

From: [REDACTED]
Cc: [REDACTED]
Subject: Hemp and cannabis-derived ingredients - BE comments
Date: mardi 19 avril 2022 12:38:02

Dear [REDACTED] Dear Cosmetics Team,

We thank you for the opportunity to comment on the draft non-paper on the status of hemp and cannabis-derived ingredients in cosmetics (version 01/03/2022).

We understand from the Judgment in Case C-663/18 that **if cannabidiol is considered as a chemical** and not as a plant extract, it cannot be regarded as a 'narcotic drug' and it is not covered by entry 306 of Annex II of the cosmetics regulation.

In this case, the eventual presence of THC would fall under Article 17 of the cosmetics regulation applicable to traces of prohibited substances. The ALARA principle and safety considerations would then trigger a high level of purity.

Concerning claims for cosmetic products containing cannabidiol considered as a chemical, we are of the opinion that they should only be based on cannabidiol as an isolated substance and not refer to plant/cannabis/hemp extracts in order to ensure consistency.

A similar approach could be applied to non-psychoactive cannabinoids other than cannabidiol.

On the other hand, concerning **cannabis extracts**, we would like to point out the following issues:

Chapter 3.4.2. Leaves (not accompanied by the tops):

The flowering tops are defined as follows by the U.S. National Library of Medicine: "Flowering Tops: Tops of plants when in flower, including the stems, leaves and blooms."

In the Glossary of Botanical Terms established by the Council of Europe, flowering tops and fruiting tops are defined as follows :

- Sommité fleurie : Partie terminale florifère d'un végétal
- Sommité fructifère : Partie terminale d'un végétal portant des fruits.

These definitions include also the leaves present on the top of the plant.

Hence, leaves from the tops do fall under the ban foreseen by entry 306 of Annex II of the cosmetics regulation.

Most cannabidiol extracts are produced from the tops, or from the entire plant including the tops. The level of cannabidiol in other plant parts than the flowering or fruiting tops of the cannabis plant is so low that its extraction is far from cost-effective and cannabidiol extracts from these other plant parts are highly unlikely.

Chapter 3.4.3 Flowers (and leaves accompanied by the tops):

We do not share the view that flowers (and leaves with tops) for which the resin has not been extracted but coming from cannabis plant varieties with low levels of psychotropic substances

and are legally cultivated in the Union should not qualify as 'drugs' and as a consequence would not fall under the ban foreseen by entry 306 of Annex II of the cosmetics regulation. From our point of view, entry 306 of Annex II applies independently of cultivation criteria foreseen in Article 28(2) of the Single Convention and of the control regime provided by the Convention for 'drugs'.

The ban of substances included in Annex II is one of the pillars of the cosmetics regulation aiming at ensuring the safety of cosmetic products and applies in addition to the safety assessment of finished products at operators' levels.

The use of cannabis for other purposes is covered by other specific legislations applying independently.

For instance, for food purposes, the novel food regulation is notably applicable and only the following plant parts are considered as not novel: "Some products derived from the Cannabis sativa plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel." The substance cannabidiol itself is currently a non-authorized novel food. Cf

https://webgate.ec.europa.eu/fip/novel_food_catalogue/#

Chapter 3.5 Other hemp and cannabis-derived products:

The description of this category is far too vague to allow for any conclusion on the application of entry 306 of Annex II of the cosmetics regulation.

For cannabis/hemp extracts, only seeds, roots, sprouts and their extracts seem to be clearly and in all cases not covered by entry 306 of Annex II of the cosmetics regulation.

On the other hand, when the resin has not been extracted, extracts from flowering or fruiting tops, extracts from the leaves or stems in the tops and extracts from the whole plant would, from our point of view, fall under the ban foreseen by entry 306 of Annex II of the cosmetics regulation.

If this ban is considered not adequate regarding safety considerations, the opinion of the SCCS should be asked and followed by an adaptation of entry 306 where appropriate.

Kind regards,

Coordinator Food supplements and Cosmetics

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