LEGALINK

INTERNATIONAL BUT PERSONAL

CANNABIS REGULATION AND CANNABIS DERIVED PRODUCTS

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.

AUSTRIA

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

1.1. Narcotics framework

In Austria, cannabis is subject to the provisions of the Austrian Narcotic Substances Act (Bundesgesetz über Suchtgifte, psychotrope Stoffe und Drogenausgangsstoffe; Suchtmittelgesetz (SMG)). The classification of cannabis as a narcotic substance is based on the UN Single Convention on Narcotic Drugs. As required by Article 36 of the UN Single Convention on Narcotic Drugs, the cultivation, production, manufacture, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale, delivery on any terms whatsoever, brokerage, dispatch, dispatch in transit, transport, importation and exportation of drugs contrary to the provisions of this Convention shall constitute punishable offences. This Article was implemented via Section 27 et seqq in Austria as follows:

a) § 27 (1) SMG – Illegal handling of narcotics (basic criminal offence):

It is a punishable offence to acquire, possess, produce, transport, import or export, or to offer to, give to or procure for a third person, cannabis containing more than 0.3% tetrahydrocannabinol (THC). The penalty is imprisonment for up to one year or a fine.

b) § 27 (1) SMG in conjunction with § 27 (2) SMG – Personal use (mitigating factor):

Pursuant to § 27 (2) of the SMG the maximum penalty is reduced to imprisonment for up to six months, if and when a person only commits an offence pursuant to § 27 (1) SMG for personal consumption of the narcotic substance.

c) § 27 (1) SMG in conjunction with § 27 (5) SMG – Addiction (mitigating factor):

Pursuant to § 27 (5) SMG the maximum penalty is one year, if and when a person commits an offence for commercial purposes (§ 27 (3) SMG; meaning with intent to

create a continued income from, among others, the sale of cannabis pursuant to § 27 (1) SMG) as part of a criminal organisation, but such person is also addicted to a narcotic substance.

d) § 35 SMG in conjunction with § 27 (1) (2) SMG – Suspension of the case:

Pursuant to § 35 SMG the public prosecutor's office must suspend criminal proceedings for a probationary period of one to two years, if and when the accused person

- was found with a quantity of narcotic substances less than the threshold quantity defined in the Threshold Quantity Regulation (Grenzmengenverordnung (GV)). For instance, for cannabis the threshold is a pure substance mass of 20 grams THC. Depending on the THC content of the product, this corresponds to 80 to 300 grams of dried cannabis flowers. The threshold quantity constitutes the quantity of an active substance that may pose great danger to life and health.

  and

- committed an offence pursuant to § 27 (1) or (2) SMG only for his or her personal consumption or the personal consumption of a third person without gaining an advantage (monetary or otherwise) from the offence.

The legislative intention is to protect from excessive criminalisation persons who commit an offence pursuant to § 27 (1) or (2) SMG for personal consumption only. However, the proceedings will be resumed in the event another narcotic drug offence is committed within the probationary period. The preliminary discontinuation of penal proceedings requires a report from the health authority as to whether the person being reported is a long-term consumer of narcotics and therefore needs a health-related measure according to § 11 SMG (medical examinations, withdrawal measures, psychotherapy, counselling interviews, provision of urine samples). However, pursuant to § 35 (4) SMG the public prosecutor must refrain from requesting a report of the health authorities, if and when the accused committed the above-mentioned offences for exclusively personal consumption or for the personal consumption of another person without gaining an advantage and if the offence was committed with regard to certain narcotics (e.g. substances or preparations derived from the cannabis plant).

e) § 27 (3) and (4) SMG in conjunction with § 27 (1) SMG – Commercial commission and commission as part of a criminal organisation (aggravating factor):

Pursuant to § 27 (3) SMG the maximum penalty could be imprisonment up to three years, if and when a person commits an offence pursuant to § 27 (1) SMG with intent to thereby create a continued income for him/herself or as a member of a criminal organisation (§ 27 (4) SMG).

f) § 28 SMG in conjunction with § 28a (1) SMG – preparation of narcotic substance trafficking (aggravating factor):

Pursuant to § 28 and § 28a SMG the maximum penalty could be imprisonment for up to three years, if and when a person illegally acquires, possesses or transports a narcotic substance exceeding the threshold quantity (pure substance mass of 20 grams THC) and with the intent to sell it.

