

Summary of the dossier: 3-Fucosyllactose

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The application is submitted pursuant to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, for the authorisation of the Human Milk Oligosaccharide (HMO) 3-fucosyllactose (3FL) produced by microbial synthesis.

HMOs are constituents in breast milk with an important role in the healthy development of infants, for example by shaping the gut microbiota, positively influencing the brain development, and contributing to a healthy immune system. 2'-fucosyllactose and lacto-N-neotetraose (LNnT) are examples of HMOs which have been authorized as novel foods.

The intended uses of 3-fucosyllactose are: (1) Infant formulae as defined by Directive 2006/141/EC; (2) Follow-on formulae as defined by Directive 2006/141/EC; (3) Dietary foods for special medical purposes as defined by Directive 1999/21/EC (excluding products from food category 13.1.5); (4) Dietary foods for infants and young children for special medical purposes as defined by Directive 1999/21/EC; and (5) special formulae for infants, all categories with a use level of 1.2 g/L.

3-FL is manufactured by fermentation using metabolically engineered strains of *E. coli* as a processing aid and the structure of this 3-FL produced by fermentation has been shown to be consistent with the structure of 3-FL as confirmed by liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS), ¹H nuclear magnetic resonance spectroscopy (NMR), ¹³C NMR, double-quantum filtered ¹H¹H correlation spectroscopy (COSY), phase-sensitive ¹H¹³C-heteronuclear single quantum correlation spectroscopy (HSQC), and phase-sensitive ¹H¹³C-heteronuclear multiple bond correlation spectroscopy (HMBC).

The 3-FL produced by fermentation is structurally identical to the 3-FL present in human breast milk. It has been the subject (as part of a mixture of HMOs which contained 16 % of 3-FL) of a 90-day toxicology study as well as a genotoxicology study, published in 2020.

The application has been prepared in accordance with the requirements of Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.