The Mycelium Authorization That Changes the Protein Innovation Equation

***Rhizomucor pusillus*, protected novel-food evidence and the industrial economics of fungal biomass in 2026**

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Abstract

The European Union's July 2026 authorisation of Rhizomucor pusillus mycelium marks more than another entry on the novel-food list. It establishes a defined, strain-specific and process-specific route to market for a fermented fungal biomass containing substantial protein and dietary fibre, while reserving the initial commercial benefit to an applicant whose protected evidence supported the safety assessment. This article examines the resulting tension between biotechnology, nutrition, process engineering and regulatory exclusivity. It evaluates what the EFSA opinion actually establishes, what the authorisation permits, why crude protein is not synonymous with nutritional performance, and how fermentation economics can be undermined by downstream processing, variability and market access. The comparison extends to Great Britain and Australia–New Zealand, where separate assessments remain relevant. A proposed research programme focuses on the interaction of fungal cell-wall architecture, digestibility, processing stability and formulation behaviour. The central argument is that the next competitive advantage will depend less on producing biomass than on demonstrating reproducible functionality, defensible nutrition and legally accessible commercialisation.

Keywords: *fungal biomass; Rhizomucor pusillus; novel foods; precision fermentation; protein quality; mycoprotein; data protection; food regulation*.

1. An authorisation with consequences beyond one ingredient

On 3 July 2026, the European Commission adopted Implementing Regulation (EU) 2026/1507, published on 6 July and applicable from 26 July, authorising Rhizomucor pusillus mycelium under the novel-food framework. The entry is specific: it concerns biomass from strain CBS 143028, produced by fermentation, harvested, pasteurised, dried and milled. It is not a general authorisation for all Rhizomucor strains, all fungal proteins or any fermentation process capable of generating a similar powder [1].

This distinction is often lost when novel-food developments are presented as evidence that a new class of ingredients has been broadly liberalised. European law attaches the authorisation to an identified substance and specifications, with defined food categories, maximum levels and labelling. A manufacturer cannot replace the organism, modify the production process materially, or assume that another biomass is legally interchangeable simply because the resulting protein percentage looks comparable.

The authorisation is especially instructive because it coincides with a five-year period of protected proprietary data. Article 2 restricts initial Union marketing to The Protein Brewery B.V., subject to the stated possibilities for consent or independently supported authorisation. The protection period ends on 26 July 2031. The mechanism protects qualifying scientific data rather than creating a permanent monopoly over an organism or a scientific concept [1,2]. For competitors, therefore, the relevant question is not merely whether a process can make fungal biomass, but whether it can establish an independent safety dossier and a commercially viable supply chain.

2. What the safety assessment establishes and what it does not

The EFSA NDA Panel concluded in its opinion first published in December 2025, subsequently amended in January 2026 without changing the safety conclusion, that the proposed biomass is safe under the specified conditions of use [3]. The dossier included identity and manufacturing information, composition, stability, genotoxicity, a 90-day toxicity study, nutritional considerations and allergenicity. The highest tested dose in the subchronic study was 19,668 mg/kg body weight per day. The panel reported upper dietary intake estimates between 539 and 1,013 mg/kg body weight per day across population groups and judged the resulting margins of exposure adequate in the context of the total evidence.

Safety is not nutritional superiority. A toxicological assessment can support market access without proving that the ingredient improves muscle protein synthesis, satiety, glycaemic outcomes or population health. Likewise, a low assessed likelihood of allergic reactions is not a guarantee of absence of individual hypersensitivity. The legal authorisation does not constitute an approved health claim. Nutrition and health communications remain subject to the separate conditions of Regulations (EC) 1924/2006 and (EU) 1169/2011 [4,5].

The compositional range itself deserves attention. The authorised specification lists crude protein of 44–68 g/100 g using nitrogen multiplied by 6.25, dietary fibre of 25–39 g/100 g, fat of 4–8 g/100 g and digestible carbohydrates not exceeding 3 g/100 g. Those figures describe an ingredient with two major structural fractions, not a purified protein isolate [1]. Its commercial identity is therefore potentially closer to a multifunctional fermentation-derived matrix than to a commodity protein powder.

The nitrogen-to-protein problem

In fungal biomass, the conventional N × 6.25 conversion can be a poor proxy for true protein because total nitrogen may include nucleic acids, chitin-associated nitrogen and other non-protein compounds. The regulatory specification uses a defined analytical convention; formulation scientists must not silently transform that number into an equivalent quantity of digestible amino acids.

