**Aspen Nutritionals Australia Pty Ltd**
ABN: 31 160 607 509
34 – 36 Chandos Street
St Leonards NSW 2065
Careline: 1800 552 229

30th May 2016

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 Infant Formula**

Aspen Nutritionals Australia Pty Ltd (Aspen Nutritionals) welcomes the opportunity to comment on Proposal P1028 Infant Formula provided by Food Standards Australia New Zealand.

Please find attached our comments to the consultation paper.

Yours faithfully,

[redacted]

[redacted]
Head of Scientific Affairs
Aspen Australia
Email: [redacted]

* Aspen Australia is comprised of Aspen Asia Pacific Pty Ltd (ABN 75 146 444 484) and its subsidiaries, including Aspen Pharmacare Australia Pty Ltd (ABN 51 096 236 985), Aspen Pharma Pty Ltd (ABN 88 004 118 594), Aspen Nutritionals Australia Pty Limited ACN 160607509 , Orphan Holdings Pty Ltd (ABN 50 115 816 209), Orphan Australia Pty Ltd (ABN 11 067 189 342) and Aspen Products Pty Ltd (ABN 17 003 144 170).

## 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 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 COMFORT infant formula
- S-26 ORIGINAL NEWBORN infant formula
- SMA infant formula
- S-26 GOLD PROGRESS follow-on formula
- S-26 ORIGINAL PROGRESS follow-on formula
- S-26 GOLD PREMGRO pre-term formula
- S-26 GOLD LBW pre-term formula
- S-26 GOLD AR specialty formula
- S-26 GOLD SOY specialty formula
- S-26 GOLD LACTOSE FREE specialty formula
- S-26 ORIGINAL LACTOSE FREE specialty formula

As a member of Infant Nutrition Council (INC), Aspen Nutritionals also supports the INC submission for Proposal P1028 – Infant Formula. Hence, we have not provided specific comments to all questions outlined in the consultation paper. Instead, we have included a summary of our overall position and company specific additional comments.

### Nutrient Composition

Due to the inconsistencies between the Code and international regulations for infant formula – particularly with regards to compositional requirements, Aspen Nutritionals supports where possible and relevant, alignment with Codex STAN 72-1981(CODEX) to reduce any international trade barriers. Aspen Nutritionals hopes that this review will bridge the gap of inconsistencies between the Code and CODEX.

### Safety

Aspen Nutritionals supports maintaining the current preparation, use and storage instruction requirements. We further support current requirements for warning, advisory and other statements and don’t believe any additional warning statements are warranted.

Aspen Nutritionals strongly disagrees with standardisation of measuring scoops as it is technically impossible to standardise measuring scoops even within our own range. The powder density of infant formula is affected by both the ingredients and the manufacturing process used and it is not possible for this to be standardised for all powdered infant formulas.

**Nutritive and Novel Foods in Infant Formula**

Aspen Nutritionals notes that this proposal will consider the regulation of nutritive substances and novel foods in infant formula.

As per our submission to P1024 Revision of the Regulation of Nutritive Substances and Novel Foods, we are of the view that there isn't sufficient justification for infant formula products to be excluded from the P1024 review when the current regulation of novel foods and nutritive substances applies to all foods including infant formula products. There is scope within the proposed framework for nutritive substances and novel foods to include additional criteria for foods for infant formula. While the issue around vulnerability of infants is valid, Aspen Nutritionals sees no justification as to why this can't be addressed within P1024.

Although the approach implemented under P1024 is for general foods, Aspen Nutritionals supports option 3, the alternative framework proposed by FSANZ. Aspen Nutritionals recognises that the *Ministerial Policy Guideline on the Regulation of Infant Formula Products* provides guidance on the pre-market assessment of substances added to infant formula products. We are of the view that this guidance is in line with option 3.

Furthermore, we are concerned that if P1024 is finalized and gazetted before P1028, there will be a regulatory gap until a process specifically for infant formula products is completed.

For these reasons, the opportunity to remove some of the ambiguity and 'jurisdictional uncertainty' would be best served, in our opinion, if Standard 2.9.1 - Infant Formula Products is included in P1024 going forward.

**Provision of Information**

All product and ingredient information that is available on an infant formula label is an important source of information for formula-feeding caregivers, which is why Aspen Nutritionals considers it to be very important that the label is permitted to contain sufficient product information that allows caregivers to make an informed choice when selecting an infant formula product. From the evidence provided in the INC submission, we note that information provided on pack does not trigger the initiation of formula-feeding. Caregivers will usually only look for this information after the decision has been made to initiate formula feeding.

