Mr. Naohiro Rokukawa
Assistant to General Manager
Sumitomo Corporation

RE: Vitamin K2 Substantial Equivalence Opinion

June 25th, 2010

Dear Naohiro Rokukawa,

I am contacting you in regard to your application for a substantial equivalence opinion made to the Food Safety Authority of Ireland (FSAI) as Competent Authority for novel food in Ireland. The request is made in accordance with *Article 3.4.* of the novel food Regulation EC No. 258/97. The novel ingredient in question is vitamin K2 from Natto Bacillus which has already received an EU novel food authorisation (Commission Decision 2009/345/EC) addressed to NattoPharma in Norway.

It is claimed in your application that the Vitamin K2 for which you are seeking a substantial equivalence opinion is identical to that authorised by Commission Decision 2009/345/EC. In support of this claim, reference is made to the 2008 annual report of NattoPharma which confirms that J-oil Mills Inc. produced the Vitamin K2 which was distributed by Sumitomo Corporation. In light of this information, and the product specification accompanying your application, the FSAI is satisfied that the Vitamin K2 produced by J-Oil Mills Inc. is substantially equivalent to that authorised by Commission Decision 2009/345/EC. This opinion relates solely to the use of Vitamin K2 under the novel food Regulation and is dependent on the current product specifications and production methods being maintained. In accordance with *Article 2* of the authorising Commission Decision, any foodstuff containing this ingredient must carry the label "Menaquinone" or "Vitamin K".

If you are satisfied with this opinion, you should notify the European Commission in accordance with *Article 5* of Regulation EC No. 258/97 before you place any foodstuff containing Vitamin K 2 on the EU market.

Commission contact details:

Mr Andreas Klepsch
European Commission
DG SANCO, Unit 6
Rue de la Loi 200
B-1049, Brussels
Belgium

Regards,

_____

Dr. Pat O'Mahony
Chief Specialist, Biotechnology