31ST May 2016

Food Standards Australia & New Zealand (FSANZ)

Submissions@foodstandards.gov.au

Dear Sir/Madam,

Re: Consultation Paper – Proposal P1028 Infant formula product (amended 4 May 2016) Submission from anonymous sponsor (The Sponsor)

We would like to thank you for the opportunity to submit our views on FSANZ's objective to revise and clarify standards relating to infant formula product in the Australia New Zealand Food Standards Code (the Code).

We trust that as per your instructions on the website you will keep this feedback, ***confidential.***

Executive Summary:

1. The Sponsor produces and markets listed complementary medicines and also are involved in the marketing & production of food products. The sponsor currently produces a range of Infant formula products Stage 1 and Stage 2, along with Stage 3 the toddler milk formulation (although not a subject of this submission).
2. The sponsor have responded to many of the questions posed in the above consultation paper, in particular Provision of information, **SD3 of Proposal P1028** and one comment in regards to **Safety & Food technology- SD2**. These are outlined at the end of this correspondence for your consideration
3. However we would briefly like to outline our views on the current issues relating to infant formula product representation of product in the Code. This is specifically relating to ingredient claims, nutritional declaration requirements, health claims and the inter-relationship between declarations in the nutrition information statement and the ingredient list.
4. We are of the strong view that infant formula product labelling restrictions keep crucial nutritional and function claims, as well as health claims, from appearing on the pack of infant formula products. The removal of such labelling restrictions would therefore enable food manufacturers to make claims, which would then consequently help to inform mothers who are reliant on formula feeding.
5. Whilst we understand and agree with the rationale for these restrictions in that breast feeding should be encouraged and promoted before offering infant formula product (IF), recent research has found that many mothers and carers who use IF are confused by labels and find it difficult to make an informed choice.
6. We are aware of recent online market research carried out on Australian mothers. The research was to provide empirical evidence to help support submissions in relation to the review of Standard 2.9.1, and the re-authorisation of the MAIF Agreement.
7. This research suggested that Caregivers have not received to date sufficient information about Infant formula product before making a decision on which one to choose. In addition it was revealed that mothers are concerned about ingredients and nutritional benefits when deciding on a specific product.

8. It also showed respondents were not aware of ingredients in the formula they purchased nor did they understand the role of ingredients in that formula.
9. Caregivers felt that insufficient information was received when purchasing a formula for the first time and that product labelling was the least useful source of information on formula.
10. The research also outlines the main reasons caregivers have cited in regards to the information they believe would be useful in making a decision in regards to the type of Infant formula product to offer to their child:

- Best formula based on nutritional needs
- Best formula substitute for breast milk
- Best formula for a child's development
- Ingredients and nutritional benefits
- Benefits and risks of using
- Best formula for allergies and health concerns
- The differences between formulas offered by particular brands.
- Difference between gold and standard formulas

11. This research therefore indicates that parents and carers want to know more about what ingredients are in IF and what the ingredients actually provide in terms of nutritional and health benefits for their child. They also want to know that they are making a suitable choice for their baby and are unable to do so whilst the ingredients in the formulation do not explain the scientifically validated benefits of the ingredients. Nor do they have any idea as to why one IF may cost significantly more than another.
12. Therefore we are of the strong view that FSANZ Standard 2.9.1. –Infant formula products & Std 1.2.7 Nutrition, health and related claims, should allow for nutrient content and function claims, as well as health claims.
13. Our proposal would be that nutrient and function claims for infants should be represented in FSANZ Standard 1.2.7. Nutrition, health and related claims – Schedule 4 (& Std 2.9.1). This Standard/s currently permits nutrition and general health claims provided certain criteria are met for adults and children, and this could be revised to include substantiated pre approved claims against specific nutrients/ingredients for infants, to inform formula-feeding caregivers.

Please find detailed response to issues raised by FSANZ:

Re: FSANZ consultation paper - Proposal P1028. Provision of Information document 3

Q3.1. Section 2.1.

Should claims about specific ingredients be permitted on packaged infant formula?

The sponsors Response:

- **We are of the view that nutrient content claims about specific ingredients should be permitted on packaged infant formula.**
- **We believe that caregivers should be provided with clarity on what ingredients are in a product. For example: Fish oil content as opposed to Algal form when supplementing with Omega 3.**
- **Consumers should know whether potential allergens are present for instance fish oil or similar ingredient.**
- **In addition some ingredients may require further clarification i.e. that Lactobacillus Acidophilus is a probiotic and the reason a probiotic may be included in an infant formula.**
- **Further, caregivers may require an explanation of some ingredients. For examples DHA is a source of omega 3. Some consumers may not have access to this information and the rationale for including DHA in a formulation.**

If yes, then how should they be regulated?

