Food Lawyers Network
Worldwide

CANNABIS & CBD

A Global Regulatory Trends Overview of the Regulations in the Medicinal, Nutritional, and Recreational Markets

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THE PAPER'S OBJECTIVE

As the legal status of cannabis and its derivatives, including CBD, quickly evolve around the world, it is now legally available in a number of countries for medicinal or recreational purposes. Products with cannabis ingredients are available in various forms, including without limitation, dried plant, topical, and edible. Edible forms of cannabis, which are consumed in food form, have food-like legal and regulatory considerations and addition the cannabis itself.

In twenty chapters this booklet summarises the legal situation of cannabis/CBD in a cross-section of jurisdictions around the globe. Each author of a national chapter[1] gives a brief description of the overall regulation of these substances and the direction the jurisdiction is going. It explains the recreational use of cannabis or CBD products and its regulation (that is, the ability to legally (or tolerantly) purchase cannabis products) as well as their medical use. Branding and marketing of cannabis/CBD is discussed for each country concerned and also the forms they be sold (joints, tinctures, food, cosmetics etc.) and what cannabis accessories can be marketed. Not discussed are agricultural aspects like hemp production. Given regulations on cannabis or CBD products is in a constant state of flux, future challenges are also discussed.

[1] For lack of a common approach there is no supranational chapter on the legal situation in the European Union. A helpful publication is the "Commission services non-paper: Overview of the EU *acquis* applicable to cannabis in its different forms and components" of 19/2/2021 (Council document 10189/21). On 19/11/2020, the Court of Justice of the European Union delivered a judgment on the marketing of cannabidiol in Case C-663/183, which has implications for this issue. Neither discussed are the International Drug Control Conventions and the approach the World Health Organisation (WHO) is taking toward cannabis/CBD.

ARGENTINA

Martín J. Mosteirin

Background

Argentine legal system only permits the medicinal, therapeutic and/or palliative use of the cannabis plant. Recreational, edible, and industrial hemp manufacturing, distribution, commercialization and use of cannabis is forbidden by law so far.

In order to regulate the medical and scientific research on the medicinal cannabis, Law 27,350 (*"Medicinal Use of the Cannabis Plant Law"*) and its regulatory Decree No. 883/2020 created and regulated the National Program for the Study and Research of the Medicinal Use of the Cannabis Plant, its By-products, and Non-Conventional Treatments (the "Program").

With the aim of regulating the personal and recreational use of cannabis, Bill No. 4773-D-2020 on the *"Regulation of personal and recreational use of Cannabis"* was submitted to Congress for debate. However, there is no specific date for this law to come into force as the voting date for this Bill has not been set yet.

Although industrial hemp is currently forbidden under criminal laws applicable to recreational cannabis in Argentina, on July 15, 2021, the Senate gave preliminary approval to the Bill No. 0047-PE-2021 on the *"Regulatory framework for the manufacturing, industrialization and commercialization chain of the cannabis plant, its seeds and its by-products for industrial and/or medicinal use"* to develop the medicinal cannabis and industrial hemp industries. Thus, this Bill seeks to legalize and develop the use of hemp in the textile, footwear, cosmetics, food, wood, and car industries, among others. The voting date of the House of Representatives has not been appointed yet.

In conclusion, the use of cannabinoid drugs in Argentina is only authorized for medicinal purposes (medicinal cannabis) since cannabinoid drugs (non-medicinal) are considered as "narcotics" and therefore their commercialization and use are prohibited by current applicable laws (Section 3 of Law on Narcotics No. 17,818). In this regard, ANMAT Regulation No. 885/2010 defines "narcotic" as any psychotropic substance with high potential to produce abusive and/or dependent behaviour (psychological/physical, with a similar profile to morphine, cocaine, marijuana, etc.), acting on its own or through conversion into an active substance that exerts these effects.

Recreational

Recreational cannabis manufacture, distribution, commercialization, and use are illegal under several regulations in the country.

In this regard, Decree-Law No. 7,672/63 (validated by Law No. 16,478), as amended by Law No. 20,449, approves the Single Convention on Narcotic Drugs of 1961, and bars the use of cannabis for non-medical and non-scientific purposes [Section 49].

Furthermore, Law No. 17,818 ("*Narcotic Drugs*") establishes that the production, manufacture, export, import, commercialization and use of cannabis is prohibited, as well as the rest of the narcotic drugs contained in Schedule IV of the Single Convention on Narcotic Drugs of 1961 [Section 3].

Likewise, Law No. 19,303 ("*Psychotropic Drugs*") states that the production, manufacture, export, import, commercialization and use of THC (Tetrahydrocannabinol) is prohibited, as well as the rest of psychotropic drugs contained in List I [Section 3].

Law No. 21,671 ("*Prohibition of Cannabis*") also prohibits the possession, import, export, commercialization, and transit through the national territory of cannabis (its oils, resin, and seeds) [Section 2].

Moreover, Law No. 21,704 approves the 1971 United Nations Convention on Psychotropic Substances, while Law No. 24,072 approves the United Nations Convention against the Illicit Traffic of Narcotic Drugs and Psychotropic Substances.

In addition, Law No. 23,737 ("*Criminal Law*"): establishes in Section 5 that a person may be subject to imprisonment for four (4) to fifteen (15) years and a fine of forty-five (45) to nine hundred (900) fixed units if, without authorization or for an unlawful purpose, that person: (a) plants, cultivates plants, or stores seeds, chemical precursors, or any other raw material used to produce or manufacture narcotic drugs or elements used for such purposes; (b) produces, manufactures, extracts, or prepares narcotics; (c) trades narcotic drugs, chemical precursors, or any other raw material used for narcotic production or manufacture or uses narcotics for marketing purposes, distribution, payment, or stores or transports narcotics; and/or (d) trades plants or their seeds, usable for narcotic production, possesses these plants/seeds for marketing purposes, distributes them, provides them in payment, or stores or transport them. In addition:

(i) If such acts were done by a person who carries out an activity whose performance depends on an authorization, license or qualification from the public authority, a special disqualification of five (5) to fifteen (15) years also applies.

(ii) In the case of subsection (a), when the quantity sown or cultivated is small and other circumstances exist, and there is an unequivocal indication that it is intended as a narcotic for personal use, then the penalty is from one (1) month to two (2) years of imprisonment.

(iii) In the case of subsection (e), when the delivery, supply or provision is occasional and free of charge, and its quantity is small and other circumstances exist, and it unequivocally appears that it is for the personal use of the recipient then the penalty is from six (6) months to three (3) years of imprisonment.

Also, Law No. 11,179 ("*Argentine Criminal Code*") states that the term "narcotic drugs" includes narcotic drugs, psychotropic substances and other substances that can cause physical or psychological dependency, which are included in the lists that are elaborated and updated periodically by Decree of the Executive Branch [Section 77].

Finally, Decree No. 560/19 establishes the 2019 lists of narcotic drugs. Among the individual substances considered narcotic drugs, we find cannabis and THC and, within the chemical groups considered narcotic drugs we find several groups of synthetic cannabinoids.

Medical

Medicinal, therapeutic and/or palliative use of the cannabis plant and its by-products is legal in Argentina. The usage of cannabinoid drugs is authorized for medicinal purposes only.

Law No. 27,350 sets forth the main regulatory framework for medical and scientific research into the medicinal, therapeutic and/or palliative use of the cannabis plant and its derivatives, guaranteeing and promoting comprehensive healthcare. The Program, created by this law and its regulatory Decree No. 883/2020, aims at providing patients with access to cannabis oils and medicines.

At the moment, seventeen (17) provinces of Argentina have adhered to this law: Buenos Aires, Catamarca, Chaco, Chubut, Ciudad Autónoma de Buenos Aires, Corrientes, Entre Ríos, Jujuy, La Rioja, Misiones, Neuquén, Rio Negro, Salta, San Juan, Santa Cruz, Tierra del Fuego and Tucumán. Other provinces such as La Pampa, Mendoza, Santa Fe and Santiago del Estero enacted their own medicinal cannabis regulation, while Córdoba, Formosa and San Luis have neither adhered to Law No. 27,350 nor regulated their own legal framework.

The National Ministry of Health ("MoH") is the authority in charge of regulating medicinal cannabis. In provinces that adhere to Law No. 27,350, the local health authorities can also grant authorizations and have their own registries, provided that the National MoH is notified.

In addition, The National Agency of Medicines, Foods and Medical Technology (the "ANMAT", after its acronym in Spanish) has jurisdiction over the import of cannabis and its by-products [Section 7 of Decree No. 883/2020], while the National Council of Scientific and Technical Research ("CONICET", after its acronym in Spanish) and the National Agricultural Technology Institute (the "INTA," after its acronym in Spanish) are authorized to grow cannabis for medical research purposes and for the production of the medicine to be provided to patients enrolled in the Program [Section 6 of Decree No. 738/17].

Moreover, the National Seed Institute ("INASE," after its acronym in Spanish) regulates the conditions for the manufacture, propagation, handling, and conditioning activities carried out in greenhouses and/or fields growing cannabis [Section 6 of Decree No. 883/2020].

Finally, the main regulatory authorities with jurisdiction over Cannabinoid Drugs are the MoH, the National Comprehensive Drug Policy Department (the "SEDRONAR," after its acronym in Spanish) and the ANMAT.

Accessibility

One of the Program's purposes is to grant access to medicinal cannabis to patients that have a prescribed medical treatment with it, since cannabinoid drugs intended for therapeutic/medicinal purposes can only be purchased with a prescription from a duly licensed physician for a specific treatment.

In this regard, patients who have a medical prescription for the use of the cannabis plant and its derivatives may purchase medicinal specialties made in the country, import medicinal specialties duly registered by the health authority, or acquire magisterial formulations prepared by authorized pharmacies [Section 7 of Decree No. 883/2020]. Accordingly,there are four (4) possible ways for patients to legally access medicinal cannabis in Argentina:

- First, by acquiring cannabinoid drugs manufactured in the country, duly registered before the ANMAT or before any provincial sanitary authority. To date, there are a few registered drugs with cannabinoids as active ingredients. For example, "Convupidiol", is produced by an Argentine laboratory named Alef Medical, and obtained the first batch authorization on December 4, 2020. Due to its specific and exclusive indication for the treatment of refractory epilepsy and since it is a cannabis derivative, Convupidiol is sold under filed prescription.

- Second, is by acquiring a cannabis pharmaceutical compound from duly authorized pharmacies.

- Third, patients can access medicinal cannabis by obtaining a controlled cultivation license. In this sense, MoH Regulation No. 800/2021 approved the system for the Cannabis Program Registration (the "REPROCANN," after its acronym in Spanish) to issue authorizations to patients, valid for one (1) year from its issuance, to grow the plant themselves, through a family member, a third party or civil society organization duly authorized to that effect by the MoH. In order to apply for enrolment in the REPROCANN, a medical prescription and signed Bilateral Informed Consent are required.

- Finally, in addition to the Program, patients can obtain prescribed medicinal cannabis through the Cannabis Exceptional Access Regime regulated by MoH Regulation No. 654/2021, which allows the importation of non-registered products that contain by-products of the cannabis plant. This regime is exclusively intended for scientific research and for individual patients' use.

Law No. 27,350 and its regulatory Decree No. 883/2020 state that patients that do not have health cover, have the right to access said medicinal specialties free of charge. Otherwise, the healthcare insurance providers must guarantee access to the treatment prescribed. If a patient applies for medicinal cannabis authorization from ANMAT via the Cannabis Exceptional Access Regime, they, or their healthcare insurance providerwill be purchasing the product from abroadon their behalf.

Production of medicinal cannabis

The MoH regulates the production of medicinal cannabis and, as mentioned above, authorizes the cultivation of cannabis by CONICET and INTA for medical and/or scientific research purposes, as well as to prepare the substance for treatments.

The Program seeks to supply the local medicinal cannabis market through the production process handled by the Argentine Government setting forth that production will be prioritized and promoted through state laboratories within the National Agency of State Laboratories ("ANLAP," after its acronym in Spanish) [Section 6 of Decree No. 883/2020]. National, Provincial, Municipal and Autonomous City of Buenos Aires, the Armed Forces and the State-run University Institutions laboratories are considered state laboratories under Law No. 26,688. However, Argentine Government production is not fully in place yet, while the province of Jujuy as well as other provinces are taking their first steps in R&D and production of medicinal cannabis.

In fact, Jujuy is the leading province in the medicinal use of cannabis regulation and implementation and is the first province in Argentina to have an approved Pilot Cannabis Cultivation Plan [MoH Regulation No. 361/2019]. In this regard, the provincial state-owned company, Cannava S.E., sent its first batch of cannabis oil to public hospitals in Jujuy, 2021. As from December 2021, the medicinal cannabis oil produced by Cannava S.E is also available at pharmacies of Jujuy for any patient that has a medical prescription.

Finally, it is necessary to mention the Bill No. 4773-D-2020, which aims to provide the regulatory framework for the national manufacturing chain (and commercialization and/or export) of the cannabis plant, its seeds, and by-products for medicinal purposes and scientific research. Likewise, its purpose is to regulate the granting (and later control) of licenses to a series of productive links of greater scale and legal formality (private companies, public companies, mixed consortiums, civil associations, cooperatives, among others).

CBD and THC

Argentine cannabis legislation makes no distinction between CBD and THC as the regulatory framework does not define these terms. This lack of definitions is problematic in Argentine legislation because it implies the prohibition of industrial hemp, difficulties in importing cannabis medicines, and other related aspects.

Ingredient Source

As mentioned above, while the use of the cannabis plant and its by-products (for medicinal purposes) is legal in Argentina, industrial hemp is forbidden.

Nevertheless, Bill No. 0047-PE-2021 is intended to legalize and develop the different production and marketing chains of hemp or industrial hemp and its by-products.

Although hemp is not a narcotic drug under the terms of criminal law because it has a non-psychoactive effect, said Bill states that it is necessary to regulate and control the activity to prevent illegal cultivation of psychoactive cannabis from being hidden in hemp fields.

In addition, said Bill also aims to create the National Regulatory Agency of the Hemp and Medicinal Cannabis Industry ("ARICCAME," after its acronym in Spanish), as a decentralized body within the Ministry of Productive Development, which will have to apply an authorization regime in regard to industrial and/or horticultural hemp not intended to produce derivatives for medicinal, therapeutic, or palliative use.

Finally, within the chemical groups considered as narcotic drugs, the aforementioned Decree No. 560/19 includes several groups of synthetic cannabinoids.

Branding and Marketing

Marketing, branding and promotion of medicinal cannabis is not specifically regulated, and the general regulations applicable to the promotion of Rx medicines apply [Law on Medicines, MoH Regulation No. 627/07, among others]. Decree 883/2020 states that dispensation of medicinal cannabis shall be through the National Bank of Oncologic Drugs and/or authorized pharmacies [Section 10].

In a nutshell: the advertising of prescription drugs to the general public is forbidden in Argentina since it is considered to endanger public health [Section 37 of Regulatory Decree No. 9763/64; Section 14 of ANMAT Regulation No. 4980/2005; Section 12 of MoH Regulation No. 627/07]. MoH Regulation 627/07 sets forth that promotion of prescription drugs is only authorized when directed to health care professionals authorized to prescribe or dispense medicines only. Furthermore, promotion of Rx medicines must (i) be objective, (ii) not be misleading, (iii) favour the rational use of the medicines, and (iv) provide information about the pharmacological properties, therapeutic action, and approved indication, among other requirements. The mandatory technical-scientific information that must be provided when promoting Rx medicines includes: the generic (active ingredient) and brand name of the product, quali-quantitive formula, dosage form, indications and contraindications, adverse effects, warnings, dosage, name and address of the holder, prescription regime, and the condition of dispensing.

Edibles, Topicals, and More

The Argentine Food Code Law No. 18,284 ("AFC," after its acronym in Spanish) provides the substances that are legally authorized by the health authority to be used as food product ingredients.

Edible and drinkable food products containing cannabis are forbidden by the regulations mentioned in the "Recreational Cannabis" subtitle and this is the reason why cannabinoid drugs are not included in the AFC.

ANMAT has established its position on this subject in ANMAT Regulation No. 3,599/19, by which nutritional cannabis supplements are prohibited because of non-compliance with the authorized nutritional substances that are allowed to be a nutritional supplement.

As from November 2021,ANMAT Regulation No. 8.504/21 has authorizedthe import, manufacture, and commerce of specific CBD cosmetic products. In fact, authorized CBD cosmetics must not contain more than 0.2% w/w of THC, and must also obtain a sanitary permit as a Grade II cosmetic product. Those products must also comply with specific provisions regarding the registration filing and documentation, labelling, advertising activities, among other requirements.

Cannabis Accessories

Cannabis accessories are not specifically regulated in Argentina. General regulations such as the Consumer Protection Law (Law No. 24,240) would eventually apply to these accessories.

Accessories such as holders, pipes, water pipes, electronic smoking devices (vaporizers), ashtrays, among others, are only regulated by the regulations applicable to tobacco [Law 26.687 and its Regulatory Decree 602/2013]. By means of ANMAT Regulation No. 3226/2011, ANMAT has prohibited the importation, distribution, commercialization, advertising, and promotion of electronic nicotine delivery system known as 'electronic cigarette' and its accessories.

Importation

ANMAT is in charge of authorizing the import of medicinal cannabis and its by-products for patients who have the pathologies included in the Program and the medical indication to use the cannabis plant and its derivatives [Section 7 of Decree No. 883/2020]. Furthermore, those who do not have health coverage are entitled to have free access.

In addition, the aforementioned Cannabis Exceptional Access Regime is the importation mechanism by which patients can access medicinal cannabis.

Future Challenges

Some of the future challenges in Argentina are regulating psychoactive cannabis towards the legalization of the recreational use of cannabis, CBD, edible cannabis, etcetera. Also, from a medical perspective, it's still a challenge to extend the scope of use of cannabis to more pathologies.

There are some bills in Congress that may significantly modify the cannabinoid drugs legal framework in such a direction: Bill 1710-D-2020 on *"Regulation of psychoactive cannabis. Amendment to Law No. 27,737"*, Bill 5658-D-2020 on *"Cannabis Regulation for Health. Amendment of the Criminal Code and the Narcotics Law No. 2,3737"*, and Bill 7399/D/2018 on *"Control and State Regulation of Psychoactive Cannabis"*.

The latter has been filed in the House of Representatives and aims to create the National Institute of Regulation and Control of Psychoactive Cannabis, which would have the following powers, among others: (i) Exercising control and supervision of the cultivation, harvest, production, recollection, distribution, and provision of psychoactive cannabis; (ii) granting authorizations and licenses to produce, process, store, distribute, and sell psychoactive cannabis, as well as distributing and selling cannabis seeds for cultivation and domestic harvesting in seed sales venues and clubs; (iii) creating a "User Registry;" and (iv) Creating the "Registry of Cannabis Seed Sales Venues for Plantation, Cultivation and Domestic Harvest."

However, there is no specific date for these laws to come into force since the voting dates for these bills have not yet been appointed.

AUSTRIA

Bernd Roßkothen

Background

Hemp products are basically regulated for production, processing, conversion, acquisition and possession in the Narcotic Drugs Ordinance. CBD is not defined as a narcotic drug in Austria and is not subject to the narcotic drug regulations. By decree of the Ministry of Health from 2018, CBD was classified as novel food. Cannabis extract itself is basically defined as an addictive drug. It is legal to purchase CBD products in Austria, however, not allowed is the sale of CBD products labelled as food or cosmetics. CBD products such as oils or flowers are therefore sold as aroma products.

Recreational

Cannabis may only be cultivated if the THC content is below 0.3% in dry matter. The CBD content itself is not regulated. The assessment of CBD products from a food law perspective (oils, cosmetics) is regulated at European level (Regulation (EC) No 1223/2009 and Regulation (EU) 2015/2283). If the narcotic limit of THC at 0.3% is exceeded, there is a criminal offense falling under the jurisdiction of the criminal courts. Otherwise, the responsibility lies with the locally competent district administrative authorities. In criminal proceedings, the matter is officially controlled and investigated by AGES, a control body regularly used by the authorities and owned by the Republic of Austria. Cannabis may be cultivated in the form of plants from the EU catalogue of varieties. Otherwise, a variety approval can be obtained after passing a register examination of about 2 years.

Medical

According to the Medicinal Products Act, the cultivation of hemp for medicinal purposes with THC content is only permitted by AGES under the supervision and control of the Federal Ministry of Social Affairs – Health, Care and Consumer Protection.

In Austria, a medicinal product with cannabis active ingredients (“Sativex”) is currently approved. It contains the combination of two extracts, one derived from a THC-rich cannabis variety and one from a cannabidiol-rich variety. This medicine is approved to

improve seizure-like symptoms in patients with multiple sclerosis.

Since September 2019, CBD has been approved by the EU Commission as the active ingredient in the orphan medicinal product “Epidyolex” (approval number EU/1/19/1389) under Regulation (EC) No 141/2000. It is used, together with clobazam, in patients aged 2 years and older for the adjuvant treatment of seizures, associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS).

THC as a pure substance, also known as “dronabinol”, can be dispensed as a so-called magisterial prescription, that is, as an individual preparation of the drug directly in the pharmacy. Any physician can order such a magisterial preparation via a narcotic prescription. According to the current situation, physicians are not required to provide a narrowly defined indication.

Branding and Marketing

CBD products are not allowed to be marketed as food (novel food) or cosmetics, they are mostly marketed as aromatic oils.

Edibles, Topicals, and More

The use of hemp flowers in foodstuffs is not permitted due to the potentially very high cannabnoid content. This can also be seen in the Austrian Foodstuffs Book, Chapter B31 (Annex II: Open list of plants or parts of plants not used for the production of tea-like products). Flavours from Cannabis Sativa may only be used if they meet the criteria laid down in the Regulation (EC) No 1334/2008 on Flavours. Their use must be safe, so certain flavours from Cannabis Sativa must undergo a risk assessment before they are approved.

Flavours are added to foods to impart a particular odour and/or taste to them or to modify them. If there is a specific concentrated enrichment of active ingredients (e.g. CBD) in extracts, it can no longer be assumed that these comply with the requirements of the EC Flavour Regulation. Consequently, a functional claim of the efficacy of flavours would not be permitted from a nutritional or physiological point of view. This circumstance is particularly important to consider in the case of food supplements, as their primary purpose is neither flavouring nor satiety, but rather these products are consumed for their nutritional or physiological effects.

Hemp products without significant amounts of CBD, such as hemp seeds or hemp seed flour, do not fall under these prohibitions. These are ordinary food products sold at retail.

Extracts containing cannabinoids in food products such as confectionery or cakes fall under the rule of the Novel Food Regulation as novel foods under Regulation (EU) 2015/2283. Placing on the market is only possible within the scope of the approval of this list, but such approval is currently not available.

Only the addition of CBD as a flavouring is permitted. A CBD ingredient in products, i.e. with regard to a functional efficacy is not permitted. These can only be added as flavours to food to give them a special smell or taste or to change it (cake with hemp flavour).

An example of this would be hemp leaves, hemp seed oil, hemp seed flour etc.

Due to further EU regulation, future development will be at a European level rather than specifically at an Austrian level. Currently there is a ban on the sale by a ministerial decree.

Cannabis Accessories

Accessories are not mentioned in the Narcotic Drugs Act. Therefore, it is not subject to any specific prohibitions in distribution.

Importation

The import is subject to the same restrictions as the domestic products.

Future Challenges

In the case of a scientifically comprehensible and therapeutically meaningful indication (field of application), the prescription has recently been approved by the chief physician of the health insurance funds, and thus the costs are covered by the insurance.

More recently, the European Food Safety Authority (EFSA) conducted a risk assessment for THC in food of animal origin (http://www.efsa.europa.eu/en/efsajournal/pub/4141). The EFSA concluded that no adverse health effects are to be expected at a daily intake from such foods up to a maximum level of 1 µg THC/kg body weight (acute reference dose). This was also confirmed in Commission Recommendation (EU) 2016/2115.

Thus, the respective THC maximum levels are dependent on the consumption quantities of the foodstuffs and are to be determined for the food groups in detail. However, as long as no corresponding limits have been set, an individual risk assessment must be carried out if THC levels are detected in a foodstuff. In doing so, the marketability of the food is determined, taking into account the consumption levels and the EFSA acute reference dose.

A classification of CBD products as presentation medicinal products based on disease-related claims of the product is to be evaluated independently of a classification of the product as a functional medicinal product. As in the past, the Federal Office for Safety in Health Care (BASG) considers CBD products that are appropriately promoted as having properties to cure or alleviate or prevent human or animal diseases or pathological conditions to be presentation medicinal products. If the BASG becomes aware of such a promotion, it will take action and start an investigation.

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CANADA

Lewis Retik / Victor Zhao

Background

In Canada, medical and recreational cannabis are both legal under separate frameworks. Phytocannabinoids such as tetrahydrocannabinol (THC) and cannabidiol (CBD) are each regulated as cannabis under the federal *Cannabis Act*[1] and its *Cannabis Regulations*[2].

Recreational cannabis was legalized in Canada on October 17, 2018. Since then, the recreational cannabis regulatory framework has continued to evolve. On October 17, 2019, the cannabis legislation was amended to allow for additional classes of cannabis, namely cannabis extracts, cannabis topicals, and edible cannabis. Cannabis oils, which were previously considered a separate class, are now sold under the new product classes.

Health Canada continues to consider additional updates to the legal cannabis framework. For example, between June 19 and September 3, 2019, Health Canada consulted Canadians on their interest in the potential therapeutic use of cannabis for purposes such as pain relief without need for practitioner oversight. The proposal contemplates that products sold under this proposed framework, which Health Canada refers to as "cannabis health products" (CHPs), could potentially be authorized to make health claims to treat minor ailments, unlike cannabis products currently sold for recreational or medical purposes. Currently, only prescription drugs containing cannabis are authorized to make such health claims. At the time of writing, this proposal is on hold given the Covid-19 pandemic.

Medical cannabis has been regulated in varying forms since 1999. At that time, cannabis was regulated as a "controlled substance" under the *Controlled Drugs and Substances Act* and available only through individual exemptions. The statutory framework for medical cannabis has evolved over the years due to court challenges. Medical cannabis is now regulated under Part 14 of the *Cannabis Regulations* – Access to Cannabis for Medical Purposes. The most common methods for individuals to obtain medical cannabis require a medical document from a health care practitioner that supports their

[1] *Cannabis Act*, S.C. 2018, c. 16 ("Cannabis Act").
[2] *Cannabis Regulations*, SOR/2018-144 ("Cannabis Regulations").

use of cannabis for medical purposes. Once this medical document has been obtained, the individual must register either with the holder of a federal licence for sale to obtain medical cannabis, or register with Health Canada produce cannabis for their own medical purposes or designate another person to produce medical cannabis on their behalf. Health care practitioners may also administer cannabis products to individuals under their professional treatment, or, if practicing in a hospital, issue a written order authorizing a stated amount of cannabis to be dispensed to the individual.

This chapter does not contemplate certain low-THC products regulated as industrial hemp in Canada. Industrial hemp is defined as a cannabis plant - or any part of that plant - in which the concentration of THC is 0.3% w/w or less in the flowering heads and leaves. Industrial hemp is subject to a separate licensing regime regulated under the *Industrial Hemp Regulations*[3]. These Regulations also exempt certain industrial hemp derivatives from the application of the *Cannabis Act* if they have a THC concentration of 10 µg/g THC and are made by processing only the grain of industrial hemp.[4]

Recreational

The federal, provincial and territorial governments in Canada each participate in the regulation of recreational cannabis in Canada.

Through the *Cannabis Act* and *Cannabis Regulations*, the federal government regulates the production of cannabis and cannabis products, and sets out broad restrictions on the possession, distribution, sale, import, and export of cannabis. Cannabis products must comply with the general packaging, labelling and production requirements set out in the federal legislation. In addition, the federal legislation permits adults in Canada to possess up to the equivalent of 30 grams of dried cannabis in public places, and to grow up to four cannabis plants per residence for personal use[5].

The federal legislation sets out six classes of licence[6]:

a) a licence for cultivation;
b) a licence for processing;
c) a licence for analytical testing;
d) a licence for sale;
e) a licence for research; and
f) a cannabis drug licence.

Once produced at a federal level, recreational cannabis is sold and distributed into provincially and territorially regulated distribution channels. Each province and territory sets out its own restrictions on the distribution and sale of cannabis within its jurisdiction. These restrictions differ from jurisdiction to jurisdiction with respect to how cannabis can be sold, where stores may be located, how stores must be operated, and who is allowed to sell cannabis. In particular, each jurisdiction sets out its own framework with respect to the wholesale, physical retail sale and online sale of cannabis. Certain governmental authorities control the entire supply chain after production, whereas others license

[3] *Industrial Hemp Regulations*, SOR/2018-145 ("Industrial Hemp Regulations").
[4] Industrial Hemp Regulations, s. 2.
[5] Cannabis Act, s. 8.
[6] Cannabis Regulations, s. 8.

private entities to wholesale cannabis or operate brick and mortar retailers and/or online cannabis stores.

Each province and territory may also add its own safety restrictions on personal possession and consumption, as long as these requirements are more restrictive than the federal requirements. For example, a province or territory may increase the minimum age for consumption in their jurisdiction, but may not lower it.

While there are federal limits on the dried cannabis equivalent individuals may possess, there is no general restriction on the amount of CBD individuals may possess. Certain classes of cannabis are subject to maximum THC limits, but no such limits exist with respect to CBD. This lack of differentiation based on CBD amounts has raised concerns for industry in Canada, as low-THC, high-CBD products are regulated in the same manner as high-THC products, notwithstanding the different roles such products may play for consumers. Given the interest in access to CBD for therapeutic purposes without therapeutic oversight, future developments in the Canadian cannabis legislation may lead CBD to be regulated differently than other phytocannabinoids such as THC. However, at this time, products containing CBD are regulated in the exact same manner as THC and it makes no difference whether the product is sourced from marijuana, industrial hemp, or created synthetically.

Failure to comply with the provisions of the *Cannabis Act* and *Cannabis Regulations* constitutes a criminal offence. Depending on which provision is contravened and whether the person committing the contravention is an individual, young person or organization, the offence may be punishable with imprisonment for a period of up to 14 years or a fine in an amount in the discretion of the court[7].

Medical

The medical cannabis framework has evolved over time in Canada due to various constitutional challenges with respect to the access Canadians have to medical cannabis. Under the current regulatory framework, individuals may generally access medical cannabis once they receive a written authorization from a health care practitioner by virtue of either a medical document or written order.

Individuals with an authorization for medical cannabis can obtain medical cannabis by registering:

a) with a federally licensed seller of medical cannabis;
b) with the Minister of Health to produce their own cannabis;
c) a designated individual who will be responsible to produce cannabis for medical purposes; or
d) with the Minister of Health to possess cannabis in public above the 30 grams limit allowed for non-medical purposes, but not to produce cannabis.

Individuals may generally only seek or obtain cannabis products from one source at a time on the basis of the same medical document[8]. Exceptionally, a person or designated individual registered with the Minister of Health may use that registration certificate to obtain cannabis products other than cannabis plants or cannabis plant seeds from a

[7]See for example Cannabis Act, s. 9(5).
[8]Cannabis Regulations, s. 276.

single holder of a licence for sale, and obtain cannabis plants or cannabis plant seeds from one or more holders of a licence for sale.

As with recreational cannabis, cannabis for medical purposes is not permitted to make health claims, nor is it subject to any pre-market review for safety and efficacy. The medical cannabis framework also does not differentiate between phytocannabinoids.

Note that other than the medical cannabis framework, other cannabis products are sold for therapeutic purposes as prescription drugs and medical devices that contain cannabis. These products are marketed with health claims and are subject to pre-market authorization. The federal cannabis legislation regulates the sale of prescription drugs containing cannabis that are similarly to the federal *Food and Drugs Act*[9] and *Food and Drug Regulations*[10]. Generally, only provincially licensed pharmacists may dispense prescription drugs containing cannabis, and these drugs may only be dispensed in accordance with a prescription or written order provided by a provincially authorized health care practitioner.

In addition, the proposed cannabis health product (CHP) framework may result in a new route to market for cannabis products marketed with health claims. Between June 19 and September 3, 2019, Health Canada consulted Canadians on their interest in the potential therapeutic use of cannabis for purposes such as pain relief without need for practitioner oversight. Products sold under this potential framework could potentially be authorized to make health claims to treat minor ailments, unlike cannabis products currently sold for recreational or medical purposes. Currently, only prescription drugs and medical devices containing cannabis are authorized to make such health claims.

Branding and Marketing

In Canada, it is prohibited under the *Cannabis Act* to promote cannabis or a cannabis accessory or any service related to cannabis, unless such promotion is expressly authorized. Acceptable promotions include point-of-sale promotions indicating price and/or availability, and informational and brand-preference promotions in prescribed places that are not accessible by law to young persons[11].

In addition to these broad prohibitions, Canada's legislation sets out specific restrictions on certain promotional content. It is prohibited to promote cannabis, a cannabis accessory, or a service related to cannabis if there are reasonable grounds to believe that the promotion could create the impression that health or cosmetic benefits may be derived from the service related to cannabis, or from the use of cannabis or a cannabis accessory[12]. Similarly, the promotion must not associate the product or service with an alcoholic beverage, a tobacco product, or a vaping product[13]. The legislation also prohibits any person that sells cannabis or a cannabis accessory from inducing others to use or purchase cannabis, such as through games, draws, lotteries, or contests[14].

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[9] *Food and Drugs Act*, R.S.C., 1985, c. F-27.
[10] *Food and Drug Regulations*, C.R.C., c. 870.
[11] Cannabis Act, s. 17.
[12] Cannabis Regulations, s. 104.12.
[13] Cannabis Regulations, ss. 104.15, 104.16.
[14] Cannabis Act, s. 24.

It is also prohibited to use a cannabis brand element or the name of a person that performs certain cannabis-related activities to sponsor a person, entity, event, activity or facility, or to display such a brand element or name on a facility that is used for a sports or cultural event or activity.

General packaging and labelling restrictions may also have important impacts on a company's ability to brand and market their products. For example, plain packaging and labelling requirements apply to cannabis products in order to reduce their attractiveness and appeal, particularly to young persons. However, these restrictions on package colour and shape can prevent companies from pursuing certain distinctive advertising options.

Given the relative novelty of Canada's cannabis regulatory framework, there remain additional challenges with respect to branding and marketing cannabis. For example, the use of "brand elements" is regulated in a manner that creates uncertainty for industry members. A brand element is defined under the *Cannabis Act* as follows[15]:

brand element includes a brand name, trademark, tradename, distinguishing guise, logo, graphic arrangement, design or slogan that is reasonably associated with, or that evokes,

(a) cannabis, a cannabis accessory or a service related to cannabis; or

(b) a brand of any cannabis, cannabis accessory or service related to cannabis (*élément de marque*).

Among other restrictions, only a single brand element other than a brand name is permitted to be included on a label for cannabis, a cannabis accessory or a package[16]. This brand element must meet specific formatting requirements. However, this broad definition also raises several practical questions. For example, it is unclear whether certification marks are brand elements, or how brand elements may differ in certain situations from brand descriptions that provide additional information on a given product. Given the lack of guidance from Health Canada as of the publication of this chapter, these issues raise uncertainties for companies that wish to conduct business in the Canadian cannabis industry. If, for example, a certification company's logo could be considered a brand element that evokes a service related to cannabis, the restrictions in the federal cannabis legislation could still apply to their advertising for non-cannabis-related services.

Edibles, Topicals and More

As mentioned earlier in this chapter, the initial classes of cannabis that were authorized to be sold under the *Cannabis Act* upon legalizationincluded only dried cannabis, cannabis oils, fresh cannabis, cannabis plants, and cannabis plant seeds.

Since October 17, 2019, cannabis extracts, edible cannabis, and cannabis topicals have been added to the *Cannabis Act* as permissible classes for sale, and cannabis oils have been removed as a stand-alone class due to their inclusion in the new classes.

The new classes of cannabis are each subject to specific restrictions, including on

[15]Cannabis Act, s. 2.
[16]Cannabis Regulations, s. 104.18.

product composition and packaging. Additional restrictions also exist based on the intended method of consumption for cannabis products.

a. Edible cannabis

The federal *Cannabis Act* incorporates certain broad prohibitions relating to food safety from the *Food and Drugs Act* and sets out specific restrictions on the product formulation. This means that from a formulation perspective, much of what applies to regular foods in Canada also applies to edible cannabis, even though edible cannabis is under a completely different framework. As a basic example, edible cannabis is not permitted to contain any poisonous or harmful ingredients, or to contain any ingredients that would cause the edible cannabis to:

a) be unfit for human consumption;

b) consist in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;

c) be adulterated[17].

In addition, it is prohibited for edible cannabis to be manufactured, prepared, preserved, packaged or stored under unsanitary conditions, and edible cannabis may only be irradiated if the requirements that are set out under the *Food and Drug Regulations* for foods to be irradiated are met[18].

The cannabis legislation also sets out more specific restrictions on edible cannabis formulations.

Edible cannabis products must not contain a quantity of THC that exceeds 10 mg per immediate container, taking into account the potential to convert THCA into THC and subject to variability limits[19]. The only non-cannabis ingredients permitted in edible cannabis are food and food additives. In addition, it is prohibited to use as an ingredient any foods described in a Temporary Marketing Authorization Letter, and there are restrictions on the use of meat products, poultry products, fish, vitamins, and minerals in edible cannabis[20].

Edible cannabis products must not contain caffeine unless the caffeine is introduced through the use of ingredients that naturally contain caffeine. The total amount of this naturally occurring caffeine in each immediate container of the edible cannabis product must not exceed 30 mg[21]. In addition, edible cannabis products may only contain up to 0.5% w/w ethyl alcohol[22].

With respect to packaging and storage, it is prohibited to sell an edible cannabis product if it requires refrigeration to prevent contamination before its durable life date[23]. If the edible cannabis product's container is hermetically sealed, it is prohibited for any component of the edible cannabis product to have a pH that exceeds 4.6 and a water activity that exceeds 0.85 at a temperature of 22 ± 2°C[24].

[17]Cannabis Regulations, s. 102.1.
[18]Cannabis Regulations, s. 102.6.
[19]Cannabis Regulations, ss. 97(2), 102.7.
[20]Cannabis Regulations, s. 102.
[21]Cannabis Regulations, s. 102.2.
[22]Cannabis Regulations, s. 102.3.
[23]Cannabis Regulations, s. 102.4.
[24]Cannabis Regulations, s. 102.5.

b. Cannabis topicals

Cannabis topicals must not contain anything that may cause injury to the health of the user when the cannabis product is used as intended or in a reasonably foreseeable way[25]. Any microbial or chemical contaminants must be within generally accepted tolerance limits for human use that are established in a prescribed publication and appropriate for the topical product[26].

