

From: [REDACTED]
To: [GROW F2](#)
Cc: [REDACTED]
Subject: SV: point 11b of the Agenda - draft non-paper on CBD - DK comments
Date: vendredi 29 avril 2022 10:55:28
Attachments: [image001.png](#)

Dear Cosmetics Team

The Ministry of Environment of Denmark would like to thank you for the opportunity to provide comments on the draft non-paper on the status of Hemp- and Cannabis-derived ingredients in cosmetics.

We support the drafting of this paper, as this serves to provide more legal certainty as to the use of cannabis-derived ingredients in cosmetics. However, we have some comments.

As a general point, we see that the interest in CBD is increasing. This also means an increase in the economic interests in offering products containing CBD and similar. We are worried that if the legislation regarding CBD and cannabis-derived ingredients is unclear and/or that loopholes and/or grey zones exists between different legislations, such grey zones etc. will be exploited – especially if the cosmetics legislation shows to be less strict in terms of concentration limits, labelling, claims etc. than other legislation. In Denmark, we have already seen attempts to market CBD products as cosmetic products though they should have been qualified as dietary/food supplements or as medicinal products - and possibly also other ways of circumvention of the legislation may happen. Therefore, it is crucial that the legislation on CBD is very clear and is drawn up in a way that prevents circumvention and ensures that the health of consumers are not put at risk. And this is not only to pursue the objective of the CPR, but also the objective of the Single Convention cf. the comments to article 28 of the Single Convention as described on page 7 and 8-9 of the non-paper.

Regarding the non-paper we would like to note that the Court in judgment C-663/18 based its conclusion on whether CBD is to be seen as a drug on the premises that 1) it did not in the specific case appear to have any psychotropic effect or any harmful effect on human health on the basis of available scientific data, 2) that the cannabis variety in the case was grown lawfully in the Czech Republic, and 3) that the THC content in the substance extracted did not exceed 0,2 % cf. paragraph 72. Conversely, this suggests that if one or more of these premises were not met, then the CBD would have been qualified as a drug? And even if it should not be qualified as a drug, the threshold for qualifying a product containing CBD as safe for human health may be different when used in a cosmetic product for cosmetic purposes compared to when used in other products for other purposes, e.g. an electronic cigarette. In addition to this we also note that the Court did in fact not reject that CBD extracted from the Cannabis sativa plant in its entirety could pose a risk to public health; this was for the referring court to assess cf. paragraph 95.

Furthermore, in relation to the non-paper specifically we note the following:

- For cannabinoids other than CBD “only very limited or no data exists concerning their psychoactive properties and harmful effects on human health” and the decisive factor seems to be whether the substance can be confirmed as non-psychotropic. However, it is not clear how to differentiate psychotropic substances from non-psychotropic substances in relation to the use in cosmetic products? E.g. who should make this assessment, how should it be done, what is sufficient documentation etc.?
- For flowers and leaves accompanied by the tops the conclusion is clearly different from the current interpretation of the Single convention, since according to the text in the non-paper, flowers and leaves with tops even for which the resin *has not been extracted* will from now

on not qualify as drugs, if two conditions are met: 1) they are coming from cannabis plant with low levels of psychotropic substances, and 2) are legally cultivated in the Union. Again, it is not clear to us how it should be ensured, assessed and documented whether these conditions are actually met and in particular what level of psychotropic substances is to be qualified as “low”? Furthermore, we note, that the condition concerning the legal cultivation within the Union does not seem to be a requirement in terms of seeds and leaves without the tops. This inconsistency may also give rise to lack of clarity – and at worst: a grey zone/loophole that can be exploited by operators with economic interests at stake. It will also be difficult for the surveillance authorities to control and enforce this condition.

Therefore, to ensure that potential risks for human health have been analyzed and to avoid lack of clarity, legal loopholes and circumvention, it seems that this is a suitable occasion to consult the SCCS on whether CBD and other cannabis-derived ingredients can be safely used in cosmetics cf. article 31 of the CPR. The SCCS should therefore be mandated to assess these substances, and we suggest that the mandate should include assessment of:

- Conditions of use of CBD other cannabis-derived ingredients in cosmetics. For instance it should be investigated whether e.g. CBD can be safely used in products for oral use, taking into account systemic uptake of the substance.
- Level of purity and content of THC in the CBD and other cannabis-derived substances, which should be required in order to assure safe use.

We will be looking forward to discussing this in further detail at the next WG.

Kind regards,

[Redacted]

[Redacted]

Drinking Water and Chemicals

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Sendt: 24. februar 2022 18:27

Emne: point 11b of the Agenda

CIRCABC



You received a new message

As member of the interest group [COSMETICS - Working group on cosmetic products](#) (Category: Internal Market, Industry, Entrepreneurship and SME's), you received the following message.

Message

From the user [REDACTED]

Dear members of the Working Group on Cosmetic Products,

We would like to inform you that a **draft non-paper** concerning point 11b (CBD AND OTHER CANNABIS-RELATED INGREDIENTS) of the agenda has been shared via CIRCABC in view of the upcoming meeting of the Working Group on Cosmetic Products on 1 March 2022.

Please note that this **draft** document presents our **preliminary** views on this matter, while serving as a basis for discussion and reflection.

We would kindly invite you to share your comments on the approach presented in the draft document by the **end of April 2022**.

Kind regards,

The Cosmetics Team

Attachments:

- [Point 11b Draft Non-Paper CANNABIS-derived ingredients.docx](#):

Best regards,
The CIRCABC team
<https://circabc.europa.eu>

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