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ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

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Authorised novel food	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Other requirements**	**Data protection**
Lacto-*N*-triose II (LNT II) (produced by a derivative of *Kluyveromyces lactis* strain DSM 70799)	***Specified food category***	***Maximum levels***	1) The designation of the novel food on the labelling of food and food supplements containing it shall be ‘lacto-*N*-triose II’. 2) Milk and products thereof (including		Authorised on […][*OP, please insert the date dd.mm.yyyy - 20th day following its publication*]. This inclusion is based on proprietary scientific evidence and
	Unflavoured pasteurised and sterilised (including UHT) milk products	0.1 g/L			

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	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation	1 g/L	lactose) are listed in Annex II to Regulation (EU) No 1169/2011 among the substances or products causing allergies or intolerances, therefore foods containing that novel food should be labelled in accordance with Article 21 of Regulation (EC) No 1169/2011. 3) The labelling of food supplements containing Lacto-*N*-triose II (LNT II) (produced with a derivative of *Kluyveromyces lactis* strain DSM 70799) shall bear a statement that:		scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "Shandong Henglu Biotechnology Co, Ltd", Block B, Jiaheng Business Building, Hualong Road, Licheng District, Jinan, Shandong Province, 250100, People's Republic of China. During the period of data protection, the novel food Lacto-*N*-triose is authorised for placing on the market
	Unflavoured fermented milk products, heat-treated after fermentation	1 g/kg (products other than beverages) 0.1 g/L (beverages)			
	Flavoured fermented milk products including heat-treated products	0.1 g/L (beverages) 1 g/kg (products other than beverages)			

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	Milk-based drinks and similar products intended for young children	0.03 g/L (marketed as such or reconstituted according to the instructions)	(a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added Lacto-*N*-triose II (LNT II) are consumed the same day.		within the Union only by "Shandong Henglu Biotechnology Co, Ltd" unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of "Shandong Henglu Biotechnology Co, Ltd".
	Cereals and cereal products	1 g/L			
	Table-Top Sweeteners	3 g/kg			

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	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	0.03 g/L (beverages) 0.25 g/kg (products other than beverages)			End date of the data protection: […][*OP please insert the date dd.mm.yyyy – after 5 years*].
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013 and meal replacements for weight control	0.2 g/day			
	Flavoured drinks	0.1 g/L			

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	Foods for special medical purposes as defined in Regulation (EU) No 609/2013, excluding foods for special medical purposes intended for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended with a maximum of 2,0 g/day			
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	0.9 g/kg			
	Coffee, 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 mixes and instant mixes of these products	0.14 g/L – the maximum level refers to the products ready to use			

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	Dairy analogues, including beverage whiteners	0.018 g/L for beverages 0.18 g/kg for products other than beverages 6 g/kg for whitener			
	Infant formula as defined under Regulation (EU) No 609/2013	0.04 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	0.03 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

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	Food supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children.	2,0 g/day			

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(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order:

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Authorised novel food	**Specification**

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Lacto-*N*-triose II (LNT II) (produced by a derivative of *Kluyveromyces lactis* strain DSM 70799)	**Description:** Lacto-*N*-triose II is a concentrated white to off-white powder that is produced by a microbial fermentation process followed by a purification step to remove the source organism. **Definition:** Chemical name: 2-acetamido-2-deoxy-beta-D-gluco-hexopyranosyl-(1→3)-beta-D-galactohexopyranosyl-(1→4)-aldehydo-D-gluco-hexose Chemical formula: $C_{20}H_{35}NO_{16}$ CAS Number: 75645-27-1 Molecular mass: 545.49 Da **Source:** The novel food is produced by fermentation with a genetically modified strain (*Kluyveromyces lactis* DSM 709-2-02) of *K. lactis* DSM 70799 (ATCC 8585). **Characteristics/Composition:** Lacto-*N*-triose II (% of dry matter): ≥ 96,0 % (w/w) D-Glucose (% of dry matter): ≤ 2,0 % (w/w) D-Galactose (% of dry matter): ≤ 2,0 % (w/w) D-Lactose (% of dry matter): ≤ 3,0 % (w/w) Lacto-*N*-triitol (% of dry matter): ≤ 0,5 % (w/w) Moisture: ≤ 9,0 % (w/w) Protein: ≤ 0.01 % (w/w) Ash: ≤ 1.0 % (w/w) pH (sample solution of 5 %, 20°C): 4.0-7 **Heavy metals and contaminants:** Arsenic ≤ 0.05 mg/kg

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	Lead ≤ 0.02 mg/kg Cadmium ≤ 0.05 mg/kg Mercury ≤ 0.05 mg/kg Aflatoxin M1 ≤ 0.025 µg/kg Acetone ≤ 0.0001 % Ethanol ≤ 0.2 % **Microbiological criteria:** Total plate count: ≤ 500 CFU[1]/g Yeasts and moulds: ≤ 50 CFU/g Enterobacteriaceae: Absence in 10 g *E. coli*: Absence in 10 g *Salmonella* spp.: Absence in 25 g Coagulase-positive staphylococci: < 10 CFU/g *L. monocytogenes*: Absence in 25 g *B. cereus*: < 10 CFU/g *Cronobacte*r spp.: Absence in 25 g Endotoxins: ≤ 10 EU[2]/mg

[1] CFU: Colony Forming Units
[2] EU: Endotoxin Units

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