Hence, Aspen Nutritionals proposes that this review of infant formula includes improvements to existing labelling requirements to assist caregivers once they have made the decision to formula feed and select an infant formula product that will best suit their infant. Aspen Nutritionals believes this review of infant formula regulation can address the current lack of information on-pack available to caregivers.

Specifically, Aspen Nutritionals proposes:

- Permission for nutrient content/ingredient claims for notification of product reformulation with an explanation for the change.
- Permission for nutrient content claims for optional and differentiating nutrients
- Permission for general level health claims for optional and differentiating nutrients

## ADDITIONAL COMMENTS

### Transitional Period

While the scope of Proposal P1028 covers infant formulas only, Aspen Nutritionals notes that the changes to Standard 2.9.1 will be gazetted altogether. Hence, Aspen Nutritionals propose a transitional period of 4 years once the changes to Standard 2.9.1 are gazetted into the Code. This is to allow adequate time to implement changes, particularly for infant formula products for special dietary use as these products are often imported from overseas, hindering their speed to market and requiring longer stock in trade period.

If a 4 year transitional period is not possible, Aspen Nutritionals would expect that FSANZ will allow a stock in trade provision of at least 2 years in addition to the transitional period, which will help manufacturers to reduce any write-off of current stock and packaging costs and will allow enough time to update the products that are on shelf at time of gazettal.

### Protein

FSANZ preliminary view is to retain the current total protein content range (0.45g-0.72g/100kJ) in Standard 2.9.1 as it is consistent with Codex STAN 72-1981. However, Aspen Nutritionals considers that the protein levels are not consistent due incorrect conversion to per 100kJ in Codex. Therefore, Aspen Nutritionals is in favour of a change in the total protein content range to 0.43-0.72g/100kJ, which represents an accurate alignment with Codex STAN 72-1981total protein content range of 1.8g-3.0/100kcal using the FSANZ standard conversion factor of 4.18.

The minimum protein content of 0.43g/100kJ is also in line with the EU Regulation (EFSA, 2014)[1] minimum protein recommendation on essential composition of infant and follow-on formula. The European Childhood Obesity Programme (CHOP) study group hypothesised that a protein intake in excess of metabolic needs would increase the secretion of insulin and insulin like growth factor 1 (IGF1), possibly leading to enhanced growth during the first two years of life up to school age. They also hypothesised that this may predispose to a higher obesity risk in later life[2]. Therefore, protein levels in infant formula may impact on both the short term and longer term metabolic programming of an infant.

The safety and efficacy of infant formula with lower protein concentration than the current FSANZ minimum has been demonstrated. The CHOP study demonstrated that infants fed formula with a lower protein content of 0.42g/100kJ (1.77g/100kcal) had an early weight gain and body mass index at 6 years that resembled breast fed infants[2,3]. Ziegler et al (2015) demonstrated that the growth of infants fed a formula with 0.39g/100kJ (1.61 g/100kcal) of protein was equivalent to infants fed a control formula[4].

Inostronza et al (2014) confirmed that a protein content of 0.395g/100kJ (1.65 g/100kcal) is safe and results in weight gain closer to that of breast-fed infants[5].

Overweight and obesity is a global problem and in Australia, childhood overweight and obesity affects around one in four children[6]. Obese children have a 20-50% chance of becoming an obese adult[7]. A recent systematic review noted that there is a need for more longitudinal studies of lower protein infant formula demonstrating outcomes for adult overweight and obesity[8]. However, the outcomes in infancy and childhood also need to be considered. Patro-Golab et al noted that lowering of the protein content of infant formula could provide a promising, cost effective primary prevention measure for overweight and obesity[7]. This simple measure could reduce the burden of overweight and obesity on individuals, the healthcare system and government resources.

In addition to the proposed amendment to protein, Aspen Nutritionals supports retaining a nitrogen-to-protein conversion factor of 6.38 for milk proteins due to the scientific basis for this value. Furthermore, we recognise that a reduction of the nitrogen-to-protein conversion factor for soy proteins to 5.71 is warranted given the well documented use of this figure in scientific literature.


