31 May 2016

Food Standards Australia New Zealand
Boeing House
55 Blackall Street
BARTON ACT 2600

Subject: P1028 – Infant Formula

To whom it may concern

Thank you for the opportunity to take part in the consultation process for the proposed changes to Standard 2.9.1 Infant Formula Products (P1028 – Infant Formula). Synlait Milk Limited understand there is a need to revise the current Standard to address numerous regulatory issues and that this is an important opportunity for Food Standards Australia New Zealand (FSANZ) to provide further clarity to industry and interested parties.

Generally, Synlait Milk Ltd supports the intent of the proposal to align with international regulations for example the Codex provisions contained in CODEX STAN 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants and CAC/RCP 66-2008 Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. The proposed food safety parameters seem feasible and we understand that these changes will be addressed in a separate proposal P1039 – Microbiological Review of Infant Formula.

Synlait, as a member of the Infant Nutrition Council (INC) would like to express our support for the INC submission on P1028 - Infant Formula. Synlait are also a member of the Dairy Companies Association of New Zealand (DCANZ) and we wish to express our support of this submission also. We have itemized specific points below where we would like to further emphasize our position:

1) Calculation of protein: nitrogen conversion factors
   - Synlait supports the use of the two existing conversion factors and it is imperative that the conversion factor of N x 6.38 is retained in the Code for economic, sustainability and scientific reasons. Codex identifies a single nitrogen conversion factor of N x 6.25 with the ability to use N x 6.38 or 'other' unless scientific justification provides for the use of a different conversion factor for a particular product. Manufacturers have been using both

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conversion factors since the inception of Standard 2.9.1 Infant Formula Products. Some manufacturers have a preference over the other and are able to apply the factor that is most appropriate to the market of sale which would ensure flexibility is maintained.

2) Trans-fatty acids

- Synlait does not support a lowering of the trans fatty acid content from 4% to 3% as the Codex and Australia New Zealand Food Standards Code definitions differ, where the FSANZ definition incorporates a higher amount. Synlait supports retaining the 4% limit for milk fats as trans fatty acids play an important role in infant health such as transporting fat soluble vitamins.

3) Natural variation of amino acids

- Synlait does not support retaining the existing minimums for the amino acids; tyrosine, phenylalanine, methionine and cysteine. This is because there is a large degree of natural variability in the amount of amino acids present in milk ingredients. Synlait supports the INC proposal that the requirements for the amino acids tyrosine, phenylalanine, methionine, and cysteine are amended to be consistent with CODEX STAN 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants because the minimum levels are founded on recent data derived from the composition of breast milk.

4) Other optional substances; choline, L-carnitine and inositol

- Synlait supports the mandatory addition of choline, L-carnitine and inositol to align with CODEX STAN 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. They are essential nutrients for infants and are proven to be safe for use in Infant Formula. Synlait support the proposed minimum and maximum levels (or GULs) that are set out in the INC submission.

5) Carry-over principle

- Synlait strongly supports retaining the current carry-over principle clause, included in the Australia New Zealand Food Standards Code where it is able to be applied to Infant Formula. Codex allows the use of the carry-over principle in Infant Formula only where the additives are listed as permitted for use. It would be difficult to establish a positive list of additives and processing aids that are allowed to be carried-over into Infant Formula to cover every situation. The amount of additive present in the final formula would also be negligible. Therefore, Synlait do not support the establishment of a positive list.

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6) P1024 – Revision of the Regulation of Nutritive Substances and Novel Foods

- It is currently unclear how P1024 - Revision of the Regulation of Nutritive Substances and Novel Foods proposal will interact with P1028 - Infant Formula. As the proposal explicitly excludes Infant Formula Products, how will pre-market assessment of ingredients destined for use in Infant Formula be determined and in which Standard will the requirements be included in?

Synlait Milk Limited appreciate all the work that FSANZ has done to date to bring together a comprehensive document and fully support the objectives that FSANZ seeks to achieve. We look forward to further opportunities to comment and to providing feedback in the subsequent round of consultation.

Yours sincerely

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On behalf of Synlait Milk Limited

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