The Cosmetic Ingredient Hotlist is an administrative tool that Health Canada uses to convey certain safety-related prohibitions and restrictions on cosmetic ingredients in Canada. Health Canada has also indicated in its published guidance that this tool may be helpful in determining whether ingredients are appropriate for use in cannabis topicals.

In addition, cannabis topicals must not contain a quantity of THC that exceeds 1000 mg per immediate container, taking into account the potential to convert THCA into THC and subject to variability limits[27].

Finally, the *Cannabis Regulations* require that the cannabinoids and terpenes in a cannabis topical product must be uniformly distributed throughout the cannabis topical[28].

c. Cannabis extracts

Cannabis extracts are subject to the same requirements as cannabis topicals set out above, in addition to more stringent requirements concerning product formulation. Cannabis extract products must not contain any non-cannabis ingredients other than carrier substances, flavouring agents, and substances that are necessary to maintain the quality or stability of the cannabis product[29].

In addition, the *Cannabis Regulations* prohibit using the following substances as ingredients to produce a cannabis extract product:

a) substances that are listed in column 1 of the table in Schedule 2 to the *Tobacco and Vaping Products Act*, except that vitamins may be used in necessary amounts to maintain the quality or stability of the cannabis product; and

b) sugars or sweeteners or sweetening agents, as those terms are defined in subsection B.01.001(1) of the *Food and Drug Regulations*.

Note that a substance that would otherwise be prohibited may be included if it is naturally present in an ingredient that is used to produce the cannabis extract product and is present at a level that does not exceed naturally occurring levels for that ingredient.

In addition to the above, certain requirements apply only to certain cannabis extracts based on the intended means of consumption. If an ingredient other than a flavouring agent is used to produce a cannabis extract intended to be inhaled, it must comply with a prescribed standard[30]. Cannabis extract products must not contain ethyl alcohol unless the cannabis extract is intended for ingestion and the net weight of the extract in each immediate container does not exceed 7.5 g[31]. Cannabis extracts not in discrete

[25]Cannabis Regulations, s. 101.
[26]Cannabis Regulations, s. 101.1.
[27]Cannabis Regulations, ss. 97(2), 101.2.
[28]Cannabis Regulations, s. 101.4.
[29]Cannabis Regulations, s. 101.3.
[30]Cannabis Regulations, s. 101.3(5).
[31]Cannabis Regulations, s. 101.3(6).

units must be packaged in containers that do not permit the extract to be easily poured and drunk[32]. If the extract is in liquid form, its container cannot contain more than 90ml[33]. If the liquid extract has greater than 10 mg THC and is not intended for inhalation, its container must have an integrated dispensing mechanism (e.g., pump or metered spray for a bottle) that does not dispense more than 10 mg of THC per activation[34].

d. Additional restrictions

The *Cannabis Regulations* also set out certain requirements according to the intended route of administration of the cannabis product. Any discrete unit of a cannabis product that is intended for ingestion or nasal, rectal or vaginal use and that is not edible cannabis must not contain a quantity of THC that exceeds 10 mg, taking into account the potential to convert THCA into THC and subject to variability limits[35]. These variability limits differ according to the class of cannabis product and whether the cannabis product may be divided into discrete units or sub-units.

Cannabis Accessories

A cannabis accessory as regulated under Canada's cannabis legislation refers to a thing that is represented to be used in the consumption of cannabis, or that is sold at the same point of sale as cannabis if it is commonly used in the consumption of cannabis[36]. This includes products such as rolling papers, wraps, bongs and vaporizers, but also vaping cartridges, droppers, and mechanical pumps.

Cannabis accessories are subject to several restrictions in Canada, including that a cannabis accessory must not:

a) be contaminated[37];
b) impart a characterizing flavour to cannabis[38];
c) dispense in a single activation a quantity of cannabis extract that contains greater than 10 mg of THC if the extract is intended for ingestion, or nasal, rectal, or vaginal use[39];
d) alter or enhance the psychological effects derived from the cannabis product in a manner that may cause injury to the health of the user[40];
e) increase the potential for abuse liability of the cannabis product; or
f) increase the toxicity of the cannabis product.

In addition to the above, certain cannabis accessories are sold containing cannabis which is also subject to other requirements. If, for example, a cannabis accessory is sold containing edible cannabis, the edible cannabis must comply with the requirements set out in the edible cannabis portion of this chapter.

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[32]Cannabis Regulations, s. 122.5(1)(a).
[33]Cannabis Regulations, s. 122.3.
[34]Cannabis Regulations, s. 122.5(1)(b).
[35]Cannabis Regulations, ss. 97.1, 124(2).
[36]Cannabis Act, s. 2.
[37]Cannabis Regulations, s. 103.
[38]Cannabis Regulations, s. 103.1.
[39]Cannabis Regulations, s. 103.2.
[40]Cannabis Regulations, s. 104.

Importation

Canadian legislation authorizes importing cannabis into Canada only in limited circumstances. Under the federal *Cannabis Act,* the import or export of cannabis is permitted only if expressly authorized[41]. Although certain licences and permits may authorize the importation or exportation of cannabis, these may only be issued in respect of cannabis for medical or scientific purposes or in respect of industrial hemp[42]. Canada's federal cannabis legislation is restricted for compliance with Canada's obligations under international drug treaties.

Canada is a Party to the Single Convention on Narcotic Drugs, 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances, 1971, and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. In accordance with these international treaties, Health Canada requires that each shipment of imported or exported cannabis is authorized by a permit.

These permits are only issued by Health Canada in limited circumstances. For example, Health Canada has indicated in its published guidance the following possible situations in which it may issue an import or export permit:

a) Importing starting materials (e.g., seeds, plants) for a new licence holder;

b) Exporting cannabis products to another country that has a legal regime for access to cannabis for medical purposes; or

c) Importing or exporting small quantities of cannabis for scientific purposes (e.g., research or testing).

In order to determine whether a permit should be issued in each case, Health Canada has also indicated it considers the following:

a) Canada's obligations under international treaties;

b) Whether the application is consistent with the relevant provisions in the *Cannabis Act* and its regulations;

c) Whether the import or export will be used solely for medical or scientific purposes;

d) In the case of exports, whether the country of final destination has issued an import permit;

e) Whether there are risks to public health given that imported products are not subject to the same strict production standards or Health Canada inspections;

f) Whether there are risks to public safety and security, including the risks of diversion to the illegal market; and

g) For the import or export of drugs containing cannabis, whether import/export requirements of the *Food and Drugs Act* and its regulations have been met.

Thus far, cannabis imports into Canada have been particularly limited. While the legislation allows for cannabis importation to occur, in practice, Canada exports significantly more cannabis than it imports. In 2020 for example, Canada issued permits for dried cannabis

[41]Cannabis Act, s. 11.

[42]Cannabis Regulations, s. 204.

exports exceeding 40,000 kg. During the same period, Canada issued permits for less than 20 kg of dried cannabis imports. These import permits were issued for scientific purposes only, and less than 10 kg of dried cannabis were actually imported in that year.

Future Challenges

As Canada's cannabis legislation remains relatively new, there remain several challenges to address with respect to issues such as international trade and CBD regulation.

Although Canada's legislation authorizes the import or export of cannabis, this happens very rarely in practice in a commercial setting. Health Canada's written policies express that issue and export permits will only be issued in limited circumstances in order for Canada to remain consistent with international drug conventions. It remains to be seen whether the Canadian government will promote greater international trade in the future in a controlled and consistent manner.

As for the regulation of CBD in particular, the Canadian government has already recognized the public interest in CBD health products without the need for practitioner oversight. Regulatory amendments to allow for CBD health products would address a number of issues raised by regulating CBD in the same manner as all other cannabis products.

In particular, the current regulatory framework fails to address a major use of CBD products, namely its therapeutic uses in the relief of low-risk symptoms such as pain relief for sore muscles. Due to the prohibition on health claims for recreational cannabis, producers of CBD products are seriously restricted in their ability to convey information on these potential uses to consumers. While Health Canada may have intended for consumers to resort to the medical cannabis regime for any therapeutic uses, the requirement for practitioner oversight may act as a deterrent for consumers given their expectation that cannabis is safer or healthier to use than pharmaceuticals. As a result, consumers that wish to use cannabis for therapeutic uses currently purchase cannabis with limited point-of-sale information to differentiate the potential health benefits of different products.

Amending the federal legislation to allow for a CBD health product framework may increase opportunities for industry, provide greater transparency and clarity for consumers with minor health ailments, and allow the government additional oversight over the therapeutic uses of cannabis products through pre-market approvals.

The strict regulations on advertising and promoting cannabis products also create branding challenges for businesses operating in Canada, as they prohibit the use of many conventional marketing techniques normally used to build a brand. This impedes the ability of compliant businesses to compete with black market cannabis products that may be cheaper due to lower quality control and no costs of compliance.

As Canada's legal cannabis framework matures, new situations not expressly contemplated in the legislation continue to arise. As these situations arise, further guidance from the Canadian government will play an important role in providing consistency, clarity and transparency to Canadian consumers and industry stakeholders alike.

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CEZCH REPUBLIC

David Štros

Background

In general, cannabis in the Czech Republic is generally tolerated if it is within the valid legal framework. There are efforts to ease the rules concerning cannabis and THC, which also led to recent changes to law applicable as of 1st January 2021.

There is no general regulation, which would cover all aspects of the topic in one law, therefore all specific answers must be interpreted from specific legal regulations of specific fields of law, such as medicinal law, criminal law, food law, advertising law etc. As for use of hemp/ cannabis and CBD in other products, such as food or cosmetics etc., legal regulation is still evolving and does not provide many opportunities in this respect. CBD as such is not included on the list of addictive or psychotropic substances at all, nevertheless there is no special national regulation, which would provide general regulation of this substance.

Recreational

The crucial regulation in the Czech Republic lies in the list of addictive or psychotropic substances, which includes cannabis plants.

It has to be borne in mind that for this purpose, only certain parts of the cannabis plant are to be understood as cannabis and thus are hereby regulated, namely "*the flowering (blooming) or fruiting cyme of the cannabis plant (Cannabis) or the above-ground part of the cannabis plant of which cyme (flower) cannabis is a part*".

Thus, cannabis is not considered to be an addictive or psychotropic substance, if it does not contain the top of a plant (flower). For example, the leaves, wood fibre or seeds are out of this category, provided of course that they do not contain THC, as specified below.

Within this definition of cannabis, the law recognises several categories of narcotics and psychotropic substances with different regimes of regulation, which also include the following substances:

- narcotics in category 1, which can be handled only upon permission from or by health care professionals, which include also:
    - extract and tincture from cannabis
    - cannabis for medical purposes with standardized content of tetrahydrocannabinol
- narcotics in category 3, which can be used only for limited research, scientific and very limited therapeutic purposes defined in the treatment permit, which also include:
    - hemp as plant fibre (except cannabis for medical purposes)
    - hemp resin
- psychotropic substances (category 4), which can be used only for limited research, scientific and very limited therapeutic purposes defined in the treatment permit also include:
    - Tetrahydrocannabinol - THC

Extraction of THC and hemp resin is prohibited - it is forbidden to obtain hemp resin and substances from the group of tetrahydrocannabinols from hemp plants (genus Cannabis).

It is forbidden to grow species and varieties of the cannabis plant (genus Cannabis), which may contain more than 0.3% of tetrahydrocannabinol substances, with the exception of cultivation under a license.[1]

Cannabis plants, which are handled for industrial, technical, and horticultural purposes, so-called technical hemp, have a specific status. Such handling of technical hemp, which must not contain more than 0.3 % THC/tetrahydrocannabinol substances, does not require a permit, provided that the legal conditions are met.

CBD is not on the list of addictive or psychotropic substances and there is no legal limit for its content as an active substance.

Therefore, products made from cannabis, which do not contain THC, can be marketed, provided they meet specific requirements applicable in the respective field of law.

As of 1st January 2022, new rules have come in to force.

Hemp extract and tincture, which contain no more than 1% of substances from group tetrahydrocannabinol and which satisfy the conditions under the Act on General Security of Products, are no longer considered as an addictive substance.

The law also introduces definitions of terms, which are were missing, such as "*cannabis for medicinal purposes*", "*technical hemp plant*" (a plant from genus Cannabis, from which hemp containing not more than 1% of tetrahydrocannabinol substances may be obtained or comes from seed of varieties listed in the Common Catalogue of Varieties of Agricultural Plant Species).

[1]The prohibition shall not apply to the cultivation of varieties of the cannabis plant (genus Cannabis) for research purposes, for the breeding of new varieties and for the conservation of genetic diversity by scientific and research establishments established by law or by the State as defined in the treatment permit.

The above specified limit of THC for handling of technical hemp without permission has been changed from 0,3 % to 1 % of THC allowed in technical hemp.

As for criminal liability, apart from usual serious drug delicts, Czech criminal law recognizes the crime of unlawful cultivation of plants containing narcotics and psychotropic substances and unlawful possession of cannabis, hemp resin or psychotropic substances containing THC in the amount higher than a small amount, which is the amount higher than one usual dose of the substance.

Medical

As for medical cannabis, the law allows production and distribution of cannabis and cannabis product with content of THC higher than 0,3 %, which are otherwise forbidden as addictive/ psychotropic substances, although under strict rules and regulation and close cooperation with the State Institute for Drug Control.

Medical cannabis is defined as dried apical female inflorescences of Cannabis sativa L. (Cannabis sativa) or Cannabis indica L. (Indian hemp), where the crucial active ingredients are recognized to be cannabinoids and cannabidiols. Medical cannabis is produced as a medical preparation and it is strictly regulated, where the law specifies specifically which types of cannabis can be used (sativa and indica), what range of THC and CBD is allowed (THC 0,3% to 21%, CBD 0,1% to 19%), as well as the specific requirements on the quality of the dried plant.

The State Agency for Medical Cannabis was established as the public body granting licences to grow medical cannabis, purchase of grown and harvested medical cannabis and its distribution.

Medical preparations containing cannabis for healing purposes can be provided to patient only upon prescription by a practitioner and only in very specific cases of medical indications. It can be handed out only by registered pharmacies. The price of the preparation is partially reimbursed from the public health care insurance system.

Medical cannabis imported from abroad is allowed to be offered in Czech pharmacies as a prescription drug upon the prior approval of the Ministry of Health.

Sale and promotion of these products, as well as health claims etc. is governed by general rules for marketing of medicinal products.

As of 1st January 2022, new rules will also come in to force in this part, which will focus on the expansion of production of medical cannabis in the Czech Republic. In particular, it is intended to facilitate the acquisition of licenses and thus effectively expand its cultivation. That would then increase its availability for medical facilities and patients.

The implementing legislation for hemp extracts for medical use shall stipulate methods for producing hemp extract for medical use, analytical methods used to test active substances, conditions for labelling and storage of hemp extract for medical use, and methods of processing it as a raw material in products under the Pharmaceuticals Act.

Branding and Marketing

As far as rules for advertising and marketing of cannabis and CBD products are concerned, there is only general regulation for advertising, which covers any type of promotion of business activity, including public information about sponsorship.

In general, it is forbidden to advertise any products that cannot be sold legally. Advertising shall not promote conduct that is harmful for human health. There are also general rules for the protection of persons under 18 years of age in relation to advertising, which shall not encourage behaviour that endangers their health, mental or moral development. Furthermore, there are general rules for advertising of tobacco products, as well as advertising of products aimed at human health, which is strictly regulated and can also cover some cannabis products and statements about effects of these products on human health.

In general, advertisement of products aimedat human health shall not indicate that use of the product will improve or maintain the state of health of the user; indicate that non-use of the product may adversely affect health of persons, as well as that, it shall not promote the product with reference to recommendations of scientists, health professionals or persons who are not, but who, because of their actual or perceived social status, could encourage the use of the product.

This rule concerns both products from cannabis, as well as CBD, which may not be promoted by e.g., health care professionals or even by influencers from social media.

As for health claims, as usual, they are allowed only if used in accordance with general EU rules on this topic.

Edibles, Topicals, and More

Products of any type containing any amount of THC are prohibited. It is also forbidden to add addictive or psychotropic substances into food.

The foodstuff for which production of technical hemp has been used must not contain any - even minimal - amounts of THC, which is guaranteed by the manufacturer. Therefore, the general limit of 0.3 % THC does not apply here, and if a foodstuff contains any amount of THC, it must be withdrawn from the market. THC is therefore banned in food and is considered a contaminant.

CBD in products is not regulated in general. For other requirements, it will depend on the specific product category. As for edibles, foods and food supplements, extracts from cannabis, CBD and products made from them, they are considered by the Czech Agriculture and Food Authority as novel food or potential novel food (e.g., hemp oil) and can be marketed only under the respective EU legal regulations. A different category of products are those where CBD is not added and it is included naturally.

As for cosmetics, there is no specific regulation in relation to cosmetic products, nevertheless they must also comply with the general rule of prohibition of psychotropic substances and avoid any amount of THC.

Cannabis Accessories

This category of products concern smoking, vaping and other accessories, which are devices that can be used for consumption of all kinds of preparations, including cannabis. As such, these products are not illegal and there is no specific regulation in this area. It is only necessary to comply with the general rules of promotions and sale of the products.

It is important that their advertisement and presentation does not promote consumption of illegal addictive substances, which is a criminal offence according to the Czech criminal law.

Importation

As for the import of cannabis products into the Czech Republic, any activity is bound by the basic rule on prohibition of specific addictive psychotropic substance, which are forbidden. Import and marketing of other products as per the above depends on specific regulations for the specific product category and the principle of free movement of goods within the EU.

As for specific categories of cannabis and hemp products, which can be legally put on the market under given circumstances, import permission is required, except among others, for import of cannabis plants containing maximum 0,3 % of THC for industrial, technical and horticultural purposes.

Future challenges

It seems that legal regulation in the Czech Republic is aiming at mitigation of rules and improvement of the market with medicinal cannabis, nevertheless only practice will show, if the new rules are effective and useful.

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DENMARK

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Background

Extracts and derivates of the Cannabis sativa L. plant can be used in a variation of products, hereunder medicines, food, dietary supplements, and cosmetics. Each product category is subject to specific legislation and the legal landscape around cannabis in Denmark reflects this.

The use of 'Cannabis and CBDproducts' in Denmark is primarily authorized for medicinal purposes (medicinal cannabis) since cannabis products (non-medicinal), with a THC content above 0.2%, are prohibited euphoriant substances and therefore commercialization and use of such products is illegal according to the relevant legislation in Denmark.

The area of Cannabis and CBD, in Denmark, is predominantly characterized by the Medicinal Cannabis Pilot Programme, as the program has been extended to 2025. Thus, the political interest in the use of cannabis is centred around industrial hemp and medical purposes in Denmark.

Recreational

As a rule, recreational use of cannabis products is prohibited in Denmark, as Cannabis is subject to the restrictive rules on euphoriant substances.

The euphoriant substances subject to restrictions in Denmark are listed in the Danish Executive Order on Euphoriant Substances[1] (the Order).The Order prohibits cannabis, by which is meant all above-ground parts of plants belonging to the plant genera Cannabis from which the resin has not been removed. Fruits of the hemp plant (hemp seeds) and hemp fibres (or weeds) in isolated condition are exempt.

Any type of use is prohibited and criminalized unless the Danish Medicines Agency (the DKMA) has granted a specific authorization. Subject to certain exceptions, the import and export, sale, purchase, delivery, receipt, manufacture, processing, and possession of cannabis is thus prohibited.

[1]Executive order no. 2446 of 12 December 2022

Violation of the rules of the law or the associated orders is punishable by a fine or imprisonment for up to 2 years. In significant and more extensive cases, for example as part of organized crime, sanctions can increase to imprisonment for up to 16 years.

THC limit as of 1 July 2018

It follows from the Order on Euphoriant Substances that plants and parts of the cannabis plant and preparations made from plants or seeds of the same genus, if the plant, part of the plant or preparation has a tetrahydrocannabinol (THC) content not exceeding 0.2%, are exempted from the above rules on euphoriant substances.

Regardless of whether a product contains THC below the 0,2% limit, the regulations on medicines and foods, including dietary supplements, etc., must (nonetheless) be adhered to. As a relevant example, a cannabis oil product containing CBD may be deemed unlawful - even if it contains less than 0.2% THC - if it does not comply with the rules that apply to the specific product (cosmetics, dietary supplements, medicines etc.).

Industrial hemp

According to the Act on Euphoriant Substances and the Order on Euphoriants, it is not permitted to grow hemp in Denmark without a license from the DKMA. Only hemp varieties with a maximum content of 0.2% Tetrahydrocannabinol (THC) are authorised for cultivation of industrial hemp and hemp is typically cultivated for the following purposes: (i) wild crop, (ii) fibre production, and (iii) seed production.

The National Police contribute an opinion which is part of the assessment by the Medicines Agency. The permit, which is valid for one year, is applied for via the Danish Board of Agriculture, which is the authority responsible for the administration and control of permits. Industrial hemp may be sold, purchased, and possessed when cultivated with the authorisation of DKMA. The Danish Board of Agriculture supervises and controls adherence and specific rules apply to varieties (seed), field areas and purpose of cultivation, etc.

Medical

As a starting point, medical use of cannabis is allowed only in the form of medicines subject to prescription.

In Denmark, doctors have four options for prescribing cannabis-based products:

1. Authorised medicinal products
2. Authorisation for a so-called ‘named-patient basis’ treatment (compassionate use)
3. Magistral medicines
4. Products included in the medicinal cannabis pilot program (see below)

Medicinal products where the active substance is cannabinoids can be authorised in Denmark in accordance with the Danish Medicines Act[2].

[2]Danish Act no 99 of 16 January 2018 on medicines

Currently, only two cannabis-based medicines have been authorised in Denmark by the DKMA. The two medicines are called Sativex and Epidyolex.

1. Sativex is an oromucosal spray that is used to treat spasms in multiple sclerosis.
2. Epidyolex is a CBD based oral solution.

Medicinal Cannabis Pilot Programme

On 1 January 2018 a Medicinal Cannabis Pilot Programme (or the Programme) entered into force. The Programme allows doctors to prescribe products containing medicinal cannabis to patients. The cannabis products included in the pilot Programme are not authorised medicines.

The specific cannabis product may consist of cannabis substances from the Cannabis sativa L strain, herbal preparations and further dosage-like formulations thereof. For example, dried cannabis flowers or extracts thereof (e.g., referred to as cannabis oil, CBD oil or THC oil).

It is the assessment of the DKMA that medicinal cannabis is only relevant to consider for the following medical indications where there is sufficient evidence that medicinal cannabis may have an effect: i) Painful spasms due to multiple sclerosis, ii) Painful spasms due to spinal cord injury, iii) Nausea after chemotherapy, and iv) Neuropathic pain, i.e., pain due to disease of the brain, spinal cord or nerves.

As part of the Programme, private sector businesses may cultivate and produce cannabis products subject to certain restrictions. A license must be obtained to cultivate and produce cannabis products. A given license will reflect the actual activities carried out by the business, and the entity is subject to inspection by the DKMA before being granted a license.

The requirements imposed on businesses depend on the activities that said company is allowed to perform. When businesses cultivate cannabis, they must comply with the rules on good agricultural and collection practice, and when they produce cannabis products, they must comply with the rules on e.g., good manufacturing practice (GMP).

The Pilot Programme was set to expire by the end of 2021 but on 25 May 2021 the Danish Parliament agreed to extend the Programme for an additional period of four years.In early December 2021, a majority in Parliament therefore decided to extend the Pilot Programme from 1 January 2022 and the Amending Act on the Medicinal Cannabis Pilot Programme was adopted.

It may be noted that the Danish Parliament decided to make the production of medical cannabis permanent, thereby separating the production element from the Pilot Programme (which is only continued for a 4-year period).

Branding and Marketing

As a general rule, businesses are allowed to market and advertise products that comply with the legal framework of legislation and supplementary specialised legislative measures (*lex specialis)* on euphoriant substances, foodstuffs, cosmetics, medicinal products, etc.

It should be noted that participating in illegal activities may be considered a criminal offense. Please see below under 'Cannabis Accessories'.

In regard to the Danish Medicinal Cannabis Pilot Programme, it is not allowed to promote the following cannabis products in Denmark:

- Cannabis end-products
- Cannabis intermediate products that are included in the published list of cannabis intermediate products
- Cannabis primary (source) products

Borderline products

As described in previous sections, lawful products containing cannabis may be subject to different legislation, including rules for euphoriants, medicines, cosmetics, and foodstuffs, depending on the specific product and the marketing thereof.

Foodstuffs

In short, foodstuffs containing parts from the cannabis plant can be marketed if they are *safe* and comply with the novel food rules.

Foods must, in general, comply with the above rules on euphoriant substances. Certain parts of the hemp plant (e.g., buds, stems and roots and extracts thereof) may thus not be used in foods.

In Denmark, the legislation governing marketing of foodstuffs, such as the provisions in the General Food Law Regulation and the Food Information Regulation is enforced by the Danish Veterinary and Food Administration (the DVFA).

THC

The new "0.2% limit" for THC led many companies to believe that foods and supplements can be marketed with a THC content of up to 0,2%.

However, foods can generally not contain up to 0.2% THC, as intake of such amounts is considered harmful to health. The DVFA has set (lower) indicative action limits for safe levels of THC in foodstuffs. As an example, the indicative limit for THC in hemp seed oil is set to 4.0 mg/kg.

Novel foods

In addition, the rules on novel foods under Regulation (EU) 2015/2283 must be observed for food ingredients. The Novel food status for hemp and cannabis is stated in the EU Novel Food Catalogue. Thus, seeds, seed flour, protein powder from seeds, defatted hemp seeds and seed oil of varieties of industrial hemp listed in the EU catalogue of varieties which are free or low in THC may be used in foods.

It is particularly relevant for CBD, at present, that extracts of Cannabis sativa L. and derivative products containing cannabinoids (including CBD) are covered by the novel food rules. This applies to both the extract and products to which the extract has been

added as an ingredient. The same applies to extracts of other cannabinoid-containing plants as well as to synthetically produced cannabinoids.

Due to the harmonized legislation in this area, it is not permitted to use CBD nor cannabinoids in foods, including dietary supplements, in Denmark.

Cosmetics

Further to the above, ingredients derived from seeds (the fruit of the cannabis plant), e.g., Cannabis Sativa seed oil, and leaves not accompanied by the bud are allowed to be used in cosmetic products.

Neither the Cosmetics Regulation nor the UN Single Convention on Narcotic Drugs (1961) sets a limit for the use of cannabis in cosmetic products. Further, there is no specific regulation in Denmark. It is therefore decisive which parts of the plant are used, how these parts have been processed and whether the cosmetic product is safe for the consumer.

The European Court of Justice Case C-663/18 of 19 November 2020 states that CBD does not fall within the definition of a narcotic drug under the UN Single Convention. The EU Commission has subsequently announced that the judgment means that CBD also falls outside the definition of narcotic in Annex II of the Cosmetics Regulation and that the reference for CBD in CosIng is removed. The Danish Environmental Protection Agency has therefore stated that CBD is allowed to be used in cosmetic products, regardless of the part of the plant from which it originates, and that synthetically produced CBD is allowed to be used in cosmetic products. However, according to The Danish Environmental Protection Agency, the legal position in Denmark awaits the EU Commission's investigation of whether a ban on CBD should be introduced in the annex of the Cosmetics Regulation.

Cannabis Accessories

Cannabis accessories are not subject to regulation under Danish law, which is why ordinary purchase, possession and sale is generally permitted.

It should be noted, however, that participating in illegal activities may be considered a criminal offense. This may, for example, be the case when buying and selling accessories to such an extent that it constitutes complicity in organized crime. Depending on the circumstances marketing activities for cannabis accessories may be considered a violation of the Danish Marketing Act if products are sold with the explicit or implied intent to, as an example, cultivate cannabis plants and marketing activities for cannabis accessories may in general be considered promoting illegal activities, cf. the legislation on prohibited substances and the Danish Penal Code section 23 (incitement, aiding or abetting to a criminal act).

Importation

In the course of the Medicinal Cannabis Pilot Programme, it requires a license from the DKMA to import and distribute cannabis products. Every license is adjusted in alignment with the activities that a company seeks to perform. The Act on the Medicinal Cannabis Pilot Programme imposes strict requirements for obtaining the aforementioned license.

Future challenges

The latest significant development in the field of regulation of cannabis in Denmark is the adoption of the Medicinal Cannabis Pilot Programme, which now continues for at least 4 years. The Programme may have been adopted and extended, but is surrounded by ongoing political debate, and research is taking into consideration in relation to actual effect, experimental methods and adaptation of the Programme.

Also, the parliamentary decision to make permanent the ability for businesses to grow cannabis for medical use was well received by the industry, as the production of cannabis is no longer tied to the Pilot Programme, however still subject to the regulatory regime for medical products.

In any case, it is certain that the regulatory routes to market differ, and the regulatory landscape is continuously evolving across the different 'Cannabis and CBD' product areas.

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FINLAND

Kukka Tommila

Finland has very strict legislation and attitudes regarding narcotics. The Finnish authorities are doing whatever they can to prevent sales and use of all substances, which have anything to do with narcotics. At least for the moment, the Finnish authorities consider cannabidiol (CBD) as a harmful substance, which shall be prohibited in Finland.

It is not likely that the use of cannabis or CBD will be allowed in Finland any time soon. The estimate is that even if the EU allowed CBD, the Finnish authorities would still prohibit it in Finland on the basis of national legislation.

Cannabidiol (CBD) has been classified as a medicine in Finland. Due to this, any product that contains CBD is considered to be a prescription drug in Finland and all the restrictions concerning prescription drugs apply to CBD. This is in practice a very effective method to limit the possibilities of bringing to market different kinds of new products regardless of whether they are elsewhere classified as foods, food supplements, cosmetics or in some other product category since the medicine legislation overrules food, cosmetic and other product-specific regulations.

In Finland, products shall not contain any narcotic or psychotropic substances, such as THC. There is a zero-tolerance policy in respect of THC and not even extremely small amounts of THC are allowed. Therefore, products containing less than 0,2 % THC are considered as narcotic drugs and narcotic legislation is applied to such products in Finland. Because of this, some CBD products are considered narcotics due to their small THC content.

Recreational

Recreational cannabis and CBD are both prohibited in Finland. Cannabis is classified as a narcotic and CBD as a prescription drug in Finland.

Producing, sales, import,distribution, possession, and use of narcotics is prohibited. Criminal sanctions depend on the type of the offence. The sanction for unlawful use of narcotics is a fine or a maximum of six months imprisonment. The sanction for a

narcotics offence is a fine or a maximum of two years imprisonment. The sanction for an aggravated narcotics offence is a minimum of one and a maximum of ten years imprisonment.

Producing, sales, import and storing of medicines without permission is prohibited. Criminal sanction for a medicine offence is a fine or a maximum of one year imprisonment.

Medical

Medical use of cannabis and CBD is regulated in the same way as the use of all other prescription medicines.

Prescription medicines must obtain a marketing authorisation or a special permit from The Finnish Medicines Agency, Fimea, before they can be sold in Finland. Medicines can only be sold in pharmacies. Currently, there is only one cannabis/CBD medicine (for treating spasticity in MS) which has been granted Finnish marketing authorisation.

All other use of cannabis medicines are only possible with a special permit. The special permit can be granted for the sale of a medicinal product which has no marketing authorisation in Finland, in individual cases for special therapeutic reasons. Special permits are limited to exceptional cases where no other treatment is appropriate or yields the desired result. In order to prescribe a cannabis medicine, the doctor must assess whether the requirements are fulfilled and, if so, the doctor must apply for the special permit and be able to explain the special reasons for prescribing the medicine and prove that the case is exceptional and that no other treatments are possible.

The procedure is burdensome for doctors. Furthermore, the National Supervisory Authority for Welfare and Health closely monitors doctors applying for special permits to prescribe cannabis medicines. The authorities may restrict the rights of a doctor, if they are of the opinion that cannabis medicines are prescribed without sufficiently examining whether some other treatments could be possible. Due to this, most doctors are reluctant to prescribe cannabis medicines.

As a conclusion, it is very difficult to obtain a prescription for cannabis medicines in Finland even on strong medical grounds.

Branding and Marketing

Like sales, the marketing of cannabis and CBD products is generally prohibited.

Edibles, Topicals, and More

In respect of edibles, extracts of Cannabis sativa L. and derived products containing cannabinoids (such as CBD) are considered novel foods in Finland. This applies to the extracts themselves and any products to which they are added as an ingredient. This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are considered as novel. Marketing of novel foods requires authorisation under the Novel Food Regulation.

Furthermore, the marketing of food as having medicinal properties is always prohibited. Thus, even allowed parts of hemp, which do not contain CBD (seeds, seed oil, hemp

seed flour, defatted hemp seed) cannot be marketed using medicinal claims.

All CBD containing products for topical use, such as cosmetics and oils, are considered prescription medicines in Finland. Therefore, there cannot be legal sales of CBD cosmetics, oils or other products. Sales would require a marketing authorisation or a special permit from The Finnish Medicines Agency, Fimea, and the products could only be sold in pharmacies.

The same also applies to all other products containing CBD, since the medicine legislation overrules all product-level legislation.

Cannabis Accessories

Many cannabis accessories, such as rolling papers, pipes, water pipes, bongs and vaporizers, are also smoking accessories and thus regulated by the tobacco legislation. Marketing of all tobacco products, including smoking accessories, is prohibited, a sales license is required, the products may not be sold or otherwise supplied to persons under the age of 18, and online sale and other kinds of distance sales are forbidden.

Importation

Since in Finland CBD is considered a prescription medicine, importing CBD products is prohibited without a prescription from a doctor.

It shall be noted that the decisive factor is how the product is classified in Finland. So, even if in another country it is legal to sell CBD products, those products are still considered medicines in Finland and a prescription, or a medical certificate issued by an authorised person is required to import them. Thus, it is not allowed to import or mail-order CBD products, such as oils or cosmetics, even from countries where such products can be sold without restrictions.

If the Customs notices such a CBD product, a criminal investigation will be started on the basis of a medicine offence, or if there are even minimal traces of THC, on the basis of narcotic offence.

An exception is travellers who have a prescription for CBD medicines. They may be allowed to carry a small amount of the prescribed CBD products for personal useto Finland, provided that the product has been sold legally by a licensed seller in the country where it has been purchased and the traveller also carries the required documents. The restrictions, as well as the maximum allowed import amount, vary according to whether the medicine is imported from within or outside of the European Economic Area (EEA).

Future challenges

Even if CBD were granted a novel food authorisation in the EU, sales of CBD foodstuffs and food supplements would still not be allowed in Finland according to the current regulations as CBD has been classified as a medicine in Finland, and the medicine legislation overrules food legislation.

The Finnish environmental party, The Greens, have recently proposed that the use, possession, manufacture, and sale of cannabis would be decriminalised. They propose shifting drug policy from punishment to harm reduction.

The youth wing of the National Coalition Party made a similar call for the legalisation of cannabis last year. The other parties have not yet supported the legalisation of cannabis, but the political debate is expected to continue. The health authorities are strictly against the legalisation.

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GERMANY

Markus Grube

The German Narcotics Act ("Betäubungsmittelgesetz" – "BtMG") is decisive for the legal assessment of cannabis. According to this law, cannabis is generally classified as a narcotic unless one of the specified exceptions apply. The exceptions include plants and parts of plants that either originate from cultivation in the European Union with certified seeds or have a THC content of no more than 0.2%, provided that the placing on the market serves exclusively commercial or scientific purposes that exclude abuse for intoxication purposes.

With its decision on 19 November 2020 in Case C-663/18, the European Court of Justice confirmed its previous case law that, on the basis of the Convention on Psychotropic Substances, hemp-based narcotic drugs are subject to an import and circulation ban, so that the distributor of such products cannot rely on the European free movement of goods or the prohibition of discrimination.

However, with its decision, the Court of Justice restricted the definition of narcotic drug in such a way that it can only include substances which, on the basis of available scientific data, may have psychotropic and harmful effects to human health. Therefore, in the view of the European Court of Justice, CBD products that contain only a completely insignificant amount of a psychoactive substance do not classify as narcotic drugs. Accordingly, the decisive factor for classification is not from which parts of the cannabis plant the CBD was extracted, but whether it is capable in its concrete composition of causing psychotropic or harmful effects.

This interpretation, which is oriented towards the sense and purpose of the prohibition of narcotic drugs, has also been followed by the highest German civil court, the *Bundesgerichtshof* (BGH), in its judgement of 24 March 2021 (case number 6 StR 240/20) - at least in principle. The BGH affirmed the legislative intention in Germany to ensure a comprehensive and innovative commercial exploitation of cultivable hemp. However, the Federal Supreme Court emphasises that use for intoxication purposes is still strictly prohibited. As a result, this means that any commercial use of hemp must exclude the possibility of misuse of the products for intoxication purposes. In the case at hand, the Federal Supreme Court came to the conclusion that the narcotics law had

been violated because the cannabis tea plants offered could be baked into biscuits in high doses by way of misuse or abuse by consumers, which meant that an intoxicating effect could no longer be ruled out. It is therefore the task of every supplier of cannabis products to ensure that their products are not misused by consumers for intoxicating purposes.

Medical

The use for medical purposes is regulated in Annex III of the German Narcotics Act ("Betäubungsmittelgesetz" – "BtMG").

Branding and Marketing

A problem in the promotion of hemp foods is the exaggerated reference to the cannabis plant or alluding to narcotic effects. This can be considered as misleading the consumer if, due to the presentation of a product or the accompanying advertising measures, the consumer expects an exhilarating effect (which must not be present, as otherwise there would be a violation of narcotics law), which then does not actually occur. In extreme cases, advertising can even be considered offensive if it trivializes drug use, for example, by depicting typical symbols of drug use, such as joints, on the packaging.

Edibles, Topicals, and More

The marketing of cannabis-containing food products is a great challenge for companies, since - as already mentioned - any misuse by consumers for intoxicating purposes must be excluded. In addition, there are strict toxicological guidelines from the highest German official scientific body, the Federal Institute for Risk Assessment (BfR) (cf. BfR Questions and Answers of 16 July 2021 - https://www.bfr.bund.de/de/fragen_und_antworten_zu_den_gesundheitlichen_risiken_von_hanfhaltigen_lebensmitteln-277052.html).

