

DISCUSSION PAPER

9/03/2023

THE PURPOSE OF THIS DRAFT **INFORMAL DOCUMENT** IS TO SERVE AS BASIS FOR DISCUSSION IN THE WORKING GROUP ON COSMETIC PRODUCTS.

IT HAS BEEN PREPARED WITH THE AIM OF PROVIDING PRELIMINARY VIEWS AND FURTHER EXPLANATIONS ON THE IMPLICATIONS OF THE CJEU JUDGEMENT CASE C-663/18 **ON COSMETIC PRODUCTS**.

THE MEMBER STATES WERE INVITED TO PROVIDE THEIR COMMENTS. THEIR OPINIONS ARE SUMMARISED IN THIS DOCUMENT AND SUGGESTIONS FOR FURTHER ACTIONS HAVE BEEN ADDED. **THIS DRAFT DOES NOT COMMIT THE EUROPEAN COMMISSION AND IT IS NOT BINDING IN ANY WAY. ONLY THE COURT OF JUSTICE OF THE EUROPEAN UNION IS COMPETENT TO AUTHORITATIVELY INTERPRET UNION LAW.**

IT WILL BE FURTHER UPDATED TO TAKE ACCOUNT OF THE FUTURE DISCUSSIONS AND DEVELOPMENTS.

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Subject: Status of Hemp and Cannabis-derived ingredients in Cosmetics

1. Introduction

According to Article 14 (1) of Regulation (EC) No 1223/2009¹ of the European Parliament and of the Council of 30 November 2009 (hereinafter, ‘CPR’), cosmetic products shall not contain any of the prohibited substances listed in Annex II of that Regulation.

Entry 306 of Annex II (List of substances prohibited in cosmetic products) to CPR refers to ‘*Narcotics, natural and synthetic²: All substances listed in Tables³ I and II of the Single Convention on narcotic drugs of 1961*’.

According to the Single Convention on Narcotic Drugs, Schedules I and II are lists of drugs⁴. Article 1 (‘Definitions’) [of the 1961 Convention], defines ‘*drug*’ as ‘*any of the substances in Schedules I and II, whether natural or synthetic*’.

The list of drugs in Schedule I includes: “**CANNABIS AND CANNABIS RESIN AND EXTRACTS AND TINCTURES OF CANNABIS.**”

Article 1 of the 1961 Convention defines these terms as follows:

- “(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”.

Article 28(2) of the 1961 Convention states:

“*This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes*”.

2. State of Play

2.1 Overview

During the Working Group on Cosmetic Products in December 2018, the Commission services discussed the status of Cannabis and Cannabis-related ingredients and in January 2019, they shared a document providing a suggestion on the interpretation of entry 306 of

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549621036385&uri=CELEX:02009R1223-20180801>

² Term “natural or synthetic” does not appear in some language versions, for example the French translation states: “Stupéfiants: toute substance énumérée aux tableaux I et II de la convention unique sur les stupéfiants signée à New-York le 30 mars 1961”

³ The term ‘Tables’ refers to ‘Schedules’ of the Single Convention of 1961

⁴ https://www.unodc.org/pdf/convention_1961_en.pdf

Annex II to the CPR. In that document, it was considered that since Cannabidiol (CBD)⁵ was not included as such in the Schedules of the Single Convention on Narcotic Drugs of 1961, it was outside the scope of entry II/306 to the CPR.

During the WG of March 2019, the Commission services elaborated on the interpretation of entry 306 of Annex II, the issue of CBD specifically the case of synthetic Cannabidiol and WG members were invited to provide their views and comments. In particular, it was stated that synthetic CBD does not fall within the scope of the Single Convention and can be used as cosmetic ingredient, provided that the conditions of Article 3 (Safety) of the CPR are met and demonstrated in the cosmetic product safety report referred to in Article 10 CPR

In addition, since the use of various hemp and cannabis-derived ingredients in cosmetics products increased, the Commission services sought to address their legal status in the same document. The Commission services concluded that several changes should be made in CosIng database as regards CBD, hemp and cannabis-related ingredients based on the comments received by the WG members.

In November 2020, the judgment in Case C-663/18⁶ gave origin to numerous questions from different stakeholders as regards the implications of its conclusions for the cosmetics sector.

On 1 March 2022, the Commission services shared with the members of the Working Group on Cosmetic Products their analysis of the Court ruling and asked for written comments. Ten Member States contributed. Overall, the analysis was welcomed and considered as a step forward to achieve legal certainty and clear harmonised conditions for the use of CBD in cosmetic products.

2.2 Update

The discussion paper has been supplemented by summaries of the Member States' positions, additional explanations, and suggestions for possible next steps.

3. Analysis

3.1 Summary of the preliminary ruling Case C-663/18⁷

The Court of Appeal d'Aix-en-Provence requested a preliminary ruling questioning the conformity with EU law of the French legislation, which prohibits the marketing of CBD lawfully produced in another Member State, when it is extracted from the *Cannabis sativa* plant in its entirety and not solely from its fibre and seeds. The CBD in question was produced in the Czech Republic from hemp plants grown lawfully and using the entirety of the plant, the leaves and flowers included. It was then imported into France to be packaged in electronic cigarette cartridges.

