COMMISSION IMPLEMENTING REGULATION (EU) 2023/950

of 12 May 2023

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food 2'-Fucosyllactose

(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 2'-Fucosyllactose of synthetic and microbial source as an authorised novel food.

(4) Commission Implementing Decision (EU) 2016/376 ([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 synthetic 2'-Fucosyllactose as a novel food ingredient.

(5) On 23 June 2016, the company Glycom A/S ('the applicant'), notified the Commission, pursuant to Article 5 of Regulation (EC) No 258/97, of its intention to place on the market 2'-Fucosyllactose produced by bacterial fermentation with *Escherichia coli* strain K-12. 2'-Fucosyllactose of microbial origin produced with *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 Decision (EU) 2017/2201 ([5]) authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of 2'-Fucosyllactose produced with *Escherichia coli* strain BL21 as a novel food ingredient.

([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 Decision (EU) 2016/376 of 11 March 2016 authorising the placing on the market of 2′-O-fucosyllactose 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. 27).

([4]) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel food and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

([5]) Commission Implementing Decision (EU) 2017/2201 of 27 November 2017 authorising the placing on the market of 2′-fucosyllactose produced with Escherichia coli strain BL21 as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 313, 29.11.2017, p. 5).

(7) On 13 October 2022, 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'-Fucosyllactose. The applicant requested the removal of the obligatory condition that, when 2'-Fucosyllactose is used in combination with Lacto-*N*-neotetraose in infant formula and follow-on formula as defined in Article 2 of Regulation (EU) No 609/2013 of the European Parliament and of the Council ([6]), and in milk-based drinks and similar products intended for young children, at the currently authorised levels of up to 1,2 g/l, they should be used only at a 2:1 ratio (two parts 2'-Fucosyllactose to one part Lacto-N-neotetraose).

(8) In the application for the proposed modification in the conditions of use of 2'-Fucosyllactose, the applicant considered that the 2:1 obligatory ratio of 2'-Fucosyllactose to Lacto-*N*-neotetraose when they are used together in infant formula and follow on formula as defined in Article 2 of Regulation (EU) No 609/2013, and 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

(9) The Commission considers that the requested update of the Union list of novel foods 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 the recent opinion ([7]), concluded that the use of 2'-Fucosyllactose alone or Lacto-*N*-neotetraose alone in food supplements as defined in Article 2 of Directive 2002/46/EC of the European Parliament and of the Council ([8]) at the currently maximum authorised levels of up to 1,2 g/day or up to 0,6 mg/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.

(10) The information provided in the application and the Authority's opinion give sufficient grounds to establish that the changes in the conditions of use of the novel food 2'-Fucosyllactose are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.

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

(12) 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*.

([6]) 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).

([7]) *EFSA Journal* 2022;20(5):7257.

([8]) 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 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".	
	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	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.	
		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 under Regulation (EU) No 609/2013	1,2 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	1,2 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	12 g/kg for products other than beverages	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.'	
		1,2 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	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 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	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		