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COMMISSION IMPLEMENTING REGULATION (EU) 2026/397

of 23 February 2026

authorising the placing on the market of lacto-N-tetraose produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) as a novel food 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(1) thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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 Regulation (EU) 2020/484 ([3]) authorised the placing on the Union market of lacto-*N*-tetraose obtained by microbial fermentation using the genetically modified strain K12 DH1 of *Escherichia coli* as a novel food under Regulation (EU) 2015/2283.

(4) Commission Implementing Regulation (EU) 2023/7 ([4]) authorised the placing on the Union market of lacto-*N*-tetraose produced by derivative strains of *Escherichia coli* BL21(DE3) as a novel food under Regulation (EU) 2015/2283.

(5) On 15 October 2023, the company Inbiose N.V. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place lacto-*N*-tetraose ('LNT') obtained by microbial fermentation using a genetically modified strain (MG1655) derived from the host strain *Escherichia coli* ('*E. coli*') K12 (ATCC 700926), on the Union market as a novel food. The applicant requested for the so produced LNT to be used in the same food categories and at the same maximum levels as the currently LNT authorised by Implementing Regulation (EU) 2020/484. Subsequently, on 21 October 2025, the applicant modified the initial request in the application on the use of LNT produced by a derivative strain of Escherichia coli K-12 MG1655 (ATCC 700926) in food supplements to exclude food supplements intended for young children.

([1]) OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.

([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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

([3]) Commission Implementing Regulation (EU) 2020/484 of 2 April 2020 authorising the placing on the market of lacto-*N*-tetraose as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 103, 3.4.2020, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2020/484/oj).

([4]) Commission Implementing Regulation (EU) 2023/7 of 3 January 2023 authorising the placing on the market of Lacto-*N*-tetraose produced by derivative strains of *Escherichia coli* BL21(DE3) as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L 2, 4.1.2023, p. 21, ELI: http://data.europa.eu/eli/reg_impl/2023/7/oj).

(6) On 15 October 2023, the applicant also made a request to the Commission for the protection of the proprietary scientific studies and data, namely, identity of the novel food ([5]), production process, including information on the genetically modified production strain ([6]), composition and stability of the novel food ([7]), Absorption, Distribution, Metabolism and Excretion (ADME) ([8]), toxicological information ([9]), and the bioinformatic study for allergenicity assessment ([10]), in support of the application.

(7) On 19 January 2024, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of LNT produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(8) On 10 July 2025, the Authority adopted its scientific opinion on the 'Safety of LNT produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) as a novel food pursuant to Regulation (EU) 2015/2283' ([11]) in accordance with Article 11 of Regulation (EU) 2015/2283.

([5]) Section 2.1; Annex 2.1.01 to the application (NMR report LNT Inbiose); Annex 2.1.02 to the application (NMR shifts of LNT); Annex 2.1.03 to the application (LNT_UPLC-RI validation report INBMV1002_2021); Annex 2.1.03.01 to the application (UPLC-RI_Analytical standards CoA); Annex 2.1.04 to the application (UPLC-MSMS analysis_LNT); Annex 2.1.05 to the application (Additional NMR spectra).

([6]) Section 2.2; (Protocol for the preparation of master and working cell banks – Inbiose N.V.); Annex 2.2.04 to the application (GMM_description INB_LNT and GMM_description INB_LNT_01_updated_2024); Annex 2.2.04.02 to the application (Structure helper plasmids INB_LNT_01 and Structure and sequence helper plasmids INB_LNT_01_updated_2024); Annex 2.2.04.03 to the application (Recombinant genes INB_LNT_01); Annex 2.2.04.04 to the application (Amino acid sequences recombinant proteins INBLNT_01); Annex 2.2.04.05 to the application (Genetic information); Annex 2.2.04.06 to the application (Genomic maps of gene deletions); Annex 2.2.04.07 to the application (Contigs_LNT_fasta_file_updated_2024, full document); Annex 2.2.04.08 to the application (PROKKA_LNT_fasta file of predicted AA); Annex 2.2.04.09 to the application (LNT_Deposition certificate); Annex 2.2.04.10 to the application (Structure and sequence pINB_LNT_01); Annex 2.2.04.11 to the application (Additional AMR INB_LNT_01); Annex 2.2.04.12 to the application (Test for absence of viable cells); Annex 2.2.05 to the application (Raw materials); Annex 2.2.06 to the application (Differences pilot vs commercial); Annex 2.2.07 to the application (HACCP plan); Annex 2.2.08 to the application; Annex 2.2.08.01 to the application; Annex 2.2.09 to the application ((HACCP plan_2019).

