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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2036

of 29 July 2024

authorising the placing on the market of 2'-Fucosyllactose 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 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 authorised novel foods.

(3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes both chemically synthesised and microbiologically produced 2'-Fucosyllactose ('2′-FL') as an authorised novel food. The conditions of use, maximum levels and specific labelling requirements set out in Table 1 of the Annex to that Regulation are common for both the synthetically and the microbiologically produced 2′-FL. At the same time, in in Table 2 of the Annex of that Regulation, separate specifications are set out for chemically synthesised 2′-FL ('2'-Fucosyllactose (synthetic)') and for microbiologically produced 2′-FL ('2'-Fucosyllactose (microbial source)').

(4) On 23 March 2021, the company Kyowa Hakko Bio Co., Ltd ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place 2′-FL obtained by microbial fermentation using a genetically modified strain (SGR5) 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 2′-FL to be used in the same food categories and at the same maximum levels as the currently authorised 2'-FL. In that application, the applicant originally also proposed a change in the conditions of use of 2′-FL to extend its uses in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]), intended for infants. Subsequently, on 30 November 2023, the applicant withdrew the request for use in food supplements for infants from the application.

([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.

(5) On 23 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, a liquid chromatography-mass spectrometry ('LC-MS/MS') study, a nuclear magnetic resonance ('NMR') study, and high-performance liquid chromatography with pulsed amperometric detection ('HPLC-PAD') study for the determination of the identity of 2′-FL ([4]); a description of the genetically modified production strain of *E. coli* W (ATCC 9637) ([5]) including its genome sequence ([6]), and antimicrobial susceptibility studies ([7]); a detailed description of the production process ([8]) including the raw materials and processing aids used ([9]); methods of analysis ([10]), and compositional analyses data of the novel food ([11]); stability studies of the novel food ([12]); a Hazard Analysis Control and Critical Point ('HACCP') safety management system ([13]); solubility studies of the novel food ([14]); a bacterial reverse mutation test with 2′-FL ([15]); an *in vitro* mammalian cell micronucleus test with 2′-FL ([16]); an *in vivo* mammalian cell micronucleus test with 2′-FL ([17]); a 90-day oral toxicity study in rats with 2′-FL ([18]); and, a bioinformatics analysis study on the genome of the *E. coli* W (ATCC 9637) to detect heterologous sequences that could encode possible allergens ([19]).

(6) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission requested the European Food Safety Authority ('the Authority') on 7 December 2021, to carry out an assessment of 2′-FL produced by microbial fermentation using the mentioned genetically modified derivative strain of *Escherichia coli* W (ATCC 9637).

(7) On 26 September 2023, the Authority adopted its scientific opinion on the 'Safety of 2′-fucosyllactose (2′-FL) produced by a derivative strain (*Escherichia coli* SGR5) of *E. coli* W (ATCC 9637) as a novel food pursuant to Regulation (EU) 2015/2283' ([20]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority concluded that 2′-FL produced by microbial fermentation using a genetically modified derivative strain of *E. coli* W (ATCC 9637) is safe when used under the currently authorised conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that 2′-FL produced by microbial fermentation using a genetically modified derivative strain of *E. coli* W (ATCC 9637) when used under the currently authorised conditions of use fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(9) 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 NMR, LC-MS/MS, and HPLC-PAD tests for the determination of the identity of 2′-FL; the description of the genetically modified production strain of *E. coli* W (ATCC 9637) including its genome sequence and antimicrobial susceptibility studies; the detailed description of the production process including the raw materials and processing aids used; the compositional analyses data and the stability studies of the novel food; the bacterial reverse mutation test with 2′-FL; the *in vitro* mammalian cell micronucleus test with 2′-FL; the *in vivo* mammalian cell micronucleus test with 2′-FL; the 90-day oral toxicity study in rats with 2′-FL; and, the bioinformatics analysis study on the genome of the *E. coli* W (ATCC 9637) to detect heterologous sequences that could encode possible allergens, contained in the applicant's file, without which it could not have assessed the novel food and reached its conclusion.

