30th August 2019

Application A1155: 2'-FL and LNnT in infant formula and other products

Fonterra welcomes the opportunity to comment on Application A1155 permitting the voluntary addition of 2'-O-Fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT), 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 alone or in combination with LNnT to both infant formula products and formulated supplementary foods for young children (FSFYC) at the levels proposed.

Fonterra supports the content and views of the Infant Nutrition Council (INC) response to the CFS 2 for A1155.

Use as a nutritive substance
Fonterra notes FSANZ response to comments regarding these substances 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.

Identity & Purity
Fonterra supports the decision not to include reference to Methods of Analysis in Schedule 3.

Fonterra is disappointed that FSANZ has not considered harmonisation of purity criteria established by the European Union for these substances produced in the same manner. The proposed variation in Attachment A will already require application(s) for revision "based on equivalence notifications to the EU Commission from other manufacturers … and further amendment requests by Glycom." Fonterra encourages FSANZ to reconsider these harmonisation issues and the increased work in maintaining these identity and purity criteria.

Prohibition of use of 2'-FL and LNnT with GOS and ITF

Fonterra disagrees with FSANZ proposal to prohibit the use of 2'-FL and LNnT with Galact-oligosaccharides (GOS) and Inulin-type fructans (ITF).

Fonterra note that a complete prohibition of combinations will impact both consumers and industry. A 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 the proposal for a complete prohibition is inconsistent with the FSANZ risk assessment. We note that FSANZ considered the available evidence for this potential combined use (CFS2 - 2.3.4) and determined no adverse effects were reported in infant studies which tested formula.

The concentration of all types of oligosaccharides present in human milk averages between 7 and 11 g/L, depending on a number of factors including geographical location (McGuire *et al,* 2017). The variety of oligosaccharides present in human milk provides extensive historical evidence that these concentrations, as well as infinite combinations of individual oligosaccharides, present no safety concerns.

Marriage *et al* (2015) evaluated the tolerance of infants fed milk-based formulations containing a total of 2.4 g oligosaccharides/L (89 mg/100kJ) as GOS alone or combined with 2'-FL. All formulas were well tolerated. Kajzer *et al* (2016) evaluated the tolerance of infants fed a milk-based formula containing 0.2 g/L 2'-FL combined with 2.0 g/L scFOS. The study concluded that the experimental formula was safe and well tolerated based on reported outcomes similar to those of infants fed human milk or formula without oligosaccharides.

Infant formula products containing a combination of 2'fucosyllactose together with fructo-oligosaccharides are already available in other markets, further supporting the safe use of this combination.

In addition, Azagra-Boronat *et al* (2018) studied the role of 2′-fucosyllactose (2′-FL), a mixture of the prebiotic GOS and long-chain FOS 9:1 and their combination on RV-induced diarrhea in suckling rats. Whilst the objective of this study was not to consider safety, it does contribute to the *in vivo* data available to confirm the safety of combinations.

Fonterra suggests further consideration is given to applying the existing limits for combinations of oligosaccharides within the Code to the newly approved approved sources; together with the additional individual limits as proposed. As such, there would be no cumulative increase to the total oligosaccharide load consumed by infants.

Yours faithfully

Fonterra Co-operative Group Limited

Private Bag 11029, Fitzherbert Dairy Farm Road, Palmerston North, New Zealand

References

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Marriage BJ, *et al* (2015) Infants fed a lower calorie formula with 2'fl show growth and 2'FL uptake like breast-fed infants. J Pediatr Gastroenterol Nutr 61:649–658.

Kajzer J, Oliver JS, Marriage BJ (2016) Gastrointestinal tolerance of formula supplemented with oligosaccharides. The FASEB Journal 30:Abstract 671.4

Azagra-Boronat I, *et al* (2018) Supplementation With 2′ -FL and scGOS/lcFOS Ameliorates Rotavirus-Induced Diarrhea in Suckling Rats. Front Cell Infect Microbiol. 8: 372