Meeting

Krill Protein Hydrolysate – Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/168/04

Advisory Committee For Novel Foods and Processes

Application for Authorisation as a Novel Food for Krill Protein Hydrolysate - Additional Information from Applicant for Review.

Application Number RP1290

Issue

The Committee reviewed this application for the first time at the February 2023 meeting. Members requested further information on which to base their assessment of the novel food. The Committee are invited to consider the response from the applicant and whether it addresses the requests for information satisfactorily or if further information is required.

Members have also been provided with a draft Committee Advice Document with the aim of completing the assessment if the further information from the applicant is sufficient.

Background

1. On the 30th September 2021, the FSA received the submission for Krill Protein Hydrolysate from Aker BioMarine. The novel food is made by a proprietary and confidential method of manufacturing krill meal (full fat and defatted) via physical processes and the addition of ethanol for extraction of fats for the defatted version of the krill meal. The hydrolysis of the krill meal uses food-grade

proteases, forming the hydrolysate final product. The applicant proposes to use the novel food as an alternative source to plant and animal-based protein in food supplements only.

2. The Committee conducted a preliminary review of the application at the February 2023 meeting and asked to perform a deeper assessment of the dossier as part of the June 2023 meeting.

3. Following these reviews, the Committee suggested additional information was needed from the applicant on which to base their assessment. Information was requested on:

- Identity
- Production Process
- Composition and Specification
- Proposed uses
- ADME and Toxicology

4. The FSA's request for further information and the applicant's response are included as Annexes A and B, respectively. The most recent version of the dossier and annexes can be found in Annexes C and D respectively. All the annexes contain confidential information. Also provided is the draft CAD (Annex E) as further background on the novel food. Comments are being sought on this document at this stage.

Applicants response to request for further information

Identification

5. The Committee queried whether the use of the term 'animal alternative' in the dossier and whether this reflected the nature of the product as a substance derived from crustaceans. The Committee noted the potential for this to influence allergenicity risks. It was highlighted that risk managers may wish to consider if the term 'alternative' may be deemed misleading to consumers. Further information was sought to understand both the nature of the product and its use.

6. The response explained that the product is a protein hydrolysate; and will present a protein source in foods – similar to rapeseed protein, soy protein isolates and other non-meat proteins utilised in the UK.

Production Process

7. The Committee suggested a detailed description of the food safety management plan (HACCP plan) was needed. This was to ensure potential allergenic, biological, chemical and/or physical hazards in the manufacturing process had been considered and managed. Reassurance was sought on the effectiveness of the management steps put in place.

8. The applicant has responded to this request by providing supplied: updated hazard risk assessment; A Hazard Analysis and Critical Control Points (HACCP) plan for the Applicant's factory in Norway (Annex K [Confidential]). In addition, the applicant has provided further information on potential impurities in the manufacturing process (Annex B – p1-2 Applicant's response to RFI).

9. In light of the applicant's response the committee is asked:

- Does the provided HACCP plan provide a clearer picture of the temperature controls that are in place?
- Does the updated HACCP plan provide evidence to reassure assessors that consistent end product would be produced from the process and controls identified by the applicant?
- Are there additional parameters that should be included in the specification to ensure appropriate controls are in place and used consistently by any company making use of the authorisation for the novel food if marketed.

Composition

10. The Committee queried whether the presence of ash in the final product would be safe for consumers at the levels stated and whether the applicant had plans to mitigate the levels of ash further.

11. The applicant has responded by stating that ash is the inorganic residue remaining after the water and organic matter have been removed by heating in the presence of oxidizing agents, providing a measure of the total amount of minerals within a food product. To assess the safety of this component of the novel food, the estimated dietary intake of all minerals and inorganics for the novel food have been assessed in the application dossier, in Section 2.h.3, (Nutritional information – Minerals and Inorganics). The levels of all minerals are below the respective Upper intake Levels (ULs). As such, the novel food is not considered to pose a safety concern. Further, most batches have ash levels under

4% (see Table 2.c.1.1-1 of the application dossier), which is similar to the levels established in the specifications for other authorised novel foods in the United Kingdom.

12. The applicant has also provided the mineral content (and thereby ash content) as influenced by the source material (krill meal and the production process steps [pH regulators]). As described in the application dossier, and the updated HACCP plan (Annex B – p3 Applicant's response to RFI).

13. The Committee had suggested that more detailed compositional data for the novel food was required. This was to allow comparisons to be made between the novel food and test items used in the toxicological assessment. The applicant responded by providing additional compositional analyses in Annex C and D of the 'applicant's response to the RFI'. The applicant has also provided further information regarding batch-to-batch variation and provided information for 15 batches of the novel food.

Stability

14. The Committee advised further clarification was needed on the information provided for the stability testing. It was noted that the analyses provided for salt and fluorine levels contained data discrepancies and data gaps. With particular emphasis on the fluorine analyses which were found to be at the maximum of the proposed specification.

15. The applicant response explained that typically certain elements, including salts and fluorine, are present in the final ingredient at release and therefore limits are set as part of the product specification. The applicant discussed that as elements are known to be stable in a final food matrix and do not change or degrade during storage, these parameters were not measured in the stability study.

