

Rhizomucor Pusillus Biomass (FERMOTEIN®) Further information Paper

Committee Paper for Discussion - ACNFP/175/01

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 November 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 the remaining data gaps and the impact these have on the assessment.

The draft Committee Advice Document (CAD) has been updated to support the review of this novel food application. Members are asked to consider the CAD and provide comments.

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, and November 2025 meeting and the Committee advised further data be sought to support the progression of the review of this full novel food application. The applicant has responded to the latest request for information and provided additional information in the following areas:

- Production Process
- Composition and Specification
- ADME

3. 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. The updated draft Committee Advice Document (CAD) is attached as Annex A. The updated dossier and the annexes to the dossier are attached as Annexes B and C, respectively (these contain confidential information). The FSA's request for further information (RFI) and the applicant's response to the RFI are included as Annexes D and E, respectively (these also contain confidential information).

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.
- The Committee is asked what is the impact on the assessment from any data that is missing and what is needed to complete the review of the novel food.

ACNFP Secretariat

February 2026

Annexes

ACNFP-175-01-Annex A – Draft Committee Advice Document

ACNFP-175-01-Annex B – Updated dossier and references (Confidential)

ACNFP-175-01-Annex C – Updated Annexes (Confidential)

ACNFP-175-01-Annex D – Request for Information (RFI)

ACNFP-175-01-Annex E – Response to RFI

ACNFP-175-01-Annex F – EFSA safety assessment of *Rhizomucor pusillus* biomass