Further aggravating factors are if such crime is committed as a member of a criminal organisation or the amount of the drug exceeds 15 times the threshold stipulated in the GV.

f) § 28a SMG concerning the actual trafficking of narcotic substances (aggravating factor):

Pursuant to § 28a SMG the maximum penalty can be up to five years imprisonment, if and when a person illegally produces, imports, exports or offers, gives to or procures for a third person a narcotic substance exceeding the threshold quantity stipulated in the GV.
Further aggravating factors are if such crime is committed as a member of a criminal organisation or the amount of the drug exceeds 15 times the threshold stipulated in the GV.

How are Cannabis sativa as a plant and its seeds regulated? Plants and seeds thereof are subject to the SMG if they contain more than 0.3% THC. However, seeds and young plants that can grow into potent cannabis plants can be purchased in many shops in Austria. Whether the possession of the plants or seeds constitutes an offence depends on the intended use of the plants and seeds.

The unauthorised cultivation of cannabis plants for the purpose of obtaining narcotic substances is an administrative offence which is punishable by a fine of up to €36.30 according to § 6 (2) in connection with § 44 (1) no. 1 SMG (in case the person cannot pay the financial fine, imprisonment for failing such fine can be up to six weeks). In principle, only the act of obtaining addictive substances, i.e. the separation of the THC-containing plant parts from the plant for the purpose of obtaining addictive substances, is punishable by law. In practice, however, the courts often regard cultivation as attempted production within the meaning of the SMG.

How is Cannabidiol classified in Austria? Cannabidiol (CBD) as such (if not diluted with THC) does not qualify as a narcotic substance and is therefore not subject to the provisions of the SMG. Thus, the import and possession of Cannabis sativa plants (if the THC content is below 0.3%) with the intent to extract CBD from them is permissible.

1.2. Food products framework

In December 2018 the Austrian Federal Ministry of Labor, Social Affairs, Health and Consumer Protection (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz (BMASGK)) issued guidance restricting the use of CBD in cosmetics, food and food supplements, and as liquids for electronic cigarettes.

Austrian authorities consider food products to which CBD extract as a food ingredient is added as novel foods under Regulation 2015/2283/EU regardless of whether the extract was naturally or synthetically produced.

Novel foods are defined as foods that were not used for human consumption to a significant degree in the European Union before 15th May 1997 ("history of safe consumption") and fall into at least one of the categories listed in Article 3 (2) lit. a of the above-mentioned Regulation. Only novel foods authorised by the EU Commission and included in the European Union list of authorised novel foods in the Commission Implementing Regulation 2017/2470/EU may be placed on the market as such or used in food products in accordance with the conditions and labelling requirements laid down in the European Union list.

According to the EU novel food catalogue, synthetically obtained cannabinoids are considered novel foods, and thus require authorisation in accordance with the Novel Food Regulation. Even if extracted in a natural way, CBD is classified as a novel food, as

it is when added to traditional hempseed products. Therefore, only traditional food itself such as hempseeds, hempseed oil, hempseed flour or fat-free hempseed proteins can be legally marketed within the European Union.

The novel food catalogue is not legally binding, but many authorities in the EU use it as a reference for the purposes of the Novel Food Regulation 2015/2283/EU. Based on the novel food catalogue, authorities in the member states may refuse to permit supply of foods and food supplements containing cannabinoids, as Austria did, pending formal approval by the European Food Standards Agency (EFSA) under the Novel Food Regulation. Therefore, the Austrian position is in line with the recommendations at EU level.

The first application to the EFSA for a food supplement containing CBD for adults with a daily intake of up to 130mg was submitted by the Czech company Cannabis Pharma s.r.o. If the application is successful, the European Commission will issue an implementing regulation adding CBD as a food/ingredient to the list of approved novel foods. That approval will also specify any applicable conditions of use (e.g. maximum daily intake) or labelling requirements. Any product which differs from the approval will require a further application under the Novel Food Regulation. The application for the authorisation of food products containing cannabinoids is currently pending; no authorisation by the EU Commission has been granted yet.

