Meeting

Clostridium Tyrobutyricum (Clostridium Protein) Discussion Paper

Committee Paper for Discussion - ACNFP/173/08

Advisory Committee For Novel Foods and Processes

Application for authorisation of Clostridium Tyrobutyricum (Clostridium Protein) as a novel food

Application Number - RP1920

Issue

An application has been received under the novel food authorisation process (assimilated Regulation (EU) 2015/2283) for a powdered protein ingredient: heat inactivated, dried and purified non-viable cells of *Clostridium tyrobutyricum* (trade name "*Clostridium* protein") as a new novel food for the GB market. The Committee is asked to advise 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 uses.

Background

1. On 9 February 2023, the Food Standards Agency (FSA) and the Food Standards Scotland (FSS) received the submission for *Clostridium tyrobutyricum* (*Clostridium* protein) from Superbrewed Food, Inc.
2. The novel food consists of non-viable heat-treated and dried cells of the non-spore-forming anaerobic rod-shaped, gram-positive, butyric acid producing bacteria *Clostridium tyrobutyricum* (ASM#19) containing ≥80 g/100 of protein. The strain has been generated without genetic modification. The novel food is produced by anaerobic precision fermentation resulting in an

off-white powder.

3. The novel food is proposed to be used as an alternative or supplementary protein source and as an ingredient added to conventional foods and beverages. This applicant has stated that it is not intended to fully replace all protein sources in the diet and is restricted from use in infant formula or follow-on formula and will not be marketed for infants or young children.
4. An EU and UK authorisation for a related strain of the same genus, *Clostridium butyricum* CBM588 (C. butyricum MIYAIRI 588 ®) by a separate applicant, was authorised as a novel food in food supplements under commission implementing decision of 11th December 2014. At EU level, *C. butyricum* TO- A received a positive opinion by EFSA in May 2025 which was considered by ACNFP in September 2023 under RP1396, which was later withdrawn.
5. While *Clostridium butyricum* has not received qualified presumption of safety (QPS) status, *Clostridium tyrobutyricum* was considered by EFSA's Panel on Biological Hazards (BIOHAZ) in its 2024 update and has received QPS status for microbes intentionally added to foods.
6. To support the initial ACNFP meeting review of this new application, initial review was sought from Members by correspondence relating to the microbiological aspects of the application. Thank you to those Members for their initial review. An RFI letter was subsequently submitted to the applicant and the corresponding March and April 2025 responses received from the applicant are attached (Annex A - FSA's requests for further information and Annex B - applicant's responses). All prior RFIs and applicant responses are included in these annexes.
7. The draft CAD is attached as Annex C. The application dossier is attached as Annex D. The annexes to the dossier are attached as Annex E. All annexes contain confidential information.

Committee Action Required

- The Committee is asked whether the available data provide a satisfactory basis for evaluating the safety of the novel food under the proposed uses.
- If so, the Committee is asked whether it is content to recommend approval of the novel food as a protein 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

September 2025

Annexes

Annex A - FSA’s requests for further information [confidential]

Annex B - Applicant’s RFI responses [confidential]

Annex C – Draft Committee Advice Document [confidential]

Annex D – Application Dossier [confidential]

Annex E – Annexes and supporting files [confidential]