The BfR recommends that the toxicological assessment of hemp-containing foodstuffs be carried out on the basis of the Acute Reference Dose (ARfD) for THC of 0.001 milligram/kilogram body weight derived from the EFSA. The ARfD indicates the estimated maximum intake of THC that can be consumed in food over the course of a day at one meal or over several meals without an identifiable health risk. In the opinion of the BfR, each product to be assessed should be examined on a case-by-case basis to establish if the ARfD can be exceeded for each product. The measured THC content and the estimated consumption quantity are used for the determination. Information on estimated consumption levels is available from EFSA in the form of the "EFSA Comprehensive European Food Consumption Database" or from consumption studies. For food supplements, the recommended daily intake (RDA) can be used, which is legally required for food supplements.

The Acute Reference Dose (ARfD) was derived on the basis of studies with pure THC. The precursor substance, THC-carboxylic acid, has no psychoactive properties. From a toxicological point of view, it nevertheless seems reasonable to use total THC - i.e. the sum of THC and THC-carboxylic acid - for the toxicological assessment as a rule, provided that the measured values refer to starting products. This procedure is also

intended for the assessment of maximum levels, the setting of which is currently being discussed at a European level. For the majority of the available raw materials containing hemp, heat treatment during further food processing, e.g. roasting of hemp seeds or use of hemp seed oil for frying, cannot be excluded. Due to heating, the THC carboxylic acid detected in the starting product may have partially or completely converted into THC in the ready-to-eat food. Therefore, it seems appropriate to use the sum content of THC and THC-carboxylic acid determined in the initial product for assessments and to directly relate it to the ARfD. However, in the opinion of the BfR, this approach should be deviated from if a further thermal treatment of a product is not to be expected in individual cases. This would be the case, for example, with food supplements in the form of capsules or tablets. Here, only the measured THC content should be used for comparison with the ARfD.

In the case of hemp-based foods, it must be examined whether and to what extent they are novel foods within the meaning of Regulation (EU) 2015/2283. Should the products fall under the regulations of the aforementioned regulation, they would be subject to authorisation and may not be marketed without prior authorisation by the European Commission. The European Commission's Novel Food Catalogue (which is not legally binding) first states that some products or parts of plants derived from the Cannabis sativa plant, such as hemp seeds, hemp seed oil, hemp seed flour and defatted hemp seeds, are not intended to be novel foods. The catalogue was supplemented at the beginning of 2019 by a further entry on cannabinoids. According to this entry, cannabinoid-containing extracts from Cannabis sativa L. and their derived products are considered as novel foods, since a use for consumption on a significant scale has not been proven in the European Union before 15 May 1997. This concerns the extracts as well as all products to which they are added as an ingredient. According to the Novel Food Catalogue, synthetically obtained cannabinoids and extracts of other plants containing cannabinoids are also to be assessed as novel and require a corresponding authorisation.

According to the case law of the German administrative courts, the burden of proof that a food was used for human consumption to a significant extent in the Union before 15 May 1997 lies with the food business operator who wishes to place the product on the market. Thus, the European Commission's Novel Food Catalogue only has an indicative effect, which must be refuted by the food business operator if necessary. In the case of cannabinoids, this means that before placing the product on the market, proof must be provided that, contrary to the statement in the Novel Food Catalogue, the respective cannabidiol-containing product was already consumed to a significant extent in the EU before 15 May 1997. Such proof could not be provided in the administrative court proceedings conducted so far to the conviction of the respective court.

The assessment of natural cannabis extracts, where no selective extraction takes place, is less clear. Thus, in a single case in the German federal state of North Rhine-Westphalia, a distinction was made between non-authorised novel foodstuffs containing cannabidiol as CBD isolate or CBD-enriched hemp extracts on the one hand, and foodstuffs not subject to this prohibition containing cannabidiol either naturally or as a full-spectrum extract on the other hand (cf. Higher Administrative Court of North Rhine-Westphalia, decision of 2 March 2021, ref. 9 B 1469/20). In summary, it can be said that in general,

it is very difficult for CBD foods to gain a legally secure foothold in Germany due to the strict view of the Federal Institute for Risk Assessment and the German administrative courts.

In addition, there are so-called administrative general rulings ("Allgemeinverfügungen") in individual federal states of the Federal Republic of Germany, with which, for example, the authorities in North Rhine-Westphalia or in Hamburg generally prohibit the marketing of foodstuffs containing cannabidiol as CBD isolates or hemp extracts enriched with CBD. This would no longer be a case-by-case decision, but a general ban, which, however, would only apply nationwide.

Cannabis Accessories

These are so-called "Bedarfsgegenstände", a term that cannot be translated itself and is best explained as consumer goods that are used particularly close to the body. These products are regulated by the German "Bedarfsgegenstände-Verordnung".

Importation

No special requirements.

Future Challenges

Food containing hemp ingredients are unwelcome by German supervisory authorities, as they either contain toxicologically active ingredients or are marketed with exaggerated references to and associations with intoxicating effects, statements which are then misleading, at least with regard to food, but can also trivialize drug consumption.

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ITALY

Giorgio Rusconi / Giulia Cozzolino / Omar Cesana

Background

At the national level, the matter of cannabis draws its sources, on the one hand from the D.P.R. n. 309/1990 (so called Single Text on Narcotics) and of the other from the Law n. 242 of 2016.

According to the provisions of the Single Text on Narcotics, art. 2, it is the responsibility of the Ministry of Health to grant authorizations for "*the cultivation, production, manufacture, use, trade, export, import, transit, purchase, sale and possession of narcotic or psychotropic substances*".

Article 26 then establishes the illegality of the cultivation of cannabis "*with the exception of hemp grown exclusively for the production of fiber or for other industrial uses, other than those referred to in Article 27, permitted by the regulations of the European Union*".

Table II attached to the Presidential Decree 309/1990, mentions hemp as a drug, with the specification "Flowers, leaves, oils and resins", so it can be seen that these parts and/or derivatives of the cannabis plant are subject to the criminal legislation of the Single Text on Narcotics.

Against this regulatory context, the entire matter of (legal) Canapa Sativa has been fully regulated by Law on 2nd December No. 242 of 2016, which provides rules for the support and promotion of the cultivation and supply chain of cannabis (*Canapa sativa L.*).

The Law applies to the hemp cultivation of the accepted varieties entered in the Common Catalogue of varieties of agricultural plant species, according to Article 17 of Directive 2002/53/EC of 13 June 2002, which are not covered by application of the discipline of narcotic and psychotropic substances, prevention, treatment and rehabilitation of the related states of drug dependence, as per the Presidential Decree No 309 of 1990 (in light of this Decree Cannabis Indica is considered as a narcotic/psychotropic substance).

The cultivation of the allowed hemp varieties is permitted without the need for authorization. In any case, according to Regulation (EU) No 1307/2013, varieties used shall have a THC content not exceeding 0.2 %. However, Article 4 of law No 242 of 2016

states that, when the THC content of the cultivation is higher than 0.2% and within the limit of 0.6% the farmer cannot be charged if he/she complied with the Law's harvesting requirements.

From the allowed varieties it is possible to obtain, amongst others, "foods and cosmetics produced exclusively in compliance with the disciplines of the respective sectors".

Provided that the THC limit is respected, it is possible to use the whole part of the plant (flowers included).

Recreational

In December 2016, a legislative gap created the opportunity for legally selling cannabis with a low level of tetrahydrocannabinol (THC) and CBD. As a result, some start-ups (e.g., Easyjoint, Marymoonlight) entered the market and started selling this light cannabis (C-light, henceforth). Traditional and online media widely covered the phenomenon, and, in April 2018, a famous rapper, J Ax, also launched his branded C-light, Maria Salvador, from the title of his famous song.

In other words and following the entry into force of Law n.242 of 2016, several companies have placed Cannabis-based products on the market with percentages of psychotropic active ingredient THC lower than 0.6%, so as to make the product marketable and therefore legal, believing that the lawfulness of cultivation implied ipso facto the free sale of such products on the market.

However, the letter of the law, as well as the substantial identity - at least visually - between legal product and drug substance, has led to many problems, which first attracted attention from the investigating authority and, later, the Court of Cassation, where the contrast has recently proposed itself in all its urgency.

Two orientations have emerged in this regard. The first, more restrictive, rests on the consideration that the cultivation of drugs is illegal regardless of the concentration of THC, so that the provisions of Law No. 242 of 2016 - which, as mentioned, allow under certain conditions the cultivation of cannabis - must be considered an exceptional rule and not extendable analogically to other conduct, *i.e.* marketing.

Of opposite opinion is the pronouncement of some Judges from Preliminary Hearings that have rejected the requests for seizure made by the Public Prosecutors, considering that the law n. 242 of 2016 has created a window of lawfulness that cannot but reverberate on the marketing of the products of the same cultivation.

The Court of Cassation, invested in the matter, affirmed that the marketing to the public of cannabis sativa L. and, in particular, of leaves, inflorescences, oil, resin obtained from the cultivation of the aforementioned variety of hemp, does not fall within the scope of Law No. 242 of 2016, which qualifies as lawful only if the activity of cultivation of hemp of the varieties entered in the Common Catalogue of Agricultural Plant Species and which lists exhaustively the derivatives of the aforementioned cultivation that may be marketed, so that the transfer, sale, and generally the marketing to the public of the derivatives from the cultivation of cannabis sativa L., such as leaves, inflorescences, oil, resin, are conducts that integrate a criminal activity even in the face of a THC content lower than the values indicated by Law No. 242 of 2016.

Therefore, the Italian Court of Cassation has brought the entire discipline of cannabis back to the Presidential Decree 309/1990 for which the production of cannabis is always illegal unless it is cultivated, in compliance with Law no. 242/2016 and for the sole purposes peremptorily listed in the mentioned Law.

Medical

In Italy, with the Ministerial Decree of 23/01/2013, Surgeons and Veterinarians have the possibility to prescribe medical Cannabis. According to the Ministry of Health, "the medical use of Cannabis cannot be considered a therapy in the strict sense of the word, but rather a treatment for symptoms", suitable to alleviate many pathologies.

The doctor has total freedom to prescribe medical cannabis for charge (not reimbursable), for any pathology for which they consider it effective and in accordance with current legislation (Law 94/98). In this case the procedure is quite simple, a written prescription is used and the costs of the medicine are paid by the patient.

With the Ministerial Decree of November 9, 2015, it has been provided for reimbursement by the National Health System (or, more correctly, by the Regional Health System) for the treatment of certain pathological conditions.

There are various treatments with different varieties of medical cannabis for which reimbursement is provided, such as analgesia in diseases involving spasticity associated with pain (multiple sclerosis, spinal cord injury) that are resistant to traditional therapy or the appetite stimulating effect in anorexia.

In Italy, not all varieties of Cannabis can be used as Medical Cannabis, but only selected genetics.

To date, three subjects, institutional or private, are authorized to provide Medicinal Cannabis. In Italy, there are a total of nine varieties:

- Bedrocan, Bedica, Bedrobinol, Bediol and Bedrolite, produced by the Dutch company Bedrocan and imported through the Dutch Ministry of Health; distribution managed by authorized distributors.
- FM1 and FM2, manufactured by the Stabilimento Chimico Farmaceutico Militare in Florence, Italy; distribution handled by the Ministry of Defense.
- Pedanios 22:1 and Padanios 8:1, supplied by the German company Pedanios, European branch of the Canadian company Aurora Cannabis; distribution managed by the Ministry of Defence.

In the case of prescription by the doctor of only the active ingredient, patients can go to galenic pharmacies, which in Italy number less than 2000. Pharmacists, moreover, cannot prepare products that are not for oral or inhalation use (e.g., eye drops, suppositories, creams for external use) nor can they send them home.

To date, one cannot help but emphasize the chronic difficulty patients face in accessing prescribed care. Patients, hospitals and pharmacies have always complained about the shortage of medical cannabis throughout Italy. It is a chronic problem that has its roots

in a very long bureaucratic process and in a scarce and insufficient supply to cover the demand.

Lastly, no claims are permitted on those products.

Foodstuff

Regarding the cannabinoid THC, the aforementioned Law of 2016 asked the Ministry of Health to set the maximum limit of THC found in foods.

The Ministry issued the Ministerial Decree of November 4, 2019, where only hemp seeds (including crushed, chopped, ground) and its derivatives (oil, flour, supplements) are qualified as food, setting the following limits for them:

Hemp seeds and flour obtained from them: 2.0 mg/kg

Oil obtained from hemp seeds: 5.0 mg/kg

Food supplements containing foodstuffs derived from hemp: 2.0 mg/kg

Branding and Marketing

CBD and THC cannot be advertised.

Advertising propaganda is prohibited by article 84 of the Single Text on Narcotics, which punishes this activity with an administrative sanction ranging from 5,000 to 25,000 euros.

The sale of hemp through internet sites, as a rule, is not considered propaganda, unless the website provides precise indications on how to grow it and / or take it.

Edibles, Topicals, and More

As said, cannabis-containing products can be sold only if those are foods, cosmetics or clothes.

The actual flowers are tolerated when sold with the indication “only for technical and collecting purposes”.

THC limit is indicated by Law of 2016.

Cannabis Accessories

Since Cannabis accessories are also used to smoke tobacco, no limitations can be found.

Importation

It is not possible to privately import any kind of CBD or THC product.

Future Challenges

In our opinion, future challenges will involve the Cannabis sector from a twofold point of view.

On the one hand, the need, perhaps, to revise very restrictive rules with reference to the private and recreational use of the product. Italy has been for years a prohibitionist

country, and this has certainly contributed to the strengthening of criminal structures that import and distribute a product that has always been consumed in the country.

This is, of course, a discourse that is the prerogative of certain politics, but which should also take into consideration aspects of health policy and the fight against organized crime.

On the other hand, the increasing openness towards medical treatments with drugs containing Cannabis should lead the Ministry of Health to a strong rethink with reference to the only subject to which the cultivation of the product has been assigned, namely the army. The chronic lack of the raw material negatively affects the lives of many patients, who wait even months before receiving the treatments to which they are entitled.

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INDIA

Harsh Hiroo Gursahani / Prashant Gupta

Background

Use of cannabis and cannabinoids (CBD) have been a common topic of discussion in India. The history of the cannabis plant and its usage in India draws its roots from the *Vedic literature*, which gives reference to cannabis for its medicinal and spiritual properties. The *Vedas* in India also narrate a strong association between the deity *Shiva* and cannabis. Further, in Ayurveda, cannabis has been as a suggested ingredient in formulations to treat various issues, including pain relief, albeit in small quantities. Cannabis (in certain forms) is used and consumed across the social and spiritual landscape of India.

The primary legislation regulating the use of cannabis in India is the Narcotics Drugs and Psychotropic Substances Act, 1985 (**"NDPS Act"**). The NDPS Act prohibits and criminalises the cultivation of cannabis and production, manufacturing, possession, sale, purchase, transportation, use, consumption, importation, exportation or transhipment of any narcotic drug or psychotropic substancein India, including certain parts/preparations of cannabis, except for medical or scientific purposes. The definition of cannabis under the NDPS Act, prohibits and criminalises the usage of only certain sections of the cannabis plant.

Prohibited Forms: As per the definition of Cannabis (Hemp) under the NDPS Act, certain parts of the plant and their preparations are prohibited. The NDPS Act prohibits the sale and production of cannabis resin and flowers.These include *interalia*Charas and Ganja. Charas '*Cannabis Resin*' is the separated resin, which can either be in crude or purified form which is obtained from the cannabis plant. This also includes the concentrated preparation and resin known as hashish oil or liquid hash. Another form of hemp is Ganja '*Cannabis Flower*' which is the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops).

Regulated Forms: Certain parts of the cannabis plant are regulated for use/sale.These include oil for non-edible uses, and/or the use of seeds, stems and leaves of the cannabis plant, therefore legitimising the use of Bhang in India. Bhang is an edible mixture made from the seeds and leaves of the cannabis plant and has been excluded from its

definition, thereby allowing leaves and seeds of the cannabis plants and their usage in India. The NDPS Actempowers the government to license and permit the cultivation of any cannabis plant for industrial purposes, for obtaining fibre or seed or for horticulture purposes. Consequently, various states in India have licensed the manufacture and sale of Bhang.

Recreational

While the NDPS Act forbids the selling and making of Charas *(cannabis resin)* and Ganja (*cannabis flowers)*. However*,* the definition under Section 2(iii) of the NDPS Act does not forbid the usage of seeds and leaves. *States in India (governments) are allowed to regulate the production, distribution and sale of such forms.* Therefore, '*Bhang*' is a substance made from the seed and leaves of Cannabis that is allowed in India for recreational purposes and is frequently consumed and offered as part of festivities, even though it's highly regulated. In India, Bhang is consumed in multiple forms, Thandai being the most famous beverage among them. Thandai is a milkshake made with bhang and is very popular in the States of Delhi, Uttar Pradesh and Rajasthan during Holi (festival of colour) and Mahashivratri (the day for deity Shiva).

Under the NDPS Act, the State government in India have the power to make laws on cannabis and allow the use of Bhang. For instance, Uttar Pradesh and Rajasthan, has authorised government-licensed shops which sell the same. On the contrary, the State of Assam under the *Assam Ganja and Bhang Prohibition Act, 1958*, prohibits the retail purchase, possession and consumption of Ganja or Bhang in Assam.

Subject to restriction under the NDPS Act, the state governments in India have the power to permit and regulate the cultivation of any cannabis plant, production, manufacture, possession, transport, interstate import, interstate export, sale, purchase, consumption or use of cannabis (excluding prohibited forms such as *charas*). The State governments also have the power to provide the limits within which licenses may be given for the cultivation of any cannabis plant. Therefore, the licenses and procedures concerning cannabis differ from state to state in India. While the NDPS Act, provides an umbrella provision concerning the cannabis plant and its meaning, the state governments regulate the production, use or sale within the limits as prescribed under the NDPS Act.

Medical

Medicinal cannabis in India have been defined broadly under the NDPS Act and means any extract or tincture of cannabis (hemp). The use of cannabis for medical or scientific purposes is not prohibited in India but permitted only after taking requisite permissionsand licenses from the central or state governments. Almost all States in India identify cannabis as an intoxicant and therefore it cannot be produced or used for commercial purposes without a license. In addition to the permits/licenses, the producer, cultivator etc, are subject to high duties and taxes medical cannabis. The marketing of medicines in India is regulated by the Drugs and Cosmetics Act, 1940 (DCA). If any pharmaceutical medicine contains cannabinoids, it has to be approved by DCA for sale in India. Similarly, under Ayurveda as a branch of medicine which explicitly recognizes the use of cannabis leaves in the manufacture of ayurvedic medicines, also requires licenses and permits before the manufacturer of such medicines.

Despite, the controversies regarding the legality of the use of cannabis, cannabis has been used for treating various ailments for thousands of years. The cannabis plant has been an ingredient "in over 104 traditional medicine formulations". The changing trend in Government's policy can be seen since April 2017, when the Ministry of Health and Welfare granted the Council of Scientific and Industrial Research–Indian Institute of Integrative Medicine (CSIR-IIIM) was granted a license to grow it on a single acre of land in Jammu and Kashmir, for medical research only. On 1st February 2020, India's first Medical Cannabis Clinic was opened in Bengaluru. This shows that the support for a policy change, slowly but steadily.

Edibles, Topicals, and More

The Food Safety and Standards Authority of India (FSSAI), vide notification dated 15th November 2021, amended the Food Safety and Standards (Food Products Standards and Food Additives) Fifth Amendment Regulations, 2021, providing standards for hemp seed, hemp seed oil and hemp seed flour, for selling it as food or as an ingredient in a food for subject to conforming standards.[1] These regulations come into effect only from 1st July 2022. The level of cannabidiol (CBD) in any food for sale consisting of hemp seed or seed products is now restricted to a maximum of 75 mg/kg.[2]

According to these regulations, "*Hemp seed means the hulled, non-viable seeds obtained from cannabis Sativa/other indigenous cannabis species. The cultivation of cannabis species for hemp seeds in India shall comply with NDPS Act, 1985 and rules made thereunder.*"

The Food Safety and Standards (Food Products Standards and Food Additives) Regulations now include the following standards:

Regulation 2.16.2(i) Hemp Seeds:

S. No	Parameters	Requirements
1.	Moisture, per cent m/m, Max.	7.0
2.	Protein (N x 6.25), per cent m/m, Min.	30.0
3.	Fat, per cent m/m, Min.	45.0
4.	Ash, per cent m/m, Max.	6.0
5.	Total THC[3], mg/kg, Max.	5.0

Regulation 2.16.2(ii) Hemp Seed Oil:

S. No	Parameters	Requirements
1.	Free fatty acid, per cent m/m, Max.	0.50
2.	Peroxide value, mEq/kg, Max.	10.0
3.	Total THC, mg/kg, Max.	10.0

Regulation 2.16.2(iii) Hemp Seed Flour: means solid product after seeds are milled to a powder with or withoutextraction of oil. The flour prepared after hemp seed has been pressed to extract oil shall clearly belabelled as 'Deoiled hemp seed flour'.

[1]https://fssai.gov.in/upload/notifications/2021/11/619b553646e10Gazette_Notification_Oil_Flour_22_11_2021.pdf
[2]Effective 1st July 2022
[3]Total THC means the total amount of delta 9-tetrahydrocannabinol (THC) and delta 9-tetrahydrocannabinolic acid.

S. No	Parameters	Requirements
1.	Total THC, mg/kg, Max.	5.0

In India, many companies are using Cannabis Sativa Strain for making cloth, cosmetics, rope, printer's ink, wood preservative, detergents, soaps, and lighting oil. Even the seeds are used to produce a variety of food products. The seeds are rich in protein, fibre, and fatty acids including omega 3s and omega 6s. It is said that they have antioxidant effects and may reduce symptoms of numerous ailments, improving the health of the heart, skin, and joints.

Branding and Marketing

So far, advertisements that promote, directly or indirectly, the sale, consumption or production of any kind of intoxicants is not allowed by the Cable Television Network Rules, 1994, the Advertising Codes of Doordarshan and the Norms for Journalist Conduct issued by the Press Council of India. Also, no other regulations are in place that lays down guidelines concerning branding and marketing of cannabis, cannabidiol and tetrahydrocannabinol (THC).

For food products derived/ that uses hemp, hemp seeds or hemp oil as an ingredient, FSSAI has imposed certain additional labelling requirements. The regulations[4] mandate that the food for sale that consists of hemp seed or seed products shall not be labelled or otherwise presented for sale in a form which expressly or by implication suggests that the product has a psychoactive effect. The regulations also prevent the label from making a nutrient content claim or a health claim about cannabidiol, These products are also expressly prohibited from using the words 'cannabis', 'marijuana' or words of similar meaning or evenan image or representation of any part of the Cannabis plant (including the leaf of that plant) other than the seed.

Cannabis Accessories

Indian regulatory framework does not directly prohibit the selling of Cannabis accessories under the NDPS Act. Under consumer goods, there is separate category for cannabis accessories. Many products including but not restricted to Vape, Bongs, Chillam, etc. are widely available in the Indian market. However, there are restrictions on certain products. For example,in September 2019, the Government of India also announced a complete ban on e-cigarettes and vapes. The decision was taken to protect the country's youth following news from the US about the alarming rise in teen use with rising deaths cases there due to e-cigarettes. Additionally, there are restrictions on advertising or promotion of products that support the consumption of illegal, narcotic or psychotropic substances.

Importation

The NDPS Act regulates the import, export or transhipment of all narcotic drugs and psychotropic substances in, out or via India (including territorial waters of India), allows

[4]Regulation 2.16.6 of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations 2011 (2021 Amendment – which comes into effect only on 1st July 2022)

for importation only with valid permissions, licenses from the central government, and incompliance with the conditions stipulated therein, for restricted uses. The NDPS Act also empowers the central government to prescribe the ports and other places at which, and additional conditions and fees payable, for any kind of narcotic drugs or psychotropic substances that may be imported into India or exported from India or transhipped. Violation of these provisions attract imprisonment upto twenty years and fines.

Consequently, importation of cannabis is subject to licenses, permissions and authorisations from the Central Government only. These include interalia specific import authorisation from the Central Bureau of Narcotics, specific permissions for the use – like Drug Manufacturing License, or Hospital Trade License and intended use declarations. Additionally, any import of cannabis into India is subject to 30% basic customs duty, 5% IGST and 10% surcharge, apart from the additional taxes and specific levies by State Governments (excise duty).

Future challenges

With the entry of Hemp seeds in FSSAI, more and more companies enter the hemp space, adding to the ever-growing global hemp industry. Various companies are manufacturing products that use hemp or its by-products, in food as well as fashion industry.

The Indian cannabis market has gathered significant attention recently, with different activists/NGOs filing court petitions requesting sanctioning cannabis. These petitions contend that the medicinal benefits of cannabis are difficult to ignore, and therefore have requested for legalizing medical cannabis.

Cannabis laws in India are outdated and require reconsideration. Although legalisation is still some way off, the rising number of cannabis and hemp start-up companies, and the growing popular support for the limited use (such as medical) legalisation, indicates that the government may need to modify the existing regulations.

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THE NETHERLANDS

Gert-Jan de Jager

Background

The Netherlands has 570 (so-called) coffeeshops, spread over 102 municipalities. The government tolerates the sale of cannabis by these coffeeshops to consumers. However, the production and supply of this cannabis to coffeeshops is not tolerated and is illegal. This Dutch way of handling soft drugs like cannabis was once unique in Europe and across the world. This tolerance policy was for a long time generally regarded as the most suitable way to regulate the use of soft drugs and limit health risks for users. The idea behind the tolerance policy is that soft drugs like cannabis are less damaging to health than hard drugs, which makes it possible to apply less strict rules.

In the 1970s, this tolerance policy for the sale of cannabis in coffeeshops was introduced to separate the markets for hard and soft drugs. But this separation has also caused problems. More and more, society is drawing attention to the problems caused by the tolerance policy. Mayors in particular have indicated that they experience problems in their municipalities because of this. For example, in the area of public order, public health and subversive crime.

This is different for Cannabis sativa L. extracts and other cannabis-based products containing cannabinoids, such as cannabidiol (CBD). The use of CBD in food products is as such legal in the Netherlands. A recent clarification of the EU Novel Food Catalogue however states that products containing CBD are considered novel foods, as a history of safe use has not been demonstrated.

This applies both to the extracts themselves and to the products to which they are added as ingredients. For example, when CBD is added to hempseed oil, a marketing authorization is required and the product can no longer be marketed in the Netherlands. The novel food status also applies to extracts from other plants containing cannabinoids and to synthetically obtained cannabinoids.

New developments on cannabis

Given the issues that have risen regarding sustainability of the tolerance policy, the

government has been putting a small-scale experimentin placesince 2020. The experiment must make clear whether it is possible to supply coffeeshops with quality-controlled hemp in a closed coffeeshop chain and what the effects are on public order and public health. The purpose of the experiment is therefore to see if and how growers can supply quality-controlled cannabis to coffeeshops in a decriminalized way.

Legislation has been adjusted in such a way that cultivation, distribution and sales within the experiment are no longer punishable. This is done by the Act on the Experiment Closed Coffeeshop Chain and lower legislation based on that Act.[1] In the meantime Dutch parliament is working on new legislation to give this experiment a permanent basis in the Dutch Opium Act and therefore permanently decriminalize the selling of soft drugs.[2] The results of the experiment are to be taken into account in this legislative process.

During the experiment, coffeeshops in 10 participating municipalities sell regulated, quality-controlled cannabis. This cannabis is produced by a maximum of 10 selected growers. The first 7 growers have recently been chosen through a selection procedure and are currently setting up their cultivation facilities.[3]

Recreational

Anyone in the Netherlands is allowed to possess and/or use:

- 5 grams maximum of cannabis;
- a maximum of 5 hemp plants.

For the sale of cannabis, coffeeshops must adhere to rules (the tolerance criteria[4]). A coffeeshop owner must meet the following conditions[5]:

- No more than 5 grams of soft drugs per day per person may be sold;
- No hard drugs may be sold;
- No soft drugs may be sold to minors;
- Minors may not be admitted to a coffee shop;
- Alcohol must not be served;
- Drugs and the coffee shop may not be advertised;
- No nuisance may be caused to the surrounding area;
- The commercial stock may not exceed 500 grams;
- No admittance to or sale to anyone other than residents of the Netherlands;
- Sale of soft drugs remains punishable.

In the case that coffeeshop owners do not comply with the conditions, they can be prosecuted and the mayor can (temporarily) close the coffeeshop. In order to prevent nuisance, municipalities can impose additional requirements on a coffee shop. For

[1] wetten.nl - Regeling - Wet experiment gesloten coffeeshopketen - BWBR0042818 (overheid.nl)
[2] Kamerstuk 34165, nr. A | Overheid.nl > Officiële bekendmakingen (officielebekendmakingen.nl)
[3] Inrichting eerste 7 teeltbedrijven wietexperiment begonnen | Nieuwsbericht | Rijksoverheid.nl
[4] Gedoogbeleid softdrugs en coffeeshops | Drugs | Rijksoverheid.nl
[5] These are the (so-called) ahojgi-criteria as stipulated in paragraph 3.4 of the Guidelines Opium Act, wetten.nl - Regeling - Aanwijzing Opiumwet - BWBR0036356 (overheid.nl)

example, adjusted opening hours or a larger distance to schools.

The government wants to counteract nuisance and criminality related to coffeeshops and drug dealing. Therefore, only residents of the Netherlands are allowed to visit a coffeeshop and buy cannabis there. A resident is someone who has his/her (residential) address in a Dutch municipality and who is therefore registered there. The coffeeshop owner is required to verify that he admits only residents of the Netherlands of 18 years and older.

Medical

Under the Opium Act, all actions involving substances covered by the Opium Act are prohibited unless an exemption has been granted. For example, it is forbidden to have on hand, deliver, transport or sell substances that are on list I or list II of the Opium Act. Cannabis is on list II of this Act. An Opium dispensation can be granted by Farmatec in close cooperation with the Office of Medical Cannabis (BMC), both part of the Ministry of Public Health.[6] It may concern the cultivation of medicinal cannabis.

The BMC is a government organization responsible for the production of cannabis for medicinal and scientific purposes.[7] Pharmacists, hospitals and research institutes such as universities can contact the BMC for legal medicinal cannabis. The BMC provides the following products and services:

- Medicinal cannabis within the Netherlands to pharmacies, dispensing physicians and veterinarians;
- Medicinal cannabis to institutions and agencies in other countries if the authorities of those countries agree;
- (Medicinal) Cannabis for scientific research;
- Import and export of cannabis and cannabis resin;
- Opium exemptions for cannabis and cannabis resin.

Patients gain access to these products via a prescription.

Branding and marketing

The tolerance policy provides for far-reaching regulation: under strict conditions the sale of soft drugs in coffeeshops is tolerated. The background to this is that the government wishes to discourage the possession of cannabis for personal use, because of the health risks involved, and wants to prevent users, when purchasing cannabis, from coming into contact with drugs that have agreater health risk (hard drugs). Therefore, paragraph 3.4 of the Guidelines Opium Act stipulates that it is prohibited by law to advertise the selling of cannabis (related) products. This means no form of advertising other than a brief indication on the premises concerned.[8]

The tolerance policy does not allow selling cannabis online. Several of the conditions cannot be checked and/or met, for example the conditions that the buyer is over 18 years old, that it is not allowed to sell more than 5 grams per person and the condition

[6]Home | Farmatec this website also contains further information about applying for an import or export exemption (only for exemption holders) and information about how to report this to the government

[7]Office of Medicinal Cannabis | The Office of Medicinal Cannabis (cannabisbureau.nl)

[8]wetten.nl - Regeling - Aanwijzing Opiumwet - BWBR0036356 (overheid.nl)

that there will not be more than 500 grams of cannabis in store. The fact is, however, that the public prosecution finds it hard to find and charge webshop owners and selling cannabis online is widespread. At the moment no action is being taken against online cannabis outlets.

As for CBD, there are several rulings of the Dutch Advertising Code Committee (prior to the moment food products containing CBD are considered novel foods). CBD is increasingly being used as (an ingredient of) a food supplement. However, as soon as CBD is promoted in a way that it can heal the user of the product, CBD products must be considered medicinal products within the meaning of Section 1(1)(b) of the Dutch Medicines Act.

Under Section 84(1) of the Medicines Act, advertising for or promoting a medicine for which no marketing authorization has been granted, is prohibited. As long as no marketing authorization has been granted for the recommended CBD products, any statement stating the healing effect of the CBD product is not allowed. In case the commendation of the CBD food supplement is accompanied by (allusions to) a medical content, such statements are also in breach of Article 5.2 of the Dutch Advertising Code, which stipulates that advertising with such content is not allowed for health products.[9]

Edibles

Edibles containing cannabis are allowed in the Netherlands as long as the amount of cannabis does not exceed the amount the tolerance policy allows. That means that any edible can only contain 5 grams of cannabis.

CBD in products is not regulated in general, apart from the fact that products that contain CBD are considered novel foods and cannot be marketed without authorization. For other requirements, it will depend on the specific category of product. As for edibles, foods and food supplements, extracts from cannabis, CBD and products made from them are considered as a novel food or potentially novel food (e.g., hemp oil) and can be marketed only under the respective EU legal regulations.

Cannabis Accessories

This category of products concern smoking, vaping and other accessories, which are devices, which can be used for consumption of all kinds of preparations, including cannabis. As such, these products are not illegal and there is no specific regulation in this area. It is only necessary to comply with general rules of promotions and sale of products.

Future Challenges

For the Netherlands, future challenges lie in the results of the current experiment on the closed coffeeshop chain. Is the Netherlands based on these results going to definitely decriminalize growing, selling and using cannabis and to what extent? As there are no results yet, it is difficult to predict what the outcome of this processwill be. That there is a wish to decriminalize the growing and selling of soft drugs as soon as it is deemed prudent, that is a certainty.

[9]Advertising Code Committee 4 June 2019, 2019/00310

NIGERIA

Adeniji Oni

Background

In Nigeria, as with most other African countries, cultivation, recreational and medical use of cannabis is illegal. It is also a criminal offence to be found in possession of the plant in most of these countries as it is generally regarded as an illegal drug. However, given its prevalence and relative overt use and sale, it is clear that the enforcement of the laws have been wanting. This lack of proper enforcement and its continued criminalization in Nigeria and other parts of Africa has led to calls for its legalization especially as regards its medical and then also, recreational benefits.

The Dangerous Drugs Act, 1935 (the "DDA") is the first notable legislation against cultivation, trafficking and abuse of cannabis in Nigeria. The DDA defines Indian hemp as any plant or part of a plant of the genus cannabis; the separate resin, whether crude or purified, obtained from any part of the genus cannabis; or any preparation containing any part of cannabis.[1] The DDA confers right on the Minister of Health to make regulations and prohibitions on the control, importation, exportation, production, possession, sale and distribution of cannabis; except by persons or premises licensed or authorized in that behalf.[2] The DDA allows any person, upon production of an import certificate issued by the competent authority in any country, to be issued an export authorization further to which he may lawfully export Indian hemp from Nigeria.[3] The DDA provides that an import certificate will not be necessary where the intended exportation is destined for a country which is not a party to the Geneva International Convention relating to Dangerous Drugs, 1925 or the Geneva Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, 1931.[4] The paradoxical nature of the DDA is noteworthy, section 7(a) of the Act[5] deals with restriction on the importation and

[1]Section 2 Dangerous Drugs Act 1935
[2]Section 4 Dangerous Drugs Act 1935
[3]Section 13 Dangerous Drugs Act 1935
[4]Section 13 Dangerous Drugs Act 1935
[5]Section 7(a) Dangerous Drugs Act 1935

exportation of Cannabis, section 7(b)[6] deals with restriction on cultivation, production or sale of Cannabis, section 7(c)[7] deals with the restriction on possession of Cannabis. In the same vein, section 13(1)[8] provides for an export and import license for dangerous goods, one of which by definition includes cannabis. This further illuminates the impracticability of the DDA as a regulation.

The Indian Hemp Act of 1966 (the "IHA") retains the definition of Indian hemp as in the DDA, and a sentence of death or imprisonment for not less than twenty-one (21) years is prescribed upon conviction for a person who knowingly plants or cultivates cannabis.[9] Importation, possession and or sale of any medical preparation of cannabis is permissible provided no offence against the DDA is committed thereby. A person who exports cannabis is liable on conviction to imprisonment for a term of not less than twenty-one (21) years.[10] It is notable that the IHA fails to repeal the provision of the DDA which permits exportation of cannabis upon satisfaction of certain conditions by the prospective exporter. A few other amendments were made to the IHA with the enactment of the Indian Hemp Amendment Act in 1975 and the Indian Hemp Amendment Decree, 1984.

In 1989, the NDLEA was established pursuant to the National Drug Law Enforcement Agency Act, 1989, as amended and currently compiled as Cap.N30 Laws of the Federation 2004 (the "NDLEA Act") to enforce laws against the cultivation, processing, sale, trafficking and use of hard drugs and to empower the NDLEA as the main body of authority for drug and policy and enforcement, and to investigate persons suspected to have dealings in drugs and other related matters. By the NDLEA Act, a person who, without lawful authority, manufactures, processes, plants, grows or exports cannabis is liable upon conviction to a sentence of imprisonment for life.[11] The burden lies on the accused person to prove that he has lawful authority to carry out any of the prohibited activities.

The National Agency for Food and Drug Administration and Control Act, 1993, as amended and currently compiled as Cap N1 Laws of the Federation of Nigeria (LFN) 2004 (the "NAFDAC Act") was enacted to create a National Agency for Food and Drug Administration and Control responsible, inter alia, to ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes and grant authorization for the import and export of narcotic drugs. It is pertinent to state that the NAFDAC Act's empathy towards the use of Cannabis revolves around the medical preparation of cannabis. Also, NAFDAC does not concern itself with the cultivation of the plant, rather it deals with importation of Cannabis based products.