The Court ruled that:

⁵ See Section 3.2 for the definition of Cannabidiol.

⁶ <https://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-663/18>

⁷ [CURIA - Documents \(europa.eu\)](https://eur-lex.europa.eu/curia/doclist/curia/doclist.do?method=DocListDocList&docId=62018CJ0663)

- a) CBD extracted from the *Cannabis sativa* plant in its entirety cannot be regarded as an agricultural product, unlike, for example, raw hemp and therefore it does not fall within the scope of EU Regulations (EU) No1307/2013 and 1308/2013;
- b) The provisions on the free movement of goods within the European Union (Articles 34 and 36 TFEU) are applicable, since the CBD at issue in the main proceedings cannot be regarded as a ‘narcotic drug’:
 - i. CBD is not mentioned in Convention on Psychotropic Substances and, while it is true that a literal interpretation of the Single Convention on Narcotic Drugs might lead to its being classified as a drug, in so far as it is a cannabis extract, such an interpretation would be contrary to the general spirit of that convention and to its objective of protecting ‘the health and welfare of mankind’.
 - ii. According to the current state of scientific knowledge, which it is necessary to take into account, unlike tetrahydrocannabinol (commonly called THC), another hemp cannabinoid, the CBD at issue does not appear to have any psychotropic effect or any harmful effect on human health.
- c) The prohibition on marketing CBD constitutes a measure having equivalent effect to quantitative restrictions on imports, prohibited by Article 34 TFEU. The Court nevertheless pointed out that that the prohibition can be justified on one of the grounds of public interest laid down in Article 36 TFEU, such as the objective of protecting public health (invoked by the French Republic), provided that that legislation is appropriate for securing the attainment of that objective and does not go beyond what is necessary in order to attain it.

3.2 Relevance of the judgement in Case C-663/18 for cosmetics

The argument was raised that it is not appropriate to apply the reasoning and the findings of the Court in its judgement in Case C-663/18 to cosmetic products as the Court ruling relates to the marketing of an electronic cigarette containing CBD and the threshold for qualifying a product containing CBD as safe for human health may be different depending on the intended use of the product.

In the judgement in question, the Court pronounced itself on the status of CBD extracted from the entire plant by the process described therein. Although the judgement does not refer to the Union law on cosmetics, it rules on the qualification of CBD under the Single Convention, which is of direct relevance to the use of CBD in cosmetics.

3.3 Cannabidiol (CBD)

Cannabidiol (CBD) is one of the cannabis-related ingredients. There is no definition of CBD in the Union law applicable to the area of cosmetics. The Expert Committee on Drug Dependence defines it as *‘one of the naturally occurring cannabinoids found in cannabis plants. It is a 21-carbon terpenophenolic compound which is formed following*

decarboxylation from a cannabidiolic acid precursor, although it can also be produced synthetically.⁸

It seems clear from the judgment in Case C-663/18 that the questions focused on CBD **extracted from the entire plant with variable levels of THC not exceeding 0,2 %**, by the process described in the judgment (i.e., carbon dioxide extraction), as this is the maximum level accepted in order to qualify hemp production as eligible for direct payments in the EU⁹.

It the judgement, the CJEU concluded that CBD at stake in the main proceedings, should not be considered as a drug under the UN Single Convention on Narcotic Drugs of 1961 since CBD, according to the CJEU, ‘does not appear to have any psychotropic effect or any harmful effect on human health on the basis of available scientific data. Moreover, according to those elements in the file, the cannabis variety from which that substance was extracted, which was grown in the Czech Republic lawfully, had a THC content not exceeding 0,2 %’.¹⁰

Some Member States caution as regards the use of terminology ‘psychoactive’ and ‘psychotropic’ as CBD has some psychoactive effects and for this reason is used to treat epilepsy. One Member State referred to the assessment of the French Association of Addiction Centres¹¹ according to which the current scientific knowledge suggests that CBD is not pharmacologically inert but has psychoactive effects for sedation and inducing drowsiness. However, the Association noted that it does not have psychotropic effects as other drugs.¹²

Some Member States point to the discrepancy between the Court judgement and the interpretation of the Single Convention by the International Narcotics Control Board (INBC) according to which extracts or tinctures of cannabis (*‘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’*) are controlled as narcotic drug under the Single Convention and therefore CBD produced from such extracts or tinctures should be considered as prohibited in cosmetics.

Those Member States point that it is practically impossible to verify from which parts of the cannabis plant natural CBD has been extracted: from the parts which do not fall under the Single Convention or from fruiting tops or resin.

