COMMISSION IMPLEMENTING REGULATION (EU) 2019/1979

of 26 November 2019

authorising the placing on the market of 2'-Fucosyllactose/Difucosyllactose mixture as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 ([1]), and in particular Article 12 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283 Commission Implementing Regulation (EU) 2017/2470 ([2]) was adopted, which establishes a Union list of authorised novel foods.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on updating the Union list.

(4) On 30 April 2018, the company Glycom A/S ('the Applicant') made a request to the Commission within the meaning of Article 10(1) of Regulation (EU) 2015/2283 to place 2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL'), obtained by microbial fermentation with a genetically modified strain of *Escherichia coli* strain K12 DH1, on the Union market as a novel food. The Applicant requested for 2'-FL/DFL to be used in unflavoured pasteurised and unflavoured sterilised milk products, flavoured and unflavoured fermented milk based products including heat-treated products, cereal bars, flavoured drinks, infant formula and follow-on formula and processed cereal-based food and baby food for infants and young children, foods for special medical purposes, and total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]), and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([4]) intended for the general population excluding infants.

([1]) OJ L 327, 11.12.2015, p. 1.

([2]) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

([3]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

([4]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

(5) On 30 April 2018, the Applicant also made a request to the Commission for protection of proprietary data for a number of studies submitted in support of the application, namely, the proprietary analytical reports on the structure comparison via nuclear magnetic resonance ('NMR') of 2'-fucosyllactose and of difucosyllactose produced by bacterial fermentation with 2'-fucosyllactose and difucosyllactose naturally present in human milk ([5]), the detailed characterisation data on the production bacterial strains and their certificates ([6]), ([7]), the specifications for the raw materials and processing aids ([8]), the certificates of analyses of the various 2'-FL/DFL batches ([9]), the analytical methods and validation reports ([10]), the 2'-FL/DFL stability reports ([11]), the laboratory accreditation certificates ([12]), the 2'-FL/DFL intake assessment reports ([13]), the summary table of the statistically significant observations in the toxicity studies ([14]), a bacterial reverse mutation test with 2'-FL/DFL ([15]), an *in vitro* mammalian cell micronucleus test with 2'-FL/DFL ([16]), a 14-day oral toxicity study in the neonatal rat with 2'-FL/DFL ([17]), a 90-day oral toxicity study in the neonatal rat with 2'-FL/DFL ([18]), a bacterial reverse mutation test with 2'-Fucosyllactose ('2'-FL') ([19]) two *in vitro* mammalian cell micronucleus tests with 2'-FL ([20]), ([21]), and a 90-day oral toxicity study in the neonatal rat with 2'-FL ([22]).

(6) On 29 June 2018, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of 2'-FL/DFL as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(7) On 15 May 2019, the Authority adopted its scientific opinion 'Safety of 2'-Fucosyllactose/Difucosyllactose mixture as a novel food pursuant to Regulation (EU) 2015/2283' ([23]). That scientific opinion is in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.

(8) In its opinion, the Authority concluded that 2'-FL/DFL is safe under the proposed conditions of use for the proposed target population. Therefore that scientific opinion gives sufficient grounds to establish that 2'-FL/DFL, when used in unflavoured pasteurised and unflavoured sterilised milk products, flavoured and unflavoured fermented milk based products including heat treated products, cereal bars, flavoured drinks, infant formula and follow-on formula and processed cereal-based food and baby food for infants and young children, foods for special medical purposes, and total diet replacement foods for weight control, and in food supplements intended for the general population, excluding infants, complies with the requirements of Article 12(1) of Regulation (EU) 2015/2283.

