

Meeting

Rhizomucor Pusillus Biomass (Fermotein®) Discussion Paper

Committee Paper for Discussion - ACNFP/170/08

Advisory Committee For Novel Foods and Processes

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

Application Number - RP1215

Issue

An application has been received under the novel food authorisation process, (assimilated regulation 2015/2283 EU) for Rhizomucor pusillus biomass (Fermotein®).

The Committee is asked to advice on whether the available data provides an adequate basis for a risk assessment, and whether the novel food is safe and not nutritionally disadvantageous under the proposed use and use levels.

To support the evaluation, a draft Committee Advice Document has been prepared 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 from The Protein Brewery B.V. The novel food is a dried fungal milled mycelium product from fermentation of Rhizomucor pusillus, a filamentous wild-type fungus isolated from nature. It is proposed to be used as a protein and

dietary fibre ingredient for the general population.

2. The application dossier is attached as Annex A, the annexes to the dossier attached as Annex B and information requested ahead of the review in Annex C. All annexes contain confidential information.

3. To note, this novel food is authorised in Singapore (March 2024) for use in food categories and use levels as stated in this application and has a GRAS for use in food and beverages (USA 2021 and 2024 for the product produced from the scaled-up production process).

4. Additionally, the initial application was for two forms of Fermotein®: wet and dry. The applicant retracted the wet form and resubmitted a dossier for the dry form after the request for further information was sent out by the FSA.

5. Further to this, after EFSA made some requests for this application in parallel, the applicant requested to submit an updated version of their application to the FSA in December 2024 (Annex A). New data is highlighted in red. This consists of data sets from the initial small-scale production as well as from scale up production post Singapore authorisation. Where essential data was provided in the initial application but not the revised application, this has been added into the supporting document folder (Annex B). Whilst some documents might potentially have data/mention of the wet product, this is to be ignored. The focus of the review of the novel food as presented is for dry Fermotein® (Rhizomucor pusillus biomass).

Committee Action Required

- The Committee is asked whether the available data provide a satisfactory basis for evaluating the safety of this novel food ingredient?
- If so, the Committee is asked whether it is content to recommend approval of the novel food as an ingredient to be added to the range of foods specified?
- If not, the Committee is asked to indicate what additional data would be required?

ACNFP Secretariat

January 2025

Annexes

Annex A - Dossier and supplementary data for dossier sections.

Annex B - Supporting documents.

Annex C - Request for further information and response.