⁸ CANNABIDIOL (CBD), Critical Review Report, Expert Committee on Drug Dependence, Fortieth Meeting Geneva, 4-7 June 2018, 4-7 June 2018, CANNABIDIOL (CBD) (who.int) https://www.researchgate.net/publication/353326813_CANNABIDIOL_CBD_Critical_Review_Report_Expert_Committee_on_Drug_Dependence_Fortieth_Meeting

⁹ Regulation (EU) 2021/2115 will apply from 1 January 2023, repealing Regulation (EU) No 1307/2013. The new regulation defines hemp as an agricultural product when the THC content of a hemp variety does not exceed 0,3 %.

¹⁰ Point 72 of the judgement in Case C-663/18.

¹¹ L’association française des centres d’addictovigilance.

¹² Both terms: “psychotropic and psychoactive” are used in the Court’s judgement C-663/18 interchangeably: its paragraph 72 states “(...) the CBD at issue in the main proceeding does not appear to have any **psychotropic** effect (...)” and paragraph 75 “(...) it must be held that, since CBD does not contain a **psychoactive** ingredient (...) it would be contrary to the purpose and general spirit of the Single Convention to include it under definition of “drugs”. This Discussion Paper uses the term “psychoactive” only in quotes from paragraph 75 of the ruling.

Some Member States have drawn attention that the European Food Safety Authority (EFSA) has not been able to pronounce itself on the safety of CBD and its qualification as novel food due to the knowledge gap. On 26 April 2022, EFSA issued a statement, summarising the state of knowledge on the safety of CBD consumption and highlighting areas where more data are needed. The EFSA panel concluded: *‘The effect of CBD on liver, gastrointestinal tract, endocrine system, nervous system and on psychological function needs to be clarified. Studies in animals show significant reproductive toxicity, and the extent to which this occurs in humans generally and in women of child-bearing age specifically needs to be assessed. Considering the significant uncertainties and data gaps, the Panel concludes that the safety of CBD as a Novel Food cannot currently be established’*¹³.

The Court of Justice in the ruling refers to CBD in general as it is defined without any other substances included in it, except for impurities. To qualify as CBD, the substance must correspond to the chemical definition and must not cause psychotropic effects in humans. Since the judgement in Case C-663/18 refers to the substance as such (CBD extracted from the whole plant) and not to a specific final product (e-liquids) and given the reasoning of the Court of Justice, the same conclusion follows if CBD is assessed against the definition of ‘preparation’.¹⁴

Conclusions:

In view of the Court ruling in case C-663/18, CBD, which, according to the current state of scientific knowledge is considered not having psychotropic effects, and in addition, is extracted from cannabis plant varieties with THC content not exceeding 0,2 %¹⁵, is not covered by entry 306 of annex II to the CPR and, consequently, is not considered as prohibited substance in cosmetics.

Therefore, it could be used in cosmetic products provided that such product is safe for human health pursuant to Article 3 of CPR and its safety is properly assessed and demonstrated in the cosmetic product safety report as required by Article 10 CPR.

The Commission services could launch a Call for data and then mandate the SCCS to assess the safety of CBD in cosmetic products.

This conclusion does not cover any possible THC presence in CBD.

¹³ <https://www.efsa.europa.eu/en/efsajournal/pub/7322>

¹⁴ The Court noted in point 71 of the ruling: “(...) it is true that a literal interpretation of the provisions of the Single Convention might lead to the conclusion that, in so far as CBD is extracted 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 1 of that convention and, consequently, a ‘drug’ (...)”. The Court develops its argumentation in points 72 – 75 and concludes in point 76 “It follows that the CBD at issue in the main proceeding is not a drug within the meaning of the Single Convention”.

¹⁵ The Court referred to the maximum content of THC specified in Article 32(6) of Regulation (EU) No 1307/2013 “Areas used for the production of hemp shall only be eligible hectares if the varieties used have a tetrahydrocannabinol content not exceeding 0,2 %”. This Regulation was repealed by Regulation (EU) 2021/2115, which applies from 1 January 2023. This new act increases the maximum level of THC content in hemp varieties to 0,3 %.

3.4 Tetrahydrocannabinol (THC)

Delta-9-tetrahydrocannabinol (Δ 9-THC) is a naturally occurring psychoactive compound derived from the hemp plant *Cannabis sativa*.¹⁶

The qualification of THC as a ‘*drug*’ under the Convention on Psychotropic Substances, 1971, concluded in Vienna on 21 February 1971¹⁷ (hereinafter ‘the Convention on Psychotropic Substances’), does not prevent the Commission from regulating its presence in various products. In fact, the Commission has recently adopted Regulation (EU) 2022/1393¹⁸ as regards maximum levels of delta-9-tetrahydrocannabinol in hemp seeds and products derived therefrom. As of 1 January 2023, the level of Delta-9-tetrahydrocannabinol (Δ 9-THC) equivalents in hemp seeds cannot exceed 3.0 mg/kg (or 0,0003 %) and in hemp seed oil – 7,5 mg/kg (or 0,00075 %).

