Updated COT Evaluations 2021

In this guide

Cannabidiol (CBD)

Updated CBD position paper- Position paper on the potential risk of CBD in CBD food products: additional text summarising Committee discussions relating to dermal and inhalation exposure.

1.84 The COT 'Position paper on the potential risk of CBD in CBD food products' published in July 2020 summarised the discussions and conclusions of the COT and COM from July 2019 to May 2020 on the available toxicological information of relevance to cannabidiol (CBD) in non-medicinal food products.

Dermal exposure to CBD

1.85 The Committee discussed data of relevance to dermal exposure to CBD from CBD-containing cosmetics products. Such products include serums, creams, washes/rinse-off products, bath products, deodorants, balms, and toothpastes.

1.86 Dermal exposure to CBD may contribute to systemic exposure and/or local effects. Although absorption levels would probably be low because the compound is lipophilic, repeat application could lead to accumulation in the stratum corneum and subsequent slow diffusion into the systemic circulation. Overall, the Committee considered that dermal absorption of CBD was unlikely to be greater than from oral exposure and may be lower. Dermal absorption of CBD was likely to be less than 10% compared with oral absorption. The Committee noted that absorption of CBD from cosmetic products may also occur via inhalation of sprays and mists generated during product use. Dermal pharmaceutical CBD products may differ from cosmetic CBD products, as these may have formulations designed to maximise dermal absorption.

1.87 There was insufficient information on the pharmacokinetics and toxicity of dermal CBD to conduct a risk assessment of the safety of CBD in cosmetic products.

1.88 No conclusions could be drawn on whether dermally applied CBD poses a safety concern, nor on the potential for drug interactions. The risk from aggregate exposure to multiple CBD products, including cosmetics, could not be determined due to lack of information. No good quality *in vivo* or *in vitro* data were available to allow estimation of systemic doses.

1.89 Overall, the Committee noted that additional exposure through topically applied CBD could potentially occur, and this would increase overall systemic exposure of CBD. However, there are data gaps that need to be addressed to be able to evaluate the potential for adverse effects related to dermal exposure to CBD.

Exposure to CBD by inhalation

1.90 Inhalation exposure to CBD may occur via various sources, for example smoking CBD-containing plant material, use of electronic nicotine (and non-nicotine) delivery systems (E(N)NDS) containing e-liquids to which CBD has been added, or from aerosolised therapeutic applications.

1.91 The nature of the source material will affect the risk assessment, for example in terms of the presence or absence of thermal degradation products, and because different delivery methods may affect the bioavailability of CBD.

1.92 The available evidence base relating to potential adverse effects of inhaled CBD is small. However, some conclusions on the likelihood of toxicity from the inhalation of CBD can be inferred based on oral data. Inhalation exposures pose a potential safety concern and adverse effects could be greater than those from an equivalent oral dose as the bioavailability of inhaled CBD is often higher compared with oral exposure. Following absorption across the lung, the type of adverse effects occurring would be independent of route of exposure. Inhibitory drug interactions would be expected at levels comparable to those following oral exposure, given the apparent higher bioavailability across the lung compared with the gut. Effects on the central nervous system would be expected following inhalation, thus a health warning might be necessary relating to driving or using heavy machinery.

1.93 Some experimental data suggest a possible interaction of CBD with steroids could be a cause for concern, however this is an area of research that is currently not well understood.

1.94 Overall, there was insufficient information to generate a risk assessment regarding the safety of use of CBD in products intended for inhalation, but the available data indicated caution. The Committee agreed that the recommended upper limit of 1 mg/kg body weight per day established for dietary exposure to CBD should be applied to total combined exposure, including that from inhalation.

1.95 As a result of the COT discussions, some additional text was added to the existing position paper which summarises the discussions around dermal and inhalation exposure for inclusion in an updated position paper.

The full updated COT position paper can be found on the COT website: Updated position paper on the potential risk of CBD in CBD food

Statement on the potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e cigarettes): presence and pharmacokinetics of nicotine salts

1.96 At the end of 2020 and in 2021, the Committee considered data on the presence and pharmacokinetics of nicotine salts in electronic nicotine delivery system (ENDS) products.

1.97 It was agreed that this should be included as an addendum to the COT statement on the potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes).

The addendum to the statement will be published in due course.