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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2210

of 20 October 2023

authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* K-12 DH1 as a novel food and amending Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

(OJ L 2210, 23.10.2023, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Implementing Regulation (EU) 2025/1549 of 30 July 2025	L 1549	1	31.7.2025

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(Text with EEA relevance)

Article 1

1. 3-Fucosyllactose produced with a derivative strain of *E. coli* K-12 DH1 is authorised to be placed on the market within the Union.

3-Fucosyllactose produced with a derivative strain of *E. coli* K-12 DH1 shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the company Glycom A/S [1] is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from 12 November 2023, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Glycom A/S.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Glycom A/S.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

[1] Address: Kogle Allé 4, 2970 Hørsholm, Denmark.

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ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

▼M1

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
‘**3-Fucosyllactose (“3-FL”) (produced by derivative strain of *E. coli* K-12 DH1)**	*Specified food category*	*Maximum levels (expressed as 3-Fucosyllactose)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be “3-Fucosyllactose”. The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added 3-Fucosyllactose are consumed on the same day.		Authorised on 12 November 2023. 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, the novel food 3-Fucosyllactose produced by derivative strain of *E. coli* K-12 DH1 is authorised for placing on the market within the Union 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”. End date of the data protection: 12 November 2028.’
	Infant formula as defined under Regulation (EU) No 609/2013	1,75 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	1,75 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	2,0 g/L			
	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)			

▼M1

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	Cereal bars	25,0 g/kg			
	Milk based drinks and similar products	2,0 g/L 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)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	1,25 g/L			
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	2,0 g/L (beverages)			
		25,0 g/kg (products other than beverages)			
	Foods for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended but, in any case, not higher 1,75 g/L or 1,75 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			

▼M1

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended but, in any case, not higher 4,0 g/L or 4,0 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	4,0 g/day			

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(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order:

Authorised novel food	Specification
‘**3-Fucosyllactose (“3-FL”) (produced by derivative strain of *E. coli* K-12 DH1)**	**Description:** 3-Fucosyllactose (3-FL) is a purified and concentrated white to off-white powder produced by microbial fermentation and contains limited levels of D-Lactose, 3-Fucosyllactulose, and L-Fucose. **Definition:** 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 **Source:** Genetically modified strain of *Escherichia coli* K-12 DH1 **Characteristics/Composition:** 3-Fucosyllactose (% w/w of dry matter): ≥ 90,0 D-Lactose (% w/w): ≤ 5,0 3-Fucosyllactulose (% w/w): ≤ 1,5

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Authorised novel food	Specification
	L-Fucose (% w/w): ≤ 1,0 Sum of 3-Fucosyllactose, 3-Fucosyllactulose, D-Lactose and L-Fucose, (% w/w dry matter): ≥ 92,0 Sum of other carbohydrates (% w/w): ≤ 5,0 Moisture (% w/w): ≤ 6,0 pH (20 °C, 5 % solution): 3,2 -7,0 Ash (% w/w): ≤ 0,5 Acetic acid (% w/w): ≤ 1,0 Residual protein (% w/w): ≤ 0,01 **Heavy metals and contaminants:** Arsenic: ≤ 0,2 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg **Microbiological criteria:** Total plate count: ≤ 1 000 CFU/g Enterobacteriaceae: Absence in 10 g *Salmonella* spp.: Absence in 25 g Yeast and mould: ≤ 100 CFU/g *Cronobacter* spp.: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g Presumptive *Bacillus cereus*: ≤ 50 CFU/g Endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units’