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COMMISSION IMPLEMENTING REGULATION (EU) 2026/1507

of 3 July 2026

authorising the placing on the market of *Rhizomucor pusillus* mycelium 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 16 May 2020, the company The Protein Brewery 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 *Rhizomucor pusillus* fungus biomass on the Union market as a novel food. The applicant requested the *Rhizomucor pusillus* fungus biomass to be used as a whole food, as an ingredient in several food products, including meal replacement for weight control at levels not exceeding 40 g per meal, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]), at levels not exceeding 6 g/day for the general adult population, excluding pregnant and lactating women.

(4) On 16 May 2020, the applicant also made a request to the Commission for the protection of the proprietary scientific studies and data, namely, identity of the novel food ([4]), production process ([5]), compositional analysis ([6]), history of use ([7]), absorption, distribution, metabolism and excretion information ([8]), nutritional information ([9]), toxicological information ([10]), genotoxicity ([11]), subchronic toxicity study ([12]), human data ([13]), and allergenicity ([14]).

([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]) Annex 2.2.3 – Identity of the NF_conf.pdf; 2.2.3_Identity of the novel food_updated_June2025.pdf; 2.2.3_Appendix C1_conf.pdf; 2.2.3_Appendix C2_conf.pdf; 2.2.3_Appendix C3_conf.pdf; 2.2.3_Appendix C5_conf.pdf to 2.2.3_Appendix C8_conf.pdf.

([5]) Annex 2.3.1 – Production process_conf.pdf; 2.3.1._Appendix D1_updated.pdf; 2.3.1_Appendix D_conf.pdf; Answer to EFSA question 2_19042022.pdf.

([6]) 2.4.3. Compositional data_conf_updated_June 2025.pdf; 2.4.4_Stability_ updated Aug 2025.pdf.

([7]) 2.6_History of use_updated.pdf; 2.6_Appendix A_conf.pdf; 2.6_Appendix C_conf.pdf; 2.6_Appendix D_conf.pdf.

([8]) 2.8_ADME_updated.pdf; 2.8_Appendix A_conf.pdf.

([9]) 2.9_Nutritional information_updated_Aug 2025.pdf.

([10]) 2.10.1_General considerations_updated sept.pdf; 2.10.7.2 Specific cases microorganisms_updated.pdf; 2.10.7.2_Appendix A1 updated_05082024.pdf; 2.10.7.2_Appendix D1_conf.pdf; 2.10.7.2_BioIT BiomaX 2018 Rh pusillus_conf.pdf.pdf; 2.10.7.2_Mycotoxin overview_supplying_conf.pdf; 2.10.7.2_NGS report Baseclear Rh pusillus_conf.pdf; 2.10.7.2_WGS BaseClear description_conf.pdf.

([11]) 2.10.2_Genotoxicity_updated May 2025.pdf; HCD Ames 2021.pdf; 2.10.2_Appendix D5.pdf; Answer to EFSA question 13_22112024.pdf; 2.10.2_Appendix D7.pdf; 2.10.2_Appendix D8.pdf.

([12]) 2.10.3_Subchronic toxicity_updated.pdf; 2.10.3_Appendix D1.pdf; Answers to EFSA question 14_19042022.pdf.

([13]) 2.10.6_Human data_Updated.pdf; 2.10.6_Appendix D_datap (1).pdf; Hb values TOMMY study.xlsx.

([14]) 2.11_Allergenicity_updated.pdf; 2.11_Appendix A_updated.pdf; 2.11_Appendix D1_updated.pdf; 2.11_Appendix D2_conf.pdf; 2.11_Appendix D3_SampleN1_Results.xlsx; 2.11_Appendix D3_SampleN3_Results.xlsx; 2.11_Appendix D3_updated.pdf; 2.11_Appendix D4.pdf; 2.11_In silico homology search_updated.xlsx; Answers to EFSA questions 15 and 16.pdf; Proteome Factory_Study Report_05062020.pdf.

(5) On 7 January 2021, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of *Rhizomucor pusillus* fungus biomass as a novel food.

(6) On 29 September 2025, the Authority adopted its scientific opinion 'Safety of *Rhizomucor pusillus* biomass powder as a novel food pursuant to Regulation (EU) 2015/2283' ([15]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that *Rhizomucor pusillus* fungus biomass is safe under the proposed conditions of use for the proposed target population. Therefore, that scientific opinion gives sufficient grounds to establish that *Rhizomucor pusillus* fungus biomass, when used as a whole food, as an ingredient in food products, including, meal replacement for weight control at levels not exceeding 40 g per meal, and in food supplements at levels not exceeding 6 g/day for the general adult population, excluding pregnant and lactating women, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on analytical reports for the identity of the novel food, production process, compositional analysis, history of use, absorption, distribution, metabolism and excretion information, nutritional information, toxicological information, genotoxicity, subchronic toxicity study, human data, and allergenicity, without which it could not have assessed the novel food and reached its conclusion.

(9) 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.

