

COMMISSION IMPLEMENTING REGULATION (EU) 2019/388**of 11 March 2019****authorising the change of the specifications of the novel food 2'-fucosyllactose produced with *Escherichia coli* K-12 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 of the European Parliament and of the Council 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) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to submit a draft implementing act authorising the placing on the Union market of a novel food and updating the Union list.
- (4) Commission Implementing Decision (EU) 2016/376 ⁽³⁾ authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽⁴⁾, the placing on the market of synthetic 2'-fucosyllactose as a novel food ingredient.
- (5) Commission Implementing Decision (EU) 2017/2201 ⁽⁵⁾ authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of 2'-fucosyllactose produced with *Escherichia coli* strain BL21 as a novel food ingredient.
- (6) On 23 June 2016, the company Glycom A/S (the Applicant), informed the Commission, pursuant to Article 5 of Regulation (EC) No 258/97, of its intention to place on the market 2'-fucosyllactose produced by bacterial fermentation with *Escherichia coli* strain K-12.
- (7) In the notification to the Commission, the Applicant also submitted a report issued on 10 June 2016 by the competent authority of Ireland pursuant to Article 3(4) of Regulation (EC) No 258/97, which, on the basis of the scientific evidence submitted by the Applicant, had concluded that 2'-fucosyllactose produced with *Escherichia coli* strain K-12 is substantially equivalent to the synthetic 2'-fucosyllactose authorised by Commission Implementing Decision (EU) 2016/376.
- (8) On 16 August 2018, the Applicant made a request to the Commission to change in the specifications of the 2'-fucosyllactose produced with *Escherichia coli* strain K-12 within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The requested changes concern a decrease in the levels of the 2'-fucosyllactose from 90 % to 83 %, and increases in the levels of the minor saccharides present in the novel food, namely an increase in the levels of D-lactose from up to 3,0 % to up to 10,0 %, an increase in the levels of difucosyl-D-lactose from up to 2,0 % to up to 5,0 %.

⁽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 Decision (EU) 2016/376 of 11 March 2016 authorising the placing on the market of 2'-O-fucosyllactose as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 70, 16.3.2016, p. 27).

⁽⁴⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel food and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

⁽⁵⁾ Commission Implementing Decision (EU) 2017/2201 of 27 November 2017 authorising the placing on the market of 2'-fucosyllactose produced with *Escherichia coli* strain BL21 as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 313, 29.11.2017, p. 5).

- (9) To ensure that the overall purity of the novel food following the introduction of the above changes in its specifications, remains as high as the currently authorised 2'-fucosyllactose produced by either *Escherichia coli* strain K12 or *Escherichia coli* strain BL 21, the Applicant also proposes that the overall levels of 2'-fucosyllactose together with the minor saccharides (D-lactose, L-fucose, difucosyl-D-lactose, and 2'-fucosyl-D-lactulose) in the novel food is equal or higher than 90,0 %.
- (10) The proposed changes in the specifications of the novel food are due to the modifications in its manufacturing process that entail the replacement of the crystallisation purification step with a spray drying step which is currently used in the production of 2'-fucosyllactose by *Escherichia coli* strain BL21. This change in the purification step of the novel food production requires the increase in the use of D-lactose as the fermentation substrate in the production of 2'-fucosyllactose that explains the slight decrease in the level of 2'-fucosyllactose and the concomitant slight increases in the levels of D-lactose and of difucosyl-D-lactose in the final novel food. These proposed changes in the manufacturing are deemed necessary by the Applicant in order to reduce the energy and environmental impact of the 2'-fucosyllactose manufacturing process and to reduce the cost per unit produced.
- (11) The proposed changes do not alter the safety considerations that supported the authorisation of the 2'-fucosyllactose produced with *Escherichia coli* strain K-12. Therefore, it is appropriate to amend the specifications of the novel food '2'-fucosyllactose' at the proposed levels of 2'-fucosyllactose, of D-lactose, of difucosyl-D-lactose, and of the overall levels of 2'-fucosyllactose together with the minor saccharides (D-lactose, L-fucose, difucosyl-D-lactose, and 2'-fucosyl-D-lactulose).
- (12) The information provided in the application gives sufficient grounds to establish that the proposed changes to the specifications of the novel food '2'-fucosyllactose' comply with Article 12 of Regulation (EU) 2015/2283.
- (13) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (14) 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

The entry in the Union list of authorised novel foods as provided for in Article 6 of Regulation (EU) 2015/2283 and included in Implementing Regulation (EU) 2017/2470, referring to the novel food 2'-fucosyllactose produced with *Escherichia coli* strain K-12, shall be amended as specified in the Annex to this Regulation.

