

Summary of the dossier: Menaquinone-7 dipropionate

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This is an application for authorisation to place on the market menaquinone-7 dipropionate, the chemically synthesized provitamin of menaquinone-7 (Vitamin K₂), for use as an ingredient in various foods (beverages, cereal and cereal products, dairy products, fats and oils pasta, rice and other grains and in food supplements in the European Union (EU).

The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with the European Food Safety Authority (EFSA) guidance on the preparation and presentation of an application for authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283.

Menaquinone-7 dipropionate is produced via chemical synthesis. Menaquinone-7 dipropionate is targeted to the entire population and is intended for use in foods at levels ranging between 48 µg/kg to 1090 µg/kg and up to 167 mg/kg of menaquinone-7 dipropionate in food supplements.

Menaquinone-7 dipropionate is a high purity synthetic compound that is intended to be marketed as a functional ingredient in its own right and is not intended to replace another food. As it undergoes rapid hydrolysis in the intestine to release menaquinone-7 (vitamin K₂) and propionic acid, the intakes of menaquinone-7 dipropionate are comparable to the intakes of Vitamin K₂ as they have been previously assessed by the European Food Safety Authority (EFSA) in its Scientific Opinion "Dietary reference values for Vitamin K" from 2017 (Turck D et al., 2017), Section 3, pages 30-34, and in the Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a request from the European Commission on safety of Vitamin K₂ from 2008, Section IX, pages 8-11 ("Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a request from the European Commission on the safety of Vitamin K₂," 2008).

The mean intake of vitamin K (both phylloquinone and menaquinones) is estimated by EFSA for 9 EU countries and ranges between 72 and 196 µg/day. The P95 for the highest mean intake was 531 µg/day (Turck D et al., 2017).

In 2017, EFSA did an assessment of vulnerable groups (children, pregnant and lactating women) and concluded the adequate intake for all groups to be 1 µg/kg body weight/day (Turck D et al., 2017).

Menaquinone-7 dipropionate is a new molecule and will not be present in other food sources. However, since menaquinone-7 dipropionate is completely hydrolysed to MK-7 in the intestine before it is taken up across the intestinal wall, the combined intake data can be based on the combined intake of MK-7 as evaluated by EFSA both in 2017 and 2008 ("Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a request from the European Commission on the safety of Vitamin K₂," 2008; Turck D et al., 2017).

The application is supported by an absorption, metabolism and excretion (ADME) study which demonstrates the complete hydrolysis of menaquinone-7 dipropionate in the intestine to produce vitamin K2 and the previous (2008 and 2017) EFSA evaluations of Vitamin K2.