

Summary of the dossier: Tetrahydrocurcuminoids from turmeric

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This application for authorisation of a novel food in accordance with Regulation (EU) 2015/2283 concerns a creamy white to pale yellow crystalline powder, not less than 95% tetrahydrocurcuminoids (THCs) standardized extract obtained by hydrogenating the curcuminoids from the rhizomes of the *Curcuma longa* (turmeric) plant

While *Curcuma longa* rhizome and curcumin are clearly authorised in all foods and food supplements, respectively, and tetrahydrocurcumin is well known as cosmetic ingredient, THCs are not yet acknowledged as food ingredient.

This novel food is intended to be used as food supplement (as defined in Directive 2002/46/EC) at a maximum daily dose of 300 mg (corresponding to 4.3 mg/kg for a 70 kg person) intended for the adult population and excluding children (<18-year-old) and pregnant or lactating women. It is not intended to replace other foods. The production process including the extraction and purification of the THCs from turmeric, the composition and the resulting specifications are in accordance with European standard and regulations. Analyses have demonstrated the lack of various contaminants such as, heavy metals, microbiological contaminants, polychlorinated biphenyls (PCB), polyaromatic hydrocarbons (PAHs), and mycotoxins, among others.

As regards the safety of the novel food this is substantiated by a number of studies and the available scientific evidence. Genotoxicity studies (AMES, in vitro mammalian cell micronucleus tests) indicate no evidence of mutagenicity, clastogenicity and genotoxicity. In 14-day single dose oral gavage toxicity in rats the LD50 was set at 2000 mg/kg body weight/day. In both the 90-day repeated dose oral toxicity study and the reproductive/developmental toxicity study in rats the No Observed Adverse Effect level (NOAEL) was set at 400 mg/kg body weight/day. In a human safety study was shown the safety of the novel food given at 300 mg/day for 28 days in 20 healthy subjects. No adverse event was reported. In conclusion, the THCs from turmeric are well characterized and compliant with European Regulations. The novel food is safe and devoid of allergic potential. Thus, the novel food does not present any potential health risk to the European population.

The application has been prepared in accordance with the requirements of Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, 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 and EFSA's Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283.