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

Applicant: CBD Industries LLC, 8845 Red Oak Blvd, North Carolina 28217, United States of America.

CBD Industries LLC has constructed an application for the authorisation of Cannabidiol Isolate (>97% Cannabidiol) as a novel food ingredient for the European Union. This dossier for a novel food (NF) approval of a Cannabis sativa L. isolate (Herein 'CBD Isolate') is submitted by Legal Foods Ltd on behalf of CBD Industries LLC pursuant to Article 10 of Regulation (EC) No 2015/2283 on novel foods and novel foods ingredients. Its preparation was in accordance with the guidance issued by the European Food Safety Authority (EFSA) regarding an Article 10 submission.

The ingredient from CBD Industries LLC is of high purity (>97% Cannabidiol) and produced under GLP/GMP conditions from the *Cannabis sativa* L. plant thus of natural origin. The ingredient is fully characterised including all chemical constituents with the use validated liquid chromatography–diode array detection (LC–DAD) method for quantification of 16 cannabinoids. An identity and compositional analysis of nutritional, microbials, mycotoxins and metals were also assessed from several representative batches include when included in food forms. The ingredient fully complies with established specification. A range of accelerated and real time stability testing was carried out on the CBD Isolate including when present in final food forms such as gummies, soft gel capsules and tinctures (Food supplements). Again the composition was stable and within specification.

Due to significant gaps in the published literature including studies with limitations in study design, CBD Industries LLC commissioned a series of toxicological studies. These studies are based on a tiered approach as proposed in guidance from EFSA and the Organisation for Economic Co-operation and Development (OECD). Propriety studies included a 14-d dose range finding study with pharmacokinetics, a 90-d subchronic trial with recovery, and a combination of genotoxicity studies and reprotoxic assessments. The result demonstrated the ingredient is not genotoxic and safe over subacute and subchronic exposures at the proposed use level in food supplements. The applicant has applied for data protection in accordance with Article 26 of the novel foods regulation and confidentiality under Article 23 for certain data.

The outcome of the toxicological studies and additional evidence resulted in a NOAEL that allows for safe a daily intake of 21mg for use in food supplements and is intended for health adults over the age of 18.