

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

authorising a change of the conditions of use of galacto-oligosaccharide as a novel food 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 1852/2001¹, 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) 2017/2470² 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 Council³, 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 Council⁴. 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-

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 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).

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oligosaccharide. The application requested to increase the maximum use level of galacto-oligosaccharide in food supplements.

- (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) 2015/2283'⁵. This opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (7) In its opinion, the Authority concluded that 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 complies with Article 12(1) of Regulation (EU) 2015/2283.
- (9) 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.

⁵ EFSA Journal 2021;19(1):6384.

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Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN