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Food Standards Australia New Zealand
PO Box 5423
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Dear FSANZ,

Blackmores welcomes the opportunity to respond to the Food Standards Australia New Zealand (FSANZ) consultation paper on proposal P1028, the purpose of which is 'to revise and clarify standards relating to infant formula products comprising category definitions, composition, labelling and representation of products.'

Through our association with Bega Cheese Limited and its subsidiary Tatura Milk Industries Limited, who are members of the Infant Nutrition Council (INC), we have sighted the response to be provided by the INC on this matter. We agree with the consolidated opinions put forward in that document, but we would like to provide responses to the following questions as asked in the consultation document according to the broad themes of the consultation document. For the remaining questions, we have not provided a specific response as we support the view proposed by the INC.

Permitted forms of vitamins, minerals and electrolytes

General
Permission to add vitamins and minerals from food sources would be welcomed rather than merely stating the permitted forms. This approach is already included in the current code for Lutein, where the source is expressly permitted to be *'Lutein from Tagetes erecta L.'*

Vitamin D
There is increasing evidence to suggest that infants in Australia and New Zealand are at risk from Vitamin D insufficiency because of successful campaigns to reduce harmful sun exposure. The consensus statement by Munns et al[1], and updated by Paxton et al[2] highlight that infants are at risk of insufficient vitamin D intake with some 40-57% of neonates considered as having insufficiency. Further, the Paxton et al[2] article claims that 'the 2006 nutrient reference values for Australia have been acknowledged as being out of date'. Whilst this is not the forum for a detailed review of vitamin D status in Australian/New Zealand infants, Blackmores ask that consideration be given to

[1] Prevention and treatment of infant and childhood vitamin D deficiency in Australia and New Zealand: a consensus statement. Medical Journal of Australia, Volume 185 Number 5, 4 September 2006
[2] Vitamin D and health in pregnancy, infants, children and adolescents in Australia and New Zealand: a position statement. Medical Journal of Australia, 198 (3), 18 February 2013

whether it is appropriate to consider an increased upper limit for supplementation of vitamin D in infant formula or introduction of a GUL. The current range for supplementation equates to 360 – 520 IU / L which if administered, for example, at the same volume as indicated on Blackmores Newborn (Infant) Formula (7 x 60 ml = 420 ml) provides 151 - 218 IU of vitamin D, which is half the 400 IU adequate intake level recommended by Ross et al, 2010[3] as appropriate for infants aged 0 – 12 months. Further, this input is well below the doses used for reversal of vitamin D deficiency where administration of 1000 IU / day for three months is indicated.

Vitamin K

Forms of vitamin K1 are permitted in the code whereas there is no permission for addition of K2 to Infant Formula. Blackmores would like to suggest permission be provided for addition of K2 forms. There is increasing evidence to suggest that K2 is of importance for bone health. Indeed, Osteoporosis Australia[4] even go so far as to say, 'Vitamin K2 appears to be the most important form of vitamin K for bone health.'

Definitions and nutrient composition

Overall, our general view is that alignment of the FSANZ food standard for infant formula with codex would be the most favourable approach when regulating ingredient input to infant formulas. The codex represents a balanced and considered scientific approach to ingredient limits with regard to international requirements and where possible these limits should be used. Conversion to use of guideline upper limit (GUL) amounts for the nutrients mentioned in the consultation is particularly welcomed where there is no justification for imposing an upper limit.

Questions to submitters:

Q1.2 Which of the following options to amend the definition of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula?

(1) "satisfies by itself the nutritional requirements of infants less than 6 months of age"
(2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding"
(3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of infants from 6 months of age
(4) no change

Blackmores is of the opinion that providing a definition that includes an age range may be considered confusing and that option 1:

"satisfies by itself the nutritional requirements of infants less than 6 months of age"

is a clearer choice. An infant formula product is formulated to be suitable as a sole source of nutrition for Infants from birth until 6 months of age and the above definition clearly states this. The decision to introduce complementary foods is for a parent/carer to decide rather than hinted at in a definition with an age range. There already exists a warning that states solid foods should be offered to infants from six months old if a product is represented as being suitable for an infant of that age.

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[3] Ross CA, Taylor CL, Yaktine AL, Del Valle HB, editors. Dietary reference intakes for calcium and vitamin D. Institute of Medicine Committee to Review Dietary Reference Intakes for Calcium and Vitamin D. Washington: National Academies Press, 2010.

[4] http://www.osteoporosis.org.au/vitamin-k (accessed on 30-May-2016)

Q.1.28 What is the technological justification can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?
Whilst Blackmores agrees that the addition of L-carnitine tartrate poses no safety issues, there is evidence to suggest that use of L-carnitine tartrate may result in sulphurous taste and odours, which may adversely affect finished product acceptance of the product by Infants.

