

SUBSTANTIAL EQUIVALENCE OPINION

Gnosis Vitamin K₂

The Food Safety Authority of Ireland (FSAI) received an application in May of 2013 from Gnosis S.p.A. in Italy for an opinion on the substantial equivalence of its vitamin K₂ (oil suspension and powder) to vitamin K₂ previously authorised as a novel food by Commission Decision 2009/345/EC. The FSAI issued a favourable opinion in August of 2013. However, the FSAI opinion was only applicable the Gnosis S.p.A. vitamin K₂ presented as an oil suspension since this is the form of the comparator vitamin K₂ that is specified in the Annex of Commission Decision 2009/345/EC.

To overcome this technical difficulty and enable Gnosis S.p.A. to market the powdered form of their novel ingredient, the company submitted a second substantial equivalence request to FSAI in January of 2014. In this request, the company compared their vitamin K₂ presented in solid form with the solid form of vitamin K₂ already on the EU market. The applicant stated that vitamin K₂ authorised by Commission Decision 2009/345/EC as an oil suspension is also present on the EU market in solid form by virtue of the novel ingredient being blended with maltodextrin. In addition, the applicant cited the synthetic vitamin K₂ authorised to Kappa Biosciences AS in March 2012 which is authorised for the EU market as an oil suspension and also in solid form at high purity (min. 92%) using food grade carriers like dextrans and gum arabic.

That vitamin K₂ (oil suspension) produced by Gnosis S.p.A. is substantially equivalent to vitamin K₂ authorised for the EU market in Commission Decision 2009/345/EC has been established by the FSAI in its opinion of August of 2013. The fact that the Gnosis vitamin K₂ will be presented in a powdered form rather than an oil suspension will not alter the ingredient in terms of its composition, nutritional value, metabolism, intended use or level of undesirable substances. Therefore, the FSAI concludes that vitamin K₂ produced by Gnosis S.p.A. and presented in powdered form is substantially equivalent to vitamin K₂ already on the EU market in powdered form. This source of vitamin K₂ will adhere to the stipulations of Commission Decision 2009/345/EC and will be designated as “Menaquinone” or “Vitamin K”.