

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****(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⁾ establishing the 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) 2016/375 ⁽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 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, Glycom A/S 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 that company, had concluded that Lacto-N-neotetraose produced with *Escherichia coli* strain K-12 is substantially equivalent to the synthetic Lacto-N-neotetraose authorised by Implementing Decision (EU) 2016/375. Therefore, Lacto-N-neotetraose of microbial source was included in the Union list of novel foods.
- (7) On 23 June 2019, 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 the authorisation 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) as a novel food under the same conditions of use as the ones currently authorised for synthetic and microbial sourced Lacto-N-neotetraose. The applicant requested an update of the union list with regard to the new source of that novel food.
- (8) In addition, the applicant proposed updating some of the specifications of Lacto-N-neotetraose (microbial source) produced by that new source, as they differ from the specifications of the authorised microbiologically sourced Lacto-N-neotetraose produced with *Escherichia coli* strain K-12, as far as they concern an increase in the levels of ash from $\leq 0,4\%$ to $\leq 1,0\%$; a higher level for the presence of yeasts and moulds from the current ≤ 10 Colony Forming

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

Units ('CFU')/g of novel food for each type of microorganism to ≤ 50 CFU/g for the combination of the two; and the absence of methanol (from the current ≤ 100 mg/kg), and of Lacto-N-neotetraose fructose isomer (from the current $\leq 1,0$ %).

- (9) On 17 January 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of Lacto-N-neotetraose produced by the combined activity of the derivative strains PS-LNnT-JBT and DS-LNnT-JBT of *Escherichia coli* strain BL21(DE3) in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (10) On 22 October 2020, the Authority adopted its scientific opinion 'Safety of lacto-N-neotetraose (LNnT) produced by derivative strains of *E. coli* BL21 as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁵⁾.
- (11) In its scientific opinion, the Authority concluded that Lacto-N-neotetraose (LNnT) produced by the combined activity of the derivative strains PS-LNnT-JBT and DS-LNnT-JBT of *Escherichia coli* strain BL21(DE3) as a novel food pursuant to Regulation (EU) 2015/2283 is safe for the currently authorised conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that Lacto-N-neotetraose (LNnT) produced by the combined activity of the derivative strains PS-LNnT-JBT and DS-LNnT-JBT of *Escherichia coli* strain BL21(DE3), complies with Article 12(1) of Regulation (EU) 2015/2283.
- (12) It is therefore appropriate to amend the specifications of the microbiologically produced Lacto-N-neotetraose, to include the derivative strains PS-LNnT-JBT and DS-LNnT-JBT of *Escherichia coli* strain BL21(DE3) as the source of the novel food in addition to the authorised *Escherichia coli* strain K12 and to amend the proposed levels for the presence of ash and moulds, and yeast.
- (13) The Annex to 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 referring to the substance Lacto-N-neotetraose (microbial source) 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, 4 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁵⁾ EFSA Journal 2020;18(11):6305.

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

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| <p>Lacto-N-neotetraose (microbial source)</p> | <p>Definition: Chemical name: β-D-Galactopyranosyl-(1 \rightarrow 4)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1 \rightarrow 3)-β-D-galactopyranosyl-(1 \rightarrow 4)-D-glucopyranose Chemical formula: C₂₆H₄₅NO₂₁ CAS No: 13007-32-4 Molecular weight: 707,63 g/mol</p> <p>Source: — Genetically modified strain of <i>Escherichia coli</i> K-12, or — a combination of the genetically modified strains PS-LNnT-JBT and DS-LNnT-JBT of <i>Escherichia coli</i> BL21(DE3)</p> <p>Description: Lacto-N-neotetraose is a white to off-white powder that is produced by a microbiological process.</p> <p>Purity: Assay (water free): \geq 80 % D-Lactose: \leq 10,0 % Lacto-N-triose II: \leq 3,0 % <i>para</i>-Lacto-N-neohexaose: \leq 5,0 % Lacto-N-neotetraose fructose isomer: \leq 1,0 % Sum of saccharides (Lacto-N-neotetraose, D-Lactose, Lacto-N-triose II, <i>para</i>-Lacto-N-neohexaose, Lacto-N-neotetraose fructose isomer): \geq 92 % (% w/w dry matter) pH (20 °C, 5 % solution): 4,0-7,0 Water: \leq 9,0 % Ash, sulphated: \leq 1,0 % Residual solvents (methanol): \leq 100 mg/kg Residual proteins: \leq 0,01 %</p> <p>Microbiological criteria: Aerobic mesophilic bacteria total count: \leq 500 CFU/g Yeasts and moulds: \leq 50 CFU/g Residual endotoxins: \leq 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units'</p> |
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