As a result of the qualification of THC as a ‘*drug*’ under the Convention on Psychotropic Substances, 1971, the THC is considered as a prohibited substance in cosmetics (entry 306 in Annex II to the Cosmetics Regulation). Such qualification would still allow, on the basis of Article 17 of the CPR to accept the non-intended presence of a small quantity of THC and provided that the product is safe for human health as required by Article 3 of the CPR as demonstrated in the cosmetic product safety report referred to in Article 10 CPR. The maximum levels of delta-9-tetrahydrocannabinol (Δ 9 -THC) in hemp seeds and products derived therefrom, established in Commission Regulation (EU) 2022/1393 could be used as an indication of acceptable trace level of THC in cosmetics.

There seems to be general agreement among Member States that any presence of THC can only fall under Article 17 CPR. Some Member States accept cosmetics in which THC content reaches maximum 0,3 % for hemp extracts and products incorporating them. Other Member States consider the THC and its preparations as narcotics under the Convention on Psychotropic Substances, regardless from which part of a plant it originates or the quantity of THC in a product. That means that according to their national law, even traces of THC in a cosmetic product may constitute a criminal offence.

Conclusions:

As a result of the qualification of THC as a ‘*drug*’ under the Convention on Psychotropic Substances, 1971, the THC is considered as a prohibited substance in cosmetics (entry 306, Annex II).

THC can only be present in cosmetics at a **trace level** under conditions specified in Art. 17 CPR, provided that such a product is safe for human health pursuant to Article 3 of CPR and that this safety is properly assessed and demonstrated in the cosmetic product safety report as required by Article 10 CPR.

¹⁶ EFSA (European Food Safety Authority), Arcella D, Cascio C and Mackay K, 2020. Acute human exposure assessment to tetrahydrocannabinol (Δ 9-THC). EFSA Journal 2020;18(1):5953, 41 pp. <https://doi.org/10.2903/j.efsa.2020.5953>

¹⁷ United Nations Treaty Series, vol. 1019, No 14956.

¹⁸ Commission Regulation (EU) 2022/1393 of 11 August 2022 amending Regulation (EC) No 1881/2006 as regards maximum levels of delta-9-tetrahydrocannabinol (Δ 9 -THC) in hemp seeds and products derived therefrom.

The maximum level of THC in hemp seeds and products derived therefrom, laid down in Commission Regulation (EU) 2022/1393, could also be accepted in cosmetics as trace levels.

The Commission could launch a Call for data and then mandate the SCCS to assess the acceptable levels of THC in terms of safety requirements.

Member States which currently prohibit any presence of THC in cosmetic products, should ensure that the cosmetic products with the THC trace level can be made available on their markets.

3.5 Non-psychoactive cannabinoids other than CBD (e.g., CBG¹⁹, CBC²⁰, CBDV²¹, etc.)

As regards the status of cannabinoids other than CBD, as there is no aspect in the Court of Justice's ruling that would not be transposable to other individual non-psychoactive cannabinoids, the following should be noted:

There are several minor cannabinoids present in the cannabis plant, for example Cannabigerol (CBG), Cannabichromene (CBC), Cannabidivarin (CBDV), etc., for which there might be very limited or no data available about their psychoactive properties and harmful effects on human health.

The same conclusions as for CBD should apply to other individual cannabinoids, if there are no grounds to treat those substances differently, i.e., if they do not have psychoactive effect either according to the current state of scientific knowledge. Nevertheless, this would not be the case for those cannabinoids for which the current state of scientific knowledge cannot confirm that they do not have psychoactive effect or other harmful effects on human health.

It is important to note that the question of applying the same principles to other non-psychoactive cannabinoids (i.e., CBG, CBC, CBDV, etc.), minimises any litigation risk.

With regard to non-psychoactive cannabinoids other than CBD (e.g., CBG, CBC, CBDV, etc.) in pure form and products containing these cannabinoids in different concentrations, the analysis above would also apply with regard to their use in cosmetics. Hence, cosmetic products containing non-psychoactive (according to the current state of scientific knowledge) cannabinoids other than CBD, should not be considered '*drugs*' within the meaning of the Single Convention and the Convention on Psychoactive Substances and therefore, should not be prohibited *a priori* in cosmetic products, provided that the conditions of Article 3 of the CPR are also met, which is proved by the safety assessment and evidenced in the cosmetic product assessment report as required by Article 10 CPR.

Member States agree that the analysis relating to CBD applies to other cannabinoids (e.g., CBG, CBC, CBDV, etc.). They claim that more scientific data are needed to be able to assess these substances. The fact that cannabinoids may degrade into active substances under the influence of various physical factors (e.g., temperature) should be taken into account in the

¹⁹ Cannabigerol

²⁰ Cannabichromene

²¹ Cannabidivarin

safety assessment and the exclusion of each substance from the category of drugs should be supported by sufficient scientific data. In particular, some Member States point out that there is currently no commonly agreed methodology how to differentiate psychotropic substances from non-psychotropic substances in relation to cosmetics (with open questions relevant to which authority should be tasked with such a role, how such assessment should be done and what documentation could be considered as sufficient).

