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)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/388

of 11 March 2019

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(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 %.

(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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/388. (See end of Document for details)*

(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