A measured study of the highlights of the cannabis related legislation in Nigeria outlined above would reveal that the IHA is at the vanguard of the criminalization of cannabis cultivation and exportation in Nigeria. While the other laws, DDA, NDLEA Act and NAFDAC Act, admit the possibility of obtaining some authorization for lawful cannabis cultivation,

[6]Section 7(b) Dangerous Drugs Act 1935
[7]Section 7(c) Dangerous Drugs Act 1935
[8]Section 13(1) Dangerous Drugs Act 1935
[9]Section 2(1) The Indian Hemp Act 1966
[10]Section 4 The Indian Hemp Act 1966
[11]Section 11 (c), 20 (1) (c), 19 NDLEA Act Cap. N30 LFN 2004

sale, possession, importation and exportation in Nigeria, the IHA expressly prohibits these commercial activities save for the importation, possession and or sale of any medical preparation of cannabis, provided no offence against the DDA is committed in the process. It is also noteworthy that the possible authorization under each of the DDA, NDLEA Act and NAFDAC Act relate to the cultivation, sale, possession, importation and exportation of cannabis for medicinal purposes as none of the laws contemplate the use of cannabis for recreational purposes.

Regulation on recreational use of cannabis

Around the globe cannabis (drug) is widely used as a recreational drug and sometimes, even for spiritual purposes. In Nigeria its use for recreational use can be traced to the hip hop and pop culture closely related with Reggae which is associated with 'rastafaraianism', which is a religion with cannabis at the center of its observances. The late Afrobeat legend, Fela Anikulapo-Kuti promoted cannabis as the 'high' choice for the poor and marginalized people in the country, he could be seen smoking gigantic wraps of cannabis publicly. His Afrika Shrine in the suburbs of Ojuelegba, Lagos is till date a known center for publicly smoking the drug. Thus, made the drug prevalent among the youth as those were the choice in 60s,70ss and 90s.[12]In recent times Grammy Award Winning Artiste such as Damini Ogulu aka Burna-Boy and Ayodeji Balogun aka Wizkid both seem to have not only carried on Fela's kind of music, but also his love for the Sativa plant.

Presently, despite the criminalization of cannabis for recreational use, one is likely to find a seller at virtually every street corner, with little corner stores stocking them like they do cigarettes, salt and sugar. Jokes of absurd behavior following its use and videos of people using the cannabis leaves in place of vegetables is frequent in various media including social media in Nigeria. In May 2021, the NDLEA decided to go after supermarkets, confectionary stores and others dispensing Cannabis cookies and this has raised a lot of debate.[13] Thus, the cannabis product can be sourced in what we refer to as the black market. This is because of the criminal sanctions imposed on those who are found in possession or selling it various laws such as the IHA which prescribes imprisonment for not less than four years is prescribed, upon conviction, for a person who knowingly smokes or is in possession of cannabis.[14] Whilst for use of premises for sale or smoking of cannabis a term of ten years imprisonment without the option of fine is prescribed.[15]

A very key poser is whether the Nigerian sociocultural context is mature enough for a policy consideration of legalizing cannabis for regulated recreational use in order to participate in the global cannabis trade boom, especially when placed along the age long Nigerian tradition of been your brother's keeper. As the recreational use of cannabis might be good for an individual but bad for his immediate neighbor and even worse for children around his neighborhood.

[12]Points, The Use of Marijuana in the Rastafari Religion, accessed at https://pointsadhsblog.wordpress.com/2015/06/11/the-use-of-marijuana-in-the-rastafari-religion/ 2 June 2021.

[13]The Guardian, Fresh debate rages over regulation of medical Cannabis in Nigeria <> accessed on 16 June 2021 https://guardian.ng/features/fresh-debate-rages-over-regulation-of-medical-cannabis-in-nigeria/

[14]Section 5 of the Nigerian Indian Hemp Act

[15]Section 7 of the Nigerian Indian Hemp Act

Regulation on medicinal use of cannabis

Recently, with the discovery of the extra-ordinary medicinal capabilities of cannabis, there has been a widespread of its decriminalization in some countries. It has a plethora of medicinal benefits attributed to cannabis; it is however primarily used for pain control for chronic pain.[16]Generally, in Nigeria, it is an offence to manufacture, sell, possess, import, export or otherwise deal in cannabinoid drugs without an appropriate license. Cannabinoid drugs may however be used only for medicinal or scientific purposes subject to certain conditions.

For emphasis purpose it is critical to reiterate the position of the different existing regulations for a proper analytical discuss on the status of Medical Cannabis. Its marketing and distribution are subject to the license granted by the Minister of Health. On laws regulating medicinal use of cannabis the IHA is represents a major impediment to the cultivation and processing of cannabis in Nigeria for medical and scientific purposes. The IHA unreservedly criminalizes the planting, cultivation and or exportation of any plant of the genus cannabis in Nigeria. In contrast, the importation, possession and or sale of any medical preparation of cannabis is permissible under the IHA, provided no offence against the DDA is committed in the process. On the other hand, the NAFDAC Act provides that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes and grant authorization for the import and export of narcotic drugs. Thus, though cannabis cultivation is generally illegal, where any of such activities is targeted towards medical or scientific use authorization under each of the DDA, NDLEA Act and NAFDAC Act relating to the cultivation, sale, possession of cannabis for medicinal purposes would have to be obtained.[17]

There are essentially no express provisions for approvals to be sought or notifications to be made to any agency or body, whether prior or subsequent to the prescription of the drugs save for the fact that such prescription must be made by a registered, licensed or qualified Medical and Dental Practitioner, or veterinary surgeon. In addition to this, The Dangerous Drugs Regulations ("the Regulations") provides that prescription of these drugs must be in writing, dated and signed by the registered or licensed Medical Practitioner registered or licensed dental surgeon or qualified veterinary surgeon as the case may be, with his usual signature and address, and shall (a) specify the name and address of the person for whose use the prescription is given, (b) the total amount of the drug to be supplied on the prescription.[18]

While there are no specific guidelines for pricing and reimbursement of medical cannabis in Nigeria, authorization of medical cannabis is regulated by the following statues: Indian Hemp Act; Dangerous Drugs Act; NDLEA Act, Cap. N30, LFN, 2004; and the NAFDAC Act. The license to supply, procure, offer to supply or procure, import, export, manufacture or advertise medical cannabis for sale is granted by the Minister of Health of Nigeria and such license must be used in accordance to the terms and conditions attached to

[16]Patriot Care, can Cannabis replace Opiods for Pain Releif? https://patriotcare.org/cannabis-medicines-opiods/ accessed on 10 June 2021

[17]Regulating Cannabis Cultivation in Nigeria – The Legal History. https://www.mondaq.com/nigeria/healthcare/829982/nigeria39s-cannabis-question-balancing-the-tripod-of-law-commerce-and-politics accessed on 16 June 2021.

[18]Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs, <https://pharmaboardroom.com/legal-articles/cannabinoid-drugs-medicinal-cannabis-and-opioid-drugs-nigeria/> accessed on 16 June 2021.

it. Also, medical cannabis must be registered with NAFDAC prior to its manufacturing, importation, advertisement, sale or distribution in Nigeria. The Regulations streamlines the category of persons that can distribute this drug. Consequently, only person or organizations licensed by the Minister of Health to either manufacture, import, export or distribute cannabinoid drugs can sell or distribute these drugs.[19]

One of the issues that arises is balancing the benefits cannabis has medically and the effects its ready availability will have on those who will abuse it. this is a big issue in a society like ours where regulation of the availability of drugs over the counter is still a big challenge despite the good work of NAFDAC has done over the years. Should a law decriminalizing the use of cannabis for medical use be passed, NAFDAC should be adequately equipped and trained for the enforcement of the plant's cultivation, production, distribution, sale and licensing requirements. There is also the issue of the health risks associated with the use of cannabis such as cognitive effects, addiction, psychiatric conditions, obstructive lung disease, reproductive risks and toxic effects to the brain of adolescents and young adults.[20] The issue of regulating the percentage content of THC and CBD in these medicines also have to be taken into account, should its use for medical purposes becomes legalized.

Importation

It is necessary to emphasize that, no product containing Narcotic and Controlled Substances shall be manufactured, imported, exported, advertised, sold, distributed, or used in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN)2004, other related Legislations and the accompanying Guidelines. It is also necessary to emphasize that Narcotics, Controlled/Psychotropic substances and/or Drug precursors should not be imported without obtaining Import Permit and Permit to Clear where applicable.

Obtaining Permit to Import[21]:

1. Documentation:
    a) Companies intending to import Narcotic drugs, Psychotropic Substances and Drug precursors should visit the Federal Government of Nigeria Single Window for Trade Portal (www.trade.gov.ng) to fill the electronic application form for Permit to import Narcotic drugs, Psychotropic Substances and Drug precursors.
    b) The following documents are required to be attached for a successful Submission of the electronic form:
        - An application on the company's letter head addressed to the Director-General, National Agency for Food and Drug Administration (NAFDAC), ATTENTION: Director, Narcotics and Controlled Substances (NCS) Directorate, NAFDAC Office Complex, Isolo Industrial Estate,

[19]Ibid.

[20]Medical Board of California's Guidelines for the Recommendation of Cannabis for Medical Purposes https://www.mbc.ca.gov/Publications/guidelines_cannabis_recommendation.pdf accessed on 14 June 2021

[21]Guidelines-for-Obtaining-Permit-to-Import-Narcotics-Drugs-Psychotropic-Substances-and-Drug-Precursor.pdf (nafdac.gov.ng)

Apapa-Oshodi Expressway, Isolo, Lagos state and duly signed by the Superintendent Pharmacist of the company. The following should be indicated:

- The name of substance(s) to be imported
- The quantity(ies) of substance(s) to be imported in kilogram
- Country of origin
- Name and address of the manufacturer
- Name and address of the supplier

c) Valid Annual Licence to Practice of the Superintendent Pharmacist

d) Valid Certificate of registration/retention of premises

e) Letter of Recommendation from Registration and Regulatory Affairs Directorate (for new applicants only)

f) Proforma Invoice

g) Jacked/Used copy of previous import permit(s)

h) Disposal records for previous importation(s) according to approved template.

i) Distribution records for finished product(s) according to approved template.

j) Evidence of product registration by NAFDAC

k) Evidence of payment of stipulated fee

2. Processing of Permit

a) Upon satisfactory documentation, Company is to liaise with the Inspection & Monitoring Division of the Directorate for inspection of her facility (not applicable to new applicants)

b) Permit to Import will be processed for satisfactory applications.

c) For unsatisfactory application/documentation, a Compliance Directive(s) will be issued to the company.

3. Collection of Permit: Collection of endorsed Permit to Import is at the office of the Director, NCS.

Obtaining Permit to Clear[22]:

Companies intending to clear imported Narcotic Drugs, Controlled/ Psychotropic substances and/or Drug Precursors from the Ports are required to submit the following documents:

1. An application on the company's letter head addressed to the Director-General, National Agency for Food and Drug Administration (NAFDAC), ATTENTION: Director, Narcotics and Controlled Substances (NCS) Directorate, NAFDAC Office Complex, Isolo Industrial Estate, Apapa-Oshodi Expressway, Isolo, Lagos state duly signed by the Superintendent Pharmacist.

[22]Guidelines-for-Obtaining-Permit-to-Clear-Narcotic-drugs-Psychotropic-Substances-and-Drug-Precursors_.pdf (nafdac.gov.ng)

2. The name, quantity of each item and the port of entry should be indicated.
3. Single Goods Declaration (SGD) Form
4. Commercial Invoice
5. Pre-arrival Assessment Report (PAAR)
6. Certificate of analysis from manufacturer
7. Clean Report of Inspection and Analysis (CRIA) for shipments from China, India and Egypt
8. Packing list
9. Form M
10. Bill of lading/ Airway bill
11. Photocopy of Permit to import
12. Evidence of product registration/letter of recommendation from R & R (new applicants only)
13. Evidence of payment of stipulated fee

Future Challenges

There is currently a bill at the House of Representatives to legalize cultivation, processing and commercialization of cannabis titled: "Cultivation, Processing and Commercialization of Cannabis Bill". Though this bill as not been made accessible to the public, it is unavoidable that the said bill will be the major anchor to drive the discussion on future challenges.

Due to the current disposition of the laws and regulations on the cannabis plant in the country, it is safe to say that the branding and marketing, edibles, topicals and accessories of cannabis-based products currently is not regulated specifically. Perhaps upon a change of disposition backed by a new regulation to properly cater for the use of cannabis as a recreational or medical drug then branding, marketing and all other commercial angle will be regulated.

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NORWAY

Marie Vaale-Hallberg

Background

Generally, the Norwegian Authorities practice a strict policy on drugs and stimulants – including cannabis – and have so far inter alia not allowed any production or sales of industrial hemp with 0.2 % tetrahydrocannabinol ('THC') limit as certain other EU/EEA Member States. Currently, only the use and sale of hemp seeds without THC and with no ability to germinate, are legal in Norway.

The liberalization taking place in other countries has however not gone unnoticed in Norway, and despite the strict approach to stimulants, assessments are being made with respect to industrial hemp. In particular, the Norwegian Medicines Agency has recommended that the Norwegian rules are changed so that the use of 0.2 % of THC in products are legalized[1]. By the time this is written, the Norwegian government is assessing the recommendation from the Norwegian Medicines Agency as well as the implications of the decision from the Court of Justice of the European Union regarding cannabidiol (CBD) in a tobacco product (Case C-663/18) and also the decision from the Commission on Narcotic Drugs (CND) of 2nd December 2020. The assessments made so far have been kept confidential and are thus not available to the public at this moment.

The Norwegian rules apply to (i) products containing THC, which are prohibited regardless of the amount used in a specific product, (ii) products containing CBD, which according to current practice aredeemed as a pharmaceutical, (iii) products containing hemp seeds without THC, which may be sold legally, and (iv) the import and the use of hemp seeds without THC to be used in food and feed. No breeding of any cannabis plant is allowed.

Recreational

Any recreational use of recreational cannabis, CBD and THC is illegal.

Norway has ratified the UN Single Convention on Narcotic Drugs 1961 and the UN

[1]https://legemiddelverket.no/Documents/Om%20oss/%C3%85rsrapporter/%C3%85rsrapport%202019.pdf

Convention on Psychotropic Substances 1971. The incorporation into Norwegian law is made in the Regulation on Drugs, the Regulation on Pharmaceuticals and the Regulation on Seeds. The rules are interpreted and practiced strictly by law enforcement and other regulatory authorities.

According to the Norwegian Regulation on Drugs section 2 cf. Appendix List on Drugs, cannabis is enlisted as a drug and thus strictly prohibited. Cannabis is defined as "*all kinds of the cannabis species growing above the ground (except the seeds), provided that the resin is not extracted*". This definition thus appears to differ from the definition in the 1961 Convention[2]. It follows explicitly from the Act and Regulation on Drugs that the Drugs lists may be amended with any drugs and substances that may have a narcotic effect, in addition to substances enlisted as drugs in the two conventions.

What is specifically considered as a drug in Norway is stated in the Regulation on Drugs, section 3. Besides the substances, plants etc. enlisted in the Appendix List on Drugs, mixtures containing such substances, plants etc. are also considered as drugs. "Mixtures" in this context encompasses extracts, concentrates, dilutions and resolutions.

With respect to THC in particular, the current practice in Norway is that any amount of THC is prohibited, which means in practice any products such as a cosmetics, foods etc. containing THC - regardless ofwhether it has any narcotic properties - are by implication always illegal. Moreover, according to current practice from the Norwegian Medicines Agency, CBD is generally considered a drug and is also considered a pharmaceutical.

Products containing cannabis seeds without THC may be legally sold in Norway, including foods and cosmetics. However, seeds cannot be grown in Norway, and import presuppose that the importer can provide satisfactory documentation confirming (i) the lack of germination of the seeds and (ii) that the product does not contain THC.

The prohibition is strictly enforced, and any import, export, purchase, storage and use of a narcotic substances may be punished with a fine or imprisonment up till two years.

Foods

Any use of cannabis, THC and CBD in foods is illegal, with the exemption of seeds or products derived from seeds as outlined in section 2 above. Any use of the seeds presupposes however that the use is safe and that the product is fit for human consumption. Food Business Operators that desire to import seeds for the purpose of manufacture food stuffs in Norway, must file for a dispensation from the Norwegian Food Safety Authority, see section 7 below.

Whilst food stuffs that consist of or are based on the seeds from Cannabis sativa – for example oil and flour made out of such seeds – have been distributed in a number of different EU/EEA countries before 15 May 1997 and thus not considered novel, it is the position of the Norwegian Food Safety Authority that there is no information about CBD or other sorts of cannabinoids, extracts from Cannabis sativa and the likes which have been used in foods within the EU/EEA before 15 May 1997. Such products are thus likely

[2]Article 1 (b): *"the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated".*

to be deemed as a novel food under the current practice, should the use otherwise be legalized in the future.[3]

Food stuffs may as the main rule be marketed and sold without the need for permission or approvals from the authorities, but certain substances require notification and sometimes also approval depending on the substance at hand. As the use of THC and CBD, and other extracts from the plant, under the current rules are illegal, the addition of them to food is not yet regulated and accordingly it is not yet clear if specific notifications or applications will be required (in the future).

Cosmetics

Under the current practice, certain cosmetics that contain CBDor cannabis sativa may be legally sold and some will be defined as drugs and thus illegal. In particular, if the source in a cosmetic product is extracted from seeds of Cannabis sativa (hemp seeds) and these do not contain THC or CBD, then the product is permitted on the condition that the substance otherwise is legal for use in cosmetics. But if the cosmetic contains THC or if the CBD oil or extract is derived from other parts of Cannabis sativa than the seeds, then the product is prohibited. This is because the Norwegian authorities consider such products as drugs pursuant to the UN Drug Convention and the Drug Regulations.

Norway has incorporated Reg (EC) 1223/2009 on cosmetics into Norwegian law without reservation, and the Norwegian authorities are duly aware that the EU's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs added cannabidiol (CBD) "*derived from extract or tincture or resin of cannabis*" as a legal cosmetic ingredient to its CosIng guidelines. However, the current Norwegian practice will not be altered until further formal clarifications are made at the EU/EEA level.

For the matter of clarity, synthetic (i.e. chemically produced) CBD is permitted in cosmetic products if the product otherwise meets the requirements of the cosmetics regulations.

Medical

CBD is considered as a pharmaceutical by the Norwegian Medicines Agency and consequently, CBD cannot be used unless approved. Nevertheless,the Norwegian Medicines Agency recognises that some patient groups may benefit from treatment with medical cannabis. Therefore, doctors may apply for treating patients with medical cannabis even though such medical cannabis has not been approved for marketing in Norway. In these cases, the Norwegian Medicines Agency distinguishes between medical cannabis which contains more than 1% THC and medical cannabis which contains less than 1% THC.

For medical cannabis containing more than 1% THC, only specialists working at hospitals can apply for using such medical cannabis in the treatment of patients. The Norwegian Medicines Agency considers these applications and in order to have an application approved, the doctor must have addressed the reasons why such treatment is considered necessary for the patient.

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[3]https://www.mattilsynet.no/mat_og_vann/produksjon_av_mat/ny_mat/hamp_cannabis_sativa_cannabidiol_cbd_og_andre_cannabinoider.34397

For medical cannabis containing less than 1% THC, doctors with permission to make prescriptions for class A pharmaceuticals may apply to The Norwegian Medicines Agency for using such medical cannabis in the treatment of patients.

Permission to manufacture drugs for pharmaceutical purposes requires permission from the Norwegian Medicines Agency, cf. Act on Pharmaceuticals section 23.

Branding and marketing

Based on the current legal landscape in Norway, discussing branding and marketing of cannabis/CBD is only a theoretical exercise. Hinting about cannabis, either directly or indirectly in branding or marketing, will be taken down by relevant authorities and potentially the Norwegian Consumer Authority. Even referring to cannabis when applying for a trademark registration will be rejected as it follows from the Trademark Act section 15.1.a, that a trademark cannot be registered if it is contrary to law or public order or is liable to cause offence. The Norwegian Industrial Property Office has, in a number of application matters, and with reference to the Trademark Act section 15.1.a, refused to register trademarks which consists of the word CANNABIS. The reasoning behind these refusals is that cannabis is an illegal drug in Norway and granting trademark protection to a mark consisting of the word CANNABIS will be perceived as a public approval of the use of the word CANNABIS as a trademark for the goods and services in question, and is capable of causing offence among the Norwegian public.

In the future, if a liberalization of the rules becomes a reality, any marketing in Norway must be in accordance with good marketing practices and the Marketing Practices Act sets a limit in terms of what can be considered as good marketing practices. By means of assessing what is considered “good marketing practice”, section 2 of the Marketing Practices Acts states that it will be taken into consideration whether the marketing violates a common ethical and moral codex. The marketing of products which can be legally sold on the Norwegian market, cf. the comments above, must comply with the same rules.

Edibles, topicals and more

Reference is made to the previous comments. Basically, any sale of cannabis and products consisting of cannabis is strictly prohibited in Norway and only minor exceptions apply, e.g. in terms of products based on seeds from cannabis sativa and use of medical cannabis, cf. the comments in the previous sections.

Cannabis accessoires

The marketing and sale of cannabis accessories is not specifically regulated (as cannabis is enlisted as an illegal drug in Norway). However, any marketing of products which are specifically marketed or referred to as “cannabis accessories” will be deemed a violation of the Marketing Act, cf. the comments above in section 4.

Furthermore, many of the accessories which can be used for cannabis are also accessories which are normally used for other tobacco products, for example rolling papers, pipes, water pipes etc., and the marketing and sale of such products is regulated in the Norwegian Tobacco Act.

Advertisement of tobacco products, including accessories, is strictly regulated in Norway as all marketing (sponsorship included) is in principle banned, cf. chapter 5 of the Norwegian Tobacco Act. The sections in the Tobacco Act regarding advertisement and sponsoring of tobacco products are based on the implementation of directive 2003/33/EC (on tobacco advertisement and sponsorship).

Importation

It is prohibited to import any drugs which are enlisted in the Appendix List on Drugs, cf. the Norwegian Regulation on Drugs section 2.

Seeds of Cannabis sativa may not be grown in Norway and despite the fact that, for example, foods and cosmetics which are based on seeds of Cannabis sativa may be marketed and sold in Norway, it is prohibited to import and bring on the market seeds of Cannabis sativa if the seeds consists of narcotic substances, cf. Regulation on Seeds, Section 28.

Seeds may however be imported for use in food and feed on the condition that the Food Business Operator provides satisfactory documentation confirming (i) the lack of germination of the seeds and (ii) that the product does not contain any amount of THC.

The documentation listed above must be submitted to the Norwegian Food Safety Authority which is the authority able to grant a dispensation and thus permit import of such seeds. Any such import license will only be possible to obtain for companies and thus not individuals. Irrespective of the aforesaid, no import license is required for importing seeds of Cannabis sativa **without** hulls, flour made of seeds and the like to be used in food or feed.

Future challenges

In 2019, the Norwegian Government requested that the Norwegian Food Safety Authority and the Norwegian Medicines Agency had to assess the possibilities within the current regulation to use, import, market and produce (not grow) products containing CBD and products made of industrial hemp by 1st July 2019[4].

In the conclusion of the report, it is suggested that the current legislation (the Norwegian Regulation on drugs) should be clarified with regards to products containing a low level of THC.

Two alternatives for legal clarifications were given:

- **Alternative I):** All products containing THC, including products containing cannabis extract are covered by the definition of “drugs”. This means that only foods produced from hemp seeds that do not contain THC and cosmetics with ingredients not covered by the Convention on Drugs can be sold. (In practice, not alter the current rules and practice)
- **Alternative II):** Products from cannabis plants with the THC content < 0.2%, as well as products based on cannabis extract, are exempt from the definition of drugs. This may open up sales of products containing low amounts of THC.

[4]https://www.regjeringen.no/contentassets/f3630965333e4af2a5f1007dbdc0bad9/tildelingsbrev_mattilsynet_2019.pdf

Currently, the Government is assessing the report. At present there is no information on the timeline of any further procedures. In conjunction with this, the Norwegian authorities are assessing the current international development following the UN Commission on Narcotic Drugs (CND) meeting in December 2020 as well as the recent judgment rendered on 19 November 2020 by the Court of Justice of the European Union stating that a "*Member State may not prohibit the marketing of cannabidiol (CBD) lawfully produced in another Member State when it is extracted from the Cannabis sativa plant in its entirety and not solely from its fibre and seeds*"[5]. So far,these assessments are classified as confidential by the authorities and the content has yet to be revealed. Perhaps – a potential, limited liberalisation will be the outcome?

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[5]https://www.politico.eu/wp-content/uploads/2020/11/CP200141EN.pdf?utm_source=POLITICO.EU&utm_campaign=89d390a838-EMAIL_CAMPAIGN_2020_11_19_11_27&utm_medium=email&utm_term=0_10959edeb5-89d390a838-190657192

POLAND

Paweł Borek

Background

According to the current legal status, the cultivation of hemp may be conducted only for the needs of the textile, chemical, pulp and paper, food, cosmetic, pharmaceutical, building materials and seed industries. In Poland, there has been an increased interest in products containing CBD for the last few years. In most cases, products are declared as dietary supplements. From 2018 to 2021, almost 600 products containing CBD were reported to the Chief Sanitary Inspectorate as being marketed for the first time. Most of these products have not yet been inspected. According to the Act on food and nutrition safety of 25 August 2006 (consolidated text Dz. U. of 2020, item 2021) In order to sell a supplement, it has to be reported to the Chief Sanitary Inspector. The Chief Sanitary Inspector does not issue any decision on sale authorization or a permit. The seller may start selling products after submission of the application to the Inspection. There is a lack of any prior control. This results in many products on the market that do not comply with any regulations. Even if the Chief Sanitary Inspector orders the product to be withdrawn from the market, the producers notify as a new product, change the name or dosage and notify again *de facto* the same product. A negative practice observed on the market is the sale of products containing CBD with the information product not intended for consumption, while the packaging indicates that it is a product for consumption.

The Supreme Audit Office audited this process in sanitary inspection. It turned out that in 2014- 2016 it took an average of almost 8 months from notification to the start of the verification process, and a record of 1.5 years. In relation to more than 6,000 products, the verification process was not carried out at all. As for the verification period, it took much longer from - an average proceeding lasted over 6 years (For those that started in the years 2009 - 2010).These are figures of the length of the verification process for all applications, not only to CBD. If an inspection from the Sanitary Inspection of CBD products is initiated, the majority of products are withdrawn, by the producers.

The European Commission has authorized Poland to establish a ban on the marketing of the Finola hemp variety on its entire territory. The Commission decision was issued on 22 July 2021 and published on 26 July 2021.

In January 2021, Poland applied for the possibility to establish a ban on the marketing of the Finola hemp variety due to the fact that, after analysis, the average THC content of all samples of the Finola variety exceeded 0.2% for the second consecutive year. Poland has not yet taken any action to restrict the availability of the Finola variety.

Recreational

Recreational cannabis manufacture, distribution, commercialization, and use are illegal. Illegal cultivation of fibrous cannabis (is punishable by a fine).Permission for the cultivation of fibre hemp shall be granted by the municipality (mayor, town president) responsible for the location of the plant. Such permit may be obtained either by a natural or a legal person. The permit may not be obtained by a person who has previously been convicted of illegal fibre hemp cultivation. Act on Counteracting Drug Addiction of 29 July 2005 (consolidated text Dz. U. of 2020, item 2050).

Medical

Raw material of hemp, in which THC content is higher than 0.20% should be treated as a psychotropic substance and its intra-Community acquisition and further use for manufacturing, including extraction, requires a permit from the Chief Pharmaceutical Inspector pursuant to the Act on Counteracting Drug Addiction

In case when extraction of psychotropic substance is used to obtain a medicinal product or pharmaceutical raw material, then it is required to obtain a permit for manufacturing or importing a medicinal product and according to art. the Act on Counteracting Drug Addiction to obtain a permit for manufacturing, processing, converting, importing or distributing narcotic drugs or psychotropic substances. The above-mentioned permits are issued by the Chief Pharmaceutical Inspector. Pharmaceutical Law of 6 September 2001 (consolidated text Dz. U. of 2020, item 1977).

Branding and Marketing

There are no additional regulations in this area. This is regulated the Act on food and nutrition safety of 25 August 2006 in case of supplements by, and in case of medical products by Pharmaceutical Law of 6 September 2001.

Cannabis Accessories

Accessories are not mentioned in the Act on Counteracting Drug Addiction of 29 July 2005. Therefore, it is not subject to any specific prohibitions in distribution.

Import

The importation of hemp products is regulated by the Act on the Administration of Foreign Trade in Goods of 16 April 2004 consolidated text of 1 August 2019. (Dz.u. 2019, item 1606) and Regulation of the Minister of Economy and Labour on licences for the import of hemp from third countries of 8 February 2005 (Dz.U. No. 24, item 198). The decision on the import licence is issued by the Director General of the National Support Centre for Agriculture. A decision to import hemp is valid for 8 months from the date it is issued.

Future Challenges

On 20 April 2021, a parliamentary Act on fibre hemp was submitted to the Speaker of the Sejm. The presented project of assumptions provides for separation of a new act on cultivation of fibre hemp from the act of 29 July 2005 on counteracting drug addiction and for appropriate adjustment of the Act on granting protection to hemp. That is, the regulations on cultivation of fibre hemp were to be transferred to a new act whose main goal was to regulate cultivation and increase the permissible level of THC from 0.2 to 0.3.

The explanatory memorandum of the act identifies the main problems concerning fibre hemp in Poland:

1. bureaucratic, annual zoning procedure approved by resolution of the provincial assembly, focused on seasonal rather than year-round cultivation, burdening farmers and provincial and local administration;

2. restrictive THC level of 0.20%, i.e. lower than permitted by European law before the amendment of the European Parliament adopted on 23 October 2020 (0.2%) and after the amendment (0.3%).

3. a too narrowly defined catalogue of uses of hemp seed.

On 20 April 2021, a parliamentary Act was sent to the Parliament. The purpose of the Act was to simplify the procedures related to the cultivation of fibre hemp, to define the tasks and powers of government administration bodies and local government units and other entities with respect to the cultivation, processing, conversion, trade and possession of fibre hemp and derived products, and its provisions were to be applied to the cultivation, processing, conversion, trade and possession of fibre hemp and derived products.

Fibre hemp was to be given a new definition and understood as “plants of the species hemp (Cannabis sativa L.) in which the sum of the content of delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid (delta-9-THC-2-carboxylic acid) in the flowering or fruiting tops of plants from which the resin has not been removed does not exceed 0.3% on a dry weight basis”. As the drafters emphasised, “processing” was to mean activities leading “to the conversion of fibrous hemp into other products, materials or substances that are not narcotic drugs, psychotropic substances, precursors or new psychoactive substances”.

The proposed law was to authorise the cultivation of hemp on the basis of a permit obtained “for the purpose of breeding varieties of fibrous hemp, for use on a farm or for industrial purposes, in particular: energy, textiles, chemicals, pulp and paper, food, cosmetics, pharmaceuticals, building materials and furnishings, seed, veterinary, feed, composite materials, land reclamation and remediation, beekeeping, fertilisers, natural plant protection products, and scientific research”, while the cultivation of other hemp was to be prohibited.

On 13 January 2022, the first reading of the draft took place and the vote on it was rejected. There were 225 votes against, 211 against and 6 abstentions. The lower house of the Polish Parliament, the Sejm, consists of 460 members.

More attempts to pass legislation to regulate fibre cannabis are expected in the future. Regulations in Poland are very limited and there is no single act that would regulate all issues related to hemp cultivation, production, distribution or advertising.

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PORTUGAL

Paweł Borek

I. Background

Cannabis plant and its derived products have a large actual or potential application field, ranging from food and feed, textile fibres and seeds, medical or veterinary medicinal use, cosmetics, flavourings, food and feed additives to recreational use, amongst others.

From an agricultural perspective cannabis production based on the plant *cannabis sativa*, has a clear economic interest that should not be underestimated and has increasingly come under the attention of governments and legislators all over the world.

The main scope of this article is the Portuguese legal framework on the use of cannabis in recreational and medical settings, since all other uses are basically addressed by European law and are common to all Member States[1] with no national exceptionality.

II. Recreational use

In Portugal, the main law on the control, use and trafficking of narcotic drugs, psychotropic substances and precursors is Decree Law No 15/93, of 22 January.

This law regulates several aspects regarding penalties and criminal investigation of drug related activities, clearly distinguishing between drug use and drug trafficking.

Controlled substances are annexed to this decree law and divided into six lists. List 1 is divided into: opiates; coca derivatives; cannabis and derivatives. List 2 is divided into: hallucinogenic; amphetamines; barbiturates. List 3 includes preparations with controlled substances. List 4 includes tranquillisers and analgesics. List 5 and 6 contain precursors.

Before 2001, drug use and drug possession regardless of the motivation behind the offence was a criminal offence punishable with imprisonment.

In 2001, a new legal framework decriminalising the use and possession for use of all illicit drugs (including cannabis) was adopted, under Law No 30/2000, of 29 November.

[1]For further analysis see the "Overview of the EU acquis applicable to cannabis in its different forms and components"

Since Law 30/2000 came into force, consuming, purchasing and holding drugs and psychotropic substances for personal use (included in the lists annexed to Decree Law 15/93) have ceased to be a crime as long as the amounts concerned do not exceed the average amount necessary for personal consumption during a 10 day period

Possession of an amount of drug exceeding the average amount necessary for personal consumption during a10 days period continues to be a crime and is therefore punished according to article 40 of Decree Law 15/93 of 22 January.

The average daily amount for personal consumption was established by subsequent legislation, based on the active principle of each drug or psychotropic substance.

Although sanctions can still be applied, these are no longer the purpose of the Commission in charge of cases of illicit drug use/possession (CDTs – Comissão para a Dissuasão da Toxicodependência) received from the police, when more serious offences are not at stake (sale, trafficking). Rehabilitation and treatment of drug addiction is its main objective.

The courts are no longer responsible for dealing with these cases of consumption, acquisition and holding for personal use of drugs and psychotropic substances.

Cannabis comes under the same legal framework that is applicable to other controlled drugs.

Unfortunately, sourcing of the product for consumers continues to be a crime of trafficking (art. 21 of Decree law 15/93) and therefore an exclusive and profitable market for criminals.

Cannabis accessories (i.e., rolling papers, or wraps, holders, pipes, water pipes, bongs and vaporisers) come under no specific regulation, and therefore its trade is legal.

III. Medical use

The legal framework on the authorization of medicinal products, substances or preparations based on the plant “cannabis sativa” for medical use was laid down in Law No 33/2018 of 18 July, which also established medical prescriptions and sale in pharmacies. This law was further regulated by Decree Law No 8/2019 of 15 January and Ministerial Order No. 83/2021 of 15 April.

Medicinal products, substances or preparations based on cannabis are subject to a previous authorization issued by the national authority INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

INFARMED, I.P., is the national competent authority in charge of supervising and ruling all activities pertaining to cultivation, production, extraction and manufacture, wholesale trade, distribution to pharmacies, import and export, transit, acquisition, sales and delivery of medicines, substances and preparations based on the plant of cannabis for human medical use.

Placing medicines and substances or preparations based on cannabis for medical use on the market equally requires a marketing authorization issued by INFARMED.

Consumption of medicinal products, substances or preparations based on cannabis for human use requires a medical prescription and these products are sold exclusively in pharmacies.

As for the labelling of these medicines and substances or preparations based on cannabis, there are two different cases:

- For products classified as medicine for human use, the rules applicable to medicinal products laid down in Decree Law No. 176/2006 of 30 August, Decree Law No. 97/2015 of 1 June and Decree Law No. 282/95 of 26 October shall apply.
- For substances and preparations for human use based on cannabis, certain information is mandatory and must be written in Portuguese on the label: name of the product, nature of the substance/preparation, ingredients, pharmaceutical formula, sell-by date, storage conditions, instructions for use, batch and authorization registry number.

Special notices for the user are also mandatory for these products, including possible side effects and warnings about the risk of developing addiction.

All imports of cannabis derived medicinal products, substances and preparations are subject to a previous authorization issued by INFARMED for each operation. Only licensed operators can carry out the activity of import/export of medicines for human or veterinary use and substances and preparations based on cannabis.

Regarding the agricultural production of cannabis for industrial purposes, national legislation lays down that the variety cultivated must have a THC content under 0,2% and be included on the Common Catalogue of Varieties.

Unfortunately, the national framework on agricultural production for industrial purposes followed the rules on the use of hemp products as feed applicable in the European Union, that is allowed provided that the content of THC and Cannabidiol does not exceed the threshold set in the regulation on contaminants and undesirable substances.

IV. Trends

Currently there are two draft bills being discussed in Parliament on legalising recreational consumption, cultivation of a limited number of plants, production, distribution, importation and marketing of the plant, substances and preparations of cannabis, without medical prescription.

Since the two main parties of the political spectrum are not fundamentally opposed to a liberalisation in a greater or lesser degree, future legalisation of the recreational use of cannabis is to be expected.

Be that as it may, the national drug strategy clearly prioritises treating and rehabilitating drug addicts, promoting treatment over punishment.

It is regrettable that this strategy of openness to new ideas regarding cannabis does not extend to other illicit drugs in order to allow its legal and controlled sourcing, involving health services and pharmacies, instead of leaving the market in the hands of drug traffickers.

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RUSSIA

Maxim Alekseyev / Timur Akhundov

Russian legislation includes two levels of regulation concerning Cannabis and other drugs and drug substances:

International

- Decision of the Board of the Eurasian Economic Commission dated April 21, 2015 No. 30 "On measures of non-tariff regulation";
- Resolution of the Board of the Eurasian Economic Commission dated November 06, 2014 No. 199 "On the instructions on the registration of an application for the issuance of a license for the export and (or) import of certain types of goods and on the registration of such a license and instructions on the registration of a permit for the export and (or) import of certain types of goods".

National

- Federal Law of the Russian Federation No. 3 – FZ dated January 8, 1998 "On Narcotic Drugs and Psychotropic Substances" ('Law on Narcotic Drugs');
- Criminal Code of the Russian Federation;
- Code of the Russian Federation on Administrative Offences;
- Resolution of the Government of the Russian Federation dated June 30, 1998 No. 681 "On approval of the list of narcotic drugs, psychotropic substances and their precursors subject to control in the Russian Federation" ('Resolution No. 681');
- Resolution of the Government of the Russian Federation dated December 31, 2009 No. 1148 "On the procedure for the storage of narcotic drugs, psychotropic substances and their precursors";
- Resolution of the Government of the Russian Federation dated July 20, 2011 No. 599 "On control measures for drugs that contain small amounts of narcotic drugs, psychotropic substances and their precursors included in the list of narcotic drugs and psychotropic substances subject to control in the Russian Federation".

- In accordance with the Resolution No. 681, cannabis (marijuana), as well as tetrahydrocannabinols ('THC') are expressly included into the list of narcotic drugs, psychotropic substances and their precursors, the turnover of which is wholly prohibited in the Russian Federation ('List I'). On the basis of article 40 of Law on Narcotic Drugs, the consumption of cannabis (marijuana) is prohibited as well.

