

Summary of the dossier: (-)-trans-cannabidiol

Applicant: Cannabis Pharma, s.r.o., Masarykova 1595/54, 415 01 the Czech Republic

This is an application for authorisation to place on the market (-)-trans-cannabidiol (CBD) as a novel food in food supplements in the European Union (EU) intended for the adult population and excluding pregnant and lactating women.

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.

Cannabidiol (CBD) is to be obtained through a series of purification steps from *Cannabis sativa* L. plants. *C. sativa* is one of the first cultural crops used in many applications including food (seed oil), fibres for ropes, twines and coarse textiles and woody core for animal bedding.

Hemp seed oil has been traditionally consumed as food. It has a delicate flavour and distinctive nutty taste. It contains high concentration of poly-unsaturated fatty acids and rare omega 3 and omega 6 acids present such as gamma-linolenic and stearidonic acid, and certain phytosterols. Hemp seed and its oil is a high source of Vitamin E. Hemp seed and seed cake is a high source of vitamins and minerals: thiamin, vitamin B6, folate, iron, phosphorus, magnesium, zinc, copper and manganese.

The application contains publically available safety and toxicological information and toxicity reviews, which include acute and long terms toxicity studies in animals, and tolerance studies in humans. The overall data package as submitted aims to support the safety of cannabidiol as a novel food in food supplements for adults with a daily intake of up to 130 mg or 1.86 mg/kg body weight. As an additional precautionary measure, the food supplements containing cannabidiol will be limited to the adult population and will exclude pregnant and lactating women.