Amino-acid analysis, correction for non-protein nitrogen, protein digestibility and the quality of indispensable amino acids should be considered together. The correct interpretation is matrix- and method-dependent, not a universal discount factor.

The same caution applies to dietary fibre. A large fibre fraction may be technologically useful for water binding, texture and structure, yet it can also affect viscosity, gastrointestinal tolerance, processability and the interpretation of protein density. Product developers should establish how analytical fibre values translate into functionality in their actual food matrix, rather than treating a compositional declaration as a performance guarantee.

3. Fermentation is the beginning of the cost structure

The economics of fungal biomass depend on much more than the fermentation titre. A competitive process must coordinate substrate cost, aeration, oxygen transfer, heat removal, morphology, contamination control, harvest, pasteurisation, dewatering, drying, milling and quality release. Filamentous organisms introduce particular rheological complications: the transition between dispersed hyphae and pellets changes apparent viscosity, mixing power, mass transfer and separation behaviour. The economically optimal morphology is not necessarily the morphology giving the highest laboratory growth rate.

A plant producing biomass at an attractive upstream cost can still lose competitiveness during downstream processing. Water retained in a mycelial matrix has to be separated or evaporated; thermal treatment must deliver validated inactivation without unacceptable quality loss; drying can impair dispersibility, texture or nutritional properties. These costs interact. More aggressive mechanical dewatering may save thermal energy but change particle structure; gentler drying may preserve functionality while raising energy use and residence time.

A defensible techno-economic analysis should therefore report cost per kilogram of specification-compliant, saleable dry ingredient, not only per kilogram of biomass harvested. The denominator must reflect yield losses, rejected batches, microbiological hold times and packaging stability. Where a product is sold on a protein claim, a second denominator, -cost per kilogram of nutritionally usable protein-, may be more informative than gross powder cost.

An illustrative economic sensitivity, not a plant forecast

Consider a hypothetical operation selling 2,000 tonnes of dry biomass annually. An additional €0.20/kg in drying and utilities changes annual operating cost by €400,000; a 3% reduction in saleable yield removes 60 tonnes from the commercial output. At an illustrative contribution margin of €1.50/kg, that lost output represents €90,000 of contribution before considering fixed-cost absorption. These figures are transparent arithmetic scenarios, not measured data from The Protein Brewery or INTABIOTECH. Their purpose is to show why downstream engineering can overturn an upstream productivity advantage.

4. The authorisation is a formulation map, not an unlimited licence

The Union-list entry permits specific uses at specified maximum inclusion levels. Examples include breakfast cereals and cereal-, fruit- or vegetable-based snacks up to 30 g/100 g, biscuits up to 10 g/100 g, cereal bars up to 35 g/100 g, non-alcoholic beverages up to 10 g/100 g, and certain dairy analogues other than drinks up to 20 g/100 g.

Adult food supplements are limited to 6 g/day; the authorisation also includes specific adult meal-replacement conditions [1]. These categories are not interchangeable, and the complete annex must govern any formulation decision.

Selected authorized category	Maximum level	Development implication
Non-alcoholic beverages	10 g/100 g	Dispersibility, sedimentation, flavour and processing stability become decisive
Biscuits	10 g/100 g	Thermal behaviour, colour and water competition require testing
Cereal bars	35 g/100 g	Texture, binding and shelf-life effects may dominate
Dairy analogues excluding drinks	20 g/100 g	Emulsion, gelation and sensory integration need evidence
Adult food supplements	6 g/day	Daily-dose and mandatory population warning apply

The legal designation is “Rhizomucor pusillus mycelium”. Food supplements containing it require a warning that they should not be consumed by persons under 18 years of age or by pregnant and lactating women. The authorisation cannot be reduced to a supplier certificate declaring that an ingredient is “EU approved”; the supplier, source, category, use level and conditions of the Union-list entry must be checked [1].

For beverage developers, a 10 g/100 g legal ceiling should not be mistaken for an achievable technical dosage. Insoluble or partially soluble cell-wall structures can produce sediment, opacity, grit, fouling or instability after pasteurisation. Conversely, in bars and baked goods, the same structural characteristics may provide useful water management and texture. A functional advantage is not inherent in the legal authorisation; it is a property to demonstrate for each process.

5. Comparative regulation: one ingredient, several jurisdictions

The European Commission’s decision does not create automatic access to Great Britain. In February 2026, the UK Advisory Committee on Novel Foods and Processes published a further-information paper for the Rhizomucor pusillus biomass application, RP1215, following requests for additional information in the assessment [6]. That document establishes an active review, not an authorisation. Any current British market decision must verify the relevant FSA/FSS register and the applicable territorial rules. Northern Ireland requires separate consideration under its EU-linked arrangements.

