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COMMISSION IMPLEMENTING REGULATION (EU) 2026/386

of 20 February 2026

authorising the placing on the market of defatted rapeseed 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 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.

(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.

([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).

(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 and sulphur dioxide, and phenolic compounds, data from the analytical reports on the novel food, 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 from the analytical report on aluminium, phosphane, raw materials and water activity ([12]), data from the analytical report on sinapine and tannins ([13])), the proposed uses and use levels, and anticipated intake (raw data on dietary exposure ([14])), the nutritional information (a sodium dodecyl sulfate-polyacrylamide gel electrophoresis analysis ([15]), a 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.

(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, provided that individuals above 10 years of age do not consume foods containing the NF and food supplements containing the NF on the same day. Therefore, that scientific opinion gives sufficient grounds to establish that rapeseed protein-fibre concentrate when used 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.

([5]) Annex I.2.1 (HACCP documentation) to the application.
([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.
([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.1, I.3.2.b.1 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).
([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 from protein studies.
([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.
([22]) *EFSA Journal* 2025;23:e9631 (https://doi.org/10.2903/j.efsa.2025.9631).

(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 and sulphur dioxide, and phenolic compounds, the data from the analytical reports on the novel food, data on internal analytical methods, the stability data of the novel food and analytical protocol, the data from the analytical report on aluminium, phosphane, and water activity, the data from the analytical report on 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 (the 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 and sulphur dioxide, and phenolic compounds, data from the analytical reports on the novel food, data on internal analytical methods, stability data of the novel food and analytical protocol, data from the analytical report on aluminium, phosphane, and water activity, data from the analytical report on 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) The designation 'rapeseed protein-fibre concentrate' does not reflect the actual composition of the novel food, as its protein content remains below 50 % and it has not been demonstrated that the fibre component meets the definition set out in Annex I to Regulation (EU) No 1169/2011 of the European Parliament and of the Council ([23]). The use of the term 'protein-fibre concentrate' 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 'protein-fibre concentrate' with a name that accurately reflects the novel food's true nature and composition. The applicant accepted the proposed designation 'defatted rapeseed powder'.

(14) In accordance with the conditions of use of food ingredients and food supplements containing defatted rapeseed powder 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 defatted rapeseed powder should not be used if other foods with added defatted rapeseed powder are consumed the same day by individuals above 10 years of age.

([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).

(15) The Authority also considers that the novel food is likely to trigger allergic reactions in rapeseed-allergic individuals and also in mustard-allergic individuals owing to cross-reactivity. Therefore, it is necessary to provide for the labelling requirement to allow people who are allergic to mustard to avoid consumption of the novel food.

(16) It is therefore appropriate that the inclusion of defatted rapeseed powder 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.

(17) Defatted rapeseed 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.

(18) 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. Defatted rapeseed powder is authorised to be placed on the market within the Union.

Defatted rapeseed 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

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 five years from 15 March 2026, 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, 20 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

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

ANNEX

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
‘**Defatted rapeseed powder**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be “defatted rapeseed powder”. The labelling of food supplements containing defatted rapeseed powder shall bear a statement (a) that they should not be used if other foods containing added defatted rapeseed powder are consumed the same day; and (b) they should not be consumed by infants and children under 10 years of age. Any foodstuff containing “defatted rapeseed powder” from *Brassica rapa* L. and *Brassica napus* L.” shall bear a statement that this ingredient may cause allergic reaction to consumers who are allergic to mustard and products thereof. That statement shall appear in close proximity to the list of ingredients.		Authorised on 15 March 2026. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: “NapiFeryn BioTech Sp. z o.o.”, Stanisława Dubois 114/116, 93-465 Łódź, Poland. During the period of data protection, the novel food defatted rapeseed powder is authorised for placing on the market within the Union only by “NapiFeryn BioTech Sp. z o.o.” 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 “NapiFeryn BioTech Sp. z o.o.”. End date of the data protection: 15 March 2031.’
	Bakery products (bread and rolls, fine bakery wares)	20 g/100g			
	Bread bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Implementing Regulation (EU) No 828/2014	20 g/100g			
	Breakfast cereals	20 g/100g			
	Cereal bars	20 g/100g			
	Pasta	10 g/100g			
	Pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Implementing Regulation (EU) No 828/2014	10 g/100g			
	Non-alcoholic powdered drinks	5 g/100 ml (reconstituted according to the instructions)			
	Fruit-based liquid foodstuffs (of the “smoothie” variety)	3 g/100 g			
	Dairy analogues	5 g/100 g			
	Meat analogues	15 g/100 g			
	Soups (dry mixture) and (ready-to-eat)	5 g/100 ml (marketed as such or reconstituted according to the instructions)			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	Savoury sauces	5 g/100 g			
	Salad dressing	5 g/100 g			
	Vegetable puree	7 g/100 g			
	Nut spreads	7 g/100 g			
	Chocolate confectionary	7 g/100 g			
	Chips, crisps, fries and dough-based analogues	15 g/100 g			
	Snacks other than chips	20 g/100 g			
	Meat products	15 g/100 g			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013, excluding foods for infants and young children, and children under 10 years of age.	In accordance with the particular nutritional requirements of the persons for whom the products are intended but, in any case, not higher than 30 g/day in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Food supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children, and children under 10 years of age.	10 g/day for the general population above 10 years of age			

ELI: http://data.europa.eu/eli/reg_impl/2026/386/oj

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

Authorised novel food	Specifications
'**Defatted rapeseed powder**	**Description:** The novel food is a white to off-white dried powder remaining after aqueous and organic solvent extraction (ethanol and ethyl acetate) of hulled and dehulled cold-pressed rapeseed cake originating from non-genetically modified double low (00) cultivars of *Brassica napus* L. and *Brassica rapa* L. **Characteristics/Composition:** Crude protein (% w/w): 28-45 Fat (% w/w): ≤ 2 Ash (% w/w): ≤ 5 Moisture (% w/w): ≤ 7 Total dietary fibre (*) (% w/w): 37–70 Total glucosinolates (mmol/kg (mg/kg)): ≤ 0,1 (≤ 40) Phytates (% w/w): ≤ 2 **Heavy and other metals:** Lead (mg/kg): ≤ 0,2 Arsenic (total) (mg/kg): ≤ 0,1 Cadmium (mg/kg): ≤ 0,1 Mercury (mg/kg): ≤ 0,02 Aluminium (mg/kg): ≤ 35 **Residual solvents:** Residual ethanol (mg/kg): < 200 Residual ethyl acetate (mg/kg): < 200 **Microbiological criteria:** Total plate count: ≤ 10 000 CFU (**)/g Enterobacteriaceae: ≤ 10 CFU/g *E.coli:* Absent in 10 g *Salmonella* spp.: Absence in 25 g Yeast and moulds: ≤ 100 CFU/g Total coliform count: ≤ 10 CFU/g *B. cereus*: ≤ 100 CFU/g

(*) Total dietary fibre: The EFSA Panel interprets that "dietary fibre" refers to non-digestible polysaccharides classified as dietary fibre by EFSA for the specific purpose of setting Dietary Reference Values for carbohydrates and dietary fibre (EFSA NDA Panel, 2010).
(**) CFU: Colony Forming Units.'