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SCHEDULE 6

Regulation 5

Amendments to the Annex (domestic list of novel foods authorised to be placed on the market within Great Britain) 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 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 <i>Escherichia coli</i> K-12 DH1)	Specified food category	Maximum levels	The designation of the novel food on the labelling of food containing it is '3-fucosyllactose'.	Included in the list on 28 June 2024.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	2.0 g/L	The labelling of food supplements 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.	This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Unflavoured fermented milk-based products	2.0 g/L (beverages)		
		4.0 g/kg (products other than beverages)		
	Flavoured fermented milk-based products including heat-treated products	2.0 g/L (beverages)		
		12.0 g/kg (products other than beverages)		
	Cereal bars	25.0 g/kg		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	2.0 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
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))	2.0 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	12.0 g/kg (products other than beverages)			

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	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		Regulation (EU) 2015/2283 or with the agreement of Glycom A/S. The data protection will expire at the end of 27 June 2029.”
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	2.0 g/L (beverages) 25.0 g/kg (products other than beverages)		
	Flavoured drinks (excluding cola flavour and cola flavoured drinks)	1.25 g/L		
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003, 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))	2.0 g/day		
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 excluding food supplements for infants and young children	4.0 g/day		

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

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<p>“3-Fucosyllactose (3-FL) (produced by a derivative strain of <i>Escherichia coli</i> K-12 DH1)</p>	<p>Description/Definition:</p>
	<p>3-Fucosyllactose (3-FL) (produced by a derivative strain of <i>Escherichia coli</i> 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 <i>Escherichia coli</i> K-12 DH1.</p> <p>Chemical name: β-D-Galactopyranosyl-(1\rightarrow4)- [α-L-fucopyranosyl-(1\rightarrow3)]- D-glucopyranose</p> <p>Chemical formula: C₁₈H₃₂O₁₅</p> <p>Molecular mass: 488.44 Da</p> <p>CAS No: 41312-47-4</p> <p>Characteristics/Composition:</p> <p>Appearance: Powder, agglomerates, powder with agglomerates</p> <p>Colour: White to off-white</p> <p>Assay (water free) – Specified saccharides (includes 3-FL, D-lactose, L-fucose and 3-fucosyllactose): ≥ 92.0 w/w %</p> <p>Assay (water free) – 3-FL: ≥ 90.0 w/w %</p> <p>L-Fucose: ≤ 1.0 w/w %</p> <p>D-Lactose: ≤ 5.0 w/w %</p> <p>3-Fucosyllactulose: ≤ 1.5 w/w %</p> <p>Sum of other carbohydrates: ≤ 5.0 w/w %</p> <p>pH in 5% solution (20°C): 3.2–7.0</p> <p>Water: ≤ 6.0 w/w%</p> <p>Ash, sulphated: ≤ 0.5 w/w %</p> <p>Acetic acid (relevant only for crystallised 3-FL) : ≤ 1.0 w/w %</p> <p>Residual protein by Bradford assay: ≤ 0.01 w/w %</p> <p>Residual endotoxins: ≤ 10 EU/mg</p> <p>Heavy metals:</p>

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<p>“3-Fucosyllactose (3-FL) (produced by a derivative strain of <i>Escherichia coli</i> K-12 DH1)</p>	<p>Description/Definition:</p>
	<p>Lead: ≤ 0.1 mg/kg</p> <p>Arsenic: ≤ 0.2 mg/kg</p> <p>Mycotoxins:</p> <p>Aflatoxin M1: ≤ 0.025 µg/kg</p> <p>Microbiological criteria:</p> <p>Aerobic mesophilic total plate count: ≤ 1000 CFU/g</p> <p>Enterobacteriaceae: absent in 10g</p> <p><i>Salmonella</i> spp: absent in 25g</p> <p><i>Bacillus cereus</i>: ≤ 50 CFU/g</p> <p><i>Listeria monocytogenes</i>: absent in 25g</p> <p><i>Cronobacter</i> spp.: absent in 10g</p> <p>Yeasts: ≤ 100 CFU/g</p> <p>Moulds: ≤ 100 CFU/g</p> <p>EU: Endotoxin Units</p> <p>CFU: Colony Forming Units”.</p>