

Summary of the application: *Cannabis sativa* L. extract

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Cannabis sativa L. extract is a novel food that can be incorporated into various types of liquid forms of food supplements. It is a complex mixture of natural compounds with one main constituent - phytocannabinoid cannabidiol (CBD). The novel food ingredient is produced from *Cannabis Sativa* L. plant by supercritical CO₂ extraction followed by several purification steps. Scientific evidence demonstrates that the novel food does not pose a safety risk to human health.

This application gives an in-depth revision on safety evaluation of the proposed novel food, i.e. *Cannabis sativa* L. extract and its main constituent CBD. The Novel food in proposed uses and forms of final products was found to be safe when used according to the set precautions, warnings, and recommendations. These are based on:

- The performed toxicological studies: Acute and Long-term toxicity (90 days with the following 4-weeks of recovery period) evaluation of proposed NF ingredient on animal models;
- Data on ADME and studied adverse effects (such as effects on liver and reproductive system), certain specific conditions (e.g. concomitant use of some medication, hepatic impairment and altered immune system);
- The quantitative assessment of delta-9-tetrahydrocannabinol (THC) present as a trace contaminant in products with proposed NF ingredient for which we confirmed that the ARfD set by EFSA at 1 µg THC/kg bw/day is not exceeded taking into account the proposed formulations and maximal daily intake of the main constituent of NF ingredient, i.e. 30 mg of CBD for a 60 kg adult;
- The EFSA Food Additives Intake Model (FAIM) tool that was used for the estimation of anticipated intakes of CBD (and THC) which revealed an expected overestimation due to a broad food category applied (all types of food supplements).