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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
3'-Sialyllactose (3'-SL) sodium salt (produced by a derivative strain of <i>E. coli</i> W (ATCC 9637))	<i>Specified food category</i>	<i>Maximum levels (expressed as 3'-Sialyllactose)</i>	<p>The designation of the novel food on the labelling of the foodstuffs containing it shall be '3'-Sialyllactose sodium salt'.</p> <p>The labelling of food supplements containing 3'-Sialyllactose (3'-SL) sodium salt shall bear a statement that they should not be consumed:</p> <p>a) if foods containing added 3'-Sialyllactose sodium salt are consumed on the same day;</p> <p>b) .[by children under 3 years of age</p>		<p>Authorised on [...][<i>OP</i>, please insert the date dd.mm.yyyy - 20th day following its publication].</p> <p>This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Kyowa Hakko Bio Co., Ltd, 1-9-2, Otemachi, Choyoda-ku Tokyo, 100-0004 Japan.</p>
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,25 g/L			
	Unflavoured fermented milk-based products	0,25 g/L (beverages)			
		0,5 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated 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				

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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
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 food and baby food 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

During the period of data protection, the novel food 3'-sialyllactose sodium salt produced by a derivative strain of E. 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

Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	0,5 g/L (beverages)		<i>please insert the date dd.mm.yyyy – after 5 years</i> ].
	5,0 g/kg (products other than beverages)		
Food 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, excluding food supplements for infants and young children	1,0 g/day		

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

Authorised novel food	Specification
<p><b>3'-Sialyllactose (3'-SL) sodium salt</b> (produced by a derivative strain of <i>E. coli</i> W (ATCC 9637))</p>	<p><b>Description:</b> 3'-Sialyllactose (3'-SL) sodium salt is a purified, concentrated, white to off-white powder or agglomerate that is produced by a microbial process. It contains limited levels of Sialic acid, D-Lactose, D-Glucose, 3'-Sialyllactulose, and 6'-Sialyllactose sodium salts.</p> <p><b>Source:</b> Genetically modified strain of <i>Escherichia coli</i> W (ATCC 9637)</p> <p><b>Definition:</b> Chemical formula: C<sub>23</sub>H<sub>38</sub>NO<sub>19</sub>Na Chemical name: N-Acetyl-<math>\alpha</math>-D-neuraminyl-(2→3)-<math>\beta</math>-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Molecular mass: 655.53 Da CAS No 128596-80-5</p> <p><b>Characteristics/Composition:</b> 3'-Sialyllactose sodium salt (% w/w of dry matter): <math>\geq 82,0</math> Sialic acid (% w/w of dry matter): <math>\leq 6,0</math> D-Lactose (% w/w of dry matter): <math>\leq 3,0</math> D-Glucose (% w/w of dry matter): <math>\leq 3,0</math> Sum of 3'- Sialyllactulose and 6'-Sialyllactose sodium salts (% w/w of dry matter): <math>\leq 5,0</math> Sum of other carbohydrates<sup>a</sup> (% w/w of dry matter): <math>\leq 12,0</math> Moisture (% w/w): <math>\leq 10,5</math> Sodium (% w/w): <math>\leq 5,0</math> pH (25 °C, 5% solution): 4,5 -7,5</p>

Residual protein (% w/w):  $\leq 0,01$

**Heavy metals and contaminants:**

Arsenic (mg/kg):  $\leq 0,2$

Lead (mg/kg):  $\leq 0,2$

Cadmium (mg/kg):  $\leq 0,2$

Mercury (mg/kg):  $\leq 0,1$

Aflatoxin M1:  $< 0,025$  ( $\mu\text{g}/\text{kg}$ )

**Microbiological criteria:**

Total plate count:  $\leq 1\ 000$  CFU/g

*Enterobacteriaceae*: Absence in 10 g

*Cronobacter* spp.: Absence in 10 g

*Salmonella* spp.: Absence in 25 g

Yeasts and moulds:  $\leq 100$  CFU/g

*Listeria monocytogenes*: Absence in 25 g

Presumptive *Bacillus cereus*:  $\leq 50$  CFU/g

Residual endotoxins:  $\leq 10$  EU/mg

<sup>a</sup>Sum of other carbohydrates = 100 % w/w of dry matter – 3'-Sialyllactose (acid, % w/w of dry matter) – quantified carbohydrates ((% w/w of dry matter), Sialic acid + D-Lactose + D-Glucose + (3'- Sialyllactulose and 6'-Sialyllactose (acids)) – sodium (w/w of dry matter); CFU: Colony Forming Units; EU: Endotoxin Units