**COMMITTEE PAPER FOR DISCUSSION** **ACNFP/130/01**

**ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES**
**EGG MEMBRANE - DOSSIER 199**

## ISSUE

1. The Danish Competent Authority (CA) has prepared an initial assessment report on an application for egg membrane for use in food supplements under the Novel Foods Regulation (EC) No 258/97.

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 7 July the European Commission forwarded the initial opinion of the Danish Veterinary and Food Administration Agency on an application made by Biova LLC under Article 4 of the Regulation for egg membrane in food supplements.

4. The Commission has requested the views of Member States on the Danish CA's initial opinion. Member States have until 4 September to submit any comments and/or reasoned objections to the Danish assessment.

5. The application dossier is attached as **Annex A,** the Danish Initial Assessment Report is attached as **Annex B**. **Annex A and B** contain protected information.

### This application

6. The application from Biova LLC is for egg membrane that is separated from eggs produced for human consumption. The membrane is subject to hydrolysis concentration and drying and will be used in food supplements in powdered form. The Danish authorities have assessed the process and do not expect that this will lead to undesirable substances being formed. An assessment of the stability was undertaken and the product was found to be stable for 48 months.

7. The composition of the product is mainly protein 88%, of which Collagen is 15%, Elastin 20% and Glycoaminoglycans 5%. The applicant proposes that consumers would consume 450mg per day of egg membrane which is the equivalent to the membranes of 8-10 eggs. They do not intend the product to

replace other foods and they expect the product to have a negligible effect on the diet.

8. The intake assessment is based on the assumption that incidental consumption will occur by consumers while consuming eggs. Consumption of eggs in a number of countries was evaluated.

9. The Danish opinion comments that a limited assessment of the toxicity has been made, consisting of an acute toxicity study, a reverse mutation assay and a micronucleus test. Neither of the genotoxicity assays suggested the novel ingredient was genotoxic. One human trial was also provided with 42 participants with arthritic type joint pain with a dose of 450mg per day for 6 weeks. Some changes in blood glucose, urea and alkaline phosphatase were seen but the applicant argues these were small in magnitude and within laboratory reference values. The Danish opinion argues that safety of the product is largely based on history of safe use for eggs.

10. The opinion explores in some detail the potential allergenicity of the product. The applicant is of the view that the processing alters the egg allergens so they are unlikely to cause reactions. This point could not be verified by the Danish competent authority but they were reassured as the product would be required to use the labelling in Regulation 1169/2011 EU.

11. The opinion notes the difficulties of assessing the potential for de novo sensitisation. The evaluation consider that as the protein of the novel ingredient is similar to those in mammalian connective tissue and the hydrolysis process used is similar to gelatine it is thought unlikely that the novel ingredient would be a significant source of de novo sensitisation.

**COMMITTEE ACTION REQUIRED**

- Members are asked whether they agree with the initial opinion from the Danish CA, and whether they wish to make any comments on the application.
- The Committee's advice will form the basis for the UK's formal response to the opinion of the Danish CA.

**Secretariat**
**July 2017**

**Annexes attached:**

**Annex A** Application dossier for the approval of egg membrane in food supplements.

**Annex B** Initial Opinion of the Danish Authority – Official Sensitive