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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:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
Lacto-<i>N</i>-fucopentaose I and 2'-Fucosyllactose ('LNFP-I and 2'-FL') mixture (produced by a derivative strain of <i>E. coli</i> K-12 DH1)	<i>Specified food category</i>	<i>Maximum levels (expressed as Lacto-<i>N</i>-fucopentaose I / 2'-Fucosyllactose mixture)</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lacto- <i>N</i> -fucopentaose I and 2'-Fucosyllactose mixture'.		Authorised on [...] [<i>OP, please insert the date dd.mm.yyyy - 20th day following its publication</i>]. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "Glycom A/S", Kogle Allé 4,
	Infant formula as defined under Regulation (EU) No 609/2013	2,0 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	The labelling of food supplements containing Lacto- <i>N</i> -fucopentaose I and 2'-Fucosyllactose ('LNFP-I /2'-FL') mixture produced by a derivative strain of <i>E. coli</i> K-12 DH1 shall bear a statement that:		
	Follow-on formula as defined under Regulation (EU) No 609/2013	2,0 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	(a) they should not be consumed by children under 3 years of age; (b) they should not be		

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		<p>used, if other foods containing added Lacto-<i>N</i>-fucopentaose I and 2'-Fucosyllactose mixture and/or foods containing added 2'-Fucosyllactose are consumed on the same day.</p>	<p>2970 Hørsholm, Denmark. During the period of data protection, the novel food Lacto-<i>N</i>-fucopentaose I and 2'-Fucosyllactose mixture produced by a derivative strain of <i>E. coli</i> K-12 DH1 is authorised for placing on the market within the Union only by Glycom A/S 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</p>
Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	1,5 g/L		
Unflavoured fermented milk-based products	1,5 g/L (beverages)		
	3,0 g/kg (products other than beverages)		
Flavoured fermented milk-based products including heat-treated products	1,5 g/L (beverages)		
	15,0 g/kg (products other than beverages)		
Cereal bars	15,0 g/kg		
Milk based drinks and similar products	1,8 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	15,0 g/kg (products other than beverages)		
Beverages (flavoured drinks,			

excluding drinks with a pH less than 5)	1, 5 g/L	<p>“Glycom A/S”. End date of the data protection: [...] <i>[OP please insert the date dd.mm.yyyy – after 5 years]</i>.</p>
Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	3,0 g/L (beverages)	
	30,0 g/kg (products other than beverages)	
Food for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended but in any case not higher than the maximum levels specified for the proposed food categories or higher than 2,0 g/L or 2,0 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	
Food for special medical purposes as defined under Regulation (EU) No	In accordance with the particular nutritional requirements of the persons for whom the	

609/2013 excluding foods for infants and young children	products are intended but in any case not higher than the maximum levels specified for the proposed food categories or higher than 4,5 g/day in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	1.5 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	15 g/kg for products other than beverages		

Food supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	4,5 g/day	
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(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order [OP, please insert in the EN version in alphabetical order]:

Authorised novel food	Specification
<p>Lacto-<i>N</i>-fucopentaose I and 2'-Fucosyllactose ('LNFP-I and 2'-FL') mixture (produced by a derivative strain of <i>E. coli</i> K-12 DH1)</p>	<p>Description: Lacto-<i>N</i>-fucopentaose I and 2'-Fucosyllactose mixture is a purified and concentrated white to off-white powder produced by microbial fermentation.</p> <p>Definition: Lacto-<i>N</i>-fucopentaose I Chemical name: α-1-Fucopyranosyl-(1\rightarrow2)-β-d-galactopyranosyl-(1\rightarrow3)-2-(acet ylamino)-2- deox y-β-d-glucopyranosyl-(1\rightarrow3)-β-d-galactopyranosyl-(1\rightarrow4)-d-glucopyranose Chemical formula: C₃₂H₅₅NO₂₅ Molecular mass: 853,77 Da CAS No: 7578-25-8</p> <p>2'-Fucosyllactose Chemical name: α-L-Fucopyranosyl-(1\rightarrow2)-β-D-galactopyranosyl-(1\rightarrow4)-D-glucopyranose Chemical formula: C₁₈H₃₂O₁₅ Molecular mass: 488,44 Da CAS No: 41263-94-9</p> <p>Source: Genetically modified strain of <i>Escherichia coli</i> K-12 DH1</p> <p>Characteristics/Composition: Lacto-<i>N</i>-fucopentaose I and 2'-Fucosyllactose mixture (% w/w of dry matter): $\geq 75,0$ Lacto-<i>N</i>-fucopentaose I (% w/w of dry matter): 50,0 – 75,0 2'-Fucosyllactose (% w/w of dry matter): 15,0 – 35,0 Lacto-<i>N</i>-Tetraose (% w/w): $\leq 5,0$ 3-Fucosyllactose (% w/w): $\leq 1,0$</p>

	<p>D-Lactose (% w/w): ≤ 10,0</p> <p>Difucosyllactose (% w/w): ≤ 2,0</p> <p>Lacto-<i>N</i>-fucopentaose I fructose isomer (% w/w): ≤ 1,5</p> <p>2'-Fucosyl-D-lactulose (% w/w): ≤ 1,0</p> <p>Sum of L-Fucose and 2'-fucosyl-lactitol^a (% w/w): ≤ 1,0</p> <p>Sum of Lacto-<i>N</i>-fucopentaose I, 2'-Fucosyllactose, Lacto-<i>N</i>-Tetraose, Difucosyllactose, 3-Fucosyllactose, D-Lactose, L-Fucose, and 2'-fucosyl-lactitol, Lacto-<i>N</i>-fucopentaose I fructose isomer, and 2'-Fucosyl-D-lactulose (% w/w dry matter): ≥ 90,0</p> <p>Sum of other carbohydrates (% w/w): ≤ 6,0</p> <p>Moisture (% w/w): ≤ 8,0</p> <p>pH (20°C, 5% solution): 4,0 -7,0</p> <p>Ash (% w/w): ≤ 0,5</p> <p>Residual protein (% w/w): ≤ 0,01</p> <p>Heavy metals and contaminants:</p> <p>Arsenic: ≤ 0.2 mg/kg</p> <p>Cadmium: ≤ 0.1 mg/kg</p> <p>Lead: ≤ 0.02 mg/kg</p> <p>Mercury: ≤ 0.1 mg/kg</p> <p>Aflatoxin M1: ≤ 0.025 µg/kg</p> <p>Microbiological criteria:</p> <p>Total plate count: ≤ 1 000 CFU/g</p> <p>Enterobacteriaceae: Absence in 10 g</p> <p><i>Salmonella</i> spp.: Absence in 25 g</p> <p>Yeast and mould: ≤ 100 CFU/g</p> <p><i>Cronobacter</i> spp.: Absence in 10 g</p> <p><i>Listeria monocytogenes</i>: Absence in 25 g</p> <p>Presumptive <i>Bacillus cereus</i>: ≤ 50 CFU/g</p> <p>Endotoxins: ≤ 10 EU/mg</p>
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	^a L -Fucose and 2'-fucosyl-lactitol peaks on the High Performance Anion Exchange Chromatography with Pulsed Amperometric Detection (HPAEC-PAD) chromatogram overlap; CFU: Colony Forming Units; EU: Endotoxin Units
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