1.3. Medicinal products framework

Whether a product is classified as a medicinal product, food product, food supplement, food for special purposes, medical device or cosmetic product determines the financial effort required to bring the product on the market. This classification also determines the future marketing strategies, in particular the limitations (e.g. prohibition for certain claims concerning medicinal products). Although the terms “food”, “food supplement” and “medicinal product” have been defined on a European Union level, the delimitation still causes practical problems. Therefore, the Court of Justice of the European Union (CJEU) is regularly confronted with the question of whether or not a certain product is to be classified as a medicinal product or not.

a) Definition of medicinal product

According to Article 1 no. 2 of the Human Use Directive 2001/83/EC as amended, a medicinal product is defined as follows:

> "Any substance or combination of substances presented for treating or preventing disease in human beings.
>
> Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product."

Concerning the first sentence of Article 1 no 2 leg cit, CJEU further explained that a so-called presentation medicinal product is a product which, by its name or presentation (advertising), gives the impression to the average consumer that it is intended to cure or prevent human disease, whereas the second sentence of Article 1 no 2 leg cit describes a functional medicinal product. Based on CJEU case law, these are products which have a significant effect on human physiological functions by exerting a pharmacological action linked to the prevention or cure of a disease or to a medico-therapeutic benefit, the therapeutic efficacy of which must be scientifically demonstrated.

Cannabis undoubtedly has a pharmacological effect when the THC content exceeds 0.3% – including, among other things, an anti-psychotic, neuroprotective or anti-inflammatory effect. Whether such products fall under the scope of the Human Use Directive depends on, among other things, the intent of the manufacturer. Products simply for research purposes outside of a clinical trial would not be covered (if they can be sold at all), but when health claims can be found on the package or in the advertising such product would be considered a medicinal product. Cannabis sativa products are also available as homeopathic products (below the 0.3% THC threshold).

Not only can the pharmacological properties trigger the application of the Human Use Directive, but as mentioned above so can the presentation of the product per se. If the product is advertised using disease-related claims, the product would qualify as a medicinal product even if the THC content is below 0.3%. Austrian authorities are increasingly checking homepages advertising CBD products.

b) Marketing authorisation

To obtain a marketing authorisation for the whole European Economic Area (EEA) (the EU, Iceland, Liechtenstein and Norway) the medicinal product must go through the centralised procedure pursuant to Regulation 2004/726/EC. Applications have to be filed with the European Medicines Agency (EMA).

Because of the restrictions posed by the centralised procedure it is unlikely that a product containing cannabidiol will be authorised by this route (except where the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interests of patients or animal health at EU level.) Thus, at least a national authorisation is required.

The national procedure is regulated by the Austrian Medicinal Product Act (Bundesgesetz vom 2. März 1983 über die Herstellung und das Inverkehrbringen von Arzneimitteln; Arzneimittelgesetz (AMG)) implementing the Human Medicinal Products Directive 2001/83/EG, which stipulates in its Article 8 that an application for a marketing authorisation for a medicinal product must be submitted to the competent authority of the member state concerned. In Austria this is the Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen (BASG)). The application form can be downloaded from the homepage of the BASG. Therefore, in essence medicinal products can only be marketed if and when they are approved by the BASG or by the European Commission with certain limited exemptions, such as in the case of a named patient sale.

c) Medicinal products currently available in Austria

The finished medicinal products Sativex and Canemes, containing cannabis active substances, are authorised for medical purposes in Austria. They consist of a mixture of psychotropic THC/dronabinol and non-psychotropic cannabidiol. Sativex has its approval for spasticity associated with multiple sclerosis and Canemes for nausea and vomiting as a result of chemotherapy as well as cachexia and loss of appetite in HIV patients.

The medicinal product Epidyolex containing highly purified CBD was approved by the EU Commission for the treatment of paediatric epilepsy.

For therapeutic use, cannabinoids (dronabinol and cannabidiol) can also be made available as magistral preparations via a pharmacy. This means that a physician shall prescribe, for instance, highly purified dronabinol and predefine the exact method of its preparation. Dronabinol is synthesised from hemp flowers and is taken in fluid or capsule form. The prescribed preparation must be made directly at the pharmacy (this cannot be outsourced). Magistral preparations are normally not reimbursed by the sick funds, but there are certain exemptions.

