Summary of the dossier: Lacto-N-Tetraose (LNT)

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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 lacto-N-tetraose (LNT, chemical name β-D-Galactopyranosyl-(1→3)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose, CAS No. 14116-68-8), manufactured by fermentation using a metabolically engineered strain of Escherichia coli as a processing aid.

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.

Since 2015, two HMOs have been authorised as novel foods, namely 2'-fucosyllactose (2'-FL) and lacto-N-neotetraose (LNnT).

The intended uses of LNT are: (1) Infant formula as defined in Regulation (EU) No. 609/2013; (2) Follow-on formula as defined in Regulation (EU) No. 609/2013; (3) Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013; (4) Milk-based drinks and similar products intended for young children; (5) Foods for infants and young children for special medical purposes as defined in Regulation (EU) No. 609/2013; (6) Foods for special medical purposes as defined in Regulation (EU) No. 609/2013 excluding foods for infants and young children; and (7) Food supplements as defined in Directive 2002/46/EC. Categories (1), (2), (3) and (4) with a use level of 1.82 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer, categories (5) and (6) with use levels that are in accordance with the particular nutritional requirements of the persons for whom the products are intended, and category (7) with use levels of 4.6 g/day for general population and 1.82 g/day for infants and young children.

LNT is manufactured by fermentation using a metabolically engineered strain of E. coli as a processing aid and the structure of this LNT produced by fermentation has been shown to be consistent with the structure of LNT in human breast milk as confirmed by liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS), $^{1}H$ nuclear magnetic resonance spectroscopy (NMR), $^{13}C$ NMR, double-quantum filtered $^{1}H^{1}H$ correlation spectroscopy (COSY), phase-sensitive $^{1}H^{13}C$-heteronuclear single quantum correlation spectroscopy (HSQC), and phase-sensitive $^{1}H^{13}C$-heteronuclear multiple bond correlation spectroscopy (HMBC). These analyses determined the equivalency of the LNT manufactured by fermentation (using metabolically engineered strains of E. coli) and that found in nature.

LNT has been the subject of a toxicology study as well as a genotoxicity study. The results showed that LNT was not genotoxic and did not induce any adverse effects in the repeated dose study, when administered in doses above the use levels that are proposed in this application. The estimated anticipated daily intake of LNT via the proposed use categories at the maximum proposed use levels does not exceed the estimated daily intake of LNT from human milk calculated for breastfed infants on body weight basis.