Meeting

Rhizomucor Pusillus Biomass (FERMOTEIN®) Additional information Paper

Committee Paper for Discussion - ACNFP/174/05

Advisory Committee For Novel Foods and Processes

Application for authorisation of Rhizomucor Pusillus Biomass (FERMOTEIN®) as a novel food.

Application Number - RP1215

Issue

The Committee last reviewed this application in the June 2025 meeting where members concluded that further information was needed to complete the assessment. The Committee are invited to consider the response from the applicant, alongside the information provided to date for this application and advise on whether there is sufficient evidence to reach a conclusion. If further information is required, the Committee's advice is sought to clarify any remaining assessment areas for this novel food.

Background

1. In July 2021, the FSA received the submission for *Rhizomucor pusillus* biomass (Fermotein®) from The Protein Brewery B.V. The novel food is derived from the filamentous fungus *Rhizomucor pusillus*, a filamentous wild-type fungus isolated from nature. It is proposed to be used as a protein and dietary fibre ingredient in a range of products for the general population.

2. Following the initial review of the application at the February 2025 meeting, data gaps were raised on identity, production process, ADME, toxicology and

allergenicity. The applicant’s response was assessed by the Committee at the June 2025 meeting, resulting in a further request for information being communicated to the applicant on the production process, composition, specification, ADME and nutrition.

3. The Secretariat reviewed the response received in August 2025 and issued a subsequent request for information requesting further detail on several of the responses. The Committee is asked whether the applicants responses address the outstanding questions, providing a basis to reach conclusion on the safety of the novel food.

4. A draft Committee Advice Document (CAD) was presented to Members in the February 2025 meeting and initial amendments were raised. This is provided to Members as Annex A as background to the dossier and includes original amendments. Review of this document is not expected on this occasion. The draft CAD will be updated following the outcome of the November review.

5. The FSA’s requests for further information are included as Annex B, and the applicant’s responses are included as Annex C. Annex C includes the response to the ACNFP request for information and the subsequent RFI from the Secretariat. The updated dossier, annexes and supporting documentation are included in Annex D.

6. The Secretariat has indicated below the key areas where additional review from the Committee would be most beneficial. Specific questions where the Secretariat would welcome Member’s views are provided in the relevant sections.

Applicant response to request for information

Production

7. The Committee advised that additional information was required regarding the integrity of the strain identity and the maintenance of genetic stability. The applicant clarified that annual random testing is conducted through sequencing to validate strain identity and genetic stability during storage. The phenotype of the fungus is also monitored through microscopic analysis at regular intervals during fermentation. When the specifications of the novel food are not met, the product is not released.

8. A further request was made to the applicant requesting the associated sequencing data, a comprehensive interpretation of the results and detail of the

methods utilised. This is discussed in the response provided (Annex C - October 2025, pages 1-3). Further detail of the observable traits and the parameters the phenotypic analysis conforms to is provided in Annex C - October 2025, page 4.

9. The Committee advised further detail be requested how potential risks associated with pathogens and spoilage microorganisms are managed and the effectiveness of heat treatment steps. The applicant has clarified that there is a clear segregation between pre- and post-pasteurisation and additional process controls, the full response can be found in Annex C – August 2025, page 1-2.

10. A further request was made to the applicant to clarify which microbes are tested as part of the control, and how potential contaminating microbes are managed both pre- and post – pasteurisation. The applicant has provided further clarification of the controls, which can be found detailed in Annex C - October 2025, pages 5-8.

Questions for Members

- What further information, if any, would be needed to assess the integrity and genetic stability of the strain?
- Does the new data provided allow a conclusion on the production of the novel food to be drawn?

Composition and specification

11. Clarification was sought to understand the presence of vitamin D3 and absence of vitamin D2 in the novel food, including further clarification on the organism’s ability to synthesise vitamin D3. The applicant has clarified that the data generated demonstrated no vitamin D3 to be present in Fermotein®, stating that the levels detected were below/near the detection limit and are likely a reflection of measurement errors. The method of analysis of Vitamin D2 and D3, and the corresponding validation reports have been provided.

