

28th September 2017

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
Australia

By Email: submissions@foodstandards.gov.au

Dear Standards Management Officer,

Re: Submission to Consultation Paper P1028 Regulation of Infant formula – Infant formula products for special dietary use

Aspen Nutritionals Australia Pty Ltd welcomes the opportunity to comment on Proposal P1028 Regulation of Infant formula – Infant formula products for special dietary use provided by Food Standards Australia New Zealand.

Please find attached our comments to the consultation paper.

Yours faithfully,

Evelyn Anderson
Head of Scientific Affairs
Aspen Australia

OVERARCHING COMMENTS

Aspen Nutritionals supports breastfeeding and acknowledges that breast milk is the normal and ideal method of infant feeding. When an infant is not breastfed for a variety of medical, practical or personal reasons, the only suitable and safe alternative is an infant formula product. Aspen Nutritionals Australia Pty Ltd (Aspen Nutritionals) welcomes this review of the regulation of infant formula in the *Australia New Zealand Food Standards Code* (Code). We believe any changes made to the current regulation for infant formula should support the continued development, improvement and accessibility of infant formulas to ensure consumers continuing access to improved products and being able to make an informed choice if they are unable to, or have chosen not to, continue with breastfeeding. This is critical in ensuring the health status of the non-breastfed infant is not compromised.

Aspen Nutritionals is a market leader in infant and toddler nutrition products in Australia. Our products include infant formula, follow-on formula, specialty formula, and supplementary milk drinks for young children.

Our infant formula product names are:

- S-26 GOLD NEWBORN infant formula
- S-26 GOLD PROGRESS follow-on formula
- S-26 GOLD COMFORT infant formula
- S-26 GOLD DELICATEEZE infant formula
- S-26 ORIGINAL NEWBORN infant formula
- S-26 ORIGINAL PROGRESS follow-on formula
- SMA infant formula
- S-26 GOLD PREMGRO pre-term infant formula
- S-26 GOLD AR specialty infant formula
- S-26 GOLD SOY specialty infant formula
- S-26 GOLD LACTOSE FREE specialty infant formula
- S-26 ORIGINAL LACTOSE FREE specialty infant formula
- S-26 GOLD LI specialty infant formula
- S-26 ORIGINAL LI speciality infant formula
- S-26 GOLD LOW BIRTHWEIGHT Pre-term infant formula - hospital only product
- S-26 HUMAN MILK FORTIFIER (HMF) - hospital only product

As a member of Infant Nutrition Council (INC), Aspen Nutritionals supports the INC submission for Proposal P1028 Regulation of Infant formula – Infant formula products for special dietary use. Hence, we have not provided specific comments to all questions outlined in the consultation paper. Instead, we are providing company specific additional comments. We are also providing some comments in commercial-in-confidence.

SPECIFIC COMMENTS

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?

Aspen Nutritionals supports the sub-categories Infant Nutrition Council (INC) has proposed and believes sub-categorisations based on ingredients should be removed from the current standard. Hence we suggest that sub-sections for “products for specific dietary use based on a protein substitute”, “lactose-free formula” and “low lactose formula” are to be deleted from Standard 2.9.1. Furthermore, Aspen Nutritionals strongly disagrees that a term such as “transient” is used to distinguish between the sub-categories. This is because a condition, disorder or disease can be short term or lifelong. Hence the term “transient” adds ambiguity and not clarity.

Q5 Are there any issues with the current definition for protein substitutes?

Aspen Nutritionals notes that the definition for protein substitutes is included in Standard 2.9.1 for subsection 15 of the standard. Aspen Nutritionals is of the opinion that sub-categorisation based on ingredients should be removed from the standard as IFPSDU products should be categorised based on conditions, disorders or diseases. Protein substitutes may be used to formulate IFPSDU but also recognise that it can be used to formulate infant formula products for general use.

The currently definition of protein substitutes does not seem to include the hydrolysate of one or more of the proteins on which formula product is NOT normally based, such as “rice”. If the current definition for protein substitutes is adopted, we suggest “normally” is removed from (b) of the definition.

Q6 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?

Aspen Nutritionals believe that there is no benefit to defining any of the above types of formulas due to the lack of consensus around a universally agreed definition amongst expert groups. Vandenplas (2015) noted that “*There is no general agreement on standards to define partially hydrolysed formula (pHF) and extensively hydrolysed formula (eHF) specifically and protein/peptide size is generally used to identify each of them*”. Furthermore, Aspen Nutritionals opposes a separate definition for hypo-allergenic formula, due to lack of support for use of this type of formula for prevention of allergy by Australasian Society for Clinical Immunology and Allergy (ASCA *Guidelines - Infant Feeding and Allergy Prevention*), NHMRC (*Infant Feeding Guidelines Information for Health Workers*) and also a recent systematic review and meta-analysis (Boyle, 2016). If a definition was to be provided for protein substitutes, hypo-allergenic formula should not be included as a separate category as these formulas fit the definition of a partially hydrolysed formula.

Aspen Nutritionals note that there is some limited evidence that extensively hydrolysed casein formulas may prevent allergic disease, however, to our knowledge there is not a product of this type available in the Australian and New Zealand markets.

Q7 Are there any issues with the current definition for pre-term products?

Aspen Nutritionals does not have any issues with the current definition for pre-term products as we believe that the current definition for pre-term products includes products specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight that are used in the hospital setting (pre-term formula) and after hospital discharge (post-discharge pre-term formula).

Q8 What, if any, are the benefits of including age and weight parameters in the regulatory definition for pre-term products?

Aspen Nutritionals support the view FSANZ took in the P93 inquiry report assessment of the definition of pre-term formula and believe that this assessment is still valid. The inquiry report stated: *“the type and amount of infant formula product given to a pre-term baby is determined by the weight of the baby and biomedical parameters rather than the gestational age”* and *“for the purposes of setting a food standard category for infants born prematurely or who are low birth weight where the choice of formula is decided by medical specialists it is not necessary to include specifics about age or weight in the definition”*.

Aspen Nutritionals do not see any benefit to including age and weight parameters in the regulatory definition for pre-term products. The pre-term infant's requirements are calculated in a clinical setting where monitoring occurs under medical supervision or after hospital discharge under the guidance of a healthcare professional. The inclusion of weight and age parameters may not account for growth patterns, rates and underlying medical conditions which require further assessment by a healthcare professional. As these products are only provided via healthcare professional or via responsible institution (as is the case with post-discharge formula), this prevents inappropriate use of these products.

Q12 Are any specific compositional requirements (energy/macronutrient etc) needed in the Code for formula intended for premature or low birthweight infants, or for those suffering metabolic etc. conditions? If so, what are they?

The nutritional requirements of pre-term infants is a rapidly changing field which requires consistent evaluation of formulations in line with the most recent expert opinion. The recommended compositional requirements of pre-term infant formula is well covered by expert groups (*Agostoni, 2010 and Koletzko, 2014*) and therefore, Aspen Nutritionals do not support the inclusion of criteria for pre-term and low birthweight infant formula. Aspen Nutritionals believe that the current approach in the Code is adequate to ensure that these products are safe and effective for this population group as only those nutrients for which scientific justification can be provided can be changed.

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