INTRODUCTION

As more jurisdictions around the world move to legalize various forms of cannabis, including hemp and CBD products, recreational marijuana, and medical marijuana, the global cannabis industry continue to blaze forward. But changing and even inconsistent laws and an evolving regulatory environment have created legal uncertainties and tensions in the development of the industry and marketplace. This booklet aims to provide practitioners a summary reference for cannabis laws and regulations in various jurisdictions across the globe. Practitioners should note that because cannabis laws are quickly evolving, through the legislative process, ballot initiatives and regulatory rule implementations and changes, each jurisdiction's most recent cannabis laws and regulations should be reviewed and assessed.

A QUICK PRIMER ON CANNABIS BASICS

Cannabis vs. Marijuana vs. Hemp

Cannabis refers to a genus of plants that has three species – indica, sativa, and redueralis. Marijuana and hemp are both cannabis. Despite popular misconception, marijuana and hemp are not different species of cannabis.

Marijuana, in the common parlance, is cannabis that, when consumed, results in a "high." The "high" in marijuana is produced as a result of high tetrahydrocannabinol or THC content. Hemp, again in common usage, does not cause intoxication because it has low levels of THC.

INTRODUCTION

Some jurisdictions around the world still do not distinguish between marijuana and hemp. For example, for decades, the federal government in the U.S. did not distinguish between hemp and marijuana or the level of THC content in either – both were illegal cannabis and a controlled "Schedule I" drug.

As cannabis laws and policy have changed over the years, now, in the U.S. and, as applicable, in other jurisdictions, the legal difference between marijuana and hemp is often based upon THC content level. In the U.S., again by way of further example, the Agriculture Improvement Act of 2018 defines legal hemp as "Plant Cannabis sativa L. and any part of that plant, including cannabinoids with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." Thus, under federal law in the U.S., cannabis that has no more than 0.3% THC is legal hemp, but cannabis that contains more than 0.3% remains illegal marijuana. Each jurisdictions' definitions for each should, of course, be consulted to determine whether hemp and marijuana are distinguished from one another and where the lines of cannabis legality or illegality are drawn.

THC vs. CBD

THC and CBD are both cannabinoids found in cannabis. A cannabinoid is a naturally occurring compound that reacts with cannabinoid receptors found in our nervous system that are part of our endocannabinoid system, involved in appetite, mood, and sensing pain.

As noted, THC is a psychoactive cannabinoid in marijuana that produces a "high." CBD, or cannabidiol, is a non-psychoactive cannabinoid that may have some health benefits. But more studies are needed. CBD can be derived or extracted from hemp and marijuana. Many CBD products are derived from hemp, containing low levels of THC and higher levels of CBD. Whether CBD or CBD products are legal in any particular jurisdiction will be driven by legal definitions and parameters established by applicable regulatory authorities.

GERMANY

Rittershaus

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Germany?

a) Cannabis as a narcotic

In Germany, all plants and parts of plants belonging to the cannabis species are classified as narcotics and are therefore subject to the regulations of the German Narcotics Act (BtMG). The same applies in principle to synthetic cannabinoids, which are an essential substance group of the new psychoactive substances. This classification is based on the UN Single Convention on Narcotic Drugs of 1961, which means that all handling of cannabis and cannabinoids in Germany is generally subject to the BtMG.

1. Consumption of Cannabis

The German regulatory framework for the use of cannabis seems in a certain way paradoxical. The consumption as such is not a criminal offence, but this is practically irrelevant, since according to §§ 29, 29a BtMG both the acquisition and the possession – as necessary intermediate stages for the consumption – are subject to criminal punishment.

However, the BtMG provides for some exceptions for consumers of cannabis:

(1) In the case of minor violations, a court may, pursuant to § 29 para 5 BtMG or § 31a BtMG, refrain from imposing a criminal penalty if the offence is committed for personal consumption in small quantities. The limit for small quantities of hashish or marijuana is 0.045g of THC. However, such decision by the court is discretionary. Usually, no penalty is then imposed on first-time offenders and occasional consumers who have not previously committed other criminal offences.

(2) In addition, according to § 31 BtMG, the court can mitigate the penalty or refrain from punishment if the offender voluntarily assists in the investigation or the prevention of further offences (leniency programme).

(3) Finally, according to § 37 BtMG, punishment can be waived if the drug-addicted offender has voluntarily undergone therapy.

2. Economic Use of Cannabis

Since all plants and parts of plants of the cannabis species are classified as narcotics in Germany, the cultivation and production of, as well as any trade in, cannabis products is a criminal offence under §§ 29, 29a BtMG. In this context, the term "trading" is interpreted broadly by the courts and covers any activity directed at the sale of narcotics, even if it is only occasional, one-time or exclusively mediatory in nature.

