COMMITTEE PAPER FOR DISCUSSION **ACNFP/130/05**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

BASIC WHEY PROTEIN ISOLATE (VITALARMOR® GF-100) - DOSSIER 202

ISSUE

1. The Irish Competent Authority (CA) has prepared an initial opinion on an application under the Novel Foods Regulation (EC) No 258/97, for the authorisation of Vitalarmor® GF-100.
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 10 July 2017 the European Commission forwarded the Irish Competent Authority's (CA) positive Initial Opinion on an application made by the company Armor Protéines S.A.S., under Article 4 of the Regulation, for Basic Whey Protein Isolate (Vitalarmor® GF-100) to be placed on the EU market. Member States have until 4 September 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. Annex A and B** contain commercially sensitive and confidential information.

This application

5. This application from Armor Protéines S.A.S is for Vitalarmor® GF-100, a specific isolate of the minor basic whey proteins, consisting mainly of lactoferrin, and lactoperoxidase.
6. The novel ingredient is intended for use in infant and follow-on formula, dietary foods for weight control (specifically meal replacement beverages), dietary foods for special medical purposes and food supplements.
7. The novel ingredient mainly consists of protein (≥90%). The protein content in Vitalarmor® GF-100 is made up primarily of lactoferrin (47%) and lactoperoxidase (26%), with the remainder (approximately 20%) made up of varying low levels of other milk proteins.
8. The novel is ingredient is produced from raw cow's milk from which the cream is separated. The specific basic whey proteins are then isolated from the skimmed milk by a series of physical separation and purification steps. The

basic whey proteins are then concentrated by ultrafiltration before being pasteurised, spray dried and packaged. The production process is similar to that used to produce whey protein isolate.

9. The appropriate microbiological procedures are put in place to ensure there is no microbiological contamination in the starting material or the product. Analysis of the novel ingredient shows an absence of yeasts and moulds, *Escherichia coli, Staphylococci, Salmonella, Listeria and Cronabacter spp.*

10. The applicant has carried out an intake using EFSA's comprehensive database, the UK's Diet and Nutrition survey of Infants and Young Children (DNSIYC) and the UK National Diet and Nutrition Survey (NDNS). The applicant states the maximum recommended intake of Vitalarmor® GF-100 from food supplements for adults is 610 mg per day, reduced to ≤58 mg/day for children less than three years of age. Consideration has also been given to the additional exposure to Iron and Beta lactoferrin from consuming the novel ingredient as part of the diet. The opinion suggests both parameters would remain within permitted levels.

11. The applicant carried out a sub chronic oral toxicity study in rats where administration did not result in any treatment-related clinical signs of toxicity. The NOAEL for the novel ingredient was established as 2,000 mg/kg body weight/day, the highest dose tested.

12. The applicant has considered the allergenicity aspects and confirms that foods containing Vitalarmor® GF-100 will be labelled as containing "milk", in line with the allergen labelling requirements set out in Regulation (EU) No 1169/2011.

COMMITTEE ACTION REQUIRED

13. 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.

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

Secretariat
July 2017

Annexes attached:

Annex A: Application for the approval of for Basic Whey protein isolate (Vitalarmor® GF-100).

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