

Andreas Klepsch
DG SANCO
European Commission
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Belgium

22/01/2007

Dear Andreas,

On December 20th, 2006, the Food Safety Authority of Ireland (FSAI) formally accepted a novel food application from NattoPharma for authorisation of Vitamin K2 (Menaquinone-7) as novel food under Regulation EC No. 258/97, to be used in PARNUTS (Directive 2001/15/EC, Annex) and fortified foods (Regulation EC 1925/2006). This product has a history of use in food supplements prior to May of 1997 and is currently being assessed by the European Food Safety Authority (EFSA) with a view to inclusion in annex II of the food supplements Directive 2002/46/EC.

Under normal circumstances the FSAI would carry out a safety assessment on the product and forward a report to the Commission based on the information provided in the application. However, in order to avoid multiple parallel procedures, the FSAI has come to the conclusion that an additional assessment is required as per Article 6(3) of the novel food Regulation. In addition, other regulatory requirements pertaining to PARNUTS and fortified foods need to be addressed prior to the authorisation of Vitamin K2 for use within these food categories.

If I can be of any further assistance please let me know.

Regards,

Dr. Pat O'Mahony
Chief Specialist, Biotechnology FSAI

CC Nigel Baldwin
Cantox Health Sciences International