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April 27th, 2015

Application to market Vitamin K₂ as a novel food under Regulation (EC) No 258/97

Dear Dr. Vik,

I am contacting you in accordance with *Article 4.2* of the novel food Regulation (EC) No 258/97 (OJ L 43, 14.02.1997, p. 1) regarding the application by NattoPharma ASA of Norway to place vitamin K₂/Menaquinone7 (Branded as MenaQ7 Pure and MenaQ7 Advanced Products) on the EU market.

- The FSAI accepted an application by NattoPharma ASA on May 29th, 2014
- The FSAI submitted the initial assessment to the Commission on August 20th, 2014
- The initial assessment was disseminated to Member States on September 26th, 2014
- Reasoned objections were not raised within the 60 day comment period
- Clarifications were sought by the UK, Austria, Germany and Spain
- The applicant provided clarifications to the relevant Member States

As objections were not raised by Member States or the Commission in accordance with *Article 6.4* of the novel food Regulation, the novel ingredient and its intended use is deemed to meet the criteria set out in *Article 3.1* of that Regulation.

This letter gives effect to the authorisation of NattoPharma vitamin K₂ (specifications in the accompanying Annex) under the novel food Regulation (EC) No 258/97. However, this is without prejudice to general EU food legislation, or specifically to Regulation (EC) No 953/2009 (OJ L 269, 14.10.2009, p. 9) on substances that may be added to foods for particular nutritional uses, Directive 2002/46/EC (OJ L 183, 12.7.2002, P. 51) relating to food supplements and Regulation (EC) No 1925/2006 (OJ L 404, 30.12.2006, p. 26) on the addition of vitamins, minerals and certain other substances to food.

The Commission will receive a copy of this letter for publication and dissemination to Member States.

Regards,



Dr. Pat O'Mahony

Chief Specialist, Food Technology

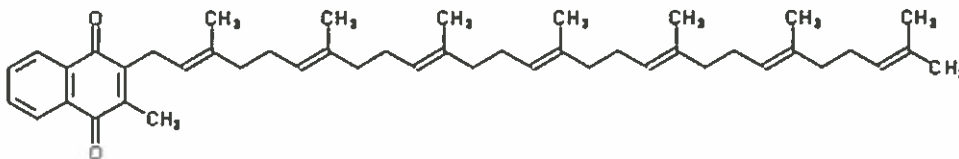
ANNEX

Specifications of Nattopharma Vitamin K₂ (Menaquinone₇)

Chemical Abstract Service (CAS) No: 2124-57-4

Molecular Formula: C₄₆H₆₄O₂

Structural Formula:



Molecular Weight: 649 g/mol

Purity: >97% Menaquinone₇

Composition: 97% - 101% all-trans Menaquinone₇

Appearance: Light yellow crystalline powder or oil