Meeting

Corn Protein Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/167/03

Advisory Committee For Novel Foods and Processes

Application for Authorisation as a Novel Food for Corn Protein - Additional information from Applicant for review.

Application Number RP1238

Issue

The Committee reviewed this application for the first time in February 2023. Since then, it has been considered at a number of meetings seeking to resolve outstanding
data gaps on production process, specification, ADME. Members input is sought to resolve the outstanding questions and find a way forward to complete the assessment.

Background

1. On the 6th September 2021, the FSA received the submission for corn protein as a novel food from Cargill R&D Centre. Corn protein is isolated from corn slurry which undergoes enzyme treatment, chemical processing, filtration, and drying to yield corn protein isolate (≥ 85% protein). Corn protein is intended to be used as an ingredient in a number of food products.

2. The Committee first reviewed this dossier at the 157th meeting, and subsequently at the 159th meeting, the 162nd meeting and the 164th meeting. Following discussion at the last meeting the Secretariat sought further information from the applicant in the following areas:

- Production Process
- Specification
- Absorption, Distribution, Metabolism and Excretion

3. To inform the discussion and further development of a Committee Advice Document (CAD), the FSA's last request for further information (Annex A) and the applicant's response (Annex B) are provided. Also provided it the draft CAD (Annex C) as further background on the novel food. Comments are not being sought on this document at this stage.

4. The Secretariat requested support from FSA exposure assessment experts to conduct an internal review of the estimated intake levels for corn protein provided by the applicant. Currently, the applicant has proposed that the novel food will only replace protein isolates in the diet. According to EFSA (2017), these foods currently represent 18% of the total daily protein intake.

5. The critical review conducted by FSA colleagues using traditional methods for determining estimated intake levels in novel food applications indicates that the exposure of corn protein in all consumers is significantly higher compared to the data reported by the applicant. This raises questions on whether the estimate in the application is realistic, and if not, has implications for the interpretation of the data and risk characterisation of the areas highlighted below. Members are asked to review this feedback and consider further issues arising from this new information (Annex D).

Outstanding points for the assessment

Production Process

6. The Committee requested further information on the mycotoxin reduction factors, with specific reference to how they are utilised in the novel food production process.

7. Members are asked to review the worked example provided and consider whether this is sufficient to demonstrate the use of the reduction factors, including the process by which raw material is excluded from the production process (Annex B: p1 – 2 RFI letter).

8. The Committee requested a more detailed explanation concerning the control of microbial growth during the production process.

9. The applicant has highlighted the steps in the production process that are not favourable to microbial growth and referred to the maximum limits specified for the microbiological criteria of the novel food (Annex B: p2 RFI letter).

10. On this basis, are Members content that the management of microbial growth and the potential for mycotoxin production has been address adequately for the assessment to be completed.

Specification

11. The Committee requested clarification on the statement that the specified moisture content of corn protein is related to low water activity.

12. Data for loss on drying and water activity in five batches of the novel food has been provided. The response indicates that although the water activity does not exceed 0.25, there is no apparent relationship between these two parameters. A maximum specified limit for water activity is suggested by the applicant.

13. Members are asked whether the information provided is sufficient (Annex B: p2 – 3 RFI letter; Annex B: References).

Absorption, Distribution, Metabolism and Excretion

14. The Committee sought evidence to demonstrate that the in vitro digestion method (Garcia-Campayo et al., 2018) used to determine the Digestible Indispensable Amino Acid Score (DIAAS) for corn protein had been validated. Members were seeking this information because the analytical methodology used by the applicant is not an internationally recognised method for determining protein quality. As such this impacts the interpretation of the evidence to reach a view on whether the product is nutritionally disadvantageous.

15. The response provided lists further references as the basis for the methods validation. Previously, the applicant provided scores for the other protein reference materials using their method and compared this data with literature values produced using classical methods for generating a DIAAS value.

16. The Committee is asked whether the response provided by the applicant is sufficient to demonstrate that the Garcia-Campayo et al. (2018) methodology can provide information that supports assessment of the quality of the protein and

therefore the potential for nutritional disadvantage (Annex B: p4 – 6 RFI letter; Annex B: References).

Questions for the Committee

17. The FSA exposure assessment reports that the estimated intake of corn protein is significantly higher than the current levels proposed by the applicant. Considering this new information, and the applicant's reported DIAAS value for corn protein, Members are asked to consider the impact this has on the overall assessment with reference to the following questions (Annex D: Question 1):

- Can the Committee reach a consensus view on whether the novel food is nutritionally disadvantageous?
- If Members consider that the novel food is nutritionally disadvantageous, would managing the intended uses of the novel food permit a positive opinion for the novel food to be reached?

18. Considering the further information on the FSA exposure estimates, the Secretariat have reviewed again the potential exposure to some mycotoxins. This suggests that the level of fumonisins could exceed the tolerable daily intake (EFSA, 2018) for these mycotoxins in some consumer sub-populations. Members are asked to consider:

- Is there is a cause for concern from mycotoxin exposure in consumers of the novel food, based on the FSA's estimated intake assessment (Annex D: Question 2).
- What implications would this have for the overall assessment of the novel food?

19. In light of the new data and in order to complete the assessment of the novel food members are asked. Has the Committee any further comments on the information needed to complete the assessment of this novel food?

ACNFP Secretariat
June 2024

Annexes

Annex A – Request for Information
Annex B – Applicant's Response to RFI letter

Annex C – Draft Committee Advice Document
Annex D – Exposure assessment