1. EFSA. (2014) Scientific opinion on the essential composition of infant and follow-on formulae. *EFSA Journal*.12 (7):3760.
2. Weber, M et al. Lower protein content in infant formula reduces BMI and obesity risk at school age: follow-up of a randomized trial. Am J Clin Nutr. 2014 May;99(5):1041-51
3. Koletzko, B. et al. Lower protein in infant formula is associated with lower weight up to age 2 y: a randomized clinical trial. Am J Clin Nutr 2009. Jun;89(6):1836-45
4. Zeigler, E. et al Adequacy of Infant Formula With Protein Content of 1.6 g/100 kcal for Infants Between 3 and 12 Months. J Pediatr Gastroenerol Nutr. 2015 Nov;61(5):596-603
5. Inostronza, J. Low-protein formula slows weight gain in infants of overweight mothers. J Pediatr Gastroenerol Nutr 2014 Jul;59(1):70-7
6. ABS (2008) *Overweight and obesity in adults, Australia, 2004–05*. ABS cat. no 4719.0. Canberra: Australian Bureau of Statistics
7. Must, A and Strauss, R. Risks and consequences of childhood and adolescent obesity. Int J obes Relat Metab Disord 1999 Mar;23 Suppl 2:S2-11
8. Patro-Golab, B Protein Concentration in milk formula, growth and later risk of obesity: A systematic review. J Nutr 2016 146:551-64

**SPECIFIC COMMENTS**

**Q2.6 What evidence can you provide that demonstrates that caregivers have difficulty finding protein source information on the labels of infant formula, and that this affects their ability to make an informed choice?**

Protein source statements are located close to the statement of ingredients for Aspen Nutritionals infant formula products. Aspen Nutritionals is not aware that our consumers are having difficulties finding protein source information on our labels. We have no reported contacts on this issue.

As for our soy based infant formula product, the word “soy” is part of the product name and hence the word “soy” appears on the front of the product label. This is in addition to the mandatory protein source statement located close to the statement of ingredients

**Q2.9 What are the cost and trade implications of prescribing the position of the statement of protein source ion the label?**

If the position of the statement of protein source is prescribed, a packaging change will be required.

Specific costs for mandating a label change have been provided in commercial in confidence.

**Q2.27 What justification can manufacturers and suppliers of infant formula in Australia and New Zealand provide to expand the permission for the food additive citric and fatty acid esters of glycerol (INS 472c) to all infant formula?**

Infant formula, follow on formula as well as formulas for special medical purposes intended for infants manufactured with amino acids and hydrolysed proteins have different hydrophobic/hydrophilic characteristics and lower emulsifying capacity than products based on whole protein. INS 472c is a preferred additive to improve the stability and organoleptic properties of products containing (partially) hydrolysed proteins, peptides or amino acids. Emulsifiers are therefore a technological requirement for these formulas to ensure both palatability and prevention of separation of the formula after reconstitution. The intended use of formulas containing hydrolysed protein is not limited to infants requiring foods for special dietary use. Standard infant formula as regulated under Standard 2.9.1 may also contain hydrolysed protein. For these reasons, the general permission of INS 472c should be expanded.

**Q3.2 Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?**

Nutrition information about macronutrient subgroups provides caregivers and healthcare professionals with accurate and valuable nutrition information about an infant formula product, which allows the caregivers and healthcare professionals to differentiate

between products (e.g. if looking for a whey dominant formula or one containing omega 3 DHA) and also helps them make an informed choice.

**Q3.4 Should it be mandatory to declare all or only specified macronutrient subgroups in the nutrition information statement? If so, which macronutrient subgroups and for what reason? For example, any subgroup of protein (whey, casein, alpha-lactalbumin etc.), or specific proteins (only whey and casein).**

Aspen Nutritionals does not support mandatory declaration of **all** macronutrient subgroups in the nutrition information statement. Aspen Nutritionals believes the voluntary inclusion of macronutrient subgroups is important and should be included in the nutrition information statement to help caregivers differentiate between different formula products, but the inclusion of these macronutrient subgroups should be voluntary in the standard.

In addition, infant formula products already require an extensive range of mandated information. Given limited space already in the nutrition information statement, additional prescribed requirements would be difficult to accommodate.

**Q3.5 If only specified macronutrient subgroups, what principles should be applied to determine which nutrients may be declared (e.g. for those fats with a specific compositional requirement, or for those nutrients that caregivers have a general understanding of their nutritional purpose in foods).**

Aspen Nutritionals believes the inclusion of these macronutrient subgroups should be voluntary.

