



## EU Commission changed its Approach towards Cannabis Legislation

### CONUSBAT's Expert Regulatory Opinion

The EU's regulation 1223/20091 states as entry 306 in Annex II that the following substances are prohibited from use in cosmetic products: 'Narcotics, natural and synthetic - All substances listed in Tables I and II of the single Convention on Narcotic Drugs<sup>2</sup> signed in NYC, NY USA on 30. March 1961'. Cannabidiol and a number of Cannabis extracts, see table 1 below, were listed in CosIng<sup>3</sup> as to be falling under the provisions of this Annex II entry and were as such prohibited from use in cosmetic products. Several of the CosIng listings have recently been revised.

The quoted UN Convention on Narcotic Drugs defines drugs in Article 1(j): 'Drug means any of the substances in Schedules I and II, whether natural or synthetic'. The list of drugs in Table I (Schedule I) includes: Cannabis, Cannabis resin and extracts and tinctures of Cannabis.

#### Article 1 of the UN Convention also defines:

- (b) "Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.
- (c) "Cannabis plant" means any plant of the genus cannabis.
- (d) "Cannabis resin" means the separated resin, whether crude or purified, obtained from the cannabis plant.

Following up on stakeholder requests on CosIng entries obviously contradictory to the UN Convention's definitions, recently, Cannabis related provisions under the EU's Cosmetics Product Regulation were newly addressed by the Commission with the following result: Cosmetic ingredients that are derived from seeds or leaves of Cannabis should not be prohibited, as they are exempted based on Article 1(b) of the UN Convention. Only ingredients derived from Cannabis, which fall within the scope of the Convention should be prohibited. The CosIng was changed for the respective entries, see Table 1 below.

#### Table 1: Cannabis Extracts now free for Use in Cosmetics

- CANNABIS SATIVA SEED OIL & EXTRACT
- CANNABIS SATIVA SEED OIL GLYCERETH-8 ESTER & PEG-8 ESTERS
- CANNABIS SATIVA SEEDCAKE & POWDER
- HYDROLYZED CANNABIS SATIVA SEED EXTRACT
- CANNABIS SATIVA STEM POWDER
- CETYLDIMETHYLAMINE HYDROLYZED HEMPSEEDATE
- DECYL HEMPSEEDATE
- HYDROGENATED HEMP SEED OIL, EXTRACT, PROTEIN & PROTEIN
- HYDROXYPROPYLTRIMONIUM CHLORIDE

Cannabidiol is not specifically listed in the schedules of the UN Drug Conventions; however, it is controlled there under if Cannabidiol is prepared as an extract or tincture of Cannabis. Accordingly, synthetically produced Cannabidiol is outside the scope of Annex II/entry 306 of Regulation (EC) 1223/2009 and no prohibition for use in cosmetic products applies. However, plant-derived Cannabidiol falls within the scope of the UN Convention and the prohibition under Annex II/306. The EU database Cosing was corrected for the respective entry and states now 'Cannabidiol (CBD) as such, irrespective of its source, is not listed in the Schedules of the 1961 Single Convention on Narcotic Drugs. However, it shall be prohibited from use in cosmetic products (II/306) if it is prepared as an extract or tincture or resin of Cannabis in accordance with the Single Convention. Please note that national legislations on controlled substances may also apply'.

In January 2019, the WHO Expert Committee on Drug Dependence (WHO ECDD) suggested several changes to be made to the UN Convention on Narcotic Drugs, amongst are recommendations on Cannabidiol. The EU Commission sees that these have currently no legal value; yet EU legislation will be reviewed when the suggested changes will be voted and adopted.

**Sources:**

**Regulation 1223/2009 – Eur-Lex**

- <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1223>

**Single Convention on Narcotic Drugs signed in NYC, NY USA | 30. March 1961**

- [https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=VI-15&chapter=6&clang=\\_en](https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-15&chapter=6&clang=_en)

**Cosing:**

- [http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details\\_v2&id=93486](http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=93486)

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Serving as one of the most important industry events, the NY-SCC sponsored exhibition attracts certain decision-makers, KOLs, Regulatory, R&D, Marketing, Formulators and offers an excellent networking opportunity.

CONUSBAT will be represented there by its President, Steven L. Hanft, M.A., Emiretus Member-SCC. To schedule a meeting with Steven, pls. contact him personally at: [steven.hanft@conusbat.com](mailto:steven.hanft@conusbat.com)



**Mark your Calendars! Cosmetics Consultants Europe (CCE) plans its next 'Open Academy' in Cyprus for November 2019** - On 4. April, CCE approved its next Open Academy, which will held in sunny Cyprus (Nicosia area)! At the appropriate time, further information will be provided on the topics, speakers,venue, specific dates, etc.

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