



Fonterra Co-operative Group Limited

19 August 2019

Dear Sir / Madam

Re: A1190 – 2'-FL in infant formula and other products

Fonterra welcomes the opportunity to comment on Application A1190 regarding the voluntary addition of 2'-O-Fucosyllactose (2'-FL) produced by microbial fermentation, in infant formula products and formulated supplementary foods for young children in Australia and New Zealand.

Fonterra supports breast feeding as the preferred method of feeding an infant. If, however, breast feeding or breast milk is not available for the infant, the only suitable alternative method of feeding is an infant formula product.

Fonterra supports FSANZ decision to permit the voluntary addition of 2'-FL in infant formula products at the proposed levels (up to a maximum of 2.4g/L). However, Fonterra does not support the FSANZ decision to exclude voluntary permissions of 2'-FL in formulated supplementary foods for young children (FSFYC). As such on review of the options, **Fonterra supports Option 3 to permit 2'-FL in both infant formula products and FSFYC.**

Fonterra supports the content and views of the Infant Nutrition Council (INC) response to the A1190.

Use as a nutritive substance

- Fonterra notes FSANZ regards these substances as being *used as a nutritive substance. Fonterra continues to welcome the consideration being given by P1024 and P1028 to a revision of the regime for Nutritive Substances and Novel Foods. Fonterra continues to consider that any regime for pre-market assessment for new ingredients should focus on safety, thereby removing the ambiguity in the existing framework whilst achieving a balance between protecting the integrity of the food supply and supporting industry innovation.

Schedule 3 drafting

- Fonterra consider that improvement could be made to the drafting proposal to improve consistency across all ingredients listed. There is an inconsistent approach to microbiological criteria – with some ingredients containing criteria and others not. We would like to take this opportunity to suggest FSANZ needs to be more transparent and consistent in its approach on what parameters are applied to ingredients within Schedule 3.
- As 2'-FL is provided from two sources, it is recommended that there be one entry for 2'-FL from microbial sources followed by information related to the two permitted sources. To be immediately followed by a definition for synthetic 2'-FL.

Exclusion of FSFYC

- Continued exclusion of FSFYC is leading to not only inconsistency against international regulations in terms of permissions for young children (>12 months). But also, now within Australia where the Therapeutic Good Administration has approved its use as a supplement for young children from age one through to senior adults.

Prohibition of use of 2'-FL with GOS and IFT

- Fonterra reiterates its previous concern with FSANZ's proposal to prohibit the use of 2'-FL with Galact-oligosaccharides (GOS) and Inulin-type fructans (ITF).
- Fonterra note that a complete prohibition of combinations will impact both consumers and industry. This lack of harmonisation will impact the viability, cost and hence the availability of innovative products for infants and young children in Australia and New Zealand. Those who manufacture and export from Australia and New Zealand will be at a disadvantage with increased complexity. Additionally, given the wide range of potential combinations, it can be foreseen that applications will continue to put pressure upon FSANZ resources.
- We consider that a complete prohibition is inconsistent with the FSANZ risk assessment. We note that FSANZ has previously considered the available evidence for this potential combined use under A1155 and determined no adverse effects were reported in infant studies which tested formula.

Yours Faithfully

