Meeting

Fusarium str. Flavolapis Discussion Paper

Committee Paper for Discussion - ACNFP/174/02

Advisory Committee For Novel Foods and Processes

Application for authorisation as a novel food for Fusarium str. Flavolapis.

Application Number - RP1637

Issue

The Committee reviewed this application for the first time at the June 2025 meeting. Members advised further information was needed to support the assessment of the novel food. The Committee are invited to consider the response from the applicant and whether this addresses the requests for information satisfactorily.

The draft Committee Advice Document (CAD) has been updated with the applicant’s response to support the review of this novel food application. Members are asked to consider the CAD, with reference to the questions below, and provide comments.

If further information is required, the Committee’s advice is sought to clarify the remaining data gaps and the impact this has on the safety assessment of the novel food.

Background

1. In July 2022, the FSA received the submission for The Fynder Group for Fy protein™. The novel food is the dried mycelium of *Fusarium* str. *flavolapis* and is intended to be used as a source of protein used in cereal bars, meat imitates,

dairy product analogues and drinks, processed fish products, and water and dairy-based desserts spoonable.

2. The Committee conducted a review of the application for the first time at the June 2025 meeting.

3. The Committee advised further data to be sought to support the progression of the review of this full novel food application. The applicant has provided additional information in the following areas:

- Identity.
- Production Process.
- Compositional information.
- Specification.
- History of Use.
- Absorption. Distribution, metabolism and excretion.
- Nutrition.
- Toxicological information.

4. The updated draft CAD is attached as Annex A. The application 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.

5. In June 2025, EFSA published their safety assessment for *Fusarium* str. *flavolapis* and concluded that the safety of the novel food could not be established. A copy of this document is provided for Members to consider as an additional source data for review (Annex F).

Outstanding considerations for this application

6. To conclude the safety assessment for the novel food under the proposed conditions of use, Members are asked to identify the remaining data gaps. The CAD has been updated with the applicant's response to the queries raised following the previous review by the Committee. Where further data is requested, Members are asked to clarify the impact of the missing data on the safety assessment.

7. The Committee is asked to review the questions raised in the CAD on the identity of the novel food, proposed use, nutritional information, and toxicological

information with respect to the information provided by the applicant. Members are then requested to consider the extent to which the applicant’s response addresses these data gaps.

8. Identity: Information was previously sought to understand whether there was a potential for mycotoxin production from *Fusarium* str. *flavolapis*. Members views are sought on to what extent the rationale described, and testing of the final product have provided reassurance that this not a risk for this novel food.

9. Proposed use: Members views are sought on the proposed uses identified by the applicant and the impact these have in the context of information on protein quality and potential exposure in consumers.

10. Toxicology: Members input is sought to identify the NOAEL for the novel food based on the 90-day oral gavage study report. The Committee is also requested to provide comments on how this information informs the margin of exposure and the assessment of the safety the novel food under the proposed conditions of use.

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to address the issues raised by the Committee at the last meeting and reach a conclusion on the novel food.
- If not, the Committee is asked to indicate what further data is required to complete the review of the novel food. Members are also requested to clarify the impact of the missing data on the assessment.

ACNFP Secretariat

November 2025

Annexes

ACNFP-174-02-Annex A – Draft Committee Advice Document.

ACNFP-174-02-Annex B – Dossier and References. [Confidential]

ACNFP-174-02-Annex C – Annexes. [Confidential]

ACNFP-174-02-Annex D – Request for Information. (RFI)

ACNFP-174-02-Annex E – Response to RFI.

ACNFP-174-02-Annex F – EFSA Safety assessment.