Summary of the application: Modification of the use levels of 3-Fucosyllactose (3-FL) produced by a derivative strain of *Escherichia coli* BL21(DE3)

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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 increase in the use levels of the novel food 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21(DE3) in infant formulae, follow-on formulae, food for special medical purposes and food supplements.

3-FL is a HiMO, produced by microbial fermentation. HiMOs are identical to 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 manufacture of 3-FL using genetically modified strains of *Escherichia coli* K-12 or *Escherichia coli* BL21(DE3) has been authorised previously.

The identity, manufacturing process, compositional data, specifications, history of use, ADME and toxicological information have been evaluated previously and 3-FL has been authorised for human consumption.

Building on the established safety of 3-FL, the applicant proposes to change the use levels for 3-FL derived from microbial source to close the gap of 3-FL intake between breastfed infants and formula fed infants. The applicant has provided a rationale to explain this request. With the information provided, the applicant is confident that the request for a change of the use levels of 3-FL is well supported.