

Media information

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EIHA versus BVL: Cannabidiol (CBD) not necessarily subject to registration as a novel food

- The European Industrial Hemp Association (EIHA) has successfully taken action against publication of the Federal Office of Consumer Protection and Food Safety (BVL)
- CBD-containing products are not generally covered by the Regulation for novel foods subject to authorisation
- In the opinion of the Federal Government and the Federal Ministry of Food and Agriculture (BMEL) only CBD isolates and CBD-enriched hemp extracts are obviously novel

Brussels / Cologne - The European Industrial Hemp Association (EIHA) has achieved a groundbreaking success in the discussion about the generally permissible trade and sale of CBD-containing products. According to the report, the German Federal Government and the Federal Ministry of Food and Agriculture (BMEL) have clearly endorsed the view of the EIHA: Foodstuffs containing parts of the hemp plant are in principle not "novel" foods within the meaning of Regulation (EU) 2015/2283. However, this does not automatically also apply to isolated CBD (cannabidiol) or extracts enriched with CBD "Thus, hemp food products made from traditionally produced extracts with the natural full spectrum of the cannabinoids contained in the hemp plant are not novel foods. For the German hemp food industry this statement by the government and the ministry is an important milestone", says Daniel Kruse, President of the EIHA.

The controversy was triggered by a publication of the Federal Office of Consumer Protection and Food Safety (BVL) on its homepage on the subject of "Food supplements with cannabidiol (CBD)" of 20.03.2019 (source: www.bvl.bund.de):

"The BVL is currently not aware of any case in which cannabidiol (CBD) could be found in foodstuffs, i.e. also in food supplements."

The BVL will continue to publish information on its homepage at another location:

"In the view of the BVL, for products containing CBDs, either an application for authorisation of a medicinal product or an application for authorisation of a novel food must be submitted before the products are placed on the market. In the context of these procedures, the safety of the product shall be demonstrated by the applicant."

The EIHA considers the above general assessment made by the BVL regarding the alleged lack of marketability of food supplements containing CBDs to be factually and legally incorrect and inaccurate. From the point of view of the EIHA, this assessment by the BVL would mean that all hemp foodstuffs would fall under the Novel Food Regulation and would therefore be subject to authorisation.

"This is so not right. CBD is a completely natural, non-psychotic ingredient of industrial hemp and has been consumed for thousands of years via the hemp seeds, flowers and leaves and processed into high-quality food, including through traditional extraction techniques," says EIHA President Kruse. "The BVL must differentiate between extracts with the natural full spectrum of cannabinoids contained in the hemp plant on the one hand and products enriched with isolates or with cannabinoids on the other. Otherwise there will be even more uncertainty for the hemp food industry and consumers in Germany".

The BVL does not take the following facts into account in the generalised statements made so far:

- Cannabidiol (CBD) is a natural substance contained in the crop *Cannabis sativa* L., which is from EU-certified cultivation and which has always been and still is mainly found in the flowers and leaves of this plant, along with other cannabinoids.
- The aforementioned plant *Cannabis sativa* L. ("hemp") and its parts, namely its seeds as well as its processed flowers and leaves, are, in the opinion of the Federal Government, "foodstuffs" within the meaning of Section 2(2) of the LFGB in conjunction with Article 2 of Directive (EU) 178/2002 and thus not medicinal products and therefore do not require a marketing authorisation as medicinal products.
- The consumption of CBD-containing parts of the plant *Cannabis sativa* L., in particular hemp leaves or flowers or their extracts, was already taking place to a considerable extent within the EU or its member states before the Novel Food Regulation came into force on 15.05.1997. Therefore, cannabis products containing CBDs are not "novel" and therefore do not require prior authorisation under Article 6 of Regulation (EU) 2015/2283 (so-called "Novel Food Regulation").
- Plant products containing CBD can therefore be marketed both as foodstuffs and as food supplements.

EIHA contradicts BVL

EIHA has written to the Federal Office of Consumer Protection and Food Safety (BVL) and submitted two written communications from the EU Commission to the companies inquiring about this, dated 2.3.1998 and 3.3.1998, in which the EU Commission, after consulting its Standing Committee on Foodstuffs, had already declared that:

"...it has been decided that foods containing parts of the hemp plant [such as hemp leaves and flowers - author's note] are not covered by Regulation (EC) No 258/97 on novel foods and novel food ingredients."

