Consultation Paper on P1028 – Infant Formula: to revise and clarify standards relating to infant formula comprising category definitions, composition and labelling

Submission from Health Protection Branch and Preventive Health Branch, Queensland Department of Health

Q2. 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.

Option 2 is preferable on the condition that 'Products for transient gastroenterological conditions' is removed from IFPSDU. These products can be moved to the standard infant formula category because there is limited scientific evidence for clinical effectiveness (with an exception of low lactose products for medically diagnosed primary chronic lactose intolerance). There is low risk associated with these products as they can be consumed without harm by healthy infants.

Allowing these products to remain in this category could create more opportunity for industry to aggressively market products to consumers that do not have a scientific basis. This would be particularly concerning for mothers who are currently breastfeeding with babies that are displaying normal baby behaviour around feeding choosing to change to formula in the mistaken belief that it will be better for their baby than breastfeeding. The *International Code of Marketing Breastmilk Substitutes* and 2016 World Health Assembly resolution 69.9 provide guidance on the inappropriate promotion of foods for infants and young children (http://www.who.int/nutrition/netcode/WHA-Policy-brief.pdf?ua=1). This resolution, aiming to protect optimal infant and young child feeding practices, was adopted by 194 countries, including Australia. The recently released 2017 World Health Organisation document titled *The International Code of Marketing of Breastmilk Substitutes: Frequently Asked Questions* explicitly states that 'there should be no form of promotion of breastmilk substitutes, except for a few medical conditions' http://www.who.int/nutrition/publications/infantfeeding/breastmilk-substitutes-FAQ2017/en/ (p 3).

Once the subcategory 'Products for transient gastrointestinal conditions' is removed from IFPSDU, the other three categories can be collapsed into one category, Infant Formula Products for Special Medical Purposes (IFPSMP). All products within this category should be used under the direction of a suitably qualified health professional, and therefore should be labelled as such.

Q3 Do you support inclusion of 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?

A definition for IFPSDU is not required if all formulas are placed in the IFPSMP category and the IFPSMP definition is used.

Q4 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?

If all categories are collapsed into one IFPSMP category, the definition is appropriate, however to acknowledge that some infants with special dietary needs are managed by other health professionals (e.g. dietitians), point (c) should read:

(c) to be used under the medical supervision of a suitably qualified health professional.

Products in this category would include the protein substitute, premature and low birthweight formulas.

Q5 - Q10

See responses from Dr Melinda White, Attachment 1.

Q11 Is there a need to prescribe names for any of the IFPSDU subcategories? If yes, what benefit would this provide?

The definitions for IFPSDU (infant formula products for special dietary use) and IFPSMP (infant formula products for special medical purposes) that are proposed in the consultation paper do not provide adequate discrimination between the overarching category definition for IFPSDU and the subcategory definition for IFPSMP.

In her submission, Dr White considers that there is no need for subcategories of IFPSDU, that it would be more meaningful to refer to these products as IFPSMP, and that a category definition would only be required for IFPSMP (see discussions on Q2 and Q3, above and in Attachment 1). A prescribed name for IFPSDU would differ from international wording requirements, but a prescribed name for IFPSMP would be consistent with Codex and EU requirements. The use of a prescribed name for IFPSMP would reinforce the idea that these infant formulas are useful only for those infants who have a medically determined condition and that they should only be used under the supervision of a suitably qualified health professional (see comment on Q26, above and in Attachment 1).

It is noted that the Codex definition for Formula for Special Medical Purposes Intended for Infants indicates that this formula is *'…specially manufactured to satisfy, by itself, the special nutrition requirements of infants with specific disorders…*'. This definition adds an additional level of rigour to the proposed definition for IFPSMP, which is dependent on the proposed definition for IFPSDU: '*an infant formula product … which is specially formulated to satisfy, either in part or fully, the special nutritional requirements of that infant…*'.

Currently there are different compositional, labelling and food additive permissions between the different subcategories of IFPSDU. However, there appear to be two main difficulties associated with the (existing) and proposed subcategories for IFPSDU.

Firstly, there is overlap between subcategories. For example, protein substitute formula containing amino acids and medium chain triglycerides are indicated for cow's milk protein allergy and malabsorption (See Q2, Attachment 1). If the formulation of an IFPSDU based on protein substitute is modified to become an IFPSMP, then does it still have to comply with compositional requirements of IFPSDU based on protein substitute, except for where it has been modified for the condition at which it is targeted? IFPSDU based on protein substitute

require labelling with *'Important Notice, Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'*; however an IFPSDU for metabolic, immunological, renal, hepatic and malabsorption conditions requires the statement that the product is not suitable for general use and should be used under supervision from a suitably qualified health professional. Presumably the *Important Notice* labelling requirement would no longer apply in this case. A decision tree, posing a series of Yes/No questions, may be useful for working out what is required in terms of composition and labelling requirements for infant formula in order to solve overlap problems.

