COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising the placing on the market of rapeseed protein concentrate 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 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 authorised novel foods.

(3) On 19 August 2022, the company NapiFeryn BioTech Sp. z o.o. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place rapeseed protein-fibre concentrate on the Union market as a novel food. The applicant requested rapeseed protein-fibre concentrate to be used as a food ingredient in a number of food products for the general population, in food for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council[3] for the general population from 10 years of age, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[4], for the general population from 10 years of age.

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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/oj).

4 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) With regard to the conditions of use of the novel food in food supplements, the applicant initially proposed the maximum intake level of 30 g/day but subsequently agreed to reduce it to 10 g/day as the substance is a source of non-digestible carbohydrates.

(5) On 19 August 2022, the applicant also made a request to the Commission for the protection of the proprietary scientific studies and data, namely, the production process (Hazard Analysis and Critical Control Point plan[5], data on analytical reports[6], steps of the manufacturing process[7], the Good Manufacturing Practice certificate[8]), the compositional data (analyses of protein, fat, ash, moisture and fibre, amino acids, glucosinolates, heavy metals, pesticides, phytate, erucic acid, total dietary fibre, high molecular weight insoluble dietary fibre, high molecular weight soluble dietary fibre, low molecular weight soluble dietary fibre, neutral detergent fibre, acid detergent fibre, acid detergent lignin, trypsin inhibitor activity, microbial purity, residual solvents, sodium benzoate sulphites, and phenolic compounds, data on analytical reports, data on internal analytical methods, stability data of the novel food and analytical protocol[9], study on the digestibility of the novel food and analytical study[10], contract research organisation report[11], data on analytical report for aluminium, phosphane, raw materials and water activity[12], data on analytical report of sinapine and tannins[13]), the proposed uses and use levels, and anticipated intake (raw data on dietary exposure[14]), the nutritional information (the Sodium Dodecyl Sulfate-Polyacrylamide Gel Electrophoresis analysis[15], the Digestible Indispensable Amino Acid Score report[16], raw data[17]), the toxicological information[18], the allergenicity[19], the history of use[20], and supplementary information[21], in support of the application.

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5 Annex I.2.1 (HACCP documentation).

6 Annex I.2.4 to I.2.11 (Data on analytical reports).

7 Annex I.2.12 (Steps of the manufacturing process).

8 GMP_Certificate_Con

9 Annex I.3.1 a.1 (Analysis of protein, fat, ash, moisture and fibre); Annex I.3.1.a.2 (Analysis of amino acids); Annex I.3.1.a.3 (Analysis of glucosinolates); Annex I.3.1.a.4 (Analysis of heavy metals); Annex I.3.1.a.5 (Analysis of pesticides); Annex I.3.1.a.6 (Analysis of phytate); Annex I.3.1.a.7 (Analysis of erucic acid); Annex I.3.1.a.8 (Analysis of TDF, HMWIDF, HMWSDF& LMWSDF); Annex I.3.1.a.9 (Analysis of NDF, ADF & ADL); Annex I.3.1.a.10 (Analysis of tripsin inhibitor activity); Annex I.3.1.a.11 (Analysis of microbial purity); Annex I.3.1.a.12 (Analysis of residual solvents); Annex I.3.1.a.13 (Analysis of sodium benzoate sulfites); Annex I.3.1.a.14 (Analysis of phenolic compounds); Annexes I.3.1.a.15 to I.3.1.a.18 (Data on analytical report); Annex I.3.1.b.2 (Data on internal analytical methods); Annexes I.3.2.a and I.3.2.b (Stability data of the novel food); Annexes 1.3.1.a.19 to 1.3.1.a.35 (Data on analytical reports); Annexes I.3.2.a.I, I.3.2.b.I and I.3.2.b.2 (Stability data of the novel food and analytical protocol);.

10 Annex I.8.2 (Study on the digestibility of the novel food and analytical study plan

11 CRO_Original (data on analytical reports)

12 Annexes I.3.1.a.36 to I.3.1.a.39, and Annex I.3.2.b.3 (Data on analytical report for phosphane, aluminium, raw materials, and water activity)