According to the EIHA, therefore, only "isolates" or "enrichments" of cannabidiol or other cannabinoids can be considered "novel" within the meaning of the Novel Food Regulation. Not novel, however, are those hemp food products that are made from traditional hemp flower/leaf extracts that contain the natural full spectrum of cannabinoids contained in the hemp plant, including the cannabinoid cannabidiol (CBD).

Insofar as the BVL does not distinguish in its online publication between "natural cannabinoids contained in the full spectrum of the hemp plant" on the one hand and "isolates" or "enrichments" of cannabinoids on the other hand, this blanket statement by the BVL of 20 March 2019 is factually incorrect and misleading.

The BVL had admitted in its reply to EIHA that hemp leaves or flowers (which thus contain natural cannabinoids such as CBDs) had in fact been used as an ingredient in foodstuffs before the Novel Food Regulation came into force, and this also included use in the form of extracts.

However, there has been no change to BVL's previous publication (as of February 24, 2020, 7:00 p.m.):

https://www.bvl.bund.de/SharedDocs/FAQ/DE/02_Unternehmer/01_Lebensmittel/03_FAQ_Hanf_THC_CBD/00_FAQ_Cannabidiol_CBD.html

Federal Government confirms EIHA's view

In the meantime, EIHA had also directly contacted the Federal Government in Germany - specifically the Federal Ministry of Food and Agriculture (BMEL) - and criticised this blanket and undifferentiated publication by the BVL, attaching the above-mentioned decisions of the EU Commission and other evidence of the traditional use of hemp as a foodstuff before 15 May 1997.

The Federal Government then declared the following in response to an inquiry by the FDP parliamentary group in the German Bundestag on 25.07.2019 on the question of the novelty of food containing hemp

"The opinions of the European Commission, which confirmed that foods containing parts of the hemp plant are not novel foods, remain valid.

However, it cannot be concluded from them that all products of the hemp plant, including for example isolated individual substances such as cannabinoids or extracts enriched with cannabinoids, would be marketable as foodstuffs.

(see printed matter 19/11922 of the German Bundestag dated 25.07.2019)

From this, it is clear that, in the view of the German Government, cannabinoids from the hemp plant are now only considered to be a 'novel food ingredient' if they are used in isolation or fortified.

Similarly, in a letter of 19.11.2019 to EIHA on this subject, the BMEL also only stated that ...

" that, according to the information available to the Commission, there is still no evidence of significant consumption of cannabidiol (CBD) enriched hemp extracts in the EU before 15 May 1997. On the contrary, according to available information, such products have only recently become available on the market.

According to the unanimous opinion of the European Commission and the EU Member States, hemp extracts enriched with CBD are thus foodstuffs requiring authorisation, provided they are not narcotics or medicinal products".

(see letter from the BMEL to the legal representative of EIHA dated 19 November 2019)

The Federal Government has thus distanced itself from the previous blanket publication of the BVL, which was criticised by EIHA, and at the same time has clearly endorsed the view of EIHA. EIHA sees this as an important success for its pan-European members and for the hemp food industry operating on the German market.

Conclusion

It should therefore be noted that the Federal Government in Germany is sticking to the earlier findings and decisions of the EU Commission, according to which foods containing parts of the hemp plant, such as hemp leaves and hemp flowers, are not covered by Art. 2 of Regulation (EU) 2015/2283 on novel foods and novel food ingredients.

The same applies also, as far as these foods contain the natural full spectrum of natural cannabinoids contained in the hemp plant, to which among others the cannabinoid cannabidiol (CBD) belongs.

However, if foods contain "CBD isolates" or "CBD-enriched hemp extracts", they are considered "novel foods" according to Art. 2 of Regulation (EU) 2015/2283 and are subject to authorisation.

It now only remains to be seen whether the BVL will finally amend and correct the content of its previous blanket and undifferentiated publication on this topic of 20.03.2019, which has already led to avoidable irritation and legal errors on the part of many state and local authorities, as well as in some cases individual courts in Germany. It also remains to be seen whether the BVL will now agree to a meeting of experts, which EIHA has already requested several times.

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About the European Industrial Hemp Association

The European Industrial Hemp Association - EIHA for short - is the European association of the hemp-processing industry with around 130 members in over 30 countries. EIHA, based in Brussels (Belgium), represents the interests of industrial hemp producers and traders at pan-European and national level. The industrial hemp sector includes the cultivation and processing of hemp fibres and seeds and cannabinoids.

The *International Conference of the European Industrial Hemp Association*, which has been held annually in Cologne since 2003, is one of the largest conferences on the subject of commercial hemp worldwide.

More at www.EIHA.org