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,

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′-fucosyl-
lactose 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 %.

(2) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance
(3) Commission Implementing Decision (EU) 2016/376 of 11 March 2016 authorising the placing on the market of 2′-O-fucosyllactose as
(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
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%.

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.

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).

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.

The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

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:

<table>
<thead>
<tr>
<th>Definition:</th>
<th>Source:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name: α-L-Fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose</td>
<td>Genetically modified strain of <em>Escherichia coli</em> K-12</td>
</tr>
<tr>
<td>Chemical formula: C_{18}H_{32}O_{15}</td>
<td></td>
</tr>
<tr>
<td>CAS No: 41263-94-9</td>
<td></td>
</tr>
<tr>
<td>Molecular weight: 488.44 g/mol</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Source:</th>
<th>Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetically modified strain of <em>Escherichia coli</em> K-12</td>
<td>2′-Fucosyllactose is a white to off-white powder that is produced by a microbial process.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Purity:</th>
<th>Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2′-Fucosyllactose: ≥ 83 %</td>
<td>2′-Fucosyllactose is a white to off white powder and the liquid concentrate (45 % ± 5 % w/v) aqueous solution is a colourless to slight yellow clear aqueous solution. 2′-Fucosyllactose is produced by a microbiological process.</td>
</tr>
<tr>
<td>D-Lactose: ≤ 10,0 %</td>
<td></td>
</tr>
<tr>
<td>L-Fucose: ≤ 2,0 %</td>
<td></td>
</tr>
<tr>
<td>Difucosyl-D-lactose: ≤ 5,0 %</td>
<td></td>
</tr>
<tr>
<td>2′-Fucosyl-D-lactulose: ≤ 1,5 %</td>
<td></td>
</tr>
<tr>
<td>Sum of saccharides (2′-Fucosyllactose, D-Lactose, L-Fucose, Difucosyl-D-lactose, 2′-Fucosyl-D-lactulose): ≥ 90 %</td>
<td></td>
</tr>
<tr>
<td>pH (20 °C, 5 % solution): 3,0-7,5</td>
<td></td>
</tr>
<tr>
<td>Water: ≤ 9,0 %</td>
<td></td>
</tr>
<tr>
<td>Sulphated ash: ≤ 2,0 %</td>
<td></td>
</tr>
<tr>
<td>Acetic acid: ≤ 1,0 %</td>
<td></td>
</tr>
<tr>
<td>Residual proteins: ≤ 0,01 %</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Microbiological criteria:</th>
<th>Heavy Metals:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerobic mesophilic bacteria total count: ≤ 3 000 CFU/g</td>
<td>Lead: ≤ 0,02 mg/kg (powder and liquid)</td>
</tr>
<tr>
<td>Yeasts: ≤ 100 CFU/g</td>
<td>Arsenic: ≤ 0,2 mg/kg (powder and liquid)</td>
</tr>
<tr>
<td>Moulds: ≤ 100 CFU/g</td>
<td>Cadmium: ≤ 0,1 mg/kg (powder and liquid)</td>
</tr>
<tr>
<td>Endotoxins: ≤ 10 EU/mg</td>
<td>Mercury: ≤ 0,5 mg/kg (powder and liquid)</td>
</tr>
</tbody>
</table>
Microbiological criteria:

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

Yeast and Moulds: $\leq 100$ CFU/g (powder); $\leq 50$ 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: $\leq 100$ EU/g (powder), $\leq 100$ EU/ml (liquid)

Aflatoxin M1: $\leq 0.025$ μg/kg (powder and liquid)