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

of **XXX**

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 1852/2001¹, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list 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) 2017/2470² 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 Council³, 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 Council⁴.

¹ OJ L 327, 11.12.2015, p. 1. ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>

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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

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, ELI: <http://data.europa.eu/eli/reg/1997/258/oj>).

⁴ 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,

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- (5) Commission Implementing Regulation (EU) 2021/900⁵ 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 Council⁶ 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) 2022/684⁷ amended the conditions of use of the novel food galacto-oligosaccharide. In particular, the use of galacto-oligosaccharide was extended to additional foods namely, dairy confectionary, cheese and processed cheese, butter and spreadable fats.
- (7) Commission Implementing Regulation (EU) 2022/1381⁸ amended the conditions of use of the novel food galacto-oligosaccharide. In particular, the use of galacto-oligosaccharide was extended 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) Commission Implementing Regulation (EU) 2024/1027⁹ amended the specifications of the novel food galacto-oligosaccharide. In particular, galactose has been removed from the specifications of the novel food which included galactose at levels greater than 0.8% of the dry matter.
- (9) Council Directive 2001/112/EC¹⁰ defines fruit juices and certain similar products intended for human consumption. Council Directive 2001/113/EC¹¹ defines fruit jams,

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, ELI: <http://data.europa.eu/eli/reg/2013/609/oj>).

⁵ 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, ELI: http://data.europa.eu/eli/reg_impl/2021/900/oj).

⁶ 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, ELI: <http://data.europa.eu/eli/dir/2002/46/oj>).

⁷ 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, ELI: http://data.europa.eu/eli/reg_impl/2022/684/oj).

⁸ 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. (OJ L 207, 9.8.2022, p. 12, ELI: http://data.europa.eu/eli/reg_impl/2022/1381/oj).

⁹ Commission Implementing Regulation (EU) 2024/1027 of 8 April 2024 amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food galacto-oligosaccharide. (OJ L, 2024/1027, 9.4.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/1027/oj)

¹⁰ Council Directive 2001/112/EC Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58, ELI: <http://data.europa.eu/eli/dir/2001/112/oj>).

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jellies and marmalades and sweetened chestnut purée intended for human consumption. These Directives lay down specific provisions regarding the designation and compositional requirements of the products within their scope. Only certain designations relating to fruit juices and similar products and fruit jams, jellies and marmalades and sweetened chestnut purée and only certain ingredients and substances authorised by these Directives may be used. While the Union list of novel foods applies without prejudice to other provisions laid down in sector specific legislation, the conditions of use of ‘galacto-oligosaccharide’, which were last changed by Implementing Regulation (EU) 2022/1381¹², do not clearly reflect the products defined in these Directives and do not designate products in line with the provisions of Directive 2001/112/EC and Directive 2001/113/EC. To ensure regulatory consistency and clarity, it is appropriate that the conditions of use of this novel food and its designation be amended in line with provisions of Directive 2001/112/EC and Directive 2001/113/EC. Therefore, modification of Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

- (10) In the conditions of use of ‘galacto-oligosaccharide’, food categories ‘bars’ and ‘cereals’ are currently authorised as separate categories. In order to ensure regulatory consistency and clarity, it is appropriate to merge those categories into a single category: ‘processed and breakfast cereals, including cereal bars’. Therefore, modification of Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.
- (11) In the conditions of use of ‘galacto-oligosaccharide’, food categories ‘baby juice’, ‘baby yogurt drink’, ‘baby dessert’, ‘baby snack’ and ‘baby cereals’ are authorised as separate categories. In order to ensure regulatory consistency and clarity, it is appropriate to merge those categories into a single category: ‘processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013’. Therefore, modification of Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.
- (12) On 21 March 2025, the company FrieslandCampina Ingredients (‘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 non-alcoholic beverages, confectionery, chewing gum, cocoa and chocolate-based products and protein products intended for the general population.
- (13) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority (‘the Authority’) on 18 July 2025, requesting it to provide a scientific opinion on the proposed extension of use of the novel food galacto-oligosaccharide.

¹¹ Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption (OJ L 10, 12.1.2002, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/113/oj>).

¹² 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 (OJ L 207, 9.8.2022, p. 12, ELI: http://data.europa.eu/eli/reg_impl/2022/1381/oj).

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- (14) On 19 November 2025, the Authority adopted its scientific opinion on the ‘Safety of the extension of use of galacto-oligosaccharides as a novel food pursuant to Regulation (EU) 2015/2283’¹³ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (15) In its scientific opinion, the Authority concluded that the novel food is safe under the proposed conditions of use, and therefore it is appropriate to amend the conditions of use of galacto-oligosaccharide.
- (16) 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.
- (17) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (18) 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,

For the Commission
The President
Ursula VON DER LEYEN

¹³ EFSA Journal. 2025;23:e9797 (<https://doi.org/10.2903/j.efsa.2025.9797>)