Public summary of the dossier: Synthetic trans-Cannabidiol

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

This is an application for authorization to place on the market *trans*-Cannabidiol (CBD) manufactured by chemical synthesis as a novel food ingredient as a substance identical to naturally occurring substance that is chemically synthesised and thus do not originate from plant material, to be used in food supplements in the European Union (EU) intended for the healthy adult population excluding pregnant and breastfeeding 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 authorization of a Novel Food in the Context of Regulation (EU) 2015/2283.

The synthetic production process is based on condensation reaction of olivetol with (1S,4R)-*p*-mentha-2,8-dien-1-ol under the catalysis of Lewis acid. The crude product is purified by repeated crystallization yielding *trans*-Cannabidiol in min 99% purity with no detectable THC.

As the manufacture of CBD by chemical synthesis yields THC as an artefact, it has to be covered by official permission for handing. CBDepot's contract manufacturer is PharmaCan, s.r.o., one of its shareholders. PharmaCan is a holder of a handling license No. 28/2017 issued on March 22, 2017, by the Ministry of Health of the Czech Republic.

According to a 40st WHO's ECDD Critical review it can be said Cannabidiol has been found to have relatively low toxicity.

Pure *trans*-Cannabidiol (whether manufactured by isolation from hemp extract or by chemical synthesis) has been used in cosmetic products in the European Union for several years. CBD was listed in the unofficial cosmetic ingredient database (CosIng) as early as 2014. First cosmetic products were notified at Cosmetic Product Notification Portal (CPNP) in 2016. Cannabidiol was officially listed in a glossary of common ingredient names for use in the labelling of cosmetic products as per COMMISSION DECISION (EU) 2019/701 of 5 April 2019 under Entry No. 4403, irrespective of its origins.

Pure *trans*-Cannabidiol (whether manufactured by isolation from hemp extract or by chemical synthesis) has been widely used in the EU and the USA in liquids for electronic cigarettes since 2014. It is also widely promoted as a pure substance in consumer packaging (usually 500mg) for various do-it-yourself preparations. As the substance itself is not under international control, such a propagation practice is indeed widespread.

Use isolated *trans*-Cannabidiol in foods and food supplements has not been documented until 2014. Its food use is widespread, however controversial, as it fulfils the definition of a Novel Food in the EU and possibly the status of New Dietary Ingredient in the USA.

The use of synthesized *trans*-Cannabidiol in foods and food supplements has not been documented yet.

Cannabidiol is an active ingredient in two authorized medicinal products in the EU. Either in a form of cannabis extract or in a form of pure compound isolated from cannabis extract. Cannabidiol is also used as an active ingredient in magistral formulas in several EU countries.

Intake of *trans*-Cannabidiol in sub-pharmacological doses positively modulates the endocannabinoid system. CBD also has prophylactic and cytoprotective effects on chronical disorders. There is clear evidence of positive immunomodulation and food intake. Intake of *trans*-Cannabidiol results in wellbeing, feeling fitness and homeostasis in general.

The applicant suggests a daily intake of *trans*-Cannabidiol of 50 mg per average adult, i.e. 0.71 mg/kg b.w.