



2024/1611

7.6.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1611

of 6 June 2024

**authorising the placing on the market of isomaltulose powder as a novel food and amending
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 ⁽¹⁾, and in particular Article 12(1) 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) On 30 April 2018, the company Evonik Operations GmbH ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place isomaltulose syrup (dried) on the Union market as a novel food. The applicant requested for the novel food to be used as a replacement for sucrose in all foods intended for the general population, excluding infant formula and follow-on formula, processed cereal-based food and baby food as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽³⁾.
- (4) On 21 March 2019, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of isomaltulose syrup (dried) as a novel food.
- (5) On 29 November 2023, the Authority adopted its scientific opinion on the 'Safety of isomaltulose syrup (dried) as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁴⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (6) In its scientific opinion, the Authority concluded that the novel food, isomaltulose syrup (dried), is safe under the proposed conditions of use. Therefore, the Authority's scientific opinion gives sufficient grounds to establish that isomaltulose powder, under the proposed conditions of use, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283. As the novel food is in powder form, the Commission is of the view that the more appropriate name reflecting true nature of the food should be isomaltulose powder.
- (7) Isomaltulose powder should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

⁽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 (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/2013/609/2023-03-21>).

⁽⁴⁾ EFSA Journal. 2024;22:e8491.

- (8) 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. Isomaltulose powder is authorised to be placed on the market within the Union.

Isomaltulose powder shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. 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, 6 June 2024.

For the Commission
The President
Ursula VON DER LEYEN

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other require-ments	Data protection
Isomaltulose powder	Specified food category	Maximum levels	<div>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be “isomaltulose powder”.</div> <div>2. The designation of the novel food on the labelling shall be accompanied by indication that the “Isomaltulose is a source of glucose and fructose”.</div>		
	All foods, excluding foods and drinks intended specifically for infants and young children				

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specification
Isomaltulose powder	<p>Description/Definition: The novel food is isomaltulose powder produced from sucrose by a microbiological process using <i>Serratia plymuthica</i>. The dry matter content is a mixture of mono-and disaccharides, mainly composed of isomaltulose (≥ 75 %) and trehalulose (≤ 13 %) and, to a minor extent, glucose, fructose, sucrose and oligosaccharides (traces).</p> <p>Characteristics/composition: Isomaltulose (% DM): ≥ 75 Trehalulose (% DM): ≤ 13 Glucose (% DM): ≤ 3 Fructose (% DM): ≤ 4 Sucrose (% DM): ≤ 5 Moisture (%): ≤ 7 Ash (%): ≤ 0,05 Protein (%): < 0,1</p>

Authorised Novel Food	Specification
	<p>Chemical identity of isomaltulose: Chemical (IUPAC) name: α-D-glucopyranosyl-(1 \rightarrow 6)-D-fructofuranose Common name: Isomaltulose CAS number: 13718-94-0 Molecular formula: C₁₂H₂₂O₁₁ Molecular weight: 342,30 g/mol</p> <p>Chemical identity of trehalulose: Chemical (IUPAC) name: α-D-glucopyranosyl-(1 \rightarrow 1)-D-fructofuranose Common name: Trehalulose CAS number: 51411-23-5 Molecular formula: C₁₂H₂₂O₁₁ Molecular weight: 342,30 g/mol</p> <p>Heavy metals: Lead (mg/kg): $\leq 0,1$</p> <p>Microbiological criteria: Total aerobic microbial count: < 100 CFU/g Total yeast and mould count: < 100 CFU/g <i>E. coli</i>: < 10 CFU/g Enterobacteriaceae: < 100 CFU/g <i>Salmonella</i>: not detected in 25 g</p> <p>CFU: colony forming units DM: dry matter'</p>