

## SCHEDULE 5

Regulation 2

## Authorisation for the placing on the market of 6'-Sialyllactose (6'-SL) sodium salt (microbial source) as a novel food

1. In Table 1 (authorised novel foods), after the entry for “3'-Sialyllactose (3'-SL) sodium salt (microbial source)” (as inserted by Paragraph 1 of Schedule 4 to these Regulations), insert the following entry—

<b>“6'-Sialyllactose (6'-SL) sodium salt (microbial source)”</b>	<i>Specified food category</i>	<i>Maximum levels (expressed as 6'-Sialyllactose)</i>	The designation of the novel food on the labelling of the foodstuffs containing it is “6'-Sialyllactose sodium salt”.	Included in the list on 30 June 2022.  This inclusion is authorised based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.  Applicant: Glycom A/S, Kogle Alle 4, DK-2970 Horsholm, Denmark.  During the period of data protection, 6'-Sialyllactose sodium salt is authorised for placing on the market within Wales 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.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/L	The labelling of food supplements containing 6'-Sialyllactose sodium salt must bear a statement that they should not be consumed:	
	Unflavoured fermented milk-based products	0.5 g/L (beverages) 2.5 g/kg (products other than beverages)	a) if foods containing added 6'-Sialyllactose sodium salt are consumed the same day;	
	Flavoured fermented milk-based products including heat-treated products	0.5 g/L (beverages) 5.0 g/kg (products other than beverages)	b) by infants and young children.	
	Beverages (flavoured drinks, excluding drinks with a PH less than 5)	0.5 g/L		
	Cereal bars	5.0 g/kg		
	Infant formula as defined in Regulation (EU) No 609/2013	0.4 g/L in the final product ready for use, marketed as such or reconstituted		

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	as instructed by the manufacturer	The data protection ends at the end of 29 June 2027."
Follow-on formula as defined in Regulation (EU) No 609/2013	0.3 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 in Regulation (EU) No 609/2013	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer  2.5 g/kg (products other than beverages)	
Milk based drinks and similar products intended for young children	0.3 g/L 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 in Regulation (EU) No 609/2013	1.0 g/L (beverages)  10.0 g/kg (products other than beverages)	
Food for special medical	In accordance with the	

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<p>purposes as defined under Regulation (EU) No 609/2013</p>	<p>particular nutritional requirements of the persons for whom the products are intended</p>			
<p>Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children</p>	<p>1.0 g/day”</p>			

2. In Table 2 (specifications), after the entry for “3’-Sialyllactose (3’-SL) sodium salt (microbial source)” (as inserted by Paragraph 2 of Schedule 4 to these Regulations), insert the following entry—

<p><b>“6’-Sialyllactose (6’-SL) sodium salt (microbial source)</b></p>	<p><b>Description:</b></p> <p>6’-Sialyllactose (6’-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 6’-sialyl-lactulose, and sialic acid</p> <p><b>Source:</b></p> <p>Genetically modified strain of <i>Escherichia coli</i> K-12 DH1</p> <p><b>Definition:</b></p> <p>Chemical formula: C<sub>23</sub>H<sub>38</sub>NO<sub>19</sub>Na</p> <p>Chemical name: N-Acetyl-<math>\alpha</math>-D-neuraminyl-(2→6)-<math>\beta</math>-D-galactopyranosyl-(1→4)-D-glucose, sodium salt</p> <p>Molecular mass: 655.53 Da</p> <p>CAS No 157574-76-0</p> <p><b>Characteristics/Composition:</b></p> <p>Appearance: White to off-white powder or agglomerate</p>
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Sum of 6'-Sialyllactose sodium salt, D-Lactose and Sialic acid (% of dry matter):  $\geq 94.0$  % (w/w)

6'-Sialyllactose sodium salt (% of dry matter):  $\geq 90.0$  % (w/w)

D-Lactose:  $\leq 5.0$  % (w/w)

Sialic acid:  $\leq 2.0$  % (w/w)

6'-Sialyl-lactulose:  $\leq 3.0$  % (w/w)

Sum of other carbohydrates:  $\leq 3.0$  % (w/w)

Moisture:  $\leq 6.0$  % (w/w)

Sodium: 2.5-4.5 % (w/w)

Chloride:  $\leq 1.0$  % (w/w)

pH (20 °C, 5 % solution): 4.5-6.0

Residual protein:  $\leq 0.01$  % (w/w)

**Microbiological criteria:**

Aerobic mesophilic bacteria total plate count:  $\leq 1\ 000$  CFU/g

*Enterobacteriaceae*:  $\leq 10$  CFU/g

*Salmonella* sp.: Absence in 25 g

Yeast:  $\leq 100$  CFU/g

Mould:  $\leq 100$  CFU/g

Residual endotoxins:  $\leq 10$  EU/mg

CFU: Colony Forming Units; EU: Endotoxin Units.""