Summary of the application: Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799

Applicant: Shandong Henglu Biotechnology Co, Ltd 25th floor, Block B, Jiaheng Business Building, Hualong Road, Licheng District, Jinan, Shandong Province, 250100 People's Republic of. China.

Shandong Henglu Biotechnology Co., Ltd intends to market Lacto-N-triose II (LNT II). The Novel Food object of this application is a human milk oligosaccharide obtained by fermentation using a recombinant K. lactis DSM709-2-02 strain.

Shandong Henglu Biotechnology Co., Ltd prepared this application in compliance with Regulation 2015/2283 on Novel Food and following 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, the European Food Safety Authority (EFSA) Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 and EFSA's Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283.

LNT II is designed to be used as a food ingredient for several alimentary products in a maximum level intended for each food category according to EFSA Food classification system. In details, those are unflavoured pasteurised and sterilised (including UHT) milk, unflavoured pasteurised and sterilised (including UHT) milk-based products, unflavoured fermented milk-based products, unflavoured fermented milk-based products including natural unflavoured buttermilk non-heattreated products, flavoured fermented milk-based products including heat-treated products, milkbased drinks and similar products intended for young children, cereal bars, table-top sweeteners, other foods for young children, infant formula as defined in Regulation No 609/2013, follow-on formula as defined in Regulation No 609/2013, processed cereal-based food and baby food for infants and young children as defined in Regulation No 609/2013, total diet replacement for weight control as defined in Regulation No 609/2013, flavoured drinks, foods for special medical purposes as defined in Regulation No 609/2013, food supplements as defined in Directive 2002/46/EC, excluding infants, bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation No 828/2014, coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as instant mixes of these products, dairy analogues, including beverage whiteners.

Human milk oligosaccharides, including LNT II, are considered a 'non-digestible oligosaccharide'. Indeed, they do not undergo any significant digestion in the upper gastrointestinal tract but, instead, reach the colon where they act as prebiotic. European Union population is already exposed to LNT II through the consumption of the Novel Foods Lacto-N-neotetraose (LNnT) and Lacto-N-tetraose (LNT).

Moreover, LNT II levels in human milk is estimated to range from 150 mg/L to 30 mg/L until the 168th day of lactation. LNT II was negative in the Bacterial Reverse Mutation Test (Ames Assay), and the In Vitro Mammalian Cell Micronucleus Test performed by the applicant. A 90-day repeated dose oral toxicity study was also conducted, deriving a NOAEL value for LNT II of 5000 mg/kg body weight/day in rats. Therefore, a maximum use level of 3500 mg/day was derived for the general adult population that corresponds to an intake of 50 mg/kg body weight/day for a 70 kg individual.

According to Article 26, data protection is asked for the toxicological studies and scientific publication. Instead, confidentiality is asked for the production process, analytical results of LNTII, and sensitive

applicant data. A non-confidential version of all the above-mentioned documents is given within the application according to the Transparency Regulation arrangements.