



2026/1306

12.6.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/1306

of 11 June 2026

authorising the placing on the market of rhamnogalacturonan-I enriched carrot extract (cRG-I) 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 17 December 2022, the company NutriLeads B.V. ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place rhamnogalacturonan-I enriched carrot fibre (cRG-I) on the Union market as a novel food. The applicant requested for the novel food to be used in a number of foods intended for the general population, food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾, foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽⁴⁾ and total diet replacement for weight control as defined in Regulation (EU) No 609/2013. Subsequently, on 15 December 2025, the applicant modified the initial request in the application on the use of rhamnogalacturonan-I enriched carrot fibre (cRG-I) in food supplements, foods for special medical purposes and meal replacement for weight control to exclude infants and young children.

⁽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⁾ 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>).

⁽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>).

- (4) On 17 December 2022, the applicant also made a request to the Commission for the protection of the following proprietary data: identity ⁽⁷⁾, compositional data ⁽⁸⁾ and toxicological information ⁽⁷⁾.
- (5) On 8 November 2023, the Commission requested the European Food Safety Authority ('the Authority') to provide a scientific opinion on rhamnogalacturonan-I enriched carrot fibre (cRG-I) as a novel food.
- (6) On 25 June 2025, the Authority adopted its scientific opinion on the 'Safety of rhamnogalacturonan-I enriched carrot fibre (cRG-I) as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁸⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (7) In its scientific opinion, the Authority concluded that that the novel food, cRG-I, a rhamnogalacturonan-rich polysaccharide fraction derived from carrot pomace, is safe under the proposed conditions of use.
- (8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the proprietary data on the identity, compositional data and toxicological information without which it could not have assessed the novel food and reached its conclusion.
- (9) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those data and studies and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2), point (b), of Regulation (EU) 2015/2283.
- (10) The applicant declared that they held proprietary and exclusive rights of reference to the relevant studies, at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.
- (11) The Commission assessed all the information provided by the applicant and considers that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, data on the identity, compositional data and toxicological information, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place rhamnogalacturonan-I enriched carrot extract (cRG-I) on the market within the Union during a period of five years from the entry into force of this Regulation.
- (12) However, such restriction of the authorisation and the reference to the data contained in the applicant's file for their sole use does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.
- (13) It is appropriate that the inclusion of rhamnogalacturonan-I enriched carrot extract (cRG-I) as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283. In line with the conditions of use of food supplements containing rhamnogalacturonan-I enriched carrot extract (cRG-I) as proposed by the applicant, it is necessary to inform the consumers in that regard by appropriate labelling of the designation of the novel food and about the uses of food supplements containing rhamnogalacturonan-I enriched carrot extract (cRG-I).

⁽⁷⁾ NF-2022-7430 2.2 Identity UPDATE 20240611 CONFIDENTIAL, Annex 2.2.01, Annex 2.2.02, Annex 2.2.03 to the application.

⁽⁸⁾ NF2022-7430 2.4. Compositional data cRG-I UPDATE 20250107 CONFIDENTIAL, Annex 2.4.04, Annex 2.4.05, Annex 2.4.06, Annex 2.4.07, Annex 2.4.08, Annex 2.4.09, Annex 2.4.10, Annex 2.4.11, Annex 2.4.12, Annex 2.4.13, Annex 2.4.14, Annex 2.4.16, Annex 2.4.17, Annex 2.4.24, Annex 2.4.25, Annex 2.4.26, Annex 2.4.27, Annex 2.4.28, Annex 2.4.29, Annex 2.4.30, Annex 2.4.42 to the application.

⁽⁷⁾ NF-2022-7430 Section 2.10. Toxicity information CONFIDENTIAL 20221214, NF-2022-7430 2.10.3.1 Genotoxicity UPDATE 20250107 CONFIDENTIAL, NF-2022-7430 2.10.3.2 Sub-chronic oral toxicity UPDATE 20240611 CONFIDENTIAL, Annex 2.10.03, Annex 2.10.04, Annex 2.10.05, Annex 2.10.06, Annex 2.10.07, Annex 2.10.10 to the application.

⁽⁸⁾ EFSA Journal 2025;23:e9537.

- (14) The applicant originally proposed that the novel food be placed on the Union market under the name rhamnogalacturonan-I enriched carrot fibre (cRG-I). In its scientific opinion, the Authority characterised the novel food as a purified, rhamnogalacturonan-rich polysaccharide fraction isolated from carrot pomace through enzymatic and physical processing steps. The Authority further noted that, although the novel food consists predominantly of non-digestible carbohydrates, they did not assess whether the material meets the legal definition of 'dietary fibre' laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council⁽⁹⁾. Therefore, it has not been demonstrated that the fibre component meets the definition set out in Annex I to Regulation (EU) No 1169/2011. The use of the term 'rhamnogalacturonan-I enriched carrot fibre (cRG-I)' in the designation of the novel food could therefore mislead consumers as to its nutritional properties and composition. Therefore, it is appropriate to replace the term 'rhamnogalacturonan-I enriched carrot fibre (cRG-I)' with 'rhamnogalacturonan-I enriched carrot extract (cRG-I)'.
- (15) Rhamnogalacturonan-I enriched carrot extract (cRG-I) 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.
- (16) 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. Rhamnogalacturonan-I enriched carrot extract (cRG-I) is authorised to be placed on the market within the Union.