Australia and New Zealand offer a second useful comparison. Food Standards Australia New Zealand published application A1366 on 13 October 2026 seeking permission for Rhizomucor pusillus mycelium as a novel food [7]. An application is not approval. The administrative assessment indicates regulatory activity but does not establish that the ingredient can already be sold under the requested conditions. For the United States, the existence of an EU novel-food approval does not itself constitute an FDA GRAS conclusion, food-additive authorisation or other lawful basis for the intended use. A product-specific US legal review is necessary.

Territory	Verified development	Commercial consequence
European Union / Spain	Implementing Regulation 2026/1507; authorised from 26 July 2026, with protected-data conditions	Check exact Union-list specifications, eligible supplier and product category
Great Britain	FSA/ACNFP application RP1215 under assessment in February 2026	Do not infer market authorisation from EU status
Australia / New Zealand	FSANZ application A1366 published 13 October 2026	Application status is not a permission to market
United States	No US clearance established by the cited EU decision	Determine the appropriate FDA legal pathway for the specific product

This divergence is commercially consequential. The same factory may need distinct market-entry dossiers, labelling systems and claims substantiation. An investor evaluating an international launch should therefore separate technical readiness from legal readiness and distinguish permitted markets from markets merely under assessment.

6. Food safety and analytical release are part of product design

The annex establishes microbiological limits, including total aerobic count not exceeding 10^3 CFU/g, Enterobacteriaceae not exceeding 10 CFU/g, absence of Salmonella in 25 g and absence of Listeria monocytogenes in 25 g. It also defines limits for heavy metals and a detailed set of mycotoxins [1]. These requirements are not peripheral compliance paperwork. They determine how the fermentation plant controls raw materials, harvest, pasteurisation, drying, environmental hygiene, packaging and shelf life.

A fungal ingredient cannot be judged safe merely because its production organism is inactivated. Thermal validation must address the organism and process conditions; subsequent contamination remains possible during drying, milling and filling. Analytical release should link microbiology with water activity, moisture, lot traceability, identity testing and relevant chemical contaminants. A change in substrate supplier or a new drying installation may alter the impurity profile even if nominal protein remains within specification.

For the buyer, a certificate of analysis is necessary but insufficient. The technical agreement should specify methods, sampling plan, change-control obligations, traceability, retesting, storage and procedures for out-of-specification lots. The question is whether the manufacturing system repeatedly delivers the authorised material, not whether one batch happens to satisfy the headline composition range.

7. Industrial applications: where the biomass may create value

There are at least three distinct industrial propositions. The first is protein fortification, where the relevant performance metrics are digestible indispensable amino acids, acceptable taste and cost per effective nutritional dose. The second is structural functionality: hydration, viscosity, binding and texture can be useful even when protein quality is not the principal selling point.

The third is nutritional reformulation, where the simultaneous presence of protein and fibre may support product design subject to the applicable nutrient-claim rules and actual compositional evidence.

These propositions should not be collapsed into a single marketing story. A bakery seeking moisture retention, a sports beverage seeking clarity and a meal replacement seeking amino-acid density require different analytical and sensory evidence. High fibre can be advantageous in one formulation and counterproductive in another. The biomass may also interact with emulsifiers, hydrocolloids, minerals, acidulants and heat treatments in ways that require experimental mapping rather than inference from powder specifications.

For companies developing innovative proteins, the strategic relevance is not a claim of ownership or access to this protected ingredient. It is the opportunity to build formulation and analytical capabilities around the broader fungal-biomass category: protein-quality assessment, dispersion engineering, shelf-life testing, ingredient interactions, sensory optimisation and jurisdiction-specific dossier design. Any project involving this particular authorised mycelium must first resolve legitimate supply and intellectual-property conditions.

8. Research & Innovation Opportunity

From nitrogen content to functional nutritional yield

The unresolved problem is how to compare fermentation-derived protein matrices when conventional crude-protein measurements do not capture digestibility, cell-wall accessibility or performance in the final food. It is already established that fungal biomass contains non-protein nitrogen and structurally complex cell-wall components. What remains uncertain for this particular authorised material, across different food processes, is the extent to which particle size, thermal history, hydration and matrix interactions change amino-acid availability and technological functionality.

