

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on Cannabidiol (CBD) (CAS/EC No. 13956-29- 1/ 689-176-3) used in cosmetic products

Commission Department requesting the Opinion: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

1. 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 World Health Organisation (WHO) Expert Committee on Drug Dependence (ECDD), CBD as 'a 21-carbon terpenophenolic compound which is formed following decarboxylation from a cannabidiolic acid precursor, although it can also be produced synthetically'. In addition, CBD is considered a non-psychoactive cannabinoid that exhibits no effects indicative of any abuse or dependence potential². Moreover, ECDD stated that CBD has been found to have relatively low toxicity, stressing nonetheless that not all potential effects have been explored.

Furthermore, 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.

'Cannabidiol' (CBD) is also the INCI name of '2-[(6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol' (CAS/EC No. 13956-29-1/689-176-3), which 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 products³ (hereunder referred to as the 'Cosmetics Regulation'). However, entry 306 of Annex II to the Cosmetics Regulation

¹ 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) <u>CANNABIDIOL (CBD) Critical Review Report Expert Committee on Drug Dependence Fortieth Meeting</u>

² https://www.who.int/medicines/access/controlled-substances/5.2 CBD.pdf

³ EUR-Lex - 02009R1223-20180801 - EN - EUR-Lex

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-663/184⁴ 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, the 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 purpose⁵, adding that 'A correct application of the precautionary 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 '6. 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.

Moreover, 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. In particular, on 26 April 2022, EFSA stated: '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'⁷.

Considering the very limited available information regarding the safety of CBD in cosmetic products, and to enable the SCCS to perform a safety assessment, a call for data⁸ to collect relevant scientific information was launched from 1 June 2023 to 30 September 2024. In view of this, the Commission, requests the SCCS to assess the safety of Cannabidiol in cosmetic products.

⁴ Case C-663/18, B S and C A, ECLI:EU:C:2020:938

⁵ Paragraph 96.

⁶ Paragraph 91.

⁷ Statement on safety of cannabidiol as a novel food: data gaps and uncertainties | EFSA

⁸ Call for data on ingredients used in cosmetic products - European Commission

2. Terms of reference

- (1) Taking under consideration the information/data submitted via the respective call for data, the SCCS is requested:
 - (a) to assess the maximum concentration of Cannabidiol that is considered safe when used in cosmetic products;
 - (b) to identify the maximum safe level of Delta- 9-tetrahydrocannabinol (THC) present as a contaminant in Cannabidiol preparations;
- (2) Does the SCCS have any further scientific concerns with regard to the use of CBD and the possible non-intended presence at trace levels of other cannabinoids, including THC, in cosmetic products?

3. Deadline

12 months.

4. Supporting documents

Input from Call for data

→ The SCCS approved this mandate by written procedure on 22 January 2025.