

Summary of the application: Cannabidiol isolated from *Cannabis sativa* L.

Applicant: HEMPOLAND spółka z ograniczoną odpowiedzialnością, Władysławowo 30A, 82-300 Elbląg, Poland

The aim of the application is to include purified cannabidiol (CBD) (99%) isolated from the *Cannabis sativa* L. plant in the Union list of novel foods.

CBD is one of the main cannabinoids of *Cannabis sativa* L. and occurs naturally together with other cannabinoids, including cannabidiolic acid (CBDA), cannabichromene (CBC), cannabigerol (CBG), cannabidivarin (CBDV), cannabidibutol (CBDB), delta-9-tetrahydrocannabinol (Δ^9 -THC), and tetrahydrocannabinolic acid (THCA). Despite similar chemical structures, cannabinoids can elicit very different physiological actions. In contrast to Δ^9 -THC, CBD does not manifest psychotropic or psychotoxic effects.

Some products derived from *Cannabis sativa* L. plant or plant parts such as seeds, hemp seed oil, hemp seed flour, defatted hemp seed, have a history of consumption in the EU and therefore are not novel. In contrast, CBD, as an isolated constituent has not been consumed to a significant degree in the EU or UK before 15 May 1997, when the first Regulation on novel food came into force, therefore it can be considered as novel.

HEMPOLAND's crystalline CBD is obtained from industrial hemp (*Cannabis sativa* L. *ssp. sativa*) by supercritical fluid extraction (SFE) using carbon dioxide and further purification methods. It is produced in a tightly controlled production process to ensure product quality and safety. Proposed CBD is of very high purity (99%) and therefore, may contain only trace amounts of impurities. HEMPOLAND's CBD is intended to be used as an ingredient in food supplements for adult population, excluding pregnant and breastfeeding women. A maximum daily intake of 35 mg of CBD has been proposed.

Results of stability tests confirming the stability of the novel food were submitted in the dossier. Scientific results on the safety of CBD are presented and discussed in the relevant sections of the application. The genotoxicity was assessed in accordance with OECD guideline and did not reveal any mutagenic potential. Publicly available data from acute, subchronic and chronic toxicity studies based on animal models together with data from human studies support the notion that the novel food does not pose any safety risk to human health under the proposed conditions. CBD has negligible allergenic potential.

Overall, the information presented in the application supports that the novel food ingredient is safe when used under the proposed conditions and the very low content of impurities does not raise safety concerns.