Call for data on ingredients used in cosmetic products

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This is a call for data on the safety **Cannabidiol (CBD)** in the framework of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

Policy fields

Internal market and industry, public health.

Target

Any interested parties, including academic and other research institutes, EU countries' authorities, manufacturers of cosmetic products, producers of the ingredient concerned, relevant industry and consumers associations.

Period of consultation

From 1 June 2023 to 30 September 2024 (15 months)

Request

The European Commission would like to invite any interested parties, including academic and other research institutes, EU countries' authorities, manufacturers of cosmetic products, producers of Cannabidiol (CBD) and consumers associations, to submit any scientific information relevant to the safety of Cannabidiol (CBD) (CAS No. 13956-29-1, EC No. 689-176-3) in pure form, as well as an extract that my contain contaminants of other cannabinoids, including trans-Δ^9-tetrahydrocannabinol (THC or delta-9-THC) (CAS No. 1972-08-3, EC No. 625-153-6), at trace levels.

Action proposed by the Commission

On 19 November 2020, the Court of Justice of the EU (CJEU) delivered a judgment in Case C-663/18[1] in response to the request for preliminary ruling questioning the conformity with EU law of the French legislation prohibiting the marketing of CBD extracted from the Cannabis sativa plant in its entirety. In 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. The Court considered that CBD is not mentioned in Convention on Psychotropic Substances and such classification would be contrary to the general spirit of that convention and to its objective of protecting '*the health and welfare of mankind*'. In addition, the Court stated that

[1] Case C-663/18, B S and C A, ECLI:EU:C:2020:938

according to the current state of scientific knowledge, unlike THC, the CBD at issue does not appear to have any psychotropic effect or any harmful effect on human health. However, it is not possible to derive from the judgement the purity level of CBD, or the THC content or the level of other relevant substances. In this respect, it is worth highlighting THC and its stereochemical variants are drugs in their own right according to the 1971 Convention on Psychotropic Substances. The Court in the ruling refers to CBD in general, without any other substances included in it, except for impurities. Since the CBD substance is defined and, according to the current state of scientific knowledge, considered as not having psychotropic effect, the presence of THC in CBD may only be residual.

EU Member States and civil society organisations have raised questions about the use of CBD in cosmetic products and the potential risk to consumer's health due to the very limited available information concerning its safety in such products. The Commission intends, therefore, to request the EU Scientific Committee on Consumer Safety (SCCS) to perform a safety assessment on CBD when used in cosmetic products, as well as on the THC content that could be deemed safe at trace levels in finished cosmetic products that contain CBD or other hemp and cannabis-derived ingredients.

In order to prepare a mandate to the SCCS, interested parties are invited to submit, in accordance with the requirements described below, any scientific information relevant for the safety assessment of CBD and the possible non-intended presence at trace levels of other cannabinoids, including THC.

Requirements

We invite you to submit data on all physicochemical properties, toxicokinetics and toxicological endpoints, assessment of exposure through consumer products and/or an indication of the suggested safe concentration levels for CBD and safe trace levels of THC or any other cannabinoid that might be present as a contaminant is such preparations.

Please provide your input with

a) The attached template-checklist
b) A table of contents
c) Numbered references

Data submitted should be in line with the SCCS 'Notes of Guidance' (testing of cosmetic ingredients and their safety evaluation - 12th revision).

How to submit your contribution

Any information should be delivered with the reference: '***Call for data – CBD***' by e-mail to GROW-COSMETICS-CALLS-FOR-DATA@ec.europa.eu by **30 September 2024** at the latest.

Background

Cannabidiol (CBD) is one of the approximately hundred naturally occurring cannabinoids found in *Cannabis* plants and may account for up to 40% of the plant's extract. However, there is no definition of CBD in the Union law applicable to the area of cosmetic products. According to WHO Expert Committee on Drug Dependence (ECDD), CBD 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*'.[2] According to ECDD, CBD is a non-psychoactive cannabinoid that exhibits no effects indicative of any abuse or dependence potential[3]. In addition, ECDD stated that CBD has been found to have relatively low toxicity, stressing nonetheless that not all potential effects have been explored.

There is a high volume of clinical research on cannabidiol including studies related to anxiety, cognition, movement disorders and pain, but there is still insufficient evidence that CBD is effective for these conditions. It is important to note that most EU countries allow, or are considering allowing, the medical use of cannabinoids (including CBD) in some form under specified conditions.

CBD (CAS No. 13956-29-1, EC No. 689-176-3) with the chemical name '2-[(6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol' is included in the European database for information on cosmetic substances and ingredients (CosIng) with the reported functions of 'skin conditioning', 'skin protecting', 'antioxidant', 'anti-sebum', etc.

Currently, CBD as such is not regulated under Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[4] (hereunder referred to as the 'Cosmetics Regulation'). However, entry 306 of Annex II to the Cosmetics Regulation prohibits '*Narcotics, natural and synthetic: All substances listed in Tables I and II of the Single Convention on narcotic drugs signed in New York on 30 March 1961*' for use in cosmetic products.

On 19 November 2020, the Court of Justice of the EU (CJEU) delivered a judgment in Case C-663/18[5] concerning the legal status of cannabidiol. In 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.

However, CJEU added that a legislation limiting the marketing of CBD could be appropriate for securing the attainment of the objective of protecting public health as long as does not go beyond what is necessary for that purpose[6], adding that '*A correct application of the precautionary*

[2] 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

[3] https://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549621036385&uri=CELEX:02009R1223-20180801

[5] Case C-663/18, B S and C A, ECLI:EU:C:2020:938

[6] Paragraph 96.

principle presupposes, first, identification of the potentially negative consequences for health of the proposed use of the substance at issue and, second, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research'[7]. In light of the CJEU ruling and the increasing number of cosmetic products reported to contain CBD, Member State authorities, as well as civil society organisations have expressed their support to assess the safety of CBD and the possible non-intended presence at trace levels of other cannabinoids, including THC.

Considering the very limited available information regarding the safety of CBD in cosmetic products, relevant scientific information should be gathered to enable the SCCS to perform a safety assessment. It should be noted 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 knowledge gaps. 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 concluding: '*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*'[8].

Pursuant to Article 31(1) and (2) of the Cosmetics Regulation, the Commission may, after consulting the SCCS, amend the Annexes to the Regulation for the purposes of adapting them to technical and scientific progress and, where there is a potential risk to human health, arising from the use of substances in cosmetic products. To determine this, relevant scientific information, and data on the safety of Cannabidiol (CBD) (CAS No. 13956-29-1, EC No. 689-176-3), would be required.

Privacy statement

[7] Paragraph 91.
[8] https://www.efsa.europa.eu/en/efsajournal/pub/7322