At the same time, the Law on Narcotic Drugs establishes that the turnover of major part of drugs (including cannabis) is allowed only for specific purposes (scientific, educational, expert and similar activities) and is subject to state monopoly (*i.e.* can be performed only by state bodies/enterprises in compliance with strict rules).

The Criminal Code of the Russian Federation provides for punishment for illegal acquisition, storage, transportation, manufacture, processing of cannabis (marijuana) in the form of imprisonment (up to life imprisonment in the most severe cases). Resolution of the Government of the Russian Federation No. 1002 dated October 1, 2012 "On approval of significant, large and especially large sizes of narcotic drugs and psychotropic substances, as well as significant, large and especially large sizes for plants containing narcotic drugs or psychotropic substances, or their parts containing narcotic drugs or psychotropic substances, for the purposes of Articles 228, 228.1, 229 and 229.1 of the Criminal Code of the Russian Federation" establishes thresholds in amounts of substances, violation of which can be classified as a crime (and its gravity) for the purposes of the Criminal Code of the Russian Federation (for cannabis the threshold for personal use is determined as 6 grams, no threshold is determined for sale and other distribution purposes – such actions are punishable for any amount). In case the amount of cannabis is less than a significant amount (for personal use), the person will be subject to administrative liability under Article 6.8 of the Code of Administrative Offenses of the Russian Federation instead of the criminal one.

In terms of CBD, the regulatory framework does not contain any direct regulation. On the one hand, List I as well as other regulatory acts do not mention CBD. Moreover, the Order of the Ministry of Sports of the Russian Federation dated December 3, 2018 No. 976 "On Approval of Lists of Substances and (or) Methods Prohibited for Use in Sports" directly allows the use of CBD for sport needs. Currently, the use of CBD in Russia is not widespread and appears to be a controversial issue in terms of import, turnover, and consumption.

To clarify the legal status of CBD, a request has been filed to the Ministry of internal affairs of the Russian Federation ("Ministry"). According to the official reply of the Ministry, CBD may be used as an ordinary product and is not subject to the control over circulation of drugs as long as it does not contain any compounds (in any, even insignificant amounts) forbidden on the basis of narcotic drug rules (for example, THC).

Recreational

1) Cannabis

The recreational use of cannabis is prohibited in any form and in any product as was mentioned above.

2) CBD

Taking into account that CBD is not explicitly included in List I and is not considered as an isomer of any drugs included in List I (and as soon as a product with CBD does not contain any other prohibited substances), the prohibitions set forth in relation to cannabis should not be applied to CBD. Still, to make sure that the turnover of the CBD-containing products in Russia is allowed, it would be important to ensure and show that the relevant product contain pure CBD without any narcotic supplements or by-products.

Thus, the set of requirements applicable to a CBD product will depend on designation of such a product to a particular group. For recreational purposes we consider that the main groups possible are food supplements and cosmetics.

Use as food supplement

In the case that a CBD product is used as an ordinary food product, turnover of such a product should not require any licenses or permissions. However, it should undergo an obligatory declaration or certification in accordance with the Technical Regulation of the Customs Union TR CU 021/2011 "On food safety" ("TR 021").

Additionally, CBD may be considered as a food additive on the basis of its nature and nutrition function conducted within the product.

In the case that CBD is defined as a food additive, its regulation is carried out on the basis of the Technical Regulation of the Customs Union (the legal predecessor of the EAEU) 029/2021 "On safety requirements to food additives, flavorings and technological aids" (**"TR 029"**). For import of any food or related products, the products must comply with the requirements of the relevant technical regulations. According to TR 029, to confirm the compliance of food additives, they should undergo compliance confirmation procedures established by TR 021.

TR 021 established the following types of compliance confirmation procedures:

(A) declaration of food products;

(B) state registration of specialized food products;

(C) state registration of food products of new type.

In general, it is necessary to self-declare the compliance of food products and state registration is established for special types of products and food products of a new type. In turn, specialized food products include:

(A) baby food, including drinking water for babies;

(B) food products for dietary medical and preventive dietary nutrition;

(C) natural mineral, medicinal table, medicinal mineral water with a mineralization of more than 1 mg / dm3 or less mineralization, containing biologically active substances in an amount not lower than balneological standards;

(D) food products for the nutrition of athletes, pregnant and lactating women;

(E) biologically active food additives.

Novel type food products under TR 021 are defined as food products (including food additives and flavorings) that were not previously used by humans for food in the customs territory of the Customs Union, namely: with a new or deliberately changed primary molecular structure; consisting of or isolated from microorganisms, microscopic fungi and algae, plants, isolated from animals, obtained from GMOs or with their use, nanomaterials and nanotechnology products; with the exception of food products obtained by traditional methods, which are in circulation and, due to experience, are considered safe.

Food products manufactured according to well-known and already used technologies, which contain components, including food additives that are already used for human consumption, are not considered food products of a new type (novel food products) even if such products and components are manufactured according to a formally new recipe.

Based on our search of public sources we do not see any registration/reference/publicly available researches in Russia which can prove that CBD has a history of safe usage (and as it was mentioned above, use of CBD in Russia is not a common practice). Thus, we cannot exclude that CBD or products which will contain CBD may be considered as food products of a new type (novel food products) and, therefore, will be subject to state registration.

Use in cosmetics

Technical Regulations of the Customs Union TR CU 009/2011 "On the safety of perfume and cosmetic products" (**'TR 009'**), does not contain any restrictions or special requirements regarding use of CBD. Thus, general requirements on turnover of cosmetics will be applied.

Cosmetic products are subject to declaration of conformity in accordance with the requirements of TR 009. Perfumery and cosmetic products that meet the requirements of TR 009 and have passed the procedure for assessing compliance must be marked with a uniform product circulation mark on the market of the EAEU member states. Besides, it should be noted that certain cosmetics products used for the purposes defined in Annex 12 of the TR 009 (cosmetics for kids, intime cosmetics etc.) should undergo state registration.

Medical

1) Cannabis

Under Article 31 of the Law on Narcotic Drugs, it is forbidden to use narcotics from List I (which includes, inter alia, cannabis) for medical purposes.

2) CBD

2.1) According to the Federal Law dated April 12, 2010 No. 61-FZ "On Circulation of Medicines" (**'Law on Medicines'**), only products qualified as medicines can be used for medical purposes. In its turn, a product may be considered as a medicine in the case where it is aimed at the prevention, diagnostics, treatment of disease; or rehabilitation; or preservation, contraception, or interruption of pregnancy. If a product affects the

structure or function of the body, it is likely to be regulated as a medicine by the Russian authorities.

It should be noted that in the case that CBD is intended to serve as medicine, it shall undergo the relevant registration procedure (including pre-clinical and clinical trials) as a medicine in Russia.

Besides, it should be noted that according to the Law on Medicines, turnover (wholesale, transportation, storage, retail etc.) of medicines is subject to licensing,

2.2) Another possible way of classification of a CBD product is qualification as a biologically active supplement.

Biologically active supplements (so called **'BADs'**, which comes out of Russian "*Биологическиактивныедобавки*") - natural and (or) identical biologically active substances, as well as probiotic microorganisms, intended for use simultaneously with food or for introduction into food products.

Unlike medicines, BADs are aimed at optimization of the human diet, compensation of the deficiency in the product substances necessary for the body. BADs are considered as food products, which are subject to the special state registration as BAD under TR 021.

It should be noted that turnover of BADs is subject to much softer requirements than turnover of medicines, however producers or sellers of BADs should not refer to any "medical" features or qualities of such products as described for medicines above.

Branding and Marketing

1) Cannabis

The promotion and advertising of cannabis (as well as any other narcotics) in the territory of Russia is prohibited by Article 4 of the Law of the Russian Federation No. 2124-1 dated December 27, 1991 "On mass media", Article 46 of the Law on Narcotic Drugs, Article 7 of the Federal Law No. 38-FZ dated March 13, 2006 "On Advertising".

2) CBD

Branding and marketing of pure CBD without any compounds controlled under the narcotic drug rules is not formally restricted.

However, the Law on Narcotic Drugs prohibits propaganda in the sphere of trafficking of narcotic drugs, psychotropic substances and their precursors. Thus, CBD advertising must not encourage consumption of drugs or display of any features connected with drugs (for example, pictures of smoking of weed, wordings on "high" effects of CBD, coloured pictures of cannabis leaves (which is generally associated with consumption of cannabis) etc.).

Edibles, Topicals, and More

1) Cannabis

Forbidden for the same reasons as food products.

2) CBD products

Taking into account the non-occurrence of CBD products on the Russian market,

no special regulations have been introduced so far. However, in the case that CBD products become common and popular, it is possible that respective regulations on forms, formulas, limits etc. could be introduced.

Cannabis Accessories

Russian regulatory framework does not directly prohibit the selling of cannabis accessories. At the same time, it is not recommended that manufacturers/sellers of such accessories overtly display connection with the use of drugs, otherwise they may be considered as propaganda of drugs, which is prohibited by the Law on Narcotic Drugs.

Moreover, Federal Law dated February 23, 2013 No. 15-FZ "On the protection of citizen health from the effects of ambient tobacco smoke, the consequences of tobacco consumption or the consumption of nicotine-containing products" stipulates certain limitations on the selling of accessories related to smoking. For instance, it is prohibited to retail smoking products (including accessories) in the following places:

- on the territories and in the premises intended for the provision of educational services, services by cultural institutions or by institutions of youth affairs, services in the field of physical culture and sports, medical, rehabilitation and sanatorium-resort services, on all types of public transport of urban and suburban communication (including ships when transporting passengers on intra-city and suburban routes), in the premises occupied by state authorities, local self-government bodies;
- at a distance of less than one hundred meters from the nearest point bordering the territory intended for the provision of educational services;
- in the territories and premises (except for duty-free shops) of railway stations, bus stations, airports, seaports, river ports, at metro stations intended for the provision of passenger transportation services, in premises intended for the provision of housing services, hotel services, services for temporary accommodation and (or) providing temporary accommodation, household services.

It is prohibited to sell smoking products and accessories to minors or to involve minors in the selling of smoking products and accessories.

Importation

1) Cannabis

Under the Regulations on the Import into the Customs Territory of the Eurasian Economic Union and Export from the Customs Territory of the Eurasian Economic Union of Narcotic Drugs, Psychotropic Substances and their Precursors ("Regulations"), the import of cannabis is carried out in the presence of a license, issued in accordance with the Instruction on the registration of an application for a license for the export and (or) import of certain types of goods and on the registration of such a license, approved by the Decision of the Board of the Eurasian Economic Commission No. 199 dated November 6, 2014. However, for avoidance of doubt, import of cannabis is allowed only for the purposes described above (i.e. not for free turnover in the territory of the Russian Federation).

2) CBD Products

Taking into account the information provided above, Russian legislation does not provide for any special requirements/restrictions with regard to the import of CBD Products.

Thus, specific import rules will depend on the type and purpose of a particular CBD product. For instance, in the case that a CBD product is qualified as a biologically active supplement (BAD), it should undergo state registration before importation to the territory of the Russian Federation while the import procedure will be subject to relevant requirements for import of food products. In the case that the relevant CBD product is considered as a medical drug, it shall be registered in Russia before import, while the import procedure will be subject to relevant requirements for import of medicines (e.g. only a duly licensed entity may import such products etc.).

Future Challenges

The analysis of the Russian legal system reveals the high degree of reluctancy to shift the strict regulatory view on drug regulation. The main challenge consists of the absence of any legislator initiatives providing for mitigation of statutory prohibitions in relation to cannabis or CBD.

The Resolution of the President of the Russian Federation dated November 23, 2020 No. 733 "On approval of the Strategy of the state anti-drug policy of the Russian Federation for the period up to 2030" also does not mitigate the rigorous attitude towards cannabinoids in the Russian legislation.

The policy mentions that legalization of various drugs is in important threat which has to be confronted by the Russian public authorities (item 9) and includesthe active prevention of legalization of recreational use of drugs (item 15) and by conducting international policy by means of active prevention of global alleviation or a re-visitation of the global narcotics control regimes in terms of their legalization.

Absence of any legalization initiatives was confirmed in the official reply which was received from the Ministry.

Finally, it should be noted that currently, Russian legislation is in the process of tightening rules for any smoking of novel tobacco products and electronic nicotine liquid products, like snuss and naswar, and is actively countering sniffing among adolescents, as well as consumption of any similar addictive products. It is assumed that this may result in CBD being treated by the Russian public authorities and officials as one of the products for which consumption should fall under strict control and limited use.

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SLOVAKIA

David Štros

Background

Legal regulation of cannabis in Slovakia is one of the strictest within the whole European Union. It was only recently that CBD was removed from the list of narcotic and psychotropic substances. In general, the approach to cannabis in Slovakia is still very cautious and no significant changes are expected. Cannabis is not even allowed to be used for medicinal purposes. Public discussion is slowly opening, but no changes of regulation are expected in the near future. For now, most of the efforts focus on mitigation of criminal sanctions for possession of marihuana, which is punished by imprisonment.

Recreational

The following substances are considered as psychotropic substances with the highest level of danger, which may be grown, produced, imported, exported, issued and transited and distributed only for the purposes of research, teaching and expertise, with the exception of the cultivation of hemp.

The list of narcotic and psychotropic substances includes:

- dry extract of plants of the genus Cannabis,
- plants of the genus Cannabis,
- tincture (ethanolic extract) from plants of the genus Cannabis,
- resin from plants of the genus Cannabis,

excluding seeds and varieties of hemp listed in a special regulation, which is Art. 9 par. 1 of Commission Delegated Regulation (EU) No 639/2014 supplementing Regulation (EU) No 182/2011 Amending Regulation (EC) No 1307/2013 laying down rules for direct payments to farmers under support schemes under the common agricultural policy and amending Annex X to that Regulation,

- the salts of the narcotic drugs mentioned in this group in all cases where these salts may exist,
- THC, chemically tetrahydrocannabinols, all stereoisomers of delta$^{6a\,(10a)}$, delta $^{6a\,(7)}$, delta^{7}, delta^{8}, delta^{10}, delta$^{9\,(11)}$ and their stereochemical variants.

Cultivation of (industrial) hemp (cannabis sativa cultivars) listed in the special regulation as per above for industrial purposes is thus allowed and special legal regulation and conditions apply, which are based on EU regulation.

Possession of narcotic or psychotropic substance (as per above) even for personal use is a criminal offence with serious consequences.

It applies that whoever unjustifiably possesses a narcotic or psychotropic substance in the amount, which corresponds to a maximum of three times the usual single dose for personal consumption, shall be punished by imprisonment for up to three years.

Imprisonment for up to five years may apply for whoever unjustifiably possesses a narcotic substance or psychotropic substance for their own use in a larger amount, which means the amount corresponding to a maximum of ten times the usual single dose for personal consumption.

CBD is not included on the list of narcotic or psychotropic substances and therefore it is not illegal as such and its use in various fields of industry depend on specific conditions. Criminal sanctions are no longer applicable either.

Medical

There is no legal regulation in Slovakia, which would allow the use of cannabis for medicinal purposes. Cannabis is listed in the group of the most serious psychotropic substances, which cannot be used for the making of medical preparations.

It is also forbidden to provide samples of medicinal preparations containing cannabis or to give them as gifts.

Branding and Marketing

As for rules for advertising of products, they apply on any type of promotion of business activity, including public information about sponsorship.

In general, it is forbidden to advertise products, for which the sale of such products is illegal. Therefore, for narcotic and psychotropic substance, any promotion or advertisement is forbidden. Information about narcotic and psychotropic substances intended for experts can be published only in expert magazines.

It is also explicitly forbidden to advertise medicinal preparations, which contain psychotropic substances.

As for advertising in general, products shall not promote conduct that is harmful to human health. There are also general rules for protection of persons under 18 years of age in relation to advertising, and to discourage behaviour that endangers their health, mental or moral development. Furthermore, there are general rules for advertising of tobacco products, as well as advertising of products aimed at human health, which is strictly regulated and can also cover some cannabis products and statements about effects of these products on human health.

As for the advertisement of food and food supplements, they cannot be presented as they have effects as medicinal preparations.

Edibles, Topicals, and More

As for edibles, foods and food supplements, it is forbidden to add narcotic or psychotropic substances into food products. No amount of THC is allowed.

Nevertheless, extracts from hemp, CBD and products made from them are considered as a novel food or potentially a novel food and thus can be marketed only under the respective EU legal regulations. In Slovakia, CBD in food and food supplements will be accepted only after approval at an EU level as a novel food.

Specific conditions may apply depending on a type of food. For example, it is explicitly defined that leaves and seeds of cannabis sativa L. are allowed as a plant, which can be used for the production of tea.

As for other fields of industry, technical hemp as such can be used in industry and CBD in products is not regulated in general. For other requirements, it depends on the specific category of product and general national requirements on them.

As for cosmetics, there is no specific regulation in relation to cosmetic products, nevertheless they must also comply with the general rule of prohibition of psychotropic substances and avoid any amount of THC.

Cannabis Accessories

This category of products relates to smoking, vaping and other accessories, which are devices that can be used for consumption of all kinds of preparations, including cannabis. As such, these products are not illegal and there is no specific regulation in this area. It is only necessary to comply with general rules of promotions and sale of products.

It is important that their advertisement and presentation does not promote or support consumption of illegal, narcotic or psychotropic substances, which is a criminal offence according to the Slovak criminal law.

Importation

Any import or transit of cannabis into/ through Slovakia is only allowed upon permission of the Ministry of Internal Affairs.

Import into the territory of the Slovak Republic in the form of consignments addressed to a depository, a free customs warehouse, a free customs zone or to the address of another person other than that specified on the import permit is prohibited. Imports into the territory of the Slovak Republic in the form of consignments addressed to a customs warehouse are also prohibited.

Future challenges

It is evident that legal regulation of cannabis in Slovakia is extremely strict, while CBD has only recently been removed from the list of psychotropic substances. Currently, discussions on the topic are mostly concerned with activities around trying to moderate the rules of criminal law and to lower criminal sanctions for possession of cannabis from that of imprisonment to a penalty.

SOUTH AFRICA

Janusz F. Luterek

Background: Legal status of cannabis

The legal status of cannabis on an international level plays a role within South Africa. This is due to South Africa being a guarantor of the 1961 *Single Convention on Narcotic Drugs*, 1971 *Convention on Psychotropic Substances*, as well as the 1988 *Convention against illicit Trafficking in Narcotic and Psychotropic Drugs*. This inevitably means that cannabis is susceptible to unique constraints.[1] In Addition to being a guarantor to the 1961 *Single Convention on Narcotic Drugs*, obligations must be complied with. Such obligations are controlling the cultivation of cannabis intended for medical use, as well as the disclosure of information to the International Narcotics Control Board relating to quantity in terms of manufacture, production and consumption of cannabis.[2] However, with all of these international constraints in place, there are currently global attempts being made to ease such restrictions on cannabis and cannabis extracts.

In terms of the legal status of cannabis on a national level, the jurisdiction of cannabis and such related substances is within the South African Health Products Regulatory Authority (SAHPRA). Cannabis is specifically regulated by schedules set out in terms of the *Medicines and Related Substances Act*[3] (hereafter referred to as 'the Act').

The schedules were amended on 22 May 2020 in the R586 Government Notice as follows:

- *"Previous entries for cannabis, dronabinol, and tetrahydrocannabinol in Schedule 7 have been deleted.*
- *Cannabidiol (CBD) is listed in Schedule 4 EXCEPT - a. in complementary medicines containing no more than 600 mg cannabidiol per sales pack, providing a maximum daily dose of 20 mg of cannabidiol, and making a general health enhancement, health maintenance or relief of minor symptoms (low-risk) claim; or*

[1] *1961 Single Convention on Narcotic Drugs Schedules* I and IV.

[2] SAHPRA "Guideline for Cultivation of Cannabis and Manufacture of Cannabis-Related Pharmaceutical Products for Medicinal and Research Purposes", https://www.sahpra.org.za/wp-content/uploads/2021/02/General-guide-to-Medicinal-Cannabis_Cultivation-or-Manufacturing.pdf (accessed on 12 July 2021).

[3] *Medicines and Related Substances* Act 101/1965.

b. processed products made from cannabis raw plant material intended for ingestion containing 0,0075 percent or less of cannabidiol where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product. Products that meet the conditions above will fall under Schedule 0. It must however be noted that this does not mean they are unscheduled but rather that they are in the lowest schedule of medicine.

- *Transdelta-9-tetrahydrocannabinol (THC) is listed in Schedule 6, except - a. in raw plant material and processed products manufactured from such material, intended for industrial purposes and not for human or animal ingestion, containing 0,2 % percent or less of tetrahydrocannabinol; b. processed products made from cannabis containing 0,001 percent or less of tetrahydrocannabinol; or c. when raw plant material is cultivated, possessed, and consumed by an adult, in private for personal consumption."*

These changes to the Schedules have several implications as per SAHPRA's communication to stakeholders of 22 May 2020:

"Firstly, the exclusion of certain CBD-containing products from Schedule 4 has been confirmed, but with important differences including daily dose limits being stipulated as well as stipulated maximum pack sizes when it comes to complementary medicines (category D medicines).

Secondly, cannabis as a plant is removed from Schedule 7. Instead, the psycho-active ingredient tetrahydrocannabinol (THC) is listed in Schedule 6, with specific exemptions made for industrial application of low-THC cannabis."

In addition to the above, the personal use of the cannabis plant by an adult in his/her private residence was enabled by the 2018 Constitutional Court judgement. However, a deadline was set in this judgement for legislation to be passed relating to the personal use of cannabis and this deadline passed on the 17th of September 2020. Accordingly, the R586 Government Notice remains the only current legislation in force that relates to the regulation of cannabis until such legislation is actually enacted.

The Cannabis for Private Purposes Bill:

The memorandum as well as the draft Cannabis for Private Purposes Bill was published on the 7th of August 2021. It is important to note that the *Cannabis for Private Purposes Bill* is yet to be enacted, thus it is not yet an Act which is legally enforceable. This is due to the fact that the Bill still needs to go through the promulgation process and authorisation by the President in order to be officially enforceable as an authoritative piece of legislation. It is yet to be confirmed when this Bill will indeed be promulgated as the President did announce it as a priority in his most recent State of the Nation Address. However, the third wave of COVID-19 has severely affected the legislative processes and their speed in Parliament. Accordingly, for present-day purposes the Bill is used simply as a guideline because it represents the approach South Africa will likely take on cannabis in the near future. This is also due to the 2018 Constitutional Court judgement that requires for such legislation to be enacted so as to decriminalise the personal private use of cannabis.

The *Cannabis for Private Purposes Bill* was drafted to give effect to the Constitutional Court decision by having jurisdiction over matters regarding offences, conviction and stipulated amounts of cannabis which may be used for personal private use. The Bill aims to –

(a) respect the right to privacy of an adult person to possess cannabis plant cultivation material; to cultivate a prescribed quantity of cannabis plants; to possess a prescribed quantity of cannabis; and to consume cannabis;

(b) regulate the possession of cannabis plant cultivation material; the cultivation of cannabis plants; the possession of cannabis; and the consumption of cannabis by an adult person;

(c) protect adults and children against the harms of cannabis;

(d) provide for the expungement of criminal records of persons convicted of possession or use of cannabis;

(e) delete and amend provisions of certain laws; and

(f) provide for matters connected therewith.[4]

Cannabis within South Africa is being regulated to such an extent in order to ensure that it is kept within reasonable limits and not misused by any means within South Africa. This has resulted in the prioritisation of the right to privacy regarding possession, consumption and cultivation of cannabis; whilst simultaneously giving rise to protection against the harms of cannabis. Thus, personal private use of cannabis has been decriminalised but the commercialisation of cannabis and any related products are still prohibited. However, for guidance relating to the near future, the *Cannabis for Private Purposes Bill* does state that 'an exchange between adult persons is permitted as long as there is no remittance'.[5]

Recreational: Personal use

The Constitutional Court declared on the 18th of September 2018 in the matter of *Minister of Justice and Constitutional Development and Others v Prince* that the cultivation of cannabis by an adult in a private place for that adult's personal consumption in private is permitted. However, this does not include commercial use. Accordingly, the commercialization of cannabis, without a SAHPRA cultivation license and registration process being followed, is currently illegal in South Africa. This will be explained later in this section.

The Cannabis for Private Purposes Bill contains the following proposed definitions:

- "Personal use" means "the exclusive use of an adult person;
- "Possess in private" means "to keep, store, transport or be in control of cannabis or a cannabis plant, respectively, in a manner that conceals it from public view"; and
- "Private place" means "any place, including a building, house, room, shed, hut,

[4]Memorandum for the Cannabis for Private Purposes Bill

[5]*Cannabis for Private Purposes Bill* 2020:sec. 2(3).

tent, mobile home, caravan, boat or land or any portion thereof, to which the public does not have access as of right".

- In terms of section 2(3) of the proposed *Cannabis for Private Purposes Bill*, the exchange, supply and attainment of cannabis will be legal as long as it does not involve remuneration. This may be in the form of cultivation material, cannabis plant(s) and simply cannabis. Therefore, this Bill only relates to cannabis that may only be used for personal means with the inclusion of cultivation for such personal means.

According to the proposed *Cannabis for Private Purposes Bill* an adult person may for the sole purpose of personal use be in possession of a stipulated amount[6] of cannabis and cultivation material thereof within the confinements of a private place. Such private place may also be within a public place; for example, a private place would be regarded as a car if the cannabis is possessed in a manner that conceals it from public view.[7]

Matters regarding THC for personal use only:

As seen in the "Background" section above, the R586 government notice, stipulates that THC is listed under Schedule 6 of the Act. However, there is an exception of THC which is contained inraw plant material that is cultivated, possessed, and consumed by an adult, in private for personal consumption

Offences in terms of the proposed Cannabis for Private Purposes Bill are categorized as follows:

Section 7 of the proposed *Cannabis for Private Purposes Bill* contains the various different penalties as follows:

> *"(a) a Class A offence, is liable on conviction to a fine or to imprisonment for a period not exceeding 15 years or to both a fine and such imprisonment;*
>
> *(b) a Class B offence, is liable on conviction to a fine or to imprisonment for a period not exceeding six years or to both a fine and such imprisonment;*
>
> *(c) a Class C offence, is liable on conviction to a fine or to imprisonment for a period not exceeding four years or to both a fine and such imprisonment; or*
>
> *(d) a Class D offence, is liable on conviction to a fine or to imprisonment for a period not exceeding two years or to both a fine and such imprisonment."*

Once more, the *Cannabis for Private Purposes Bill* is yet to be assented as an authoritative legislation, meaning that such penalties are in the present case not definite or enforceable. These offences represent the likely approach South Africa will follow once the Bill is enacted.

The various types of proposed offences are laid out in the Bill as follows:

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[6]Stipulated amounts are provided for within schedule 3 of the *Cannabis for Private Purposes Bill*. (To be used for the purposes of a guideline only).

[7]*Cannabis for Private Purposes Bill* 2020:sec. 2(1).

Section 3: Cultivation offences [8]

"(1) An adult person who in a private place cultivates:

(a) more than the prescribed quantity contemplated in section 2(1)(b), but less than a trafficable quantity of cannabis plants, is guilty of a Class C offence. (Schedule 2 stipulates such amount as, (i) Four flowering cannabis plants or cannabis plant equivalent per adult person; or (ii) eight flowering cannabis plants or cannabis plant equivalent per dwelling which is occupied by two or more adult persons.)

(b) a trafficable quantity of cannabis plants, is guilty of a Class B offence. (Schedule 4 stipulates a trafficable quantity as, (i) Six flowering cannabis plants or cannabis plant equivalent per adult person; or (ii) twelve flowering cannabis plants or cannabis plant equivalent per dwelling which is occupied by two or more adult persons.).

(c) a commercial quantity of cannabis plants, is guilty of a Class A offence. (Schedule 4 stipulates a commercial quantity as, (i) Nine flowering cannabis plants or cannabis plants equivalent per adult person; or (ii) eighteen flowering cannabis plants of cannabis plant equivalent per dwelling which is occupied by two or more adult persons.)

(2) An adult person who cultivates a cannabis plant at any place and who fails to:

(a) take reasonable measures to ensure that the cannabis plant is inaccessible to a child; or

(b) comply with any requirement or standard regarding the cultivation of cannabis plants in a private place for personal use as prescribed by regulation, is guilty of a Class C offence.

(3) An adult person who cultivates a cannabis plant in a public place, is guilty of a Class B offence.

(4) An adult person who provides to, or obtains from, an adult person without the exchange of consideration:

(a) a quantity that exceeds the prescribed quantity contemplated in section 2(3)(b), but which is less than a trafficable quantity of cannabis plants, is guilty of a Class C offence. (Schedule 3 stipulates this quantity as one flowering cannabis plant or cannabis plant.)

(b) a trafficable quantity of cannabis plants, is guilty of a Class B offence. (Schedule 4 stipulates this quantity as two flowering cannabis plants or cannabis plant equivalent.)

(c) a commercial quantity of cannabis plants, is guilty of a Class A offence. (Schedule 4 stipulates this quantity as four flowering cannabis plants or cannabis plant equivalent.)

(5) An adult person who is in possession in a public place of:

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[8] *Cannabis for Private Purposes Bill* 2020:sec. 3.

(a) a quantity that exceeds the prescribed quantity, contemplated in section 2(1)(e), but which is less than a trafficable quantity of cannabis plants, is guilty of a Class C offence. (Schedule 3 stipulates this quantity as one flowering cannabis plant or cannabis plant equivalent.)

(b) a trafficable quantity of cannabis plants, is guilty of a Class B offence. (Schedule 4 stipulates this amount as two flowering cannabis plants or cannabis plant equivalent.)

(c) a commercial quantity of cannabis plants, is guilty of a Class A offence. (Schedule 4 stipulates this quantity as four flowering cannabis plants or cannabis plant equivalent.)

(6)

(a) Any person who deals in an immature cannabis plant, is guilty of a Class C offence.

(b) Any person who deals in a flowering cannabis plant, is guilty of a Class A offence.

(7) Any person who deals in cannabis plant cultivation material, is guilty of a Class D offence.

(8) An adult person who provides to, or obtains from, an adult person without the exchange of consideration a quantity that exceeds the prescribed quantity of cannabis plant cultivation material contemplated in section 2(3)(a), is guilty of a Class D offence. (Schedule 3 stipulates this amount as 30 seeds or seedlings or any combination thereof.)

(9) Any person who is in possession in a public place of cannabis plant cultivation material or a cannabis plant that is not concealed from public view, is guilty of a Class D offence."

Section 4: Cannabis offences[9]:

"(1) Any person who is in possession in a public place of:

(a) a quantity that exceeds the prescribed quantity, contemplated in section 2(1)(c), but which is less than a trafficable quantity of cannabis, is guilty of a Class C offence. (Schedule 3 stipulates this quantity as 100 grams dried cannabis or cannabis equivalent.)

(b) a trafficable quantity of cannabis, is guilty of a Class B offence. (Schedule 4 stipulates this quantity as 200 grams dried cannabis or cannabis equivalent.)

(c) a commercial quantity of cannabis, is guilty of a Class A offence. (Schedule 4 stipulates this quantity as 300 grams dried cannabis or cannabis equivalent.)

(2) An adult person who is in possession in a private place of:

(a) a quantity that exceeds the prescribed quantity, contemplated in section 2(1)(d), but which is less than a trafficable quantity of cannabis, is guilty of a Class C offence. (Schedule 3 stipulates this amount as, (i) 600 grams dried

[9] *Cannabis for Private Purposes Bill* 2020:sec. 4.

cannabis or cannabis equivalent per adult; or (i) 1200 grams dried cannabis or cannabis equivalent per dwelling which is occupied by two or more adult persons.)

(b) a trafficable quantity of cannabis, is guilty of a Class B offence. (Schedule 4 stipulates this amount as, (i) 800 grams dried cannabis or cannabis equivalent per adult; or (ii) 1500 grams dried cannabis or cannabis equivalent per dwelling which is occupied by two or more adult persons.)

(c) a commercial quantity of cannabis, is guilty of a Class A offence. (Schedule 4 stipulates this amount as,(i) 1000 grams dried cannabis or cannabis equivalent per adult; or (ii) 2000 grams dried cannabis or cannabis equivalent per dwelling which is occupied by two or more adult persons.)

(3) An adult person who is in possession of cannabis at any place and who:

(a) fails to store such cannabis in a secure space that is inaccessible to a child; or

(b) stores such cannabis in a manner that does not comply with any requirement or standard regarding the storing of cannabis prescribed by regulation, is guilty of a Class C offence.

(4) An adult person who provides to or obtains from an adult person without the exchange of consideration:

(a) a quantity that exceeds the prescribed quantity, contemplated in section 2(3)(c), but which is less than a trafficable quantity of cannabis, is guilty of a Class C offence. (Schedule 3 stipulates this quantity as, 100 grams dried cannabis or cannabis equivalent.)

(b) a trafficable quantity of cannabis, is guilty of a Class B offence. (Schedule 4 stipulates this quantity as, 200 grams dried cannabis or cannabis equivalent.)

(c) a commercial quantity of cannabis, is guilty of a Class A offence. (Schedule 4 stipulates this quantity as, 300 grams dried cannabis or cannabis equivalent.)

(5) Any person who deals in cannabis, is guilty of a Class A offence.

(6) An adult person who transports cannabis in a vehicle on a public road in a manner that does not comply with any requirement or standard regarding the transportation of cannabis that may be prescribed by regulation, is guilty of a Class C offence.

(7) Any person who is in possession in a public place of cannabis that is not concealed from public view, is guilty of a Class C offence."

Section 5: Consumption offences[10]*:*

"(1) Any person who smokes or consumes cannabis in a public place, is guilty of a Class D offence.

(2) Any person who smokes cannabis in a public or private place in the immediate presence of any non-consenting adult person, is guilty of a Class D offence.

[10] *Cannabis for Private Purposes Bill*:sec. 5.

(3) Any person who smokes cannabis in a public or private place in the immediate presence of a child, is guilty of a Class C offence.

(4) Any person who smokes cannabis in a private place:

(a) within a distance prescribed by regulation from a window of, ventilation inlet of, doorway to or entrance into another place; or

(b) forming part of any place where persons congregate within close proximity of one another and where the smoke is likely to cause a hindrance to any person at that place, is guilty of a Class D offence.

(5) Any person who smokes or consumes cannabis in a vehicle on a public road, is guilty of a Class C offence."

Section 6: Offences which involve a child[11]:

"(1)

(a) The guardian of a child who permits a child:

(i) to possess cannabis plant cultivation material or a cannabis plant;

(ii) to deal in cannabis plant cultivation material or a cannabis plant;

(iii) subject to paragraph (b), to cultivate a cannabis plant; (iv) to possess cannabis; (v) to deal in cannabis; or

(vi) to smoke or consume cannabis, is guilty of a Class D offence.

(b) The prohibition referred to in paragraph (a)(iii) does not apply where the child assists with the cultivation of cannabis plants which the guardian of the child may lawfully possess for his or her personal use in a private place, in the presence and under the supervision of that guardian.

(2) Any person who engages a child, whether for consideration to the child or a third person or not, to deal in:

(a) cannabis plant cultivation material;

(b) a cannabis plant; or

(c) cannabis, is guilty of a Class A offence.

(3) Any person who provides to a child, whether for consideration or not:

(a) cannabis plant cultivation material;

(b) a cannabis plant; or (c) cannabis, is guilty of a Class A offence.

(4) Subject to subsection (1)(b), an adult person who engages a child, whether for consideration to the child or a third person or not, in the cultivation of a cannabis plant, is guilty of a Class A offence.

(5) Any person who administers cannabis to a child, is guilty of a Class A offence."

[11] *Cannabis for Private Purposes Bill*:sec. 6.

Legality concerning the Manufacturing, Cultivation and Sale of products containing cannabis for commercial and industrial reasons

Currently, the Department of Health and SAHPRA have prescribed that a person/ company must obtain a cultivation license as their very first step. However, these licenses are only being issued for medical and scientific research purposes. So far, 31 cultivation licenses have been issued in South Africa as per the list that is published on SAHPRA's website.[12]

Once such cultivation license is given, a permit in terms of section 22A(9)(a)(i) of the Act is needed in order to manufacture any schedule 5 or higher substance. This permit will be valid for a period of twelve months after the issued date.

A permit in terms of section 22A(9)(a)(i) allows for[13]:

- The acquisition, use and possession of cannabis and cultivation for low-THC cannabis known as hemp.
- The acquisition, use and possession regarding research by scientific means or educational means.
- The acquisition, use, possession as well as dispense by a medical practitioner for the sole purposes of treatment or prevention of a medical condition of a patient.

Access to cannabis pharmaceutical products and how section 22A of the Act regulates such access

There are currently no registered pharmaceutical products containing cannabis in South Africa as per SAHPRA's communication to stakeholders. Accordingly, in order to register such product, it would have to comply with R586 as stipulated above.

A patient who is in possession of a prescription for a pharmaceutical product containing cannabis (which is licensed the country it originates from) will be permitted under section 22A(5) of the Act as follows:

"Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance shall not be sold by any person other than -

(a) a pharmacist, pharmacist intern or a pharmacist's assistant acting under the personal supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription;

(b) a pharmacist or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;

(c) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;

[12]https://www.sahpra.org.za/cannabis-cultivation-licences/

[13]Omarjee "Cannabis and Related Substances Legislation and Regulations", http://www.sahpra.org.za/wp-content/uploads/2020/03/Cannabis-and-Related-Substances_MG_10032020_Glenhove_final.pdf (accessed on 12 July 2021).

(d) a medical practitioner or dentist, who may; (i) prescribe such substance; (ii) compound or dispense such substance only if he or she is the holder of a licence as contemplated in section 22C(l)(a);

(e) a veterinarian who may prescribe, compound or dispense such substance;

(f) a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may- (i) prescribe only the Scheduled substances identified in the Schedule for that purpose; (ii) compound and dispense the Scheduled substances referred to in subparagraph (i) only if he or she is the holder of a licence contemplated in section 22C(l)(a)."

Therefore, if there are any medicinal products containing cannabis which fall outside of the regulations contained in the R586, patients with the permitted prescriptions may obtain such medicinal product containing cannabis. These medicinal products containing cannabis must be permitted in the country of origin.