With the passing of the so-called "Cannabis Law" in March 2017, the legal framework for the marketing of cannabis in Germany was somewhat liberalised and the use of the cannabis plant for certain medical purposes was legalised. In the following cases the classification as narcotic and thus the criminal liability was abolished:

(1) For the seed, provided that it is not intended for illegal cultivation (BtMG Annex 1 Cannabis lit a)).

(2) For products in which the content of tetrahydrocannabinol (THC) does not exceed 0.2%, provided that the trade of these products (with the exception of cultivation) is exclusively for commercial or scientific purposes, which excludes the purpose of intoxication (BtMG Annex 1 Cannabis lit b)).

However, the scope of this exemption is discussed controversially in Germany. The (still) predominant opinion holds that such commercial or scientific purpose must exist not only on the part of the seller, but also on the part of the end user. When selling products with low THC content, it must therefore be ensured that the buyer processes this product and ultimately manufactures a harmless product, such as rope, paper or textiles. Such commercial purpose does not exist when cannabis products made from industrial hemp are sold to end users for consumption.

According to this opinion, this exemption provision is only intended to develop the market potential of hemp as raw material and its potential uses for industrial and possibly energetic purposes and not to supply the population with low-THC-content preparations for personal consumption, and especially not to soften the general legal ban on cannabis.

Although according to the wording of the statute and the (still) prevailing opinion this constitutes a criminal offence, many low-THC-content cannabis products, especially cosmetics, are now also sold to consumers in Germany on the basis of the aforementioned exemption. In practice, a kind of legal grey area has been established where these transactions are tolerated by the authorities. However, there are also increasing voices that want to generally allow the distribution of low-THC-content cannabis and cannabinoid products on a secure legal basis.

(3) For cannabis plants, if they are planted as protective strips beet plants and destroyed before flowering (BtMG Annex 1 Cannabis lit c)).

(4) For cannabis plants the cultivation of which exclusively uses certified seed of varieties listed in the joint catalogue of agricultural plant species (useful hemp) referred to in article 9 of Delegated Regulation (EU) No 63912014 on 15th March of the year of cultivation (BtMG Annex I Cannabis lit d)).

(5) For cannabis plants from a cultivation that is used for medicinal purposes under state control according to articles 23 and 28 para 1 of the 1961 Single Convention on Narcotic Drugs, as well as in preparations that are authorised as finished medicinal products (BtMG Annex 1 Cannabis lit d)).

However, irrespective of the exceptions described above, the cultivation of cannabis plants in Germany always requires governmental authorisation. Only the cultivation of cannabis by an agricultural enterprise according to para (4) above is subject only to notification.

b) Food

3. Foods with Added Cannabis (with low THC content)

There also exists controversy on the question whether the distribution of food and beverages produced by using ingredients with a THC content of less than 0.2% is permissible or banned under the BtMG, so the legal situation in this respect is unclear as well.

According to one opinion, the distribution of food or beverages made with hemp with a THC content of less than 0.2%, such as bakery and pasta products, confectionery, sausages, dairy products, tea mixtures, lemonades, beer etc is only permitted if the end consumer purchases the product for a commercial or scientific use and not for consumption. As a consequence, the sale of such products for purposes of consumption would always be prohibited and, at least formally, even subject to criminal punishment.

According to the opposing opinion, trade in food products containing cannabis is permitted if the processing has resulted in a "harmless product", which excludes the possibility of abuse for intoxication purposes. The assessment of whether a product is “harmless” is based on the following thresholds issued by the Federal Office of Consumer Protection and Food Safety (BVL):

- 5µg/kg THC for alcoholic and non-alcoholic beverages
- 5000 µg/kg THC for edible oils
- 150 µg/kg THC for all other foods

If these thresholds are adhered to, the cannabis-containing products are harmless, since an abuse for intoxication purposes can be excluded and the consumption does not pose any health risk. In this case, food containing hemp ingredients is subject to the exemption of the BtMG and not subject to criminal law, but only governed by food law. However, this question has not yet been finally decided in Germany.

Apart therefrom, it is clearly permissible to distribute food only containing or made from cannabis seeds, as these are not subject to BtMG.

4. Food with added CBD

According to the EU Commission and the competent authorities of the EU member states, foods and food ingredients containing extracts of Cannabis sativa L. and derived products (CBD) generally fall within the scope of Regulation (EU) 2015/2253 Novel Food Regulation (NFR) as novel foods. Whether or not a product fulfils the requirements to be classified as a novel food under Article 3 para 2 lit a and therefore subject to authorisation must be determined by the respective manufacturer in each individual case. CBD is not classified as a novel food or novel food ingredient if the substance has been used for human consumption to a significant extent within the EU before 15th May 1997 or the substance has a history of use as a safe food in the EU.

