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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

on authorising the placing on the market of 3'-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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on authorising the placing on the market of 3'-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)

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) 2021/96[3] authorised the placing on the Union market of 3'-Sialyllactose sodium salt as a novel food under Regulation (EU) 2015/2283.

(4) Commission Implementing Regulation (EU) 2023/113[4] authorised the placing on the Union market of 3'-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) 2024/1047[5] authorised the placing on the Union market of 3′-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) 2021/96 of 28 January 2021 authorising the placing on the market of 3'-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 31, 29.1.2021, p 201, ELI: http://data.europa.eu/eli/reg_impl/2021/96/oj).

4 Commission Implementing Regulation (EU) 2023/113 of 16 January 2023 authorising the placing on the market of 3′-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 15, 17.1.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/113/oj).

(6) On 23 June 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 3'-Sialyllactose ('3′-SL') sodium salt obtained by microbial fermentation using a genetically modified strain *Escherichia coli* ('*E. coli*') K-12 MG1655 INB-3SL_01 derived from the host strain *E. coli* K12 MG1655 (ATCC 700926), on the Union market as a novel food. The applicant requested for the so produced 3′-SL sodium salt to be used in the same food categories and at the same maximum levels as the currently 3′-SL sodium salt authorised by Commission Implementing Regulation (EU) 2021/96.

(7) On 23 June 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) 2024/1047 of 9 April 2024 authorising the placing on the market of 3′-Sialyllactose sodium salt produced using a derivative strain of *Escherichia coli* W (ATCC 9637) as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L, 2024/1047, 10.4.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/1047/oj).

6 Section 2.1 to the application (identity of the novel food and identity of the novel food_updated ADR1); Annex 2.1.02 (NMR report); Annex 2.1.03 to the application (UPLC_RI validation report INBMV1001); Annex 2.1.04 to the application (UPLC–MSMS analysis 3SL).

7 Section 2.2 to the application (Production process, Production process_updated_ADR1 and Production process_updated_ADR2); Annex to the application (ADR2_PP); Annex 2.2.04 to the application (GMM_description and GMM_description_updated ADR1); Annex 2.2.04.02 to the application (Structure helper plasmids and Structure sequence plasmids_INB_3SL_01 _updated_ADR1); Annex 2.2.04.03 to the application (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_3SL_fasta file and contigs_3SL_fasta file_updated ADR1); Annex 2.2.04.07 to the application (PROKKA_3SL_fasta file); Annex 2.2.04.08 to the application (Deposition certificate); Annex 2.2.04.09 to the application (structure and sequence pINB-3SL_01); Annex 2.2.04.10 to the application (additional AMR INB_3SL_01); Annex 2.2.04.11 to the application (Test for absence of viable cells); Annex 2.2.05 to the application (Raw materials 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 (HACCP plan); Annex 2.2.08 to the application (determination of residual processing aid in 3′-SL sodium salt powder batches); Annex 2.2.09 to the application (HACCP plan_2019); Annex 2.2.10 to the application (effect of heat treatment_3SL); Protocol for the preparation of master and working cell banks to the application.