In addition, according to some Member States, if the non-psychotropic cannabinoids (e.g., CBD, CBG, CBC, etc.) are extracted from 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, they will still be considered by the International Narcotics Control Board (INCB)²² and the national competent authorities as narcotics.

Conclusions:

Cannabinoids other than CBD (i.e., CBG, CBC, CBDV, etc.), without psychotropic effects according to the current state of scientific knowledge, are not covered by entry 306 of annex II to the CPR and can be used in cosmetic products provided that such products are safe for human health pursuant to Article 3 of CPR and that this safety is properly assessed and demonstrated in the cosmetic product safety report as required by Article 10 CPR.

The responsible person should provide evidence in the cosmetic product safety report that the cannabinoid, other than CBD, present in the product does not have psychotropic effects according to the current state of scientific knowledge.

The assessment of the psychotropic nature of a substance is not within the mandate of the SCCS and, therefore, is out of its scope. However, the safety assessment of ingredients used in cosmetics falls under the remit of the SCCS. Consequently, the Commission could mandate the SCCS to assess the safety of non-psychotropic cannabinoids used in cosmetic products.

3.6 Extracts from different parts of the hemp/cannabis plant²³

3.6.1 Seeds (not accompanied by the tops)

In Article 1(1)(j), the Single Convention defines ‘drug’ as ‘any of the substances in Schedules I and II, whether natural or synthetic’. Schedule I lists ‘*cannabis and cannabis resin and extracts and tinctures of cannabis*’, but the definition of ‘*cannabis*’ set out in Article 1(1)(b) of the Single Convention explicitly excludes seeds as it refers to ‘*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*’.

²² The International Narcotics Control Board (INCB) is an independent, quasi-judicial expert body established by the Single Convention on Narcotic Drugs of 1961 by merging two bodies: the Permanent Central Narcotics Board, created by the 1925 International Opium Convention, and the Drug Supervisory Body, created by the 1931 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic, <https://www.incb.org/incb/en/about.html>

²³ The analysis in this section does not take into account the THC level as it was subject to a separate analysis in point 3.4.

Conclusions:

Since seeds, when not accompanied by the tops, do not fall within the definition of ‘cannabis’ set out in the Single Convention, they do not qualify as ‘drugs’ and consequently are not covered by entry 306 of annex II to the CPR.

The different preparations from seeds could therefore be used in cosmetic products provided that any THC presence is at trace level (see conclusions in point 3.4) and that such products are safe for human health pursuant to Article 3 of CPR and that this safety is properly assessed and demonstrated in the cosmetic product safety report as required by Article 10 CPR.

3.6.2 Leaves (not accompanied by the tops)

As mentioned above for seeds, the Single Convention defines as ‘drug’ ‘*cannabis and cannabis resin and extracts and tinctures of cannabis*’ and defines ‘cannabis’ as ‘*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 [...]*’. Therefore, the Single Convention **explicitly excludes** ‘*leaves when not accompanied by the tops*’ from the definition of ‘cannabis’ and therefore **does not qualify them as ‘drugs’**.

In any case, even if it is true that the Single Convention provides for measures concerning leaves and that the commentary on that Convention published by the United Nations states that ‘*[i]t was suggested at the Plenipotentiary Conference that leaves, unlike the tops, were not suitable for smoking*’, **it results from the Single Convention itself and the commentary that leaves should not be considered as ‘drugs’**.

First, it results from Article 2 of the Single Convention that leaves of the cannabis plant are subject to different rules than ‘drugs’ (see paragraph 7 on leaves and paragraphs 1 to 6 on ‘drugs’). The commentary explicitly and repeatedly states that leaves are not considered as ‘drugs’²⁴.

Second, the above-mentioned statement that ‘*[i]t was suggested at the Plenipotentiary Conference that leaves, unlike the tops, were not suitable for smoking*’ is followed by an

²⁴ ‘2. *The seeds and the leaves of the plant when not accompanied by the tops are excluded from [the] definition [of ‘cannabis’]. The provisions of the Convention concerning cannabis therefore do not apply to such leaves. “Marihuana” cigarettes containing material derived only from the leaves are consequently not subject to the provisions governing cannabis. [...]*’ (page 3), ‘*[...] leaves [of the cannabis plant not accompanied by the tops of that plant] are, [...] excluded from the definition of cannabis, are not separately listed in Schedules I and II and are therefore not “drugs” within the meaning of that word in the Single Convention*’ (page 11), ‘6. Article 22 would not, on the other hand, cover a situation in which only the leaves of the cannabis plant (not accompanied by the tops) are diverted into the illicit traffic, since the leaves are not “drugs”[.]’ (page 276), ‘*[t]he cannabis plant is grown for its fibre, its seeds, for drugs (cannabis and cannabis resin) and for its leaves [The leaves are consumed in different ways by smoking or as ingredient of beverages or sweets; the leaves are not “drugs”; see article 1, subparagraphs (b) and (/), and Schedules I and II.]’ (Paragraph 1 and footnote 1 in page 312), ‘1. The leaves of the cannabis plant, when not accompanied by the tops of the plant, are not “cannabis”, and being listed neither in Schedule I nor in Schedule II are not “drugs” in the sense of the Single Convention [...]*’ (page 315).

explanation which does not refer to the fact that the Plenipotentiary Conference was unaware of the potential psychoactive effects but to other considerations²⁵.

