

Summary of the application: Cannabidiol (CBD)

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Cannabidiol or CBD is a proposed novel food that can be incorporated into various types of liquid forms of food supplements. It is a natural compound present in a plant *Cannabis Sativa* L. from which it can be isolated by alcohol extraction and further purification steps.

Scientific evidence demonstrating that the novel food does not pose a safety risk to human health: This application gives an in-depth overview of the safety of CBD as a novel food ingredient. In general, CBD in the proposed forms of final products was found to be safe when used according to the following precautions, warnings, and recommendations: In case of any adverse effects after using product with CBD, the administration shall be discontinued. If the product with proposed NF ingredient (CBD) is used in accordance with the instructions, the adverse effects are not expected. The product is intended for healthy adult males and females. Male and female adults with moderate or severe hepatic impairment, with a long-term medical therapy, those with suppressed immune system and males who would like to procreate and have confirmed deficits in fertility shall consult with their doctor prior using such products. The product is not recommended for pregnant and breastfeeding women, babies and children. The simultaneous use of other food supplements and conventional foodstuffs with considerable amounts of CBD is not recommended. The maximal recommended daily dose of CBD in food supplements is 60 mg (or 1 mg CBD/kg bw/day). This dose shall not be exceeded. Moreover, the proposed daily use level (or intake) of CBD in food supplements is 25 mg of CBD for a 60 kg adult, which equals to 0.4 mg CBD/kg bw/day. To reduce the within-day fluctuations in plasma levels of CBD, it is recommended that CBD products are administered after a similar meal in terms of fat content.

All these precautionary statements have been established by the gathered data from studies evaluating potential adverse effects (such as effects of CBD on liver and reproductive system), certain specific conditions (e.g. concomitant use of some medication, hepatic impairment and altered immune system), bioavailability (especially in terms of food effects) and general knowledge on foodstuffs.

In addition, the safety of CBD was evaluated also in terms of the potential presence of a specific contaminant or by-product, delta-9-tetrahydrocannabinol (THC), which is a psychoactive compound that can be found in isolated CBD at trace amounts (≤ 0.03 wt.%). Due to negligible amounts present in final product and considering the proposed maximal daily intake of 60 mg CBD it was concluded the presence of THC does not represent a health risk. Namely, the acute Reference Dose (ARfD) which was set by EFSA at 1 μg THC/kg bw/day was not exceeded. Moreover, laboratory stability studies confirmed the stability of final products and no formation of THC within the proposed shelf-life.

The potential presence of typical plant-derived contaminants has been evaluated by a number of chemical analyses where it was revealed that isolated CBD does not contain any contaminant present at amounts that could potentially represent any health risk. Finally, the EFSA Food Additives Intake Model (FAIM) tool that was used for the estimation of anticipated intakes of CBD (and THC) revealed an expected overestimation due to a broad food category applied (food supplements).

Regardless, based on these data and as a safety precaution the simultaneous use of other CBD products was advised against. It is important to note that the conclusions of the World Health Organisation (WHO) report on CBD of 2018 are similar to the conclusions represented in this application. Namely, CBD is generally well tolerated with a good safety profile and adverse effects may be a result of interactions with drugs as described above. In addition, CBD exhibits no effects indicative of any abuse or dependence potential. Most importantly, WHO stated that there is no evidence of recreational use of CBD or any public health related problems associated with the use of pure CBD. The latter is especially important due to the fact that CBD as an isolated compound is not psychoactive and does not represent a substance that would fall under the scope of narcotic drugs according to Single Convention on narcotic drugs from 1961.