COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising the placing on the market of rhamnogalacturonan-I enriched carrot fibre (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[3], foods for special medical purposes as defined in

[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).

Regulation (EU) No 609/2013[4] and total diet replacement for weight control as defined in Regulation (EU) No 609/2013.

(4) On 17 December 2022, the applicant also made a request to the Commission for the protection of the following proprietary data: identity[5], compositional data[6] and toxicological information[7].

(5) On 8 June 2022, 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.

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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).

5 NF-2022-7430 2.2 Identity UPDATE 20240611 CONFIDENTIAL, Annex 2.2.01_HPSEC_cRG-I_batches 02-05 CONFIDENTIAL Annex 2.2.02_HPSEC_cRG-I_batches 06-08 CONFIDENTIAL, Annex 2.2.03_HPSEC_cRG-I_batches 09-12 CONFIDENTIAL to the application.

6 NF2022-7430 2.4. Compositional data cRG-I UPDATE 20250107 CONFIDENTIAL, Annex 2.4.04_Summary compositional data cRG-I UPDATE 20240611 CONFIDENTIA, Annex 2.4.05_CoA batch 002 CONFIDENTIAL, Annex 2.4.06_CoA batch 004 CONFIDENTIAL, Annex 2.4.07_CoA batch 005 CONFIDENTIAL, Annex 2.4.08_CoA batch 006 CONFIDENTIAL, Annex 2.4.09_CoA batch 007 CONFIDENTIAL, Annex 2.4.10_CoA batch 008 CONFIDENTIAL, Annex 2.4.1 1_CoA batch 009 CONFIDENTIAL, Annex 2.4.12_CoA batch 010 CONFIDENTIAL, Annex 2.4.13_CoA batch 011 CONFIDENTIAL, Annex 2.4.14_CoA batch 012 CONFIDENTIAL, Annex 2.4.16 stability data CoAs T1 CONFIDENTIAL, Annex 2.4.17 stability data CoAs T2 update 20230323 CONFIDENTIAL, Annex 2.4.24_Methanolysis_cRG-I_batches 02-05 update 20230323 CONFIDENTIAL, Annex 2.4.25_Methanolysis_cRG-I_batches 06-08 update 20230323 CONFIDENTIAL, Annex 2.4.26_Methanolysis_cRG-I_batches 09-012 update 20230323 CONFIDENTIAL, Annex 2.4.27 stability data CoAs T3 CONFIDENTIAL, Annex 2.4.28_CoA stability T4 tested batch 011 CONFIDENTIAL, Annex 2.4.29 stability T5 all tested batches 20230920 PUBLIC, Annex 2.4.30_CoA Luff batches 8-12 CONFIDENTIAL, Annex 2.4.42_CoA stability data T6 CONFIDENTIAL 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 Ames assay CONFIDENTIAL, Annex 2.10.04 MnVit Human Lymphocytes CONFIDENTIAL, Annex 2.10.05 Dose-range finding study for OECD 408 CONFIDENTIAL, Annex 2.10.06 90 days oral toxicity study CONFIDENTIAL, Annex 2.10.07 Comparison pilot and commercial scale cRG-I CONFIDENTIAL, 20221216 Annex 2.10.10_Ames assay 4 batches CONFIDENTIAL to the application.

8 *EFSA Journal.* 2025;23:e9537.

(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 fibre (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 fibre (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 fibre (cRG-I) as proposed by the applicant, it is necessary to inform the consumers in that regard by appropriate labelling about the uses of food supplements containing Rhamnogalacturonan-I enriched carrot fibre (cRG-I).

(14) Rhamnogalacturonan-I enriched carrot fibre (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.

(15) 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 fibre (cRG-I) is authorised to be placed on the market within the Union.

   Rhamnogalacturonan-I enriched carrot fibre (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.[9] 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 [*the date of entry into force of this Regulation*] [*OP please insert the date*], 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.

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,

For the Commission
The President
Ursula VON DER LEYEN

[9] Address: Bronland 12-N 6708 WH Wageningen, The Netherlands