COMMISSION IMPLEMENTING REGULATION (EU) 2023/1583

of 1 August 2023

amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food Lacto-*N*-neotetraose (microbial source)

(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]) has established a Union list of authorised novel foods.

(3) 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.

(4) Pursuant to Article 5 of Regulation (EC) No 258/97, on 1 September 2016, the company Glycom A/S informed the Commission of its intention to place on the market Lacto-*N*-neotetraose of microbial source produced with genetically modified *Escherichia coli* strain K-12 as a novel food ingredient. Lacto-*N*-neotetraose of microbial origin produced with genetically modified *Escherichia coli* strain K-12 was included in the Union list of novel foods on the basis of that notification when the Union list was established.

(5) Commission Implementing Regulation (EU) 2019/1314 ([5]) amended the specifications of the novel food Lacto-*N*-neotetraose (microbial source) produced with genetically modified *Escherichia coli* strain K-12.

(6) Commission Implementing Regulation (EU) 2021/912 ([6]) amended the specifications of the novel food Lacto-*N*-neotetraose (microbial source) to allow Lacto-*N*-neotetraose produced by the combined activity of the genetically modified strains PS-LNnT-JBT and DS-LNnT-JBT derived from *Escherichia coli* strain BL21(DE3) to be placed on the market under the same conditions of use as the ones previously authorised for Lacto-*N*-neotetraose.

([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 foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

([5]) 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 (OJ L 205, 5.8.2019, p. 4).

([6]) Commission Implementing Regulation (EU) 2021/912 of 4 June 2021 authorising changes in the specifications of the novel food Lacto-*N*-neotetraose (microbial source) and amending Implementing Regulation (EU) 2017/2470 (OJ L 199, 7.6.2021, p. 10).

(7) On 15 November 2022, the company Chr. Hansen A/S ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the specifications of Lacto-*N*-neotetraose (microbial source) produced by the combined activity of the derivative strains PS-LNnT-JBT and DS-LNnT-JBT of *Escherichia coli* strain BL21(DE3). The applicant requested for the reference to the specific genetically modified derivative strains PS-LNnT-JBT and DS-LNnT-JBT of *Escherichia coli* BL21(DE3) used to produce Lacto-*N*-neotetraose (microbial source) to be replaced by the generic mention of both strains. In addition the applicant requested a change in the specifications of Lacto-*N*-neotetraose (microbial source) so that it can be produced using authorised derivative strains of *Escherichia coli* K-12 and/or of *Escherichia coli* BL21(DE3) rather than the current limitation of using either the authorised derivative strain of *Escherichia coli* K-12 or the authorised derivative strains of *Escherichia coli* BL21(DE3).

(8) The applicant justified the request for the proposed changes in the specifications of Lacto-*N*-neotetraose (microbial source) to replace the specific mention of PS-LNnT-JBT and DS-LNnT-JBT of *Escherichia coli* strain BL21(DE3) by a more generic mention of production and optional degradation strains as being a more accurate way to describe the respective functions of the two strains in the production process as assessed ([7]) by the European Food Safety Authority ('the Authority'), and as a means to allow for more flexibility to the applicant and other food business operators to use authorised derivatives of *Escherichia coli* strain BL21(DE3) in line with their respective functions rather than limiting their production to the specific derivative strains PS-LNnT-JBT and DS-LNnT-JBT. In addition, in the applicant's view this modification would also align the authorised specifications of Lacto-*N*-neotetraose produced with derivative strains of *Escherichia coli* strain BL21(DE3) to the authorised specifications of other novel foods produced with production and optional degradation derivative strains of *Escherichia coli* BL21(D3) in which specific derivative strains are not mentioned. The applicant also justified the request to allow use of combinations of authorised derivative strains of the *Escherichia coli* strains, namely *Escherichia coli* K-12 and/or *Escherichia coli* BL21(DE3) as an additional means to allow for flexibility to the applicant and other food business operators to use authorised derivative strains of *Escherichia coli* in the production of Lacto-*N*-neotetraose.

(9) The Commission considers that the requested update of the Union list concerning the change of the specifications of Lacto-*N*-neotetraose proposed by the applicant, is not liable to have an effect on human health and that a safety evaluation by the Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The parent *Escherichia coli* strains BL21(DE3) and K-12 and their genetically modified derivative strains used in the production of Lacto-*N*-neotetraose have been positively assessed by the Authority ([8]) and in the context of a notification pursuant to Article 5 of Regulation (EC) No 258/97, respectively. Their use in the production of Lacto-*N*-neotetraose with or without the additional use of the optional degradation derivative strain of *Escherichia coli* strain BL21(DE3) will produce Lacto-*N*-neotetraose in line with the authorised specifications, and consequently will not affect the safety profile of the authorised novel food.

(10) The information provided in the application and the above Opinion of the Authority give sufficient grounds to establish that the changes to the specifications of Lacto-*N*-neotetraose (microbial source), are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.

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

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([7]) *EFSA Journal* 2020;18(11):6305.
([8]) *EFSA Journal* 2020;18(11):6305.

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with 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, 1 August 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) 2017/2470, in Table 2 (Specifications), 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 **Description/Source** Lacto-*N*-neotetraose is a white to off-white powder that is produced by a microbiological process using genetically modified strain of *Escherichia coli* K-12, and/or of *Escherichia coli* BL21(DE3). An additional optional genetically modified degradation strain of *Escherichia coli* BL21(DE3) may be used in the production process to degrade intermediate carbohydrate by-products and remaining starting carbohydrate substrates. **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 % (% w/w dry matter) pH (20 °C, 5 % solution): 4,0-7,0 Water: ≤ 9,0 % Ash, sulphated: ≤ 1,0 % Residual solvents (methanol): ≤ 100 mg/kg Residual proteins: ≤ 0,01 % **Microbiological criteria** Aerobic mesophilic bacteria total count: ≤ 500 CFU/g Yeasts and moulds: ≤ 50 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units'