COMMISSION IMPLEMENTING REGULATION (EU) 2019/1314

of 2 August 2019

authorising the change of the specifications of the novel food Lacto-*N*-neotetraose 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]) 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 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) 2016/375 ([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 chemically synthesized Lacto-*N*-neotetraose as a novel food ingredient.

(5) Pursuant to Article 5 of Regulation (EC) No 258/97, on 1 September 2016, the company Glycom A/S ('the Applicant'), informed the Commission of its intention to place on the market Lacto-*N*-neotetraose of microbial source produced with Escherichia coli strain K-12 as a novel food ingredient.

(6) In the notification to the Commission, the Applicant also submitted a report issued 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 Lacto-*N*-neotetraose produced with *Escherichia coli* strain K-12 is substantially equivalent to the synthetic Lacto-*N*-neotetraose authorised by Commission Implementing Decision (EU) 2016/375. Therefore, Lacto-*N*-neotetraose of microbial origin was included in the Union list of novel foods.

(7) On 18 December 2018, the Applicant pursuant to Article 10(1) of Regulation (EU) 2015/2283, requested a change in the specifications of the Lacto-*N*-neotetraose with *Escherichia coli* strain K-12 in order to reduce the energy and environmental load of the Lacto-*N*-neotetraose manufacturing process and reduce the cost per unit produced. The changes concern a decrease in the levels of the Lacto-*N*-neotetraose from equal or greater than 92 % to equal or greater than 80 %, 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 %, and an increase in the levels of *para*-Lacto-*N*-neohexaose from up to 3,0 % to up to 5,0 %.

(8) To ensure that the overall purity of the novel food after the requested changes are introduced in its specifications remains as high as the currently authorised Lacto-*N*-neotetraose, the Applicant also proposes that the sum of the levels of Lacto-*N*-neotetraose and of the minor saccharides (D-Lactose, Lacto-*N*-triose II, *para*-Lacto-*N*-neohexaose, and Lacto-*N*-neotetraose fructose isomer) in the novel food is equal or greater than 92,0 %.

([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) 2016/375 of 11 March 2016 authorising the placing on the market of Lacto-*N*-neotetraose 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. 22).*
([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).

(9) The requested 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 Lacto-*N*-neotetraose by *Escherichia coli* strain K-12. The applicant therefore requested to amend the entry of Lacto-*N*-neotetraose of microbial origin in the Union list of authorised novel foods in order to reflect that change in the purification step of the manufacturing process.

(10) The Commission considered that the requested modifications involving saccharides of the authorised novel food which are also components of the human milk while maintaining an overall high sum of those and the other minor saccharides present in the novel food, do not alter the safety considerations that supported the authorisation of the synthetic Lacto-*N*-neotetraose and the Lacto-*N*-neotetraose produced with *Escherichia coli* strain K-12, and therefore do not necessitate a consultation of the European Food Safety Authority.

(11) Taking into account the above considerations, the requested changes comply with Article 12(1) of Regulation (EU) 2015/2283. Therefore, it is appropriate to amend the specifications of the novel food Lacto-*N*-neotetraose of microbial origin produced with *Escherichia coli* strain K-12 at the proposed levels of Lacto-N-neotetraose, of D-Lactose, and of *para*-Lacto-*N*-neohexaose, and of the overall levels of Lacto-*N*-neotetraose together with minor saccharides (D-Lactose, Lacto-*N*-triose II, *para*-Lacto-N-neohexaose, and Lacto-*N*-neotetraose fructose isomer).

(12) 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 referring to the substance Lacto-*N*-neotetraose 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, 2 August 2019.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

In Table 2 (Specifications) of Implementing Regulation (EU) 2017/2470, the entry for 'Lacto-*N*-neotetraose (microbial source)' is replaced by the following:

'Lacto-*N*-neotetraose (microbial source)	**Definition:** Chemical name: β-D-Galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose Chemical formula: $C_{26}H_{45}NO_{21}$ CAS No: 13007-32-4 Molecular weight: 707,63 g/mol **Source:** Genetically modified strain of *Escherichia coli* K-12 **Description:** Lacto-*N*-neotetraose is a white to off-white powder that is produced by a microbiological process. **Purity:** Assay (water free): ≥ 80 % D-Lactose: ≤ 10,0 % Lacto-*N*-triose II: ≤ 3,0 % *para*-Lacto-*N*-neohexaose: ≤ 5,0 % Lacto-*N*-neotetraose fructose isomer: ≤ 1,0 % Sum of saccharides (Lacto-*N*-neotetraose, D-Lactose, Lacto-*N*-triose II, *para*-Lacto-*N*-neohexaose, Lacto-*N*-neotetraose fructose isomer): ≥ 92 % pH (20 C, 5 % solution): 4,0-7,0 Water: ≤ 9,0 % Ash, sulphated: ≤ 0,4 % Residual solvents (methanol): ≤ 100 mg/kg Residual proteins: ≤ 0,01 % **Microbiological criteria:** Aerobic mesophilic bacteria total count: ≤ 500 CFU/g Yeasts: ≤ 10 CFU/g Moulds: ≤ 10 CFU/g Residual endotoxins: ≤ 10 EU/mg

CFU: Colony Forming Units; EU: Endotoxin Units'