At this stage a magistral preparation of cannabidiol is still not reimbursed because, based on the reimbursement conditions for inclusion of a medicinal product, such preparations still lack sufficient proof concerning efficacy from a social security perspective (this is a different standard as for obtaining a marketing authorisation). In an individual case, they can be reimbursed, namely if there is a medical need and no comparable product is listed in the Reimbursement Codex. This means that a physician being employed by the sick fund will review the case and can approve that the costs are taken over. If the assessment is in favour of the patient, magistral preparations of dronabinol or CBD are reimbursed.

Magistral preparations are most likely to be used for patients with spasticity, paralysis, multiple sclerosis and other nervous disorders, for the relief of chronic pain that does not respond to any other therapy (cancer, diseases of the nervous system), or loss of appetite, nausea and vomiting in cancer and AIDS patients.

1.4. Tobacco products framework

The distribution of

- tobacco products or
- nicotine-containing e-cigarettes or liquids

containing vitamins or other additives, which give the impression that these products have a health benefit or present lesser health risks is expressly prohibited pursuant to the Austrian Tobacco- and Non-Smoker Act (Bundesgesetz über das Herstellen und Inverkehrbringen von Tabakerzeugnissen und verwandten Erzeugnissen sowie die Werbung für Tabakerzeugnisse und verwandte Erzeugnisse und den Nichtraucherinnen- bzw. Nichtraucherschutz (Tobacco- and Non-Smoker Act or TNRSG)) based on EU Directives 2014/40/EU and 2001/37/EG (TPD II).

The background of this regulation is above all that certain additives could mislead the consumer into believing that the consumption of a tobacco or related product has a health benefit and poses fewer health risks in comparison to normal cigarettes.

Recent analysis results of the Austrian Agency for Health and Food Safety (Agentur für Gesundheit und Ernährungssicherheit (AGES)) as well as relevant studies showed that THC acid (THCa) in normal cigarettes is converted into THC when tobacco or related products are heated or consumed, thus increasing the THC content, even beyond the 0.3% THC limit. Such consumption would then be covered by the SMG, triggering the penalties as stipulated in the SMG. In the view of the former Austrian Ministry of Health, the mandatory 0.3% THC limit must be interpreted in the context of tobacco law as meaning that it is only considered to be met if the THC content does not exceed 0.3% even after conversion of THCa into THC during the incineration process.

Tobacco and related products to which CDB or hemp are added that do not meet the legal requirements of the Tobacco- and Non-Smoker Act therefore cannot be sold to consumers. If such products are found on the market, they must be reported to the locally competent administrative authority. The latter shall conduct administrative penal proceedings in this regard – if necessary, on the basis of an official inspection and examination by AGES – in accordance with § 14 TNRSG.

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

In a European Union context, Austria has always been seen as a rather conservative country when it comes to the regulation of the consumption of narcotic substances. Even though the liberal Green Party is currently part of the Government, a general legalisation or decriminalisation of cannabis comparable to the Dutch model is currently not up for discussion.

Concerning the needs of patients: In its 2019 report, the Austrian Supreme Sanitary Council, an advisory body to the BMASGK, stated that, based on the current legal situation, Austrian patients have sufficient access to cannabis-based medicinal products, either in the form of magisterial preparations or as finished drugs (Sativex and Canemes). Dronabinol, which is used in pain therapy and is subject to the Narcotic Substances Act, could be prescribed in the form of drops or capsules.

The Council also confirmed that reimbursement of the costs is possible if there is a medical justification approval by a physician of the sick fund and no comparable product is listed in the Reimbursement Codex.

With regard to the use of medicinal hemp (dried flowers of the cannabis plant), the report states that there is no scientific evidence that this has advantages over the use of cannabis-based preparations already available on the market. In general, knowledge about the useful medical use of cannabinoids is still very patchy, the authors say. Further clinical research should therefore be conducted.

As for all medicinal products, the authorisation procedure for medicinal products, be it before the EMA or the BASG, is long and costly. Mandatory pre-clinical and clinical studies, the gathering of necessary documentation and the back and forth between applicant and the competent authorities take up a lot of resources. This is a general challenge.

