LEGALINK

INTERNATIONAL BUT PERSONAL

CANNABIS REGULATION AND CANNABIS DERIVED PRODUCTS

INTRODUCTION

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

A QUICK PRIMER ON CANNABIS BASICS

Cannabis vs. Marijuana vs. Hemp

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

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

INTRODUCTION

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

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

THC vs. CBD

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

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

COLOMBIA

MTA – Muñoz Tamayo Asociados

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

The regulatory framework for the use of cannabis for medicinal and scientific purposes is established across a series of legal norms, as follows.

1. Legislative Act 02 of 2009

As indicated above, Legislative Act 02 of 2009, which modified article 49 of the Colombian Political Constitution, paved the way for the regulation of cannabis and cannabis derived products in Colombia, by allowing the medicinal use of cannabis for the first time. Pursuant to this Legislative Act "possession and consumption of narcotic or psychotropic substances is prohibited, unless prescribed by a doctor."

It is important to mention that the constitutional reform introduced by Legislative Act 02 of 2009 prohibited drug use without medical prescription, abolishing the so-called personal dose (dosis personal), meaning that the use of cannabis was only permitted with medical prescription. However, the above-mentioned constitutional reform did not impose any sanctions for the consumers of cannabis without a medical prescription.

2. Law 787 of 2016

As a result of the constitutional reform introduced by Legislative Act 02 of 2009, the Colombian Congress enacted Law 1787 of 2016, which aims to create a regulatory framework that allows safe and informed access to the medicinal and scientific use of cannabis and its derivatives or by-products in the Colombian national territory. Law 1787 establishes: (i) the authorities responsible for controlling the use of cannabis in Colombia; (ii) the system and method for calculating the fees charged by the competent authorities for the issuance of the various licences; and (iii) the penalties that might be imposed on licence holders that do not comply with the provisions of Law 1787, among other general provisions.

3. Decree 613 of 2017

Decree 613 of 2017 established the regulatory framework of Law 1787 in relation to the secured and informed access for the medical and scientific use of cannabis. In this sense, Decree 613 introduced definitions such as the difference between psychoactive and non-psychoactive cannabis (as mentioned, the latter has less than 1% THC in dry weight content) and regulates the different types of licences (and their modalities) that can be requested before the competent authorities to develop activities in relation to cannabis in Colombia, namely:

(i) Licence for the cultivation of psychoactive cannabis (Licencia de cultivo de cannabis psicoactivo).

(ii) Licence for the cultivation of non–psychoactive cannabis (Licencia de cultivo de cannabis no psicoactivo).

(iii) Licence for the manufacturing of cannabis derivatives or by-products (Licencia de fabricación de derivados de cannabis), and

(iv) Licence for the use of cannabis seeds for sowing or planting (Licencia de uso de semillas para siembra).

Decree 613 further makes it compulsory to comply with certain conditions and standards. For example, the licences for use of seeds and for cultivation of non-psychoactive cannabis require a description of the equipment and the areas of land to be used under the licence, as well as relevant safety protocols. Similarly, the licences for cultivation also require prior approval involving an inspection visit from the competent authority, and licences for cultivation of non-psychoactive cannabis require a manufacturing permit or a contract with the buyer of the relevant harvest, a description of the equipment and areas of land to be used thereunder, and a cultivation plan that covers all the years for which the licence is requested.

In turn, if the purpose of the application is scientific research, regardless of the type of licence, documentation is required accrediting the research project to be conducted by a university or an established company that proposes to engage in scientific research.

Decree 613 also regulates the allocation of quotas (cupos), that is, the maximum number of psychoactive cannabis plants each licence holder is allowed to grow. This norm established the Technical Group on Quotas (Grupo Técnico de Cupos (GTC)), whose function is to analyse, evaluate and monitor all matters related to the allocation of quotas in conformity with the Single Convention on Narcotic Drugs of 1961. The Technical Group on Quotas is also responsible for designing a guide to quantify the need for psychoactive cannabis and determine the quota that Colombia will register with the International Narcotics Control Board (INCB).

