

Summary of the application: Allanblackia seed oil

Applicant: Unilever NV/Unilever PLC

The novel food application concerns request for authorisation for an extension of use of Allanblackia seed oil. The extension of use of Allanblackia seed oil is proposed for: 1) Mixes of vegetable oils and milk up to a maximum use level of 30% (w/w). 2) An increase in the authorised maximum use level in yellow fat spreads and cream based spreads from 20 to 30% (w/w).

Due to Allanblackia seed oil's specific fatty acid profile and the arrangement of the fatty acids on the triglyceride backbone Allanblackia seed oil is highly suitable for use as a fat that serves to structure the fat phase and helps stabilise the product to obtain the desired consistency and mouth feel for the products of interest (commonly described as 'hardstock'). Allanblackia seed oil is collected, extracted and refined using the same processes that are currently used for other edible vegetable oils and which have been evaluated in the original application.

This dossier demonstrates that the proposed use of Allanblackia seed oil in mixes of vegetable oils and milk and in yellow fat and cream based spreads as compared to their original counterparts offers a product which has a healthier nutritional profile. The original Novel Food dossier for Allanblackia seed oil presented a series of toxicology studies to confirm the safety of Allanblackia seed oil. These include genotoxicity studies and a sub-chronic feeding study in rats. Allanblackia oil was shown to be non-genotoxic in both a bacterial mutation assay and an in vitro gene mutation assay in mouse lymphoma cells. In the 13-week oral toxicity study the intake of Allanblackia seed oil was 11.3 and 14.7g/kg body weight/day for male and female rats respectively. In this subchronic rat study Allanblackia seed oil produced no adverse effects. The evaluation of all available animal and human safety data on Allanblackia seed oil leads to the conclusion that its use in yellow fat and cream based spreads and in mixes of vegetable oils and milk at a level up to 30%, Allanblackia seed oil would not be expected to produce any acute or chronic adverse effects in individuals consuming these products. Based on the results of the pivotal toxicology study from which the NOAEL (No Observed Adverse Effects Level) was derived, Allanblackia seed oil did not produce any safety issues at the dose tested. It can be concluded that the same margins of safety would be derived for other standard vegetable oils, demonstrating that Allanblackia seed oil has a comparative safety profile to other oils and fats which are currently consumed in the diet.

The present application provides the detailed intake assessment of Allanblackia seed oil for 2 countries (the United Kingdom and the Netherlands) and also for the EU using the EFSA Comprehensive database. Allanblackia seed oil intakes based on the Dutch food consumption databases are used to represent potential highest intake estimates from proposed uses. The highest calculated absolute Allanblackia seed oil intake based on the proposed uses was observed in male older adults aged 51 to 69 years, with an all-user mean intake of 8.5 g/day and an intake of 19.3 g/day at the 95th percentile. The highest calculated Allanblackia seed oil

intake in relation to body weight were observed in Dutch male toddlers (aged 2 to 3 years), with a mean intake in all-users of 0.24 g/kg body weight/day and an intake of 0.52 g/kg body weight/day at the 95th percentile. The anticipated human intakes of Allanblackia seed oil reported in this application are significantly lower (i.e., an intake of 0.52 g/kg body weight/day at the 95th percentile) than the intake at which no adverse effects were observed in relevant studies (i.e., 11.3 and 14.7 g/kg body weight/day).

The evaluation of all available animal safety data on Allanblackia seed oil leads to the conclusion that its use in yellow fat and cream based spreads and mixes of vegetable oils and milk at a level up to 30% Allanblackia seed oil would not be expected to produce any acute or chronic adverse effects in individuals consuming these products.

Allanblackia seed oil will be used as an alternative to other oils and fats which are currently consumed in fat spreads and mixes of vegetable oils and milk products. When Allanblackia seed oil is used in these products, there is a resultant impact on the fatty acid composition due to the different fatty acid profile of Allanblackia seed oil than the fats currently used in these products. In all products the total fat remains the same, however saturated fatty acids decrease and monounsaturated fatty acids increase when Allanblackia seed oil replaces hard fats in each product. Food products where part of the palm (kernel) oil, coconut oil or butter fat is replaced by Allanblackia seed oil will thus have a more beneficial fatty acid composition in relation to cardiovascular disease in comparison to the original products.