Initial assessment of di-magnesium malate (DMM) as a novel food ingredient
Regulation (EC) No. 258/97

Name of Applicant: ALBION LABORATORIES, Inc. trading as ALBION®

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Novel Food Category: 1.2(c)

Introduction

On May 29th of 2015 the Food Safety Authority of Ireland (FSAI) accepted an application from Albion Laboratories Inc. in the USA for the authorisation of di-magnesium malate (DMM) as a novel food ingredient in accordance with Regulation (EC) No 258/97. The applicant provided scientific evidence along with an expert opinion that DMM is a unique compound (CAS No 67 1197-50-5) containing a magnesium malate complex ($Mg_2(OH)_2C_4H_4O_5$) and is not just a simple mixture of magnesium and malic acid. DMM is produced under good manufacturing practices (GMP) using malic acid and magnesium oxide as raw materials. Malic acid naturally occurs in apples and other fruits and is an authorised additive (E 296), while magnesium oxide is also an authorised additive (E 530). DMM is produced as a white to off-white powder and dissociates to malic acid and magnesium in the GI tract. Heavy metal contaminants (lead, arsenic, mercury and cadmium) as well as maleic and fumaric acid are controlled by product specifications. The possibility for microbiological contamination is also considered and the novel ingredient is subject to relevant specifications. Using mineral content and pH as indicators of chemical stability the applicant demonstrates that DMM is stable for three years when stored at ambient temperature in a sealed container.

The applicant intends to use the novel ingredient as a source of magnesium in a number of food categories including PARNUTS (foods for particular nutritional uses-with the exception of infant formula and baby foods), fortified foods and food supplements, all of which are currently regulated by separate legislative instruments; Directive 2009/39/EC, Regulation (EC) No. 1925/2006 and Directive 2002/46/EC respectively. This would represent a new source of magnesium in the various food categories but should not affect the overall intake of magnesium.

The ingredient is classified as novel by the applicant under *Article 1.2(c)* of the novel food Regulation (EC) No 258/97; "foods and food ingredients with a new or intentionally modified primary molecular structure". To assess wholesomeness, the applicant considered the novel ingredient to fall into Class 1.2 of Commission Recommendation 97/618/EC: "Pure chemicals or simple mixtures from non-GM sources; the source of the novel food has no history of food use in the Community".

Conclusion

Commission Regulation (EC) No 1170/2009 amends Directive 2002/46/EC and Regulation (EC) No 1995/2006 in regard to the list of vitamins and minerals and their forms that can be added to foods, including food supplements. Various sources of magnesium are already on this list, including magnesium malate, though di-magnesium malate is not included. Amendment of this list is subject to the provisions in Directive 2002/46/EC and Regulation (EC) No 1995/2006 in which safety consideration by the European Food Safety Authority (EFSA) is envisioned.

The Annex to Commission Regulation (EC) No 953/2009 lists the substances that may be added for specific nutritional purposes to foods for particular nutritional uses (PARNUTS). Amending this Annex can only be achieved in accordance with the provisions set out in Directive 2009/39/EC and which requires consideration of safety aspects by EFSA.

Therefore, to be authorised for the uses intended by the applicant (PARNUTS, food supplements and fortified foods), the novel food ingredient must undergo a safety assessment by EFSA in line with the specific legislation governing those food categories. For this reason, and in order to avoid multiple safety assessments, the FSAI has concluded that further assessment is required in line with *Article 6.3* of the novel food Regulation (EC) No 258/97.