

Summary of the application: Extension of use of 2'-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 extension of use of the novel food 2'-fucosyllactose (2'-FL) produced from a microbial source (*E. coli* BL21(DE3)), for several food categories.

2'-FL is a Human identical Milk Oligosaccharide (HiMO), produced either by chemical synthesis or microbial fermentation. The manufacture of 2'-FL using the strain *E. coli* BL21(DE3) has been authorised previously. HiMOs are identical to Human Milk Oligosaccharides (HMOs) present in human breast milk, where they have an important function for infant nutrition, the development of the microbiome and a healthy immune system.

The identity, manufacturing process, compositional data, specifications, ADME and toxicological information have been evaluated previously and 2'-FL has been authorised for human consumption. Building on the established safety of 2'-FL, the applicant proposes to increase the use levels for Infant formula as defined in Regulation (EU) No 609/2013, Follow-on formula as defined in Regulation (EU) No. 609/2013, Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No. 609/2013, and Milk-based drinks and similar products intended for young children.

The applicant has provided information and performed intake assessment calculations to describe the changes in potential exposure of infants and the remaining population related to the increased use levels of 2'-FL.

To support the increase of Use Levels, the applicant has provided literature references to prove the natural occurrence of 2'-FL concentrations in human breast milk as well as an infant study which confirms the tolerability and safety of 2'-FL at the proposed concentrations.

With this comprehensive set of information, the applicant is confident that the safety of 2'-FL used at these proposed increased concentrations in the described categories of infant nutrition is well supported.