



Bundesamt für  
Verbraucherschutz und  
Lebensmittelsicherheit

Federal Office for Consumer Protection and Food Safety  
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**By email**

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YOUR REFERENCE

YOUR LETTER OF 30 November 2010

REFERENCE 101-3120-30/0008 (2010)  
(please cite in your reply)

DATE 23 March 2012

**Regulation (EC) No 258/97 of the European Parliament and of the Council of  
27 January 1997 concerning novel foods and novel food ingredients**

Request to place on the market a novel food/novel food ingredient in accordance with  
Article 4(1) of the above Regulation

**'Vitamin K<sub>2</sub> (Menaquinone-7)'**

Dear Sir/Madam,

Concerning the above request I attach herewith authorisation concerning the placing on  
the market of 'Vitamin K<sub>2</sub> (Menaquinone-7)'.

You will be sent an invoice for the authorisation under separate cover.

Yours faithfully,  
pp.

Signed

Dr. Gerd Fricke

Head of Department



Federal Office for Consumer Protection and Food Safety

## **Enclosure**

### **Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients**

Authorisation to place on the market a novel food/novel food ingredient pursuant to Article 4(2) of the above-mentioned Regulation

#### **Vitamin K<sub>2</sub> (Menaquinone-7)**

Applicant: The company Kappa Bioscience AS, Oslo Innovation Center, Gaustadalléen 21, 0349 Oslo, Norway

1. On 3 December 2010, Kappa Bioscience AS, Oslo Innovation Center, Gaustadalléen 21, 0349 Oslo, Norway submitted an application to the competent authority in Germany, the *Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* [Federal Office for Consumer Protection and Food Safety] (BVL) for authorisation concerning Vitamin K<sub>2</sub> (Menaquinone-7) as a novel food/novel food ingredient. The product essentially comprises all-trans Menaquinone-7. The application also related to products derived from Vitamin K<sub>2</sub> (Menaquinone-7) to be marketed in formulations with vegetable oils or as a powder (called K2VITAL™ products).
2. On 6 October 2011, the BVL presented its initial assessment report, which was prepared on the basis of the opinion of the *Bundesinstitut für Risikobewertung* [Federal Institute for Risk Assessment] (BfR). The report concluded that Vitamin K<sub>2</sub> (Menaquinone-7) and the K2VITAL™ products derived from it met the requirements of Article 3(1) of Regulation (EC) No 258/97.
3. The European Commission forwarded the initial assessment report to the Member States on 23 November 2011.
4. Neither the European Commission nor the Member States presented reasoned objections to the marketing of Vitamin K<sub>2</sub> within a period of 60 days as specified in Article 6(4) of Regulation (EC) No 258/97.
5. It is therefore concluded on the basis of the initial assessment report that Vitamin K<sub>2</sub> (Menaquinone-7) meets the criteria of Article 3(1) of Regulation (EC) No 258/97. This applies to marketing in accordance with the conclusions of the initial assessment report, which means that:
6. Vitamin K<sub>2</sub> (Menaquinone-7) and the K2VITAL™ products derived from it must meet the specifications attached to this letter.
7. It should be noted that, notwithstanding this authorisation, the products must comply with general food legislation.
8. If Vitamin K<sub>2</sub> (Menaquinone-7) and K2VITAL™ products derived from it are used

as food additives, the requirements of Regulation (EC) No 1925/2006, in particular, must be observed. If Vitamin K<sub>2</sub> (Menaquinone-7) and K2VITAL™ products derived from it are used in dietary foods, the requirements of Regulation (EC) No 953/2009, in particular, must be observed. If Vitamin K<sub>2</sub> (Menaquinone-7) and K2VITAL™ products derived from it are used in food supplements, the requirements of Directive 2002/46/EC, in particular, must be observed.

9. I assume that you will reply to the questions raised by the Member States, in so far as you have not yet done so.
10. Kappa Bioscience AS is entitled to market Vitamin K<sub>2</sub> (Menaquinone-7) and K2VITAL™ products derived from it under the conditions laid down in this letter, which is being forwarded to the European Commission, which will send it to the Member States and publish it if appropriate.

## **Annex**

### **Specifications of Vitamin K<sub>2</sub> (Menaquinone-7)**

Chemical Name	(all-E)-2-(3,7,11,15,19,23,27-Heptamethyl-2,6,10,14,18,22,26-octacosahptaenyl)-3-methyl-1,4-naphtalenedione
CAS Number	2124-57-4
Structural formula	[See original]
Molecule formula	C <sub>46</sub> H <sub>64</sub> O <sub>2</sub>
Molecular weight	649 g/mol
Appearance	Yellow powder
Purity	Max. 6% cis-isomer, max. 2% other impurities
Content	98-102% Menaquinone-7 (including at least 92% all-trans-Menaquinone-7)