15 September 2017

Project Manager
Food Standards Australia New Zealand
PO Box 10559
The Terrace
Wellington 6143
NEW ZEALAND

Email: submissions@foodstandards.gov.au

Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *Consultation paper – Proposal P1028: Regulation of Infant formula – Infant formula products for special dietary use.*

Yours sincerely

Katherine Rich
Chief Executive

CONSULTATION PAPER – PROPOSAL P1028: REGULATION OF INFANT FORMULA – INFANT FORMULA PRODUCTS FOR SPECIAL DIETARY USE.

Submission by the New Zealand Food & Grocery Council

15 September 2017

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the *Consultation paper – Proposal P1028: Regulation of Infant formula – Infant formula products for special dietary use.*

2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $31 billion in export revenue from exports to 195 countries – some 72% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 44% of total manufacturing income. Our members directly or indirectly employ more than 400,000 people – one in five of the workforce.

OVERARCHING COMMENTS

3. NZFGC is pleased to see the expansion of P1028 to include consideration of infant formula products for special dietary use (IFPSDU) since formula for this most vulnerable of all population groups starts with the standard infant formula regulated by the rest of Standard 2.9.1.

4. We support the INC's proposal on the regulatory framework that comprises three subcategories based on purpose: *Subcategory 1*: Products for premature or low birthweight infants, *Subcategory 2*: Products for less serious disorders, diseases or medical conditions and *Subcategory 3*: Products for serious disorders, diseases or medical conditions. We have discussed this further under the heading 'regulatory framework'. We support an overarching definition of IFPSDU and a definition for the products in Sub-category 3. As with INC, we do not support a definition for infant formula products for special medical purposes nor a categorisation based on an ingredient such as protein.

5. It is important throughout the review to understand that products for IFPSDU are almost all imported from Europe or the US. The specialised nature of them together with the small quantities results in the need to accommodate flexibility in composition and labelling since most of the products would be used under health care or medical supervision at least at the outset.

6. In relation to pre-term infants, we do not support age or weight ranges, the definition or naming the product.

7. Composition: NZFGC considers the current compositional arrangements for IFPSDUs are working well and to go further could impact on supply and sale to Australia and New Zealand for products that already have a well-established history of safe use. We support INC's position on nutrient parameters, that these should not be introduced.

8. NZFGC sees no benefit from a requirement relating to scientific data for safety, benefit of effectiveness since all IFPSDUs must have compositional modifications that are based on acceptable scientific data and address the specific condition. Again, requirements such as these would seriously jeopardise trade.

9. Food Additives: Food additives are essential in the manufacture of infant formula products generally and IFPSDUs in particular. We support INC proposals for a more efficient framework for food additives and the inclusion of all the food additives listed for consideration in the consultation paper.

10. Safety: NZFGC considers provisions relating to potential renal solute load (PRSL) for any infant formula product and IFPSDU to be redundant.

11. Contaminants: NZFGC supports INC positions on the specific contaminants identified.

12. Labelling: As noted above, the vast majority of IFPSDUs used in Australia and New Zealand are imported in small, specialist quantities for use under medical supervision. Flexibility in labelling is key to maintaining the supply of products recognising a lot of the use of products is by specialists or under HCP advice.

DETAILED COMMENTS

Regulatory Framework and Definitions (Q2-Q8 and Q10-Q11)

13. NZFGC supports the INC's proposal on the regulatory framework that comprises three subcategories based on purpose:
    - *Subcategory 1*: Products for premature or low birthweight infants,
    - *Subcategory 2*: Products for less serious disorders, diseases or medical conditions and
    - *Subcategory 3*: Products for serious disorders, diseases or medical conditions.

14. Three factors are important in this framework:
    - consistency to the greatest extent possible with Codex standards and guidelines.
    - flexibility for composition (for innovation to meet the highly specialised needs of the target infants) and for labelling (to ensure relabelling is not required)
    - no ingredient-based category.