([7]) Section 2.3; Annex 2.3.01 to the application (ash content); Annex 2.3.02 to the application (carbohydrates); Annex 2.3.03 to the application (endotoxins); Annex 2.3.04 to the application (Enterobacteriaceae); Annex 2.3.05 to the application (pH analysis); Annex 2.3.06 to the application (Microbiology); Annex 2.3.07 to the application (Protein content); Annex 2.3.08 to the application (Water content); Annex 2.3.09 to the application (Heavy metals); Annex 2.3.10 to the application (Mycotoxins); Annex 2.3.11 to the application (Absence of rDNA); Annex 2.3.12 to the application (Method description results qNMR (Inbiose)); Annex 2.3.12.01 to the application (Method Validation: Quantitative Nuclear Magnetic Resonance (qNMR) Measurement); Annex 2.3.13 to the application (Minor carbohydrates UPLC-RI); Annex 2.3.14.01 to the application (Determination of HMOs by LC-MSMS); Annex 2.3.14.02 to the application (Validation report_LC-MSMS); Annex 2.3.15 to the application ((LNT solubility report and LNT solubility report_updated_2024); Annex 2.3.16 to the application (Calculation matrix composition LNT; Excel sheet: LNT spec.; Excel sheet: qNMR LNT % DM); Annex 2.3.18 to the application (Inbiose's LNT_Stability study_Powder 40C 70RH); Annex 2.3.19 to the application (Summary stability study LNT 40 °C_75 % RH; Excel sheet: 40_75; Excel sheet: graphs 40_75; Excel sheet: microbio); Annex 2.3.20 to the application (Inbiose's LNT_Stability study_Powder 25C 60RH and Inbiose's LNT_Stability study_Powder 25C 60RH_CONFIDENTIAL_Updated_updated_2024); Annex 2.3.21 to the application (Summary stability study LNT 25 °C_60 % RH Excel sheet: 25_60 Excel sheet: graphs 25_60 Excel sheet: microbio and Summary stability study LNT 25 °C_60 %; RH_Updated_updated_2024; Excel sheet: 25_60; Excel sheet: graphs 25_60; Excel sheet: microbio); Annex 2.3.22 to the application (Inbiose's LNT_Stability study_Liquid food matrices); Annex 2.3.23 to the application (Inbiose's LNT_Stability study_Infant formula); Annex 2.3.24 to the application (Manufacturing of the infant formula); Annex 2.3.30 to the application (Peak identification LNT); Protocol for the preparation of master and working cell banks – Inbiose N.V.; P1512_R03_v01 –17 NOV 2020; P1679_R01_v01_INB_signed); P1512_R03_v01 –17 NOV 2020 (method description for monitoring HMOs in food ingredients and food matrices); P1679_R01_v01_INB_signed (evaluation of alternative filter membrane for sample preparation in hmo lc-ms method).

([8]) Section 2.7.

([9]) Section 2.9; Subsection 2.9.2 (Mutagenicity and genotoxicity studies); Subsection 2.9.3 (Sub-chronic oral toxicity study in the rat); Annex 2.9.01 to the application (Mutagenicity study LNT OECD 471); Annex 2.9.02 to the application (Genotoxicity study LNT OECD 487); Annex 2.9.03 to the application (OECD 408 formulation analyses); Annex 2.9.04 to the application (Report Validation urine analysis); Annex 2.9.05 to the application (Validation plasma analysis); Annex 2.9.06 to the application (Dose-range finding study); Annex 2.9.07 to the application (Report subchronic oral tox study LNT OECD 408); Appendix B.3 (the summary table of statistically significant observations in toxicity studies).

([10]) Annex 2.10.01 to the application (allergen results).

([11]) *EFSA Journal* 2025;23:e9610, https://doi.org/10.2903/j.efsa.2025.9610.

(9) In its scientific opinion, the Authority concluded that LNT produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) is safe when used under the proposed conditions of use. Therefore, the scientific opinion gives sufficient grounds to establish that LNT produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) when used under the currently authorised conditions of use fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(10) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the following data: identity of the novel food, production process, including information on the genetically modified production strain, composition and stability of the novel food, Absorption, Distribution, Metabolism and Excretion (ADME), toxicological information, and the bioinformatic study for allergenicity assessment without which it could not have assessed the novel food and reached its conclusion.

(11) The applicant declared that they held proprietary and exclusive rights of reference to the scientific studies and data at the time they submitted the application.

(12) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, scientific studies and data, namely, identity of the novel food, production process, including information on the genetically modified production strain, composition and stability of the novel food, Absorption, Distribution, Metabolism and Excretion (ADME), toxicological information, and the bioinformatic study for allergenicity assessment should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place LNT produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) on the market within the Union during a period of five years from the entry into force of this Regulation.

