EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

on authorising the placing on the market of 6'-sialyllactose sodium salt 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)

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(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) 2021/82[3] authorised the placing on the Union market of 6'-Sialyllactose sodium salt 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) 2023/948[4] authorised the placing on the Union market of 6'-Sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21(DE3), as a novel food under Regulation (EU) 2015/2283.

(5) Commission Implementing Regulation (EU) 2023/2215[5] authorised the placing on the Union market of 6′-Sialyllactose sodium salt produced by derivative strain of *Escherichia coli* W (ATCC 9637), 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) 2021/82 of 27 January 2021 authorising the placing on the market of 6'-sialyllactose sodium salt 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 29, 28.1.2021, p 16, ELI: http://data.europa.eu/eli/reg_impl/2021/82/oj).

4 Commission Implementing Regulation (EU) 2023/948 of 12 May 2023 authorising the placing on the market of 6′-Sialyllactose sodium salt produced by derivative strains of Escherichia coli BL21(DE3) as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L 128, 15.5.2023, p. 52, ELI: http://data.europa.eu/eli/reg_impl/2023/948/oj).

(6) On 28 April 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 seeking authorisation to place 6'-Sialyllactose ('6′-SL') sodium salt obtained by microbial fermentation using a genetically modified strain *Escherichia coli ('E. coli')* K-12 MG1655 INB-6SL_02 derived from the host strain *E. coli* K12 (ATCC 700926), on the Union market as a novel food. The applicant requested the so produced 6′-SL sodium salt to be used in the same food categories and at the same maximum levels as the currently 6′-SL sodium salt authorised by Commission Implementing Regulation (EU) 2021/82.

(7) On 28 April 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[6], production process, including information on the genetically modified production strain[7], composition and stability of the novel food[8], Absorption,

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5 Commission Implementing Regulation (EU) 2023/2215 of 23 October 2023 authorising the placing on the market of 6′-Sialyllactose sodium salt produced by derivative strain of Escherichia coli W (ATCC 9637) as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L, 2023/2215, 24.10.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2215/oj).

6 Section 2.1 to the application (identity of the novel food and identity of the novel food_updated _2024); Annex 2.1.02 to the application (NMR report); Annex 2.1.03 to the application (validation report 6′-SL analysis); Annex 2.1.04 to the application (UPLC-MSMS analysis 6 SL).

7 Section 2.2 Production process, Production process_Updated_2024 and Production process_updated ADR2) to the application; Annex 2.2 Annex 2.2.04 to the application (GMM description_Updated and GMM description_updated_2024); Annex 2.2.04.02 to the application (structure helper plasmids, Structure and sequence plasmids INB_6SL_02); Annex 2.2.04.03 to the application (inserted recombinant genes); Annex 2.2.04.04 to the application (Amino acid sequences recombinant proteins); Annex 2.2.04.05 to the application (genetic information); Annex 2.2.04.06 to the application (Contigs_6 SL fasta_file and Contigs_6 SL fasta_file_updated_2024); Annex 2.2.04.07 to the application (PROKKA_6 SL_fasta file); Annex 2.2.04.08 to the application (6 SL GEN1_Deposition certificate); Annex 2.2.04.09 to the application (6 SL GEN2_Deposition certificate); Annex 2.2.04.10 to the application (Structure and sequence pINB_6 SL_01); Annex 2.2.04.11 to the application (Additional AMR INB 6_SL_02); Annex 2.2.04.12 to the application (Test for absence of viable cells); Annex 2.2.05 to the application (Raw material and Raw materials_updated ADR2); Annex 2.2.06 to the application (Differences pilot vs commercial and Differences pilot vs commercial_updated ADR2); Annex 2.2.07 to the application (HACCP plan); Annex 2.2.08 to the application (determination of residual processing aid in 6′-SL sodium salt powder batches); Annex 2.2.09 to the application ((HACCP plan_2018); Annex 2.2.10 to the application (effect of heat treatment_6SL); Protocol for the preparation of master and working cell banks.

8 Section 2.3 to the application (Compositional data, Compositional data_updated_2024 and Compositional data_updated_ADR2); Annex 2.3.01.01 to the application (ash content_1st GEN 6SL); Annex 2.3.01.02 to the application (carbohydrates ww_1st GEN 6SL); Annex 2.3.01.03 to the application (endotoxins_1st GEN 6SL); Annex 2.3.01.04 to the application (Enterobacteriaceae_1st GEN 6SL); Annex 2.3.01.05 to the application (pH analysis_1st GEN 6SL); Annex 2.3.01.06 to the application (Microbiology_1st GEN 6SL); Annex 2.3.01.07 to the application (sodium_1st GEN 6SL); Annex 2.3.01.08 to the application (Protein content_1st GEN 6SL); Annex 2.3.01.09 to the application (Water content_1st GEN 6SL); Annex 2.3.01.10 to the application (Heavy metals_1st GEN 6SL); Annex 2.3.01.11 to the application (Mycotoxins_1st GEN 6SL); Annex 2.3.01.12 to the application (chlorides_1st GEN 6SL); Annex 2.3.02.01 to the application (ash content_2nd GEN 6SL); Annex 2.3.02.02 to the application (carbohydrates (ww)_2nd GEN 6SL); Annex 2.3.02.03 to the application (endotoxins_2nd GEN 6SL); Annex 2.3.02.04 to the application (Enterobacteriaceae_2nd GEN 6SL); Annex 2.3.02.05 to the application (pH_2nd GEN 6SL); Annex 2.3.02.06 to the application (microbiology_2nd GEN 6SL); Annex 2.3.02.07 to the application (sodium_2nd GEN 6SL); Annex 2.3.02.08 to the application (protein content_2nd GEN 6SL); Annex 2.3.02.09 to the application (water content_2nd GEN 6SL); Annex 2.3.02.10 to the application (heavy metals_2nd GEN 6SL); Annex 2.3.02.11 to the application (mycotoxins_2nd GEN 6SL); Annex 2.3.02.12 to the application (absence of rDNA_6SL); Annex 2.3.02.13 to the application (chlorides_2nd GEN 6SL); Annex 2.3.03.01 to the application to the application (Carbohydrates_Calculation matrix_6SL_GEN1_HPAEC_PAD Excel

Distribution, Metabolism and Excretion (ADME)[9], toxicological information[10], and the bioinformatic study for allergenicity assessment[11], in support of the application.

