COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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 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.

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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[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 Commission Implementing Regulation (EU) 2020/484. Subsequently, on 21 October 2025, the applicant modified the initial request in the application on the use of LNT in food supplements to exclude young children.

(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,

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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).

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

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

7 Section 2.3; Annex 2.3.01 (ash content); Annex 2.3.02 (carbohydrates); Annex 2.3.03 (endotoxins); Annex 2.3.04 (Enterobacteriaceae); Annex 2.3.05 (pH analysis); Annex 2.3.06 (Microbiology); Annex 2.3.07 (Protein content); Annex 2.3.08 (Water content); Annex 2.3.09 (Heavy metals); Annex 2.3.10 (Mycotoxins); Annex 2.3.11 (Absence of rDNA); Annex 2.3.12 (Method description results qNMR (Inbiose); Annex 2.3.12.01 (Method Validation: Quantitative Nuclear Magnetic Resonance (qNMR) Measurement); Annex 2.3.13 (Minor carbohydrates UPLC-RI); Annex 2.3.14.01 (Determination of HMOs by LC-MSMS); Annex 2.3.14.02 (Validation report_LC-MSMS); Annex 2.3.15 ((LNT solubility report and LNT solubility report_updated_2024); Annex 2.3.16 (Calculation matrix composition LNT; Excel sheet : LNT spec.; Excel sheet : qNMR LNT % DM); Annex 2.3.18 (Inbiose's

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 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 as a novel food pursuant to Regulation (EU) 2015/2283'[11] in accordance with Article 11 of Regulation (EU) 2015/2283.

(9) In its scientific opinion, the Authority concluded that LNT is safe when used under the currently authorised conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that LNT 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.

LNT_Stability study_Powder 40C 70RH); Annex 2.3.19 (Summary stability study LNT 40 °C_75 % RH; Excel sheet: 40_75; Excel sheet : graphs 40_75; Excel sheet : microbio); Annex 2.3.20 (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 (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 (Inbiose's LNT_Stability study_Liquid food matrices); Annex 2.3.23 (Inbiose's LNT_Stability study_Infant formula); Annex 2.3.24 (Manufacturing of the infant formula); Annex 2.3.30 (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 (Mutagenicity study LNT OECD 471); Annex 2.9.02 (Genotoxicity study LNT OECD 487); Annex 2.9.03 (OECD 408 formulation analyses); Annex 2.9.04 (Report Validation urine analysis); Annex 2.9.05 (Validation plasma analysis); Annex 2.9.06 (Dose-range finding study); Annex 2.9.07 (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 (allergen results).

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

(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 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 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 should not be used if other foods with added LNT are consumed the same day.

(15) It is appropriate that the inclusion of Lacto-N-tetraose 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) Lacto-N-tetraose 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 the date of entry into force of this Regulation [*OP please insert the date*], 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 five 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,

For the Commission
The President
Ursula VON DER LEYEN

[12] Address: Technologiepark 82, bus 41, 9052 Zwijnaarde, Belgium.