

## Summary of the application: Cannabidiol (CBD)

Applicant: BSPG Laboratories Ltd., 3rd Floor, South Pod, Discovery Park House, Ramsgate Road, Sandwich, Kent CT13 9ND.

BSPG Laboratories Ltd. (BSPG) intends to market Cannabidiol (CBD) as a novel food ingredient in the European Union (EU). 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.

BSPG's CBD is extracted from industrial hemp (*Cannabis sativa* L.) before being purified and crystallised to produce the final ingredient, which is highly pure (minimum purity of 98%) and does not contain any detectable (0.000006% limit of detection) tetrahydrocannabinol (THC) or any other controlled cannabinoid. The production of BSPG's CBD follows Hazard Analysis Critical Control Points (HACCP) principles in a tightly controlled process. Analysis of several independent, representative batches of BSPG's CBD demonstrates that the manufacturing process produces a consistent ingredient, which meets the established specifications, and is free of contaminants.

BSPG's CBD is intended for use in food supplements for adults, excluding pregnant or lactating women. Consumption of CBD would not be nutritionally disadvantageous for consumers under the proposed conditions of use in food supplements.

BSPG commissioned toxicology studies (conducted following the methods described in OECD guidelines and according to the principles of GLP) assessing genotoxicity, subchronic toxicity, and reproductive and developmental toxicity of the novel food as it is intended to be marketed (*i.e.* the test item was manufactured according to the described production process and met the compositional characteristics and proposed specifications for BSPG's CBD). BSPG's CBD was confirmed as non-genotoxic, and was well tolerated in the subchronic and reproductive and developmental studies.

The allergenic potential of BSPG's CBD is considered to be very low, as it is composed of almost 100% CBD (*i.e.* contains negligible protein), the production process removes any proteins from the source, and there are no reports of allergenicity to CBD in any of the numerous published human studies conducted with other forms of CBD.

These data support that BSPG's CBD is safe for use under the proposed conditions.