

**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****(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 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> establishing a Union list of authorised novel foods was adopted.
- (3) On 20 January 2014, the company Yakult Pharmaceutical Industry Co., Ltd. informed the Commission, pursuant to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council <sup>(3)</sup>, of its intention to place on the market ‘galacto-oligosaccharide’ 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>. Therefore, galacto-oligosaccharide was included in the Union list of novel foods.
- (4) On 3 March 2020, the company Yakult Pharmaceutical Industry Co., Ltd. (‘the applicant’) submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 to change the conditions of use of the novel food ‘galacto-oligosaccharide’. The applicant requested to increase the maximum use level of the novel food galacto-oligosaccharide in food supplements from 0,333 kg GOS/kg food supplement (33,3 %) to 0,450 kg GOS/kg food supplement (45,0 %) for the general population. During the application process, the applicant agreed to exclude infants and young children from the request.
- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority (‘the Authority’) on 18 June 2020, requesting it to provide a scientific opinion by carrying out an assessment for the change of the conditions of use of galacto-oligosaccharide as a novel food.
- (6) On 17 December 2020, the Authority adopted its scientific opinions on the ‘Safety of a change in the conditions of use of galacto-oligosaccharides as a novel food ingredient in food supplements pursuant to Regulation (EU) 2015/2283’ <sup>(5)</sup>. This opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

<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> EFSA Journal 2021;19(1):6384.

- (7) In its opinion, the Authority concluded that the proposed increase in the maximum use level of galacto-oligosaccharide as a novel food in food supplements is safe under the proposed changes of the conditions of use.
- (8) The opinion of the Authority gives sufficient grounds to establish that galacto-oligosaccharide under the proposed conditions of use for the general population, excluding infants and young children, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (9) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (10) 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. The entry in the Union list of authorised novel foods as provided for in Article 6 of Regulation (EU) 2015/2283 and included in the Annex to Implementing Regulation (EU) 2017/2470, referring to the novel food galacto-oligosaccharide, shall be amended as specified in the Annex to this Regulation.
- 2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in 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, 3 June 2021.

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

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for the novel food '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
'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)		
	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*		