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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2102

of 30 July 2024

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food 2'-Fucosyllactose and as regards the specifications of the novel food 2'-Fucosyllactose produced with a derivative strain of *Escherichia coli* BL-21

(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 30 June 2021, the company Chr. Hansen A/S ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change in the conditions of use of 2'-FL. The applicant requested to increase in the maximum authorised levels of 2'-FL in infant formulae and follow-on formulae as defined in Article 2 of Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]), from the currently authorised 1,2 g/L in both infant formulae and follow-on formulae to 3,0 g/L in infant formulae and to 3,64 g/L in follow-on formulae.

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 28 September 2022 requesting it to provide a scientific opinion on the proposed increase in the maximum authorised levels of 2'-FL in infant formulae and follow-on formulae.

(6) On 26 September 2023, the Authority adopted its scientific opinion on the 'Safety of the extension of use of 2′-fucosyllactose (2′-FL) as a novel food pursuant to Regulation (EU) 2015/2283' ([4]), in accordance with Article 11 of Regulation (EU) 2015/2283.

([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.
([4]) *EFSA Journal* 2023;21(11):8334.

(7) In its scientific opinion, the Authority concluded that 2′-FL is safe when used in infant formulae and follow-on formulae at the proposed maximum levels of 3,0 g/L and 3,64 g/L respectively, and therefore it is appropriate to amend the conditions of use of 2′-FL.

(8) The information provided in the application and the Authority's scientific opinion give sufficient grounds to establish that the changes to the conditions of use of 2′-FL are in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(9) On 27 October 2023, the applicant submitted another application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change in the specifications of 2'-FL produced by fermentation using a derivative strain of *Escherichia coli* BL-21. The applicant requested the increase in the authorised maximum levels of residual endotoxins from the currently authorised ≤ 100 Endotoxin Units ('EU')/g (or ≤ 0,1 EU/mg) of novel food for the powder form or ≤ 100 EU/ml (or ≤ 0,1 EU/µl) of novel food for the liquid form to ≤ 10 EU/mg of novel food for the powder form or ≤ 10 EU/µl of novel food for the liquid form.

(10) The applicant requested to increase the residual endotoxins for 2'-FL produced by fermentation using a derivative strain of *Escherichia coli* BL-21 to align them to those of the already authorised 2'-FL produced with a derivative strain of *Escherichia coli* K-12, which is authorised under the same conditions of use, and that of other authorised human identical milk oligosaccharides which are also authorised at identical or similar residual endotoxin levels in infant formulae and follow-on formulae.

(11) The Commission considers that the requested update of the Union list of novel foods to increase the residual endotoxins in the specifications of 2'-FL produced with a derivative strain of *Escherichia coli* BL-21 is not liable to have an effect on human health, and that a safety evaluation by the Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The Authority's opinions ([5]), ([6]), ([7]) on other currently authorised human identical milk oligosaccharides with residual endotoxin levels ≤ 10 EU/mg of novel food and with the same or similar conditions of use as 2'-FL produced with a derivative strain of *Escherichia coli* BL-21, concluded that these maximum levels of residual endotoxins, are safe.

(12) The information provided in the applications and the Authority's existing opinions give sufficient grounds to establish that the changes in the conditions of use of 2'-FL to increase its maximum use levels in infant formulae and follow-on formulae and the changes in the specifications of 2'-FL produced by fermentation using a derivative strain of *Escherichia coli* BL-21 to modify the levels of residual endotoxins, are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.

(13) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(14) 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

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

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

([5]) *EFSA Journal* 2019;17(6):5717.
([6]) *EFSA Journal* 2022;20(5):7329.
([7]) *EFSA Journal* 2023;21(6):8026.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 30 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the entry for 2'-Fucosyllactose is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'2′-Fucosyllactose	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "2′-Fucosyllactose". 2. The labelling of food supplements containing 2′-Fucosyllactose shall bear a statement that the supplements should not be used if other foods with added 2′-fucosyllactose are consumed the same day. 3. The labelling of food supplements containing 2′-Fucosyllactose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added 2′-fucosyllactose are consumed the same day.'	
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	1,2 g/l		
	Unflavoured fermented milk-based products	1,2 g/l for beverages		
		19,2 g/kg for products other than beverages		
	Flavoured fermented milk-based products including heat-treated products	1,2 g/l for beverages		
		19,2 g/kg for products other than beverages		
	Dairy analogues, including beverage whiteners	1,2 g/l for beverages		
		12 g/kg for products other than beverages		
		400 g/kg for whitener		
	Cereal bars	12 g/kg		
	Table-top sweeteners	200 g/kg		
	Infant formula as defined in Regulation (EU) No 609/2013	3,0 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Follow-on formula as defined in Regulation (EU) No 609/2013	3,64 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013	12 g/kg for products other than beverages		
		1,2 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer		

ELI: http://data.europa.eu/eli/reg_impl/2024/2102/oj

	Milk based drinks and similar products intended for young children	1,2 g/l for milk-based drinks and similar products in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	4,8 g/l for drinks		
		40 g/kg for bars		
	Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Implementing Regulation (EU) No 828/2014	60 g/kg		
	Flavoured drinks	1,2 g/l		
	Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	9,6 g/l – the maximum level refers to the products ready to use		
	Food supplements as defined in Directive 2002/46/EC, for the general population, excluding infants	3,0 g/day for general population		
		1,2 g/day for young children		

(2) in Table 2 (Specifications) 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".
'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	
	Description: 2′-Fucosyllactose is a white to off-white 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 Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g Endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units	**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. **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) Cadmium: ≤ 0,1 mg/kg (powder and liquid) Mercury: ≤ 0,5 mg/kg (powder and liquid)	**Description:** 2′-Fucosyllactose is a white to off white/ivory powder that is produced by a microbiological process. **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 Ethanol: ≤ 1 000 mg/kg **Microbiological criteria**: Total plate count: ≤ 500 CFU/g Yeasts and Moulds: ≤ 100 CFU/g	

		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: ≤ 10 EU/mg (powder), ≤ 10 EU/µl (liquid) Aflatoxin M1: ≤ 0,025 µg/kg (powder and liquid) CFU: Colony Forming Units; EU: Endotoxin Units	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	End date of the data protection: 16 May 2028.'