Rhamnogalacturonan-I enriched carrot extract (cRG-I) 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

Only the company NutriLeads B.V.⁽¹⁰⁾ is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from 2 July 2026, unless a subsequent applicant obtains an authorisation for the novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of the company NutriLeads B.V.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of the company NutriLeads B.V.

⁽⁹⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18, ELI: <http://data.europa.eu/eli/reg/2011/1169/oj>).

⁽¹⁰⁾ Address: Bronland 12-N. 6708 WH Wageningen, NETHERLANDS.

Article 4

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, 11 June 2026.

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 in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
Rhamnogalacturonan-I enriched carrot extract	<i>Specified food category</i>	<i>Maximum levels</i>	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be “Rhamnogalacturonan-I carrot extract”. 2. The labelling of food supplements containing the novel food shall bear a statement that the food supplements should not be consumed by children under 3 years of age.		Authorised on 2 July 2026. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: NutriLeads B.V., Bronland 12-N. 6708 WH Wageningen, NETHERLANDS. During the period of data protection, the novel food Rhamnogalacturonan-I enriched carrot extract (cRG-I) is authorised for placing on the market within the Union only by NutriLeads B.V., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of NutriLeads B.V. End date of the data protection: 2 July 2031.’
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	1 500 mg/day for the general population above 3 years of age			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013, excluding foods for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	1 500 mg/day			
	Meal replacement for weight control, excluding meal replacement for infants and young children	500 mg/meal			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	Processed cereal based food and baby food for infants and young children as defined by Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of infants and young children and with a maximum of 625 mg/100 ml (for beverages) and 450 mg/100 g (meals)			
	Muesli and similar mixed breakfast cereals	5 000 mg/100 g			
	Cereal bars	3 750 mg/100 g			
	Fruit based drinks, except product defined in part I of Annex I to Directive 2001/112/EC	500 mg/100 ml			
	Biscuits, rusks and cookies	3 750 mg/100 g			
	Soups and soup concentrates	750 mg/100 ml (marketed as such or reconstituted according to the instructions)			
	Flavoured milk-based drinks	750 mg/100 g			
	Yogurt based drinks	750 mg/100 g			
	Milk analogues	750 mg/100 g			
	Cream analogues	10 000 mg/100 g			

Authorised novel food	Conditions under which the novel food may be used	Additional specific labelling requirements	Other requirements	Data protection
	Cheese analogues	3 750 mg/100 g		
	Yogurt analogues	1 200 mg/100 g		

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

Authorised Novel Food	Specifications
Rhamnogalacturonan-I enriched carrot extract	<p>Description/Definition: The novel food is an extract of carrot pomace selectively enriched for rhamnogalacturonan-I domains by an enzymatic process (degrading selectively the pectin portion), followed by inactivation of the enzymes and further purification, heat treatment, drying and pasteurisation. <i>Source: Daucus carota L., subspecies Sativus.</i></p> <p>Physical and chemical properties: Colour: Off-white to beige Odour/taste: Neutral Solubility: soluble in water Water activity: < 0,6</p> <p>Composition: Rhamnogalacturonan-I: ≥ 70 % Rhamnose: ≥ 9 % Moisture: ≤ 7 % Free sugars: ≤ 3 % Soluble dietary fibre: ≥ 60 % Total dietary fibre: ≥ 70 % Crude protein: ≤ 4 % Ash: ≤ 5 % Fat: ≤ 2 %</p> <p>Contaminants: Lead: ≤ 1,0 mg/kg Cadmium: ≤ 1,0 mg/kg Arsenic: ≤ 0,1 mg/kg Mercury: ≤ 0,1 mg/kg Perchlorate: ≤ 0,05 mg/kg</p>

Authorised Novel Food	Specifications
	<p>Microbiological criteria: TAMC: $\leq 1 \times 10^3$ CFU/g TYMC: $\leq 1 \times 10^2$ CFU/g <i>Bacillus cereus</i>: $< 1 \times 10^2$ CFU/g Enterobacteriaceae: $< 1 \times 10^2$ CFU/g <i>Escherichia coli</i>: < 10 CFU/g <i>Salmonella</i> spp.: not detected in 25 g <i>Listeria monocytogenes</i>: not detected in 25 g Sulphite reducing anaerobes: < 30 CFU/g</p> <p>Abbreviations: CFU, colony forming units; TAMC, total aerobic microbial count; TYMC, total yeast and mould count.’</p>