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.

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising the placing on the market of 3′-Sialyllactose sodium salt produced by a derivative strain of *Escherichia coli* W (ATCC 9637) 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 25 March 2021, the company Kyowa Hakko Bio 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 3′-Sialyllactose ('3′-SL') sodium salt, obtained by microbial fermentation using a genetically modified strain (*Escherichia coli* NEO3) derived from the host strain *Escherichia coli* (*E. coli*) W (ATCC 9637), on the Union market as a novel food. The applicant requested for the so produced 3′-SL sodium salt to be used in unflavoured pasteurised and unflavoured sterilised milk products, unflavoured fermented milk-based products, flavoured fermented milk-based products including heat-treated products, beverages (flavoured drinks excluding drinks with a pH less than 5), cereal bars, infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council[3], processed cereal-based food and baby food for infants and young

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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).

children as defined in Regulation (EU) 609/2013, milk-based drinks and similar products, total diet replacement foods for weight control as defined in Regulation (EU) 609/2013, foods for special medical purposes as defined in Regulation (EU) 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. With regard to conditions of use, the applicant also proposed that food supplements containing 3′-SL sodium salt produced with the derivative strain of *E. coli* W (ATCC 9637) should not be consumed if other foods with added 3′-SL sodium salt are consumed on the same day. Subsequently, on 19 October 2023, the applicant modified the initial request in the application for the use of 3′-SL sodium salt produced using the derivative strain of *E. coli* W (ATCC 9637) in food supplements to exclude infants and children under three years of age.

(4) On 26 March 2021, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data, namely, a liquid chromatography-mass spectrometry ('LC-MS/MS'), a nuclear magnetic resonance ('NMR') and a high-performance liquid chromatography – charged aerosol detection ('HPLC-CAD') study for the determination of the identity of 3′-SL[5]; a description of the genetically modified 3′-SL sodium salt production strain[6]; a detailed description of the production process[7]; a bacterial reverse mutation test with 3′-SL sodium salt[8]; an *in vitro* mammalian cell micronucleus test with 3′-SL sodium salt[9]; an *in vivo* mammalian cell micronucleus test with 3′-SL sodium salt[10]; an *in vivo* mammalian cell micronucleus test with 6′-Sialyllactose ('6′-SL') sodium salt[11]; a bacterial reverse mutation test with 6′-SL sodium salt[12]; a 90-day oral toxicity study in rats with 3′-SL sodium salt[13]; a bioinformatics analysis study on the genome of the *E. coli* W (ATCC 9637) to detect heterologous sequences that could encode possible allergens[14]; and, a 90-day oral toxicity study in rats with 6′-SL sodium salt[15], submitted in support of the application.

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, on 7 December 2021, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of 3′-SL sodium salt obtained by microbial fermentation using a genetically modified strain of *E. coli* W (ATCC 9637), as a novel food.

(6) On 3 August 2023, the Authority adopted its scientific opinion on the 'Safety of 3′-sialyllactose ('3′-SL') sodium salt produced by a derivative strain (*Escherichia coli*

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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 Kyowa Hakko Bio Co., Ltd, 2021, 2022, and 2023 (unpublished).