(10) 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 evidence and data, namely, identity of the novel food, production process, compositional analysis, history of use, absorption, distribution, metabolism and excretion information, nutritional information, toxicological information, genotoxicity, subchronic toxicity study, human data, and allergenicity should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place *Rhizomucor pusillus* fungus biomass on the market within the Union during a period of five years from the entry into force of this Regulation.

(11) However, restricting the authorisation of *Rhizomucor pusillus* fungus biomass and the reference to the scientific evidence and data contained in the applicant's file for the sole use by them 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.

(12) The use of the term '*Rhizomucor pusillus* fungus biomass' in the designation of the novel food could mislead consumers as to its identity and composition. Therefore, it is appropriate to replace the term '*Rhizomucor pusillus* fungus biomass' with the designation '*Rhizomucor pusillus* mycelium' proposed by the applicant.

(13) It is appropriate that the inclusion of *Rhizomucor pusillus* mycelium 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.

(14) *Rhizomucor pusillus* mycelium 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,

([15]) *EFSA Journal*, 2025;23:e9707, https://doi.org/10.2903/j.efsa.2025.9707.

HAS ADOPTED THIS REGULATION:

Article 1

1. *Rhizomucor pusillus* mycelium is authorised to be placed on the market within the Union.

Rhizomucor pusillus mycelium 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 The Protein Brewery B.V. ([16]) 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 26 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 The Protein Brewery 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 The Protein Brewery 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, 3 July 2026.

For the Commission
The President
Ursula VON DER LEYEN

([16]) Goeseelsstraat 10, 4817 MV, Breda, Netherlands.

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
'***Rhizomucor pusillus* mycelium**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "*Rhizomucor pusillus* mycelium". The labelling of food supplements containing "*Rhizomucor pusillus* mycelium" shall bear a statement that they should not be consumed by persons under 18 years of age, and pregnant and lactating women.		Authorised on 26 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: "The Protein Brewery B.V.", Goeseelsstraat 10, 4817 MV, Breda, Netherlands. During the period of data protection, the novel food *Rhizomucor pusillus* mycelium is authorised for placing on the market within the Union only by "The Protein Brewery 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 "The Protein Brewery B.V.". End date of the data protection: 26 July 2031.'
	Rhizomucor pusillus mycelium powder				
	Breakfast cereals, and cereal-, fruit- or vegetable-based snacks	30 g/100 g			
	Biscuits	10 g/100 g			
	Cereal bars	35 g/100 g			
	Dairy analogues except drinks	20 g/100 g			
	Non-alcoholic beverages	10 g/100 g			
	Flatbread and steamed breads	20 g/100 g			
	Chocolate confectionery	15 g/100 g			
	Cocoa-based spreads	20 g/100 g			
	Meal replacements for weight control for the adult population (as drinks)	Maximum 2 meals/day up to a maximum of 40 g/day			
	Food supplements as defined in Directive 2002/46/EC, for the general adult population, excluding pregnant and lactating women	6 g/day			

ELI: http://data.europa.eu/eli/reg_impl/2026/1507/oj

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

Authorised novel food	Specification
'***Rhizomucor pusillus* mycelium**	**Description:** The novel food is the biomass of the fungus *Rhizomucor pusillus* (strain CBS 143028), which has been produced via fermentation. The biomass is then harvested, pasteurised to inactivate the viable fungus cells, dried and milled into a whitish odourless powder. *Rhizomucor pusillus* is a filamentous fungus belonging to the Mucoraceae family. **Characteristics/Composition:** Moisture: 4-7 g/100 g Crude protein content (N × 6,25): 44-68 g/100 g Total fat content: 4-8 g/100 g Total dietary fibre: 25-39 g/100 g Total digestible carbohydrates: ≤ 3 g/100 g Ash: ≤ 6 g/100 g **Microbiological criteria:** Total aerobic microbial count: ≤ 10^3 CFU (*)/g *Bacillus cereus*: ≤ 100 CFU/g *Clostridium perfringens*: < 10 CFU/g Coagulase-positive staphylococci: ≤ 50 CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Escherichia coli*: ≤ 10 CFU/g *Listeria monocytogenes:* Not detected in 25 g *Salmonella* spp.: Not detected in 25 g Yeasts and moulds: < 100 CFU/g (*) CFU = Colony Forming Units **Heavy metals:** Arsenic (As): ≤ 0,1 mg/kg Cadmium (Cd): ≤ 0,1 mg/kg Lead (Pb): ≤ 0,1 mg/kg Mercury (Hg): ≤ 0,1 mg/kg **Mycotoxins:** Aflatoxins (B1, B2, G1, G2): < 0,1 µg/kg Diacetoxyscirpenol: < 20 µg/kg Fumonisins (B1, B2): < 100 µg/kg HT2 Toxin: < 7,5 µg/kg T2 Toxin: < 7,5 µg/kg Nivalenol: < 150 µg/kg Ochratoxin A: < 1,0 µg/kg Deoxynivalenol (DON): < 150 µg/kg Zearalenone: < 20 µg/kg'