

**Application for Vitamin K2 (Menaquinone-7,
MK-7) as a Substance Used for a Nutritive
Purpose in Food for Special Medical Purposes**

Novozymes Australia Ltd.

April | 2024

Executive Summary

Novozymes A/S seeks to expand Vitamin K2 (Menaquinone-7, or MK-7) use to the Food for Special Medical Purposes (FSMPs) in Australia and New Zealand. Vitamin K2 (MK-7) is a long-chain menaquinone, which is a form of Vitamin K. Vitamin K2 in this petition is manufactured by Novozymes A/S through production of a purified concentrate that is then diluted to the required potency in sunflower oil.

Vitamin K2 (MK-7) is permitted as a source of Vitamin K for nutritional purposes in the European Union and is Generally Recognized as Safe (GRAS) for use in nutritional beverages in the United States. Additionally, beverage products containing Vitamin K2 are on the market in many additional countries including Vietnam, Malaysia, Philippines and Singapore.

This application includes scientific evidence supporting addition of Vitamin K2 (MK-7) in FSMPs. The physical and chemical characteristics, bioavailability, metabolism, and biological activity of Vitamin K2 are well-established and described in detail. The history of consumption outlines exposure to Vitamin K2 as an inherent nutrient in traditionally consumed foods, as well as its use as a dietary and food supplement. Safety has also been established by a battery of standard *in vitro* and *in vivo* safety studies, as well as by outcomes from multiple human clinical trials. The safety of Vitamin K2 (MK-7) in these products has been assessed positively by the European Food Safety Authority (EFSA), and the United States Food and Drug Administration.

The applicant is making the Application to ensure regulatory certainty noting Section 2.9.5-6(c) of the Code allows for the addition of other permitted substances to FSMPs regardless of form; Vitamin K is permitted to be added to FSMPs by Section 29-7 in the form of Vitamin K1 as phylloquinone (phytonadione).

In summary, this application is seeking for permission the use of Vitamin K2 (MK-7) as an additional permitted form of the currently permitted Vitamin K in FSMPs via an amendment of Schedule 29-20. No amendment to mandatory composition or labelling requirements are being proposed in this application.