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.

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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
3-Fucosyllactose (‘3-FL’) (produced by a derivative strain of *E. coli* K-12 DH1)	***Specified food category***	***Maximum levels (expressed***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘3-Fucosyllactose’. The labelling of food supplements containing 3-Fucosyllactose (3-FL) 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 3-Fucosyllactose are consumed on the same		Authorised on […][*OP, 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: “Glycom A/S”, Kogle Allé 4, 2970 Hørsholm,
	Infant formula as defined under Regulation (EU) No 609/2013	1,75 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	1,75 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Unflavoured pasteurised and	2,0 g/L			

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	unflavoured sterilised (including UHT) milk products		day.		Denmark. During the period of data protection, the novel food 3-Fucosyllactose produced by a derivative strain of *E. coli* 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 "Glycom A/S". End date of the data
	Unflavoured fermented milk-based products	2,0 g/L (beverages)			
		4,0 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	2,0 g/L (beverages)			
		12,0 g/kg (products other than beverages)			
	Cereal bars	25,0 g/kg			
	Milk based drinks	2,0 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	1,25 g/L			
	Total diet replacement foods	2,0 g/L (beverages)			

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	for weight control as defined under Regulation (EU) No 609/2013	25,0 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 excluding foods for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended but in any case not higher 1,75 g/L or 1,75 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	4,0 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*]:

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Authorised novel food	Specification
3-Fucosyllactose (‘3-FL’) (produced by a derivative	**Description:** 3-Fucosyllactose (3-FL) is a purified and concentrated white to off-white powder produced by microbial fermentation and contains limited levels of D-Lactose, 3-Fucosyllactulose, and L-Fucose. **Definition:** Chemical name: β-D-Galactopyranosyl-(1→4)- [α-L-fucopyranosyl-(1→3)]- D-glucopyranose Chemical formula: $C_{18}H_{32}O_{15}$ Molecular mass: 488.44 Da CAS No: 41312-47-4 **Source:** A genetically modified strain of *Escherichia coli* K-12 DH1 **Characteristics/Composition:**

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strain of *E. coli* K-12 DH1)	3-Fucosyllactose (% of dry matter, w/w): ≥ 90,0 D-Lactose (% w/w): ≤ 5,0 3-Fucosyllactulose (% w/w): ≤ 1,5 L-Fucose (% w/w): ≤ 1,0 Sum of 3-Fucosyllactose, 3-Fucosyllactulose, D-Lactose and L-Fucose, (% w/w): ≥ 92,0 Sum of other carbohydrates (% w/w)[a]: ≤ 5,0 Moisture (% w/w): ≤ 6,0 pH (5% solution): 3,2 -7,0 Ash (% w/w): ≤ 0,5 Acetic acid[a] (% w/w): ≤ 1,0 Residual protein (% w/w): ≤ 0,01 **Heavy metals and contaminants:** Arsenic: ≤ 0.2 mg/kg Aflatoxin M1: ≤ 0.025 µg/kg **Microbiological criteria:** Total plate count: ≤ 1 000 CFU/g Enterobacteriaceae: Absence in 10 g *Salmonella* spp.: Absence in 25 g Yeast and mould: ≤ 100 CFU/g *Cronobacter* spp.: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g Presumptive *Bacillus cereus*: ≤ 50 CFU/g Endotoxins: ≤ 10 EU/mg [a] Only relevant for the novel food crystallised with acetic acid. CFU: Colony Forming Units; EU: Endotoxin Units

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