

January 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 assessment that voluntary addition of 2'-FL alone or in combination with LNnT is safe and suitable for addition to infant formula products and formulated supplementary foods for young children.

### **Use as a nutritive substance**

An interim decision was taken in 2008 providing express permission for the addition of inulin-derived oligosaccharides (IDS) and galacto-oligosaccharides (GOS) in infant formula products independent of deeming these ingredients to be 'nutritive substances' (P306). For consistency, this approach was extended for the approval of another oligosaccharide, inulin type fructans (ITF) (A1055) pending the outstanding review of Standard 2.9.1 and the reviews of the definition of nutritive substances. Since these reviews remain in progress, it is surprising that FSANZ has concluded that other oligosaccharides are "used as a nutritive substance". This has the potential to create inconsistencies and reaffirms comments in response to P1024 that the concept/definition of nutritive substance should be deleted from the Code.

### **Ingredient Specification**

Fonterra notes that the specifications listed in SD1\_Risk Assessment Tables 2.3 and 2.4 which are proposed to be included in Schedule 3 also reference Methods of Analysis. We believe that it would be inconsistent with specifications currently included in Schedule 3 to include the method and would limit both manufacturers and enforcement agencies as well as future methods improvement.

Also, we wish to draw attention to the recent revision of the purity criteria in the Commission Implementing Regulation (EU) 2018/1023 for this novel food. Industry continues to innovate in this area to provide products that more closely deliver outcomes aligned to those observed in infants that are breast fed. Fonterra notes that alternative sources of 2'-FL have been demonstrated as safe and suitable for this age group. It could be anticipated that these may in future be brought to market in Australia and New Zealand to the benefit of local consumers and exporters that manufacture products for overseas markets where this ingredient is permitted. Hence Fonterra suggest that the purity criteria adopted by FSANZ reflect those currently in force in Europe.

**Prescribed Name**

Although 2'-Fucosyllactose and Lacto-N-neotetraose are commonly used names to describe these ingredients, Fonterra considers it unnecessary to prescribe the names and suggests compliance with Standard 1.2.4—4 is sufficient.

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

FSANZ concluded that no adverse effects were reported in infant studies which tested formula supplemented with 2'-FL in combination with GOS or scFOS (Marriage *et al*, 2015; Kajzer *et al*. 2016). Although these studies did not use the maximum amounts of scFOS or GOS permitted in the Code it would be inconsistent with the data to prohibit all combinations in foods for this age group. 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.

Yours faithfully

Fonterra Co-operative Group Limited

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

**References**

Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods

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