Cannabidiol: a trendy substance in a fuzzy regulatory landscape

This article was first published by EU Food Law on March 19, 2019. Marketing Cannabidiol (CBD) in the EU has become more complex and, in some cases, is subject to national restrictions.

Shops selling products containing Cannabidiol (CBD) are popping-up across Europe drawing more and more attention on the legality, write Katia Merten-Lentz and Manon Ombredane of international law firm Keller & Heckman.

Cannabis sativa L is a well-known plant made up of more than 480 compounds, including over 100 cannabinoids composed of both psychoactive and non-psychoactive compounds[1] including CBD. CBD contained in food products like tinctures is often derived from the industrial hemp variety cannabis sativa L. which contains low level of Delta-9-tetrahydrocannabinol (THC)[2] (<0,2%).

Setting aside the question of the classification of cannabis under International Drug Control Conventions[3] and the possible safety issue related to the presence of THC, food containing CBD must - as any other foodstuff - comply with the food legislation. This includes Regulation (EU) 2015/2283 on novel foods[4] as well as the general principle set out under the General Food Law[5] according to which food must not be unsafe[6]. Novel foods catalogue modified What recently caught the attention of national authorities across Europe, as evidenced by the multiplication of RASFF notifications, is the European Commission decision to modify the Novel Food catalogue. In a recent meeting of the European Commission’s Working Group on Novel Food, the European Commission and the Member States agreed to modify the entries related to cannabis sativa L, cannabidiol and cannabinoid in the Novel Food catalogue in a tentative to clarify the regulatory landscape for food products containing CBD.

Accordingly, the new entry for Cannabis Sativa L. is now clearly stating that:

“In the European Union, the cultivation of Cannabis sativa L. varieties is permitted provided they are registered in the EU’s ‘Common Catalogue of Varieties of Agricultural Plant Species’ and the tetrahydrocannabinol (THC) content does not exceed 0.2 % (w/w). 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. Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities”

In parallel, the new entry for “Cannabinoids”[7] provides that:

“The hemp plant (Cannabis sativa L.) contains a number of cannabinoids and the most common ones are as follows: delta-9-tetrahydrocannabinol (&Delta;9-THC), its precursor in hemp, delta-9-tetrahydrocannabinolic acid A (&Delta;9-THCA-A), delta-9-tetrahydrocannabinolic acid B (&Delta;9-THCA-B), delta-8-tetrahydrocannabinol (&Delta;8-THC), cannabidiol (CBD), its precursor in hemp cannabidiolic acid (CBDA), cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabivarin (&Delta;9-THCV). Without
Generally, a food which has not been used for human consumption to a significant degree within the Union before 15 May 1997 and which falls within the categories set out under Article 3(2)(a) of the Regulation (EU) 2015/2283 on novel foods must be subject to a risk assessment and authorization prior to the placing on the EU market. During a previous meeting of the Working Group on Novel Foods, the European Industrial Hemp Association (EIHA) was invited to present arguments supporting the fact that hemp extract containing CBD should not be considered novel, notably based on its history of safe use in the EU. But, following the meeting, it seems that none of the EIHA arguments could convince the European Commission and the Member States to consider hemp extract containing CBD as not novel.

Accordingly, the way forward for business operators decided to sell hemp extract and derived products containing CBD in the EU is to go through the Novel Food procedure set out under Regulation (EU) 2015/2283. To this date, only one dossier has been submitted to the European Commission aiming at supporting the safety of cannabidiol as novel food in food supplements for adults at a daily intake of up to 130mg or 1.86mg/kg. Member state differences On the other side, for products that may contain CBD such as “seed oil” but which are not novel due to their history of consumption in the EU, the placing on the EU market is not simple as well. As pointed out under the entry for Cannabis sativa L., “other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States.”

This is for instance the case in Belgium that restricts the marketing of food derived from Cannabis Sativa L. The plant is listed in the List 1 “Hazardous plants that cannot be used as or in foodstuffs” of the Royal Decree of 29 August 1997 on the manufacture of and trade in foodstuffs composed of or containing plants or plant-based preparations.

Hence, even though the recent modification of the Novel Food catalogue may have brought some clarity regarding the novel food classification, business operators wishing to market CBD on the EU market must avoid other pitfalls and notably, they must pay attention to possible national restrictions that may apply to food products derived from Cannabis sativa L.


[2] Main psychoactive constituent of cannabis

[3] In this respect, the World Health Organization recently recommended rescheduling cannabis and its chemical components under international drug treaties.


[7] The entry for CBD refers to the entry “cannabinoids”

[8] E.g. food consisting of, isolated from or produced from plants or food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances.

[9] Held on 16 October 2018

[10] EIHA presentation is available at:
http://eiha.org/media/2019/01/18-10-16_NF-WG-EIHA-Presentation-Released-final.pdf