ANNEX

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

(1) In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for 2′-Fucosyllactose is replaced by the following:

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Authorised novel food	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Other requirements**
2′-Fucosyllactose	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘2′-fucosyllactose’. 2. The labelling of food supplements containing 2′-fucosyllactose shall bear a statement that the supplements should not be used if other foods with added 2′-fucosyllactose are consumed the same day. 3. The labelling of food	
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	1,2 g/l		
	Unflavoured fermented milk-based products	1,2 g/l for beverages		
		19,2 g/kg for products other than beverages		

Flavoured fermented milk-based products including heat-treated products	1,2 g/l for beverages	supplements containing 2′-fucosyllactose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added 2′-fucosyllactose are consumed the same day.	
	19,2 g/kg for products other than beverages		
Dairy analogues, including beverage whiteners	1,2 g/l for beverages		
	12 g/kg for products other than beverages		
	400 g/kg for whitener		
Cereal bars	12 g/kg		
Table-top sweeteners	200 g/kg		
Infant formula as defined under Regulation (EU) No 609/2013	3,0 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	3,64 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	12 g/kg for products other than beverages
	1,2 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer
Milk based drinks and similar products intended for young children	1,2 g/l for milk-based drinks and similar products in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
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
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	4,8 g/l for drinks
	40 g/kg for bars
Bread and pasta products bearing statements on the absence or reduced presence of gluten in	60 g/kg

accordance with the requirements of Implementing Regulation (EU) No 828/2014	
Flavoured drinks	1,2 g/l
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 mixes and instant mixes of these products	9,6 g/l — the maximum level refers to the products ready to use
Food supplements as defined in Directive 2002/46/EC, for the general population, excluding infants	3,0 g/day for general population
	1,2 g/day for young children

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(2) in Table 2 (Specifications) the entry for 2′-Fucosyllactose (microbial source) is replaced by the following:

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Specifications					**Data protection**
	Definition: Chemical name: α-L-Fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose Chemical formula: $C_{18}H_{32}O_{15}$ CAS No: 41263-94-9 Molecular weight: 488,44 g/mol				2′-Fucosyllactose produced with a genetically modified strain of Corynebacterium glutamicum ATCC 13032 authorised on 16 May 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: “Advanced Protein Technologies Corporation”, 7th Floor GyeongGi-BioCenter, 147, Gwanggyo-ro, Yeongtong-gu, Suwon-si Gyeonggi-do, 16229 South Korea. During the period of data protection, 2′-Fucosyllactose produced with a genetically modified strain of Corynebacterium glutamicum ATCC 13032 is authorised for placing on the market within the Union only by “Advanced Protein Technologies Corporation” unless
2′-Fucosyllactose (microbial source)	**Source:** Genetically modified strain of *Escherichia coli* K-12	**Source:** Genetically modified strain of *Escherichia coli* BL-21	**Source**: Genetically modified strain of *Corynebacterium glutamicum* ATCC 13032	**Source:** Genetically modified strain of *Escherichia coli* W ATCC 9637	
	(3) Description: (4) 2′-Fucosyllactose is a white to off-white powder that is produced by a microbiological process. **(5)** **(6)** **(7)**	**Description:** 2′-Fucosyllactose is a white to off white powder and the liquid concentrate (45 % ± 5 % w/v) aqueous solution is a colourless to slight yellow clear aqueous solution. 2′-Fucosyllactose is produced by a microbiological process.	**Description:** 2′-Fucosyllactose is a white to off white/ivory powder that is produced by a microbiological process.	2′-Fucosyllactose is a white to off white/ivory powder that is produced by a microbiological process.	

	(8) Purity: (9) 2′-Fucosyllactose: ≥ 83 % (10) D-Lactose: ≤ 10,0 % (11) L-Fucose: ≤ 2,0 % (12) Difucosyl-D-lactose: ≤ 5,0 % (13) 2′-Fucosyl-D-lactulose: ≤ 1,5 % (14) Sum of saccharides (2′-Fucosyllactose, D-Lactose, L-Fucose, Difucosyl-D-lactose, 2′-Fucosyl-D-lactulose): ≥ 90 % (15) pH (20 C, 5 % solution): 3,0-7,5 (16) Water: ≤ 9,0 % (17) Sulphated ash: ≤ 2,0 % (18) Acetic acid: ≤ 1,0 % (19) Residual proteins: ≤ 0,01 %	**Purity:** 2′-Fucosyllactose: ≥ 90 % Lactose: ≤ 5,0 % Fucose: ≤ 3,0 % 3-Fucosyllactose: ≤ 5,0 % Fucosylgalactose: ≤ 3,0 % Difucosyllactose: ≤ 5,0 % Glucose: ≤ 3,0 % Galactose: ≤ 3,0 % Water: ≤ 9,0 % (powder) Ash, sulphated: ≤ 0,5 % (powder and liquid) Residual proteins: ≤ 0,01 % (powder and liquid) **Heavy Metals:** Lead: ≤ 0,02 mg/kg (powder and liquid) Arsenic: ≤ 0,2 mg/kg (powder and liquid) Cadmium: ≤ 0,1 mg/kg (powder and liquid) Mercury: ≤ 0,5 mg/kg (powder and liquid) **Microbiological criteria:** Total plate count: ≤ 104 CFU/g (powder), ≤ 5 000	**Purity:** 2′-Fucosyllactose (w/w dry matter): ≥ 94,0 % D-Lactose (w/w dry matter): ≤ 3,0 % L-Fucose (w/w dry matter): ≤ 3,0 % 3-Fucosyllactose (w/w dry matter): ≤ 3,0 % Difucosyllactose (w/w dry matter): ≤ 2,0 % D-Glucose (w/w dry matter): ≤ 3,0 % D-Galactose (w/w dry matter): ≤ 3,0 % Water: ≤ 9,0 % Ash: ≤ 0,5 % Residual proteins: ≤ 0,005 % **Contaminants**: Arsenic: ≤ 0,03 mg/kg Aflatoxin M1: ≤	**Purity:** 2′-Fucosyllactose (w/w dry matter): ≥ 82,0 % D-Lactose (w/w dry matter): ≤ 5,0 % L-Fucose (w/w dry matter): ≤ 1,0 % 3-Fucosylgalactose (w/w dry matter): ≤ 3,0 % Difucosyllactose (w/w dry matter): ≤ 3,0 % Sum of D-Glucose and D-Galactose (w/w dry matter): ≤ 1,0 % Sum of other carbohydrates[a] (w/w dry matter): ≤ 8,0 % Water: ≤ 9,0 % Ash: ≤ 0,5 % Residual proteins: ≤ 0,001 % pH (5% solution, 25	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 "Advanced Protein Technologies Corporation". End date of the data protection: 16 May 2028. 2′-Fucosyllactose produced with a genetically modified strain of *Escherichia coli* W (ATCC 9637) 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: "Kyowa Hakko Bio Co., Ltd", 1-9-2, Otemachi, Choyoda-ku Tokyo, 100-0004 Japan. During the period of data

	(20) Microbiological criteria: (21) Aerobic mesophilic bacteria total count: ≤ 3 000 CFU/g (22) Yeasts: ≤ 100 CFU/g (23) Moulds: ≤ 100 CFU/g (24) Endotoxins: ≤ 10 EU/mg (25) CFU: Colony Forming Units; EU: Endotoxin Units (26)	CFU/g (liquid) Yeasts and Moulds: ≤ 100 CFU/g (powder); ≤ 50 CFU/g (liquid) Enterobacteriaceae/Coliforms: absence in 11 g (powder and liquid) Salmonella: negative/100 g (powder), negative/200 ml (liquid) Cronobacter: negative/100 g (powder), negative/200 ml (liquid) Endotoxins: ≤ 10 EU/mg (powder), ≤ 10 EU/µl (liquid) Aflatoxin M1: ≤ 0,025 µg/kg (powder and liquid) CFU: Colony Forming Units; EU: Endotoxin Units	0,025 µg/kg Ethanol: ≤ 1 000 mg/kg **Microbiological criteria**: Total plate count: ≤ 500 CFU/g Yeasts and Moulds: ≤ 100 CFU/g Enterobacteriaceae: absence in 10 g *Salmonella*: absence in 25 g *Cronobacter* spp.: absence in 10 g Endotoxins: ≤ 100 EU/g CFU: Colony Forming Units; EU: Endotoxin Units	°C): 4.5-8.5 **Contaminants**: Arsenic: ≤ 0,2 mg/kg Lead: ≤ 0,02 mg/kg Cadmium : ≤ 0,1 mg/kg Mercury : ≤ 0,1 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg **Microbiological criteria**: Total plate count: ≤ 1 000 CFU/g Yeasts and Moulds: ≤ 100 CFU/g Enterobacteriaceae: absence in 10 g *Salmonella*: absence in 25 g *Cronobacter* spp.: absence in 10 g *Listeria monocytogenes*: absence in 25 g Presumptive *Bacillus cereus* : ≤ 50 CFU/g Endotoxins: ≤ 10	protection, 2′-Fucosyllactose produced with a genetically modified strain of *Escherichia coli* W (ATCC 9637) is authorised for placing on the market within the Union only by "Kyowa Hakko Bio 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 "Kyowa Hakko Bio Co., Ltd". End date of the data protection: […][*OP please insert the date dd.mm.yyyy – after 5 years*].

	EU/mg [a] Sum of other carbohydrates = 100% w/w dry matter – 2'-FL (% w/w dry matter) – (% dry matter of quantified carbohydrates (i.e. D-lactose, L-fucose, D-glucose and D-galactose, fucosylgalactose, and difucosyllactose) – ash (% w/w dry matter). CFU: Colony Forming Units; EU: Endotoxin Units	

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