COMMITTEE PAPER FOR DISCUSSION **ACNFP/128/09**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

REFINED SHRIMP PEPTIDE CONCENTRATE MANUFACTURED FROM NORTHERN SHRIMP *(PANDALUS BOREALIS))* – DOSSIER 209

ISSUE

1. The Finnish Competent Authority (CA) has prepared comments on an application under the Novel Foods Regulation (EC) No 258/97, for the authorisation of refined shrimp peptide concentrate.
2. The Committee is asked whether it agrees with the initial opinion and whether it would like to make any further comments on this application. The Committee's advice will form the basis for the UK's formal response to the Commission.

Background

3. On 14 March 2017 the European Commission forwarded the Finnish Competent Authority's (CA) positive Initial Opinion on an application made Marealis AS under Article 4 of the Regulation, for refined shrimp peptide concentrate extracted from northern shrimp (*Pandalus borealis*) to be placed on the market. Member States have until 19 May 2017 to submit any comments and/or reasoned objections to the Finnish assessment.
4. The application dossier is attached as **Annex A**, the Finnish Initial Assessment Report is attached as **Annex B.** An addendum to the dossier has also been provided for completeness at **Annex C.** Annex A, B and C contains commercially sensitive and confidential information.

This application

5. The peptide concentrate is a powder made from parts of the shrimp that are often discarded in shellfish processing, such as the shell and head. The peptides make up over 87% of the product. Dry matter content is more than 95%, with fat and carbohydrates content each at 1%. The applicant states that the amino acid composition of the shrimp peptide concentrate has not been modified and it is equivalent to the amino acid composition of shrimp flesh. The specification is detailed in **pg. 13-23 Annex A and pg. 1-2 Annex B.**
6. The Finnish assessment requested further information on the astaxanthin content of the product. After considering the addition information the Finnish concludes that the astaxanthin content is very low, and under the detection limit of the method used and is therefore satisfied that the product does not contribute to the astaxanthin intake in the diet.

7. The proteins from the shells are extracted via an enzymatic process and the peptide mixture derived from this is refined. The end product is an off-white powder. Only shrimps are used for the production of shrimp peptide and other fish and crustaceans are removed prior to production. The CA view is that the production process complies with the good manufacturing practices. The production process is discussed **pg.24-28 Annex A and pg. 4-5 Annex B**.
8. The Finnish CA considers that the microbiological risks of the product are controlled when the product is manufactured as stated in compliance with HACCP controls.
9. In Europe shrimp shells are mainly used as aquaculture feed and have not been widely consumed. The novel food supplement is equivalent to consuming shrimps at a level of 8 to 28g per day. The novel food is to be used in food supplements at a daily dose of 1200 mg, by taking two 600mg tablets. The main purpose of taking the supplement is to have a positive effect on controlling blood pressure and the product is targeted towards this. No assessment of the efficacy of the product has been made under the novel food legislation.
10. The reverse mutation test showed no mutagenicity. Based on the sub-chronic toxicity study, the NOAEL would be 1400 mg/day in a 70 kg person with the safety factor 100 for humans. Two randomized, double-blind, placebo-controlled clinical trials were carried out; a pilot study of 68 adults and a study of 144 adults consumed the shrimp peptide concentrate of 1200 mg/day for 8 weeks. In both studies no statistically significant differences were observed between the groups with regard to nutrient intake, safety specifications analysed from blood or incidence of adverse effects. The novel food was also observed to have a lowering effect on mild or moderate hypertension. The applicant states that it has not identified any risk groups for the use of the product; however it has not been studied in children. The toxicity studies is discussed **pg. 56-65 Annex A and pg. 4-5 Annex B**.

    The applicant has suggested the risks of the product with regard to allergic reactions are minimal due to the size of the peptides. In light of the target group, allergenicity and potential interactions with medication the applicant has proposed labelling for the novel food supplement. Proposed labelling is highlighted on **pg. 13 Annex B.** The Secretariat notes that the Food Information for Consumers Regulation (1169/2011 EU) sets out requirements for the labelling of foods produced from allergens such as crustaceans in addition to specific labelling required under a novel foods authorisation.

COMMITTEE ACTION REQUIRED

11. Members are asked whether they agree with the initial opinion from the Finnish Authority and whether they wish to make any comments on the application.
12. The Committee's advice will form the basis for the UK's formal response to the opinion of the Finnish Competent Authority.

Secretariat
April 2017

Annexes attached:

Annex A	Application for the approval of refined shrimp peptide concentrate manufactured from Northern Shrimp *(Pandalus borealis)*.
Annex B	Initial Opinion of the Finnish Competent Authority.
Annex C	Addendum to the dossier.