- **We are of the view that a voluntary statements should be permitted in the standard (Infant formula) to allow manufacturers to describe ingredients in their product.**
- **It should be permitted to describe the action of the ingredient. For example : contains fish oil which is a source of omega 3, Contain Algal oil which is a source of omega 3, DHA which is a source of omega 3, contains bifidobacterium lactis which is a probiotic.**
- **Nutrient and function claims may be represented and structured similar to FSANZ Standard 1.2.7. – schedule 4 with specific requirements so as to provide information required for informed choices of the caregiver.**

Q3.2 Section 2.3

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

The sponsors Response:

- **Yes, we are of the view that macronutrient subgroups are of great value i.e. breaking down protein into Casein and/or Whey or for instance how much of specific omega 3's are in the 'Fat' category.**

Q3.3 Section 2.3

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?

The sponsor Response:

- **We are of the view that the Standard should include permission to declare nutrition information about macronutrient subgroups in the nutritional information statement.**

Q3.4 Section 2.3

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 sponsor Response:

- **We are of the view that all macronutrient subgroups declarations should be voluntary. We believe caregivers would wish to know for instance how much Omega 3 EPA or DHA is in the product compared to omega 3 ALA, a less bioavailable form of omega 3 -EPA/DHA.**
- **Similarly, the protein subgroups are important to be declared as casein content may be required for assessment of potential allergens.**
- **To regulate that ALL subgroup declarations be made mandatory would place a burden on the industry in terms of cost and difficulty of implementation, as meticulous testing would then have to be carried.**
- **In addition technology may change and future sub groups may be discovered that may not currently exist. It could be that some sub groups be made mandatory but voluntary declaration of other sub groups of macronutrients become voluntary but permission is granted to state them if known.**

Q3.5 Section 2.3

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).

The sponsor Response:

- **We do not believe that specified macronutrient subgroups should be applied.**

Q3.6 Section 2.3

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?

The sponsors Response:

- **We are of the view that this will not mislead the caregiver – but would on the contrary provide further clarity on the ingredients used in the products.**

Q3.7. Section 2.3

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

The sponsors Response:

- **The cost would be high for industry if implementation of mandatory macronutrients subgroups were to be proposed–**
- **To prohibit macronutrient subgroups would provide a dis-service to the caregiver who would want to be made aware of what type of sub - macronutrients are included in their products. It is difficult to see how this constitutes a 'nutrient content claim' as currently.**

Q3.8. Section 2.4

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

The sponsors Response:

- **We are NOT aware that there is evidence that caregivers and health professionals are confused by differences in ingredient listings and Nutritional information panels.**

Q3.9. Section 2.5

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

The sponsors Response:

- **We do not believe it is necessary to align nutrient declarations in the nutritional information panel to that of the ingredients.**

Q3.10. Section 2.4

Which base units of expression do stakeholders find to be of greatest value?

The sponsors Response:.

- **100 ml for liquid concentrate. We are of the view that current label requirements should remain.– otherwise labels may become more confusing with more detail where space may be limited.**
- **It is simple in regards to current labelling for health professionals to calculate requirements of feeds if an infant requires additional nutrition as in 'failure to thrive' infants.**

Q3.11. Section 2.5

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

The sponsors Response:

- **We are of the opinion that there may be confusion if different base units of expression are used.**

Q3.12. Section 2.5

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?

The sponsors Response:

- **We are of the view that *a voluntary* declaration of 100g of powder is appropriate. See Notes Q3.10**

Q3.13. Section 2.5

What would the cost and trade implications be of mandating these base units?

The sponsors Response:

- **This would be costly and may create confusion**

Q3.14. Section 2.5

Should the voluntary use of the base unit of per 100 kJ be permitted?

The sponsors Response:

- **No – it is unnecessary in our view**

Q3.15. – Q3.18 - Section 2.6 & 2.7 -

The sponsors Response:

- **We have no comments to offer for these questions**

Q3.19. Section 2.8

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

The sponsors Response:

- **We are of the view that it is very important to be able to state changes in a products composition in an infant formula product - and that this change should be able to be stated clearly on the product Label and also on a product website.**

Q3.20.Section 2.8

What information about the change in composition would caregivers and health professionals find useful?

The sponsors Response:

- **It would be important to be able to inform the caregiver when changes in ingredients affect potential for allergens i.e. addition of fish oil or Algal omega 3, or removal/substitution of same.**
- **In addition when amounts/values of ingredients have changed, this may affect a regular user who would not be aware of the differences in values that may affect their application of the feed. i.e. in a failure to thrive infant.**

Q3.21.Section 2.8

What are the cost and trade implications of a standardised approach to a product reformulation on infant formula packages? -

The sponsors Response

- **No comment**

Re: FSANZ consultation paper - Proposal P1028. Safety & Food Technology – document 2

Q4.15.Section 6.4

Should *all* or only *certain* substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?

The sponsors Response

- **No, The FSANZ code for infant formula guides the formulation requirements and limits therefore this would be deemed as a red tape and a unnecessary utilization of the resources.**

Conclusion:

We would again like to thank you for this opportunity for stakeholders to provide important feedback in regards to the FSANZ Consultation Paper P1028, addressing specific issues associated with the production, safety and provision of information in relation to Infant Formula Products.

We also look forward to any industry updates about the outcome of Stakeholder submissions in relation to this Consultation Paper, in the near future.

Best Regards,

On behalf of The Sponsor