

20th October 2021

The Registrar
Food Standards Australia and New Zealand
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To whom it may concern

**Submission: “Consultation paper 3 – Regulatory framework and definitions:
Proposal P1028 – Infant Formula”**

Dietitians are registered health professionals who meet standards required by the New Zealand Dietitians Board under the Health Practitioners Competency Assurance Act (HPCA) 2003. In New Zealand, by law, dietitians must be registered with the Dietitians Board and hold a current practising certificate, work within a specified scope of practice, participate in a continuing competency programme, and adhere to a Code of Ethics.

Dietitians New Zealand Incorporated (Dietitians NZ) is the professional association of registered dietitians and associated nutritional professionals. With a membership of approximately 650, we represent the largest group of fully trained food and nutrition professionals in New Zealand. Dietitians NZ exists to build a strong and sustainable profession that empowers New Zealanders around food and nutrition; and inspire change to enhance the health and wellbeing of Aotearoa, New Zealand. We trust the comments made in our submission will be given due consideration.

Dietitians NZ responds as follows to the questions presented by Food Standards Australia and New Zealand regarding Proposal P1028 – Infant Formula.

Questions related to products for metabolic, immunological, renal, hepatic and malabsorptive conditions (section 5.5.2)

5) Is there any evidence that current practice in relation to low lactose products or the manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions pose a health concern or risk?

Inborn Errors of Metabolism (IEM)

Dietitians practising in the area of IEM are not aware of any health concerns or risk related to the manganese content of formula used in the management of metabolic diseases or that metabolic patients have different requirements for manganese from the general population. A PubMed search was undertaken, and we did not find any scientific papers discussing health concerns or risk related to the manganese content of formula used in the management of metabolic diseases.

Questions related to specific compositional requirements (section 5.5.3)

11) Are there any health concerns from current practice using products that contain MCT oil?

MCT oil and IEM

Dietitians practising in the area of IEM have not experienced any health concerns from current practice using products which contain MCT. However, there are some IEM of fatty acid oxidation where high MCT containing formulas should be avoided including Medium chain acyl-CoA dehydrogenase (MCAD deficiency) and Multiple acyl-CoA dehydrogenase deficiency (MADD). Metabolic dietitians support and review the nutrition management of these infants and advise on the appropriate IFPSDU Infant formula products for special dietary use and IFPSMP Infant formula products for special medical purposes if required to treat/manage any other health condition in these patients using PHARMAC Special authority SA or Named Patient Pharmaceutical Assessment (NPPA).

Medium-chain triglycerides and preterm formula

Medium-chain triglycerides (MCTs) derived from fractionated coconut oil are widely used in the production of preterm infant formula. MCTs have high water solubility and are easily absorbed by preterm infants with an immature digestive system and even by those with low intraluminal bile salts and pancreatic lipase levels [1]. Greater MCT compared to long-chain saturated fatty acid absorption means a higher total fat absorption and a slight benefit for the absorption of calcium that would otherwise be bound to unabsorbed long-chain saturated fatty acids. However, the improved fat absorption does not generally lead to a higher energy intake because MCTs have lower energy content. A Cochrane meta-analysis comparing infants fed high MCT versus low MCT formula shows little or no difference in the pattern of growth for any primary short-term growth outcomes [2]. There are some disadvantages with a high MCT formula. Formulas with a large MCT component in infant formula, bring a risk of essential fatty acid deficiency [3]. MCTs also increase the osmolality of the formulas, which is associated with a higher risk of osmotic diarrhoea. Evidence to date indicates that the provision of fat in preterm formula as MCTs may be beneficial if limited to not more than 40% of fat intake [1].

Questions related to extension of use beyond infancy for IFPSMP (section 5.6.2)

14) What is the maximum labelled age on products suitable for use beyond infancy? What are the parameters that indicate when the product is no longer appropriate?

Parameters that indicate when the product is no longer appropriate in management of inborn errors in metabolism include but not limited to:

- Growth: acceptable weight gain no longer being met using the IFPSMP. This can be excessive or inadequate weight gain
- Protein, energy, fat type (LCT and MCT) and CHO as % energy requirements, as required for specific medical condition are no longer being met by the IFPSMP
- Micronutrient needs no longer being met

Further comments within scope of Proposal P1028 – Infant formula:

Specialised infant formula products

The Standard needs to be flexible enough to allow specialised infant formula products that meet EU regulation, CODEX or USA standards for certain medical conditions to be sold in Australia and New Zealand, without unnecessary red tape. Specialised infant formula such as preterm, inborn errors and allergy are low volume products with one formulation used worldwide from only a few companies, presumably because it is not economic to produce small batches for each country. Our patients are very reliant on these products. Therefore, it is counterproductive for the FSANZ code to give tight specifications for these products only allowing the nutrient related to the condition to be altered for two reasons. Firstly, this may mean we cannot use a perfectly appropriate European formulation for example, that would be fine in every other way except that it is designed to meet European nutrient specifications, e.g vitamins and minerals. Secondly, it may well be that the European formulation is actually more nutritionally appropriate because European authorities update their regulations every 10 years in response the latest evidence, but FSANZ does this much less frequently leading to our out-dated regulations precluding the use of a more evidence based new formulation. This is a constant source of frustration for Dietitians who prescribe these products.

5.6.4 Distribution and access

Proposed restrictions of sale of special formula e.g., Allergy to pharmacy only

We do not support this move and what is the reason for changing how they are distributed currently? This does not assist equity of access as smaller towns may not have a pharmacy or a pharmacy that chooses to stock these products. The products tend to be more expensive if sold in a pharmacy. Pharmacists are not necessarily familiar with the products and able to give advice, as evidenced by the dispensing errors that are already made by pharmacists with these products, which tend to have very similar brand names. It is better to see the full range of “Aptamil” in a supermarket for example if a parent is looking for Aptamil Pepti Junior because they are less likely to buy the first or only “Aptamil” formula they see in a pharmacy instead of the “right” one. The products are already available online so restricting them to “pharmacy only” is no longer applicable. Within the current consumer and pandemic environment, there is more purchasing online and having these products available in supermarkets is appropriate and helpful for the consumer.

Thank you for the opportunity to make a submission.

Yours faithfully

Contributors to this submission are members of the Dietitians NZ Paediatric Special Interest Group (SIG)

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References

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2. Perretta, L.; Ouldibbat, L.; Hagadorn, J.I.; Brumberg, H.L. High versus low medium chain triglyceride content of formula for promoting short-term growth of preterm infants. *Cochrane Database Syst. Rev.* 2021, 2, CD002777, doi:10.1002/14651858.CD002777.pub2.
3. Los-Rycharska, E.; Kierszewicz, Z.; Czerwionka-Szaflarska, M. Medium chain triglycerides (MCT) formulas in paediatric and allergological practice. *Prz Gastroenterol* 2016, 11, 226-231, doi:10.5114/pg.2016.61374.