In their decisions rendered so far, German authorities have always classified CBD products as a novel food. Currently, a number of applications for approval under the Novel Food Regulation are pending before the EU Commission. In this context, the European Industrial Hemp Association (EIHA) has commissioned the scientific studies necessary for such applications, which must prove the safety of CBD-containing products on behalf of all its members, since the costs of such studies are prohibitively expensive for the individual applicant.

Surprisingly, in June 2020 the EU Commission issued a preliminary assessment that products containing CBD should generally be classified as narcotics or pharmaceuticals and would therefore not be marketable as food. This would be a severe blow for the European hemp industry. However, a final decision is still pending.

c) Hemp as Tobacco Substitute

The production of cigarettes, cigars, tobaccos, inhalants or incense sticks made from cannabis for distribution to end consumers for purposes of consumption is always subject to the provisions of the BtMG, as the consumer does not pursue any economic purpose that excludes abuse for intoxication purposes.

d) Medicines

1. With Added Cannabis

In Germany, drugs are defined and regulated by the German Medicines Act (AMG) as substances that are intended to cure or prevent diseases. Cannabis can be used both in finished medicinal drugs and in drugs individually produced by pharmacies. For these individually produced medicinal drugs, as long as the main manufacturing steps of the

individual drugs are carried out by a pharmacy, no manufacturing authorisation or drug approval is required.

However, in any case the customer or patient needs either a medical prescription or a special permit to obtain such drugs.

2. Medical Prescriptions

A physician may only prescribe cannabis as a medicinal drug if he has concluded, based on his own examination, that its use is permissible and necessary according to the recognised rules of medical science. The prescription must be made in the context of medical treatment, must be medically indicated and may not be made if the intended purpose can be achieved by other means, for example by therapy with a drug that is not a narcotic. Otherwise, a medical prescription of narcotics such as cannabis is not permitted. According to § 13 para 2 sent 1 BtMG, prescription narcotics may only be dispensed in pharmacies and only on presentation of a special medical prescription for narcotics.

3. Exemption

Another possibility for the legal acquisition of cannabis as a medicinal drug is to obtain an exemption for acquisition or self-cultivation. This may only be granted for a purpose in the public interest, which may also be the therapy of an individual, if this is indicated from a medical point of view and if this indication is confirmed by a public health officer. Such an exemption is not possible, however, if the illness of the person concerned can be treated with a similarly effective prescription drug. Finally, the applicant for such exemption must prove he has necessary expertise and reliability.

bb) Medicinal Drugs with Added CBD

The Committee of Independent Experts on Prescription Medicinal Products has determined that CBD has a number of pharmacological effects and should therefore be classified as a medicinal drug. As a result, CBD was included in Annex 1 of the German Drug Prescription Ordinance (AMVV) in October 2016, which, however, only regulates the dispensing and not the general classification of the drug. The classification of products with added CBD must therefore be made by the competent state authorities on a case-by-case basis. Currently, there are only two products on the market in Germany that contain cannabinoid-based active ingredients.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Germany?

See question 1

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Germany?

See question 1

4. Which body is responsible for legislative controls relating to CBD?

The responsibilities of the various authorities depend on the nature of the products with added CBD.

In Germany, the Federal Opium Agency (BOPST) which is part of the Federal Institute for Drugs and Medical Devices (BfArM) is responsible for issues related to CBD as a medicinal drug.

The enforcement of regulations for food and food supplements in Germany is basically the task of the respective competent authorities of the federal states. However, these authorities work closely with the Federal Office of Consumer Protection and Food Safety (BVL).

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Germany?

a) CBD as a Medical Device?

An extremely creative but dubious option to market CBD products without Government approval is currently used by the Hamburg-based manufacturer LeafPharma, which classifies its product as a medical device.

Unlike medicinal products, medical devices achieve their main effect primarily by physical means and have no significant pharmacological, immunological or metabolic effect.

The manufacturer LeafPharma explains its classification of over 50 CBD products as medical devices as follows: "Thanks to our unique manufacturing process, the substance acts remotely through electromagnetic waves and triggers a purely physical impulse without chemically binding to the receptor. Once the signal receiver has reacted to the

electromagnetic waves, a conformational change takes place so that no more substances can dock. Consequently, only a physical effect takes place".

However, this is heavily criticised, especially by pharmacists, and described as dubious. It is also extremely doubtful whether this classification would stand up to judicial review.

b) Cosmetics

The use of CBD in cosmetics is currently experiencing a real hype, with consumers able to purchase numerous CBD oils, creams and lotions both online and in a number of physical stores mainly in major cities.

From the perspective of narcotics law, both the seeds and the other components of the cannabis plant can be used for the production of cosmetics, as long as the cannabis plants used for this purpose either originate from a cultivation with certified seeds or their THC content does not exceed 0.2 %. In addition, unlike food or beverages, cosmetics cannot be abused for intoxication purposes, so they are generally considered to fall under the exemption of the BtMG.