Internationally registered cannabis pharmaceutical products:

SAHPRA has not registered any pharmaceutical products containing cannabis however; there are a few cannabis pharmaceutical products which are registered internationally. These cannabis pharmaceutical products consist of:

- Dronabinol (previously registered in South Africa),
- Nabilone,
- Orobuccal spray (contains partly CBD and partly THC), and
- Cannabidiol.
- Licensing for the permission of medicinal use of cannabis:
- In order to legally cultivate, manufacture and use cannabis for Medicinal purposes; a SAHPRA cultivation license is required.
- This cultivation license is limited to medical and research purposes. It allows a candidate to cultivate for the following regarding cannabis, cannabis resin and cannabinoids:
- Cultivation and production.
- Testing and extraction.
- Medicinal manufacturing of a registered product containing CBD.
- Import of CBD being a raw material as an Active Pharmaceutical Ingredient; registered products containing CBD; and medicines containing THC[14].
- Export and distribution of medicinal products containing cannabis.
- Scientific testing of both product and medicines containing cannabinoid.
- A candidate must hold both the cultivation license and the section 22A(9)(a)(i) permit. Such candidate will be permitted to:

[14]Importing products containing THC would need a section 11 import permit as per the Act in terms of schedule 6 substances.

- Cultivate and possess cannabis for the purpose of medicinal use, as well as process and package both bulk cannabis and cannabis as a raw material for the purpose of export. This allows for the sale and export of such to license holders or warranted overseas vendors.
- Extract CBD, THC and cannabinoids from the cannabis plant and be in possession of such. In addition, allowing for the production of a registered medicine containing cannabis. Holders of both permit and license will be permitted to sell such to license holders or warranted overseas vendors.
- Testing of cannabis for scientific purposes relating to the raw material, intermediates, and bulk of cannabis as an herbal material.

If cultivation of cannabis occurs for purposes other than stipulated in terms of the Act regarding the system for permit and license, then it will result in an offence as per section 29(k) of the Act:

Any person who contravenes any provision of section 22A, 22C(5) and (6), 22F, 22G or 22H or contravenes or fails to comply with any condition imposed thereunder; shall be guilty of an offence.

The Act prescribes penalties for any offence which falls under section 29 of the Act. These penalties include the following:

"(1) Any person who is convicted of an offence referred to in section 29 shall be liable to a fine, or to imprisonment for a period not exceeding 10 years.

(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any medicine or Scheduled substance in respect of which the offence has been committed to be forfeited to the State.

(3) Any medicine or Scheduled substance forfeited under this Act shall be destroyed or otherwise dealt with as the Director-General may direct.

(4) Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty provided for in this section."

Relevant ingredient source:

Once a candidate holds a license and permit as discussed above, such candidate will be allowed to manufacture, possess, use, sell and supply a product containing cannabis listed under schedule 6.

It must be noted that any product which contains cannabidiol (CBD) and/or tetrahydrocannabinol (THC), is required to registered with SAHPRA; and may only be obtained upon prescription by a warranted medical practitioner; or by a registered Health Professions Act person(s).

Unless such product containing cannabis for medicinal purposes complies with schedule 0 of the R586 amendment of the schedules under the Act.

In order for a pharmaceutical product containing cannabis to be valid, such product would have to comply with the complementary medicine requirements set out in the Act and the General Regulations.

The Act defines a complementary medicine as:

"complementary medicine" *means any substance or mixture of substances that-*

(a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by the Authority;

(b) is used or purporting to be suitable for use or manufactured or sold for use-

(i) in maintaining, complementing or assisting the physical or mental state; or

(ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human being or animal; and

(c) is used-

(i) as a health supplement; or

(ii) in accordance with those disciplines as determined by the Authority"

The General Regulations under the Act classifies complementary medicines as follows:

"9(1) Medicines shall be classified into categories aa follows:

(d) Category D Complementary medicines intended for use in humans and animals which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine.

(2) Medicines in category D shall be classified into the following sub-categories:

(a) discipline-specific medicines with such disciplines as determined by the Authority; and

(b) health supplements.

(3) Medicines in Categories A and D (human complementary medicine) are subdivided into classes as per Annexure 1.

(4) Medicines in category C and D (veterinary complementary medicines) are subdivided into classes as per Annexure 2."

Cannabis in a foodstuff[15]

Cannabis could possibly be used as an additive in a foodstuff. The *Foodstuffs, Cosmetics and Disinfectants Act: Regulations relating to Miscellaneous Additives in Food* defines a"food additive" as:

"any substance, regardless of its nutritive value, that is not normally consumed as a food by itself and not normally used as a typical ingredient of the food, which is added intentionally to a food for technological (including organoleptic) purposes in the manufacture, processing, preparation, treatment, packing, packaging, transport or storage of the food, and results, or may reasonably be expected to result directly or indirectly in such a substance, or its by- products, becoming a component of, or

[15]Facts "CBD is Not a Foodstuff", https://www.factssa.com/news/cbd-is-not-a-foodstuff/ (accessed on 12 July 2021).

otherwise affecting the characteristics of such foods and excludes any substance added to foods for maintaining or improving nutritional qualities or any contaminants and sodium chloride."

For such a foodstuff containing cannabis as an additive to be valid it must comply with the following:

- Must be safe;
- Must not contravene the Act; and
- Must possess a license in terms of section22C(1)(b).

Hemp (such asHemp protein powder, Hemp seeds, Hemp tea, Hemp fibre, Hemp oil and Hemp powder) is permitted to be an ingredient within a foodstuff, provided that it contains no CBD or THC and a certificate of analysis would be required to prove this. There must also be no health claims in connection with the sale of the product in any advertising or labelling or the product would fall under the Act as opposed to falling under a foodstuff.

Cannabis as a beverage[16]

Since cannabis is not regarded as a foodstuff in terms of the *Foodstuffs, Cosmetics and Disinfectants* Act; cannabis may not be used as an ingredient within a beverage.

However, according to the R1769 soft drink regulations cannabis may be used as an additive in terms of flavouring.[17] This is because the actual substance of cannabis will not be used and it will merely be a flavouring that tastes like cannabis but does not contain any real cannabis.

When it comes to alcoholic beverages, the draft amendment of the Liquor Regulations excludes cannabis or anything derived therefrom, including synthetic compounds. However, cannabis flavouring may be used in alcoholic beverages provided is does not contain any cannabis and is merely a flavouring.

Cannabis as a Cosmetic

According to the *Foodstuffs, Cosmetics and Disinfectants* Act, "cosmetic" means:

"any article or substance (except a drug as defined in the Drugs Control Act, ·1965 (Act No. 101 of 1965)) intended to be rubbed, poured, sprinkled or sprayed on or otherwise applied to the ·human body for purposes of cleansing, beautifying, promoting attractiveness or improving or altering the appearance, and includes any part or ingredient of any such article or substance."

R586 excludes complementary medicines and processed productsmade from cannabis raw plant material intended for ingestioncontaining 0,0075 percent or less from Schedule 4 and places theminto Schedule 0 meaning it is still a medicine. The exclusion does not apply to cosmetics as it is specifically applied to complementary medicines (which is excluded in the definition of a cosmetic) and processed products intended

[16]Tomkow-Coetzer and Mazzone 2021.
[17]R1769 Soft drinks Regulations.

for ingestion.On the other hand, R586 states that any processed products madefrom cannabis containing 0,001 percent or less oftetrahydrocannabinol would still fall under a Schedule 0 medicine.Accordingly, a cosmetic containing any amount of THC would still fallunder the Act and would not be permissible.However, there is a possibility for CBD to be added as an ingredientin a cosmetic provided there are no health claims and absolutely noTHC (Certificate of Analysis will be required to prove contents).The quantity of CBD that can be used in a cosmetic is still to beconfirmed.

Medicinal products

Advertising, marketing and branding of any medicinal product must comply with the regulations and requirements stipulated within the Act. Specifically, section 20 of the Act and regulation 42 of the General Regulations[18].

Advertisements:

Section 18 of the Act deals with labelling and advertisements and says the following:

"(1) No person shall sell any medicine or Scheduled substance unless the immediate container or the package in which that medicine or Scheduled substance is sold bears a label stating the prescribed particulars.

(2) No person shall advertise any medicine or Scheduled substance for sale unless such advertisement complies with the prescribed requirements.

(3) The label referred to in subsection (1) shall be approved by the council

(4) The council may authorise a deviation from the prescribed format and contents of any label.

(5) The Minister may prescribe additional requirements for the labelling of medicines."

Section 20 of the Act deals with the publication or distribution of false advertisements concerning medicines and says the following;

"(1) No person shall -

(a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning any medicine; or

(b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any medicine is other than that stated by the council in terms of subparagraph (ii) of paragraph (a) of section twenty-two or state or suggest that any medicine should be used for a purpose or under circumstances or in a manner other than that stated by the council in terms of subparagraph (iii) or paragraph (a) of that section."

Regulation 42 of the General Regulations deals with the advertising of medicines and states the following:

"(1) Medicines in Schedules 0 to 1 May be advertised directly to the public. (General Regulations 42(1))

[18]*Medicines and Related Substances* Act: General Regulations.

(2) Medicines which contain a substance listed as Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 may be advertised-

(a) only for the information of pharmacists, medical practitioners, dentists, veterinarians, practitioners, and other authorised prescribers; or

(b) in a publication which is normally or only made available to persons referred to in paragraph (a).

(3) Subregulation (2) shall not be so construed as to prohibit informing the public of names, pack sizes and strengths of medicines which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 provided that no inference is made to the registered indication.

(4) No advertisement for a medicine may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medicine with regard to its safety, quality or efficacy where such evidence has been accepted by the Authority in respect of such medicine and incorporated into the approved professional information of such medicine.

(5) An advertisement for a medicine shall contain –

(c) (ii) in the case of a complementary medicine (aa) a statement identifying the discipline of the medicine where relevant; (bb) an indication that the medicine must be used in accordance with the applicable complimentary discipline and principles where relevant; and (cc) if the medicine has not received registration with the authority the following disclaimer: "This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

(6) In the case of an advertisement for a medicine which contains more than one active ingredient, no specific reference shall be made to the specific properties of any individual active ingredient unless a reference of this nature has been approved by the Authority for inclusion in the professional information of such medicine.

(7) When a medicine is advertised verbally for the first time to persons contemplated in subregulation 2(a), written information, which shall include at least the information referred to in regulation 11 or regulation 14, shall simultaneously be given to the person to whom the oral advertisement is directed, and when the medicine is advertised orally on subsequent occasions such information shall be available on request."

Labelling:

Medicinal products which are intended for human use need to comply with regulation 10 of the General Regulations and section 18 of the Act. This means that the container of the medicinal product must have a label consisting of the following:

- Information regarding the name and schedule of substances contained within such product.
- Where the medicine is registered, the registered number of such medicine must be contained; and accompanying the registered number must be the words "Act 101/1965".

- Description of the dosage of such medicinal product, and its recommended dosage.
- Expiry date and manufactured date.
- The address and name of the business of which is the holder of the registration license.
- Warnings and Precautions.

In terms of a complementary medicine, the discipline must be stated. It must also indicate that such medicine must be used as per the discipline. However, if the complementary medicine is not registered it must contain the following wording "This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Product documentation:

Documentation including professional information; patient information leaflets and instructions on the use of such product should also be provided.

- Professional Information is regulated in terms of regulation 11 of the General Regulations. This information must be provided for either in the form of a hard copy or electronically. Furthermore, the information must consist of:
    - Schedule of which such medicine is considered to be a part of.
    - The name of the product as well as the description of the dosage.
    - The names of the active ingredients within the medicinal product. Information of measured amounts of each ingredient must be included.
    - Clinical trial information.
    - Any and all pharmacological information.
    - Storage instructions.
    - Symptoms and warnings.
    - The address and name of the business of which is the holder of the registration license.
- Patient Information leaflets are regulated by regulation 12 of the General Regulations. This information must be provided with the product by any of the following means, either by securing such information onto the product container; or incorporating the information as part of the product container. Furthermore, this information must consist of:
    - The name of the product as well as the description of the dosage.
    - Warnings and precautions.
    - Instructions regarding the use of the medicine.
    - Any side-effects which may arise.
    - Storage instructions.

- The address and name of the business of which is the holder of the registration license.

Non-medicinal products containing CBD

Any marketing and advertisements of non-medicinal products such as cosmetics, are regulated by the *Foodstuffs, Cosmetics and Disinfectants* Act.; the *Consumer Protection* Act[19]; and the Advertising Regulatory Board (ARB) composed Code of Advertising Practice.

It is important to note that cannabis is not a food ingredient as the *Foodstuffs, Cosmetics and Disinfectants Act* defines a "foodstuff" as follows:

""foodstuff" means any article or substance (except a drug as defined in the Drugs Control Act, 1965 (Act No. 101 of 1965)) ordinarily eaten or drunk by man or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part or ingredient of any such article or substance."

Due to the fact that cannabis is not "ordinarily" eaten or drunken, the substance itself is not a foodstuff.

However, it is still possible that it can be used as food additive. This will be discussed late on in the template.

Cannabis Assessoires

There are no regulations for cannabis accessories specifically. However, since some of these accessories may be used as a tobacco product the *Tobacco Product Control* Act[20]may be enforced. For example, rolling paper may be used as a tobacco product.

Tobacco Product Control Act:

This Act regulates the following:

- Sale or advertisement of tobacco products must contain health warnings.
- No tobacco product is allowed to be sold to persons under the age of 16 years.
- Majority of these accessories may be regulated to some extent in terms of the *Consumer Protection* Act, however, such accessories are not regulated.

It must be noted that the *Control of Tobacco Products and Electronic Delivery Systems* Bill has been drafted. This means that once enacted it may regulate tobacco products to a greater extent. However, this relates only to tobacco products. The only 'cannabis accessory' which may be regulated through this Bill would be vaporizers.

Importation

Section 22C(6) of the Act states that:

"No manufacturer, wholesaler or distributer referred to in subsection (1)(b) shall manufacture, import or export, act as a wholesaler of or distribute, as the case may

[19]

[20]Tobacco Product Control Act 83/1993.

be, any medicine unless he or she is the holder of a license contemplated in the said subsection."

Therefore, in order to import cannabis, such person must be a holder of a 22C(1)(b) license of the *Medicines and Related Substances* Act. This can be obtained by making an application to SAHPRA for such license.[21] Once a license in terms of section 22C(1)(b) of the Act is obtained, you may import cannabis.

The following may be imported regarding cannabis:

- A medicine containing THC. However, in order to import such product, you would have to additionally obtain a section 11 import permit as it is classified as a schedule 6 substance.
- Medicine containing CBD.
- Raw material CBD.
- Registered Medicine containing CBD.

It must be noted that section 2 of the *Foodstuffs, Cosmetics and Disinfectants* Act prohibits any importation regarding any foodstuffs, cosmetics or disinfectant which do not comply with the Act.

Current challenges

Legislation regarding cannabis is the greatest challenge to date, and will continue to be a challenge in the future for South Africa. Currently legislation restricts the use, access and possession of cannabis to a great extent. This is done by making provisions regarding extreme punishments for offences relating to cannabis. Therefore, the potential commercialization and creation of a new business sector regarding cannabis is overlooked.

In addition, the medicinal advancement of which cannabis can offer is drastically slowed down. This is because SAHPRA has not registered any products containing cannabis as well as the fact that very few cultivation licenses have been issued not issued. To date there are about 31 cultivation license holders.

It must also be noted that since legislation and regulations regarding cannabis are too restrictive, many manufacturers do not entirely understand the legislation and regulations relating to cannabis products. In addition, any persons who would need access to internationally registered cannabis products, would need to go through a strict and lengthy process in order to obtain registered cannabis medicinal products.

Furthermore, legislation and regulations regarding cannabis are not being enforced. There are currently many 'cannabis products' on the market and being sold to the public which do not comply with the legislation and regulation nor are they registered by SAHPRA.

[21]SAHPRA "License Application to Cultivate, Manufacture or Import Cannabis for Medicinal Purposes", https://www.sahpra.org.za/wp-content/uploads/2021/02/Application-for-Licence_Medicinal-Cannabis-00000002.pdf (accessed on 12 July 2021).

Future challenges

If the legislation and regulations regarding cannabis continue to be poorly enforced within South Africa, it could lead to public health and safety issues. Furthermore, the jurisdiction of cannabis should lie with the Department of Health; the Department of Agriculture, Land Reform and Rural Development; and the Department of Trade and Industry. This is because cannabis is an article which falls within the jurisdiction of all three of these departments. If the jurisdiction of cannabis continues to lie with the Department of Justice, then it will only regulate cannabis by means of the justice system within South Africa therefore, limiting cannabis and what it has to offer medically, agriculturally and economically.

Additionally, there is a possibility of a challenge which may arise in the near future regarding the *Cannabis for Private Purposes Bill*. In terms of the present-day, this Bill is yet to be assented and therefore, is not regarded as an authoritative legislation which may be enforced. However, once the Bill does indeed become an authoritative legislation; the challenge which arises is that this Bill will further enforce the fact that most of these products are in fact illegal and the commercialization of these products would be prevented entirely.

In addition, if legislation and regulations regarding cannabis continue to be extremely restrictive it will only create more criminal penalties in terms of access, distribution and possession of cannabis.

Cannabis trade and production is already illegal in nature and extremely restrictive legislation and regulations will force people to continue such illegal business with greater consequences.

The future legalisation and proper regulation of the cannabis industry could aid in South Africa's failing economy and this is what the proposed Bill fails to provide for.

❖❖❖

SPAIN

Silvia Bañares Vilella

Background

Regulation of Cannabis Sativa, Cannabinoids (particularly CBD) is quite old and somehow, aligned with the most restrictive interpretations of International regulations. At the same time, some aspects are still unregulated. However, there are several proposals at political level that will be discussed and maybe developed in the near future.

Ordinary Foods

Spain fully applies the current criteria applicable in the EU regarding novel foods; therefore, only foodstuffs that have a history of consumption prior to May 1997 are considered as safe. According to it:

a) seeds, seed oil, hemp seed flour, defatted hemp seeds not exceeding 0.2% of THC are not novel (0.3% according to EU Parliament resolution of 23/10/2020)

b) Cannabinoids (as THC, CBD, CBG etc) and other parts of Cannabis sativa L (as flowers, leaves and stems) or its extracts are considered as novel

In these cases, mutual recognition might not be applied

Several ordinary foodstuffs containing other parts or cannabinoids have been withdrawn from the market and included in the RASFF system

http://www.aesan.gob.es/AECOSAN/web/noticias_y_actualizaciones/noticias/2019/caniamo.htm

Food Supplements

Currently, there are 19 food supplements already marketed and notified in Spain. Cannabis Seeds Oil is their main ingredient.

Cosmetics

CBD extracted from cannabis flowers is not permitted in cosmetic products (Regulation (EU) No. 1223/2009 on cosmetic products). However, CBD of synthetic origin it is allowed.

Research

Cultivation of Cannabis Sativa for researching or other scientific purposes requires an administrative authorisation from Spanish Medical and Health Products Agency.
https://www.mapa.gob.es/es/agricultura/temas/producciones-agricolas/notainformativasobreelcultivodecanamo_tcm30-560351.pdf
There are currently 13 companies and institutions authorised for researching purposes and 10 more for scientific or medical purposes.
https://www.aemps.gob.es/medicamentos-de-uso-humano/estupefacientes-y-psicotropos/autorizaciones-vigentes-emitidas-por-la-aemps-para-el-cultivo-de-plantas-de-cannabis/

Recreational

Recreational use of Cannabinoids is merely admitted for private/domestic consumption or if consumed in authorised/retail places.
The tenancy of 20 up to 100 gr is admitted as private/domestic consumption. Otherwise, it will be considered as an administrative fault or, depending on the circumstances, as a criminal fault.
As an administrative infraction, the sanctions vary between 601 and 10,400 EUR (according article 39 of the Spanish Organic Law 4/2015 on the Protection of Citizens' Security)
https://boe.es/buscar/pdf/2015/BOE-A-2015-3442-consolidado.pdf
As a criminal fault, article 368 of the Spanish Criminal Code establishes that "Those who carry out acts of cultivation, preparation or trafficking, or who otherwise favour or facilitate the unlawful consumption of toxic drugs, narcotics or psychotropic substances, or who possess them for those purposes, shall be punished with imprisonment from three to six years and a fine of one to three times the value of the drug as the criminal offence, if they are substances or products that cause serious damage to health, and of imprisonment from one to three years and a fine from one to two times the amount in the remaining cases.
Notwithstanding what is set forth in the preceding Paragraph, the Courts of Law may impose a lower degree of punishment than those stated in view of the scarce importance of the facts and the offender's personal circumstances. This power may not be made use of if any of the circumstances referred to in Articles 369bis and 370 concurs.
https://www.boe.es/buscar/act.php?id=BOE-A-1995-25444
Some regions in Spain (as Catalonia) admit "Cannabis clubs", namely, private associations where Cannabis is bought and consumed by its members. However, their existence is currently questioned: two rulings of the Supreme Court (23/11/2020 and 30/11/2020) and Superior Court of Catalonia (23/7/2021) have stated their illegality.Consequently, regions as Navarra, Basque Country or Catalonia are closing these clubs.
At its turn, electronic devices containing CDB are also forbidden in Spain
https://www.hacienda.gob.es/Documentacion/Publico/Tabacos/Expendedurias/Circular%203-2020%20CMT-firmada.pdf

Medical

All medicines used in Spain must obtain an authorization from the Spanish Medical and Health Products Agency, which will grant it after evaluating its quality, safety and

efficacy. Likewise, any modification must be authorized by the Spanish Medical and Health Products Agency or it must be informed about it.
Evaluations aim to ensure a positive balance between benefit and risk of using the drug at all stages of its commercialization.
The AEMPS has only authorized Sativex as a pharmaceutical drug that Contains Delta-9-THC and CBD.
It can only be prescribed by medical doctors and bought in pharmacies.

Branding and Marketing

Specific regulations applicable to foodstuffs, cosmetics, medicinal products, etc. might be taken into account while developing any product containing Cannabis/CBD products. Branding and marketing of cannabis/CBD products depends so much on the product category.

Future Challenges

Last June, a new initiativewas submitted to the Spanish Congress to evaluate therapeutic uses of Cannabis Sativa. The results are expected to be released by the end of November 2021.

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SWEDEN

Per Lidman, Setterwalls and Magnus Friberg, Gulliksson

with a special thanks to Oskar Svenburg, Setterwalls, for invaluable support and research

Background

Cannabis and any preparations containing THC are prohibited under Swedish penal law.

Swedish regulatory authorities have applied a restrictive position against products containing CBD for oral use or inhalation.

Marketing and sale of cosmetics containing CBD is not prohibited but any marketing activities should take care to avoid content stating or indicating medicinal effects (which may violate medicinal product rules) and content that convey a positive impression of cannabis or other narcotics (which may violate marketing law).

Recreational

Cannabis (except cannabis seeds) and preparations containing THC qualify as narcotics under Swedish penal law. Therefore, use, purchase or possession of cannabis constitutes a drug offence. The same is true for preparations containing THC, regardless of the THC amount and regardless whether the preparation has been processed from industrial hemp. Criminal sanctions range from fines to prison sentences of six months for lesser drug offences, up to three years for regular drug offences and from two to seven years of prison for serious drug offences.[1]

Industrial hemp (as defined by the applicable EU regulations) in its plant form, and which is grown by farmers subject to an application for farm payments (production subsidies - *Sw. gårdsstöd* under applicable EU regulations), is excluded from the Swedish legal definition of cannabis and therefore not a drug offence under Swedish penal law. The exemption does not cover products that can be extracted from an industrial hemp (which qualify as narcotics if they contain THC).[2]

There are no prohibitions against use, purchase or possession of preparations containing

[1]Sections 1-3 of the Swedish Narcotic Drugs Penal Act; Annex 1 of the Swedish Narcotic Drug Controls Ordinance (1992:1554); Swedish Supreme Court case NJA 2019 p. 531.

[2]Annex 1 of the Swedish Narcotic Drug Controls Ordinance (1992:1554).

CBD under Swedish penal law (provided that the preparation does not contain THC) or regulatory rules. Marketing, selling and importing CBD products is however subject to requirements under Swedish regulatory law (as outlined below in this article).

Medical

Medicinal products with marketing authorisation

Marketing and sales of medicinal products requires authorisation from the Swedish Medical Products Agency (the MPA). There are currently two medicinal products containing cannabis extracts approved for the Swedish market. One contains CBD and is approved for treatment of rare types of epilepsy, while the other one contains both CBD and THC and is approved for treatment of spasticity. Both are prescription drugs.

Medicinal products containing cannabis in plant form

There are no approved medicinal products containing cannabis in plant form on the Swedish market. However, there are instances where individual pharmacies have applied and been granted a license from the MPA for dispensing a medicinal product containing cannabis which is not approved in Sweden. The granting of a license requires that the individual patient's needs of treatment cannot be met by any approved medicinal product on the Swedish market. The application has to be supported by a prescribing physician and submitted by the dispensing pharmacy. The average yearly number of granted licenses for non-approved medical products containing cannabis is unknown, but assumed to be below 100 per year.[3]

Medicinal products containing CBD

Products qualify as medical products if they: (1) may be used as a medicinal product due to the effect of its CBD content; or (2) is marketed in conjunction with claims ofhaving properties for treating or preventing disease.[4] It is prohibited to market and sell medicinal products without a marketing authorisation.[5]

Additionally, it is currently unclear if marketing and selling non-approved CBD products for oral use or inhalation is permitted at all under current Swedish regulatory law. The MPA has adopted a restrictive position issuing prohibitions against preparations containing CBD for oral use or inhalation, arguing that the products in question qualify as medicinal products not only due to reasons (1)-(2) (as outlined above), but also because (3) the actual and potential consumers, of the CBD products in question, buy them because of perceived medical effects of CBD. Some of these MPA prohibitions have been appealed and tried in the first instance, administrative court of Uppsala, which to date has upheld the MPA's prohibitions subject to appeal. While the court has disagreed with the MPA's reason (1) outlined above, it has agreed with reasons (2) and (3) in the cases at hand. It is unclear whether the MPA and the first instance court have considered reason (3) applicable only to the products in question or have also considered the findings applicable to CBD preparations for oral use or inhalation in

[3]The Swedish Act regarding control of narcotics; The MPA regulations HSLF-FS 2018:25 regarding license and LVFS 2011 : 9 regarding control of narcotics.

[4]Chapter 2, Section 1 of the Swedish Medicinal Products Act.

[5]Chapter 5, Section 1 of the Swedish Medicinal Products Act.

general.[6] We are not aware of any higher administrative court case law. In summary it is therefore currently unclear if marketing and selling non-approved CBD products for oral use or inhalation is permitted at all under current Swedish regulatory law. Current court practise however indicates that it is not permitted.

Branding and Marketing

Marketing of cannabis or any preparation containing THC is a drug offence under Swedish penal law.[7]

Marketing of CBD products that qualify as medicinal products (as outlined in answers above) is not permitted without prior marketing authorisation.[8]

Marketing of food and food supplements containing CBD is not permitted (as outlined in answers below).[9]

There are no general prohibitions against marketing of cosmetics containing CBD.

Marketing that conveys a positive impression of narcotics (which includes cannabis or any preparation containing THC) is not permitted. Case law is sparse regarding under what circumstances it may be allowed to include images of the cannabis plant in marketing. Current case law from the Swedish Advertising Ombudsman (the self-regulatory organisation founded by the Swedish advertising industry) indicates that images of cannabis in conjunction with any messages, product names or representations that state or imply positive properties of cannabis is not permitted.[10]

Applications for national trademarks reproducing the word cannabis, or images of cannabis, or other narcotics, can be denied under the Swedish Trademark Act's prohibition against trademarks contrary to law, public standard practice or the public order.[11]

Edibles, Topicals, and More

Marketing or sales of cannabis or any preparation containing THC is a drug offence under Swedish penal law.[12]

Marketing or sales of edible products containing CBD or CBD products for inhalation is not permitted under regulatory law. As outlined above, both the MPA and the current lower court case law has applied a restrictive position issuing prohibitions against a wide variety of preparations containing CBD for oral use or inhalation, arguing that the

[6] Administrative court of Uppsala judgments of 29 August 2019 in cases 2636-18, 1338-19, 6967-18, 2634-18 and 2633-18.

[7] Section 1, para. 1, item 5 of the Swedish Narcotic Drugs Penal Act; Swedish Supreme Court case NJA 2019 p. 531.

[8] Chapter 5, section 1 of the Swedish Medicinal Products Act and Section 5 of the Swedish Marketing Practices Act.

[9] Article 6.2 of the Novel Foods Regulation (EU) 2015/2283 and Section 5 of the Swedish Marketing Practices Act.

[10] Section 5 of the Swedish Marketing Practices Act and Article 1 of the ICC Advertising and Marketing Communications Code; Swedish Advertising Ombudsman decisions in cases 2102-32, 2002-27, 1510-188 and 1009-195.

[11] Chapter 2, Section 7, para. 1, item 1 of the Swedish Trademark Act; Swedish Supreme Administrative Court case R78 2:9.

[12] Section 1, para. 1, item 5 of the Swedish Narcotic Drugs Penal Act; Swedish Supreme Court case NJA 2019 p. 531.

products in case qualify as medicinal products which require marketing authorisation. Furthermore, marketing or sale of edible food products containing CBD (that do not qualify as medicinal products) is not permitted without an EU novel food authorisation. CBD is categorized as a novel food under the European Novel Food Regulation (EU) 2015/2283 which is naturally applied by the Swedish Food Agency.[13] There are novel food applications for CBD pending at the European level but to our knowledge, none have yet been approved.

Marketing and sales of edible products from some industrial hemp parts such as seeds, seed oil, hemp seed flour, defatted hemp seed is permitted since they do not qualify as novel food.[14]

Marketing or sales of other edible products containing industrial hemp, however, are currently not permitted under regulatory law. The Swedish Food Agency has adopted the position that such industrial hemp products constitute novel food under the European Novel Food Regulation (EU) 2015/2283, although the relevant entry in the Novel Food Catalogue is unclear and pending further clarification from the EU institutions.[15]

It is prohibited to include cannabis or preparations containing THC (or other narcotics) in cosmetic products.[16]

There are no general prohibitions against marketing of topical cosmetics containing CBD, as long as the general requirements for cosmetic products are met.

Cannabis Accessories

As long as the accessories are not marketed for cannabis-related use or obviously have no other realistic use than for cannabis products (which are as set out below prohibited) there are no specific restrictions.

Importation

Narcotics

Importing cannabis or any preparation containing THC is a drug trafficking offence under Swedish penal law.[17] Exemptions can be granted by the MPA in accordance with regulations (LVFS 2011:9).

Products containing CBD that qualify as medicinal products

There are no prohibitions against professional actors importing CBD medicinal products from EEA countries (as long as they are not placed on the market without a marketing authorisation). Import of medicinal products from non-EEA countries requires either a manufacturing authorisation or a specific import license from the MPA.[18]

[13]Articles 3.2 and 6.2 of the Novel Foods Regulation (EU) 2015/2283; EU Novel Food Catalogue entry "Cannabinoids"; Swedish Food Agency's public statement on this webpage link and Section 5 of the Swedish Marketing Practices Act.

[14]Articles 3.2 and 6.2 of the Novel Foods Regulation (EU) 2015/2283; EU Novel Food Catalogue entry "Cannabis sativa L"; Swedish Food Agency's public statement on this webpage link.

[15]Articles 3.2 and 6.2 of the Novel Foods Regulation (EU) 2015/2283; EU Novel Food Catalogue entry "Cannabinoids"; Swedish Food Agency's public statement on this webpage link and Section 5 of the Swedish Marketing Practices Act.

[16]Article 14 and item 306 in Annex 2 of the Cosmetic Products Regulation (EC) 1223/2009.

[17]Section 6 of the Penalties for Smuggling Act.

[18]Chapter 9, Section 1 of the Swedish Medicinal Products Act.

CBD medicinal products can be imported for personal use during travelling, provided that the products: (1) are imported for the recipient's personal use; (2) have been acquired for medicinal use; (3) the traveller can provide proof of conditions (1) and (2) e.g. a written certificate from the prescribing physician; and (4) the amount of products do not exceed one year's consumption if imported from an EEA country or three month's consumption if imported from a non-EEA country.

CBD medicinal products cannot be imported for personal use by mail unless they are the subject of a marketing authorisation covering Sweden.[19]

CBD products that qualify as food or cosmetics

There are currently no specific prohibitions against importing CBD food products (as long as they are not placed on the market in violation of the Novel Food Regulation, see above).

There are no specific prohibitions against importing CBD-containing cosmetic products.

Future Challenges

While the Swedish authorities have applied a more restrictive approach to the use of cannabis and CBD, there has been reports that the granting of licences for importing cannabis products for medical use to individual patients in Sweden has increased.

The developments concerning CBD edible products depends on the progress of the novel foods application review ongoing at the European Food Safety Authority.

As cosmetic products containing CBD grow in popularity, an increase in case law concerning permitted marketing content for such products should be expected.

[19]Sections 7-8 of the MPA's importing regulations LVFS 1996:5.

UKRAINE

Lana Sinichkina / Mariia Baranovych

Background

As of today, the cannabis market in Ukraine is not fully legalized, since this herb and cannabinoids are referred to a group of substances, the circulation of which is prohibited in accordance with the Resolution of the Cabinet of Ministers dated May 6, 2000 No. 770 "On approval of the List of Narcotic Drugs, Psychotropic Substances and Precursors".

However, recently the Cabinet of Ministers of Ukraine adopted Resolution dated April 07, 2021 No. 324 "On Amendments to the List of Narcotic Drugs, Psychotropic Substances, and Precursors", which permits the use of some cannabis-based products for medical purposes. This Resolution was criticized by some patient organizations and members of the Ukrainian Parliament, as it does not fully solve the problem of a lack of patients' access to the necessary medicinal products which are based on medical cannabis.

Currently, some members of the Ukrainian Parliament are working on the adoption of a new Law, that would allow fuller legalization of medical cannabis.

Both the Criminal Code of Ukraine and the Code of Administrative Offences of Ukraine provide for liability for illegal sowing or cultivation of hemp, as well as for illegal manufacture, acquisition, storage, transportation or shipment of cannabis.

For instance, according to the Code of Administrative Offences of Ukraine:

- illegal sowing or illegal cultivation of hemp in the quantity of up to 10 plants entails a fine (in the amount UAH 306 – 1700, i.e. approx. EUR 10 – 55) with confiscation of illegal plants;[1]
- illegal production, purchase, storage, transportation of narcotic drugs in small amounts with no intent to further sale of such narcotic drugs entails a fine (in the amount UAH 425 – 850, i.e. approx. EUR 14 – 28), or public works for 20 – 60 hours, or administrative arrest for the term of up to 15 days.[2]

[1]Article 106[2] of the Code of Administrative Offences of Ukraine
[2]Article 44 of the Code of Administrative Offences of Ukraine

- According to the Criminal Code of Ukraine:
- illegal sowing or illegal cultivation of hemp in the quantity of 10 and more plants entails a fine (in the amount UAH 1700 – 8500, i.e. approx. EUR 55 – 275) or arrest for a term of up to 6 months, or restriction of liberty for a term of up to 3 years, or imprisonment for a term of 3 – 7 years;[3]
- illegal production, purchase, storage, transportation or shipping with no intent to further sale of narcotic drugs entails a fine (in the amount UAH 17000 – 85000, i.e. approx. EUR 550 – 2750) or corrective works for the term of up to 2 years, or arrest for a term of up to 6 months, or restriction of liberty for a term of up to 5 years, or imprisonment for the term of up to 8 years;[4]
- illegal production, purchase, storage, transportation, shipping with intent to further sale or sale of narcotic drugs entails imprisonment for 4 – 12 years with confiscation of property.[5]

Recreational use of cannabis

As of today, recreational use of cannabis is prohibited in Ukraine.

Medical cannabis

In April 2021, the Cabinet of Ministers of Ukraine adopted the abovementioned Resolution dated April 07, 2021 No. 324 "On Amendments to the List of Narcotic Drugs, Psychotropic Substances, and Precursors". Right now, it is the only legal act that governs the use of medical cannabis in Ukraine.

According to the abovementioned Resolution:

- The substance 'cannabidiol isolate' shall not be subject to state control measures under the Resolution of the Cabinet of Ministers of Ukraine dated May 6, 2000 No. 770 "On Approving the List of Narcotic Drugs, Psychotropic Substances and Precursors".
- The psychotropic substances Nabilone (a synthetic cannabinoid that mimics the action of tetrahydrocannabinol THC) and Nabiximols (a standardized cannabis extract with the same content of THC and cannabidiol) are included on the list of psychotropic substances with limited circulation. Thus, Nabilone and Nabiximols are now allowed for use in medical practice on prescription.

The circulation of the psychotropic substances Dronabinol, Nabilone and Nabiximols is allowed only in the form of medicinal products or in the form of substances intended for the production, manufacture of such medicinal products.

Branding and Marketing

Advertising of cannabis is prohibited in Ukraine.
Besides, as it was mentioned earlier, two cannabis-based medicines (Nabilone and Nabiximols) are allowed only with a doctor's prescription. Though it is prohibited to advertise prescription medicines among patients, promotional materials on such Rx medicines may be:

[3]Article 310 of the Criminal Code of Ukraine
[4]Article 309 of the Criminal Code of Ukraine
[5]Article 307 of the Criminal Code of Ukraine

- placed in specialized editions intended for healthcare institutions and doctors, as well as
- disseminated in seminars, conferences and symposia on medical issues.[6]

Edibles, Topicals, etc.

Currently this issue is not regulated in Ukraine.

Cannabis Accessories

Currently this issue is not regulated in Ukraine.

Importation

Currently this issue is not regulated in Ukraine.

Future challenges

Recently a number of Draft Laws aimed at regulation of hemp circulation for medical purposes, scientific and scientific-technical activity (i.e. draft laws under reg. No. 4553 dd. 29.12.2020, reg. 4553-1 dd. 18.01.2021 and reg. No. 5596 dd. 02.06.2021) have been registered in the Ukrainian Parliament.