([4]) Kyowa Hakko Bio Co., Ltd, 2019, 2020, 2021, and 2022 (unpublished).
([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, 2021, 2022, and 2023 (unpublished).
([9]) Kyowa Hakko Bio Co., Ltd, 2021, 2022, and 2023 (unpublished).
([10]) Kyowa Hakko Bio Co., Ltd, 2021, 2022, and 2023 (unpublished).
([11]) Kyowa Hakko Bio Co., Ltd, 2021, 2022, and 2023 (unpublished).
([12]) Kyowa Hakko Bio Co., Ltd, 2021, 2022, and 2023 (unpublished).
([13]) Kyowa Hakko Bio Co., Ltd, 2021 (unpublished).
([14]) Kyowa Hakko Bio Co., Ltd, 2021 and 2023 (unpublished).
([15]) Kyowa Hakko Bio Co., Ltd, 2020 (unpublished).
([16]) Kyowa Hakko Bio Co., Ltd, 2022 (unpublished).
([17]) Kyowa Hakko Bio Co., Ltd, 2019 (unpublished).
([18]) Kyowa Hakko Bio Co., Ltd, 2020 (unpublished).
([19]) Kyowa Hakko Bio Co., Ltd, 2021 and 2022 (unpublished).
([20]) EFSA Journal 2023;21(11):8333.

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

(11) The applicant declared that, under national law at the time they submitted the application, they held proprietary and exclusive rights of reference to scientific studies and data from the NMR, LC-MS/MS, and HPLC-PAD tests for the determination of the identity of 2′-FL; the description of the genetically modified production strain of *E. coli* W (ATCC 9637) including its genome sequence and antimicrobial susceptibility studies; the detailed description of the production process including the raw materials and processing aids used; the compositional analyses data and the stability studies of the novel food; the bacterial reverse mutation test with 2′-FL; the *in vitro* mammalian cell micronucleus test with 2′-FL; the *in vivo* mammalian cell micronucleus test with 2′-FL; the 90-day oral toxicity study in rats with 2′-FL; and, the bioinformatics analysis study on the genome of the *E. coli* W (ATCC 9637) to detect heterologous sequences that could encode possible allergens, 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, scientific studies and data from the NMR, LC-MS/MS, and HPLC-PAD tests for the determination of the identity of 2′-FL; the description of the genetically modified production strain of *E. coli* W (ATCC 9637) including its genome sequence and antimicrobial susceptibility studies; the detailed description of the production process including the raw materials and processing aids used; the compositional analyses data and the stability studies of the novel food; the bacterial reverse mutation test with 2′-FL; the *in vitro* mammalian cell micronucleus test with 2′-FL; the *in vivo* mammalian cell micronucleus test with 2′-FL; the 90-day oral toxicity study in rats with 2′-FL; and, the bioinformatics analysis study on the genome of the *E. coli* W (ATCC 9637) to detect heterologous sequences that could encode possible allergens, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place 2′-FL produced with 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.

(13) However, restricting the authorisation of 2′-FL produced with a derivative strain of *E. coli* W (ATCC 9637) and the reference to the scientific 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.

(14) It is appropriate that the inclusion of 2′-FL 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) 2′-FL 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. 2′-Fucosyllactose obtained by microbial fermentation using a derivative strain of *Escherichia coli* ('*E. coli*') W (ATCC 9637) is authorised to be placed on the market within the Union.

2′-Fucosyllactose obtained by microbial fermentation using a derivative strain of *E. 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 ([21]) 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 19 August 2024, 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 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 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, 29 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

([21]) Address: Nakano Central Park South, Nakano 4-10-2, Nakano-ku, Tokyo 164-0001, Japan.