On the contrary, the commentary to the Single Convention seems to indicate that the Plenipotentiary Conference took into account the risks resulting from leaves without qualifying them as ‘drugs’.

For instance, as regards the fact that cannabis resin is specifically listed as a ‘drug’, the commentary refers to the need to cover resin obtained from leaves and explains the following: *‘If the resin were not specifically subjected to international control[,] it might, if obtained from the tops, be considered to be covered by the Convention as part of the tops, i.e. of “cannabis”; but it is held that some resin—however small its quantity may be—might be obtained from 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 [...].’* (Page 5)²⁶

A footnote in the part of the commentary concerning the provision that requires the Parties to apply measures of supervision to substances which do not fall under the Convention, but which may be used in the illicit manufacture of drugs (Article 2(8)), recognises that *‘[t]he leaves of the cannabis plant governed by article 28, para. 3, may have the same kind of effect as cannabis, however weak.’*²⁷

Last, as regards the obligation of the Parties to adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant (Article 28(3) of the Single Convention), the commentary seems to indicate again that potential effects of leaves were already taken into account when it states that *‘Parties are not bound to prohibit the consumption of the leaves for non-medical purposes, but only to take the necessary measures to prevent their misuse’ and that ‘[t]his might involve an obligation to prevent the consumption of very potent leaves, or of excessive quantities of them.’*²⁸

However, even if, the Single Convention does not qualify leaves when not accompanied by the tops as ‘drugs’, it needs to be noted that the Convention allows the Parties to prohibit the cultivation of leaves and their consumption for non-medical purposes if they consider these measures necessary to prevent their misuse. Some Member States and other Parties to the Single Convention might, therefore, apply the control measures required for ‘drugs’ to leaves even when not accompanied by the tops while others do not. These differences are allowed by the Single Convention, but they may impact the uniform application of the Union secondary legislation referring to that Convention.

Conclusions:

Since leaves, when not accompanied by the tops, do not fall within the definition of ‘cannabis’ set out in the Single Convention, leaves do not qualify as ‘drugs’ and consequently are not covered by entry 306 of annex II to the CPR.

²⁵ ‘2. [...] It was suggested at the Plenipotentiary Conference that the leaves, unlike the tops, were not suitable for smoking “since they were green and burned very quickly if they were dried”. It has, however, been found that marihuana cigarettes seized from the illicit traffic in fact contain leaves’ (page 3 of the commentary).

²⁶ It adds however that ‘[t]he resin [...] becomes “cannabis resin” only when it is “separated” from the plant; without such a separation it remains a part of the cannabis plant, and if in the top part, of “cannabis”’ (page 5).

²⁷ Footnote 2 of page 70.

²⁸ Page 316.

The extracts from leaves could, therefore, be used in cosmetic products provided that any THC presence is at trace level (see conclusions in point 3.4) and such products are safe for human health pursuant to Article 3 of CPR and that this safety is properly assessed and demonstrated in the cosmetic product safety report as required by Article 10 CPR.

Member States which currently prohibit the presence of leaves in cosmetic products should ensure that the cosmetic products with such ingredients can be made available on their markets.

3.6.3 Flowering or fruiting tops of the cannabis plant

It results from the wording of the Single Convention, and in particular from the definition of ‘cannabis’, that ‘flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when non accompanied by the tops) (also referred in this Discussion Paper as ‘flowers’) from which the resin has been extracted do not qualify as ‘drugs’, while flowers for which the resin has not been extracted do qualify as ‘drugs’. Therefore, similar for leaves, the situation as regards flowers differs from the situation as regards CBD, considered by the Court of Justice, in that the Single Convention explicitly regulates the qualification of flowers as ‘drugs’ or not, depending on whether or not the resin has been extracted.

In view of the Court judgement in Case C-663/18 a possible interpretation of the Single Convention could be considered that flowers (and leaves with tops) from cannabis plants of varieties with low levels of psychotropic substances are not subject to the control regime provided by the Convention for ‘drugs’ even if the resin has not been extracted.

Conclusions:

Since the flowering or fruiting tops of the cannabis plant from which the resin has been extracted do not fall within the definition of ‘cannabis’ set out in the Single Convention, they do not qualify as ‘drugs’ and consequently their extracts are not covered by entry 306 of annex II to the CPR.

Member States which currently prohibit the presence of flowering or fruiting tops of the cannabis plant from which the resin has been extracted in cosmetic products should ensure that the cosmetic products with such ingredients can be made available on their markets.

