional composition.

Question 30: What evidence can you provide to support concerns regarding inappropriate access to any IFPSDU?

The paediatric dietitians considered that the availability of these products in Western Australia is high. Several are Pharmaceutical Benefit Scheme (PBS) listed which ensures appropriate prescription, and patients therefore receive a subsidised cost. They also considered inappropriate access in terms of use when not clinically indicated or no evidence to support it therapeutic effect does occur relatively regularly. For example the use of colic infant formulas despite a lack of scientific evidence of efficacy and suitability.

International examples may also inform this consultation. In the US, a critical review of marketing claims of infant formula products found 13 product labels that were making gastrointestinal and colic related claims. Authors found there was "insufficient evidence to support the claims that removing or reducing lactose, using hydrolyzed or soy protein or adding pre-/probiotics to formula benefits infants with fussiness, gas, or colic yet claims like "soy for fussiness and gas" encourage parents who perceive their infants to be fussy to purchase modified formula." The authors concluded that their

"increased regulation of infant formula claims was warranted."[3]

In summary, the DOH considers regulatory controls are needed to ensure there is a clear link for consumers that IFPSDU are designed for specific medical purposes, and that access and use requires medical supervision. This is required to help prevent failure to diagnose genuine medical conditions, and to support appropriate supervision and management of the condition. Given the vulnerability of this group of infants, the DOH strongly supports a proportionate and consistent risk management approach to that already taken for adults i.e at the very least, the same level of regulatory controls required to manage the risks for adults using foods for special medical purposes under Standard 2.9.5 of the Code.

Thank you for considering the above comments. Should you wish to discuss any of these comments please do not hesitate to contact

Yours sincerely

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[3] Belamarich, Peter F., Risa E. Bochner, and Andrew D. Racine. "A critical review of the marketing claims of infant formula products in the United States." *Clinical pediatrics* 55.5 (2016): 437-442.