12. The Committee advised that justification that the level of RNA present in the novel food does not pose a health concern, including a comparison between RNA levels in the novel food with information available on the level of RNA that is associated with uric acid formation in human tissues. The full response can be found in Annex C - August 2025 – page 3-7. To comply with the additional RNA intake, the applicant has updated the food categories uses for Fermotein® (Table 2.7 - Annex C – August 2025, page 4-6).

13. A further request was communicated to the applicant to provide further detail on how RNA levels are assured at the growth stage. The applicant has provided further data to demonstrate the growth rate (Annex C - October 2025, page 8-9).

14. The applicant has clarified that the variation in the moisture present in the novel food is related to the efficiency of the drying process. The drying process has been optimised following the scale up of the production plant, and a reduction in the variation in moisture content has now been observed. (Annex C – August 2025, page 7).

15. A further request was communicated to the applicant to provide detail on the changes to the drying process to improve its efficiency. The applicant has clarified the details of the drying process and the controls applied. (Annex C - October 2025, page 10).

16. The applicant was also asked to further address the additional data provided on water activity in the August response. Specifically, details of the testing and how the monitoring of water is routinely implemented into the safety management/HACCP for the production process. Testing parameters have been provided (Annex C - October 2025, page 10).

Questions for Members

- Does the updated information on the maximum RNA content allow for a conclusion to be drawn on the safety of the novel food?
- Does the information provided on the moisture present in the novel food appropriately address the query raised, or is further information required for assessment?
- Are Members able to conclude on the impact of the composition and specification data on safety of the novel food based on the additional information provided?

Specification

17. The Committee advised that the applicant consider having specification that includes limit criteria for *Rhizomucor pucillus* cells as this application is based on those cells being inactivated. The applicant has clarified that they have a validated process to ensure the absence of viable cells and spores form the production organism. The novel food is only released if total mould <100 CFU/g and so, the applicant does not agree that specification limit criteria for *Rhizomucor pucillus* is required (Annex C – August 2025, page 8).

18. The Committee asked for further justification of the values selected for the specification of the novel food. The applicant has clarified that the specification presented are not based on a dry weight basis. The applicant states that the specification for protein was set to allow for as high as technologically possible based on the production method. For moisture, the applicant states the specification allows for an increase in moisture level during shelf life. For fibre, the applicant states the content has been analysed within the range specified across five batches. Therefore, the applicant suggests that the specification remains as previously detailed (Annex C – August 2025, page 8).

Questions for Members

- Based on the additional justifications provided by the applicant, are Members able to conclude on the specification of Fermotein®, or is further information required from the applicant to allow a conclusion to be reached?

ADME

19. The applicant has clarified that the SDS-PAGE image included in the previous response was produced using Fermotein® before and after digestion using the Infogest protocol. However, a study report has not been provided.

20. The applicant has clarified that no study report is available for the *in vitro* ileal protein digestibility study performed by Nutricontrol. The applicant has provided further detail on the data provided for protein digestibility to demonstrate that Fermotein® is not nutritionally disadvantageous (Annex C – August 2025, page 10-11).

Questions for Members

- Is the data provided for assessment adequate to allow a conclusion on the digestibility of the novel food to be reached in the absence of the full study reports. If not, the Committee is asked to advise what further data should be requested from the applicant?

Nutrition

21. The Committee had advised that to assess nutritional disadvantage, the calculated factor based on amino acid calculations should be used. The applicant has included the calculated protein content with nitrogen to protein (N:protein) conversion factor based on the amino acid calculation.

22. The Committee recommended that nutritional data was compared to current UK data. The applicant has updated the nutritional section of the dossier to include a comparison to current UK data.

Committee Action Required

- The Committee is asked whether the responses from the applicant are sufficient to reach a conclusion on the safety of this novel food.
- If not, the Committee is asked to indicate what further data is required.
- Members are also asked to indicate any points that need to be updated in the CAD for further review by the Committee.

ACNFP Secretariat

November 2025

Annexes

Annex A – Draft CAD (as background information)

Annex B – Requests for further information

Annex C – Applicants response to RFI’s

Annex D – All supporting documentation