SCHEDULE 4 Regulation 2

Authorisation for the placing on the market of 3'-Sialyllactose (3'-SL) sodium salt (microbial source) as a novel food

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". The labelling of food supplements containing 3'-Sialyllactose sodium salt must bear a statement that they should not be consumed: a) if foods containing added 3'-Sialyllactose sodium salt are consumed the same day; b) by infants and young children.		Included in the list on 30 June 2022. This inclusion is 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, 3'-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 sterilised (including UHT) milk products	0.25 g/L unflavoured			
	Flavoured fermented milk-based products including heat-treated products	0.25 g/L (beverages) 2.5g/kg (products other than beverages)			
	Unflavoured fermented milk-based products	0.25 g/L (beverages) 0.5 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 in 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 in 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		The data protection ends at the end of 29 June 2027."
	Processed cereal-based food and baby food for infants and young children as defined in 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 (products other than beverages)		
	Milk-based drinks and similar products intended for young children	0.15 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	0.5 g/L (beverages) 5g/kg (products other than beverages)		
	Food for special medical purposes as defined in	In accordance with the particular nutritional		

	Regulation (EU) No 609/2013	requirements of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children	0.5 g/day”			

2. In Table 2 (specifications), after the entry for “Selenium-containing yeast (*Yarrowia lipolytica*) biomass” insert the following entry—

“**"3’-Sialyllactose (3’-SL) sodium salt (microbial source)**	**Description:** 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 **Source:** Genetically modified strain of*Escherichia coli* K-12 DH1 **Definition:** Chemical formula: $C_{23}H_{38}NO_{19}Na$ Chemical name: N-Acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-Dglucose, sodium salt Molecular mass: 655.53 Da CAS No 128596-80-5 **Characteristics/Composition:** Appearance: White to off-white powder or agglomerate Sum of 3’-Sialyllactose sodium salt, D-Lactose, and Sialic acid (% of dry matter): ≥ 90.0 % (w/w)

	3’-Sialyllactose sodium salt (% of dry matter): ≥ 88.0 % (w/w) D-Lactose: ≤ 5.0 % (w/w) Sialic acid: ≤ 1.5 % (w/w) 3’-Sialyl-lactulose: ≤ 5.0 % (w/w) Sum of other carbohydrates: ≤ 3.0 % (w/w) Moisture: ≤ 8.0 % (w/w) Sodium: 2.5 – 4.5 % (w/w) Chloride: ≤ 1.0 % (w/w) pH (20 °C, 5 % solution): 4.5 -6.0 Residual protein: ≤ 0.01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g *Enterobacteriaceae*: ≤ 10 CFU/g *Salmonella* sp.: Absence in 25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units."”