With regard to cannabis-based medicinal products, a further hurdle arises in Austria, namely that only AGES may cultivate medical cannabis and distribute it to authorised buyers (see Question 3). Also, the reimbursement of cannabis-based medicinal products is dependent on the individual formulation (oral, nasal, etc) of the product.

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

The production, processing, transformation, acquisition and possession of narcotic drugs is, according to § 2 (1) Narcotic Substance Decree (Verordnung der Bundesministerin für Arbeit, Gesundheit und Soziales über den Verkehr und die Gebarung mit Suchtgiften (SV)), generally only permitted with the approval of the Federal Minister of Health.

Since an amendment to the SMG in 2008 the AGES may cultivate medical cannabis and distribute it to authorised buyers, usually pharmaceutical companies. According to § 6 (2), in connection with § 6a SMG only AGES or a subsidiary established for this purpose is permitted to cultivate plants to produce narcotic drugs, in concreto for the manufacture of medicinal products.

The amendment also gave private pharmaceutical companies the opportunity to buy up to a quarter of the subsidiary's shares from AGES.

AGES has been producing cannabis through its subsidiary commercially since 2010 in 3,000 square metres of greenhouses in Vienna, where production and research are carried out simultaneously.

In 2016 the Austrian Constitutional Court (Verfassungsgerichtshof (VfGH)) ruled that restricting the permission to cultivate medical cannabis to a company owned by the Republic of Austria guarantees – in a constitutionally justifiable manner – the control necessary to prevent abuse and to protect public health (VfGH 24.11.2016, G 61/2016).

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

The BMASGK is responsible for proposing new laws or amendments thereof, enacting regulations in the field of narcotic substances, issuing, amending and revoking administrative decrees and deciding on applications for import and export licences of drugs.

BASG is subordinate to the BMASGK and has been entrusted with a large number of tasks concerning marketing approvals for medicinal products, approvals and inspections for clinical trials of medicinal products and medical devices, and pharmacovigilance and vigilance in the field of medical devices. The BASG relies thereby on the expertise and personnel of AGES.

AGES advises the BMASGK on questions of public health, animal health, food safety (novel foods), food safety and consumer protection. AGES is a private entity owned by the Republic of Austria, represented by the BMASGK as well as the Ministry of Agriculture. As mentioned under Question 3, only AGES is legally entitled to produce medicinal cannabis in Austria.

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

In its decree of December 2018, the BMASGK classified CBD extracts as novel food pursuant to the Regulation 2015/2283/EU. This means that CBD cannot be used as a food ingredient as long as it is not authorised by the EU Commission as mentioned

above under question 1.2. Most sellers have therefore adapted their CBD product labels and sell oils, flowers etc only as aromatic products rather than food products. Nevertheless, there can be additional requirements for certain food products. Natural hemp oil, for instance, must be extracted from hemp seeds authorised in the EU plant variety database which is published based on Article 17 of Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species.

The BMASGK based its 2018 decree concerning CBD on the EU Regulation on Novel Foods, although the accompanying catalogue of novel foods clearly states that CBD extracts are a novel food only if the CBD content exceeds the CBD content naturally occurring in the plant. However, the Regulation 2015/2283/EU does not specify what percentage of CBD is considered natural. The BMASGK considers food products or cosmetics containing CBD and products suitable or intended for consumption with CBD, as well as extracts such as CBD oil, to be illegal. But if the same CBD oil is sold as an aromatic oil for fragrance lamps, it is not subject to any prohibition or restriction on sale.

Whether this legal opinion of the BMASGK is in line with EU law, in particular the Cosmetic Regulation, can be doubted. Until recently, CBD oils were still sold in pharmacies as food supplements, but the clever pharmacist no longer advertises them as such.

Until the CJEU rules on this subject, there is a risk that selling CBD food products containing CBD as an ingredient or cosmetics triggers an administrative fine (see question 1.3.).

6. What are the testing specifications in Austria 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?

6.1. Narcotic Substances

If the official examination of a product shows a THC content of more than 0.3%, the possession or distribution of it is reported to the responsible public prosecutor's office in accordance with SMG.

