This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising the placing on the market of 3-Fucosyllactose 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)

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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) Commission Implementing Regulation (EU) 2021/2029[3] authorised the placing on the Union market of 3-Fucosyllactose obtained by microbial fermentation using the genetically modified strain K12 MG1655 of *Escherichia coli ('E. coli')* as a novel food under Regulation (EU) 2015/2283.

(4) Commission Implementing Regulation (EU) 2023/52 [4] of 4 January 2023 authorised the placing on the market of 3-Fucosyllactose produced by a derivative strain of Escherichia coli BL21(DE3) as a novel food under Regulation (EU) 2015/2283.

(5) On 25 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 3-Fucosyllactose ("3-FL") 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 3-FL to be used in infant formula

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1 OJ L 327, 11.12.2015, p. 1.

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).

3 Commission Implementing Regulation (EU) 2021/2029 of 19 November 2021 authorising the placing on the market of 3-Fucosyllactose (3-FL) 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 415, 22.11.2021, p. 9).*

4 Commission Implementing Regulation (EU) 2023/52 of 4 January 2023 authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of Escherichia coli BL21(DE3) as a novel food and amending Implementing Regulation (EU) 2017/2470 *(OJ L 3, 5.1.2023, p. 1).*

and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council[5], 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, foods 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 of the European Parliament and of the Council[6] intended for the general population. Subsequently, on 15 June 2023, the applicant modified the initial request in the application on the use of 3-FL in food supplements to exclude infants and young children. The applicant also proposed that food supplements containing 3-FL should not be used if other foods with added 3-fucosyllactose are consumed the same day.

(6) On 25 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, high performance liquid chromatography-electrospray ionisation-mass spectrometry ('HPLC-ESI-MS/MS'), nuclear magnetic resonance ('NMR') spectroscopy, and high-performance anion-exchange chromatography with pulsed amperometric detection ('HPAEC-PAD') method validation and the results for the determination of the identity of 3-FL[7]; a detailed description of the genetically modified 3-FL production strain[8]; a detailed description of the production process [9]; detailed composition analysis and stability test results[10]; a bacterial reverse mutation test with 3-FL[11]; an *in vitro* mammalian cell micronucleus test with 3-FL[12]; a 14-day dose range finding oral toxicity study in rats with 3-FL[13]; and, a 90-day oral toxicity study in rats with 3-FL[14].

(7) On 4 October 2021, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of 3-Fucosyllactose obtained by microbial

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5 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).

6 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).

7 Glycom A/S 2021 and 2022 (unpublished).

8 Glycom A/S 2021 and 2022 (unpublished).

9 Glycom A/S 2021 and 2022 (unpublished).

10 Glycom A/S 2021 (unpublished).

11 Phipps KR, Lozon D, Stannard DR, Gilby B, Baldwin N, Miks MH, Lau A and Röhrig CH, 2022. Neonatal subchronic toxicity and in vitro genotoxicity studies of the human-identical milk oligosaccharide 3-fucosyllactose. Journal of Applied Toxicology, 2022, 1–17.

12 Phipps KR, Lozon D, Stannard DR, Gilby B, Baldwin N, Miks MH, Lau A and Röhrig CH, 2022. Neonatal subchronic toxicity and in vitro genotoxicity studies of the human-identical milk oligosaccharide 3-fucosyllactose. Journal of Applied Toxicology, 2022, 1–17.

13 Phipps KR, Lozon D, Stannard DR, Gilby B, Baldwin N, Miks MH, Lau A and Röhrig CH, 2022. Neonatal subchronic toxicity and in vitro genotoxicity studies of the human-identical milk oligosaccharide 3-fucosyllactose. Journal of Applied Toxicology, 2022, 1–17.

14 Phipps KR, Lozon D, Stannard DR, Gilby B, Baldwin N, Miks MH, Lau A and Röhrig CH, 2022. Neonatal subchronic toxicity and in vitro genotoxicity studies of the human-identical milk oligosaccharide 3-fucosyllactose. Journal of Applied Toxicology, 2022, 1–17.

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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.

(8) On 27 April 2023, the Authority adopted its scientific opinion on the 'Safety of 3-fucosyllactose produced by a derivative strain of *E. coli* K-12 DH1 as a novel food pursuant to Regulation (EU) 2015/2283'[15] in accordance with Article 11 of Regulation (EU) 2015/2283.

(9) In its scientific opinion, the Authority concluded that 3-FL is safe under the proposed conditions of use for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that 3-FL, 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, foods 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, complies with the authorisation requirements of Article 12(1) of Regulation (EU) 2015/2283.

(10) In its scientific opinion, the Authority considered that it could not have reached its conclusions on the safety of the 3-FL without the scientific studies and data on the HPLC-ESI-MS/MS, NMR spectroscopy, and HPAEC-PAD method validation and the results for the determination of the identity of 3-FL; the detailed description of the genetically modified 3-FL production strain; the detailed description of the production process; the detailed composition analysis and stability test results; the bacterial reverse mutation test with 3-FL; the *in vitro* mammalian cell micronucleus test with 3-FL; the 14-day dose range finding oral toxicity study in rats with 3-FL; and, the 90-day oral toxicity study in rats with 3-FL.

(11) 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)(b) of Regulation (EU) 2015/2283.

(12) The applicant declared that they held proprietary and exclusive rights of reference to the scientific studies and data on the HPLC-ESI-MS/MS, NMR spectroscopy, and HPAEC-PAD method validation and the results for the determination of the identity of 3-FL; the detailed description of the genetically modified 3-FL production strain; the detailed description of the production process; the detailed composition analysis and stability test results; the bacterial reverse mutation test with 3-FL; the *in vitro* mammalian cell micronucleus test with 3-FL; the 14-day dose range finding oral toxicity study in rats with 3-FL; and, the 90-day oral toxicity study in rats with 3-FL, under national law at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data and studies.

(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, the scientific studies and data on the HPLC-ESI-MS/MS, NMR spectroscopy, and

[15] EFSA Journal 2023;21(6):8026.

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HPAEC-PAD method validation and the results for the determination of the identity of 3-FL; the detailed description of the genetically modified 3-FL production strain; the detailed description of the production process; the detailed composition analysis and stability test results; the bacterial reverse mutation test with 3-FL; the *in vitro* mammalian cell micronucleus test with 3-FL; the 14-day dose range finding oral toxicity study in rats with 3-FL; and, the 90-day oral toxicity study in rats with 3-FL, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place 3-fucosyllactose 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.

(14) However, restricting the authorisation of 3-FL 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 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 line with the conditions of use of food supplements containing 3-FL 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-FL should not be consumed by infants and children under 3 years of age and should not be used if other foods with added 3-FL are consumed the same day.

(16) It is appropriate that the inclusion of 3-FL produced with a derivative strain of *E. coli* K-12 DH1 as a novel food in the Union list of novel foods contains also the required conditions of use, specifications and other information related to its authorisation, as referred to in Article 9(3) of Regulation (EU) 2015/2283.

(17) 3-FL 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.

(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-Fucosyllactose produced with a derivative strain of *E. coli* K-12 DH1 is authorised to be placed on the market within the Union.

   3-Fucosyllactose 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.

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Article 2

Only the company Glycom A/S[16] 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 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

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16 Address: Kogle Allé 4, 2970 Hørsholm, Denmark.