(13) However, restricting the authorisation of LNT produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) and the reference to the scientific data contained in the applicant's file for the sole use by them does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.

(14) In accordance with the conditions of use of food supplements containing LNT produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers with an appropriate label that food supplements containing LNT produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) should not be used if other foods with added LNT are consumed the same day.

(15) It is appropriate that the inclusion of LNT using a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) as a novel food in the Union list of novel foods contains also the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

(16) LNT using a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(17) 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

1. Lacto-*N*-tetraose produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) is authorised to be placed on the market within the Union.

Lacto-*N*-tetraose produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the company Inbiose N.V. ([12]) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from 16 March 2026, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Inbiose N.V.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of Inbiose N.V.

Article 4

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, 23 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

([12]) Address: Technologiepark 82, bus 41, 9052 Zwijnaarde, BELGIUM.

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
‘**Lacto-*N*-tetraose (“LNT”) (produced by a derivative strain of *Escherichia coli* K-12 MG1655)**	*Specified food category*	*Maximum levels (expressed as lacto-N-tetraose)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be “lacto-*N*-tetraose”. The labelling of food supplements containing lacto-*N*-tetraose (LNT) shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added lacto-*N*-tetraose are consumed the same day.		Authorised on 16 March 2026. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: “Inbiose N.V.”, Technologiepark 82, bus 41, 9052 Zwijnaarde, Belgium. During the period of data protection, the novel food Lacto-*N*-tetraose is authorised for placing on the market within the Union only by “Inbiose N.V.” unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of “Inbiose N.V.”. End date of the data protection: 16 March 2031.’
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	1,0 g/L			
	Unflavoured fermented milk-based products	1,0 g/L (beverages) 10 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	1,0 g/L (beverages) 10 g/kg (products other than beverages)			
	Beverages (flavoured drinks)	1,0 g/L			
	Cereal bars	10 g/kg			
	Infant formula as defined under Regulation (EU) No 609/2013	0,8 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	0,6 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	0,6 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 5 g/kg for products other than beverages			

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Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	Milk based drinks and similar products	0,6 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 5 g/kg for products other than beverages			
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	2,0 g/L (beverages) 20 g/kg (products other than beverages)			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	2,0 g/day for the general population above 3 years			

(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order:

Authorised Novel Food	Specification
'Lacto-N-tetraose ('LNT') (produced by a derivative strain of *Escherichia coli* K-12 MG1655)	**Definition:** Chemical formula: $C_{26}H_{45}NO_{21}$ Chemical name: β-D-Galactopyranosyl-(1 → 3)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1 → 3)-β-D-galactopyranosyl-(1 → 4)-D-glucopyranose Molecular mass: 707,63 Da CAS No 14116-68-8 **Description:** Lacto-*N*-tetraose is a white to off-white powder produced by microbial fermentation and further isolated, purified and concentrated. **Source:** Genetically modified strain of *Escherichia coli* strain K-12 MG1655 (ATCC 700926)

Authorised Novel Food	Specification
	Characteristics/Composition: Sum of lacto-*N*-tetraose, D-Lactose and lacto-*N*-triose II (% of dry matter): ≥ 90 % (w/w) Lacto-*N*-tetraose (% of dry matter): ≥ 85 % (w/w) D-Lactose: ≤ 7 % (w/w) Lacto-*N*-tetraose fructose isomer: ≤ 1 % (w/w) Lacto-*N*-triose II: ≤ 7 % (w/w) Sum of other carbohydrates (*): ≤ 5 % (w/w) Water: ≤ 7 % (w/w) Protein: ≤ 0,01 % (w/w) Ash: ≤ 0,5 % (w/w) pH (20 °C, 10 % solution): 4,0-6,5 **Contaminants:** Arsenic: ≤ 0,2 mg/kg Cadmium: ≤ 0,1 mg/kg Lead: ≤ 0,02 mg/kg Mercury: ≤ 0,1 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg **Microbiological criteria:** Aerobic plate count: ≤ 1 000 CFU/g Yeasts and moulds: ≤ 100 CFU/g *Enterobacteriaceae*: Absence in 10 g *Salmonella* sp.: Absence in 25 g *Cronobacter* spp.: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g *Bacillus cereus*: ≤ 50 CFU/g Endotoxins: ≤ 10 EU/mg

(*) *N*-Acetylglucosaminyl lacto-*N*-tetraose (GlcNac-LNT); galacto-oligosaccharides (GOS); galactosyllacto-*N*-tetraose (Gal-LNT); para-lacto-*N*-hexaose II (pLNH II).
CFU: Colony Forming Units; EU: Endotoxin Units.'