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Fonterra Co-operative Group Limited Submission on:

FSANZ Consultation Paper – Proposal P1028 20-17

Regulation of Infant formula- Infant formula products for special dietary use

28th September 2017

1. Fonterra welcomes the opportunity to provide the following comments on the Proposal to amend the regulation of infant formula products for special dietary use (IFPSDU). As a member of the Infant Nutrition Council (INC) Fonterra fully supports the INC submission on P1028 20-17. In our comments below, we will take the opportunity to highlight a few points of particular importance.

2. Currently the Food Standards Code has a unique approach in sub-categorisation of IFPSDU and specific composition criteria for products based on protein substitutes, relative to other international regulatory frameworks. The review of the regulatory framework for IFPSDU is an opportunity to further align requirements to Codex and other international regulations, and to review scientific rationale for the current requirements against the most recent scientific evidence.

3. IFPSDU are designed for dietary management of specific conditions, diseases or disorders. The current approach of IFPSDU sub-categorisation is based on both ingredients used and condition or disease, which results in regulatory ambiguity when determining the requirements for a product (e.g. a product using protein hydrolysate could be designed for a healthy infant, a pre-term infant or an infant with specific allergies). Fonterra supports maintaining sub-categorisations based on the condition or disease, but does not support retaining sub-categorisation based on the ingredients used. We therefore support the removal of the current protein substitutes sub-category.

4. Additionally, the specific composition criteria for the protein substitutes are not aligned with Codex or other international requirements and as per the scientific rationale provided in the INC submission under Question 13, are not necessary. Fonterra supports the current approach taken in two subcategories of Standard 2.9.1 for IFPSDU composition to comply with general infant formula product requirements except where it would prevent the sale of an infant formula product specifically formulated for a specific condition, disease or disorder. This approach allows for flexibility in composition requirements to ensure formulations are based on the latest scientific evidence, is aligned with Codex and international requirements and should be applied to all IFPSDU.

5. Question 15 asks whether there are any benefits including additional requirements for scientific data. The safety and suitability of IFPSDU can be assured by existing regulatory requirements by the overarching Food Act requirements in Australia and New Zealand. More specifically, scientific evidence is required by Standard 2.9.1 to support composition deviations for a specific condition, disease or disorder from general infant formula. Therefore manufacturers already have appropriate scientific evidence that the product is appropriate for the specific condition, disorder or disease that it is intended to address. IFPSDU are highly specialised products and requirements for safety and suitability must continue to be aligned internationally to ensure imported products continue to be available.

6. Question 16 requests submitters to comment on the requirements for micronutrients and nutritive substances. As noted in our previous submissions on P1028 and P1024 (Proposal to amend the regime for regulation of novel foods and nutritive substances), Fonterra supports expansion of the scope of P1024 to include all standards in the Code, including 2.9.1. FSANZ has recently proposed extending the scope of P1024 to include all standards except for 2.9.1, but we note that exclusion of Standard 2.9.1 still creates risks related to consistency, timing and approach.

7. Fonterra does not agree with a rationale for exclusion of Standard 2.9.1 based on the vulnerability of the population group. We note that Standard 2.9.1 is not differentiated from the general food supply under the current regulatory regime for novel foods, and the need to take account of specific Policy Guidelines and the characteristics of the population group applies to other parts of the Code. Further, P1028 only covers infant formula while Standard 2.9.1 also covers follow-on formula products. It is not clear how these products will be handled under the novel foods regime should there be a gap in timing between P1024 and P1028. Finally, under the currently proposed regime for P1024, the term 'nutritive substances' would be deleted. This term is used in Standard 2.9.1. If P1024 proceeds ahead of P1028, then this will become an orphan term in Standard 2.9.1 with no definition or regulatory context.

8. Therefore, we continue to submit that the same framework as applied to general foods, with specific differentiation to address the vulnerability of the population group should be extended to products covered under Standard 2.9.1. If Standard 2.9.1 is not included within the scope of P1024, then special consideration be given to the timing of these reviews to ensure there are no gaps or inconsistencies introduced inadvertently..

9. Fonterra welcomes the opportunity to continue to engage with FSANZ on the consideration of the regulation of IPSDU, and on the review of regulations for general infant formula. If there are any queries relating to this submission, please contact

Yours faithfully

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