**Q3.6 If nutrition information about macronutrient subgroups is provided, is there potential for caregivers of formula-fed infants to be misled about the nutritional value of formula?**

Any nutrient listed in the nutrition information statement must be correct and truthful. Whether the level is innate or added, the total amount on the label of the infant formula will be correct and is verified via analytical testing.

The only concern that Aspen Nutritionals has with **mandating** macronutrient subgroups is if a macronutrient subgroup was listed in the nutrient information statement that the product doesn't necessarily contain. For example if sugar was listed as a mandated macronutrient subgroup in the nutrition information statement under carbohydrate, the value listed for sugars in the nutrition information statement would include those sugars naturally present in milk based products (e.g. lactose) rather than table/cane sugar. This may give the wrong impression to the caregiver and with no other means of communicating nutrient information to caregivers, due to the current prohibitions on nutrient content and health claims for infant formula, there is potential for a caregiver to be confused.

Aspen Nutritionals supports the voluntary inclusion of macronutrient subgroups that are relevant for the specific product to provide meaningful information to the caregiver, which will help assist them in making an informed choice.

**Q3.7 What would the cost and trade implications of mandating macronutrient subgroups or conversely expressly prohibiting them?**

By prescribing (or prohibiting) macronutrient subgroups new product labels would be needed and there would be additional associated costs involved with changing labels, including company resources and associated write-off costs of current labels

By mandating **ALL** of the macronutrient subgroups there could also be challenges including these all in the nutrition information statement, depending on the extent of the prescribed subgroup list, as previously stated in this submission there is limited space already available on an infant formula label due to prescribed requirements, and challenges on smaller pack sizes.

Also, if additional macronutrient subgroups were mandated there would also be additional analytical testing costs for those mandated macronutrient subgroups that are not currently voluntarily labelled.

Aspen Nutritionals believes the inclusion of these macronutrient subgroups should be voluntary, as this information helps caregivers differentiate between different formula products, to make an informed choice.

Specific costs for mandating a label change have been provided in commercial in confidence

**Q3.8 Is there any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations?**

Aspen Nutritionals does not have any evidence to show that caregivers and healthcare professionals are confused by the differences between ingredient declarations and nutrition information declarations.

Ingredient declarations and nutrition information statements are fundamentally different. The ingredient list includes the source of the ingredient and in some cases is a more complex term. For example, sodium ascorbate is listed in the ingredient list for the source of vitamin C in the product, where by the nutrition information statement would list vitamin C for this example. However, the amount of vitamin C listed in the nutrition information statement would include sources of added vitamin C (e.g. sodium ascorbate) as well as naturally occurring from other sources in the product.

Nutrients in the product could come from a wide range of sources (either added or innate, or a combination of both) and often the summation is in the nutrition information statement whereas the sources are usually listed in the ingredients list.

**Q3.9 Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?**

Aspen Nutritionals does not support aligning the names of ingredients with nutrient declarations in the nutrition information statement.

As already stated in Q3.8 the ingredient list and nutrition information statements are fundamentally different, the ingredient list includes the source of, for example vitamins and minerals, while the nutrition information statement just lists the total amount (naturally occurring and added) of the vitamins and minerals.

**Q3.10 Which base units of expression do stakeholders find to be of greatest value?**

Aspen Nutritionals supports the continuation of nutrition information being expressed as 100mL in the nutrition information statement.

In addition, Aspen Nutritionals would support the voluntary option of including the base units of per 100g, per 100kJ and per 100kcal in the nutrition information statement if required by the infant formula manufacturer. This would be particularly useful for those markets that have adopted the Codex provision of allowing harmonisation with those requirements on an as needs basis.

**Q3.11 Is there any evidence that caregivers are confused by the use of different base units of expression?**

Aspen Nutritionals is not aware of any evidence of caregiver confusion.

**Q3.12 In addition to the current requirement to declare nutrition information per 100 mL as consumed, should it be mandatory or voluntary to declare per 100 g of powder (or per 100 mL for liquid formula) as sold?**

Aspen Nutritionals supports the voluntary declaration of per 100g of powder. An infant formula label already requires a number of prescribed labelling with mandated font sizes which can leave limited space on the label. Mandating an additional column in the nutrition information statement may be difficult to accommodate on the label (especially for small pack sizes).

