Meeting

Beta-Lactoglobulin Discussion Paper

Committee Paper for Discussion - ACNFP/174/03

Advisory Committee For Novel Foods and Processes

Application for authorisation as a novel food for Beta-Lactoglobulin

Application Number - RP1571

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 April 2022, the FSA received the submission from Perfect Day Foods for beta-lactoglobulin. The novel food is manufactured by microbial fermentation using a genetically modified strain of the fungus, *Trichoderma reesei*, The novel food is intended to be used in the following food categories: dairy products and analogues, edible ices, confectionary, bakery wares, salts, spices, soups, sauces,

salads and protein products, food intended for total diet replacement for weight control as defined in assimilated Commission Regulation (EC) No. 609/2013, beverages, ready-to-eat savouries and snacks, and desserts.

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.
- Proposed uses.
- Nutritional information.
- Allergenicity,

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.

Outstanding considerations for this application

5. 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.

6. The Committee is asked to review the questions raised in the CAD on the identity of the novel food, production process, compositional information, stability, proposed use, and allergenicity 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.

7. Identity: Members are asked for comments on whether the information provided demonstrates BLG in the novel food is equivalent to bovine BLG.

8. Production process: The Committee’s input is sought regarding the safety of the genetically modified organism in the novel food production process and the effectiveness of the sterile filtration process.

9. Compositional information: The applicant has provided further information concerning the variation in the arsenic and fat content of the novel food. To address concerns around the potential spray dryer malfunctions, additional batch on microbial content is also provided. Members views sought on whether this data addresses the issues raised.

10. Stability: Members are asked to comment on the updated stability data and whether this address previous concerns raised. If not, the Committee is asked to clarify the impact on the safety of the novel food.

11. Proposed use: Members views are sought on the proposed uses identified by the applicant (e.g., dairy alternative products), the safe use of the novel food by allergic consumers, and the potential nutritional disadvantage when dairy products are replaced by the novel food.

12. Allergenicity: To inform risk management, members input is sought on whether the evidence presented provides a basis to consider the allergenicity of the novel food and the novel food as equivalent.

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.
- If not, the Committee is asked to indicate what further data is required and the feedback that should be given to the applicant.

ACNFP Secretariat

November 2025

Annexes

ACNFP-174-03-Annex A – Draft Committee Advice Document

ACNFP-174-03-Annex B – Dossier and References [Confidential]

ACNFP-174-03-Annex C – Annexes [Confidential]

ACNFP-174-03-Annex D – Request for Information (RFI)

ACNFP-174-03-Annex E – Response to R**FI**