COMMITTEE PAPER FOR DISCUSSION **ACNFP/129/09**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

LUMIVIDA® (HEN EGG WHITE LYSOZYME HYDROLYSATE) – DOSSIER 209

ISSUE

1. The Irish Competent Authority (CA) has prepared comments on an application under the Novel Foods Regulation (EC) No 258/97, for the authorisation of LumiVida® (Hen Egg White Lysozyme Hydrolysate).
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 31 May 2017 the European Commission forwarded the Irish Authority provided Competent Authority's (CA) positive Initial Opinion on an application made by DSM Nutritional Products Ltd under Article 4 of the Regulation, for LumiVida® a hydrolysate from hen egg white lysozyme to be placed on the market. Member States have until 28 July 2017 to submit any comments and/or reasoned objections to the Irish assessment.
4. The application dossier is attached as **Annex A**, the Irish Initial Assessment Report is attached as **Annex B.** An addendum which answers additional questions raised by Irish Competent at **Annex C.** Annex A, B and C contains commercially sensitive and confidential information.

This application

5. Lysozyme is an authorised food additive in the EU (E1190), but also occurs naturally in chicken eggs and has a significant history of consumption within the EU. However, the hydrolysate of hen egg white lysozyme is considered to be a novel food ingredient in the EU and requires authorisation under the Novel Food Regulation.

6. Hen egg white lysozyme is a non-glycosylated protein comprised of 129 amino acids The novel ingredient comprises a distinct set of peptides of varying amino acid length (primarily di- and tri-peptides) and composition, many of which are rich in tryptophan. It is produced by the hydrolysis of hen egg white lysozyme using a food grade protease (subtilisin).

7. The applicant proposes to use the novel ingredient in food supplements and as a fortification ingredient in non-alcoholic drinks and a range of low protein foods including chocolate and confectionary. The suggested purpose is

nutritional seeking to maintain a favourable tryptophan/ large neutral amino acids (LNAA) ratio which is required to achieve the purported health benefits. The target population are adolescents and adults.

8. The intake assessment of the novel ingredient is considered in some detail in the clarifications. The applicant has suggested that intake of the ingredient would be self-limiting due to the taste and high cost of the product. They suggest the level of tryptophan that consumers would be exposed to would be lower than protein based foods.

9. As the novel ingredient is a hydrolysed from of a dietary protein with a long history of use no ADME study was undertaken. There is a suggestion that the hen's egg lysozyme would be more bioavailable than other forms. Consideration has been given to any potential impacts on other pathways influence by tryptophan including melatonin and niacin systems with the applicant suggesting that evidence available suggests these would not be negatively impacted.

10. The microbial specification was assessed and was found to be met consistently. 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 epitopes are still present in the product. They recognise that the product will require labelling in line with 1169/2011 EC as an ingredient derived from egg.

COMMITTEE ACTION REQUIRED

12. Members are asked whether they agree with the initial opinion from the Irish 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 Irish Competent Authority.

Secretariat
June 2017

Annexes attached:

Annex A: Application for the approval of LumiVida® (Hen Egg White Lysozyme Hydrolysate.
Annex B: Initial Opinion of the Irish Competent Authority.
Annex C: Answers to additional questions raised by Irish Competent Authority.