Summary of the dossier: Cannabidiol

Applicant: Chanelle McCoy CBD LTD, Chanelle House, Barrack Street, Loughrea, Co. Galway, H62 YX07, Ireland

Chanelle McCoy CBD LTD ("Chanelle") has prepared an application for authorisation of cannabidiol (CBD) as a novel food ingredient in the European Union (EU). The application was 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.

Chanelle's CBD is a highly pure (97 to 102% purity) ingredient produced by chemical synthesis in a multi-step process under controlled conditions. The identity of the ingredient is well characterised, as demonstrated by analyses using a variety of analytical methods including infrared spectroscopy, nuclear magnetic resonance spectroscopy, mass spectrometry and ultraviolet–visible spectroscopy. Analysis of several independent, representative batches of CBD demonstrates that the manufacturing process produces a consistent ingredient, which complies with the established specifications.

CBD is intended for use in food supplements at up to 25 mg/day by adults in the general population; it is not intended for consumption by infants, young children, or pregnant or lactating women. The daily anticipated intake for a 70 kg adult at this proposed use level is equivalent to 0.36 mg/kg body weight/day. Consumption of CBD would not to be nutritionally disadvantageous for consumers under the proposed conditions of use in food supplements.

Several published toxicology studies on other forms of CBD (including CBD extracted from hemp, or hemp extracts containing CBD) should not be considered as pivotal studies for assessing the safety of Chanelle's CBD. Firstly, the test articles used in the published studies were not carried out with the novel food as it is intended to be marketed; differences in the source and composition of hemp-extracted CBD compared with Chanelle's CBD (the subject of this novel food application) may reasonably be expected to result in different biological and toxicological profiles. Secondly, the studies identified in the literature were generally not conducted in accordance with Good Laboratory Practice (GLP) or applicable international testing guidelines.

Conversely, Chanelle commissioned toxicology studies in accordance with the tiered approach to the safety assessment of food additives (described in the EFSA *Guidance for submission for food additive evaluations*), which is the also the default approach for safety assessment of novel foods. These studies were conducted using Organisation for Economic Co-operation and Development (OECD) guidelines and according to the principles of GLP, using the novel food as intended to be marketed (*i.e.* the test material was manufactured according to the described production process and met the compositional characteristics and proposed specifications for Chanelle's CBD). The results for the combination of Tier 1 and Tier 2 genotoxicity tests demonstrated that Chanelle's CBD is not an *in vivo* genotoxin, and the results of the Tier 1 90-day study show that Chanelle's CBD was generally well tolerated after repeat dose subchronic exposure.

As Chanelle's CBD is composed of almost 100% CBD produced under stringent GMP by chemical synthesis and none of the raw materials or processing aids used in the production process contain any

of the allergens specified under Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, it can be concluded that the allergenic potential of Chanelle's CBD is very low. This is substantiated by the absence of any reports of allergenicity to CBD in any of the numerous human studies conducted with other forms of CBD.

Together, the weight of the available evidence on Chanelle's CBD support the safe use of the ingredient under the proposed conditions of use.