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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising the placing on the market of Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 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 novel foods.

(3) On 6 February 2024, the company Shandong Henglu Biotechnology Co, Ltd ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 on the Union market as a novel food. The applicant requested the Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 to be used in a number of foods intended for the general population and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[3] for the general population excluding infants and young children.

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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 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51, ELI: http://data.europa.eu/eli/dir/2002/46/oj).

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(4) On 6 February 2024, the applicant also made a request to the Commission for the protection of the proprietary scientific studies and data relating to toxicological information[4].

(5) On 29 July 2024, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of place Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 as a novel food.

(6) On 1 July 2026, the Authority adopted its scientific opinion "Safety of Lacto-N-triose II as a Novel food pursuant to Regulation (EU) 2015/228[5]" in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 is safe when used under the proposed conditions of use. Therefore, the scientific opinion gives sufficient grounds to establish that Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 when used under the proposed conditions of use fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283

(8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on analytical reports for toxicological information without which it could not have assessed the novel food and reached its conclusion.

(9) 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.

(10) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific evidence and data relating to toxicological information should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 on the market within the Union during a period of five years from the entry into force of this Regulation.

(11) However, restricting the authorisation of Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 and the reference to the scientific evidence and 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.

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4 Annex 24_Ames test.pdf; Annex 25_Micronucleus test.pdf; ANNEX-Q67 Lacto-N-triose II In Vitro Micronucleus Assay in Chinese Hamster Ovary Cells.pdf; Annex 26_Dose range finding study.pdf; Annex 27_Subchronic toxicity study.pdf; Annex 35 - Specification methods description.pdf.

5 *EFSA Journal*. 2026;24:e10257.

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(12) As the novel food contains lactose derived from milk, which is listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council[6], as one of the substances or products causing allergies or intolerances, food and food supplements containing Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 should be appropriately labelled following the requirements of Article 21 of that Regulation.

(13) It is appropriate that the inclusion of Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

(14) Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 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.

(15) 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*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 is authorised to be placed on the market within the Union.

   Lacto-*N*-triose II (LNT II) produced with a derivative of *Kluyveromyces lactis* strain DSM 70799 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 Shandong Henglu Biotechnology Co, Ltd [7] is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five 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

[6] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

[7] Block B, Jiaheng Business Building, Hualong Road, Licheng District, Jinan, Shandong Province, 250100, People's Republic of China.

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protected pursuant to Article 3 or with the agreement of Shandong Henglu Biotechnology Co, Ltd.

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 Shandong Henglu Biotechnology Co, Ltd.

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

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