4.6.5 Phospholipids
Will this limit also allow for composition of soy and Canola based formulas that have intrinsically higher natural phospholipid levels including phosphatidylserine, which is beneficial? Would the limits only apply to supplemented levels and exclude naturally occurring amounts ?

Safety and food technology

Q2.3 What evidence can you provide that could be used to estimate the prevalence of the practice of caregivers adding other foods to infant formula in Australia and New Zealand?
Blackmores is aware that this practice does occur having received information from care givers calling the care line, however we do not believe that it is widespread. The labelling instructions on Infant Formula are quite clear about the risks of not preparing exactly according to the label. It may be appropriate, following advice of a healthcare professional, to add to the formula but this information should not be provided on the label.

Q2.7 What evidence can you provide that demonstrates consistent placement of the statement of protein source on the label would provide a benefit to caregivers?
Q2.8 If so, should there be a requirement to prescribe the position of the statement of protein source on the label e.g. on the front of the package?
Blackmores has only had very minimal queries requesting information about the protein source with no queries indicating that the information was difficult to find. Therefore mandating the position of the protein source statement would appear to not be of concern to care givers. Blackmores is not in favour of additional regulatory burden where the case for implementation is not proven.

7.4 Arsenic
Blackmores notes that there is no current limits stipulated for ‘arsenic (inorganic)’ and ‘arsenic, total’ in the current code and recorded levels of arsenic were very low in an analysed sample group of infant formulas. Whilst this is a welcome observation, innovation in Infant Formula could result in use of protein sources e.g. rice which contain relatively high amounts of organic arsenic. FSANZ has identified that organic forms are ‘relatively low’ risk, so Blackmores advocates that limits are potentially provided for harmful inorganic forms.

Q2.32 - Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.
Blackmores strongly supports retaining the principle of carry-over applying to Infant Formula. There are a number of raw materials that require additives during manufacture that would otherwise not be possible to use if the carry-over principle is not permitted. The quality of Infant formula would suffer should this permission be excluded. To prevent use of undesirable additives e.g. BHT being ‘carried-over’ a list of prohibited food additives for use in Infant Formula raw material ingredients would provide more clarity than a list of permitted additives. Also there could be an occasion where the additive is not permitted as an additive in the final product, yet it is an allowable vitamin form e.g. ascorbyl palmitate. In this case, enforcement of a prohibition of the carry-over principle would be difficult because the additive switches to an allowable vitamin form and would be detected as such in finished product testing despite being ‘introduced’ as a carry-over additive.

Provision of information

Q3.1 - Should claims about specific ingredients be permitted on packaged infant formula?
The provision of information about the composition of Infant Formula is important to inform care givers about the product. Explicit permission to include nutrient content claims would be an appropriate way to inform care givers about the composition of the product and would promote innovation in Infant Formula formulation. Regulation of these claims would be consistent with the previous section about novel ingredients. The declaration of specific ingredients could not deviate from those ingredients that are already found within many infant formulas. For example, alpha-lactalbumin, lactoferrin or specialised fatty acid profiles such as oleic-palmitic-oleic (OPO or sn2 palmitate) are already present in many formulas but not expressly stated. The reason for including these ingredients is because of their presence in breast-milk and documented functional health benefits for infants. Declaration of OPO, alpha-lactalbumin or lactoferrin content on the label of Infant Formula would provide a way to communicate the presence of beneficial, value-added components of a formula to the care giver. Further information about the function or benefit of alpha-lactalbumin, lactoferrin or OPO (sn2 palmitate) would be sought from a healthcare professional who would be aware of the benefits of these ingredients.

Q3.2 - Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?
Blackmores believes that caregivers currently suffer from a lack of information regarding the difference between the various Infant Formula products that are available. Specifically both consumers and health care professionals seek easier access to more information about macronutrient subgroups e.g. whey : casein ratio information. There have been a number of enquiries to the customer care line asking for further information about the product. Provision of this information on the product label is the most accessible.

Q3.3.- Should the Standard include permissions to declare nutrition information about macronutrient subgroups (in addition to mandatory nutrition information currently set out in clause 16 of the existing Code and section 2.9.1–21 of the revised Code) in the nutrition information statement?
Blackmores believes that permission should be given to declare macronutrient subgroups. See above comment regarding Q3.1.

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).
The provision of additional information should not be mandatory. The headline level of macronutrients necessary for maintaining health e.g. protein, carbohydrates etc are already declared.

Q3.8 Is there any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations?
Blackmores is not aware of confusion arising from the use of technical name for an ingredient versus common name in the ingredient panel. There is a general understanding that the list of ingredients is different to the nutrition information. And merely listing the ingredient as vitamin E to match the nutritional panel would reduce transparency.