COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising the placing on the market of Lacto-*N*-fucopentaose I and 2'-Fucosyllactose mixture produced by a derivative strain of *Escherichia coli* K-12 DH1 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 3 March 2021, the company Glycom A/S ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place a mixture of Lacto-*N*-fucopentaose I and 2'-Fucosyllactose ('the LNFP-I /2'-FL mixture') obtained by microbial fermentation, using a genetically modified strain of *E. coli* K-12 DH1, on the Union market as a novel food. The applicant requested for the LNFP-I/2'-FL mixture to be used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council[3], in unflavoured pasteurised and unflavoured sterilised (including UHT) milk products, unflavoured and flavoured fermented milk-based products including heat-treated products, cereal bars, milk based drinks and similar products, processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, food for special medical purposes as defined in Regulation (EU) No 609/2013, beverages (flavoured drinks, excluding drinks with a

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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 Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35, ELI: http://data.europa.eu/eli/reg/2013/609/oj).

pH less than 5), total diet replacement for weight control as defined in Regulation (EU) No 609/2013, 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. Subsequently, on 16 January 2024, the applicant modified the initial request in the application on the use of the LNFP-I /2'-FL mixture in food supplements, to exclude from the scope of the application infants and children under three years of age. Concerning the conditions of use, the applicant also proposed that food supplements containing the LNFP-I /2'-FL mixture should not be used, if other foods with added LNFP-I /2'-FL are consumed on the same day.

(4) On 3 March 2021, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data submitted in support of the application, namely, liquid chromatography- mass spectrometry ('LC-MS') and liquid chromatography tandem mass spectrometry ('LC-MS/MS'), nuclear magnetic resonance ('NMR'), and High Pressure Liquid Chromatography – Pulsed Amperometric Detection ('HPLC-PAD') method validation and results, for the determination of the identity of the LNFP-I/2'-FL mixture[5]; a detailed description of the genetically modified LNFP-I/2'-FL mixture production strain[6] and production strain certificates[7]; raw material and processing aid specifications[8]; a detailed description of the production process[9]; detailed composition analyses[10]; the results of the stability studies[11]; the quantitative analyses of the levels of LNFP-I and of 2'-FL in human milk[12]; the intake assessment of the LNFP-I/2'-FL mixture[13]; a bacterial reverse mutation with the LNFP-I/2'-FL mixture[14]; an *in vitro* mammalian cell micronucleus test with the LNFP-I/2'-FL mixture[15]; and, a 90-day oral toxicity study in rats with the LNFP-I/2'-FL mixture[16].

(5) On 1 July 2021, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of the LNFP-I/2'-FL mixture obtained by microbial fermentation, using a genetically modified production strain, derived from the host strain *E. coli* K-12 DH1, as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(6) On 26 October 2023, the Authority adopted its scientific opinion on the 'Safety of Lacto-*N*-fucopentaose I / 2'-Fucosyllactose ('LNFP-I /2'-FL') mixture as a novel food pursuant to Regulation (EU) 2015/2283'[17] in accordance with Article 11 of Regulation (EU) 2015/2283.

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4 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).

5 Glycom A/S 2020 and 2022 (unpublished).

6 Glycom A/S 2020 and 2022 (unpublished).

7 Glycom A/S 2020 (unpublished).

8 Glycom A/S 2019 (unpublished).

9 Glycom A/S 2020 and 2022 (unpublished).

10 Glycom A/S 2020 and 2022 (unpublished).

11 Glycom A/S 2020, 2022 and 2023 (unpublished).

12 Glycom A/S 2021 (unpublished).

13 Glycom A/S 2022 (unpublished).
B. Gilby 2020a (unpublished).

14 B. Gilby 2020a (unpublished).

15 B. Gilby 2020b (unpublished).

16 D. Sannard 2020 (unpublished)

17 EFSA Journal 2023;21e8412; https://doi.org/10.2903/j.efsa.2023.8412.

(7) In its scientific opinion, the Authority concluded that the LNFP-I /2'-FL mixture produced by a derivative strain of *E. coli* K-12 DH1 is safe under the proposed conditions of use for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that the LNFP-I /2'-FL mixture produced by a derivative strain of *E. coli* K-12 DH1, when used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013, unflavoured pasteurised and unflavoured sterilised (including UHT) milk products, unflavoured and flavoured fermented milk-based products including heat-treated products, cereal bars, milk based drinks and similar products, processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, food for special medical purposes as defined in Regulation (EU) No 609/2013, beverages (flavoured drinks, excluding drinks with a pH less than 5), total diet replacement for weight control as defined in Regulation (EU) No 609/2013, and in food supplements as defined in Directive 2002/46/EC, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(8) In that opinion, the Authority also concluded that although the applicant did not propose maximum use levels for the use of LNFP-I /2'-FL mixture in food for special medical purposes as defined in Regulation (EU) No 609/2013, the maximum levels used in this type of food should not be higher than the maximum levels specified for the proposed uses or the maximum use levels proposed for food supplements as defined in Directive 2002/46/EC. In light of the fact that uses of the novel food are proposed for food supplements intended for the general population excluding infants and young children, the conditions of use of this novel food should distinguish between food for special medical purposes intended for infants and young children and that intended for the general population above the age of three years. Hence, appropriate maximum levels of the novel food that are proposed for use in food supplements should be included in the conditions of use according to the population age.

