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 (Text with EEA relevance)

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

(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 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)] was adopted, which establishes a Union list of authorised novel foods.

(3) On 16 July 2018, the company Glycom A/S ('the applicant') submitted a request to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place lacto-*N*-tetraose ('LNT'), obtained by microbial fermentation with a genetically modified strain of *Escherichia coli,* strain K12 DH1, on the Union market as a novel food. The applicant requested for LNT to be used in unflavoured pasteurised and unflavoured sterilised milk products, flavoured and unflavoured fermented milk based products including heat-treated products, cereal bars, flavoured drinks, infant formula and follow-on formula, processed cereal-based food, baby food for infants and young children, milk-based drinks and similar products intended for young children, foods for special medical purposes, and total diet replacement foods for weight control, as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council[(3)], and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[(4)] intended for the general population excluding infants. The applicant also proposed that food supplements containing LNT should not be used if breast milk

which naturally contains LNT and/or other foods with added LNT, are consumed the same day.

(4) On 16 July 2018, the applicant also made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application, namely, the proprietary analytical reports on the structure comparison via nuclear magnetic resonance ('NMR') of LNT produced by bacterial fermentation with LNT naturally present in human milk[(5)], the detailed characterisation data on the production bacterial strains[(6)] and their certificates[(7)], the specifications for the raw materials and processing aids[(8)], the certificates of analyses of the various LNT batches[(9)], the analytical methods and validation reports[(10)], the LNT stability reports[(11)], the detailed description of the production process[(12)], the laboratory accreditation certificates[(13)], the LNT intake assessment reports[(14)], an *in vitro* mammalian cell micronucleus test with LNT[(15)] and its summary table of the statistically significant observations[(16)], a second *in vitro* mammalian cell micronucleus test with LNT[(17)] and its summary table of the statistically significant observations[(18)], two *in vitro* mammalian cell micronucleus tests with the related compound, lacto-*N*-neotetraose[(19)], a bacterial reverse mutation test with LNT[(20)], a 14-day oral toxicity study in the neonatal rat with LNT[(21)], a 90-day oral toxicity study in the neonatal rat with LNT[(22)] and its summary table of the statistically significant observations, and a 90-day oral toxicity study in the neonatal rat with lacto-*N*-neotetraose[(23)].

(5) On 30 August 2018, 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.

(6) On 30 October 2019, the Authority adopted its scientific opinion 'Safety of lacto-*N*-tetraose (LNT) as a novel food pursuant to Regulation (EU) 2015/2283'[(24)] in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that LNT is safe under the proposed conditions of use for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that LNT, when used in in unflavoured pasteurised and unflavoured sterilised milk products, flavoured and unflavoured fermented milk based products including heat-treated products, cereal bars, flavoured drinks, infant formula and follow-on formula, processed cereal-based food, baby food for infants and young children, milk-based drinks and similar products intended for young children, foods for special medical purposes, and total diet replacement foods for weight control, as defined in Regulation (EU) No 609/2013, and in food supplements as defined in Directive 2002/46/EC intended for the general population excluding infants, complies with the authorisation requirements of Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority considered that it could not have reached its conclusions on the safety of the LNT without the data from the proprietary analytical reports on the structure comparison via nuclear magnetic resonance ('NMR') of LNT produced by bacterial fermentation with LNT naturally present in human milk, the detailed characterisation data on the production bacterial strains and their certificates, the specifications for the raw materials and processing aids, the certificates of analyses

of the various LNT batches, the analytical methods and validation reports, the LNT stability reports, the detailed description of the production process, the laboratory accreditation certificates, the *in vitro* mammalian cell micronucleus test with LNT and its summary table of the statistically significant observations, a second *in vitro* mammalian cell micronucleus test with LNT and its summary table of the statistically significant observations, a bacterial reverse mutation test with LNT, a 14-day oral toxicity study in the neonatal rat with LNT, and a 90-day oral toxicity study in the neonatal rat with LNT and its summary table of the statistically significant observations.

(9) Following the receipt of the Authority's scientific opinion, the Commission requested the applicant to further clarify the justification provided with regard to their the proprietary analytical reports on the structure comparison via NMR of LNT produced by bacterial fermentation with LNT naturally present in human milk, the report on the detailed characterisation data on the production bacterial strains and their certificates, the report on the specifications for the raw materials and processing aids, the certificates of analyses of the various LNT batches, the analytical methods and validation reports, the LNT stability reports, the detailed description of the production process, the laboratory accreditation certificates, the *in vitro* mammalian cell micronucleus test with LNT and its summary table of the statistically significant observations, a second *in vitro* mammalian cell micronucleus test with LNT and its summary table of the statistically significant observations, a bacterial reverse mutation test with LNT, a 14-day oral toxicity study in the neonatal rat with LNT, and a 90-day oral toxicity study in the neonatal rat with LNT and its summary table of the statistically significant observations as referred to in point (b) of Article 26(2) of Regulation (EU) 2015/2283.

(10) The applicant declared that, at the time the application was made, they held proprietary and exclusive rights of reference to the studies under national law and that therefore third parties could not lawfully access or use these studies.

(11) 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, the data contained in the applicant's file which served as a basis for the Authority to establish the safety of the novel food and to reach its conclusions on the safety of LNT, and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of LNT should be restricted to the applicant for that period.

(12) However, restricting the authorisation of LNT and of the reference to the data contained in the applicant's file for the sole use of the applicant, does not prevent other 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 authorisation under Regulation (EU) 2015/2283.

(13) In line 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 breast

milk which naturally contains LNT and/or other foods with added LNT are consumed the same day.

(14) The Annex to Regulation (EU) 2017/2470 should be 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-tetraose as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2 For a period of five years from the date of entry into force of this Regulation only the initial applicant:

Company: Glycom A/S;

Address: Kogle Allé 4, DK-2970 Hørsholm, Denmark,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of the applicant.

3 The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

Article 2

The data contained in the application file on the basis of which lacto-N-tetraose has been assessed by the Authority, claimed by the applicant as fulfilling the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283, shall not be used for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of the applicant.

Article 3

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

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, 2 April 2020.

For the Commission

The President

Ursula VON DER LEYEN