16. The applicant also acknowledged the maximum fluorine levels and explained that the specification limit of 25 mg/kg for fluoride was set to reflect the batch data and was set on the basis of a thorough, and conservative, safety evaluation of fluoride intake following Krill Protein Hydrolysate consumption (see Section 2.h.3 of the application dossier). On this basis, even if the fluoride were to be present at the specification level (2.5 times higher than typical values), the estimated daily intakes of fluoride would be well below the UL for all age groups at the estimated high-level intake.

17. The Committee also queried the variation in enterococci levels observed within the stability. The applicant was requested to justify the presence of enterococci in the provided stability samples and provide additional reasoning as to why there was a notable variation in the levels of enterococci present within the samples.

18. The applicant response explained that the 12-month stability report provided in the original application, clearly stated the relatively high enterococci count at the earlier time points of the stability study were likely due to misinterpretation by the laboratory.

19. Since this time, the laboratory has updated its procedures, and levels at 12 and 24 months have been low (Annex F [Confidential and Proprietary]). As discussed in the stability report, the sample material is inherently not likely to support microbial proliferation whereby the levels of all other parameters were either non-detectable or considerably lower than the specification limits.

20. An additional stability study has been started, and the 12-month interim report is enclosed (Annex F [Confidential and Proprietary]). Enterococcus has not been analysed in this study; however, in a similar manner to the study above, the levels of other microbiological parameters confirm the microbiological stability, with levels far below the specification limits established, as would be expected in a dry material.

21. The applicant explained that Enterococci will be measured at the next timepoint (t=18 months) to confirm the stability for this parameter. The applicant also stated that Enterococci can be added to the periodic testing regime to ensure consistent absence at release and that Krill Protein Hydrolysate is a dry powder that does not inherently support microbial growth.

Proposed uses and anticipated intake

22. The Committee queried the rationale for the proposed labelling of the product, and the nature of the risks that the applicant was seeking to manage in order to ensure these were appropriately assessed.

23. The applicant response explained that the proposed labelling not to consume multiple sources of the novel food was to be consistent with other authorised novels food. The concern they were addressing was one of the potential for cumulative exposure from food and food supplement sources, as this would result in the potential for very high (~70 g) intake of the novel food. They viewed that

the risk for such cumulative consumption to be very low. The main contributor among foods is powdered beverage bases as well as functional drinks.

24. The Committee also raised concerns over the wide range of proposed uses where a crustacean based food would not normally be expected and whether this represented a risk for those with allergies to crustaceans. Further information was requested on how this particular concern would be managed if the food is being used in products where crustaceans are unconventional.

25. The applicant responses explains that Krill Protein Hydrolysate is a premium ingredient and its presence in final foods will be highlighted in the labelling/presentation of the final foods. The intention is to formulate various kinds of functional protein drinks; thus, consumers will find the krill protein mineral water among other functional protein drinks. It is noted that the authorised novel ingredient “Fish peptides from "*Sardinops sagax*” is permitted in foods based on yoghurt, yoghurt drinks, fermented milk products, and powdered milk; Flavoured water, and vegetable-based drinks; Breakfast cereals; Soups, stews and soup powders. As such the proposed uses are consistent with other authorised novel foods.

26. The presence of crustaceans would be labelled to be in compliance with Annex II of assimilated Regulation (EU) 1169/2011. This would provide an additional source of information for effected consumers.

Absorption, distribution, metabolism and excretion (ADME) and Toxicology

27. To support the safety of the novel food the applicant has used a weight of evidence approach based on test materials with similar compositions to the novel food. In order to verify the validity of the weight of evidence approach, the Committee suggested a comparison be made of the composition of the novel food to the test items used in the toxicity information submitted. information was sought on the relevance of toxicological studies to review of the novel food in order to justify not providing a 90-day study on the novel food itself.

28. Members recommended that the toxicology section should explain exactly how each item of evidence submitted contributed to a conclusion regarding the safety of the novel food.

29. The applicant responded by replacing and expanding upon the original Table 2.i.6-1 (See Annex B) to provide the compositional data on a study by study (i.e., test article by test article) basis, as requested. The applicant has also reviewed the test articles in the studies included in the original Table 2.i.6-1 and concluded that several test articles were not representative of the Krill Protein Hydrolysate and/or the study endpoints did not contribute to the safety rationale. As such, those studies were removed from the dossier. A summary of the studies removed from the dossier is provided in Table 1.b-1 of Annex B – RFI Letter – Toxicology Specific.

30. Table 2.i.6.1-1 provided in Annex B and in the original novel food dossier now provides summaries of the submitted animal studies on krill protein–containing ingredients. This table has been expanded to provide information on the relevance of each test item to the novel food and the contribution of each study to the safety conclusion.

31. Based on the response from the applicant the Committee is asked:

- Is the weight of evidence approach for the subchronic toxicology considered appropriate for this novel food based on the evidence presented.
- What should be considered as the basis for the safe upper intake for the novel food.

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.
- If a conclusion can be reached, Members are asked to comment on the draft Committee Advice Document in order to ensure this reflects the assessment that has been undertaken and the conclusions reached.

ACNFP Secretariat

September 2024

Annexes

Annex A – RFI Letter

Annex B – RFI Letter – Toxicology Specific

Annex C – Applicant’s Response to RFI Letters

Annex D – Updated Technical Dossier

Annex E – Draft Committee Advice Document (CAD)