(8) On 21 February 2024, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of 6′-SL sodium salt 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.

(9) On 15 December 2025, the Authority adopted its scientific opinion on the 'Safety of 6′-SL sodium salt produced with a derivative strain (*Escherichia coli* K-12 MG1655 INB-6SL_02) of *E. coli* K-12 MG1655 (ATCC 700926), as a novel food pursuant to Regulation (EU) 2015/2283'[12] in accordance with Article 11 of Regulation (EU) 2015/2283.

(10) In its scientific opinion, the Authority concluded that 6′-SL sodium salt 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 6′-SL sodium salt 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.

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sheet: gen 1); Annex 2.3.03.02 to the application (Carbohydrates_Calculation matrix_6SL_GEN2_HPAEC_PAD Excel sheet: gen 2); Annex 2.3.03.03 to the application (Carbohydrates_Calculation matrix_6SL_GEN1 and 2_qNMR Excel sheet: qNMR 6SL_Na %DM); Annex 2.3.05 to the application (report solubility 6SL and report solubility 6SL_updated_2024); Annex 2.3.06 to the application (6SL_qNMR method); Annex 2.3.06.01 to the application (qNMR validation); Annex 2.3.07 to the application (UPLC_RI_method validation report_INBMV1001); Annex 2.3.08 to the application (minor carbohydrates UPLC-RI); Annex 2.3.09.01 to the application (analyses of the unidentified carbohydrate fraction LC-MS); Annex 2.3.09.02 to the application (study on 6SL unidentified carbohydrate fraction); Annex 2.3.09.03 to the application (metabolite detection in the 6′-SL sodium salt batches produced by the 2nd generation strain); Annex 2.3.10 to the application (6SL_Stability study_Powder 40C 75RH); Annex 2.3.11 to the application (summary stability study 6SL 40C_75 RH Excel sheet: 40_75 Excel sheet: graphs 40_75 Excel sheet: microbio); Annex 2.3.12 to the application (6SL_Stability study_Powder 25C 60RH, 6SL_Stability study_Powder 25C 60RH_Updated_2024 and 6SL_Stability study_Powder 25C 60RH_updated_ADR2); Annex 2.3.13 to the application (summary stability study 6SL 25C_60 RH, summary stability study 6SL 25C_60 RH_Updated_2024 and summary stability study 6SL 25C_60 RH_updated_ADR2 Excel sheet: 25_60 Excel sheet: graphs 25_60 Excel sheet: microbio); Annex 2.3.14.01 to the application (6SL_Stability study_Liquid food matrices); Annex 2.3.14.02 to the application (6SL_Stability study_Granola bars); Annex 2.3.14.03 to the application (production of infant formula containing 6′-SL_Na); Annex 2.3.14.04 to the application (6SL_Stability study_Infant formula); Annex 2.3.17.01 (peak identification 6SL 1st Gen); Annex 2.3.17.02 to the application (peak identification 6SL 2nd Gen); Annex 2.3.18.01 to the application (6SLu_Production); Annex 2.3.18.02 to the application (6SLu_Identity).

9 Section 2.7 Absorption, Distribution, Metabolism and Excretion (ADME) to the application.

10 Section 2.9 (toxicological information) to the application; Subsection 2.9.2 to the application (mutagenicity and genotoxicity studies); Subsection 2.9.3 to the application (sub-chronic oral toxicity study in the rat); Annex 2.9.01 to the application (mutagenicity study 6′-SL OECD 471); Annex 2.9.02 to the application (genotoxicity study 6′SL OECD 487); Annex 2.9.03 to the application (genotoxicity 6′-SL OECD 473); Annex 2.9.04.01 to the application (validation urinalysis); Annex 2.9.04.02 to the application (validation plasma analyses); Annex 2.9.04.03 to the application (OECD 408 DRF study 6′-SL); Annex 2.9.04.04 to the application (formulation analyses); Annex 2.9.04.05 to the application (report subchronic oral tox study 6′-SL OECD 408); Appendix B.3 to the application (summary table of statistically significant observations in toxicity studies_DRF study 6′-SL); Appendix B.3 to the application (summary table of statistically significant observations in toxicity studies_subchronic oral tox study 6′-SL).

11 Annex 2.10.01 (allergen results) to the application.

12 EFSA Journal. 2026;24:e9856 https://doi.org/10.2903/j.efsa.2026.9856).

(11) 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.

(12) 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.

(13) 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 6′-SL sodium salt 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.

(14) However, restricting the authorisation of 6′-SL sodium salt 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.

(15) In accordance with the conditions of use of food supplements containing 6′-SL sodium salt 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 6′-SL sodium salt produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) should not be used if other foods with added 6′-SL are consumed on the same day.

(16) It is appropriate that the inclusion of 6′-SL sodium salt 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.

(17) 6′-SL sodium salt 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.

(18) 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. 6′-sialyllactose sodium salt produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) is authorised to be placed on the market within the Union.

   6′-sialyllactose sodium salt 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.[13] 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 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,

For the Commission
The President
Ursula VON DER LEYEN

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