SUBSTANTIAL EQUIVALENCE OPINION

Gnosis Vitamin K_2

The Food Safety Authority of Ireland (FSAI) received an application in May of 2013 from Gnosis S.p.A. for an opinion on the substantial equivalence of its vitamin K_2 to a similar vitamin K_2 product previously authorised as a novel food by Commission Decision 2009/345/EC. Though vitamin K_2 is naturally present in several dietary sources, the Gnosis vitamin K_2 is the product of fermentation with *Bacillus subtilis* spp. *Natto* and, like the authorised comparator, it therefore falls within the scope of the novel food Regulation (EC) No 258/97. The Gnosis vitamin K_2 comprises primarily menaquinone-7 (MK-7) with minor amounts of menaquinone-6 (MK-6). The production process for the novel ingredient is similar to that for the authorised comparator and comprises a fermentation process followed by extraction and purification using standard procedures to yield a concentrated extract that is then blended with soyabean oil prior to packaging. 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 stipulates that the Gnosis vitamin K_2 is presented as an oil suspension with a similar stability profile to the authorised comparator. Similar to the authorised vitamin K_2, the Gnosis product contains vitamin K_2 (primarily MK-7 with minor amounts of MK-6) at levels $\geq$1,500 ppm (0.15%) in an oil suspension. The only compositional difference is that the authorised vitamin K_2 is presented as a sunflower oil suspension while the Gnosis vitamin K_2 is presented as a soybean oil suspension.

Nutritional value

The novel ingredient and the authorised vitamin K_2 can be considered nutritionally equivalent since both products provide a standardised amount of vitamin K_2 to the diet, while differences in the source of formulation aids do not impact on the nutritional value of the ingredient. Based on dietary exposure estimates, the vegetable

oil formulation used for this novel ingredient (like that for authorised vitamin K_2) would not make a significant nutritional contribution to overall fat intakes.

Metabolism

Since the novel ingredient and the authorised vitamin K_2 are both standardised extracts of vitamin K_2 from the fermentation of *B. subtilis* spp. *Natto* with no nutritional difference, the applicant does not expect there to be any differences in the metabolism of the two products.

Intended use

The applicant intends to market the novel ingredient at the same levels and in the same food categories as the authorised ingredient. This will include foods for particular nutritional uses (PARNUTS) and fortified foods, in accordance with the requirements of the relevant legislation including Directive 2001/15/EC and Regulation (EC) No 1925/2006.

Undesirable substances

The potential for contamination with undesirable substances is expected to be comparable for the novel ingredient and the authorised vitamin K_2 on the basis of their similar manufacturing processes and final composition. Analytical data confirm the absence of heavy metals (lead, cadmium, arsenic and mercury) at levels of toxicological concern while data on the level of microbial contaminants were satisfactory.

Conclusion

The FSAI is satisfied from the information provided by the applicant that vitamin K_2 manufactured by Gnosis S.p.A. and presented as an oil suspension is substantially equivalent to the authorised vitamin K_2 product (manufactured by NattoPharma) currently authorised for use in the EU as a source of vitamin K by Commission Decision 2009/345/EC. The vitamin K_2 manufactured by Gnosis will adhere to the stipulations of Commission Decision 2009/345/EC and will be designated as "Menaquinone" or "Vitamin K".