Meeting

Corn Protein Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/162/04

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 at the February 2023 meeting where members advised further information be requested. The Committee is invited to consider the response from the applicant and whether it addresses the request for clarification satisfactorily or if further information is required.

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 chemical processing, filtration, and drying to yield corn protein concentrate (≥ 65% protein). Enzyme treatment prior to the chemical processing steps yields a 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 again at the 159th meeting. Further information was sought from the applicant in the following areas:

- **Production Process**

- **Specification**
- **Absorption, Distribution, Metabolism and Excretion**

3. The Committee is asked whether the applicant's response addresses the outstanding questions from their request for information. 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.

Applicant's response to request for further information

Production Process

4. The Committee requested that the applicant clarify the meaning of the terms "wash out the mycotoxins" and "ionizable mycotoxin".

5. The applicant states that the adjusting the pH and calcium concentration increases the solubilization of some mycotoxins because their water solubility is dependent on their ionic charges. As a result of increased solubility these mycotoxins are more efficiently removed (washed out) during filtration and washing (Annex B: p1 RFI Letter).

6. The Committee highlighted the need to clarify the terms "data being collected in Orhangazi" and "validation is needed" in the HACCP plan.

7. The applicant states they have established "mycotoxin reduction factors" for each mycotoxin to be able to estimate the expected levels in the final product based on the levels in the raw material. The applicant further states that continuous validation and refining are required, so data is collected on corresponding raw materials, intermediate streams and final product levels (Annex B: p1 RFI Letter).

Specification

8. The Committee noted that the proposed specification limit for aerobic plate count (10,000 cfu/g) was significantly higher than the values reported in the compositional analysis. Members queried whether the batches analysed were representative of the range of values expected under production conditions and sought clarification on the sources of variability during the scale up that would warrant the higher specification level.

9. The applicant states that since the source of the novel food is an agricultural crop, the microbiological load and quality varies. A significant reduction in microorganisms is observed during enzyme processing, ethanol extraction and the removal of the solvent under thermal conditions (Annex B: p1 RFI Letter).

10. Historical batch analysis indicates that for most samples, the APC 1,000 cfu/g; however, a smaller number of samples produce APC between 3,000 and 10,000 cfu/g. On this basis, the applicant states that the proposed specification limit of APC 10,000 cfu/g is achievable for most production batches (Annex B: p 1 – 2 RFI Letter).

11. The applicant remarks that the limit highlighted by the Committee (APC 5,000 cfu./g) would create a higher level of uncompliant batches with subsequent waste, without making a significant difference from a safety perspective (Annex B: p2 RFI Letter).

Absorption, Distribution, Metabolism and Excretion

12. At the 159th meeting, the applicant provided data from an *in vitro* digestibility study to support their statement that the novel food is digested in a similar way to corn. The Committee noted that the study did not follow an internationally recognised method which made the data difficult to interpret. Members requested the applicant provide further information so that the outcomes from the digestibility studies are compared to data generated using internationally recognised procedures for assessing protein digestibility.

13. The applicant has provided a summary which reports the DIAAS scores for CPC and CPI (Annex B: Annex_1_8_2_protein_digestibility_DIASS.pdf). Results from corrected *in vitro* protein digestibility values are shown below.

Table 1: DIAAS calculation based on estimated (from *in vitro/in vivo* correlation) *in vivo* protein digestibility of CPC and CPI (93%)

	Corn protein concentrate (CPC)	**Corn protein isolate (CPI)**

6 months to 3 years old	28 (lysine)	27 (lysine)
Adult	33 (lysine)	32 (lysine)

14. The applicant has provided an explanation for using the corrected *in vitro* protein digestibility values rather than the uncorrected *in vitro* protein digestibility values for determining the DIAAS scores for CPC and CPI (Annex B: Tables 3 and 4 in Annex_1_8_2_protein_digestibility_DIASS.pdf).

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to address the data gaps identifed 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

August 2023

Annexes

Annex A – Request for Information

Annex B – Applicant’s Response to RFI letter