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20/10/2021

Dear Standards Management,

Proposal P1028 Infant Formula – Consultation Paper 3 – Regulatory Framework and Definitions

Fonterra is a global dairy nutrition company owned by 10,000 farmers and their families. With a can-do attitude and collaborative spirit, we are a world leading dairy exporter. We draw on generations of dairy expertise and are one of the world's largest investors in dairy research and innovation, to produce more than two million tonnes annually of value-added advanced dairy ingredients, foodservice and consumer products for over 140 markets.

Fonterra has a long history in the manufacture of paediatric nutrition, with more than 50 years of experience in producing world class infant formula and young child formulas globally. Fonterra produces formula and ingredients for large multinational and major regional paediatric companies and is one of the world's largest contract manufacturers of paediatric nutrition formula and ingredients.

Fonterra welcomes the opportunity to provide comments and information to FSANZ on **P1028 – Infant Formula, Consultation Paper 3 – Regulatory Framework and Definitions**. We thank FSANZ for the consideration of the comments outlined in this submission.

Fonterra supports the continued protection of breastfeeding noting the many benefits this has for both mothers and infants. For non-breast fed infants that are fed infant formula, Fonterra supports a regulatory approach that ensures the best possible nutrition for such infants. This includes measures to ensure appropriate food safety and protection of public health, while allowing for continued innovation including scientific and technical development of infant formula. Fonterra supports harmonization with relevant Codex standards as a means of reducing trade barriers, unless there is strong scientific justification for a different approach.

Fonterra supports the content and views of the Infant Nutrition Council (INC) P1028 submission. In conjunction with the Scientific and Technical INC working group, Fonterra have invested significant time in developing aligned industry positions on the key issues and questions through P1028 as summarized by the INC response. In light of this, and rather than repeat INC responses in full, Fonterra have selected key areas of P1028 where we are well placed from both our dairy and infant formula expertise to provide information or elaboration on certain topics.

We thank FSANZ for the consideration of the comments outlined in both ours and the INC submission. If there are any queries relating to this submission, please contact us.

Yours Sincerely,

[REDACTED]

2.0 Novel Foods

2.1 Pre-market assessment requirements

FSANZ proposes to not proceed with a separate review of novel foods and nutritive substances applicable to IFP under P1028. Future assessment of P1024 will consider the broader review of the Code's provisions for novel foods and nutritive substances applicable to all foods.

Fonterra Response:

- We support FSANZ's proposed approach to include IFP in a broader review of P1024 as this is a horizontal standard that applies to both infant formula and other foods. This is important to reduce inconsistency and ambiguity within the Code, ensure efficient process and address issues across the system.
- We recommend that priority be given to progression of P1024 to facilitate innovation within the food sector. Further clarity from FSANZ on next steps to keep this progressing would be greatly appreciated.

2.2 Novel Foods – Schedule 25

FSANZ proposes to add the conditions listed in Table 5 to novel foods listed in Schedule 25, these are listed as:

- α -cyclodextrin
- γ -cyclodextrin
- Diacylglycerol oil (DAG oil)
- Isomaltulose
- D-tagatose
- Trehalose

FSANZ state this will achieve the original intention of the assessments for these novel foods which is to restrict them from use in infant formula, infant foods, and formulated supplementary foods for young children.

Fonterra Response:

- We consider that schedule 25 permissions should outline conditions for populations that were not part of the risk assessment. Such conditions should be included when Schedule 25 is updated, not retrospectively.
- We support clarification being provided in the Code on use of novel foods to align with risk assessments for infant formula and follow on formula (IFPs) only.
- We do not support formulated supplementary foods for young children being included within scope of the proposal. This is based on the view that food categories outside 2.9.1 are not in scope of P1028. The FSANZ website states the purpose of the P1028 review is "*standards related to infant formula (for use from birth to <12 months of age)*". In addition, FSFYC products are for young children aged one to four years, and this is a life stage where young children are consuming more family foods, where these family foods may contain novel foods their consumption would only be expected to make a very small part of the diet.

QUESTION 1: To manufacturers, please provide information on whether the substances listed in Table 5 are used in infant formula products, food for infants and formulated supplementary food for young children.

- Fonterra do not use substances listed in Table 5 of CP3 in infant formula products.

4 Definitions

4.1 Definition of infant formula product

FSANZ proposes to update the IFP definition to remove "*based on milk or other edible food constituents of animal or plant origin which*" to allow the definition to cover IF, FOF and IFPSDU.

Fonterra Response:

- We do not support removal of this section of the definition due to misalignment with Codex. This text is important in defining IF and FOF, which within Codex is covered under Essential Composition (3.1) requirements.
- We support the definition being amended as follows which would cover all IFPs (IF, FOF, IFPSDU) within Standard 2.9.1 while also creating closer alignment with Codex:
 - *An infant formula product means a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have proven to be safe for infant feeding that is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants depending on the age of the infant.*

4.2 Definition of infant formula

FSANZ proposes the definition for infant formula be amended by removing '4 to' in part (b) of the definition.

Fonterra Response:

- We recognise that other definitions for IF referenced by FSANZ (i.e. Ministerial Policy Guidelines, Codex, EU) do not include an age range. Rather they make reference to introduction of complementary foods.
- We consider that inclusion of an age range for IF:
 - Creates potential confusion though the Infant Formula Definition “*satisfies by itself the nutritional requirements of infants under the age of 6 months*” and overarching definition for infant “*Infant means a person under the age of 12 months*”.
 - May restrict FSANZ's ability to respond to evolving science in the future creating the need for further code updates. This is reflected by the range of research into the optimal age to introduce complementary feeding to address food allergies. Current research is investigating the introduction of allergenic foods from as young as 1 month (Sakihara et al, 2021) through 4 months and beyond (Schroer B et al 2020; Comberiati P et al 2019; Heine RG 2018; Fewtrell M et al (ESPGHAN) 2017).
- Based on the above challenges that an age range creates, we recommend the below definition be considered for (b), which also aligns with other global definitions:
 - *Satisfies by itself the nutritional requirements of infants for the first months of life until the introduction of complementary feeding as recommended by health authorities and is subsequently [or continues to be] suitable as the principal liquid source of nourishment.*

4.3 Other definitions

FSANZ proposes to remove the definitions for soy-based infant formula and medium chain triglycerides on the basis that they are self-explanatory. And retaining the definition for pre-term formula.

Fonterra Response:

- Support the maintenance of Medium Chain Triglyceride definition on the basis that this term is clarified to “MCT oil”.
- Definition for “MCT oil” should be included if restrictions are retained to remove ambiguity in ensuring MCTs are considered those which are predominately C8:0 and C10:0, while excluding other oils which may contain a small proportion of naturally occurring MCTs.

References

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Heine RG. Food Allergy Prevention and Treatment by Targeted Nutrition. *Ann Nutr Metab*, 2018;72 Suppl 3:33-45. DOI: 10.1159/000487380

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Schroer B, Groetch M, Mack DP, Venter C. Practical Challenges and Considerations for Early Introduction of Potential Food Allergens for Prevention of Food Allergy. *Journal of Allergy Clinical Immunology Practice*, 2021;9(1):44-56.e1. DOI: 10.1016/j.jaip.2020.10.031