(9) In its opinion, the Authority considered that the data from the analytical NMR reports on the structure comparison of 2'-fucosyllactose and of difucosyllactose produced by bacterial fermentation with 2'-fucosyllactose and difucosyllactose naturally present in human milk, the detailed characterisation data on the production bacterial strains, the specifications for the raw materials and processing aids, the certificates of analyses of the various 2'-FL/DFL batches, the bacterial reverse mutation test with 2'-FL/DFL, the *in vitro* mammalian cell micronucleus test with 2'-FL/DFL, the 90-day oral toxicity study in the neonatal rat with 2'-FL/DFL, and the summary table of the statistically significant observations in the 90-day toxicity study, served as a basis to establish the safety of the novel food. Therefore, it is considered that the conclusions on the safety of 2'-FL/DFL could not have been reached without the data from the reports of these studies.

([5]) Glycom 2018 (unpublished).
([6]) Glycom 2018 (unpublished).
([7]) Glycom/DSMZ 2018 (unpublished).
([8]) Glycom 2018 (unpublished).
([9]) Glycom 2018 (unpublished).
([10]) Glycom 2018 (unpublished).
([11]) Glycom 2018 (unpublished).
([12]) Glycom 2018 (unpublished).
([13]) Glycom 2018 (unpublished).
([14]) Flaxmer 2018 (unpublished) and Philips K. R., N. Baldwin, B. Lynch, J. Flaxmer, A. Šoltésová, M. H. Mikš, C. H. Röhrig. 2018. Safety evaluation of the human-identical milk oligosaccharides 2'-fucosyllactose and difucosyllactose. Food and Chemical Toxicology 120:552-565.
([15]) Šoltésová, 2017 (unpublished) and Philips et al. 2018. Food and Chemical Toxicology 120:552-565.
([16]) Gilby 2017 (unpublished) and Philips et al. 2018. Food and Chemical Toxicology 120:552-565.
([17]) Flaxmer 2017 (unpublished) and Philips et al. 2018. Food and Chemical Toxicology 120:552-565.
([18]) Flaxmer 2018 (unpublished) and Philips et al. 2018. Food and Chemical Toxicology 120:552-565.
([19]) Verspeek-Rip 2015 (unpublished).
([20]) Verbaan 2015a (unpublished).
([21]) Verbaan 2015b (unpublished).
([22]) Penard 2015 (unpublished).
([23]) EFSA Journal 2019;17(6):5717.

(10) Following the receipt of the Authority's considerations, the Commission requested the Applicant to further clarify the justification provided with regard to their proprietary analytical NMR reports on the structure comparison of 2'-fucosyllactose and of difucosyllactose produced by bacterial fermentation with 2'-fucosyllactose and difucosyllactose naturally present in human milk, the detailed characterisation data on the production bacterial strains, the specifications for the raw materials and processing aids, the certificates of analyses of the various 2'-FL/DFL batches, the bacterial reverse mutation test with 2'-FL/DFL, the *in vitro* mammalian cell micronucleus test with 2'-FL/DFL, the 90-day oral toxicity study in the neonatal rat with 2'-FL/DFL, and the summary table of the statistically significant observations in the 90-day toxicity study, and to clarify their claim to an exclusive right of reference to those reports and studies, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.

(11) The Applicant declared that, at the time the application was made, they held proprietary and exclusive rights of reference to the studies under national law and that therefore third parties could not lawfully access or use these studies.

(12) The Commission assessed all the information provided by the Applicant and considered that the Applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore the data from the studies contained in the Applicant's file which served as a basis for the Authority to establish the safety of the novel food and to reach its conclusions on the safety of 2'-FL/DFL, and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of 2'-FL/DFL should be restricted to the Applicant for that period.

(13) However, restricting the authorisation of 2'-FL/DFL and of the reference to the studies contained in the Applicant's file for the sole use of the Applicant, does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such authorisation under Regulation (EU) 2015/2283.

(14) The use of 2'-FL/DFL should be authorised without prejudice to Regulation (EU) No 609/2013 laying down requirements on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.

(15) The use of 2'-FL/DFL should also be authorised without prejudice to Directive 2002/46/EC laying down requirements on food supplements.

