

DIRECTORATE-GENERAL FOR INTERNAL
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Chemicals and Consumer Industries
Consumer Industry

BMSGPK - III/A/6 (Lebensmittelsicherheit und
Verbraucherinnen- und Verbraucherschutz:
stoffliche und technologische Risiken, Gentechnik)

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Dear [REDACTED]

Cannabidiol (CBD) is an ingredient whose use in cosmetic products is booming. Beside the use of synthetic CBD, CBD obtained from the plant Cannabis Sativa is also used. Different production methods of herbal CBD are known. Source materials are either flowers, the leaves (incl. stems) or the whole plant. Mainly extracts with different degrees of purification are used, with purities of CBD up to 99%. The unintended presence of delta-9-THC also varies; up to THC-free extracts.

The question that needs to be addressed is the legal classification of these cosmetic ingredients, especially considering the entry 306 of Annex II of Regulation (EC) No. 1223/2009.

Starting point:

According to Article 14 in conjunction with Annex II, No. 306 of Regulation (EC) No. 1223/2009, cosmetic products should not contain:

- "Narcotics, natural and synthetic: any substance listed in Tables I and II of the Single Convention on Narcotic Drugs signed in New York on 30 March 1961".

Schedule I of the Single Convention contains the following entry: "Cannabis, cannabis resin, and extracts and tinctures of cannabis:

- **Cannabis** in the Single Convention is defined as follows: "The term 'cannabis' means the flowering or fruiting tops of the cannabis plant from which the resin has not been extracted by whatever name they may be designated (excluding the seeds and leaves when not accompanied by the tops)."
- **Cannabis resin** in the Single Convention is defined as follows: "The term "cannabis resin" means the separated resin, whether crude or purified obtained from the Cannabis plant."
- **Cannabis plant** in the Single Convention is defined as follows: "The term "cannabis plant" means any plant of the genus Cannabis."

The glandular hairs produce the resin on the cannabis plant. This consists of 80-90% cannabinoids, as well as essential oils, high polymer phenols, terpenes and waxes. Thus, the source of the cannabinoids detected, especially CBD, is the resin of the cannabis plant.

CBD is obtained by extraction from the resin. Extraction is a well-known separation process. One could now conclude that herbal CBD is part of the separated resin in the sense of the definition and the purification to 99% is a purification of the resin in the sense of the above mentioned definition. On the other hand, the origin of herbal CBD might be the flowers and fruiting stems, from which the resin has not been extracted.

The Single Convention does not provide an exception with respect to leaves or stems in the definition of resin. Consequently, the resin of the leaves would also be inadmissible under the Single Convention. This interpretation based on the commentary of the United Nations Office on Drugs and Crime (UNODC) (2) is:

"(1) The resin can be found principally in the tops of the plant. If the resin were not specifically subjected to international control - as is done by its express mentioning in Schedule 1 annexed to the single convention and its definition in the subparagraph under consideration - it might, if obtained from the tops, to be considered to be covered by the convention as part of the tops, i.e. of "cannabis"; but it is held that some leaves and even from the upper part of the stalk whose capacity to yield resin is, however, said to disappear after the fruits are mature. It would be difficult to distinguish resin obtained from the tops from that derived from other parts of the plant. The specific subjection to control of the resin whatever its origin thus facilitates the tasks of enforcement. (2) [...] The single convention on the other hand applies its comprehensive control régime to

cannabis resin of the male as well as the female plants. It does not exclude any part of the cannabis plant as source of the resin. It states that cannabis resin means the resin "obtained from the cannabis plant".

Therefore, as the Federal Ministry of Health, we have previously assumed that CBD from the plant, even if extracted from the leaves, falls under the Prohibitory Entry 306. However, it is also clear that the Prohibitory Entry 306 does not cover synthetic CBD.

We also saw this view supported by the Commission's COSING entry, which also does not link synthetic CBD to Prohibitory Entry 306, while herbal CBD (obtained from extracts, tinctures, or resin of cannabis) is linked to prohibition entry 306 under CosIng.

However, this approach was questioned by the ECJ Judgement of November 19, 2020 (C-663/18)¹.

This case dealt with CBD - extracted from the entire cannabis plant used in liquids. Here, the ECJ takes into account the objective of the Single Convention and comes to the following conclusion:

"It follows that the CBD at issue in the main proceedings is not an drug within the meaning of the Single Convention."

This is primarily justified because CBD has no proven psychotropic effect. It should further be pointed that according to the EJC that a literal interpretation of provisions of the Single Convention might lead to the conclusion that CBD, in so far as it is obtained from a plant of the Cannabis genus and that plant is used in its entirety - including its flowering or fruiting tops - it constitutes a cannabis extract within the meaning of Schedule I of that convention and, consequently a "drug" within the meaning of Article 1(1)(j) of that convention.

In the meantime, the United Nations commission on narcotic drugs (63rd reconvened CBD) also held votes on some adaption to the Single Convention. There were proposals for amendments to the Single Convention, which could have led to a clarification of the above-mentioned question. However, these amendments were rejected. Extracts and tinctures remain in Annex I. The clarification via a footnote on cannabis and cannabis resin in Annex I that preparations consisting mainly of CBD and containing no more than 0.2%

¹ <https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A62018CJ0663>

delta-9-THC do not fall under international control was also rejected. Only the deletion of cannabis and cannabis resin from Annex IV was accepted. However, this is of no relevance for cosmetic products.

Conclusion:

Therefore, it is unclear to us as a competent authority how to assess CBD extracted from the cannabis plant, in terms of prohibition entry 306.

For the purpose of an harmonized approach within the European Union, the EU Commission is invited urgently to present its view on the clarification of this issue.

In a further step, it would be appropriate to have a common Risk Assessment of CBD by an official scientific body (e.g. SCCS). In the context of the review of the obligatory safety report for cosmetics, currently the responsible persons in Austria are not able to present convincingly data to prove the safety of the substance. There is a lack of generally accepted toxicological parameters (e.g. NOAEL) as a point of departure for the safety assessment.

Best regards