It is important that the labelling requirements for IFPSDU reflect the risk, if any, for a healthy infant.

Secondly there is the problem that there may be limited scientific basis for IFPSDU for transient gastroenterological and feeding conditions. This issue is discussed further in Q15 below, and in Attachment 1.

Q12 - Q14

See responses from Dr Melinda White, Attachment 1.

Q15 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?

All infant formula in the IFPSMP category should meet the criteria as standard infant formula or breast milk substitute, with the exception of the specific nutrient modification for defined clinical indications, supervised by a suitably qualified health professional.

As noted in the consultation paper, both EU and US legislation contain a specific requirement that the special formulation (i.e. composition) of the IFPSDU type product be based on sound medical and nutritional principles and for the use of the product to be demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of the intended population.

Standard 2.9.1 allows for changes to nutritional composition to deviate from general requirements for infant formula when this is necessary for the intended use of the product. This approach is based on the expectation that any compositional changes will be based on medical and nutritional principles and are safe and effective in meeting the specific nutritional requirements of the infants for whom it is intended

The main problem in the regulation of IFPSDU concerns infant formula for transient gastroenterological and feeding conditions, which are currently in the market and for which there is limited scientific basis for their use. Valid concerns about these products have been previously expressed by stakeholders, and are given in the Table to Section 7.2 in the consultation paper.

As mentioned in the response to Q2, there is concern that retaining products for transient gastroenterological and feeding conditions within the category for IFPSDU could create more opportunity for industry to aggressively market products which do not have an adequate scientific basis. This would be particularly concerning if mothers, who are currently breastfeeding babies that are displaying normal baby behaviour around feeding, choose to

change to formula in the mistaken belief that it will be better for their baby than breastfeeding.

It is acknowledged that some protection is provided to consumers by the requirements that these infant formulas be labelled with the condition, disease or disorder for which they have been specially formulated, together with the labelling 'not suitable for general use', and 'use under medical supervision'. Because these formulas are approximately 25% more expensive than general formula, labelling and price may be the best way to restrict their use. The marketing of some products for specific medical conditions without an adequate scientific basis could be an issue for Australian Consumer Law as it could be seen to be 'false and misleading'. Although these products in general use are unlikely to cause physical harm to healthy infants, an indirect consequence of their use is that their higher cost may result in financial hardship for care givers.

Therefore, making a provision in the *Australia New Zealand Food Standards Code* that IFPSDU must be demonstrated to be safe, beneficial and effective in meeting the specific nutritional requirements of the intended infant subpopulation may eliminate the need for the subcategory IFPSDU for transient gastroenterological and feeding conditions.

Q25 To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?

See response from Dr Melinda White, Attachment 1.

Q26 Would you support the requirement for a statement that the product must be used under medical supervision, where the wording is not prescribed (an approach which harmonises with the overseas and international requirements)? Please describe your reasons why you do/do not support.

We would support the statement: 'the product must be used under supervision from a suitably qualified health professional', for the reason given in Q4, above.

Q27 Are there any specific FSMP labelling requirements that you consider applicable to a particular type of IFPSDU?

The statement in Standard 2.9.5—10 (1)(b) that … *any precautions and contraindications associated with consumption of the food* (FSMP) is applicable to all IFPSDUs when consumption by a healthy infant could result in a problem. Codex also requires a warning statement in the case of FSMPs which pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.

Other issues

Issue 1. Some IFPSDU do not comply with the definition for infant formula or infant formula product.

For example, a breast milk fortifier does not comply with these definitions, because, by itself, it is not the sole or principal liquid source of nourishment for infants.

Issue 2. Is there any inconsistency for labelling provisions in Standard 2.9.1 and Standard 1.2.7 - Health Claims and Schedule 4?

Standard 1.2.7—2 defines the term, *claim*, as '*an express or implied statement, representation, design or information in relation to a food or a property of food which is* ***not*** *mandatory in this Code'*. Standard 2.9.14—2 **requires** a statement indicating '(*d) the condition, disease or disorder for which the product has been specially formulated and (e) the nutritional modifications, if any, which have been made to the product*'.

Although both Schedule 4 and Standard 2.9.1 define lactose-free as no detectable lactose, Schedule 4 defines low lactose as no more than 2 g of lactose/100g of food whereas Standard 2.9.1 defines low lactose as no more than 0.3 g of lactose/100ml formula product. This difference may require drafting into Schedule 4.

Issue 3. Japanese regulations for infant formula

The consultation paper discusses EU, USA and Codex requirements for infant formula and attempts to harmonize the labelling and compositional requirements so that there is no disruption to trade for IFPSMP. However, some IFPSMP are manufactured in Japan. Consideration of Japanese regulations for infant formula may need to be taken into account in further development of Proposal P1028.