

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

EN

## 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:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
<b>Lacto-<i>N</i>-tetraose ('LNT') (produced by a derivative strain of <i>Escherichia coli</i> K-12 MG1655)</b>	<b><i>Specified food category</i></b>	<b><i>Maximum levels (expressed as lacto-<i>N</i>-tetraose)</i></b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'lacto- <i>N</i> -tetraose'.  The labelling of food supplements containing lacto- <i>N</i> -tetraose (LNT) shall bear a statement that a) they should not be consumed by children under 3 years of age; b) they should not be used if other foods containing added		Authorised on [...][ <i>OP</i> , please insert the date dd.mm.yyyy - 20th day following its publication]. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "Inbiose
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	1,0 g/L			
	Unflavoured fermented milk-based products	1,0 g/L (beverages) 10 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	1,0 g/L (beverages) 10 g/kg (products other than beverages)			
	Beverages (flavoured	1,0 g/L			

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

	drinks)				
	Cereal bars	10 g/kg			
	Infant formula as defined under Regulation (EU) No 609/2013	0,8 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	0,6 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	0,6 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 5 g/kg for products other than beverages			
	Milk based drinks and similar products	0,6 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 5 g/kg for products other than beverages			
			lacto- <i>N</i> -tetraose are consumed the same day.		N.V”, Technologiepark 82, bus 41, 9052 Zwijnaarde, Belgium. During the period of data protection, the novel food Lacto- <i>N</i> -tetraose is authorised for placing on the market within the Union only by “Inbiose N.V” 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 “Inbiose N.V”. End date of the data

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	2,0 g/L (beverages) 20 g/kg (products other than beverages)			protection: [...] [OP please insert the date dd.mm.yyyy – after 5 years].
Foods for special medical purposes as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
Food supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	2,0 g/day for the general population above 3 years			

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

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

Authorised Novel Food	Specification
<p><b>Lacto-<i>N</i>-tetraose ('LNT')</b>  <b>(produced by a derivative strain of <i>Escherichia coli</i> K-12 MG1655)</b></p>	<p><b>Definition:</b>  Chemical formula: C<sub>26</sub>H<sub>45</sub>NO<sub>21</sub>  Chemical name: β-D-Galactopyranosyl-(1→3)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose  Molecular mass: 707.63 Da  CAS No 14116-68-8</p> <p><b>Description:</b>  Lacto-<i>N</i>-tetraose is a white to off-white powder produced by microbial fermentation and further isolated, purified and concentrated.</p> <p><b>Source:</b> Genetically modified strain of <i>Escherichia coli</i> strain K-12 MG1655 (ATCC 700926)</p> <p><b>Characteristics/Composition:</b>  Sum of lacto-<i>N</i>-tetraose, D-Lactose and lacto-<i>N</i>-triose II (% of dry matter): ≥ 90 % (w/w)  Lacto-<i>N</i>-tetraose (% of dry matter): ≥ 85 % (w/w)  D-Lactose: ≤ 7% (w/w)  Lacto-<i>N</i>-tetraose fructose isomer: ≤ 1 % (w/w)  Lacto-<i>N</i>-triose II: ≤ 7 % (w/w)  Sum of other carbohydrates*: ≤ 5 % (w/w)  Water: ≤ 7 % (w/w)  Protein: ≤ 0.01 (w/w)  Ash: ≤ 0.5% (w/w)  pH (20 °C, 10% solution): 4.0 -6.5</p>

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

	<p><b>Contaminants</b></p> <p>Arsenic: <math>\leq 0.2</math> mg/kg</p> <p>Cadmium: <math>\leq 0.1</math> mg/kg</p> <p>Lead: <math>\leq 0.02</math> mg/kg</p> <p>Mercury: <math>\leq 0.1</math> mg/kg</p> <p>Aflatoxin M1: <math>\leq 0.025</math> µg/kg</p> <p><b>Microbiological criteria:</b></p> <p>Aerobic plate count: <math>\leq 1000</math> CFU/g</p> <p>Yeasts and moulds: <math>\leq 100</math> CFU/g</p> <p><i>Enterobacteriaceae</i>: Absence in 10 g</p> <p><i>Salmonella</i> sp.: Absence in 25 g</p> <p><i>Cronobacter</i> spp.: Absence in 10 g</p> <p><i>Listeria monocytogenes</i>: Absence in 25 g</p> <p><i>Bacillus cereus</i>: <math>\leq 50</math> CFU/g</p> <p>Endotoxins: <math>\leq 10</math> EU/mg</p>
--	--

\* N-Acetylglucosaminyl lacto-N-tetraose (GlcNac-LNT); galacto-oligosaccharides (GOS); galactosyllacto-N-tetraose (Gal-LNT); para-lacto-N-hexaose II (pLNH II). CFU: Colony Forming Units; EU: Endotoxin Units'