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, 11 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

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

The entry for '2'-Fucosyllactose' (microbial source) in Table 2 (Specifications) is replaced by the following:

Definition:

Chemical name: α -L-Fucopyranosyl-(1 \rightarrow 2)- β -D-galactopyranosyl-(1 \rightarrow 4)-D-glucopyranose

Chemical formula: $C_{18}H_{32}O_{15}$

CAS No: 41263-94-9

Molecular weight: 488,44 g/mol

Source:

Genetically modified strain of *Escherichia coli* K-12

Source:

Genetically modified strain of *Escherichia coli* BL21

Description:

2'-Fucosyllactose is a white to off-white powder that is produced by a microbial process.

Purity:

2'-Fucosyllactose: ≥ 83 %

D-Lactose: $\leq 10,0$ %

L-Fucose: $\leq 2,0$ %

Difucosyl-D-lactose: $\leq 5,0$ %

2'-Fucosyl-D-lactulose: $\leq 1,5$ %

Sum of saccharides (2'-Fucosyllactose, D-Lactose, L-Fucose, Difucosyl-D-lactose, 2'-Fucosyl-D-lactulose): ≥ 90 %

pH (20 C, 5 % solution): 3,0-7,5

Water: $\leq 9,0$ %

Sulphated ash: $\leq 2,0$ %

Acetic acid: $\leq 1,0$ %

Residual proteins: $\leq 0,01$ %

Microbiological criteria:

Aerobic mesophilic bacteria total count: $\leq 3\ 000$ CFU/g

Yeasts: ≤ 100 CFU/g

Moulds: ≤ 100 CFU/g

Endotoxins: ≤ 10 EU/mg

Description:

2'-Fucosyllactose is a white to off white powder and the liquid concentrate (45 % \pm 5 % w/v) aqueous solution is a colourless to slight yellow clear aqueous solution. 2'-Fucosyllactose is produced by a microbiological process.

Purity:

2'-Fucosyllactose: ≥ 90 %

Lactose: $\leq 5,0$ %

Fucose: $\leq 3,0$ %

3-Fucosyllactose: $\leq 5,0$ %

Fucosylgalactose: $\leq 3,0$ %

Difucosyllactose: $\leq 5,0$ %

Glucose: $\leq 3,0$ %

Galactose: $\leq 3,0$ %

Water: $\leq 9,0$ % (powder)

Ash, sulphated: $\leq 0,5$ % (powder and liquid)

Residual proteins: $\leq 0,01$ % (powder and liquid)

Heavy Metals:

Lead: $\leq 0,02$ mg/kg (powder and liquid)

Arsenic: $\leq 0,2$ mg/kg (powder and liquid)

Cadmium: $\leq 0,1$ mg/kg (powder and liquid)

Mercury: $\leq 0,5$ mg/kg (powder and liquid)

Microbiological criteria:

Total plate count: $\leq 10^4$ CFU/g (powder), $\leq 5\ 000$ CFU/g (liquid)

Yeasts and Moulds: ≤ 100 CFU/g (powder); ≤ 50 CFU/g (liquid)

Enterobacteriaceae/Coliforms: absence in 11 g (powder and liquid)

Salmonella: negative/100 g (powder), negative/200 ml (liquid)

Cronobacter: negative/100 g (powder), negative/200 ml (liquid)

Endotoxins: ≤ 100 EU/g (powder), ≤ 100 EU/ml (liquid)

Aflatoxin M1: $\leq 0,025$ $\mu\text{g}/\text{kg}$ (powder and liquid)