

COMMISSION IMPLEMENTING REGULATION (EU) 2021/50**of 22 January 2021****authorising an extension of use and a change in the specifications of the novel food '2'-fucosyllactose/difucosyllactose mixture' and amending 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⁾ which establishes a Union list of authorised novel foods was adopted.
- (3) Commission Implementing Regulation (EU) 2019/1979 ⁽³⁾ authorised, in accordance with Regulation (EU) 2015/2283, the placing on the market of microbial source 2'-fucosyllactose/difucosyllactose mixture ('2'-FL/DFL') as a novel food. Therefore, 2'-FL/DFL was included in the Union list of novel foods.
- (4) On 17 March 2020, the company Glycom A/S ('the applicant') submitted an application to the Commission to extend the use and to change the specifications of 2'-FL/DFL in accordance with Article 10(1) of Regulation (EU) 2015/2283. The applicant requested to extend the use of 2'-FL/DFL in milk-based drinks and similar products intended for young children at levels of 1,2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer in the authorised uses. In addition, the applicant requested to provide for a more generic description of the production process for the novel food, in particular to remove 'spray drying' from the description of the final drying step in the production process as other techniques, for example, freeze drying, are also used; to remove the term 'amorphous' from the description of the novel food in its final form as the novel food is a powder or agglomerates depending on the drying method used; and, to include 3-fucosyllactose, one of the minor components of the novel food in the sum of the oligosaccharides comprising the novel food rather than in the sum of the other minor carbohydrates where it is currently listed.
- (5) The requested changes in the conditions of use concerning the extension of use of the novel food in milk-based drinks and similar products intended for young children, and in the specifications concerning the drying method and the appearance of the novel food were part of the original application for the authorisation of 2'-FL/DFL as a novel food in accordance with Regulation (EU) 2015/2283 that was assessed favourably by the European Food Safety Authority ('the Authority') in its scientific opinion 'Safety of 2'-fucosyllactose/difucosyllactose mixture as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁴⁾. Therefore the Commission considers that another opinion of the Authority is not necessary.

⁽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⁾ 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 (OJ L 308, 29.11.2019, p. 62).

⁽⁴⁾ EFSA Journal 2019;17(6):5717.

- (6) The request to include 3-fucosyllactose in the sum of the oligosaccharides comprising the novel food rather than in the sum of the other minor carbohydrates where it is currently listed, was not included in the original application that was assessed favourably by the Authority. That application made reference to the potential of DFL to be hydrolysed to produce 3-fucosyllactose, which was detected at low levels. The Commission considers that the requested change in the way that 3-fucosyllactose is included in the specifications of 2'-FL/DFL in light of the fact that it is present in the novel food at low levels and below the levels naturally found in human milk, is not liable to change the effects of this authorised novel food on human health. Therefore, the Commission considers that another opinion of the Authority is not necessary.
- (7) It is therefore appropriate to amend the Union list on the conditions of use and on the specifications of 2'-FL/DFL to authorise its use in milk-based drinks and similar products intended for young children at levels of 1,2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer, in the authorised uses, to provide for a generic description of the production process for the novel food and to remove 'spray drying' from the description of the final drying step in the production process, to remove the term 'amorphous' from the description of the novel food, and to include 3-fucosyllactose in the sum of the main oligosaccharides comprising the novel food.
- (8) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (9) 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. The entry in the Union list of authorised novel foods, as provided for in Article 6 of Regulation (EU) 2015/2283 referring to microbial source '2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL)' shall be amended as specified in the Annex to this Regulation.
2. 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.

Article 2

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, 22 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

- (1) in Table 1 (Authorised novel foods), the conditions under which the novel food '2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL) (microbial source)' may be used are added:

Conditions under which the novel food may be used	
'Specified food category'	Maximum levels
Milk-based drinks and similar products intended for young children	1,2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer'

- (2) in Table 2 (Specifications), the entry for 2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL) (microbial source) is replaced by the following:

Authorised Novel Food	Specification
'2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL) (microbial source)	<p>Description/Definition: 2'-Fucosyllactose/Difucosyllactose mixture is a purified, white to off-white powder or agglomerates thereof that is produced by a microbial process.</p> <p>Source: Genetically modified <i>Escherichia coli</i> strain K-12 DH1</p> <p>Characteristics/Composition: Appearance: White to off white powder or agglomerates Sum of 2'-Fucosyllactose, Difucosyllactose, D-Lactose, L-Fucose, and 3-Fucosyllactose (% of dry matter): $\geq 92,0$ % (w/w) Sum of 2'-Fucosyllactose and Difucosyllactose (% of dry matter): $\geq 85,0$ % (w/w) 2'-Fucosyllactose (% of dry matter): $\geq 75,0$ % (w/w) Difucosyllactose (% of dry matter): $\geq 5,0$ % (w/w) D-Lactose: $\leq 10,0$ % (w/w) L-Fucose: $\leq 1,0$ % (w/w) 2'-Fucosyl-D-lactulose: $\leq 2,0$ (w/w) Sum of other carbohydrates (*): $\leq 6,0$ % (w/w) Moisture: $\leq 6,0$ % (w/w) Ash, sulfated: $\leq 0,8$ % (w/w) pH (20 °C, 5 % solution): 4,0 -6,0 Residual protein: $\leq 0,01$ % (w/w)</p> <p>Microbiological criteria: Aerobic mesophilic total plate count: ≤ 1000 CFU/g Enterobacteriaceae: ≤ 10 CFU/g <i>Salmonella</i> sp.: Negative/25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units</p>

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