For instance, the Draft Law of Ukraine "On Amendments to Certain Legislative Acts of Ukraine Concerning the Regulation of Hemp Circulation for Medical Purposes, Scientific and Scientific-Technical Activity" reg. No. 4553 dd. 02.06.2021 offered:

- to exclude medicinal hemp and industrial hemp from the list of plants, the cultivation of which is prohibited in Ukraine;
- to exclude industrial hemp and products made from it from the list of narcotic drugs, if the content of tetrahydrocannabinol in the dry weight of such products does not exceed 0.2 percent;
- to designate an authorized body in the field of medicinal cannabis circulation, which would carry out licensing of economic activity in this area;
- to make the circulation of medicinal cannabis traceable;
- to mark each batch and unit of packaged products made of medicinal cannabis with a unique code;
- to create a public electronic register of displaced medicinal cannabis;
- to ensure the release of drugs based on medicinal cannabis exclusively by electronic prescription;
- to allow activities aimed at development of new narcotic drugs or psychotropic substances with the purpose of application of such drugs in medicinal practice or for scientific and scientific-technical purposes;
- to allow the storage of medicinal products made of medicinal cannabis without the use of special premises and (or) equipment to an individual who has purchased such medicinal products for the purpose of medical use in an amount not exceeding the amount allowed for such a person by a prescription issued to him/her by a doctor;

[6]Article 21 of the Law of Ukraine "On Advertising"

- to allow the purchase of drugs based on medicinal cannabis on the basis of an electronic prescription in pharmacies of all forms of ownership if they have the appropriate license, etc.

On July 13, 2021 the Ukrainian Parliament returned the abovementioned Draft Law to its initiators for further improvement.

Currently a number of members of the Ukrainian Parliament are working on a new draft law in order to ensure fuller legalization of medical cannabis.

On November 17, 2021 a new Draft Law "On Amendments to Certain Legislative Acts of Ukraine Concerning the Regulation of the Circulation of Cannabis Plants for Medical, Industrial Purposes, Scientific and Scientific-Technical Activities" was submitted for public discussion. This new Draft Law was developed by the Ministry of Health of Ukraine with support of the State Enterprise "Medical procurement of Ukraine". As far as the concept of this Draft Law is highly supported by a number of members of the Ukrainian Parliament, this Draft Law has a high chance of being adopted in the year 2022.

The abovementioned new Draft law proposes to introduce the following changes into the Ukrainian legislation:

1) The percentage of tetrahydrocannabinol in the dry mass in varieties of Cannabis for medical purposes shall be determined by the State Service of Ukraine on Medicines and Drugs Control. Cannabis for industrial purposes, goods made from them, products of their processing, if the content of tetrahydrocannabinol in the dry mass of such goods or processed products does not exceed 0.2%, shall not be considered to be a narcotic drug, psychotropic substance or precursor, circulation of which is prohibited on the territory of Ukraine. The determination of tetrahydrocannabinol content in plants of the genus Cannabis shall be carried out by conducting laboratory tests conducted by enterprises, institutions and organizations belonging to the sphere of management of the central executive body implementing state policy in the field of drugs, psychotropic substances, their analogues and precursors.

2) Entities that will be engaged in cultivation of varieties of plants of the genus Cannabis for medical purposes will be obliged to receive a license to conduct such activities.

3) The circulation of varieties of plants of the genus Cannabis for medicinal purposes, products of their processing and medicines produced or manufactured from them shall be allowed in scientific activities and medical practice, provided that control and traceability is ensured at all stages of such circulation. Besides, the means of ensuring traceability shall be as follows:

   - marking of each batch and unit of packaged products with a unique bar code;
   - maintaining an electronic register of movement of plant varieties of the genus Cannabis at all stages of circulation;
   - ensuring the release of medicinal products made from varieties of cannabis exclusively on electronic prescription in accordance with medical indications.

4) Legal entities that have received a license to carry out activities for the cultivation or use of varieties of plants of the genus Cannabis for medical, industrial purposes, scientific and scientific-technical activities shall:

   – enter into an agreement with a testing laboratory for quality control of medicinal products to carry out activities in accordance with the legislation on technical regulations and conformity assessment, or ensure the continued operation of such a laboratory in the production complex where cultivation is carried out, in order to control product quality and control the content of tetrahydrocannabinol in it;

   – provide access to the National Police to the areas and facilities where cultivation, storage, use or destruction of such plants, products of their processing take place, for selection and examination of samples of such products.

5) Activities related to the development of new narcotic drugs or psychotropic substances shall be allowed only with the aim of their use for medical purposes or for scientific and scientific-technical activities in any form. Development of new narcotic drugs or psychotropic substances shall be carried out by scientific institutions of state, communal and private forms of ownership if they have a license for this type of activity. New narcotic drugs or psychotropic substances may be applied in medical practice subject to their state registration and given the results of clinical trials conducted in accordance with the legislation on medicinal products.

The purchase of medicinal products containing Cannabis by an individual for medical indications shall be carried out based on a doctor's prescription, issued in electronic form. Retail sale to individuals of medicinal products produced (manufactured) from varieties of plants of Cannabis for medical purposes, which will be allowed for use in medical practice, shall be carried out in pharmacies of all forms of ownership if they have a license for this activity.

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SWITZERLAND

Karola Krell Zbinden

Background

The cannabis plant (Cannabis sativa or Cannabis indica) contains over 80 so-called cannabinoids. A wide range of cannabidiol-containing products are available in Switzerland. These products are regulated in several Federal Acts and controlled by different Federal and Cantonal control authorities.[1]

With the exemption of cannabis resin (hashish), cannabis and cannabis preparations with a total THC content of less than 1.0% are not regarded as narcotics[2]. Authorisation is therefore not required to handle cannabis or cannabis preparations made from hemp with a total THC content of less than 1.0%. Unlike THC (tetrahydrocannabinol), CBD is not subject to the Narcotics Act (NarcA, SR 812.121) because it does not produce a comparable psychoactive effect.

The Federal Office of Public Health (FOPH) is responsible for the registration of tobacco substitutes containing CBD in retail packs (in practice: under 250 grams) and for cannabis and cannabis products with a THC content of at least 1.0 %. If the product is a therapeutic product (medicinal product or medical device), the Swiss Agency for Therapeutic Products (Swissmedic) is responsible. The Federal Food Safety and Veterinary Office (FSVO) is responsible for foodstuffs and e-cigarettes or liquids for electronic cigarettes containing cannabis and CBD. The Federal Office for Agriculture (FOAG[3]) is responsible for commercial cultivation in the agricultural and horticultural production sectors. In Switzerland, agricultural production of all varieties of hemp seeds that are not classified as narcotics (total THC content of less than 1.0%) are permitted since January 1, 2021. If the hemp is intended for use as animal feed, the provisions of the feed legislation apply.

[1] Information on the website of the Swiss Federal Food Safety and Veterinary Office on cannabis, Products containing cannabidiol (CBD) Overview and implementation guide https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/bewilligung-und-meldung/bewilligung/cannabis-cannabidiol.html

[2] List D of the Narcoti Lists Ordinance (NarcLO-FDHA; SR 812.121.11)

[3] https://www.blw.admin.ch/blw/en/home/nachhaltige-produktion/pflanzliche-produktion/hanf.html

Category	Crop	THC*	Use	Legal base	Competence
recreational Cannabis	flower	> 1%	Tobacco substitutes, cannabis and cannabis products, other than medicinal	NarcA	FOPH
medical Cannabis	flower	> 1%	medicinal	NarcA Therapeutic Products Act (TPA)	Swissmedic
CBD-hemp	flower	< 1%	medicinal recreational (e-cigarettes, cosmetics, foods, chemical product)	TPA / Applicable legislation	Swissmedic FSVO
oil and fibre hemp	seed, shoot	< 1%	industrial	AgricA	FOAG

Depending on the classification of the respective product, the corresponding Swiss legislation is applied.

Recreational

Cannabis with more than 1% THC

The use of cannabis **for smoking** with a tetrahydrocannabinol (THC) content of at least 1% is generally prohibited in Switzerland. Since 2013, cannabis use by adults may be punished with a fixed penalty of CHF 100.00. By contrast, the possession of up to 10 g of cannabis for personal use is not considered a criminal offence. However, the Juvenile Criminal Law Act applies to minors. Use is particularly widespread among adolescents and young adults. One in ten adolescents aged between 15 and 24 have smoked cannabis within the last month. Use decreases with age and becomes a niche phenomenon.

For years, the level of cannabis use among adolescents in Switzerland has been among the highest in Europe. The number of students who have consumed cannabis has declined significantly since 2002. In addition, most young people only consume it from time to time and then give it up completely after a certain period. Only a small proportion (less than 4%) develop problematic use.[4]

The aim of the fixed penalty procedure was to standardise prosecution of all cannabis users in Switzerland and reduce administrative and legal costs. This aim has only partly been achieved, as there are still considerable differences between cantons regarding implementation of the fixed penalty procedure.

Cannabis with less than 1% THC

Cannabis flowers **intended for smoking** with a high proportion of cannabidiol (CBD) and less than 1% THC can be sold and purchased legally.

[4] https://www.bag.admin.ch/bag/en/home/gesund-leben/sucht-und-gesundheit/cannabis.html

Under the food legislation, smoked tobacco substitutes are regulated by the Tobacco Ordinance (TobO; SR 817.06). According to Article 3 TobO, manufacturers or importers must notify the FOPH of **tobacco substitutes** that they market under their own brand to the consumer in retail packages weighing less than 250g. Products that are intended for smoking or vaping or can be used for this purpose must be notified. Distributors who sell these products as resellers and do not manufacture them themselves are not required to notify the products. However, as part of their self-control under the Foodstuffs Act, they must ensure that the product has been notified to the FOPH by the manufacturing or importing company/person.

Tobacco products for smoking that consist of **a mixture of tobacco/tobacco substitute** (e.g. low-THC cannabis, herbs) are considered flavoured tobacco products. They may contain a total of low-THC cannabis or herbs as a "harmless plant component" for flavouringup to 15% by mass, in cut and rolled tobacco up to 20% by mass, in water pipe tobacco up to 70% by mass (article 6, 1 lit. a Tobacco Ordinance). For such products, a notification is not required. For products with higher contents, an authorisation for increased additive contents must be obtained by the FOPH (article 6, 3 Tobacco Ordinance).

Cannabis products with less than 1% THC are not subject to the Narcotics Act and are therefore increasingly exploited commercially. Recreational cannabis products cannot be sold and advertised at will. Depending on the product category, their industrial processing and marketing is subject to the Therapeutic Products Act (TPA, SR 812.21[5]), the Foodstuffs Act (FSA, SR 817.0 [6])or the Product Safety Act (PrSG, SR 930.11[7]). Raw materials intended for further processing by establishments into final products are subject to the provisions of the Chemicals Act (ChemA; SR 813.1[8]).

To raise awareness of the legal framework among potential suppliers, Swissmedic, the Federal Office of Public Health, the Federal Food Safety and Veterinary Office and the Federal Office for Agriculture have developed a fact-sheet.

CBD-containing products with less than 1% THC

The range of CBD-containing products on the Swiss market is extensive. It includes raw materials such as cannabis buds or powder with a high CBD content, extracts in the form of oils or pastes and ready-to-use products such as capsules, food supplements, liquids for e-cigarettes, smoked tobacco substitutes, scented oils, chewing gums and ointments, some of which are marketed as personal care products. Once a product has been assigned to a particular product category, the corresponding Swiss legislation is applied. If the legal requirements in relation to a specific intended use are not met, a product may not be placed on the market.

As ready to use products

The final products are classified on a case-by-case basis taking account of all the relevant factors, including composition, intended use, dosage, etc. The person who

[5] https://www.fedlex.admin.ch/eli/cc/2001/422/en
[6] https://www.fedlex.admin.ch/eli/cc/2017/62/en
[7] https://www.fedlex.admin.ch/eli/cc/2010/347/de
[8] https://www.fedlex.admin.ch/eli/cc/2004/724/en

places the product on the market is required to provide information on the intended use (e.g. medicinal product, medical device, foodstuff, cosmetic, chemicals). The different control authorities are responsible for control, depending on how the products are classified. In case of doubt, the control authority assigns a product to specific legislation and takes the necessary measures.

To decide which legislation is applicable, it is necessary to consider all the properties and claims, both implicit and explicit, relating to a product in an overall assessment and to weigh them up on a case-by-case basis. Some suppliers state on their websites that the products may not be used for medical purposes for legal reasons. Other websites, on the other hand, include links to sites describing medical uses of cannabis. Therapeutic claims are evidently being made for such products, and they are therefore subject to the legislation governing therapeutic products.

For the necessary delimitation different guidance documents have been published.[9]

As raw material

Raw materials (in the form of substances or preparations) are governed by the provisions of the chemical products legislation. They are used for further processing in products and are therefore typically marketed to manufacturers (B2B). The manufacturers are responsible for correct processing in compliance with the specific legal requirements governing the final products. If raw material is intended for use by the consumer, the distributor (who is the manufacturer under the terms of the Chemicals Ordinance) must self-control the legality of possible and probable uses that could occur. If this review identifies uses that are subject to special legislation, or if such uses appear plausible, the requirements of this legislation must be observed.

Medicinal

Medicinal products

In accordance with Article 4 paragraph 1 letter a TPA (SR 812.21), ready-to-use CBD-containing products with a medical intended use are regarded as medicinal products and, in accordance with Article 9 paragraph 1 TPA, may not be placed on the market without authorization.

Establishments which prepare, distribute or dispense CBD-containing medicinal products always require a corresponding authorization from Swissmedic or the canton.

Cannabis containing medicinal products are authorized in Switzerland as ready-to-use therapeutic products and as magisterial preparations. They contain THC and CBD. For example, Epidiolex® was also authorized in Switzerland on 10 February 2021 under the proprietary name Epidyolex® for the adjuvant treatment of convulsions associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients from 2 years of age.

In accordance with article 9, 2, lit a TPA and considering the respective provisions of the legislation governing therapeutic products, medicinal products containing CBD may be prepared and dispensed in pharmacies (magisterial preparation) under the following conditions:

[9] https://www.swissmedic.ch/swissmedic/en/home/services/questions-on-delimitation.html

1. A prescription by a physician
2. The prescription should be issued by a specialist in the indications for which currently authorized medicinal products have been approved.
3. If, in exceptional, justified cases, a doctor issues a prescription for a different indication, the prescription should only be prepared after consultation with the respective physician, and it should be documented accordingly.
4. The medicinal product must be prepared with CBD that has been produced in compliance with the relevant GMP requirements to a quality standard that meets the requirements of monograph C-052 Cannabidiol of the current German Drug Codex DAC/NRF as a minimum.
5. Preparation at the pharmacy level must comply with the GMP requirements of the current Swiss pharmacopoeia (Pharmacopoea Helvetica, Ph. Helv., GMP for small quantities of medicinal products).

Medical devices

A CBD-containing product with a medical intended use, the primary effect of which in or on the human body according to its intended use is not achieved by pharmacological, immunological, or metabolic products, but the mode of action of which is supported by the CBD contained in the product, may comply with the definition of a medical device as stipulated in Article 14 of the Medical Devices Ordinance (MedDO; SR 812.213).

The classification of a CBD-containing medical device is guided by Article 5 MedDO and Annex IX of Directive 93/42/EEC (MDD), and by Rule 13 in Annex IX MDD, which states: "All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC [sic. source document cites Directive 65/65/EEC], and which is liable to act on the human body with action ancillary to that of the devices, are in Class III."

This classification will not change with the new EU Medical Device Regulation (MDR) since the following continues to apply under Rule 14 of Annex VIII MDR: "All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, [...] and that has an action ancillary to that of the device, are classified as class III."

Medical devices may generally contain plant extracts which provide color or flavor, for example. In all cases in which medical devices may contain pharmacologically active substances or plant extracts, the manufacturer must perform a case-by-case assessment of whether the product must be classified as a medicinal product or a medical device and, if it is a medical device, the class to which it belongs. This also applies to CBD since it is known to have a pharmacological, although not a psychoactive, effect.

Article 45 paragraph 2 TPA and Article 9 paragraph 2 MedDO6 require anyone who places a medical device on the market (e.g. manufacturers or distributors) to be able to demonstrate that the fundamental requirements are met and the claimed efficacy and performance exist. The conformity assessment procedure, the necessary certification and the declaration of conformity are based on Annex 3 MedDO (Art. 10 para. 1 MedDO7).

Branding and Marketing

Depending on the classification or the respective product, the product may be branded and marketed according to the corresponding legislation. There are no specific rules apply for branding and marketing of cannabis and CBD products in Switzerland.

Edibles, Topicals, and More

Products sold as foodstuff

Article 4, 1 FSA defines foodstuffs as any substances or products that are intended for consumption by, or that can reasonably be expected to be consumed by, humans in processed, partially processed or unprocessed form. Medicinal products, narcotics and psychotropic substances are not regarded as foodstuffs (article 4, 3 FSA).

It is a basic precondition that foodstuffs must be safe (article 7 FSA). This means that they may be neither harmful to health nor unsuitable for consumption by humans (article 8 of the Ordinance on Foodstuffs and Utility Articles, FUAO, SR 817.02).

However, foodstuffs that were not used for human consumption to a significant degree prior to 15 May 1997, either in Switzerland or in a Member State of the EU, must be authorized by the FSVO or by the European Commission. CBD and extracts of cannabis sativa L. and derivatives containing cannabinoids that are used in/as foodstuffs (e.g., hemp seed oil with added CBD, food supplements with CBD) are classified as such "novel foods" also in Switzerland.

On the contrary cannabis hemp seeds, hemp seed oil, hemp seed flour and defatted hemp seeds are not considered as "novel". Furthermore, in Switzerland herbal tea obtained from the leaves of the cannabis plant is not considered to be a novel foodstuff, also if used as flavoring for foodstuffs. The precondition for this is that the herbal tea is used as an aqueous infusion and in no other form (e.g., concentrated or as a syrup).

Now the FSVO is not in progress to evaluation an application for authorization of CBD for used in foodstuffs.

If the presence of CBD is indicated on the labelling of a product derived from cannabis like "contains CBD" this may be considered as nutritional or health-related information or an indication of the presence of an ingredient in a product. Such a "claim" must fulfill specific legal requirements. No health-related information is currently permitted for CBD.[10]

Products sold as cosmetics

A cosmetic product must be safe (article 15 FSA). The safety of the individual ingredients must be documented in a safety report (article 57 FUAO). Furthermore, references of any kind to effects of cosmetics that lead to the cure, the relief, or the prevention of diseases (e.g., medical, or therapeutic properties) are forbidden (article 47, 3 FUAO).

CBD may be used in cosmetics if it is synthetically prepared or obtained from various parts of the cannabis plant (a plant of the genus Cannabis). Synthetic CBD is not

[10] For further information, see https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/bewilligung-und-meldung/bewilligung/cannabis-cannabidiol.html

specifically regulated. The use of "cannabis" (buds and fruiting tops from which the resin has not been extracted) and products prepared from them (e.g., hemp extracts, CBD) in cosmetics is forbidden. Seeds and leaves not accompanied by the flowering or fruiting tops may be used in cosmetics. The resin obtained from the cannabis plant (no matter from which parts of the plant) may not be used in cosmetics. A product with a total THC content of at least 1.0% is subject to the provisions of the Narcotics Law.

Products sold as utility articles (e.g., CBD-containing liquids for e-cigarettes)

CBD-containing liquids for e-cigarettes are classified as utility articles. According to Article 5 FSA, these are defined as articles coming into contact with mucous membranes and when used correctly or in the normally expected manner may only release substances in quantities without any risk to health.

Substances that confer pharmacological effects on such products may not be added. Accordingly, it is not permitted to add CBD to liquids for e-cigarettes in pharmacologically effective doses. This also applies to information which suggests that the product is a therapeutic product.

Refill cartridges for e-cigarettes are governed by the chemical products' legislation. This means that the person placing the product on the market must practice self-control and fulfil the obligations, including labelling and registration in the product register.

Products sold as chemicals

The Chemicals Act primarily regulates the packaging and labelling of chemical products. Before placing chemical products on the market, the responsible manufacturer is required to practice "self-supervision". However, if the presentation of a product is suggestive of or implies uses that would be covered by other legal provisions, its marketability must be assessed according to these provisions (see article 1, 5, lit. c Ordinance on chemical products).

Example: CBD-containing "scented oil" is sold in a cartridge for e-cigarettes: in this case the foodstuffs/utility articles legislation, not chemicals legislation, forms the basis for the assessment of the product's marketability (see V.3.). For the purposes of practical marketing, marketable cartridges of this kind must be labelled and notified in accordance with chemical products' legislation. Further examples could include cannabis oils and cannabis tinctures which are sold without a medical prescription but with the intention of using them orally in the expectation of a pharmacological effect, in which case the therapeutic products legislation would apply.

If the product is subject to the provisions of the ChemO, the manufacturer must assess whether the chemical product may pose a threat to the life or health of humans or the environment.

Accordingly, the manufacturer must classify, package, and label the product in accordance with the provisions of the Chemicals Ordinance (ChemO; SR 813.11) and compile a safety data sheet. If the presentation is not suggestive of any other use, CBD-containing products such as perfumed oils may well be placed on the market legally under the terms of the chemical products' legislation.[11]

[11] For further information see Common Notification Authority for Chemicals www.anmeldestelle.admin.ch/chem/en/home.html

Cannabis Accessories

There are no specific regulations on cannabis accessories such as rolling papers or wraps, holders, pipes, water pipes, bongs, and vaporizers in Switzerland. Marketing of this accessories is subject to the general Product Safety Act (PrSG).

Importation

Swissmedic cannot issue a no-objection certificate (NOC) for the import or export of cannabis or cannabis preparations with a total THC content of less than 1.0% since these substances or products are subject to the international Single Convention on Narcotic Drugs.

To comply with the narcotics legislation, importers are required to prove that the products they intend to import have a total THC content of less than 1.0%. Corresponding proof in the form of a batch-specific certificate of analysis for the delivery in question issued by a laboratory accredited to ISO/IEC 17025 or by a GMP laboratory must be provided.

Import requirements in connection with seed legislation do no longer exist since 1st January 2021. However, a plant passport is generally required for planting material respectively a phytosanitary certificate for imports from third countries.

Future challenges

There are several political motions to change the current legal framework for the use of CBD in foodstuffs. However, if the question of safe use is not answered, Switzerland will not make the move to legalize such use. This is even more the case, as long as CBD considers to be a non-authorized “novel food” in the EU.

According to the Swiss Federal Office of Public Health it is currently not clear whether use of cannabis products with a low THC content can impair the ability to drive. The FOPH therefore recommends persons or entities placing products on the market to inform consumers accordingly.

The Swiss Parliament adopted an amendment to the law on facilitated access to cannabis medicinal products on 19 March 2021. On 24 June 2020, the Federal Council submitted a dispatch to parliament on the amendment of the Narcotics Act (BetmG), which provides for the facilitation of the handling of cannabis for medicinal purposes. The bill was largely uncontroversial in parliamentary deliberations and was adopted by both chambers of parliament on 19 March 2021.

The amendment to the law that was passed makes it easier for thousands of patients to access cannabis medicines as part of their treatment. This mainly affects cases of cancer or multiple sclerosis, where cannabis-containing medicines can alleviate chronic pain.

For the implementation of the amendment, adjustments to the Narcotics Control Ordinance and the Narcotics Directory Ordinance are necessary.

On the other hand, there is no change for cannabis for non-medical purposes: it remains prohibited.

Through the amendment of the law, the cultivation, processing, production, and trade of medicinal cannabis will be subject to the authorization and control system of Swissmedic - just like other narcotics used for medical purposes (for example, cocaine, methadone, morphine). Treatment with cannabis medicinal products will no longer require an exceptional authorization from the FOPH. The commercial export of cannabis for medical purposes will be permitted. The law on seeds and planting material will be amended so that the cultivation of medicinal cannabis is also simplified in agriculture.

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UNITED KINGDOM

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Background

Regulation of cannabis and cannabis derived substances depends on its purpose. Cannabis is a Class B drug and its use is prohibited for recreational use. However, since 2019 there has been some relaxation for the use of cannabis for medical uses and in FMCG sector, particularly in relation to edibles and topicals.

How cannabis is regulated will depend on what exactly the substance is and what it is to be used for:

- Cannabis, Cannabinol, substances containing Tetrahydrocannabinol ('THC') – prohibited except in exceptional medical circumstances.
- Hemp and related products, such as cold-pressed oils are acceptable in foods and cosmetics.
- Cannabidiol (CBD, with no THC). CBD is found within hemp and cannabis. CBD extracts can be derived from most parts of hemp or cannabis plants. They are selectively extracted, concentrating CBD and removing or reducing other chemical components. CBD is potentially acceptable in medicines, cosmetics or foods provided specific criteria are met and relevant licences or authorisations are in place.

The current UK government has confirmed it has no plans to reconsider the classification of Cannabis as a controlled drug nor is there any intention to decriminalise its use.

Recreational

Cannabis and Cannabinol are Class B controlled drugs under the Misuse of Drugs Act 1971 ('MDA 1971') and listed in Schedule 1 of the Misuse of Drugs Regulations 2001 ('MDR 2001') and in the Misuse of Drugs Designation Order 2015 ('2015 Order'). As such, recreational use is prohibited.

Under the MDA 1971, it is a criminal offence to supply, possess, or sell a controlled substance. An offence can be committed by individuals, officers of corporate bodies and corporate bodies.

The maximum punishment for production, or being concerned in the production, of a Class B controlled drug on a summary conviction is 12 months, the prescribed sum of £5,000 or both. On indictment the sentence is 14 years imprisonment or a fine or both.

The offence of supplying or offering to supply a Class B controlled drug or being involved in either activity or having possession of a controlled drug with intent to supply it to another carries the same maximum penalties. Summary conviction of having possession of a Class B controlled drug is punishable by 3 months in prison, £2,500 or both and on indictment it is 5 years or a fine, or both.

With less serious instances of offending (ie suspects are in possession of a small amount of cannabis for personal use and admits to an offence) the police have power to issue a Cannabis Warning; an informal warning. Under the Association of Chief Police Officers ('ACPO') guidelines, the Cannabis Warning, is to be used as part of a hierarchy of enforcement:

- First offence, no aggravating factors - Cannabis Warning;
- Second offence, no aggravating factors – Penalty Notices for Disorder;
- Third offence – arrest.

Cannabidiol ('CBD') in its pure form is not a controlled drug and therefore can be used in FMCGs if certain conditions are met. Essentially this means such goods cannot contain any controlled cannabinoids (or any THC, the psychoactive substance found in Cannabis, or Tetrahydrocannabivarin ('THC-V'), unintentionally or otherwise. If it does it will be viewed as a controlled drug. Therefore the starting point for any edible or topical FMCGs which contain CBD in the UK is that it must be THC free. If it meets this requirement it can be used in foods and cosmetics and can be made available via normal retail channels (both on-line and via bricks & mortar stores).

CBD is regulated as a Novel food in the UK and must be authorised before it can be placed on the market. However there are some variations across the different jurisdictions. In England & Wales, foods containing CBD can be sold provided a novel food authorisation application was submitted by 31 March 2021. After this date, only products which were on the market on or prior to 13 February 2020 and for which theFood Standards Agency ('FSA') has received an application which is subsequently validated will be allowed to remain on the market. In its guidance, the FSA also states that '"*no new CBD extracts or isolates, including new brands, should be sold until they have the necessary authorisation. A validated application is not sufficient to put new products on the market". "On the market"*has the usual meaning for food products and includes not just offering for sale but also holding for the purpose of sale, and any other form of transfer including distribution. The FSA has adopted a strict interpretation to 'new products' to include changes to the size of the product as well as changes to excipients. See below for further details.

The position in Scotland is different as the sale of foods containing CBD oil are not permitted until a Novel Food authorisation has been granted. In Northern Ireland, foods containing CBD continue to be regulated under EU law.

Cannabis and CBD can also be used in a small number of authorised medicines; all of which must hold a marketing authorisation and are classified as prescription only

medicines. In turn, this means they can only be prescribed by certain doctors and must be dispensed via a pharmacy.

Medicinal

The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018 amended the MDR 2001 such that certain cannabis-based products are authorised for medicinal use ('CBPM'). CBPM is a defined category of cannabis, cannabis resin, cannabinol and cannabinol derivatives, which are listed in Schedule 2 to the MDR 2001 and removed from designation under the 2015 Order.

There are three broad requirements that a CBPM product is required to satisfy:

- the product is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative;
- it is produced for medicinal use in humans; and
- is a medicinal product or a substance for use as an ingredient of, or in the production of, a medicinal product.

Whilst, in principle, there is no restriction on what CBPM may be prescribed for, the NHS acknowledges that, currently, it is only likely to be prescribed for the following conditions and only where other treatments are not available or have not helped:

- children and adults with rare, severe forms of epilepsy
- adults with vomiting or nausea caused by chemotherapy
- people with muscle stiffness and spasms caused by multiple sclerosis (MS)

In the UK, prescribing cannabis-based products for medicinal use is restricted to only those clinicians listed on the Specialist Register of the General Medical Council.

The Medicines & Healthcare products Regulatory Agency ("MHRA") has published its opinion that products containing CBD used for medical purposes are medicinal products (i.e. medicine) which will require authorisation. Medicinal products are any substance or combination of substances which:

- are presented as having properties for treating or preventing disease in human beings; and
- may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Currently there are no marketing authorisations for products containing CBD.

It is an offence under the Human Medicines Regulations 2012 to sell or supply or to advertise a medicinal product which does not have authorisation.

Branding and Marketing

Branding and marketing for products containing these substances is regulated in accordance with whether it is a medicine, cosmetic or food. The advertising of controlled drugs is prohibited.

In all circumstances, advertising for "legal" products may not link to illegal drug use either explicitly or by implication and the advertising must make absolutely clear the category of product being advertised. For example, a cosmetic must not imply it is a medicine (and vice versa) and a medicine must not imply it is a food.

In addition to the law governing advertising, the UK Code of Broadcast Advertising ("BCAP Code") and the UK Code of Non-broadcast Advertising and Direct & Promotional Marketing ("CAP Code") are enforced by the Advertising Standards Authority. These Codes reflect the law but are not themselves law.

Prescription only medicines including, but not limited to cannabis-based products are authorised for medicinal use may not be advertised to the public.

In the event that a CBD product is licensed as an over the counter ("OTC") medicine, i.e. for sale via pharmacy or general sale at a retailer, the following requirements would apply:

- All medicines advertising aimed at consumers must carry certain items of essential information: the name of the product; a therapeutic indication (and any additional information that is required for that particular product) in line with the marketing authorisation; the common name of the active ingredient (where there is only one active ingredient); and an invitation to read the leaflet or label.
- Scientists, health care professionals and celebrities may not be used in advertising for medicines.
- Claims in advertising for the product cannot go beyond the therapeutic claims allowed in the marketing authorisation and cannot imply its effects are guaranteed.
- Medicines advertisements may not include information which might lead to an erroneous self-diagnosis by a consumer.

Foods and food supplements

CBD foodstuffs and food supplements are subject to the same requirements as other foods. Health and nutrition claims in food advertising in Great Britain[1] are regulated by Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as retained in the UK with amendments for Brexit ("UK NHCR").

Health claims may only be made for foods if they are listed on the Great Britain nutrition and health claims ("GB NHC") register. General health claims (e.g. "good for you") must be accompanied by an authorised claim listed on the GB NHC register.

There are currently no health claims for CBD listed as authorised on the GB NHC and therefore no health claims can be made in association with food products. It is possible to add other substances or nutrients which have authorised health claims but such claims are limited to the specific nutrients rather than the products.

The Consumer Protection from Unfair Trading Regulations 2008 ('CPRs') prohibit misleading commercial practices, including misleading advertising to consumers. Amongst other things they prohibit misleading actions and omissions. In practice this means that evidence must be held substantiating any claims made in advertising for

[1] Health and nutrition claims in food advertising in Northern Ireland must follow the NHCR as it applies in the EU.

CBD products which are not regulated by the UK NHCR.

Advertising for hemp based foods must also comply with the CPRs and UK NHCRs.

Cosmetics

Claims for cosmetics must not mislead and efficacy claim must be backed up with evidence. Presenting a cosmetic as a medicines could lead to enforcement action from the MHRA.

Health claims are permitted in relation to cosmetics but care must be taken not to present the cosmetic as having medicinal qualities. This means claims that the product treat or prevent and disease or adverse conditions are not permitted. However cosmetic claims are. For example, a claim that a cosmetics could "alleviate stress" would be viewed as a medicinal claim but a claim such as "use as part of your relaxing bedtime routine" is likely to be acceptable.

The CAP Code, which includes advertising in social media and on advertiser's own website has specific restrictions on cosmetics advertising. For example, advertising should not refer to the relief of symptoms or the superficial signs of ageing unless evidence is held and unqualified claims such as "cure" or "rejuvenation" should not be used. Claims about the action that a cosmetic has on or in the skin should distinguish between the composition of the product and the benefits achieved through its application, such as massage. Advertising should not refer to the prevention, delaying or masking of premature ageing in anything other than in temporary terms.

Edibles, Topicals, and More

Cannabis extracts are available in various forms in the UK. The legality and availability of cannabis products varies depending on the level of tetrahydrocannabinol ('THC') contained within them.

High THC / Non-medicinal use cannabis products

As set out above the starting point is that cannabis is a Class B controlled drug under Part II, Schedule 2, of MDR 2001 and designated 2015 Order.

As such, it is unlawful to possess, supply, produce, import or export this drug except under a Home Office licence.

Cannabis-based products for medicinal use ('CBPM')

The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018 amended the MDR 2001 such that certain cannabis-based products are authorised for medicinal use ('CBPM'). CBPM is a defined category of cannabis, cannabis resin, cannabinol and cannabinol derivatives, which are listed in Schedule 2 to the MDR 2001 and removed from designation under the 2015 Order.

There are three broad requirements that a CBPM product is required to satisfy:

- The product is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative;
- it is produced for medicinal use in humans; and
- is a medicinal product or a substance for use as an ingredient of, or in the production of, a medicinal product.

Whilst, in principle, there is no restriction on what CBPM may be prescribed for, the NHS acknowledges that, currently, it is only likely to be prescribed for the following conditions and only where other treatments are not available or have not helped:

- children and adults with rare, severe forms of epilepsy
- adults with vomiting or nausea caused by chemotherapy
- people with muscle stiffness and spasms caused by multiple sclerosis (MS)

In the UK, prescribing cannabis-based products for medicinal use is restricted to only those clinicians listed on the Specialist Register of the General Medical Council.

Low THC industrial hemp and use of non-controlled parts of the cannabis plant

A Home Office licence may be issued for the cultivation of cannabis plants with a low THC content in order to obtain hemp seeds. Licences are limited to use of non-controlled parts of the cannabis plant only, i.e. seeds and fibre.

Hemp seeds are cold-pressed to produce hemp oil, which contains a mix of nutrients, proteins and fats. It can be used in food supplements, cooking oils and body care products.

CBD-based cosmetics

CBD extract is becoming increasingly popular in the realm of wellness and beauty, and is used in a range of products including facial oils, moisturisers, make up, candles and even perfume.

Pursuant to Regulation (EU) No 1223/2009 on Cosmetic Products and the Single Convention on Narcotic Drugs 1961, only CBD ingredients that: (i) have not been sourced from the flowering or fruiting tops of the cannabis plant, and (ii) synthetically produced CBD, are permitted in the UK and EU as an ingredient in cosmetic products.

Pursuant to Annex 1 of the Regulation, CBD cosmetics must be subject to a safety test. In the UK, this entails an assessment by a safety assessor from the Cosmetic, Toiletry and Perfumery Association (CTPA), a UK industry body.

In April 2019, the CPTA reiterated the following information on CBD in cosmetics in a paper, *The Legal Status of Cannabis and Cannabis Extracts in Finished Cosmetics in the UK:*

Pure synthetic CBD and pure plant-based CBD are not controlled drugs under MDA 1971 and MDR 2001; and

If the following criteria are met, plant derived CBD may be used in finished cosmetic products:

- the CBD must not be derived from the flowering or fruiting tops of the plant or the whole plant where the flowering or fruiting top remains intact for processing (including 'hemp' varieties); and
- the CBD must be in pure form and not contain any controlled substances such as specific controlled cannabinoids; or
- the characteristics and use of the CBD (and any impurities) are such that all three limbs of the exempt product definition in the 2001 Regulations are met.

In addition, the CPTA clarified that seeds, and any extracts or oil from the seeds, (after separation from the rest of the plant) can be used in finished cosmetic products in the UK provided their use and the finished product are safe. The use of extracts from leaves in a finished cosmetic product is also not prohibited, providing they are not accompanied by the flowering tops.

In February 2021, following a ruling from the European Court of Justice, the European Commission updated the Cosmetic Ingredients (CosIng) Database, an EU list of ingredients and substances that can be included in cosmetic products, to include natural hemp-derived CBD.

CBD as food and tinctures

In recent years there has been an upsurge in food and drink products that are dominant in CBD, and CBD extracts contained in food or food supplements are now widely available in shops, cafés and for sale online. Products include oils, drops or tinctures, gel capsules, sweets and confectionery, bread and other bakery products and hot and cold drinks.

In January 2019, CBD extract and isolate products were allocated 'novel food' status on the basis that there is insufficient evidence to show a history of consumption in the EU before May 1997. Notably, hemp and hemp products are not deemed to be novel foods because there is evidence of their widespread consumption prior to this date.

Due to this allocation, food business are required to apply for authorisation of their CBD products to be placed on the GB market. Once a CBD product is authorised, the authorisation applies to that product only and the business is required to use the exact same production methods as described within the authorisation.

In England and Wales, the deadline for food businesses to submit novel food authorisation applications was 31 March 2021. Following this date, only products that were on the market on 13 February 2020 and for which the FSA had received an application that was subsequently validated are allowed to remain on the market.

The FSAhas advised that businesses may continue to sell existing CBD products whilst they await the outcome of an application, provided that the products are not incorrectly labelled, are not unsafe, and do not contain substances that fall under drugs legislation. No new CBD extracts or isolates, including new brands, are permitted to be sold until they have the necessary authorisation.

To date, no CBD products have been authorised to be placed on the GB market.

In addition to the novel food authorisation process, CBD food and food supplements are subject to standard food laws.

Cannabis Accessories

There are no specific regulations relating to the use of cannabis/CBD accessories and general product liability/consumer protection laws apply. Although many of the accessories used to inhale CBD are the same as those used to inhale nicotine, if a specific product is not intended for use with nicotine there is no requirement for it to comply with the Tobacco and Related Products Regulations 2016.

Otherwise, the regulation of CBD accessories will depend upon how the product is intended to be used and under what category it is classed.

Importation

As set out above, non-medicinal, high THC products are controlled drugs and it is therefore unlawful to import them, except under a Home Office licence.

