Meeting

Corn Protein Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/159/02.

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 requested further information. 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 reviewed this dossier for the first time on the 8th February 2023 where further information was sought from the applicant in the following areas:

- Production Process
- Compositional Analysis
- Specification
- Absorption, Distribution, Metabolism and Excretion
- Nutritional Information

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. Members requested clarification on the role of hydrogen peroxide in the production process.

5. The applicant has stated that the hydrogen peroxide is a processing aid that is used to wash out ionisable mycotoxins and free sulphite. The hydrogen peroxide decreases the concentration of the sulphite by oxidation to sulphate (Annex B: p1 response to RFI letter). The applicant refers to the HACCP plan in relation to control of sulphite levels (Annex B: Annex_1_3_3_Conf_Hazards).

6. The Committee also requested confirmation that the hydrogen peroxide is suitable for the manufacture of the novel food (Annex B: p1 response to RFI letter and Annex_1_3_3_Conf_Hazards).

7. The applicant states that residues of hydrogen peroxide are monitored as part of the HACCP plan and are generally below the limit of quantification (approximately 0.00005 mg/g of corn protein. The applicant further states that any residues present would not present a safety concern.

Composition Analysis

8. Members requested that the macronutrient parameters for the novel food are presented in one table as they are currently presented in Tables 1 and 11 for corn protein concentrate and Tables 2 and 12 for corn protein isolate.

9. Updated versions of the tables showing the macronutrient parameters have been provided (Annex B: p2 response to RFI letter).

Specification

10. The Committee requested clarification on the selection of the specification limits for aerobic plate count (10,000 cfu/g) and yeast (5,000 cfu/g) and moulds (5,000 cfu/g) as these are significantly higher than those reported on the compositional analysis data.

11. The applicant has requested that the aerobic plate count remain at the current level of 10,000 cfu/g due to “significant constraints at industrial level”. Also, the applicant remarks that traditional and novel vegetable proteins offered on the market in Europe have an APC limit at 10,000 cfu/g (Annex B: p3 response to RFI letter).

12. The applicant has proposed that the level for yeasts and moulds in be reduced to ‘Yeasts and Moulds 100 cfu/g’ (Annex B: p3 response to RFI letter).

13. Members requested that the specification for the novel food should be updated with all relevant macronutrient parameters. The applicant has updated the specification sheet in response to this request (Annex B: p3 response to RFI letter).

Absorption, Distribution, Metabolism and Excretion

14. Members queried the statement that corn protein is expected to be absorbed, digested, metabolised and excreted identically to corn as no evidence was provided to support this statement in the dossier.

15. The applicant has provided two study reports to support their original statement. The first study compares the *in vitro* digestion of corn protein (76.8% protein) with other commercially available protein isolates. The applicant notes that corn protein has a similar digestion to pea protein, corn protein, canola protein and vital wheat gluten (Annex B: Annex_1_8_1 Digestibility_Corn_Protein).

16. The second study evaluates of impact of processing on digestibility by comparing the *in vitro* digestibility of CPI and corn gluten meal. The applicant states that the *in vitro* digestion of corn protein is comparable to corn gluten meal

(Annex B: Annex_1_8_1 Digestibility_Corn_Protein).

Nutritional Information

17. The Committee requested clarification concerning the reported values for lysine in Table 13. This data indicates that the quantity of lysine is roughly equivalent in corn protein concentrate (CPC) and corn protein isolate (CPI) despite the protein content of CPC reporting as 68-69% (Table 1) and CPI reporting as 89-91% (Table 2).

18. The applicant has responded by stating that the amino acids in Table 13 are presented as the amino acid profile (% of total amino acids), not % of the Novel Food (Annex B: p4 response to RFI letter).

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to clarify the concerns discussed 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 April 2023

Annexes

Annex A – Request for Information.

Annex B – Applicant’s Response to Request for Information.