COMMISSION IMPLEMENTING REGULATION (EU) 2023/961

of 12 May 2023

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food Lacto-*N*-neotetraose

(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 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 novel foods.

(3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes Lacto-*N*-neotetraose of synthetic and microbial source as authorised novel food.

(4) Commission Implementing Decision (EU) 2016/375 ([3]) authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ([4]), the placing on the market of chemically synthesised Lacto-*N*-neotetraose as a novel food ingredient.

(5) Pursuant to Article 5 of Regulation (EC) No 258/97, on 1 September 2016, the company Glycom A/S, notified the Commission of its intention to place on the market Lacto-*N*-neotetraose of microbial source produced with genetically modified *Escherichia coli* strain K-12 as a novel food ingredient. Lacto-*N*-neotetraose of microbial origin produced with genetically modified *Escherichia coli strain* K-12 was included in the Union list of novel foods on the basis of that notification when the Union list was established.

(6) Commission Implementing Regulation (EU) 2019/1314 ([5]) amended the specifications of the novel food Lacto-*N*-neotetraose (microbial source) produced with genetically modified *Escherichia coli* strain K-12.

(7) Commission Implementing Regulation (EU) 2021/912 ([6]) amended the specifications of the novel food Lacto-*N*-neotetraose (microbial source) to allow the novel food Lacto-*N*-neotetraose produced by the combined activity of the genetically modified strains PS-LNnT-JBT and DS-LNnT-JBT derived from *Escherichia coli* strain BL21(DE3) to be placed on the market and be used in the previously authorised uses and at the previously authorised use levels.

([1]) OJ L 327, 11.12.2015, p. 1.

([2]) Commission Implementing Regulation (EU) No 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 Decision (EU) 2016/375 of 11 March 2016 authorising the placing on the market of Lacto-*N*-neotetraose as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 70, 16.3.2016, p. 22).

([4]) Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel food and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

([5]) Commission Implementing Regulation (EU) 2019/1314 of 2 August 2019 authorising the change of the specifications of the novel food Lacto-*N*-neotetraose produced with Escherichia coli K-12 under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 205 5.8.2019, p. 4).

([6]) Commission Implementing Regulation (EU) 2021/912 of 4 June 2021 authorising changes in the specifications of the novel food Lacto-*N*-neotetraose (microbial source) and amending Implementing Regulation (EU) 2017/2470 (OJ L 199, 7.6.2021, p.10).

(8) On 3 October 2022, the company Glycom 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 Lacto-*N*-neotetraose. The application requested for Lacto-*N*-neotetraose to be used in infant formula, follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([7]), at the currently authorised levels of up to 0,6 g/l, without the obligatory use in combination with 2′-Fucosyllactose at a 1:2 use ratio (one part Lacto-*N*-neotetraose with two parts 2′-Fucosyllactose), and in milk-based drinks and similar products intended for young children without the obligatory use in combination with 2′-Fucosyllactose at a 1:2 use ratio when the two novel foods are added separately.

(9) In the application for the proposed modification in the conditions of use of Lacto-*N*-neotetraose, the applicant considered that obligatory use of a combination of Lacto-*N*-neotetraose with 2′-Fucosyllactose at a 1:2 ratio when they are used together in infant formula and follow-on formula as defined in Article 2 of Regulation (EU) No 609/2013, or at different ratios with 2′-Fucosyllactose when the two are used in combination in milk-based drinks and similar products intended for young children, unnecessarily limits the ability of food business operators to place on the market these foods with different ratios of those two oligosaccharides.

(10) The Commission considers that the requested update of the Union list concerning the change in the conditions of use of Lacto-*N*-neotetraose proposed by the applicant is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. In this regard, the Authority in a recent opinion ([8]) concluded that the use of Lacto-*N*-neotetraose alone or 2′-Fucosyllactose alone in food supplements as defined in Article 2 of Directive 2002/46/EC of the European Parliament and of the Council ([9]) at the currently maximum authorised levels of up to 0,6 mg/day or up to 1,2 g/day respectively, is safe and the resulting intakes of each of these oligosaccharides from these uses would be lower than the intakes of Lacto-*N*-neotetraose or 2′-Fucosyllactose from human milk which naturally contains them.

(11) The information provided in the application and existing Authority's opinions gives sufficient grounds to establish that the changes in the conditions of use of the novel food Lacto-*N*-neotetraose should be approved.

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

(13) 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.

([7]) 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).

([8]) EFSA Journal 2022; 207(5):7257.

([9]) 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).

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

Done at Brussels, 12 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for lacto-*N*-neotetraose is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'**Lacto-*N*-neotetraose**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'lacto-*N*-neotetraose'. 2. The labelling of food supplements containing lacto-*N*-neotetraose shall bear a statement that the supplements should not be used if other foods with added lacto-N-neotetraose are consumed the same day. 3. The labelling of food supplements containing lacto-*N*-neotetraose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added lacto-*N*-neotetraose are consumed the same day.'	
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,6 g/l		
	Unflavoured fermented milk-based products	0,6 g/l for beverages		
		9,6 g/kg for products other than beverages		
	Flavoured fermented milk-based products including heat-treated products	0,6 g/l for beverages		
		9,6 g/kg for products other than beverages		
	Dairy analogues, including beverage whiteners	0,6 g/l for beverages		
		6 g/kg for products other than beverages		
		200 g/kg for whitener		
	Cereal bars	6 g/kg		
	Table-top sweeteners	100 g/kg		
	Infant formula as defined under Regulation (EU) No 609/2013	0,6 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Follow-on formula as defined under Regulation (EU) No 609/2013	0,6 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 under Regulation (EU) No 609/2013	6 g/kg for products other than beverages		
		0,6 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer		

	Milk based drinks and similar products intended for young children	0,6 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 under 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	2,4 g/l for drinks		
		20 g/kg for bars		
	Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	30 g/kg		
	Flavoured drinks	0,6 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	4,8 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	1,5 g/day for general population 0,6 g/day for young children		