Meeting

Cetylated Fatty Acids Discussion Paper

Committee Paper for Discussion - ACNFP/153/06

Advisory Committee For Novel Foods and Processes

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

Additional Information from applicant for review – Application number 200

Issue

1. The Committee reviewed this application for the first time at the November 2021 meeting. They requested further information on which to base their assessment of the novel food ingredient. Members are invited to consider the response from the applicant and whether it addresses the requests for information satisfactorily or if further information is required.

Background

2. On the 10th February 2021, the FSA received the submission for Cetylated Fatty Acids for 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 Cetylated Fatty Acids dossier at a 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 has provided a response to the Committee on these areas and the Committee is asked whether this addresses the outstanding questions on the dossier. To inform the discussion and further development of an opinion, the FSA's requested further information (Annex A) and the applicant's response (Annex B) are provided. The applicant has also provided a revised and consolidated version of their dossier in Annex C and a copy of a confidential report concerning the ADME of cetylated fatty acids in Annex D. A draft opinion has been prepared and is provided in Annex E.

Applicant's response to request for further information

Production Process

5. The Committee requested clarification on how the zinc catalyst was removed from the reaction vessel once the esterification of the cetyl alcohol with the myristic acid and oleic acid was completed. The applicant has responded by stating that the catalyst is removed during the discolouration with bleaching earths and a filtration step.

6. The Committee sought clarification on whether the zinc catalyst introduced contaminants into the cetylated fatty acids and to what extent this was managed by the process. The applicant stated that to the best of their knowledge the zinc powder did not introduce any contaminants.

7. The Committee requested evidence from the applicant that the oleic acid does not undergo an isomerisation reaction and form trans fatty acids during the removal of water from the reaction vessel. The applicant has stated that they cannot exclude the possibility of trans fatty acids forming during this step. They further state that trans fatty acids generally form after much longer reaction times (more than 8 hours) and at higher temperatures (above 230°C) than are used in the production process.

8. The applicant also referred to the FSA Eatwell Guide (Nidirect Government Services, 2022) which states "…it's recommended that trans fats should make up no more than two per cent of the energy (calories) you get from your diet. For adults, this is no more than 5g a day". The applicant further points to the fact that

the novel food is intended for use at up to 2.1 g/day. This means the consumption of trans fat from the novel food would never be close to a reaching a level that is considered unsafe, and in reality, would be negligible.

ADME

9. The Committee requested the applicant provide further evidence on how and where in the digestive tract the cetylated esters are broken down and their fate.

10. The applicant has provided a copy of a study report [confidential] concerning the ADME of cetylated fatty acids. The applicant states that this study demonstrates that the novel food ingredient behaves in the same way as the cetyl alcohol and the fatty acids. They further state that this indicates that cetylated fatty acids would be tolerated in the same way as the cetyl alcohol and fatty acids.

11. The Committee noted that some fat-based foods are not well tolerated in humans. They requested that the applicant comment on the digestibility of cetylated fatty acids and whether they were any risks to consumers.

12. The applicant refers to the FSA Eatwell Guide (FSA, 2020) which states that adult men and women should eat less than 30g and 20g of saturated fat per day, respectively. Since the cetylated fatty acids are intended to be used up to a maximum of 2.1 g/day, the applicant believes that there is no reason for tolerability to be a concern.

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to address its concerns in regard to the issues discussed at the last meeting.
- If so, the Committee is asked, whether it is content to recommend approval of Cetylated Fatty Acids produced by Pharmaneutra S.p.a. A draft opinion is provided for consideration at Annex E.
- If not, the Committee is asked to indicate what further data is required and the feedback that should be given to the applicant.

Annexes (Confidential)

Annex A – Request for Information

Annex B – Applicant’s Response to Request for Information

Annex C – Revised Dossier and References

Annex D – Study report on ADME of cetylated fatty acids [confidential]

Annex E – Draft Summary Paper for RP200