COMMITTEE PAPER FOR DISCUSSION **ACNFP/130/02**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

CHONDROITIN SULPHATE (MYTHOCONDRO) – DOSSIER 188

ISSUE

1. The Dutch Competent Authority (CA) has prepared an initial opinion on an application under the Novel Foods Regulation (EC) No 258/97, for the authorisation of Chondroitin Sulphate Sodium.
2. The Committee is asked whether it agrees with the positive 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 16 June 2017 the European Commission forwarded the Dutch Competent Authority's (CA) positive Initial Opinion on an application made by the company Gnosis, under Article 4 of the Regulation, for Chondroitin Sulphate Sodium to be placed on the EU market. Member States have until 4 September 2017 to submit any comments and/or reasoned objections to the Dutch assessment.
4. The application dossier is attached as **Annex A**, the Dutch Initial Assessment Report is attached as **Annex B. Annex A and B** contain commercially sensitive and confidential information.

This application

5. This application from Gnosis is for the sodium salt of chondroitin sulphate, a sulphated glycosaminoglycan. When bound to protein, these glycosaminoglycans make up an essential component of human and animal tissues. Chondroitin sulphate is one of the key components of cartilage.
6. The novel ingredient is produced biosynthetically using a specific non-genetically modified strain of *Escherichia coli*. The polysaccharide is separated from the biomass and any fructose is removed. The chondroitin is purified through a series of steps, using conventional methods. Sulphate groups are added by chemical synthesis and the highly purified chondroitin sulphate (sodium salt) is dried to powder form.

7. The novel ingredient is intended to be marketed as an alternative to traditional products containing chondroitin sulphate from animal sources. The proposed daily dose is for 1.2 g in food supplements.

8. The applicant has carried out a 90-day toxicological study in rats. No statistically significant differences were found between the experimental groups and the control group in terms of weight and feed intake. However, statistically significant differences were seen in terms of blood tests and the weight of certain organs. The applicant considers that the differences have no toxicological relevance.

9. There were no concerns raised on any undesirable substances such as heavy metals. The stability testing showed that there was no visible decrease in chondroitin sulphate content or changes in the product's appearance during the two year test period.

10. The microbial specification was assessed and was found to be met consistently. There were no virulence factors, live *E. coli*, or DNA fragments from the production strain detected. Regular testing for microbial parameters will be undertaken by the applicant once in production.

11. The applicant has considered the allergenicity aspects and suggests allergenic potential would be very low. The applicant expresses that as the novel ingredient is similar in composition to existing animal-derived chondroitin sulphate, no additional allergenicity concerns are anticipated. The applicant also considers that the protein content is negligible at ≤0.5% and should not be a concern.

COMMITTEE ACTION REQUIRED

12. Members are asked whether they agree with the initial opinion from the Dutch Authority and whether they wish to make any comments on the application.

13. The Committee's advice will form the basis for the UK's formal response to the opinion of the Dutch Competent Authority.

Secretariat
July 2017

Annexes attached:

Annex A: Application for the approval of LumiVida® (Hen Egg White Lysozyme Hydrolysate.

Annex B: Initial Opinion of the Dutch Competent Authority. – Official Sensitive