A plausible research hypothesis is that controlled mechanical or enzymatic modification of biomass structure could improve the balance between digestibility and dispersibility without destroying desirable fibre functionality. This is a proposed research pathway, not a demonstrated advantage of a specific treatment or an authorised modification of the novel food. Any material change in the authorised ingredient or manufacturing process would require a separate assessment of regulatory implications.

A rigorous programme would first characterise nitrogen fractions, amino-acid profile, cell-wall polysaccharides, particle-size distribution, microscopy, rheology and water-binding capacity. It would then compare standardised in-vitro digestion and, where justified, validated protein-quality methods across untreated and processed matrices. Parallel studies would evaluate beverage sedimentation, heat stability, sensory attributes and shelf-life microbiology. The economic module should express energy, water, yield and waste per kilogram of nutritionally functional ingredient. Finally, a regulatory gate should assess whether process changes remain within the authorised identity and specifications or trigger additional novel-food work.

A second line of research could examine whether fermentation substrate and process morphology influence trace impurities, nutritional composition and downstream separability. Such investigations must distinguish known manufacturing variables from claims of a previously undiscovered mechanism. Patent and freedom-to-operate analysis would be essential before any

commercial development, especially where the applicant's proprietary dossier, strain rights or processing know-how may be relevant.

9. A practical decision framework for ingredient developers

Before committing to a fungal-protein programme, management should answer four linked questions. Is the ingredient legally available to the company for the intended territory and use? Can the supplier repeatedly meet identity, contaminant and microbiological specifications? Does the material provide demonstrable nutritional or functional value in the actual food matrix? And does the contribution margin remain attractive after hydration, processing, sensory correction, quality release and distribution losses?

The most common analytical error is to answer only the third question with a laboratory prototype. The most common legal error is to treat a European authorisation as universal permission for a fungal category. The most common economic error is to compare ingredient prices per kilogram without correcting for effective dose, usable protein, losses and processing burden. A cross-functional stage-gate process should force each assumption into an auditable evidence record before the next capital commitment.

10. Conclusions

The 2026 authorisation of Rhizomucor pusillus mycelium is a substantive advance for fermentation-derived foods, but its significance lies in its precision. It identifies a strain, a manufacturing route, a compositional and safety specification, permitted food categories and a period of protected evidence. The decision confirms that a defined fungal biomass can meet European novel-food requirements; it does not establish universal safety, superior nutrition or unrestricted market access for other fungal materials.

For the industry, the larger lesson is methodological. Future competition in innovative proteins will be determined by the ability to connect fermentation biology with downstream engineering, nutritional measurement, food functionality, rigorous quality systems and jurisdiction-specific legal access. Biomass output is an intermediate metric. The commercial endpoint is a safe, lawful and reproducibly useful ingredient delivered at a defensible total cost.

References and primary sources

[1] Commission Implementing Regulation (EU) 2026/1507 of 3 July 2026. Official Journal, 6 July 2026. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32026R1507

[2] Regulation (EU) 2015/2283 on novel foods, particularly Articles 10, 12, 26 and 27. https://eur-lex.europa.eu/eli/reg/2015/2283/oj

[3] EFSA NDA Panel. Safety of Rhizomucor pusillus biomass powder as a novel food. EFSA Journal 2025;23(12):e9707. Amended 29 January 2026. DOI: 10.2903/j.efsa.2025.9707. https://doi.org/10.2903/j.efsa.2025.9707

[4] Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. https://eur-lex.europa.eu/eli/reg/2006/1924/oj

[5] Regulation (EU) No 1169/2011 on the provision of food information to consumers. https://eur-lex.europa.eu/eli/reg/2011/1169/oj

[6] UK Advisory Committee on Novel Foods and Processes. Rhizomucor pusillus biomass (FERMOTEIN®): Further information paper, application RP1215. Published 2 February 2026. https://www.gov.uk/government/publications/175th-acnfp-meeting-11-and-12-february-2026/rhizomucor-pusillus-biomass-fermotein-further-information-paper

[7] Food Standards Australia New Zealand. Application A1366: Rhizomucor pusillus mycelium as a novel food. Published 13 October 2026. https://www.foodstandards.gov.au/food-standards-code/applications/a1366-rhizomucor-pusillus-mycelium-novel-food

[8] Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. https://eur-lex.europa.eu/eli/reg_impl/2017/2470/oj

[9] EFTA. EEA-Lex factsheet on Regulation (EU) 2026/1507, including incorporation status in October 2026. https://www.efta.int/eea-lex/32026r1507

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