SUBSTANTIAL EQUIVALENCE OPINION

Vitamin K_2

The Food Safety Authority of Ireland (FSAI) received an application on December 21st, 2011 from Viridis Biopharma Pvt. Ltd for an opinion on the substantial equivalence of its vitamin K_2 to the same ingredient previously authorised to NattoPharma by Commission Decision 2009/345/EC. The NattoPharma vitamin K_2 is produced by fermentation with *Bacillus subtilis*, subspecies *natto* which is then extracted, purified and presented in an oil suspension. The vitamin K_2 from Viridis Biopharma is derived from fermentation with *Bacillus licheniformis* (EFSA QPS status, 2011) which is then extracted, purified and presented in an oil suspension. Commission Decision 2009/345/EC stipulates that the novel ingredient is designated as "Menaquinone" or "Vitamin K" and that menaquinone-7 (MK-7) is the primary constituent, with menaquinone-6 (MK-6) present to a smaller but undefined extent. The applicant considers the ingredient to be novel within the category of "foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae" as stipulated in *Article 1.2(d)* of the novel food Regulation EC No. 258/97.

Composition

The applicant provides HPLC chromatogram evidence that demonstrates a vitamin K_2 profile for the novel ingredient that is very similar to the authorised ingredient, with MK-7 as the primary constituent and a minor presence of MK-6. The chromatogram also demonstrates that the novel ingredient appears to contain less of the unknown impurities with shorter retention times that are more prominent in the authorised ingredient. Batch analysis demonstrates satisfactory heavy metal and microbiological profiles while protein is not detectable.

Nutritional Value and Metabolism

As the composition of vitamin K_2 from both sources is very similar, it is reasonable to assume that the nutritional value and metabolism of vitamin K_2 will also be equivalent. The novel ingredient is presented in an oil suspension (coconut oil and glycerol monostearate) which primarily accounts for the fat, carbohydrate and mineral

content, similar to the authorised ingredient which contains sunflower oil. The applicant intends to prepare three different formulations containing vitamin K_2, two of which will have alpha-tocopherol added as an antioxidant. The applicant has determined that the vitamin K_2 is stable in the different preparations under normal and accelerated conditions.

Intended Uses

The applicant intends to use the novel ingredient for the same purposes as the authorised ingredient which includes foods for particular nutritional uses (PARNUTS) and fortified foods in compliance with Regulation EC No. 1925/2006 and Directive 2001/15/EC.

Level of Undesirable Substances

Bacillus licheniformis is on the EFSA qualified presumption of safety list (EFSA QPS status, 2011) and is credited with not having any toxigenic activity. The extraction and purification process ensures a high grade oily vitamin K_2 extract with the ingredient specification and batch analysis provided by the applicant demonstrating results equivalent to those for the authorised ingredient. The applicant provides data on the levels of heavy metals and the microbiological content in the final ingredient as well as data from a number of oral toxicity studies in animals that did not identify any potential health concerns. Hexane is used in the extraction process but is not detected in the final ingredient, while the absence of protein from the final ingredient provides reassurance with respect to allergens.

Conclusions

The FSAI is satisfied from the information provided by the applicant that vitamin K_2 produced by Viridis Biopharma Pvt. Ltd is substantially equivalent to vitamin K_2 authorised for marketing to NattoPharma through Commission Decision 2009/345/EC. The Viridis Biopharma vitamin K_2 will be designated as "Menaquinone" or "Vitamin K", as stipulated in Commission Decision 2009/345/EC.