



2024/1027

9.4.2024

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**

(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 ⁽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 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 ⁽³⁾, 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 ⁽⁴⁾.
- (5) On 28 July 2023, 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 specifications of the novel food galacto-oligosaccharide. The applicant requested the removal of galactose from the specifications of the novel food which currently include galactose at levels greater than 0.8% of the dry matter.
- (6) The applicant justified their request for the proposed change in the specifications of galacto-oligosaccharide by the introduction of additional purification steps in its production. That additional purification aims to remove monosaccharides like galactose to produce a higher purity galacto-oligosaccharide.
- (7) The Commission considers that the requested change in the specifications of galacto-oligosaccharide is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. Galactose has a history of safe use as a constituent of the normal diet when dairy products are consumed. As a result, it is authorised to be present in the

⁽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 food 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, 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>).

novel food at minimal levels of 0,8% or more and without a maximum authorised level as it does not raise safety concerns. Thus, irrespective of the purification steps during the production, the specifications do not need to require a certain level of galactose in the novel food.

- (8) The information provided in the application gives sufficient grounds to establish that the changes to the specifications of the novel food are in accordance with the conditions laid down in Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (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

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 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Table 2 (**‘Specifications’**) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for ‘Galacto-oligosaccharide’ is replaced by the following:

Authorised Novel Food	Specifications
‘Galacto-oligosaccharide	Description/Definition: Galacto-oligosaccharide is produced from milk lactose by an enzymatic process using β -galactosidases from <i>Aspergillus oryzae</i> , <i>Bifidobacterium bifidum</i> , <i>Pichia pastoris</i> , <i>Sporobolomyces singularis</i> , <i>Kluyveromyces lactis</i> and <i>Papiliotrema terrestris</i> . GOS: min. 46 % Dry Matter (DM) Lactose: max. 40 % DM Glucose: max. 22 % DM Ash: max. 4,0 % DM Protein: max. 4,5 % DM Nitrite: max. 2 mg/kg’