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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’-Sialyllactose (‘3’-SL’) sodium salt (produced by a derivative strain of Escherichia coli K-12 MG1655 (ATCC 700926)	***Specified food category***	***Maximum levels (expressed as 6’-Sialyllactose)***	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘3’-Sialyllactose sodium salt’. The labelling of food supplements containing 3’-Sialyllactose (3’-SL) sodium salt 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’-Sialyllactose sodium		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: “Inbiose N.V.”, Technologiepark 82, bus 41, 9052 Zwijnaarde, Belgium.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,25 g/L			
	Flavoured fermented milk-based products including heat-treated products	0,25 g/L (beverages) 0,5 g/kg (products other than beverages)			
	Unflavoured fermented milk-based products	0,25 g/L (beverages) 2,5 g/kg (products other than beverages)			
	Beverages (flavoured drinks excluding drinks, with a pH less than 5)	0,25 g/L			
	Cereal bars	2,5 g/kg			

	Infant formula as defined under Regulation (EU) No 609/2013	0,2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	salt are consumed on the same day.		During the period of data protection, the novel food 3'-Sialyllactose sodium salt 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 protection: […][*OP please insert the date dd.mm.yyyy – after 5 years*].
	Follow-on formula as defined under Regulation (EU) No 609/2013	0,15 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	0,15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 1,25 g/kg for products other than beverages			
	Milk-based drinks and similar products	0,15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	0,5 g/L (beverages) 5,0 g/kg (products other than beverages)			
	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	0,5 g/day for the general population above 3 years			

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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
3’-Sialyllactose (‘3’-SL’) sodium salt (produced by a derivative strain of Escherichia coli K-12 MG1655 (ATCC 700926)	**Definition:** Chemical formula: $C_{23}H_{38}NO_{19}Na$ Chemical (IUPAC) name: Sodium; (2S,4S,5R,6R)-5-acetamido-2-[(2R,3S,4S,5R,6S)-3,5-dihydroxy-2-(hydroxymethyl)-6-[(2R,3R,4R,5R)-4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl]oxyoxan-4-yl]oxy-4-hydroxy-6-[(1R,2R)-1,2,3-trihydroxypropyl]oxane-2-carboxylate Molecular mass: 655.53 Da Alternative chemical names: • N-Acetyl-α-D-neuraminyl-(2 → 3)-β-D-galactopyranosyl-(1 → 4)-D-glucopyranose, sodium salt • 3′-N-acetylneuraminyl-d-lactose sodium salt • α-D-Neu5Ac-(2 → 3)-β-d-Gal-(1 → 4)-D-Glc sodium salt CAS No 128596-80-5(sodium salt)/35890-38-1(acid) **Description:** 3′-Sialyllactose sodium salt is a white to off-white powder produced by microbial fermentation and subsequently retrieved, purified and concentrated. **Source:** The production strain is a genetically modified strain (*Escherichia coli* K-12 MG1655 INB-3SL_01) of the parental strain *E. coli* K-12 MG1655 (ATCC 700926) **Characteristics/Composition:** 3′-Sialyllactose sodium salt (% w/w dry matter): ≥ 88 % D-Lactose (w/w dry matter): ≤ 5.0 % Sialic acid (w/w dry matter): ≤ 5.0 % Sum of 3′-SL sodium salt, sialic acid and lactose (% w/w dry matter): ≥ 90 % 3′-Sialyllactulose (% w/w dry matter): ≤ 5.0 % Sum of other carbohydrates* (% w/w dry matter): ≤ 3.0 % Water (w/w): ≤ 8.0 %

	Protein (w/w): ≤ 0.01 % Sodium (% w/w): 2.5 - 4.5 % Chloride (% w/w): ≤ 1.0 % Total ash (% w/w): ≤ 9.0% pH (20 °C, 10% solution): 4.0 -6.5 **Contaminants** Arsenic: ≤ 0.2 mg/kg Cadmium: ≤ 0.1 mg/kg Lead: ≤ 0.05 mg/kg Mercury: ≤ 0.1 mg/kg Aflatoxin M1: ≤ 0.025 µg/kg **Microbiological criteria:** Aerobic plate count: ≤ 1000 CFU/g Yeasts and moulds: ≤ 100 CFU/g *Enterobacteriaceae*: Absence in 10 g *Salmonella* sp.: Absence in 25 g *Cronobacter* spp.: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g *Bacillus cereus*: ≤ 50 CFU/g Endotoxins: ≤ 10 EU/mg * Sum of other carbohydrates (detected by UPLC–RI and identified by direct infusion–mass spectrometry) includes sucrose,trisaccharide/GOS DP3 (galacto- oligosaccharide with a degree of polimerisation of 3), 3′-sialylated disaccharide/GOS DP2(galacto- oligosaccharide with a degree of polimerisation of 2) and 3′-sialylated lactobionic acid. CFU: Colony Forming Units; EU: Endotoxin Units

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