

EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate E - Food and feed safety, innovation **E.2 - Food processing technologies and novel foods**

Brussels, SANTE.E2/RP/amf (2020)5586764

Dear Mr Kozàr,

Subject: The Future of Cannabidiol (CBD)

I refer to your email of 2 September (Ares(2020)4576893 and Ares(2020)4580097) to Ms Bucher, Ms Bury and Ms Chaze who asked me to answer your query regarding the above mentioned subject.

The Commission is aware of the growing market of products containing Cannabis sativa L. extracts and we have taken note of your concerns on this topic.

The elements brought forward in your email will be taken into account by the Commission when drawing its final position.

Insofar as products containing *Cannabis sativa* L. extracts, in particular CBD, would not be considered as medicinal products, the Commission is currently considering their legal status as 'food'. The Commission has received over 50 applications for the authorisation of hemp-derived products, notably CBD (cannabidiol) under the Novel Food Regulation (Regulation (EU) 2015/2283¹). This Regulation applies to foods for which no history of safe consumption of these products before 15 May 1997 can be sufficiently demonstrated. The placing on the market of 'novel foods' is subject to a pre-market authorisation in accordance with the Novel Food Regulation. In the context of such an authorisation procedure, the Commission must verify whether the individual applications fall within the scope of the Novel Foods Regulation and whether the data requirements are fulfilled. This includes a verification of whether the specific products fall within the definition of 'food' laid down in the General Food Law (Regulation (EC) No 178/2002²).

The General Food Law excludes from the definition of 'food', substances that are narcotic or psychotropic as defined by the applicable United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol³ and the United Nations

United Nations Treaty Series, vol. 978, No 14152.

By email to: office@encod.org

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)

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)

Convention on Psychotropic Substances of 1971⁴. It is therefore essential, when considering cannabis-based-foods to verify whether the concerned substances or plant parts can actually be considered foods or not.

Recently, as a result of this verification, doubts arose as regards the possible qualification of CBD and other cannabinoids as 'food'. Although cannabidiol and other non-psychoactive cannabinoids that can be obtained from the Cannabis sativa L plant are not explicitly mentioned in the schedules of the International Drug Control Conventions, they are, in the Commission's preliminary view, covered by the description of the production method laid out in Schedule I of the Narcotics Convention (i.e. "extracts and tinctures of cannabis"). It follows that cannabidiol and other non-psychoactive cannabinoids, when extracted from "cannabis", would have to be considered as substances falling within the scope and under the control mechanisms of that Convention and therefore qualify as "drug" thereunder. In that case, such substances cannot be regarded as food pursuant to Article 2(g) of Regulation (EC) 178/2002.

The Commission has informed the applicants having requested an authorisation for such products under the Novel Food Regulation of its preliminary views. It invited them to provide comments within two months after receipt of the request. The Commission will consider the comments and arguments provided and take a decision on the validity of the concerned applications afterwards. This assessment is complex and still ongoing. We are unfortunately unable for the moment to predict when a final position will be taken.

Yours sincerely,

[e-signed]

Bruno Gautrais Head of Unit

2

⁴ United Nations Treaty Series, vol. 1019, No 14956