Meeting

Corn Protein Further Information Discussion Paper

Committee Paper for Discussion - ACNFP/164/04

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 first reviewed this application in February 2023, and again at the April 2023 and September 2023 meetings. At the last meeting members advised further information be requested on a few outstanding aspects. 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.

In light of the previous discussion on having a Committee Advise Document (CAD) to support review, a CAD has been prepared. The Committee is also invited to consider the CAD and provide comments with a view of finalising the assessment for this novel food.

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.

3. The Committee first reviewed this dossier at the 157th meeting, the 159th meeting and the 162nd 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. 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 a CAD, the FSA’s requested further information (Annex A) and the applicant’s response (Annex B) are provided.

4. The Secretariat has also drafted a Committee Advice Document for corn protein as a novel food which can be found in Annex C. Members are asked to comment on the text and whether this represents an accurate summary of the assessment of this novel food.

5. Subsequent to receiving the applicant's response to the RFI letter, the FSA has been informed that the applicant will no longer be seeking authorisation for corn protein concentrate. This is a commercial decision based on the expected market for the product and the application going forward will focus solely on corn protein isolate. The CAD has been prepared on this basis.

Applicant’s response to request for further information

Production Process

6. The Committee requested clarification on which mycotoxins are included in the applicant statement that mycotoxins are removed more efficiently in the production process following further development of the production process. The Committee sought further information on which mycotoxins are controlled, along with a description on how the mycotoxin reduction factors are derived, and evidence of their effectiveness in estimating the mycotoxin levels in the novel food.

7. Analytical data confirmed that the level of aflatoxins, deoxynivalenol, ochratoxin A, T2 and HT2 toxins and zearalenone were below the limit quantification in five independent batches of the novel food. Fumonisins were

detected in the corn protein, up to 400 µg/kg.

8. The applicant states that the following mycotoxins are monitored: aflatoxins, deoxynivalenol, fumonisins, ochratoxin A, T2 and HT2 toxins and zearalenone. (Annex B: p1 Response to RFI Letter).

9. The applicant states that reduction factors are used to avoid processing of raw material with inadequate levels of mycotoxins, rather than estimating the levels of mycotoxins in the novel food. The mycotoxin levels of the final product are directly related to the mycotoxin levels of the raw materials (Annex B: p1 Response to RFI Letter).

10. The reduction factors have been determined for each mycotoxin and are derived from analyses of mycotoxin levels in raw materials and corresponding final products. These reductions factors and are expressed as the ratio of mycotoxin level in final product and mycotoxin level in raw material. Earlier established reduction factors are continuously validated with fresh process data and when necessary further fine-tuned (Annex B: p1 Response to RFI Letter).

Specification

At previous meetings, Committee members queried the Aerobic Plate Count (APC) set in the specification given that the novel food batch data reported significantly lower levels: 10, 50, 80, 110 and 3,700 CFU/g. In previous responses, the applicant had indicated that level of microbial contamination in the starting materials was variable. The applicant explained that realistic distribution of outcomes show that if the majority of the production samples (86.1%) is under 1,000 CFU/g, there will still be a number of samples are between 3,000 and 10,000 CFU/g (± 8.7%). In this condition, a limit of 10,000 CFU/g can be considered as reachable for most of the production lots, avoiding waste.

11. In light of this data, the Committee requested an explanation for the variation in the moisture content parameter and whether this was linked to the variation in levels of microbial growth.

12. The applicant states that they do not observe a correlation between moisture content and APC. Further, a moisture content of less than 12% is related to a low water activity that does not allow any microbial growth (Annex B: p1 – 2 Response to RFI Letter).

13. Given the applicant’s response, the Committee is asked to reach a consensus on the microbiological specifications of the novel food and how this supports the safety of the novel food.

14. The Committee sought clarification on whether the control of pH was linked to the safety of the product, and subsequently should be a measure in the final product specification.

15. The applicant remarked that the pH changes are not linked to microbiological safety of the novel food, but are used to optimise the amylase activity at pH 5.5, and improve the extraction of fumonisins at pH 6.5 to 7.0 (Annex B: p2 Response to RFI Letter).

16. The applicant states that the variation in pH are not expected to have an impact on the measured APC in the novel food (Annex B: p2 Response to RFI Letter). No specific food safety impact is linked to the management of pH in the novel food production.

Absorption, Distribution, Metabolism and Excretion

17. The Committee requested that the applicant provide a table comparing the novel food and the reference standards analysed during the *in vitro* digestion assay (whey protein, pea protein, vital wheat gluten, canola protein and rice protein) to the Digestibility Indispensable Amino Acid Score (DIAAS) values for the reference standards available from the literature. This information was sought to inform the assessment of the novel food for potential nutritional disadvantage.

18. The applicant identified several published papers that report DIAAS values for the reference standards. These values were compared to the results generated by the applicant using the *in vitro* digestion assay (Annex B: Table, p3 Response to RFI Letter). This table is reproduced below.

Table 1. DIAAS for different reference proteins, based on the 0.5-3 years (FAO 2013)

Protein source	Ref 1	Ref 2	Ref 3	Ref 4	Ref 5	Applicant data

Wheat		48 (Lys)	39 (Lys)	40	40	28 (Lys)
Pea		70 (Met+Cys)	66 (Met+Cys)	100	65	72 (Met+Cys)
Canola		72 (Lys)			70	
Whey		85 (His)	90 (His)			
Rice		47 (Lys)	52 (Lys)	64		67 (Met+Cys)
Corn	38 (Lys)	36 (Lys)	38 (Lys)	42	42	
Corn Feed	45 (Lys)					
Corn Gluten Meal	25 (Lys)					
Novel food						27 (Lys)

Lys = lysine; Met = methionine; Cys = cysteine; His = histidine;

Ref 1: CVB Feed Table 2018 (www.cvbdiervoeding.nl)

Ref 2: Herreman et al. (2020) – average of several datasets

Ref 3: Hertzler et al. (2020)

Ref 4: Van der Heijden et al. (2023)

Ref 5: Ertl et al. (2016) – value reported for canola cake

Applicant data – submitted in response to previous ACNFP request for information – reviewed at 162nd meeting [18th September 2023]

19. The Committee is asked to consider whether this information influences their views on the nutritional impact of corn protein in consumers of the novel food.

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to address the data gaps identified 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.
- The Committee is asked to review the Committee Advice Document for this novel food and comment on whether this accurately reflects the conclusions of the assessment.

ACNFP Secretariat

February 2024

Annexes

Annex A – Request for Information

Annex B – Applicant’s Response to RFI letter

Annex C – Draft Committee Advice Document