Summary of the application: trans-Cannabidiol (CBD) from *Cannabis sativa* L.

Applicant: CBDepot, 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), manufactured by a proprietary production process, using distillation and isolation of alcoholic extract of *Cannabis sativa* L. as a novel food ingredient to be used in food supplements in the European Union (EU) intended for the healthy adult population, excluding pregnant and breastfeeding women. Other labelling requirements are included in the dossier.

Isolated Cannabidiol contains 98 - 102% of 2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol. The content of controlled substances Tetrahydrocannabinols (THCs) is less 0.0020% as demonstrated by proprietary and validated analytical method applied under Good Manufacturing Practices (GMP) conditions. Maximum daily intake has been set to 20 mg for an average adult, or 0.27 mg / kg body weight.

Ingredient safety has been demonstrated by a battery of Tier 1 and Tier 2 proprietary studies which the applicant considers as newly developed scientific evidence or scientific data. 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