

Cannabidiol in food and cosmetics



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Introduction

The marketing of cannabidiol (CBD) extracts as food supplements is a relatively new trend and CBD is increasingly common in the food and beverage sector (eg, in sweets, cakes and beer). Hemp contains approximately 60 cannabinoids, including the psychotropic tetrahydrocannabinol (THC) and the non-psychotropic CBD. Although there are no long-term studies on how it affects health, experts have argued that CBD can have anxiolytic, neuroprotective, anti-psychotic, anti-inflammatory and anti-spasmodic effects.

While there are signs of greater liberalisation with respect to hemp use internationally, the Austrian government has resisted this trend. Under the Controlled Substances Act and the Controlled Substances Regulation, only cannabis resin and cannabis inflorescence and infructescence with a THC concentration of more than 0.3% THC qualify as narcotics. The active substance THC may be used in pharmaceuticals, whereas the use of the hemp blossom as a drug is not permitted. The other parts of hemp plants – such as seed, leaves and cannabinoids contained therein (except for THC) – do not qualify as narcotics.

Decree

In October 2018 the Ministry of Labour, Social Affairs, Health and Consumer Protection published a decree⁽¹⁾ outlining its legal opinion on product regulations which prohibit CBD use in food and cosmetics. While such decrees are only internal administrative instructions, the ministry published this decree in a press release and on its website for public effect.

According to the decree, products derived from the inflorescence and infructescence of certain hemp species are excluded from narcotics legislation if:

- their THC content does not exceed 0.3%; and
- the production of narcotics in a concentration that could be misappropriated in a simple or economic manner is impossible.

The ministry generally considers extracts containing cannabinoid used in food (primarily in food supplements such as CBD oil) as novel food (as set out in EU Regulation 2015/2283) and thus not marketable, since there is no marketing authorisation for such products.⁽²⁾ Both the Community code relating to medicinal products⁽³⁾ and the Austrian Act on Medicinal Products⁽⁴⁾ determine whether a product is considered a medicinal product by distinguishing between medicinal products by function and medicinal products by presentation.

A 'medicinal product by function':

- significantly influences human physiological functions through a pharmacological effect in connection with the prevention or treatment of a disease; or

- has a medical therapeutic benefit.(5)

According to the ministry, the data obtained from a recent PubMed study on the application of CBD is insufficient to assess any therapeutic effect therein. Therefore, CBD is not considered a medicinal product by function. Further, extracts which contain CBD are considered medicinal products if preventive, healing or remedial properties are attributed to such products in advertising (ie, medicinal products by presentation).(6) Therefore, the ministry prohibits the marketing of food products containing CBD.

In respect of the use of cannabis sativa L and its extracts in cosmetics, the ministry refers to Article 14(1)(a) in connection with Appendix II(306) of the EU Cosmetic Products Regulation (1223/2009). Article 14(1)(a) prohibits the use of the substances listed in Appendix II. Appendix II lists 'natural and synthetic narcotics', which are defined as any substance listed in Schedules I and II of the Single Convention on Narcotic Drugs 1961, including cannabis and its extracts. Therefore, the ministry also prohibits the marketing of cannabis and its extracts in cosmetics.

Comment

The ministry's apodictic qualification of CBD products as novel food and medicinal products by presentation is questionable.

While the EU Novel Food Catalogue(7) qualifies extracts of cannabis sativa L and derived products containing cannabinoids as novel foods (as a history of consumption has not been demonstrated), the hemp plant (cannabis sativa L) itself is qualified in the catalogue as follows:

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 plants species and the THC content does not exceed 0,2 %. 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.

Contrary to the ministry's decree, cannabis sativa L and seeds, seed oil, hemp seed flower and defatted hemp seed are not novel. The oil obtained from the hemp plant by cold pressing the seeds naturally contains low levels of CBD. Numerous foods which contain hemp and CBD (eg, teas, oils and flour) are not novel and therefore are not subject to the novel food regulation. They are also not medicinal products by presentation, provided that no preventive, healing or remedial properties have been attributed to products containing these ingredients (eg, hemp oil or hemp seed oil derived from the hemp plant); thus, they can be marketed as food supplements.

Further, the assessment of the use of CBD in cosmetics is questionable. Contrary to the impression created by the decree, the EU Cosmetic Products Regulation contains no general prohibition on CBD use in cosmetics. Irrespective of its source, CBD *per se* is not listed in the schedules of the Single Convention on Narcotic Drugs; however, the schedules list cannabis and cannabis resin, extracts and tinctures. According to the convention, CBD in cosmetic products is prohibited only if it is prepared from cannabis resin, extract or tincture.

Therefore, rather than providing legal certainty, the ministry's decree merely reflects headlines relating to the government's narcotics programme ("prohibition of the sale of hemp seed and hemp plants" and "tightening of certain provisions in the narcotics act").

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Endnotes

(1) BMASGK-75100/0020-IX/B/16a/2018.

(2) An application to use CBD extract in food supplements has been pending since 2016.

- (3) Directive 2001/83/EC.
- (4) BGBl 185/1983, as amended.
- (5) ECJ C-358/13 and ECJ C-181/14.
- (6) In the absence of a marketing authorisation, such products may not be marketed.
- (7) ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm#

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