6 Kyowa Hakko Bio Co., Ltd, 2021, 2022, and 2023 (unpublished).

7 Kyowa Hakko Bio Co., Ltd, 2021, 2022, and 2023 (unpublished).

8 Kyowa Hakko Bio Co., Ltd, 2020 (unpublished).

9 Kyowa Hakko Bio Co., Ltd, 2022 (unpublished).

10 Kyowa Hakko Bio Co., Ltd, 2020 (unpublished).

11 Kyowa Hakko Bio Co., Ltd, 2020 (unpublished).

12 Kyowa Hakko Bio Co., Ltd, 2020 (unpublished).

13 Kyowa Hakko Bio Co., Ltd, 2021 (unpublished).

14 Kyowa Hakko Bio Co., Ltd, 2021 (unpublished).

15 Kyowa Hakko Bio Co., Ltd, 2021 (unpublished).

NEO3) of *Escherichia coli* W (ATCC 9637) as a novel food pursuant to Regulation (EU) 2015/2283'[16], in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that 3′-SL sodium salt is safe under the proposed conditions of use and for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that 3′-SL sodium salt produced with derivative strain of *E. coli* W (ATCC 9637), when used in unflavoured pasteurised and unflavoured sterilised milk products, unflavoured fermented milk-based products, flavoured fermented milk-based products including heat-treated products, beverages (flavoured drinks excluding drinks with a pH less than 5), cereal bars, infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children, milk-based drinks and similar products, total diet replacement foods for weight control, foods for special medical purposes, and in food supplements, complies with the authorisation requirements laid down Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on scientific studies and data from the LC-MS/MS, the NMR and the HPLC-CAD study for the determination of the identity of 3′-SL; the description of the genetically modified 3′-SL sodium salt production strain; the detailed description of the production process; the bacterial reverse mutation test with 3′-SL sodium salt; the *in vitro* mammalian cell micronucleus test with 3′-SL sodium salt; the *in vivo* mammalian cell micronucleus test with 3′-SL sodium salt; the bioinformatics analysis study on the genome of the *E. coli* W (ATCC 9637) to detect heterologous sequences that could encode possible allergens; and the 90-day oral toxicity study in rats with 3′-SL sodium salt, contained in the applicant's file, without which it could not have assessed the novel food and reached its conclusion.

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

(10) The applicant declared that it held proprietary and exclusive rights of reference to the scientific studies and data, namely, the LC-MS/MS, the NMR and the HPLC-CAD study for the determination of the identity of 3′-SL; the description of the genetically modified 3′-SL sodium salt production strain; the detailed description of the production process; the bacterial reverse mutation test with 3′-SL sodium salt; the *in vitro* mammalian cell micronucleus test with 3′-SL sodium salt; the *in vivo* mammalian cell micronucleus test with 3′-SL sodium salt; a bioinformatics analysis study on the genome of the *E. coli* W (ATCC 9637) to detect heterologous sequences that could encode possible allergens; and the 90-day oral toxicity study in rats with 3′-SL sodium salt, under national law at the time of submission of the application and that third parties cannot lawfully access, use or refer to those data and 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 scientific studies and data submitted in support of the application, namely, the LC-

[16] EFSA Journal 2023;21(9):8224.

MS/MS, the NMR and the HPLC-CAD study for the determination of the identity of 3′-SL; the description of the genetically modified 3′-SL sodium salt production strain; the detailed description of the production process; the bacterial reverse mutation test with 3′-SL sodium salt; the *in vitro* mammalian cell micronucleus test with 3′-SL sodium salt; the *in vivo* mammalian cell micronucleus test with 3′-SL sodium salt; the bioinformatics analysis study on the genome of the *E. coli* W (ATCC 9637) to detect heterologous sequences that could encode possible allergens; and the 90-day oral toxicity study in rats with 3′-SL sodium salt, 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 using a derivative strain of *E. coli* W (ATCC 9637) on the market within the Union during a period of five years from the entry into force of this Regulation.

(12) However, restricting the authorisation of 3′-SL sodium salt produced using a derivative strain of *E. coli* W (ATCC 9637) 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.

(13) In line with the conditions of use of food supplements containing 3′-SL sodium salt produced using a derivative strain of *E. coli* W (ATCC 9637), as proposed by the applicant, it is necessary to inform consumers by appropriate labelling that food supplements containing 3′-SL sodium salt, produced with a derivative strain of *E. coli* W (ATCC 9637), should not be consumed by infants and children under three years of age and should not be used if other foods with added 3′-SL sodium salt are consumed on the same day.

(14) It is appropriate that the inclusion of 3′-SL sodium salt produced using a derivative strain of *E. coli* W (ATCC 9637) 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.

(15) 3′-SL sodium salt produced using a derivative strain of *E. coli* W (ATCC 9637) 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.

(16) 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 using a derivative strain of *Escherichia coli* W (ATCC 9637) is authorised to be placed on the market within the Union.

3′-Sialyllactose sodium salt produced using a derivative strain of *Escherichia coli* W (ATCC 9637) 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 Kyowa Hakko Bio Co., Ltd.[17] 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 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 Kyowa Hakko Bio 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 5 years from the date of entry into force of this Regulation, without the agreement of Kyowa Hakko Bio 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
Ursula VON DER LEYEN

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