For per 100mL liquid formula, as it is already commercially reconstituted, per 100mL as consumed, equates to per 100mL as sold, so we consider this is not relevant for infant formulas as the applicable base unit of measure can be 100mL (either *already* reconstituted, or as sold).

**Q3.13 What would the cost and trade implications be of mandating these base units?**

Mandating an additional column in the nutrition information statement would require a change to the current infant formula label, and as mentioned in Q3.12 it would be difficult to fit on the label due to the already mandated labelling requirements for infant formula. In addition, there would also be additional costs to industry as the extra column in the nutrition information statement would require checking and rechecking of the labelled values by the infant formula company staff.

Specific costs for mandating a label change have been provided in commercial in confidence.

**Q3.14 Should the voluntary use of the base unit of per 100 kJ be permitted?**

Aspen Nutritionals supports the voluntary use of the base unit of per 100 kJ being permitted. If this voluntary use is permitted then Aspen Nutritionals asks that FSANZ also allow the voluntary use of the base unit of per 100kcal being permitted as this is in line with permissions in Codex STAN 72-1981: "*9.3 Declaration of Nutritive Value: c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (**or** per 100 kilojoules) is permitted*".

**Q3.15What impacts, if any, would there be if the declaration requirements for macronutrients, micronutrients, nutritive substances, inulin-type fructans and galacto-oligosaccharides are based on 'average quantity', instead of 'average amount'?**

Whilst the proposed change would require a change to the product label (and may also require a communication from FSANZ to alert consumers of the change), Aspen Nutritionals would support the change to average quantity as this is consistent with other standards in the Food Standards Code.

**Q3.16 Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?**

Due to the current prohibitions on nutrient content and health claims for infant formula, the nutrition information is the only credible source of nutrition information the caregiver has to inform their purchase decisions.

**Q3.17 Would a consistent approach to format across product labels assist consumer understanding of this information?**

Aspen Nutritionals does not support a mandated approach to formatting of product labels. Given limited space on the infant formula label already due to prescribed requirements, mandated formatting may be difficult, and flexibility would need to be

allowed for smaller pack sizes.

**Q3.18 If the format was prescribed, what would be the impacts including costs to industry and trade considerations of changing labels?**

As already mentioned in this submission, by prescribing any change to standard 2.9.1 new product labels would be needed and there would be additional associated costs involved with changing labels, including company resources and associated write-off costs of current labels.

Specific costs for mandating a label change have been provided in commercial in confidence.

**Q3.19 How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?**

Currently if there has been a reformulation to an infant formula product, the caregivers are alerted of the change via a lid sticker on pack or via the company website. However, the information that is communicated to the caregiver is very limited (e.g. new or improved or 'minor reformulation').

For healthcare professionals, changes in composition are communicated by company representatives, either via written communications, or face-to-face visits. However due to the vast number and geographical location of healthcare professionals in Australia, Aspen Nutritionals' access to all healthcare professionals is often limited. In addition, the healthcare professionals would not have contact with all the caregivers using our infant formula products so the communication of compositional changes may not (and in most cases will not) reach the relevant caregivers.

Due to the current prohibitions on nutrient content and health claims, infant formula labels cannot clearly communicate what has changed to the caregiver. Aspen Nutritionals would like FSANZ to allow permissions to provide information on pack (either via a lid sticker or on the product label) allowing an explanation of the exact change to the product as this communication would reach every caregiver purchasing the product, and offers a credible source of information, exactly relevant to the product to be consumed.

**Q3.20 What information about the change in composition would caregivers and health professionals find useful?**

From our experience through our company careline, caregivers are interested in **ANY** change to the product they are feeding their infant, particularly in the first 6 months when the product they are feeding their child plays the role of a sole source of nutrition.

Caregivers would find communication of **ANY** formulation change important, especially if the change in formulation involves the introduction of a new ingredient. It is important

that caregivers know what ingredients are used in the infant formula product they are feeding their infant especially if the reformulation was to introduce a new allergen (e.g. the product may have been reformulated with an optional ingredient like DHA, and the source of DHA is derived from fish) or from a dietary preference point of view (e.g. for religious, cultural or lifestyle choice such as Halal, Kosher, or vegetarian).

**Q3.21What are the cost and trade implications of a standardised approach to a product reformulation on infant formula packages?**

Aspen Nutritionals is not clear what is meant by a “standardised approach to a product reformulation” for this question. SD3 (page 17) does not mention a standardised approach or outline what would be required and therefore we are unable to provide comment on this question.