COMMITTEE PAPER FOR DISCUSSION **ACNFP/122/XX**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

DI-CALCIUM MALATE (DCM) DOSSIER 186

ISSUE

The Irish competent authority has prepared comments on an application for Di-Calcium Malate (DCM) under the novel foods regulation (EC) No 258/97. 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

1. On 23 October the European Commission forwarded the Irish Food Safety Authority's initial opinion on an application made by Albion Laboratories Inc. under Article 4 of the Regulation, for Di-Calcium Malate (DCM). The Irish CA explains that DCM is new source of calcium and would need to be added to the list of vitamins and minerals and their forms that can be added to foods and food supplements. In order to amend this list, DCM is subject to the provisions in Directive 2002/46/EC and Regulation (EC) No 1995/2006 in which it would need to undergo safety consideration by EFSA. For this reason, and in order to avoid multiple safety assessments, the Irish CA has concluded that it would be most appropriate for the application to be forwarded to EFSA to undergo a single full assessment.
2. The Commission has requested the views of Member States on the Irish CA's initial opinion. Member States have until 21December 2015 to submit any comments and/or reasoned objections to the Irish assessment. Any comments would be forwarded to EFSA to assist with their safety assessment.
3. The application dossier is attached as **Annex A,** the Irish Initial Assessment Report is attached as **Annex B.** Annex A and B contain protected information.

This application

4. The novel food ingredient is described as a white to off powder with little scent, that is slightly soluble in water. DCM is a compound containing a calcium malate complex where calcium is bound to malic acid. The applicant states that DCM is a unique calcium malate compound rather than a mixture of calcium hydroxide and malic acid.

5. In this initial application, Albion Laboratories, Inc. proposes placing DCM on the European market to use as a direct replacement for permitted forms of calcium within the regulated food categories of PARNUTS Foods (with the exception of baby foods and infant formula), food supplements and fortified foods. The levels of addition of the novel food ingredient would be similar to other forms of calcium currently approved for use in these categories. The levels would follow those set out in the Annex of the Commission Regulation (EC) No 953/2009, Annex II 1170/2009 and Annex III 1170/2009 respectively.

6. The applicant has considered the ADME mentioning DCM will dissociate and hydrolyse into calcium and malate ions in the presence of stomach acids as it passes through the upper GI tract and will be absorbed in the small intestine. The applicant suggests that DCM has an absorption profile that will allow it to be absorbed over a longer time period than other form of calcium, resulting in improved blood levels of calcium. Unabsorbed DCM will be excreted in the faeces. ADME information for both calcium and malate are detailed in the dossier as is information on calcium homeostasis.

7. To support the toxicological assessment, the applicant has provided data for an acute toxic study (oral gavage) in rats was provided by the applicant to suggest the LD50 of 5,000 mg/kg body weight. This study had a small number of subjects n=3. No studies are provided on the sub chronic toxicity, genetic toxicity, carcinogenicity or reproductive or development toxicity for the novel ingredient. However, the current animal and human studies for both calcium and malate are detailed.

8. The applicant comments that DCM can have contaminants of lead, cadmium, maleic acid and furmaric acid as a result of contamination in the starting materials. However they note that levels of the contaminants are measured and

monitored with each batch being tested to ensure it meets the purity criteria and provide data to support this. There is also the possibility of trace levels of impurities from unreacted starting materials calcium hydroxide and malic acid.

9. The initial opinion by the Irish CA did not highlight any microbiological, toxicological or nutritional concerns with the dossier. The applicant has carried out the relevant analysis on four batches of DCM, to support this suggestion.

10. The Irish CA report that the applicant demonstrates that DCM is stable for three years when stored at ambient temperature in a sealed container. is the applicant reports that while the product was considered stable there was a reduction in the calcium content of the sample as a result of moisture gain. Based upon pH, the applicant suggested there is no chemical breakdown or further reaction of the product during the 3 years it was stored.

COMMITTEE ACTION REQUIRED

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

Secretariat

November 2015

Annexes attached:

Annex A Application for the approval of Di-Calcium Malate (DCM)

Annex B Initial Opinion of the Irish Authorities