8 Section 2.3 to the application (compositional data, Compositional data_updated ADR1 and Compositional data_updated ADR2); Annex to the application (Annex_ADR3_CD); 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 (sodium); Annex 2.3.08 to the application (protein content); Annex 2.3.09 to the application (water content); Annex 2.3.10 to the application (heavy metals); Annex 2.3.11 to the application (mycotoxins); Annex 2.3.12 to the application (chlorides); Annex 2.3.13 to the application (absence of rDNA); Annex 2.3.14 to the application (method description results qNMR (Inbiose)); Annex 2.3.15 to the application (minor carbohydrates UPLC-RI); Annex 2.3.16.01 to the application (Carbohydrates_Calculation matrix_UPLC-RI Excel sheet: 3-SL Sodium salt); Annex 2.3.16.02 to the application (Carbohydrates_Calculation matrix_qNMR Excel sheet: qNMR 3SL_Na %DM); Annex 2.3.17.01 to the application (determination of HMOs by LC–MSMS); Annex 2.3.17.02 to the application (validation report_LC–MSMS); Annex 2.3.18 to the application (3SL solubility report and 3SL solubility report_updated_ADR1); Annex 2.3.19 to the application (3SL_Stability study_Powder 40C 75RH); Annex 2.3.20 to the application (Summary stability study 3SL 40_75RH Excel sheet: 40_75 Excel sheet: graphs 40_75 Excel sheet: microbio); Annex 2.3.21 to the application (3SL_Stability study_Powder 25C 60RH_Updated and 3SL_Stability study_Powder 25C 60RH_Updated_ADR1); Annex 2.3.22 to the application (Summary stability study 3SL 25_60RH Excel sheet: 25_60 Excel sheet: graphs 25_60 Excel sheet: microbio, and Summary stability study 3SL

Distribution, Metabolism and Excretion (ADME)[9], toxicological information[10], the bioinformatic study for allergenicity assessment[11], and other relevant scientific studies[12], in support of the application.

(8) On 18 March 2024, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of 3′-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 4 March 2026, the Authority adopted its scientific opinion on the 'Safety of 3′-SL sodium salt produced with a derivative strain *(Escherichia coli* K-12 MG1655 INB-3SL_01) of *E. coli* K-12 MG1655 (ATCC 700926), as a novel food pursuant to Regulation (EU) 2015/2283'[13], in accordance with Article 11 of Regulation (EU) 2015/2283.

(10) In its scientific opinion, the Authority concluded that 3′-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 3′-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.

(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, the bioinformatic study for allergenicity assessment, and other relevant scientific studies 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

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25_60RH_Updated ADR1 Excel sheet: 25_60 Excel sheet: graphs 25_60 Excel sheet: microbio); Annex 2.3.23 to the application (3SL_Stability study_Liquid food matrices); Annex 2.3.24 to the application (3SL_Stability study_Infant formula); Annex 2.3.25 to the application (manufacturing of the infant formula); Annex 2.3.31 to the application (peak identification 3SL); Annex 2.3.32.01 to the application (3SLu_Production); Annex 2.3.32.02 to the application (3SLu_Identity).

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

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 (subchronic oral toxicity study in the rat); Annex 2.9.01 to the application (mutagenicity study 3′-SL OECD 471); Annex 2.9.02 to the application (genotoxicity study 3′SL OECD 487); Annex 2.9.03 to the application (OECD 408 formulation analyses); Annex 2.9.04 to the application (validation plasma analysis); Annex 2.9.05 to the application (validation urinalysis); Annex 2.9.06 to the application (dose-range finding study); Annex 2.9.07 to the application (OECD 408_Subchronic study report); Appendix B.3 to the application (Summary table statistically significant observations toxicity studies_DRF study 3′-SL and Summary table statistically significant observations toxicity studies_Subchronic oral tox study 3′-SL).

11 Annex 2.10.01 to the application (allergen results).

12 Method description for monitoring HMOs in food ingredient and food matrices (P1512_R03_v01); Evaluation of alternative filter membrane for sample preparation in HMO LC–MS method (P1679_R01_v01_INB_signed).

13 EFSA Journal. 2026;24:e10009 - https://doi.org/10.2903/j.efsa.2026.10009).

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, the bioinformatic study for allergenicity assessment, and other relevant scientific studies should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place 3′-SL sodium salt produced by a derivative strain of *Escherichia coli* K-12 MG1655 (ATCC 700926) on the market within the Union for a period of five years from the entry into force of this Regulation.

(14) However, restricting the authorisation of 3′-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 3′-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 3′-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 3′-SL sodium salt are consumed on the same day.

(16) It is appropriate that the inclusion of 3′-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) 3′-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. 3′-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.

   3′-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.[14] 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

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