Initial Assessment

Calcium-L-Methylfolate

Name of Applicant: Merck Eprova AG, Schaffhausen, Switzerland

Contact person: Dr. Albert Bär, Bioresco Ltd.

Assessing Competent Authority: Food Safety Authority of Ireland

Novel Food Classification: The applicant has categorised the novel ingredient as Class I (Pure chemicals or simple mixtures from non-GM sources)

Introduction

An application for the authorisation of the calcium salt of L-5-Methyltetrahydrofolic acid (L-5-MTHF-Ca) as a novel food ingredient under Article 4 of the Novel Food Regulation (EC) No. 258/97 was submitted to the Food Safety Authority of Ireland (FSAI) in June of 2007. The application was submitted by Bioresco Ltd. acting on behalf of Merck Eprova AG, Switzerland. The application was formally accepted by the FSAI on July 3rd, 2007.

The safety of L-5-MTHF-Ca as a source of folate in foods has already been assessed by EFSA (The EFSA Journal (2004) 135, 1-20), a copy of the report is attached. The EFSA safety assessment concluded that, on the basis of available data, there were no safety concerns relating to the use of L-5-MTHF-Ca at the upper tolerable level of 1 mg/adult person/day in foods intended for the general population, as well as in foods for particular nutritional uses (PARNUTS) and food supplements. EFSA also concluded that at this upper limit, the level of calcium contributed to the average diet (0.08mg/adult person/day) would be insignificant relative to the upper tolerable level for calcium of 2,500 mg/person/day.

At a meeting of the Standing Committee for the Food Chain and Animal Health (General Food Law Section) on February 9th, 2006, Member States were unanimously in favour of the addition of L-5-MTHF-Ca to the Annex of Directive 2001/15/EC (PARNUTS) and Annex II of Directive 2002/46/EC (Food Supplements). Respective amendments of these Directives have been published and are now in force. The primary goal of the current application is the authorisation of L-5-MTHF-Ca as a novel food ingredient under the Novel Food Regulation (EC) No. 258/97. The application specifically addresses the safety requirements of the Novel Food Regulation in relation to the inclusion of L-5-MTHF-Ca in the lists of authorised vitamins under Regulation (EC) No. 1925/2006 (Annex II) and Directive 2006/141/EC (Annex III).

Conclusion

The EFSA safety assessment of 2004 received unanimous support from Member States resulting in the inclusion of L-5-MTHF-Ca as a vitamin source that can be used in PARNUTS and food supplements. EFSA did not identify any safety concerns related to the use of L-5-MTHF-Ca in foods intended for the general population. In addition, further studies carried out on L-5-MTHF-Ca since that EFSA safety assessment have not revealed any safety concerns that would necessitate further EFSA evaluation. The upper tolerable limit of 1 mg/adult person/day set for folic acid initially by the Scientific Committee for Food in 2000 and subsequently supported by EFSA is applicable to the combined intake of folic acid and the calcium salt of L-5-MTHF. Taking all of these factors into consideration, the FSAI is satisfied that the use of L-5-MTHF-Ca as a novel food ingredient in foods intended for the general population (including foods covered by Regulation EC No. 1925/2006) does not raise any safety concerns. The use of L-5-MTHF-Ca as a novel food ingredient will be subject to the ingredient specifications as outlined. Its use as a food ingredient must have regard to any additional regulatory requirements including, for example, further assessment that may be required prior to the inclusion of L-5-MTHF-Ca in Annex III of Directive 2006/141/EC.