In case of flowering or fruiting tops of the cannabis plant from which resin **has not** been extracted, the seemingly prevailing interpretation at the international level and among many EU Member States is that they should be considered as drug and should be subject to the control under the Single Convention.

3.6.4 Root and Stem

Roots and stems of hemp and/or cannabis plants are not listed in the schedules of the Single Convention and based on current knowledge they do not have psychotropic effects either. In addition, they do not qualify as ‘drugs’ since the definition of ‘cannabis’ refers to the ‘flowering or fruiting tops of the cannabis plant’ and explicitly excludes some other parts of the plant such as seeds and leaves when not accompanied by the tops. Even if root and stem

are not excluded from the definition, they are not the '*flowering or fruiting tops of the cannabis plant*' and there seems to be no reason to consider that those parts of the plant should not be treated in the same way as seeds and leaves when not accompanied by tops.

Conclusions:

Since roots and stem do not fall within the definition of '*cannabis*' set out in the Single Convention, the roots and stem do not qualify as '*drugs*' and consequently are not covered by entry 306 of annex II to the CPR.

The different preparations from roots and stem could, therefore, be used in cosmetic products provided that any THC presence is at trace levels (see conclusions in point 3.4) and such products are safe for human health pursuant to Article 3 of CPR and that this safety is properly assessed and demonstrated in the cosmetic product safety report as required by Article 10 CPR.

Member States which currently prohibit any presence of roots and stems in cosmetic products, should ensure that the cosmetic products with roots and stems can be made available on their markets.

3.6.5 Calluses and Sprouts

Calluses and sprouts are not listed in the schedules of the Single Convention and based on current knowledge they do not have psychotropic effects either. In addition, do not qualify as '*drugs*' since the definition of '*cannabis*' refers to the '*flowering or fruiting tops of the cannabis plant*' and explicitly excludes some other parts of the plant such as seeds and leaves when not accompanied by the tops. Even if calluses and sprouts are not excluded from the definition, they are not the '*flowering or fruiting tops of the cannabis plant*' and there seems to be no reason to consider that those parts should not be treated in the same way as seeds and leaves when not accompanied by tops.

Conclusions:

Since calluses and sprouts do not fall within the definition of '*cannabis*' set out in the Single Convention, they do not qualify as '*drugs*' and consequently are not covered by entry 306 of annex II to the CPR.

The different preparations from calluses and sprouts could, therefore, be used in cosmetic products provided that any THC presence is at trace levels (see conclusions in point 3.4) and such products are safe for human health pursuant to Article 3 of CPR and that this safety is properly assessed and demonstrated in the cosmetic product safety report as required by Article 10 CPR.

Member States which currently prohibit any presence of calluses and sprouts in cosmetic products should ensure that the cosmetic products with such ingredients can be made available on their markets.

3.7 Other hemp and cannabis-derived products

Hemp and/or cannabis-derived products are typically extracts containing various non-psychoactive cannabinoids (based on the current scientific knowledge) used in different concentrations.

Conclusions:

The hemp and/or cannabis-derived products which do not fall within the definition of '*cannabis*' set out in the Single Convention, they do not qualify as '*drugs*' and consequently are not covered by entry 306 of annex II to the CPR.

The different preparations from hemp and/or cannabis-derived products could, therefore, be used in cosmetic products provided that any THC presence is at trace levels (see conclusions in point 3.4) and such products are safe for human health pursuant to Article 3 of CPR and that this safety is properly assessed and demonstrated in the cosmetic product safety report as required by Article 10 CPR.

4. Suggested further steps

Notwithstanding the points made above, seeking the opinion of the SCCS on the safety of CBD and other cannabis-derived ingredients when used in cosmetic products is supported by Member States and could be a possible way forward. The scientific committee could be mandated, in particular, to assess:

- a) the safety of CBD and other cannabis-derived ingredients when used in cosmetic products (including the aggregate exposure to such ingredients from cosmetics);
- b) the level of purity of CBD and other cannabis-derived ingredients that will allow a safe use in cosmetics;
- c) the level of the THC content in various cosmetic ingredients and preparations in terms of safety.

The assessment would focus only on the safety of human health, and it would not prejudice other considerations including any legal qualification of any of these substances as drugs.

The Commission services will revise this Discussion Paper in the light of technical and scientific knowledge and other possible developments in this field while taking under consideration any additional comments and clarifications provided by Member States.

5. Relevant CosIng entries

The Commission is not responsible for assigning INCI names to cosmetic ingredients that appear in CosIng database. In line with the conclusions of this Discussion Paper, few modifications in the CosIng entries are presented below:

- a) There should be only one entry for CBD;

- b) Cannabis extracts should be considered as prohibited substance as it cannot be excluded that they derive from the flowering or fruiting tops from which the resin has not been extracted;
- c) Flower extracts should be considered as prohibited substance if it cannot be excluded that they derive from the flowering or fruiting tops from which the resin has not been extracted;
- Leaf extracts should be considered as prohibited substance if it cannot be excluded that leaves were accompanied by flowering or fruiting tops from which the resin has not been extracted.