15. Access and distribution differs across the Sub-categories but supervision for the likes of Sub-categories 1 and 3 would reflect a common feature in relation to medical supervision. Sub-category 2 would involve HCP or medical supervision at the outset and potentially continuing.

16. We support an overarching definition of IFPSDU and a definition for the products in Sub-category 3. As with INC, we do not support a definition for infant formula products for special medical purposes nor a categorisation based on an ingredient such as protein. We also oppose prescribed names for trade and supply reasons.

17. It is important throughout the review to understand that products for IFPSDU are almost all imported from Europe or the US. The specialised nature of them together with the small quantities results in the need to accommodate flexibility in composition and labelling since most of the products would be used under health care or medical supervision at least at the outset.

18. In relation to pre-term infants, we do not support age or weight ranges, the definition or naming the product. Age and weight ranges are somewhat arbitrary and medical supervision ensures appropriate use of relevant products. The definition is also problematic in not reflecting the situation of combinations of pre-term and low birth weight. Naming of the product should be avoided because of trade implications and potential disharmonisation with EU and US.

Human milk fortifiers (Q9)

19. NZFGC appreciates these products are problematic because they are currently imported under Standard 2.9.5 but logic suggests that they be covered by Standard 2.9.1. The greatest concern is around the loss of flexibility for the composition and labelling of these products. They are essential supplements to breast feeding and anything that can be done for a mother to encourage continuation of breastfeeding should be the overriding

goal. Therefore, so long as the framework provided for the same level of flexibility that is achieved under Standard 2.9.5, these products should move to Standard 2.9.1 possibly under *Sub-category 1*.

Composition (Q12-Q18)

20. NZFGC considers the current compositional arrangements for IFPSDUs are working well and there is already a well-established history of safe use. To go further could impact on supply and sale to Australia and New Zealand for products. We support INC's position on nutrient parameters, that these should not be introduced for the same reasons. It is important to note that because of differences in micro and macro nutrient parameters internationally (EU, US and Codex) it's important that IFPSDU regulation accommodates differences in these areas even when not specific to a disease or condition. INC uses an example of vitamin D which shows that overlapping requirements increasingly narrows the available range to a point where manufacturing cannot be achieved.

21. NZFGC sees no benefit from a requirement relating to scientific data for safety, benefit of effectiveness since all IFPSDUs must have compositional modifications that are based on acceptable scientific data and address the specific condition. Again, requirements such as these would seriously jeopardise trade.

Food Additives (Q19-

22. Food additives are essential in the manufacture of infant formula products generally and IFPSDUs in particular. We support INC proposals for a more efficient framework for food additives and the inclusion of all the food additives listed for consideration in the consultation paper. The key issue for the current food additives framework is the arbitrary nature of separation based on product type (infant formula product), food matrix (eg liquid) and ingredients (eg soy and non-intact protein). In fact, the manufacturer selects food additives based on *a combination of* technical elements not necessarily limited to only the food matrix and ingredients. Other elements have to account for raw material variability, manufacturing variability and analytical variability. The best food additive for the function should be available for the manufacturer to use, not limited by arbitrary separation.

Safety- Potential Renal Solute Load (PRSL) (Q24)

23. NZFGC considers provisions relating to PRSL for any infant formula product and IFPSDU to be redundant. With a general trend towards lower protein content in most infant formulas in recent years, and ever greater alignment with breast milk levels, the PRSL has become less important clinically, as high solute loads are not being provided.

Contaminants

24. : NZFGC supports INC positions on the specific contaminants identified and especially in relation to removing the ML for aluminium on the basis of a lack of evidence of there being a problem. Without evidence, this provision should be removed.

Labelling (Q25-Q

25. As noted above, the vast majority of IFPSDUs used in Australia and New Zealand are imported in small, specialist quantities for use under medical supervision. Flexibility in labelling is key to maintaining the supply of products recognising a lot of the use of products is by specialists or under HCP advice.