

## SCHEDULE 6

Regulation 6(2)(d)

Insertion of entry in Table 1 in the Annex to Commission Implementing Regulation (EU) 2017/2470 for 3-Fucosyllactose (produced by a derivative strain of *Escherichia coli* K-12 DH1)

“3-Fucosyllactose (3-FL)	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of food containing it is “3-fucosyllactose”.	Included in the list on 28 June 2024.
(produced by a derivative strain of <i>Escherichia coli</i> K-12 DH1)	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	2.0 g/l 2.0 g/l (beverages)	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	4.0 g/kg (products other than beverages)		Applicant: Glycom A/S, Kogle Allé 4, 2970 Hørsholm, Denmark.
	Flavoured fermented milk-based products including heat-treated products	2.0 g/l (beverages)		
	Cereal bars	12.0 g/kg (products other than beverages)		
	Infant formula and follow-on formula as defined in <a href="#">Regulation (EU) No. 609/2013</a>	25.0 g/kg		During the period of data protection, 3-fucosyllactose is authorised for placing on the market, within England, 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
	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 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Foods for special medical purposes as defined in <a href="#">Regulation (EU) No. 609/2013</a>	2.0 g/l (beverages) in the final product ready for use,		
	Total diet replacement for weight control as defined in <a href="#">Regulation (EU) No. 609/2013</a>	marketed as such or reconstituted as instructed by the manufacturer		
	Flavoured drinks (excluding cola			

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

flavour and cola flavoured drinks)	12 g/kg (products other than beverages)	agreement of Glycom A/S.
Food supplements as defined in the Food Supplements (England) 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))	In accordance with the particular nutritional requirements of the persons for whom the products are intended.	The data protection will expire at the end of 27 June 2029.”
Food supplements as defined in the Food Supplements (England) Regulations 2003 excluding food supplements for infants and young children	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	

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