	INCI name (as it appears in CosIng database)	Status
1	BEHENYL CANNABIS SEEDATE	
2	CANNABIDIOL - DERIVED FROM EXTRACT OR TINCTURE OR RESIN OF CANNABIS	
3	CANNABIDIOL - SYNTHETICALLY PRODUCED	
4	CANNABIDIOL TRISILOXANE	
5	CANNABINOIDS	II/306
6	CANNABINOL	
7	Cannabis and Cannabis resin; Cannabis sativa, ext.	II/306
8	CANNABIS SATIVA CALLUS CULTURE LYSATE EXTRACT	
9	CANNABIS SATIVA CALLUS EXTRACT	
10	CANNABIS SATIVA CALLUS LYSATE	
11	CANNABIS SATIVA EXTRACT	II/306
12	CANNABIS SATIVA FLOWER EXTRACT	II/306 if resin has not been extracted from flowers
13	CANNABIS SATIVA FLOWER/LEAF EXTRACT	II/306 if resin has not been extracted from flowers
14	CANNABIS SATIVA FLOWER/LEAF/STEM EXTRACT	II/306 if resin has not been extracted from flowers
15	CANNABIS SATIVA FLOWER/LEAF/STEM OIL	II/306 if resin has not been extracted from flowers
16	CANNABIS SATIVA FLOWER/LEAF/STEM WATER	II/306 if resin has not been extracted from flowers
17	CANNABIS SATIVA LEAF EXTRACT	II/306 if leaves were accompanied by flowering or fruiting tops
18	CANNABIS SATIVA LEAF/STEM	II/306 if leaves were accompanied by flowering or fruiting tops
19	CANNABIS SATIVA LEAF/STEM WATER	II/306 if leaves were accompanied by flowering or fruiting tops
20	CANNABIS SATIVA ROOT EXTRACT	
21	CANNABIS SATIVA SEED EXTRACT	
22	CANNABIS SATIVA SEED OIL	
23	CANNABIS SATIVA SEED OIL ETHYL GLYCINATE AMIDES	
24	CANNABIS SATIVA SEED OIL GLYCERETH-8 ESTERS	
25	CANNABIS SATIVA SEED OIL PEG-8 ESTERS	
26	CANNABIS SATIVA SEED OLEOSOMES	
27	CANNABIS SATIVA SEED WATER	
28	CANNABIS SATIVA SEED/STEM OIL	II/306
29	CANNABIS SATIVA SEEDCAKE	
30	CANNABIS SATIVA SEEDCAKE POWDER	
31	CANNABIS SATIVA SPROUT	
32	CANNABIS SATIVA SPROUT EXTRACT	
33	CANNABIS SATIVA STEM EXTRACT	II/306
34	CANNABIS SATIVA STEM POWDER	II/306
35	CANNABIS SEED OIL DIMER DILINOLEYL ESTERS/DIMER DILINOLEATE COPOLYMER	
36	CANNABISAMIDOPROPYL DIMETHYLAMINE	
37	CANNABISAMIDOPROPYL HYDROXYSULTAINE	
38	CAPRYL CANNABIS SEEDATE	
39	CETYLDIMETHYLAMINE HYDROLYZED HEMPSEEDATE	
40	DECYL HEMPSEEDATE	

41	DIOSCOREA BATATAS BULB/LIGUSTRUM JAPONICUM FRUIT/(ANGELICA GIGAS/GASTRODIA ELATA ROOT)/(CANNABIS SATIVA/IMPATIENS BALSAMINA/PAULOWNIA TOMENTOSA/PLATYCLADUS ORIENTALIS SEED)/GLEDITSIA SINENSIS THORN/ACORUS GRAMINEUS/ECLIPTA PROSTRATA/MENTHA HAPLOCALYX/WOLFIPORIA EXTENSA EXTRACT	
42	ETHYL CANNABIS SEEDATE	
43	HYDROGENATED CANNABIS SATIVA SEED OIL	
44	HYDROGENATED HEMP SEED OIL	
45	HYDROLYZED CANNABIS SATIVA SEED EXTRACT	
46	HYDROLYZED HEMP SEED EXTRACT	
47	HYDROLYZED HEMP SEED PROTEIN	
48	HYDROLYZED HEMP SEED PROTEIN HYDROXYPROPYLTRIMONIUM CHLORIDE	
49	ISOSTEARYL CANNABIS SEEDATE	
50	POLY(DIMER HEMPSEED OIL)	
51	POLYGLYCERYL-4 HEMP SEEDATE	
52	POLYGLYCERYL-4 POLYCASTORATE/HEMPSEEDATE	
53	POTASSIUM HEMPSEEDATE	
54	STEARYL CANNABIS SEEDATE	
55	SODIUM HEMPSEEDAMPHOACETATE	

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