13 Annex 1.3.5.1 and 1.3.5.2 (Data on analytical report of sinapine and tannins)

14 Annex I.6.1 (Raw data on dietary exposure); Annexes I.6.1.1 and I.6.1.2 (Raw data); Annex I.6.10 (Raw data).

15 Annex I.8.1.a. SDS-PAGE (Data on analytical report)

16 Annex I.8.3. DIAAS (Data in the digestibility study report and analytical study plan)

17 Raw_data

18 Annex I.9.1 (Literature review report).

19 Annex I.10.1.a (Data of study report on allergenicity).

20 GRAS_dossier_NFB_RapteinTM30_FINAL; GRN_1122_NQL_final_trans

21 Appendixes.2_replies_April_1 to 11.

(6) On 26 May 2023, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of rapeseed protein-fibre concentrate as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(7) On 27 August 2025, the Authority adopted its scientific opinion on the safety of rapeseed protein-fibre concentrate as a novel food[22] in accordance with Article 11 of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority concluded that rapeseed protein-fibre concentrate is safe under the proposed conditions of use. However, it also concluded that the rapeseed protein-fibre concentrate from *Brassica rapa* L. and *Brassica napus* L. may trigger allergic reactions in people allergic to mustard. Therefore, that scientific opinion gives sufficient grounds to establish that rapeseed protein-fibre concentrate when used under the proposed conditions of use, and provided that the labelling of the foods containing rapeseed protein-fibre concentrate from *Brassica rapa* L. and *Brassica napus* L. is such to allow people who are allergic to mustard to avoid consumption of those foods, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(9) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the following data: the production process (Hazard Analysis and Critical Control Point plan, and steps of the manufacturing process), the compositional data (analyses of protein, fat, ash, moisture and fibre, amino acids, glucosinolates, heavy metals, pesticides, phytate, erucic acid, total dietary fibre, high molecular weight insoluble dietary fibre, high molecular weight soluble dietary fibre, low molecular weight soluble dietary fibre, neutral detergent fibre, acid detergent fibre, acid detergent lignin, trypsin inhibitor activity, microbial purity, residual solvents, sodium benzoate sulphites, and phenolic compounds, data on analytical reports, data on internal analytical methods, stability data of the novel food and analytical protocol, data on analytical report for aluminium, phosphane, and water activity, data on analytical report of sinapine and tannins), the proposed uses and use levels, and anticipated intake (raw data on dietary exposure), the nutritional information (the Digestible Indispensable Amino Acid Score report), the toxicological information, the allergenicity, and supplementary information in support of the technical dossier without which it could not have assessed the novel food and reached its conclusion.

(10) The applicant declared that they held proprietary and exclusive rights of reference to the scientific studies and data at the time they submitted the application.

(11) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific studies and data, namely, the production process (Hazard Analysis and Critical Control Point plan, and steps of the manufacturing process), the compositional data (analyses of protein, fat, ash, moisture and fibre, amino acids, glucosinolates, heavy metals, pesticides, phytate, erucic acid, total dietary fibre, high molecular weight insoluble dietary fibre, high molecular weight soluble dietary fibre, low molecular weight soluble dietary fibre, neutral detergent fibre, acid detergent fibre, acid detergent lignin, trypsin inhibitor activity, microbial purity, residual solvents, sodium benzoate sulphites, and phenolic compounds, data on analytical reports, data on internal analytical methods, stability data of the novel food and analytical protocol, data on

[22] EFSA Journal 2025;23:e9631 (https://doi.org/10.2903/j.efsa.2025.9631).

analytical report for aluminium, phosphane, and water activity, data on analytical report of sinapine and tannins), the proposed uses and use levels, and anticipated intake (raw data on dietary exposure), the nutritional information (the Digestible Indispensable Amino Acid Score report), the toxicological information, the allergenicity, and supplementary information in support of the technical dossier should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place rapeseed protein-fibre concentrate on the market within the Union during a period of five years from the entry into force of this Regulation.

(12) However, restricting the authorisation of rapeseed protein-fibre concentrate 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) Pursuant to Annex I to Regulation (EU) No 1169/2011 on the provision of food information to consumers[23], the nutrient fibre is specifically defined. The Commission considers that the fibre component of the novel food 'rapeseed protein-fibre concentrate' does not meet this definition. The use of the term 'fibre' in the designation of this novel food could therefore mislead consumers as to its nutritional properties and composition. It is, therefore, appropriate to exclude the term 'fibre' from the official designation and to provide for appropriate labelling measures to prevent consumer confusion.

(14) In accordance with the conditions of use of food ingredients and food supplements containing rapeseed protein concentrate as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers with an appropriate label that food ingredients and food supplements containing rapeseed protein concentrate should not be used if other foods with added rapeseed protein concentrate are consumed the same day in individuals above 10 years of age.

(15) It is appropriate that the inclusion of rapeseed protein concentrate as a novel food in the Union list of novel foods contains also the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

(16) Rapeseed protein concentrate 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.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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[23] 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).

HAS ADOPTED THIS REGULATION:

Article 1

1. Rapeseed protein concentrate is authorised to be placed on the market within the Union.

   Rapeseed protein concentrate 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 NapiFeryn BioTech Sp. z o.o. [24] 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 that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of NapiFeryn BioTech Sp. z o.o.

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 five years from the date of entry into force of this Regulation without the agreement of NapiFeryn BioTech Sp. z o.o.

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

[24] Address: Stanisława Dubois 114/116, 93-465 Łódź, Poland