

EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed Section Novel Food and Toxicological Safety of the Food Chain 27 February 2023

CIRCABC Link: <u>https://circabc.europa.eu/ui/group/55b2edd3-069e-40fd-ad4a-8b163f54ff1f/library/72cd2fa8-</u> c961-4aee-82f7-281384f0f74a?p=1&n=10&sort=name_ASC

SUMMARY REPORT

A.01 Statement on cannabidiol as novel food.

At the request of one Member State and in collaboration with the other Member States the Commission presented the following statement on cannabidiol as novel food, which was endorsed by the Committee:

The hemp plant (Cannabis sativa L.) contains more than 100 different cannabinoids, the most common ones being cannabidiol (CBD) and its precursor acidic form cannabidiolic acid (CBD and CBDa respectively), cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabinol and its precursor acid form (Δ 9-THC and Δ 9-THCa respectively).

In its judgment in case C-663/18^[11], the Court of Justice of the European Union concluded that cannabidiol (CBD) should not be considered as a drug within the meaning of the United Nations Single Convention on Narcotic Drugs of 1961^[21] insofar as it does not have a psychotropic effect. The Commission therefore, considers that cannabidiol can be considered as 'food', provided that the other conditions of Article 2 of the General Food Law^[31] are met.

In accordance with Regulation (EU) 2015/2283 (the 'Novel Food Regulation')^[4], foods for which a history of human consumption to a significant degree within the Union before 15 May 1997 cannot be demonstrated, are novel and may not be placed on the market within the Union as such, or used in foods until they have been authorised and included in the Union list of authorised novel foods.

A history of consumption to a significant degree within the EU prior to 15 May 1997 has not been demonstrated for CBD or any other cannabinoids, or products containing either CBD and/or other cannabinoids derived from the Cannabis sativa L. plant. Therefore, with the exception of the THC cannabinoids, they are considered novel foods until acceptable and verifiable evidence to the contrary is provided. The THC cannabinoids are considered as a drug within the meaning of the United Nations Single Convention on Psychotropic Substances of 1971 and can therefore not be considered as "food". In the EU legislation the presence of THC in food is regulated by the legislation on contaminants. The Commission has received over 190 applications for the authorisation of CBD and extracts of Cannabis sativa L. and derived products containing cannabinoids under the Novel Food Regulation. Of these applications, so far 20 have been considered by the Commission to be valid and are currently being evaluated by EFSA. In a statement^[51] of June 2022, EFSA identified several potential hazards and determined that many data gaps relating to possible health effects need to be filled before the evaluations of the safety of CBD and hemp extracts can progress.

At present, there has been no authorisation of CBD, of any other cannabinoids, nor of products containing either CBD and/or other cannabinoids derived from the Cannabis sativa L. plant under Regulation (EU) 2015/2283 on novel foods.

Member States have the primary responsibility for the correct application, implementation and enforcement of EU legislation.

^[1] Judgment of the Court in Case C-663/18 of 19 of November 2020, B S and C A (Commercialisation du cannabidiol - CBD), ECLI:EU:C:2020:938.

^[2] United Nations Treaty Series, vol. 978, No 14152.

^[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1.

^[4] Regulation (EU) 2015/2283 of 25 November 2015 on novel foods. OJ L327, 11.12.2015, p. 1.

^[5] EFSA Journal 2022;20(6):7322