Cetylated Fatty Acids Discussion Paper 155

Committee Paper for Discussion - ACNFP/155/04

Advisory Committee for Novel Foods and Processes

Application for Authorisation as a Novel Food for Cetylated Fatty Acids.

Draft Summary Opinion for Review - Application number 200

Issue

1. The Committee reviewed this application for the first time at the November 2021 meeting and the response to the request for further information in June 2022. Following this assessment, Members had no further questions, and requested that the Secretariat draft a summary opinion for cetylated fatty acids as a novel food. This was presented to the Committee at the September 2022 meeting for consideration. Following comments from Members, the Committee is invited to consider the revised draft summary opinion for this novel food.

Background

- 2. On the 7th March 2021, the FSA received the submission for Cetylated Fatty Acids from Pharmaneutra S.p.a by Intertek Scientific and Regulatory Consultancy Services. The Cetylated Fatty Acids are produced by reacting cetyl alcohol with myristic acid and oleic acid. The resulting esters (cetylated fatty acids) are then mixed with olive oil. This finished product is intended to be used as an ingredient in food supplements.
- 3. The Committee reviewed the dossier at the ACNFP meeting on 24th November 2021, where they identified areas requiring further information to assess the safety of the novel food and its proposed use. Information was requested on the

- Production Process
- ADME
- 4. The applicant provided a response to the Committee on these areas which Members reviewed at the June 2022 meeting. Following the assessment by the Committee, no further information was sought from the applicant.
- 5. The Committee formally requested that the ACNFP Secretariat draft a summary opinion for cetylated fatty acids as a novel food. This paper was presented to the Committee at the September 2022 meeting for review.
- 6. Following comments from Members, the draft summary opinion for this novel food has been revised. This paper can be found in **Annex A.**

Committee Action Required

• The Committee is asked to review the draft summary opinion for this novel food. The Secretariat are seeking comments on the content and level of detail in the paper from the Committee Members.

ACNFP Secretariat October 2022

Annexes

Annex A - Revised Draft Opinion for Cetylated Fatty Acids as a novel food