

SUBSTANTIAL EQUIVALENCE OPINION

Sungen Bioscience Vitamin K₂

The Food Safety Authority of Ireland (FSAI) received an application in January of 2016 from Sungen Bioscience Co., Ltd of China for an opinion on the substantial equivalence of its vitamin K₂ (trade name: Natto K₂) to the same ingredient previously authorised to NattoPharma by Commission Decision 2009/345/EC. The NattoPharma vitamin K₂ is produced by fermentation with *Bacillus subtilis*, subspecies *natto* which is then extracted, purified and presented in an oil suspension. The Sungen Bioscience vitamin K₂ is also produced by fermentation with non-GM *Bacillus subtilis* natto (strain number CGMCC 8400) which has been deposited with the China General Microbiological Culture Collection Center. After completion of the fermentation process, the biomass is collected by membrane filtration and vitamin K₂ is selectively extracted from this biomass using food grade fully refined soyabean oil, which is then filtered to remove any solid impurities. To make a powder form of the Natto K₂, a food grade carrier such as dextrin is added to the oily suspension. The applicant considers Natto K₂ to be novel and fall within the category of “foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae” as set out in *Article 1.2(d)* of the novel food Regulation EC No. 258/97. Sungen vitamin K₂ is made up primarily of menaquinone-7 (MK-7), with lower levels of menaquinone-6 (MK-6) present, and will be designated as “Menaquinone” or “Vitamin K” on foods containing it. Natto K₂ is light sensitive and has a shelf life of 24 months at room temperature in a sealed container.

Composition

The applicant provides HPLC chromatogram evidence which demonstrates that MK-7 is the primary constituent, with a minor presence of MK-6. Vitamin K₂ is present in the oil suspension at $\geq 1,500 \mu\text{g/g}$ (ppm) and in the powder form at $1,000 \mu\text{g/g}$ (ppm). The carriers used are fully refined soybean oil and dextrin which make up the physical bulk of the final product. Batch analysis demonstrates satisfactory heavy metal and microbiological profiles.

Nutritional Value and Metabolism

The vitamin K₂ from both sources is identical and so it is reasonable to assume that the nutritional value and metabolism of Natto K₂ will also be equivalent to the authorised comparator. The novel ingredient is presented in an oil suspension (fully refined soybean oil) and as a powder (using a carrier such as dextrin) which primarily accounts for the non-vitamin K₂ content such as carbohydrate and fat.

Intended Uses

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

Level of Undesirable Substances

Both vitamin K₂ ingredients are produced by fermentation with *Bacillus subtilis*, which is on the EFSA qualified presumption of safety list (EFSA QPS status, 2015) and is not associated with any toxigenic activity. The extraction with fully refined soybean oil and purification process ensures a high grade oily vitamin K₂ extract. The applicant provides satisfactory data on the levels of heavy metals and the microbiological content in the final ingredient.

Conclusions

The FSAI is satisfied from the information provided that vitamin K₂ produced by Sungen Bioscience Co., Ltd. is substantially equivalent to vitamin K₂ authorised for marketing to NattoPharma through Commission Decision 2009/345/EC. The Sungen vitamin K₂ will be designated as “Menaquinone” or “Vitamin K”, as set out in Commission Decision 2009/345/EC.