(16) The use of 2'-FL/DFL should be authorised without prejudice to Regulation (EU) No 1308/2013 of the European Parliament and Council of 17 December 2013 establishing a common organisation of the markets in agricultural products ([24]) laying down requirements for agricultural products, in particular on milk and milk products.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. 2'-FL/DFL as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of five years from the date of entry into force of this Regulation only the initial Applicant:

Company: Glycom A/S;
Address: Kogle Allé 4, DK-2970 Hørsholm, Denmark,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 to this Regulation or with the agreement of Glycom A/S.

([24]) OJ L 347, 20.12.2013, p. 671.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

4. The authorisation provided for in this Article shall be without prejudice to the provisions of Regulation (EU) No 609/2013, of Directive 2002/46/EC, and Regulation (EU) No 1308/2013.

Article 2

The studies and reports contained in the application file on the basis of which 2'-FL/DFL has been assessed by the Authority, claimed by the Applicant as fulfilling the requirements laid down in Article 26(2) of Regulation (EC) 2015/2283, shall not be used for the benefit of any 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 3

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

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.

Done at Brussels, 26 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

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:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)	**Specified food category**	**Maximum levels**	The designation of the novel food on the labelling of the foodstuffs containing it shall be "2'-Fucosyllactose/Difucosyllactose mixture". The labelling of food supplements containing the 2'-Fucosyllactose/Difucosyllactose mixture shall bear a statement that they should not be used if breast milk or other foods containing added 2'-Fucosyllactose and/or Difucosyllactose are consumed the same day.		Authorised on 19.12.2019. 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, DK-2970 Hørsholm, Denmark. During the period of data protection, the novel food 2'-Fucosyllactose/Difucosyllactose mixture 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: 19.12.2024.'
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	2,0 g/L			
	Unflavoured fermented milk-based products	2,0 g/L (beverages) 20 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	2,0 g/L (beverages) 20 g/kg (products other than beverages)			
	Beverages (flavoured drinks)	2,0 g/L			
	Cereal bars	20 g/kg			
	Infant formula as defined under Regulation (EU) No 609/2013	1,6 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	1,2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based food and baby food for infants and young children as defined under Regulation (EU) No 609/2013	1,2 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
		10 g/kg for products other than beverages			
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	4,0 g/L (beverages) 40 g/kg (products other than beverages)			
	Food for special medical purposes as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food Supplements as defined in Directive 2002/46/EC intended for the general population excluding infants	4,0 g/day			

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

Authorised Novel Food	Specification
'2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)	**Description/Definition:** 2'-Fucosyllactose/Difucosyllactose mixture is a purified, white to off-white amorphous powder that is produced by a microbial process. After purification, the 2'-Fucosyllactose/Difucosyllactose mixture is isolated by spray drying. **Source:** Genetically modified strain of Escherichia coli strain K-12 DH1 **Characteristics/Composition** Appearance: White to off white powder or agglomerates Sum of 2'-Fucosyllactose, Difucosyllactose, Lactose and Fucose (% of dry matter): ≥ 92,0 % (w/w) Sum of 2'-fucosyllactose and difucosyllactose (% of dry matter): ≥ 85,0 % (w/w) 2'-Fucosyllactose (% of dry matter): ≥ 75,0 % (w/w) Difucosyllactose (% of dry matter): ≥ 5,0 % (w/w) D-Lactose: ≤ 10,0 % (w/w) L-Fucose: ≤ 1,0 % (w/w) 2'-Fucosyl-D-lactulose: ≤ 2,0 % (w/w) Sum of other carbohydrates (*): ≤ 6,0 % (w/w)

Authorised Novel Food	Specification
	Moisture: ≤ 6,0 % (w/w) Ash, sulfated: ≤ 0,8 % (w/w) pH (20 °C, 5 % solution): 4,0-6,0 Residual protein: ≤ 0,01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g *Enterobacteriaceae*: ≤ 10 CFU/g *Salmonella* sp.: Negative/25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units

(*) 3'-Fucosyllactose, 2'-Fucosyl-galactose, Glucose, Galactose, Mannitol, Sorbitol, Galactitol, Trihexose, Allo-lactose and other structurally related carbohydrates.'