From a regulatory point of view, according to Article 14(1)(a) of Regulation (EC) No 1223/2009, cosmetic products may not contain narcotics as defined in Tables I and II of the Single Convention on Narcotic Drugs. These are e.g. cannabis, cannabis resin, extracts and cannabis structures, but not cannabis seeds and leaves, as long as they are not accompanied by the flowers.

Thus, cannabis seeds can be used for cosmetics regardless of their origin, but the leaves and stems can only be used if the cannabis plants either originate from cultivation with certified seeds or if their THC content does not exceed 0.2 %.

For advertising claims relating to cosmetic products, the requirements of Regulation (EU) No. 655/2013 must be taken into account. According to this regulation, such claims must be substantiated by sufficient and verifiable evidence and must not advertise properties beyond the proven effects. Since the cannabis plant and its effects are still quite unexplored in many areas, restraint is therefore required, especially in connection with the advertising of the supposed numerous positive effects in the field of personal hygiene, and in particular statements on health-related topics should be avoided.

c) Other use (e.g. as a fragrance, aroma or similar)

Products with CBD added can also be sold as unregulated products, e.g. as a fragrance or flavouring that is explicitly not intended for consumption. The distribution of these products is permitted if the THC content is below 0.2%.

d) European Court of Justice

The grey area of the legal treatment of CBD products will possibly be clarified in many areas by a judgement of the European Court of Justice (Case C-663/18) which is expected shortly. In this case, the French authorities have prohibited the import and sale of a vape for e-cigarettes containing CBD with a THC content of less than 0.2% which was legally sold in the Czech Republic and have criminally prosecuted the directors of the importing company. This case was brought before the ECJ by the Court of Appeal in Aix-en-Provence, asking the court to answer the question whether a member state can prohibit the import of cannabidiol oil from another member state if it is derived from the whole hemp plant and not only from its fibres and seeds.

In his opinion published on 14th May 2020, the Advocate General considered that the measures taken by the French judiciary were violations to the principle of the free movement of goods:

"Articles 34 and 36 TFEU [free movement of goods] preclude a Member State from prohibiting the importation of cannabidiol oil from another Member State if it is extracted from the whole hemp plant and not only from its fibres and seeds, since, according to the current state of scientific knowledge, it is not established that CBD oil has psychotropic effects. It is, however, for the national court to satisfy itself that no risk has been identified and exhaustively assessed scientifically, in particular in relation to the non-psychotropic effects of CBD. If it concludes that such a risk exists and that such an assessment has been made, it must satisfy itself that an alternative measure less restrictive of the free movement of goods could have been adopted, such as the fixing of a maximum level for CBD."

If the ECJ follows the opinion of the Advocate General, which it does in the majority of cases, this ruling is likely to have a significant impact on the regulatory treatment of CBD products in all EU member states.

e) Conclusion

The marketing of products with added CBD in Germany currently still happens in a legal grey area. Nevertheless, the trade with CBD products is booming in Germany too. In the

big cities numerous stores are opening which exclusively sell CBD products, even if this business model does not have a secure legal basis. Some large drugstore chains have therefore removed CBD products from their shelves - at least in the food and beverage sector.

6. What are the testing specifications for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

a) Food

Food must not be unsafe in accordance with Article 14 of Regulation (EC) No 178/2002. Against this background, it must be ensured that the thresholds for THC set by the Federal Institute for Risk Assessment (BfR) are not exceeded for foods made from hemp which are not medicinal products or novel foods.

In 2000 the German Federal Institute for Health Consumer Protection and Veterinary Medicine (BgVV) published thresholds for the maximum Δ9-THC content in different food groups. These are 5 µg/kg for non-alcoholic and alcoholic beverages, 5000 µg/kg for edible oils and 150 µg/kg for all other foods and refer to ready-to-eat processed foods (BgVV 2000).

It is the responsibility of the producers to comply with the corresponding thresholds, otherwise sanctions according to the food and narcotics regulations may be imposed.

b) Medicinal Drugs

For medicinal drugs, on the other hand, a very extensive approval procedure applies, in which the pharmaceutical quality, the efficacy and the safety of the medicinal drug must be proven in clinical studies with detailed documentation. When a marketing authorisation is granted, it is initially valid for only five years, and in special cases only for one year. After five years it must be reviewed whether the medical benefit of the medicinal drug is still greater than its possible risks, e.g. due to side effects. The holder of the marketing authorisation must also notify the Federal Office for Drugs and Medical Devices (BfArM) of any changes to the medicinal drug. Larger changes may only be implemented with the prior approval of the BfArM.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

There exist currently no such limits. However, this could change if necessary following the judgement of the European Court of Justice (Case C-663/18), which is expected shortly.

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