Meeting

Rhizomucor Pusillus Biomass (FERMOTEIN®) Further information Paper

Committee Paper for Discussion - ACNFP/172/03

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 at the February 2025 meeting where members suggested 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 information 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 from The Protein Brewery B.V. The novel food is a dried fungal milled mycelium product consisting of the biomass 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, queries and data gaps were raised on identity, production process,

composition and specification, proposed uses, ADME, nutrition, toxicology and allergenicity. The Committee is asked whether the applicant's response addresses the outstanding questions, providing a basis to reach conclusions on the safety of the novel food.

3. To inform the discussion, the draft CAD discussed in February will be referred to. The requested further information and the applicant's response is in Annex A and the supporting data and updated dossier is in Annex B.

Outstanding considerations for this application

4. Identity: Following the applicant's response, the Committee is asked whether the additional data provided on genome sequencing provides reassurance that sufficient parts of the sequence were available for the bioinformatic analysis. Comments from members are sought on whether this provides sufficient information to characterise the source of the novel food?
5. Composition: The applicant was requested to consider using the nitrogen conversion factor calculated from the amino acids and use this consistently across the application. The applicant has highlighted the need for consistency with the requirements of nutrition labelling (assimilated regulation 1169/2011) which is intended to allow comparison between products by consumers. It was noted that members preferred the calculated conversion based on amino acid sequence as this provided a clearer basis for considering nutritional disadvantage.
6. Members views are sought on the impact on the assessment of maintaining use of the default factor (6.25). Comments are also sought on the applicant's justification on the approach given in the presence of non-protein nitrogen sources.
7. Is the applicant's argument on levels of RNA (4.67%-4.99%) being safe for consumption based on its degradation, the dietary fibre mitigating uric acid-related effects supported by the evidence presented? Does the information provided support the conclusion that the novel food's RNA content is of no health concern?
8. Nutrition: Queries were raised with the applicant on the interpretation of the conclusions made by the TIM report and the DIAAS report. The applicant has provided further justification for the use of the references cited to provide a basis of comparing the protein quality of the novel food to chicken.
9. The Committee is asked whether the applicants argument provides sufficient evidence to support the conclusion that novel food is a good source of protein. Members views are also sought on the relevance of the Tiny-TIM limitations on the overall quality of the assessment. Is the comparative

DIAAS data presented appropriate in this evaluation?

10. Allergenicity: Following the applicants updated bioinformatics report and the proteomics analysis, does this novel food pose a allergenicity risk? Are there additional considerations for allergenicity for the use of mycoprotein like substances in the UK population?

Queries had been raised on the mass spectrometry, which the applicant sought clarification. What impact does the new data have on the assessment?

Committee Action Required

- The Committee is asked whether the response from the applicant is 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

June 2025

Annexes

Annex A - The applicant's response to request for further information

Annex B - Supporting documents