Cannabis-based medicinal products for use in humans ("CBMP") are not designated under the 2015 Order, but the import of these products is closely regulated. In addition to a Home Office licence, importers are required to hold either an MHRA Wholesale Dealer's Licence or a Manufacturer's (Specials) Licence, depending on whether the product is being imported from an EEA or non-EEA country. The importer is also required to provide the MHRA with various declarations and certificates in respect of the composition and source of the product, and comply with the MHRA's detailed record-keeping requirements.

In March 2020, the Department of Health and Social Care and the Home Office announced a slight relaxation in import restrictions to try to overcome delays to patients.

CBD as an isolated substance, in its pure form, is not a controlled drug under the MDA 1971 and MDR 2001, and may be imported without a licence. However, if a CBD product is detected to contain more than 0.01% THC (or other cannabinoid), even unintentionally, the product would be deemed to be a controlled substance.

On the basis that it is extremely difficult to isolate pure CBD, and many products either do not fully disclose their contents, or do not undergo sufficient analysis to determine their content accurately and consistently, the Home Office concedes to taking a cautious approach. That is, that a CBD product is highly likely to be controlled under the MDA 1971 / MDR 2001 due to the likelihood of its other cannabinoid content.

Additional import requirements apply to CBD products depending on their product category. For example, CBD food and drink products would be subject to specific import requirements regarding composition, labelling etc.

Future Challenges

The Mayor of London, Sadiq Khan, has indicated that he will launch a review to examine the feasibility of decriminalising cannabis, in a similar approach to that taken by Canada and parts of the US. The likelihood of legislative change has been met with scepticism, with critics pointing to the reluctance of the Government and the medical profession to give meaningful backing to CBMP, despite it being authorised for use in late 2018. Overcoming the stigma of a drug that has been illegal in the UK for so long will be difficult and there are staunch advocates both for and against its legalisation.

With regard to CBD food products, the time and costs required to obtain novel food authorisation will continue to be a challenge for food businesses. Savills UK notes the number of CBD oil users doubled from 125,000 to 250,000 between 2017 and 2018 and, based on current figures, the UK market for CBD is expected to be worth £1 billion by 2025.

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UNITED STATES

Suzan Onel / Daniel Logan

Chapter on U.S. Law (Kleinfeld, Kaplan & Becker, LLP)[1]

The Regulation of Hemp, Cannabis, and CBD in the United States

The legal status of cannabis and its derivatives in the United States is complex because of the tension between federal and state laws. The situation is further complicated by the varying legal definitions and industry and consumer confusion as to what constitutes marijuana, hemp, cannabidiol (CBD), full-spectrum hemp extract, broad-spectrum hemp extract, and cannabis derivatives and products. Layered onto this ever-shifting prism are the differing legal frameworks that apply to conventional food products, dietary supplements, consumer products, drug products, and controlled substances.

Because both federal and state laws remain in flux, this chapter is intended as a high-level primer that provides an overview as to how the federal laws and enforcement are evolving in relation to hemp, cannabis, and CBD when intended for use in food and dietary supplements. The focus of this chapter will be on the U.S. Food and Drug Administration (FDA), although we will briefly discuss other federal agencies and touch on state activity. A detailed discussion of the use of cannabis-related substances in prescription and over-the-counter drug products is outside the scope of this chapter, as is the medical and recreational use of marijuana[2] (the marketing of which is illegal under federal law but permitted by some states), because these topics could be individual chapters on their own.

I. Background on the Current State of Cannabis Regulation in the United States

The regulatory authority for cannabis and cannabis products primarily rests with three federal agencies within the United States government: the Drug Enforcement Administration (DEA); the U.S. Department of Agriculture (USDA); and the FDA.

A. The Drug Enforcement Administration (DEA)

The DEA is the agency charged with controlling the availability of various substances,

[1] *For questions, please contact T. Daniel Logan, Suzan Onel, Daniel Dwyer, or Will Woodlee at Kleinfeld, Kaplan & Becker, LLP. Research and citations are current as of September 2021.*

[2] We note that, even if a state has legalized medical or recreational marijuana, such action has no effect on federal law. *See, e.g.*,Congressional Research Service, State Marijuana "Legalization" and Federal Drug Law: A Brief Overview for Congress at 2 (May 29, 2020), https://crsreports.congress.gov/product/pdf/LSB/LSB10482/2.

including medical and illicit drugs. It enforces the Controlled Substances Act (CSA), under which substances are sorted into enumerated "schedules" by statute or DEA regulation, with differing restrictions on substances in each schedule. Note that individuals and entities manufacturing, distributing, or possessing controlled substances in violation of the CSA may be subject to substantial criminal penalties, including incarceration.

Under the CSA, "any quantity" of "marihuana" (or marijuana) and its derivatives, as well as tetrahydrocannabinol (THC), are deemed to be Schedule I controlled substances.[3]

Prior to legislative changes in 2018, "Marihuana" (or marijuana) was defined as:

… all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

21 U.S.C. § 802(16) (2018).

This definition was altered with the enactment of the Agricultural Improvement Act of 2018 (commonly known as the 2018 Farm Bill),[4] which explicitly removed "hemp" from the definition of "marijuana." It also removed tetrahydrocannabinols in "hemp" from the Schedule I listing for THC.[5] The amended definition of "hemp" is as follows:

The term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

Agricultural Marketing Act of 1946, § 297A (as amended by the 2018 Farm Bill), 7 U.S.C. § 1639*o*(1).

Thus, the 2018 Farm Bill differentiates between varieties of cannabis based on the level of delta-9 THC in the plant or product.[6] While the 2018 Farm Bill removes "hemp" from the CSA definition of "marihuana" based on low levels of delta-9 THC, cannabis plants, derivatives, or products containing delta-9 THC in amounts more than 0.3% by dry weight are still "marihuana" and subject to stringent control under the CSA.

Following the 2018 Farm Bill, the DEA issued a rulemaking to conform its regulations (in particular, definitions of "tetrahydrocannabinols" and "marijuana extract") with the statutory changes made by the 2018 Farm Bill. In that rulemaking, the agency explained that "[i]n order to meet the…definition of hemp, and thus qualify for the exception in the definition of marihuana, a cannabis-derived product must itself contain 0.3% or less [delta-9] THC on a dry weight basis…[i]t is not enough that a product is labeled

[3] 21 C.F.R. § 1308.11(d)(23) ("marihuana"), (31) ("tetrahydrocannabinols").

[4] Pub. L. No. 115-334, 132 Stat. 4490, 5018 (Dec. 20, 2018).

[5] *Id.*

[6] Cannabis typically contains various isomers of THC; delta-9 is the isomer of THC that is the primary psychoactive component of cannabis. Establishment of a Domestic Hemp Production Program, 86 Fed. Reg. 5596, 5614 (Jan. 19, 2021) (codified at 7 C.F.R. Part 990). Except where specified, when used in this chapter, THC is intended to mean delta-9 THC.

or advertised as "hemp."[7] It further explained that "a cannabis derivative, extract, or product that exceeds the 0.3% [delta -9] THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less [delta-9] THC on a dry weight basis."[8]

B. The U.S. Department of Agriculture (USDA)

Following the enactment of the 2018 Farm Bill, cannabis plants meeting the definition of "hemp" may be grown, processed, transported, and sold; the cultivation of such plants falls under the ambit of the USDA.

1. *Domestic Hemp Growth*

Domestic growth and processing of hemp is regulated by the USDA and the individual states where such activities are taking place. Initially, in 2014, legislation permitted "State departments of agriculture and institutions of higher learning…[to] produce hemp as part of a pilot program for research purposes."[9] The 2018 Farm Bill, codified at 7 U.S.C. § 1639o *et seq.*, expanded this authorization to broadly permit the growth and production of hemp as an agricultural crop. The statute specifies that the primary regulatory authority for overseeing such activities may be either by States, Indian Tribes, or the USDA.[10]

A state or Indian Tribe that wants to assert such authority must submit a hemp production plan to the USDA; once such plan is approved, cultivation in the state can occur under the parameters set forth in the plan subject to auditing by the USDA.[11] As of July 2021, 24 states have USDA-approved hemp production plans.[12] For states where hemp production is not covered by an approved plan, USDA has issued regulations setting forth its own plan under which hemp may be legally grown.[13] The requirements and controls on growth of hemp under either a state/tribal plan or the USDA plan are numerous and more stringent than those for other crops and include sampling and testing procedures.

2. *Imported Hemp (Grown or Produced Outside of the United States.)*

Hemp may be imported into the United States, but it is subject to specific requirements. For example, viable hemp seed must be accompanied by a phytosanitary certificate to verify the origin of the seed and confirm that no plant pests are detectable. If originating in Canada, viable hemp seed must be accompanied by a Federal Seed Analysis Certificate.[14]

Imported hemp is not subject to the controls imposed on domestic hemp cultivation by USDA and state/tribal rules (such as specific sampling and testing procedures).

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[7] Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639, 51,641 (Aug. 21, 2020).

[8] *Id.*

[9] Establishment of a Domestic Hemp Production Program, 84 Fed. Reg. 58,522, 58,5223 (Oct. 31, 2019) (citing the Agricultural Act of 2014 (2014 Farm Bill), Pub. L. No. 113-79).

[10] 7 U.S.C. §§ 1639p, 1639q.

[11] 7 U.S.C. § 1639p.

[12] USDA.gov, Status of State and Tribal Hemp Production Plans for USDA Approval, https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review(accessed July 23, 2021).

[13] 7 U.S.C. § 1639q; Establishment of a Domestic Hemp Production Program, 86 Fed. Reg. 5596.

[14] 84 Fed. Reg. at 58,522; *see also* CBP.gov, Importing hemp seeds into the U.S. (Sep. 27, 2019), https://help.cbp.gov/s/article/Article-1751?language=en_US.

To date, no specific guidance has been issued by the DEA, USDA, or FDA regarding importation of hemp-containing or hemp-derived products.[15]

C) The Food and Drug Administration (FDA)

While the 2018 Farm Bill removes hemp from the ambit of the CSA, it expressly preserves the FDA's authorities under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act (PHSA), including its authority to issue regulations and guidelines that "relate to the production of hemp" under the foregoing statutes.[16]

The FDA has stated that it "treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products - meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance…regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill."[17] Accordingly, products falling under the FDA's regulatory purview must be broadly compliant with the requirements for the relevant category of product (e.g., food, dietary supplement, drug, etc.) before such products may be distributed or sold in interstate commerce.

1. *Foods*

Under the FFDCA, "food" is defined as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[18]

The FFDCA, at 21 U.S.C. § 331(ll) prohibits:

The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved [by the FDA], a biological product licensed [by the FDA], or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless –

(1) such drug or such biological product was marketed in food before any approval of the drug…before licensure of the biological product…and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) [The FDA], in [it]s discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food…[19]

This statutory provision, often called the "prior drug exclusion," prohibits the distribution or sale of food (including animal foods and feeds) containing the active ingredient in an approved drug product or a drug for which "substantial clinical investigations" have been undertaken and where the existence of such investigations has been made public.

The FDA has concluded that Section 331(ll) prohibits THC and CBD from being added to

[15]*See* FDA.gov, FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) (Jan. 1, 2021), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#importexport ("Can I import or export cannabis-containing or cannabis-derived products?").

[16]7 U.S.C. § 1639(c).

[17]FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[18]21 U.S.C. § 321(f).

[19]21 U.S.C. § 331(ll).

foods. The prohibition on the use of THC in food is based on the use of THC (dronabinol) as the active ingredient in two approved drug products: Marinol capsules (and generics) and Syndros oral solution.[20] Similarly, the prohibition on the use of CBD in food is based on its use as the active ingredient in Epidiolex, an approved drug.[21] The FDA has also cited as a basis for the exclusion of both THC and CBD the existence of substantial clinical investigations that had been made public, highlighting, for example, a press release regarding clinical trials for Sativex.[22]

The prior drug exclusion provides two relevant exceptions. First, the prohibition does not apply if the active ingredient was marketed in food *before* a drug was approved or before substantial clinical investigations were instituted. The FDA has repeatedly asserted that, based on the available evidence, neither THC nor CBD qualifies under this exception.[23] Second, the statute permits the FDA to issue a regulation permitting the use of an ingredient prohibited by the prior drug exclusion. To date, the FDA has not initiated rulemaking to promulgate a regulation allowing the use of THC or CBD in food. Notably, the FDA has *never* issued a regulation under this provision for *any* substance.[24] While the prior drug exclusion does not prohibit "[i]ngredients that are derived from parts of the cannabis plant that do not contain THC or CBD" from being added to food,[25] other cannabis derivatives may be prohibited from food use in the future if they are the subject of "substantial clinical trials" before they are legally marketed in food products. Furthermore, to the extent that the prior drug exclusion does not apply, one must still comply with the other provisions of the FFDCA, which could pose challenges to lawfully marketing foods containing cannabis or hemp.

For example, by statute, all ingredients added to food must either be approved food additives or "generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use"[26] (or otherwise exempt from the definition of "food additive"). Foods containing an unsafe food additive are adulterated and may not be distributed or sold.[27]

Food additives are approved via submission of a food additive petition supported by scientific evidence that the substance is safe under its conditions of intended use; the FDA may approve a petition and issue a regulation if it determines that there is reasonable certainty of no harm to consumers when an additive is used as proposed.[28] To date, no food additive petitions have been submitted or approved for cannabis or cannabis-derived ingredients. Interestingly, the FDA has not said that it would not consider or approve a food additive petition for cannabis-derived substances (other than THC or

[20] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[21] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15; FDA.gov, FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy (Jun. 25, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.

[22] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[23] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[24] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[25] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[26] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15; 21 U.S.C. § 321(s); 21 U.S.C. § 348.

[27] 21 U.S.C. § 342(a)(2)(C); 21 U.S.C. § 348(a).

[28] FDA.gov, Overview of Food Ingredients, Additives & Colors (revised April 2010), https://www.fda.gov/food/food-ingredients-packaging/overview-food-ingredients-additives-colors; 21 U.S.C. § 348(c).

CBD) in the future, and thus it has not closed out this potential pathway.[29]

Because no cannabis or cannabis-derived ingredients are currently approved food additives, the other common way to lawfully enter the market as a food ingredient is for the ingredient to be determined to be GRAS through scientific procedures (or, for substances used in food prior to 1958, through experience based on common use in food).[30] The FDA has established a GRAS notification process that allows individuals to voluntarily inform the agency that they consider a substance as GRAS under the conditions of its intended use in food.[31] While the FDA will not "approve" or "deny" such submissions, the agency may respond that it has "no questions" about a submission which indicates that, "[b]ased on the information provided by the notifier, as well as other information available to FDA, the Agency has no questions at this time regarding the notifier's conclusion that the notified substance is GRAS under the conditions of its intended use…[;] [h]owever, the Agency has not affirmed the GRAS status of the notified substance under the conditions of its intended use…"[32] GRAS notifications, including underlying data and information, and FDA responses, are published on the FDA's website and may be relied on by other entities.[33]

The FDA's notification process is not mandatory; companies may elect to market a food substance on the basis of an internal conclusion (also known as a self-affirmation) that a substance is GRAS. However, the FDA has emphasized that it is "[f]undamental to *all* conclusions of GRAS status … that general recognition of safety requires *common knowledge* throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use."[34] Moreover, this general recognition of safety must be based on "the application of *generally available and accepted* scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles."[35] Accordingly, entities electing to self-affirm an ingredient's GRAS status must base that determination on publicly available safety data and information and risk FDA enforcement should it disagree with the company's internal assessment.

In 2018, the FDA evaluated GRAS notifications for hulled hemp seed, hemp seed protein, powder, and hemp seed oil.[36] The FDA had "no questions" about the submitter's conclusions that the use of the aforementioned hemp seed products were safe for the intended use as described and concluded that "these products can be legally marketed in human foods for the uses described in the notices."[37] It further explained that "[t]he

[29] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[30] Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,970 (Aug. 17, 2016); 21 C.F.R. § 170.30(a).

[31] 21 C.F.R. Part 170, Subpart E. GRAS ingredients are also listed by way of example in 21 C.F.R. Part 182 and GRAS ingredients affirmed by petition appear at 21 C.F.R. Part 184.

[32] 81 Fed. Reg. at 55,015.

[33] 21 C.F.R. § 170.275; FDA.gov, GRAS Notices (last updated Jul. 21, 2021), https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices.

[34] Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,970 (Aug. 17, 2016) (emphasis added); 21 C.F.R. § 170.30(a).

[35] 81 Fed. Reg. at 54,970(emphasis added); 21 C.F.R. § 170.30(b).

[36] FDA.gov, FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food (Dec. 20, 2018), https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food.

seeds of the plant do not naturally contain THC or CBD…[;] [t]he hemp seed-derived ingredients that are the subject of these GRAS notices contain only trace amounts of THC and CBD, which the seeds may pick up during harvesting and processing when they are in contact with other parts of the plant…[;] [c]onsumption of these hemp seed-derived ingredients is not capable of making consumers 'high.'"[38]

Other entities can now rely on these GRAS notifications to support their use of the notified ingredients in the identified foods, including as a source of "protein, carbohydrates, oil, and other nutrients to beverages (juices, smoothies, protein drinks, plant-based alternatives to dairy products), soups, dips, spreads, sauces, dressings, plant-based alternatives to meat products, desserts, baked goods, cereals, snacks and nutrition bars."[39]

While it may be possible for other cannabis ingredients and derivatives to be used in food products on the basis of an internal GRAS self-affirmation or a GRAS notification, in reality such a determination could be difficult given the dearth of publicly available research regarding the safety of cannabis and hemp-derived substances in foods. Additionally, such an undertaking is further complicated for CBD by the fact that the FDA has announced that, "[b]ased on the lack of scientific information supporting the safety of CBD in food, … it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food."[40]

2. *Dietary Supplements*

The FFDCA's definition of "dietary supplement" broadly includes "a product … intended to supplement the [human] diet that bears or contains one more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; or (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake." A dietary supplement must be "intended for ingestion," but cannot be represented "for use as a conventional food or as a sole item of a meal or the diet…."[41]

Dietary supplements are deemed to be foods within the meaning of the FFDCA for most purposes.[42] While "dietary ingredients" used in a dietary supplement are exempt from the food additive definition,[43] they must not adulterate the supplement.[44] In contrast, all non-dietary ingredients (e.g., excipients, fillers, stabilizers, binders) must be "used in accordance with a food additive regulation or be GRAS for their intended use (unless they qualify for another exception to the food additive definition)."[45]

Similar to the prior drug exclusion described above, the definition of "dietary supplement"

[37] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[38] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[39] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[40] FDA.gov, FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns (Nov. 25, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details.

[41] 21 U.S.C. § 321(ff)(1),(2).

[42] 21 U.S.C. § 321(ff).

[43] 21 U.S.C. § 321(s)(6).

[44] 21 U.S.C. § 342(f).

[45] Guidance for Industry - Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements at 5 (January 2014), https://www.fda.gov/media/87680/download.

under the FFDCA excludes:

[A]n article that is approved as a new drug…, certified as an antibiotic…, or licensed as a biologic…, or… an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the [FDA], in the [it]s discretion, has issued a regulation, after notice and comment, finding that the article would be lawful…[46]

The above provision additionally encompasses products that have been "authorized for investigation as a new drug," meaning those products that are the subject of Investigational New Drug applications (INDs), are excluded from the dietary supplement definition.[47]

Based on the same rationale for prohibiting the use of THC and CBD in foods, the FDA "has concluded that THC and CBD products are excluded from the dietary supplement definition."[48] While this provision provides an exception for substances marketed as dietary supplements or conventional foods prior to the substance's approval as a drug or before authorization of an IND, the FDA has "concluded that this is not the case for THC or CBD."[49] Similarly, the FDA could promulgate a regulation finding that THC or CBD would be lawful for use in dietary supplements in its discretion or in response to an outside petition, but, to date, it has not done so.[50] In fact, several industry groups have filed citizen petitions urging the agency to establish a regulatory pathway to market dietary supplements containing hemp-derived CBD.[51] To date, the FDA has not issued a final response.

In order to market a dietary supplement containing a "new dietary ingredient" (NDI), a manufacturer or distributor must submit a New Dietary Ingredient Notification (NDIN) to the FDA at least 75 days prior.[193] A dietary ingredient is "new" if it was not "marketed in the United States before October 15, 1994."[53] The NDIN must "include information demonstrating that a dietary supplement containing the new dietary ingredient will

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[46] 21 U.S.C. § 321(ff)(3)(B).

[47] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15 ("FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect…[u]nder FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.").

[48] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[49] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15.

[50] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15("When a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act, the exclusion applies unless FDA, in the agency's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Act…[t]o date, no such regulation has been issued for any substance.").

[51] Citizen Petition from Council for Responsible Nutrition, "Citizen Petition Requesting FDA Establish a Regulatory Pathway to Legally Market Dietary Supplements Containing Hemp-Derived Cannabidiol (CBD)" (Jun. 16, 2020), *available at https://www.regulations.gov/document/FDA-2020-P-1582-0001*; Citizen Petition from Consumer Healthcare Products Association, "A Citizen Petition Requesting FDA Establish a Regulatory Pathway to Legally Market Dietary Supplements Containing Cannabidiol (CBD) by Issuing a Regulation Finding that the Article, CBD, is Lawful" (Nov. 14, 2019), *available athttps://www.regulations.gov/document/FDA-2019-P-5394-0001.*

19321 U.S.C. § 350b(a).

[53] 21 U.S.C. § 350b(d).

reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling."[54] Because there is no authoritative list of non-"new" dietary ingredients, manufacturers and distributors bear the burden of determining if a dietary ingredient is "new" and, if not, "documenting either that a dietary supplement that contained the dietary ingredient was marketed before October 15, 1994, or that the dietary ingredient was marketed for use in dietary supplements before that date."[55] Notably, an NDIN is not required where the "dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered."[56] Similar to GRAS notifications, the FDA does not approve or deny NDINs, but instead responds by issuing a letter that acknowledges the submission and either raises no objections or raises objections based on safety concerns or other regulatory issues.[57] "A dietary supplement is adulterated if it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury."[58]

The FDA has objected to NDINs filed for hemp-derived CBD, stating that such products are excluded from the dietary supplement definition under 21 U.S.C. § 321(ff)(3)(B)(i).[59] More recently, the FDA has also objected to NDINs for "full spectrum" hemp extracts.[60] The agency concluded that the products were "CBD products" because each contained "significant amounts of CBD per mL," "was designed to ensure consistent levels of CBD," and, when incorporated in a finished product, was marketed as a CBD product.[61] Similarly, the FDA has objected to an NDIN for a "full spectrum" hemp oil ingredient containing 25.5% CBD.[62]

X. Enforcement: Product Labeling and Advertising

Despite the risks associated with using THC and CBD in foods and dietary supplements, the U.S. market for CBD products in these forms is flourishing and predicted to grow.[63]

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[54] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15; 21 U.S.C. § 350b(b).

[55] FDA.gov, New Dietary Ingredients in Dietary Supplements - Background for Industry (Oct. 26, 2020), https://www.fda.gov/food/new-dietary-ingredients-ndi-notification-process/new-dietary-ingredients-dietary-supplements-background-industry.

[56] 21 U.S.C. § 350b(a)(1).

[57] Draft Guidance for Industry: New Dietary Ingredient Notifications and Related Issues at 54 (August 2016), https://www.fda.gov/media/99538/download.

[58] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), *supra* note 15; 21 U.S.C. § 342(f)(1)(B).

[59] Letter to Mark MacAuley (Aug. 29, 2019), *available at https://www.regulations.gov/document/FDA-2019-S-0023-0032.*

[60] In industry usage, "broad spectrum extract" is generally understood to comprise a "a resinoid hemp extract comprising a wide range of relatively hydrophobic hemp constituents, which has been processed to remove THC such that the THC has been found to be non-detectable by a compliant laboratory using a fit-for purpose method with a limit of detection of less than 0.01%," whereas "full spectrum hemp extract" is "a resinoid hemp extract comprising a wide range of relatively hydrophobic hemp constituents, including but not limited to any naturally-occurring THC, other cannabinoids, and terpenes, that has been processed without intentional removal of any compounds and has a final THC quantification of not greater than 0.3%." American Herbal Products Association, Hemp Lexicon at 11-12 (March 2021), https://www.ahpa.org/Portals/0/PDFs/HempLexicon/21_0325_AHPA_Hemp_Lexicon_Final.pdf.

[61] Letter to Tim Orr (Jul. 23, 2021), *available athttps://www.regulations.gov/document/FDA-2021-S-0023-0053;* Letter to Irwin Naturals (Jul. 23, 2021), *available at https://www.regulations.gov/document/FDA-2021-S-0023-0050.*

[62] Letter to Cannaworks, Inc. (Aug. 29, 2019), *available athttps://www.regulations.gov/document/FDA-2019-S-0023-0029.*

This is at least partially due to the FDA's limited enforcement activity regarding such products.

To date, the FDA's enforcement actions against CBD products have been risk-based. The FDA has announced that it "will continue to monitor the marketplace and take action as needed to protect the public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and that are being marketed for therapeutic uses for which they are not approved" such as claims that CBD can treat Alzheimer's, cancer, or AIDS.[64]

Although the FDA has stated that it "does not have a policy of enforcement discretion with respect to any CBD products,"[65] its selective enforcement appears to prioritize the targeting of those products bearing or marketed with curative or therapeutic claims on the label, labeling, or advertising. For example, between 2018-2020, the FDA issued 49 warning letters to companies marketing CBD containing products allegedly marketed with disease treatment/prevention claims.[66] More recently, in 2021, the FDA issued warning letters to two firms marketing CBD products based on alleged website claims that the products were "intended to mitigate, prevent, treat, diagnose, or cure COVID-19."[67] Such claims would render the products unapproved new drug products that may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA.[68] The FDA has issued warning letters to other entities on the basis of "pain relief," "anti-inflammatory," "anti-bacterial," "neuroprotective" claims as well as a litany of similar asserted claims.[69]

To the extent that the recipient company also markets food products containing CBD, the FDA has included language in its warning letters explaining that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food to which CBD has been added due to the application of the prior drug exclusion (21 U.S.C. § 331(ll)).[70] Moreover, the FDA has concluded that foods containing CBD are adulterated because

[63] Congressional Research Service, FDA Regulation of CBD Consumer Products and Considerations for Congress at 22 (Jan. 21, 2020), https://crsreports.congress.gov/product/pdf/R/R46189.

[64] *Id.*

[65] FDA.gov, "Remarks by Dr. Sharpless at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds," (May 31, 2019), https://www.fda.gov/news-events/speechesfda-officials/remarks-dr-sharpless-fda-public-hearing-scientific-data-and-information-about-products-containing.

[66] FDA.gov, Warning Letters and Test Results for Cannabidiol-Related Products (updated Aug. 5, 2021), https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products. A warning letter is an enforcement action that identifies violative conduct and provides the recipient 15 working days to respond. It is typically the agency's first action and could be followed by more stringent activity such as injunction and/or seizure.

[67] Warning Letter to Evolved Ayervedic Discoveries, Inc./BioCBDPlus (Feb. 11, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/evolved-ayurvedic-discoveries-incbiocbdplus-609772-02112021; Warning Letter to Cannafyl (Mar. 1, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cannafyl-611957-03012021.

[68] 21 U.S.C. § 321(p)(defining "new drug"); 21 U.S.C. § 355(a)("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.").

[69] Warning Letter to Honest Globe, Inc. (Mar. 15, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/honest-globe-inc-597177-03152021; Warning Letter to G & L Wellness, LLC (Dec. 22, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/g-l-wellness-llc-609572-12222020.

[70] *See, e.g.*, Warning Letter to MB Solutions/BioSpectrum CBD (Jul. 22, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mb-solutions-llcbiospectrum-cbd-610649-07222021.

CBD is an unapproved food additive.[71] The FDA's warning letters also cast doubt on the possibility that CBD could be determined to be GRAS, even putting aside the prior drug exclusion, due to safety issues. In one warning letter, the agency noted that it has "identified potential for liver injury from CBD and potentially harmful interactions with certain drugs" and how "studies in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels, and impair sexual behavior in males."[72]

The Federal Trade Commission (FTC), the federal regulatory agency responsible for monitoring advertising and promotional material to assure the content is truthful and non-misleading, has joined the FDA in issuing warning letters targeting CBD-containing products, ordering some of the recipient companies to cease making unsupported health claims and to pay monetary penalties.[73] Separately, the FTC has filed complaints against sellers of deceptively marketed CBD products.[74] For example, one complaint alleged that the respondent company made unsupported and false claims that its CBD oils, pain-relief cream, coffee, and gummies were "able to treat pain better than prescription medications such as OxyContin" and "scientifically proven to improve many serious health conditions—including chronic pain and hypertension—and provide neurological benefit—such as preventing age-related cognitive decline."[75] The FTC also filed a proposed administrative order that "prohibits the respondents from making certain prevention, treatment, or safety claims about dietary supplements, foods, and drugs, unless they have the human clinical testing to substantiate the claims" and required the company to pay $30,000 in fines.[76]

Separately, any product, including those containing hemp or cannabis derivatives, "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"[77] is at risk of being treated as a drug by the FDA. If such product is not generally recognized as safe and effective for the claimed usage, the product is a "new drug" that may not be distributed or sold absent prior approval from the FDA.[78] The FDA has issued warning letters to companies marketing hemp products (not advertised as containing CBD) for allegedly making such claims about hemp seed[79] and hemp.[80]

The FDA has been largely silent about those products that do not contain CBD and/or

[71] *Id.*

[72] *Id.*

[73] *See, e.g.*, Warning Letter to Rooted Apothecary, LLC (Oct. 10, 2019), https://www.ftc.gov/system/files/attachments/press-releases/ftc-fda-warn-florida-company-marketing-cbd-products-about-claims-related-treating-autism-adhd/cbd_warning_letter_10-22-19.pdf.

[74] FTC.gov, FTC Announces Crackdown on Deceptively Marketed CBD Products (Dec. 17, 2020), https://www.ftc.gov/news-events/press-releases/2020/12/ftc-announces-crackdown-deceptively-marketed-cbd-products.

[75] Complaint, In the Matter of EpicHouse, LLC et al., https://www.ftc.gov/system/files/documents/cases/2023094epichousecomplaint.pdf.

[76] Proposed Agreement Containing Consent Order, In the Matter of EpicHouse, LLC et al., https://www.ftc.gov/system/files/documents/cases/2023094epichouseorder.pdf.

[77] 21 U.S.C. § 321(g)(1).

[78] 21 U.S.C. §§ 321(p), 331(d), 355(a).

[79] Warning Letter to Aegeia Skin Care, LLC (Feb. 17, 2017), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aegeia-skin-care-llc-512736-02172017, ("Hemp Seed [an ingredient in the product]: "Other notable benefits: Helps heal skin lesions…Reduces inflammation of skin and joints[…]Contains pain-killing and anti-nausea properties").

[80] Warning Letter to Irie Star, LLC (Jul. 6, 2017), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/irie-star-llc-524242-07062017 ("Hemp [(an ingredient in your product)] … reduces redness and is recommended for the treatment of psoriasis and eczema.").

do not make drug claims.

II. Other Considerations for Foods and Dietary Supplements

A. Safety and GMPs

All food products, regardless of whether they contain a cannabinoid, are required to comply with the FDA's good manufacturing practice regulations (GMPs) at 21 C.F.R. Parts 110 and 117. These regulations impose requirements for, among other things: sanitation, equipment, grounds, and personnel practices; process controls intended to ensure that foods are not prepared, packed, or held under insanitary conditions; and hazard analysis and risk-based preventive controls.

Similarly, all dietary supplements, regardless of whether they contain a cannabinoid, are required to comply with the current Good Manufacturing Practices (cGMPs) regulations of 21 C.F.R. Part 111 (as well as certain Subparts of Part 117). Part 111 contains requirements for use of a quality system to ensure that finished dietary supplement products and, as applicable, components and in-process materials, meet established specifications for identity, purity, strength, and composition as well as for limits on potential adulterating contaminants.

Particularly when using botanical materials derived from hemp, compliance with either set of (c)GMPs may present unique challenges for identity and contaminant specification confirmation, both with respect to residual THC levels and with respect to pesticide, heavy metals, and, as applicable, solvent residues.

Separately, food and dietary supplements are also both subject to extensive labeling requirements[81] as well as reporting[82] and registration requirements.[83]

B. Claims and substantiation

The lawful marketing of any food or dietary supplement product also requires compliance with applicable laws and regulations relating to product claims. First and foremost, this would include avoidance of any disease claims, which could cause the FDA to object to the product as an unapproved new drug.

A food or dietary supplement may bear authorized health or qualified health claims, assuming compliance with the terms of any applicable authorizing regulation[84] or enforcement discretion letter,[85] respectively. Products may also bear authorized nutrient-content claims that comply with applicable FDA regulations. If "structure/ function" claims are used for dietary supplements, they must comply with the requirements of 21 C.F.R. § 101.93, including, for example, the requirements for use of a disclaimer ("This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.") in connection with the claims and notification of the FDA of use of the claim within 30 days of the marketing of the product.

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[81] *See generally* 21 C.F.R. Part 101.

[82] Food products are subject to the Reportable Food Registry ("RFR") requirements, 21 U.S.C. § 350f(d). Dietary supplements are required to report "serious adverse events" under 21 U.S.C. § 379aa-1.

[83] 21 C.F.R. Part 1, Subpart H.

[84] 21 C.F.R. Part 101, Subpart E.

[85] FDA.gov, Qualified Health Claims: Letters of Enforcement Discretion (updated Mar. 23, 2021), https://www.fda.gov/food/food-labeling-nutrition/qualified-health-claims-letters-enforcement-discretion.

Companies also must assure that all product claims are appropriately substantiated at the time of their dissemination. The nature of the substantiation would largely depend on the claim and circumstances. However, products with health-related claims will need to meet the FTC's "competent and reliable scientific evidence" substantiation standard (i.e., scientific evidence that has been evaluated by qualified experts, using methods that experts accept as accurate). As noted above, based on current FTC and FDA statements, care should be exercised in relation to any health-related claim for cannabinoids.

C. State issues

For hemp and products containing hemp derivatives such as CBD, the situation is complex at the state level.

Nearly all states have legalized the growth of hemp.[86] Further, states generally follow the FDA's position that those hemp derived ingredients that have been found to be GRAS may be added to foods and dietary supplements. However, despite the FDA's statements indicating that CBD may not be added to foods and that "CBD products" do not qualify as dietary supplements, numerous states expressly permit the sale of such products, including Maine,[87] Texas,[88] and West Virginia.[89] In contrast, other states, such as Georgia, have taken the position that the sale of products containing CBD intended for ingestion is prohibited.[90] And some states have modified their controlled substance laws to restrict delta-8 THC, including Nevada[91] and Florida.[92] Interestingly, the District of Columbia has not recognized "hemp" as a commodity,[93] and thus the sale of anything containing hemp could be subject to the jurisdiction's marijuana possession and transfer provisions.[94]

Beyond this, many states impose differing testing, packaging, labeling, and registration requirements. For instance, under California's Proposition 65 law, any product must bear a warning if that product would expose consumers to any amount of THC, even if the amount of THC in the product is less than 0.3% by weight.[95] The maddening patchwork of laws makes uniform compliance difficult – products that arguably may not be sold under federal law may arguably be sold under the laws of certain states, but not others.

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[86]Me. Rev. Stat. tit. 22, § 2158-A ("Notwithstanding any provision of law to the contrary, food, food additives or food products that contain hemp, including cannabidiol derived from hemp, are not considered to be adulterated under this subchapter based solely on the inclusion of hemp or cannabidiol derived from hemp.").

[87]Tex. Health & Safety Code Ann. § 443.201(a) ("A person may possess, transport, sell, or purchase a consumable hemp product processed or manufactured in compliance with this chapter.").

[88]W. Va. Code R. §61-30-2.14 ("'Hemp product' or 'Hemp commodity' means any product derived from, or made by, processing hemp plants or plant parts, that are prepared in a form available for commercial sale. This includes, but is not limited to: … Hemp edibles and drinks…").

[89]Georgia Department of Agriculture, CBD Oil Still Unlawful as a Food Additive in Georgia (May 10, 2019), http://agr.georgia.gov/cbd-oil-still-unlawful-as-a-food-additive-in-georgia.aspx.

[90]Nev. Rev. Stat. Ann. § 453.139 ("THC" means delta-9-tetrahydrocannabinol and any structural, optical or geometric isomer thereof, including, without limitation: …1. Delta-8-tetrahydrocannabinol…").

[91]Fla. Stat. Ann. § 893.03(1)(a)(190)(a) ("Tetrahydrocannabinols.--Any tetrahydrocannabinols naturally contained in a plant of the genus Cannabis, the synthetic equivalents of the substances contained in the plant or in the resinous extracts of the genus Cannabis, or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity, including, but not limited to … Delta 8 tetrahydrocannabinols.").

[92]D.C. Code Ann. § 48-901.02(3).

[93]D.C. Code Ann. § 48-904.01.

[94]P65warnings.ca.gov, THC (Δ⁹-Tetrahydrocannabinol or Delta-9-Tetrahydrocannabinol), https://www.p65warnings.ca.gov/fact-sheets/thc (last accessed Sept. 3, 2021); Cal. Health & Safety Code § 25249.6.

Further, even where ingestible products containing CBD or similar hemp extracts are legal for sale, states impose testing, labeling, packaging requirements that differ.

D. Consumer class action and product liability

Finally, cannabinoid-containing products could be the target of putative class-action lawsuits by consumers who allege that the products are misleadingly marketed because they are expressly or implicitly presented as lawful substances when they are not. Many suits brought on such basis have been stayed pending FDA regulatory action on hemp-derived ingestible products.[96] Plaintiffs could also challenge claims made for the products, especially if the claims are worded as drug claims that would be inconsistent with FDA requirements. Other risks include the possibility of products liability lawsuits, particularly if an injury arises from a defect caused by a lack of quality control (such as a failure to meet specifications for identity, strength, purity, and composition). Additionally, there is the risk of lawsuits due to the presence of THC above the 0.3% level.

[96] *See, e.g.*, Dasilva v. Infinite Prod. Co. LLC, No. CV 19-10148-DMG (EX), 2021 WL 900642 (C.D. Cal. Mar. 3, 2021); Colette v. CV Scis., Inc., No. 219CV10227VAPJEMX, 2020 WL 2739861 (C.D. Cal. May 22, 2020); Snyder v. Green Roads of Fla. LLC, 430 F. Supp. 3d 1297, 1308 (S.D. Fla. 2020).

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