If a person is stopped and searched by the police and possesses CBD flowers, such person will be treated as having violated the SMG. Simply based on the suspicion of a violation of the SMG, the police can then confiscate the flowers and interrogate such person. The CBD flowers will be examined by an official lab and the case may end up at the public prosecutor's office if the THC content exceeds 0.3%.

6.2. Food products

According to § 76 of the Food Safety and Consumer Protection Act (Bundesgesetz über Sicherheitsanforderungen und weitere Anforderungen an Lebensmittel, Gebrauchsgegenstände und kosmetische Mittel zum Schutz der Verbraucherinnen und Verbraucher; Lebensmittelsicherheits- und Verbraucherschutzgesetzes (LMSVG)) the Austrian Food Book (Codex Alimentarius Austriacus) serves to stipulate designations, definitions, testing methods and evaluation principles as well as guidelines for the production and marketing of goods.

From a legal point of view, the Austrian Food Book is classified as a (refutable) "objective expert opinion". The administrative courts as well as the civil courts in unfair trade practices cases normally refer to the Austrian Food Book.

For example, the entry for hemp oil says:

> "1.6.6 Hemp seed oil (hemp oil)
> Hemp seed oil is obtained from the seeds of the hemp plant (Cannabis sativa). Cold-pressed hemp seed oil has a green-yellowish, sometimes also a brown-green colour with a grassy scent and a tart nutty taste.
> Not to be confused with essential hemp oil (obtained from leaves and flowers) or hashish oil (oily resin extract with a high THC content).
> For the production of hemp seed oil, only hemp seeds from seed varieties are used which meet the applicable approval conditions (see also EU Register of Varieties of Hemp:
> http://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/search/public/index.cfm?event=SearchVariety&ctl_type=A&species_id=240&variety_name=&listed_in=0&show_current=on&show_deleted=).
> With regard to the cannabinoid content, suitable preparation of the raw materials must be ensured within the framework of good manufacturing practice."

The last sentence of 1.6.6. Austrian Food Book above imposes on companies an obligation to establish, based on good manufacturing practices, a quality system ensuring that the legal THC threshold of 0.3% is complied with.

6.3. Medicinal products

The Regulation concerning the Manufacturing of Medicinal Products (Arzneimittelbetriebsordnung 2009 (AMBO 2009)) applies to all companies that manufacture, control or place on the market medicinal products or active substances, unless they are excluded from the scope of the AMBO 2009.

The AMBO 2009 stipulates that every company must operate an effective and functional pharmaceutical quality assurance system.

Within the framework of the quality assurance system, manufacturers are obliged to comply with Good Manufacturing Practice (GMP). According to § 2 Z 8 AMBO 2009, Good Manufacturing Practice is the part of pharmaceutical quality assurance which ensures that medicinal products are consistently manufactured and controlled according to quality standards that correspond to their intended use. As a source for the principles and guidelines of Good Manufacturing Practice for medicinal products, the AMBO 2009 refers to among others, Volume 4 of the Notice to Applicants. For the Good Manufacturing Practice for active substances, the Delegated Regulation (EU) 1252/2014 applies.

This system shall ensure that any medicinal product manufactured in the EU, even only for export purposes, is produced in line with GMP, thus guaranteeing a high protection for human health.

6.4. Tobacco products

In the course of their regular inspections of traders, manufacturers and importers, the inspection bodies of the BMASGK take samples of tobacco products and related products, which are then examined and assessed by AGES. If infringements of the provisions of the Tobacco- and Non-Smoker Act (TNRSG) are detected, a report is made to the competent local administrative authority on the basis of the penal provisions of § 14 TNRSG.

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

There are no regional limits on the quantity of CBD.

For air travel within the EU and the Schengen countries, the legal situation in the country of entry is taken into account. In Austria the THC limit of 0.3% applies. “Cannabis herbs and cannabis resin" (exceeding 0.3% THC) are explicitly mentioned in § 24 (6) Narcotic Substance Decree as narcotic substances which may not be imported to, exported from or carried along in Austria. This could pose an infringement on the free movement of goods, so according to the Ministry of Health "the examination of a possible necessary adaptation of the Austrian provisions on the cross-border transport of medicinal products containing narcotic drugs in international travel is pending.”

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