

## SCHEDULE 4

Regulation 3

## Authorisation of 3'Sialyllactose (3'-SL) sodium salt (microbial source)

1. In Table 1 (authorised novel foods), after the entry for Selenium-containing yeast (*Yarrowia lipolytica*) biomass insert the following entry—

"3'-Sialyllactose (3'-SL) sodium salt (microbial source)	Specified food category	Maximum levels (expressed as 3'-Sialyllactose)	The designation of the novel food on the labelling of the foodstuffs containing it is "3'-Sialyllactose sodium salt".	Included in the list on 30 June 2022.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.25 g/L		This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Flavoured fermented milk-based products including heat-treated products	0.25 g/L (beverages)	The labelling of food supplements containing 3'-Sialyllactose sodium salt must bear a statement that they should not be consumed:	
	Unflavoured fermented milk-based products	0.25 g/L (beverages) 0.5 g/kg (products other than beverages)	a) if foods containing added 3'-Sialyllactose sodium salt are consumed the same day,	During the period of data protection, the novel food 3'-sialyllactose sodium salt is authorised for placing on the market within Scotland only by Glycom A/S, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.25 g/L	b) by infants and young children.	
	Cereal bars	2.5 g/kg		
	Infant formula as defined in Regulation (EU) 609/2013	0.2 g/L in the final product ready for use, marketed as such or		

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<p>Follow-on formula as defined in Regulation (EU) 609/2013</p>	<p>reconstituted as instructed by the manufacturer</p> <p>0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</p>	<p>scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S.</p>
<p>Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) 609/2013</p>	<p>0.15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</p>	<p>The data protection will expire at the end of 29 June 2027.</p>
<p>Milk-based drinks and similar products intended for young children</p>	<p>1.25 g/kg for products other than beverages</p> <p>0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</p>	
<p>Total diet replacement foods for weight control as defined in Regulation (EU) 609/2013</p>	<p>0.5 g/L (beverages)</p> <p>5 g/kg (products other than beverages)</p>	
<p>Food for special medical purposes as defined in</p>	<p>In accordance with the particular nutritional requirements</p>	

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	<p>Regulation (EU) 609/2013</p> <p>Food supplements as defined in the Food Supplements (Scotland) Regulations 2003, excluding food supplements for infants and young children</p>	<p>of the persons for whom the products are intended</p> <p>0.5 g/day.”</p>			
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2. In Table 2 (specifications), after the entry for Selenium-containing yeast (*Yarrowia lipolytica*) biomass insert the following entry—

<p><b>3'-Sialyllactose (3'-SL) sodium salt (microbial source)</b></p>	<p><b>Description:</b></p> <p>3'-Sialyllactose (3'-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, 3'-sialyl-lactulose, and sialic acid.</p> <p><b>Source:</b> 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→3)-<math>\beta</math>-D-galactopyranosyl-(1→4)-D-glucose, sodium salt</p> <p>Molecular mass: 655.53 Da</p> <p>CAS No 128596-80-5</p> <p><b>Characteristics/Composition:</b></p> <p>Appearance: White to off-white powder or agglomerate</p> <p>Sum of 3'-Sialyllactose sodium salt, D-Lactose, and Sialic acid (% of dry matter): <math>\geq 90.0</math> % (w/w)</p> <p>3'-Sialyllactose sodium salt (% of dry matter): <math>\geq 88.0</math> % (w/w)</p> <p>D-Lactose: <math>\leq 5.0</math> % (w/w)</p> <p>Sialic acid: <math>\leq 1.5</math> % (w/w)</p> <p>3'-Sialyl-lactulose: <math>\leq 5.0</math> % (w/w)</p>
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Sum of other carbohydrates:  $\leq 3.0$  % (w/w)

Moisture:  $\leq 8.0$  % (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:  $\leq 1000$  CFU/g

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

*Salmonellasp.*: 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”