(9) In its scientific opinion, the Authority considered that it could not have reached its conclusions on the safety of the LNFP-I /2'-FL mixture produced by a derivative strain of *E. coli* K-12 DH1 without the scientific studies and data submitted in support of the application, namely, the LC-MS and LC-MS/MS, the NMR, and HPLC-PAD method validation and results for the determination of the identity of the LNFP-I/2'-FL mixture; a detailed description of the genetically modified LNFP-I/2'-FL mixture production strain and production strain certificates; raw material and processing aid specifications; a detailed description of the production process; detailed composition analyses; the results of the stability studies; the quantitative analyses of the levels of LNFP-I and of 2'-FL in human milk; the intake assessment of the LNFP-I/2'-FL mixture; a bacterial reverse mutation with the LNFP-I/2'-FL mixture; an *in vitro* mammalian cell micronucleus test with the LNFP-I/2'-FL mixture; and, a 90-day oral toxicity study in rats with the LNFP-I/2'-FL mixture.

(10) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those scientific studies and data, and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2), point (b) of Regulation (EU) 2015/2283.

(11) The applicant declared that it held proprietary and exclusive rights of reference to the scientific studies and data on the LC-MS and LC-MS/MS, the NMR, and the HPLC-PAD method validation and results for the determination of the identity of the LNFP-

I/2'-FL mixture; the detailed description of the genetically modified LNFP-I/2'-FL mixture production strain and production strain certificates; the raw material and processing aid specifications; the a detailed description of the production process; to detailed composition analyses; the results of the stability studies; the quantitative analyses of the levels of LNFP-I and of 2'-FL in human milk; the intake assessment of the LNFP-I/2'-FL mixture; the bacterial reverse mutation with the LNFP-I/2'-FL mixture; the *in vitro* mammalian cell micronucleus test with the LNFP-I/2'-FL mixture; and, the 90-day oral toxicity study in rats with the LNFP-I/2'-FL mixture, under national law, at the time it submitted the application, and that third parties cannot lawfully access, use or refer to those data and studies.

(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, the scientific studies and data on the LC-MS and LC-MS/MS, the NMR, and the HPLC-PAD method validation and results for the determination of the identity of the LNFP-I/2'-FL mixture; a detailed description of the genetically modified LNFP-I/2'-FL mixture production strain and production strain certificates; raw material and processing aid specifications; a detailed description of the production process; detailed composition analyses; the results of the stability studies; the quantitative analyses of the levels of LNFP-I and of 2'-FL in human milk; the intake assessment of the LNFP-I/2'-FL mixture; a bacterial reverse mutation with the LNFP-I/2'-FL mixture; an *in vitro* mammalian cell micronucleus test with the LNFP-I/2'-FL mixture; and, a 90-day oral toxicity study in rats with the LNFP-I/2'-FL mixture, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place the LNFP-I/2'-FL mixture produced with a derivative strain of *E. coli* K-12 DH1 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 the LNFP-I/2'-FL mixture produced with a derivative strain of *E. coli* K-12 DH1 and the reference to the scientific studies and data contained in the applicant's file for its sole use 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 line with the conditions of use of food supplements containing the LNFP-I/2'-FL mixture produced with a derivative strain of *E. coli* K-12 DH1 as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers with an appropriate label that food supplements containing that novel food should not be consumed by infants and children under three years of age and should not be used, if other foods with added LNFP-I/2'-FL are consumed on the same day.

(15) It is appropriate that the inclusion of the LNFP-I/2'-FL mixture produced with a derivative strain of *E. coli* K-12 DH1 in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

(16) The LNFP-I/2'-FL mixture produced with a derivative strain of *E. coli* K-12 DH1 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*-fucopentaose I and 2'-Fucosyllactose mixture produced with a derivative strain of *E. coli* K-12 DH1 is authorised to be placed on the market within the Union.

   Lacto-*N*-fucopentaose I and 2'-Fucosyllactose mixture produced with a derivative strain of *E. coli* K-12 DH1 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 Glycom A/S[18] 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 of entry into force of this Regulation*], 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 Glycom A/S.

Article 3

The scientific studies and 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 Glycom A/S.

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

[18] Address: Kogle Allé 4, 2970 Hørsholm, Denmark.