SCHEDULE 6

Regulation 6

Amendments to the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of 3-fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1) as a novel food

1. In Commission Implementing Regulation (EU) 2017/2470, the Annex (list of novel foods) is amended as follows.

2. In Table 1 (authorised novel foods), after the entry for "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)" insert the following entry—

"**3-Fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1)**	*Specified food category* Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products Unflavoured fermented milk-based products Flavoured fermented milk-based products including heat-treated products Cereal bars Infant formula and follow-on formula as defined in Regulation (EU) No609/2013(**1**) Milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months)) Food for special medical purposes	*Maximum levels* 2.0 g/l 2.0 g/l (beverages) 4.0 g/kg (products other than beverages) 2.0 g/l (beverages) 12.0 g/kg (products other than beverages) 25.0 g/kg 2.0 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 2.0 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	The designation of the novel food on the labelling of food containing it is "3-fucosyllactose". The labelling of food supplements intended for infants and young children must bear a statement that they should not be consumed if breast milk or food with added 3-fucosyllactose is consumed on the same day.	Included in the list on 28 June 2024. 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 Allé 4, 2970 Hørsholm, Denmark. During the period of data protection, 3-fucosyllactose 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

(**1**) EUR 2013/609, amended by S.I. 2019/651, 2023/28. S.I. 2019/651 was amended by S.I. 2020/1476, 2023/28.

	as defined in Regulation (EU) No609/2013 Total diet replacement for weight control as defined in Regulation (EU) No609/2013 Flavoured drinks (excluding cola flavour and cola flavoured drinks) Food supplements as defined in the Food Supplements (Wales) Regulations 2003 intended for infants (persons under the age of 1 year (12 months)) and young children (persons aged 1 year (12 months) up to the age of 3 years (36 months)) Food supplements as defined in the Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and young children	12.0 g/kg (products other than beverages) In accordance with the particular nutritional requirements of the persons for whom the products are intended 2.0 g/l (beverages) 25.0 g/kg (products other than beverages) 1.25 g/l 2.0 g/day 4.0 g/day		scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S. The data protection will expire at the end of 27 June 2029.”

3. In Table 2 (specifications), after the entry for “2’-Fucosyllactose/Difucosyllactose mixture (‘2’-FL/DFL’) (microbial source)” insert the following entry—

“**3-Fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1)**	**Description/Definition** 3-Fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1) is a purified carbohydrate powder or agglomerate containing at least 90% of 3-fucosyllactose on a dry

matter basis obtained from microbial fermentation with a genetically modified strain of *Escherichia coli* K-12 DH1.

Chemical name: β-D-Galactopyranosyl-(1→4)- [α-L-fucopyranosyl-(1→3)]- D-glucopyranose

Chemical formula: $C_{18}H_{32}O_{15}$

Molecular mass: 488.44 Da

CAS No: 41312-47-4

Characteristics/Composition

Appearance: Powder, agglomerates, powder with agglomerates

Colour: White to off-white

Assay (water-free) – Specified saccharides (includes 3-FL, D-lactose, L-fucose, and 3-fucosyllactulose): ≥ 92.0 % (w/w)

Assay (water-free) – 3-FL: ≥ 90.0 % (w/w)

L-Fucose: ≤ 1.0 % (w/w)

D-Lactose: ≤ 5.0 % (w/w)

3-Fucosyllactulose: ≤ 1.5 % (w/w)

Sum of other carbohydrates: ≤ 5.0 % (w/w)

pH in 5% solution (20°C): 3.2 – 7.0

Water: ≤ 6.0 % (w/w)

Ash, sulphated: ≤ 0.5 % (w/w)

Acetic acid (relevant for crystallised 3-FL): ≤ 1.0 % (w/w)

Residual protein by Bradford assay: ≤ 0.01 % (w/w)

Residual endotoxins: ≤ 10 EU/mg

Heavy metals

Lead: ≤ 0.1 mg/kg

Arsenic: ≤ 0.2 mg/kg

Mycotoxins

Aflatoxin M1: ≤ 0.025 µg/kg

	Microbiological criteria Aerobic mesophilic total plate count: ≤ 1000 CFU/g Enterobacteriaceae: absent in 10g *Salmonella* spp.: absent in 25g *Bacillus cereus*: ≤ 50 CFU/g *Listeria monocytogenes*: absent in 25g *Cronobacter* spp.: absent in 10g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g EU: Endotoxin Units CFU: Colony Forming Units”.