

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/1381****of 8 August 2022****amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food galacto-oligosaccharide****(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 <sup>(1)</sup>, 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 <sup>(2)</sup> has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes galacto-oligosaccharide as an authorised novel food.
- (4) Pursuant to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council <sup>(3)</sup>, galacto-oligosaccharide has been authorised to be placed on the market as a novel food to be used in a number of foods, including infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council <sup>(4)</sup>.
- (5) Commission Implementing Regulation (EU) 2021/900 <sup>(5)</sup> amended the conditions of use of the novel food galacto-oligosaccharide. In particular, the use level of the novel food galacto-oligosaccharide in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council <sup>(6)</sup> was increased from 0,333 kg galacto-oligosaccharide/kg of a food supplement (33,3 %) to 0,450 kg galacto-oligosaccharide/kg of a food supplement (45,0 %) for the general population, excluding infants and young children.
- (6) Commission Implementing Regulation (EU) 2022/684 <sup>(7)</sup> amended the conditions of use of the novel food galacto-oligosaccharide. In particular, the use of galacto-oligosaccharide has been extended to additional foods namely, dairy confectionary, cheese and processed cheese, butter and spreadable fats.

<sup>(1)</sup> OJ L 327, 11.12.2015, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel foods ingredients (OJ L 43, 14.2.1997, p. 1).

<sup>(4)</sup> 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).

<sup>(5)</sup> Commission Implementing Regulation (EU) 2021/900 of 3 June 2021 authorising a change of the conditions of use of the novel food 'galacto-oligosaccharide' under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 197, 4.6.2021, p. 71).

<sup>(6)</sup> 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).

<sup>(7)</sup> Commission Implementing Regulation (EU) 2022/684 of 28 April 2022 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food galacto-oligosaccharide (OJ L 126, 29.4.2022, p. 10).

- (7) On 29 June 2020, the company GLNP BV ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the conditions of use of the novel food galacto-oligosaccharide. The applicant requested to extend the use of galacto-oligosaccharide to foods for special medical purposes as defined by Regulation (EU) No 609/2013 intended for the general population, excluding infants and young children.
- (8) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 12 July 2021, requesting it to provide a scientific opinion on the change of conditions of use of the novel food galacto-oligosaccharide.
- (9) On 28 February 2022, the Authority adopted its scientific opinion on the 'Safety of the extension of use of galacto-oligosaccharides as a novel food in food for special medical purposes pursuant to Regulation (EU) 2015/228' <sup>(8)</sup> in accordance with Article 11 of Regulation (EU) 2015/2283.
- (10) In its scientific opinion, the Authority concluded that the proposed change is safe under the proposed conditions of use, and therefore it is appropriate to amend the conditions of use of galacto-oligosaccharide.
- (11) The information provided in the application and the opinion of the Authority give sufficient grounds to establish that the changes to the conditions of use of the novel food are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and 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*.

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

Done at Brussels, 8 August 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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<sup>(8)</sup> EFSA Journal 2022;20(3):7203.

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for 'galacto-oligosaccharide' is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'Galacto-oligosaccharide'	<i>Specified food category</i>	<i>Maximum levels (expressed as ratio kg galacto-oligosaccharide/kg final food)</i>			
	Food supplements as defined in Directive 2002/46/EC	0,333			
	Food supplements as defined in Directive 2002/46/EC, excluding infants and young children	0,450 (corresponding to 5,4 g galacto-oligosaccharide/serving; maximum 3 servings/day up to a maximum of 16,2 g/day)			
	Foods for special medical purposes as defined by Regulation (EU) No 609/2013, excluding infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended but not more than 0,128 (corresponding to a maximum of 8,25 g galacto-oligosaccharide/day)			
	Milk	0,020			
	Milk drinks	0,030			
	Meal replacement for weight control (as drinks)	0,020			
	Dairy analogue drinks	0,020			
	Yoghurt	0,033			
	Dairy based desserts	0,043			
	Frozen dairy desserts	0,043			
	Fruit drinks and energy drinks	0,021			
	Infant meal replacement drinks	0,012			
	Baby juice	0,025			
	Baby yogurt drink	0,024			
	Baby dessert	0,027			

Baby snack	0,143			
Baby cereals	0,027			
Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	0,013			
Juice	0,021			
Fruit pie filling	0,059			
Fruit preparations	0,125			
Bars	0,125			
Cereals	0,125			
Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	0,008			
Dairy confectionery	0,05			
Cheese and processed cheese	0,1			
Butter and spreadable fats	0,1'			