ANNEX

In Table 2 (Specifications) of the Annex to Implementing Regulation (EU) 2017/2470 the entry for 2′-Fucosyllactose (microbial source) is replaced by the following:

"**Specifications**					**Data protection**
	Definition: Chemical name: α-L-Fucopyranosyl-(1 → 2)-β-D-galactopyranosyl-(1 → 4)-D-glucopyranose Chemical formula: $C_{18}H_{32}O_{15}$ CAS No: 41263-94-9 Molecular weight: 488,44 g/mol				2′-Fucosyllactose produced with a genetically modified strain of *Corynebacterium glutamicum* ATCC 13032 authorised on 16 May 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "Advanced Protein Technologies Corporation", 7th Floor GyeongGi-BioCenter, 147, Gwanggyo-ro, Yeongtong-gu, Suwon-si Gyeonggi-do, 16229 South Korea. During the period of data protection, 2′-Fucosyllactose produced with a genetically modified strain of *Corynebacterium glutamicum* ATCC 13032 is authorised for placing on the market within the Union only by "Advanced Protein Technologies Corporation" unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of "Advanced Protein Technologies Corporation". End date of the data protection: 16 May 2028. 2′-Fucosyllactose produced with a genetically modified strain of *Escherichia coli* W (ATCC 9637) authorised on 19 August 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of
2′-Fucosyllactose (microbial source)	**Source:** Genetically modified strain of *Escherichia coli* K-12	**Source:** Genetically modified strain of *Escherichia coli* BL-21	**Source**: Genetically modified strain of *Corynebacterium glutamicum* ATCC 13032	**Source:** Genetically modified strain of *Escherichia coli* W ATCC 9637	
	Description: 2′-Fucosyllactose is a white to off-white powder that is produced by a microbiological process.	**Description:** 2′-Fucosyllactose is a white to off white powder and the liquid concentrate (45 % ± 5 % w/v) aqueous solution is a colourless to slight yellow clear aqueous solution. 2′-Fucosyllactose is produced by a microbiological process.	**Description:** 2′-Fucosyllactose is a white to off white/ivory powder that is produced by a microbiological process.	**Description:** 2′-Fucosyllactose is a white to off white/ivory powder that is produced by a microbiological process.	
	Purity: 2′-Fucosyllactose: ≥ 83 % D-Lactose: ≤ 10,0 % L-Fucose: ≤ 2,0 % Difucosyl-D-lactose: ≤ 5,0 % 2′-Fucosyl-D-lactulose: ≤ 1,5 % Sum of saccharides (2′-Fucosyllactose, D-Lactose, L-Fucose, Difucosyl-D-lactose, 2′-Fucosyl-D-lactulose): ≥ 90 % pH (20 °C, 5 % solution): 3,0-7,5 Water: ≤ 9,0 % Sulphated ash: ≤ 2,0 % Acetic acid: ≤ 1,0 % Residual proteins: ≤ 0,01 % **Microbiological criteria:** Aerobic mesophilic bacteria total count: ≤ 3 000 CFU/g	**Purity:** 2′-Fucosyllactose: ≥ 90 % Lactose: ≤ 5,0 % Fucose: ≤ 3,0 % 3-Fucosyllactose: ≤ 5,0 % Fucosylgalactose: ≤ 3,0 % Difucosyllactose: ≤ 5,0 % Glucose: ≤ 3,0 % Galactose: ≤ 3,0 % Water: ≤ 9,0 % (powder) Ash, sulphated: ≤ 0,5 % (powder and liquid) Residual proteins: ≤ 0,01 % (powder and liquid) **Heavy Metals:** Lead: ≤ 0,02 mg/kg (powder and liquid) Arsenic: ≤ 0,2 mg/kg (powder and liquid)	**Purity:** 2′-Fucosyllactose (w/w dry matter): ≥ 94,0 % D-Lactose (w/w dry matter): ≤ 3,0 % L-Fucose (w/w dry matter): ≤ 3,0 % 3-Fucosyllactose (w/w dry matter): ≤ 3,0 % Difucosyllactose (w/w dry matter): ≤ 2,0 % D-Glucose (w/w dry matter): ≤ 3,0 % D-Galactose (w/w dry matter): ≤ 3,0 % Water: ≤ 9,0 % Ash: ≤ 0,5 % Residual proteins: ≤ 0,005 % **Contaminants**: Arsenic: ≤ 0,03 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg	**Purity:** 2′-Fucosyllactose (w/w dry matter): ≥ 82,0 % D-Lactose (w/w dry matter): ≤ 5,0 % L-Fucose (w/w dry matter): ≤ 1,0 % Fucosylgalactose (w/w dry matter): ≤ 3,0 % Difucosyllactose (w/w dry matter): ≤ 3,0 % Sum of D-Glucose and D-Galactose (w/w dry matter): ≤ 1,0 % Sum of other carbohydrates[a] (w/w dry matter): ≤ 8,0 % Water: ≤ 9,0 % Ash: ≤ 0,5 % Residual proteins: ≤ 0,01 %	

	Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g Endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units	Cadmium: ≤ 0,1 mg/kg (powder and liquid) Mercury: ≤ 0,5 mg/kg (powder and liquid) **Microbiological criteria:** Total plate count: ≤ 10^4 CFU/g (powder), ≤ 5 000 CFU/g (liquid) Yeasts and Moulds: ≤ 100 CFU/g (powder); ≤ 50 CFU/g (liquid) Enterobacteriaceae/Coliforms: absence in 11 g (powder and liquid) Salmonella: negative/100 g (powder), negative/200 ml (liquid) Cronobacter: negative/100 g (powder), negative/200 ml (liquid) Endotoxins: ≤ 100 EU/g (powder), ≤ 100 EU/ml (liquid) Aflatoxin M1: ≤ 0,025 µg/kg (powder and liquid) CFU: Colony Forming Units; EU: Endotoxin Units	Ethanol: ≤ 1 000 mg/kg **Microbiological criteria**: Total plate count: ≤ 500 CFU/g Yeasts and Moulds: ≤ 100 CFU/g Enterobacteriaceae: absence in 10 g *Salmonella*: absence in 25 g *Cronobacter* spp.: absence in 10 g Endotoxins: ≤ 100 EU/g CFU: Colony Forming Units; EU: Endotoxin Units	pH (5 % solution, 25 °C): 4,5-8,5 **Contaminants**: Arsenic: ≤ 0,2 mg/kg Lead: ≤ 0,02 mg/kg Cadmium: ≤ 0,1 mg/kg Mercury: ≤ 0,1 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg **Microbiological criteria**: Total plate count: ≤ 1 000 CFU/g Yeasts and Moulds: ≤ 100 CFU/g Enterobacteriaceae: absence in 10 g *Salmonella*: absence in 25 g *Cronobacter* spp.: absence in 10 g *Listeria monocytogenes*: absence in 25 g Presumptive *Bacillus cereus:* ≤ 50 CFU/g Endotoxins: ≤ 10 EU/mg	Regulation (EU) 2015/2283. Applicant: "Kyowa Hakko Bio Co., Ltd", 1-9-2, Otemachi, Choyoda-ku Tokyo, 100-0004 Japan. During the period of data protection, 2′-Fucosyllactose produced with a genetically modified strain of *Escherichia coli* W (ATCC 9637) is authorised for placing on the market within the Union only by "Kyowa Hakko Bio Co., Ltd" unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of "Kyowa Hakko Bio Co., Ltd". End date of the data protection: 19 August 2029".

ELI: http://data.europa.eu/eli/reg_impl/2024/2036/oj

				[a] Sum of other carbohydrates = 100 % w/w dry matter – 2′-FL (% w/w dry matter) – (% dry matter of quantified carbohydrates (i.e. D -lactose, L-fucose, D -glucose and D-galactose, fucosylgalactose, and difucosyllactose) – ash (% w/w dry matter) CFU: Colony Forming Units; EU: Endotoxin Units	