Finally, Decree 613 also regulates and establishes certain protective measures for small and medium-scale growers. It establishes the criteria to define small and medium-scale growers, as well as the need to design alternative mechanisms that will ensure effective access to the licensing system with a differentiated approach, which aims to protect applicants in indigenous communities or in minority groups. Additionally, as part of its social approach, Decree 613 obliges the holders of a licence to manufacture cannabis derivatives to source at least 10% of their assigned quota of cannabis from small or medium-scale growers who hold licences for the cultivation of cannabis. Furthermore, the decree gives smaller growers priority in the allocation of quotas and the advantage of being able to apply for a licence to grow cannabis for scientific purposes without the need to have a licence to manufacture derivatives, or links with someone who holds one.

Decree 613 was followed by a series of resolutions that aimed to strengthen the legal framework of cannabis for medicinal and scientific purposes, the most relevant of which are established below.

4. Resolution 579 of 2017

In relation to the small and medium national cannabis growers, producers and sellers, Resolution 579 of 2017 issued by the Ministry of Justice and Law establishes the criteria to define whether a person can be considered as a small or medium cannabis grower, producer or seller. Under said resolution, small and medium cannabis growers include not only growers but also medicinal cannabis producers and traders who, acting as individuals, cultivate the plant on a total area not exceeding half a hectare. The resolution also allows for licences to be awarded to associations (esquemas asociativos) of small and medium-scale growers.

5. Resolution 2891 of 2017

Resolution 2891 of 2017 issued by the Ministry of Health and Social Protection establishes the tariff schedule for the evaluation, monitoring and control of the manufacturing licences for cannabis derivates for medicinal and scientific use.

6. Resolution 2892 of 2017

The Ministry of Health and Social Protection issued Resolution 2892 of 2017 establishing the technical regulations related to licensing for the production and manufacturing of cannabis derivatives or by-products.

7. Decree 2106 of 2019

Finally, Decree 2106 of 2019 modified the provisions of Law 787 and unified the platforms and requirements demanded by environmental authorities for applications for environmental concessions, authorisations or licences. Additionally, pursuant to Decree 2106 of 2019, INVIMA is the competent authority for the issuance of licences for the manufacturing of cannabis derivatives or by-products (licencia de fabricación de derivados), which were formerly being issued by the Ministry of Health and Social Protection. Thus, all regulations which refer to the Ministry of Health and Social Protection as the authority responsible for issuing the above-mentioned licences should now be interpreted as referring to INVIMA, except for the provisions of Article 9 of Law 1787, concerning the establishment of the relevant fees.

The table below summarises the current regulatory framework for the use of cannabis and cannabis derivatives for medicinal and scientific purposes. It is important to note that the recreational use of cannabis in Colombia is prohibited.

Regulation	Comment
Legislative Act 02 of 2009	Legalises the use and consumption of cannabis with a doctor's prescription.
Law 1787 of 2016	Creates a regulatory framework that permits safe and informed access to cannabis and its derivatives
Decree 613 of 2017	Regulates Law 1787 of 2016, introduces definitions and conditions for obtaining the various types of licences.

Decree 631 of 2018	Introduces modifications and instructions concerning the source of seeds (fuente semillera)
Resolution 577 of 2017	Establishes technical regulations governing the assessment and monitoring of licences for the use of seeds for planting/sowing and licences for the cultivation of psychoactive and non-psychoactive cannabis plants.
Resolution 578 of 2017	Establishes the tariff schedule for the assessment and monitoring services that must be paid for by individuals and companies applying for licences.
Resolution 579 of 2017	Establishes criteria for defining small and medium-scale growers, producers and traders of medicinal cannabis in Colombia.
Resolution 2891 of 2017	Establishes the tariff schedule for assessment, monitoring and control services applicable to licences to manufacture cannabis derivatives for medicinal and scientific purposes.
Resolution 2892 of 2017	Establishes technical regulations governing the award of licences for the production and manufacture of cannabis derivatives.
Decree 2106 of 2019	Amends Law 1787 and aims to simplify applications and proceedings.

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

There are different challenges in allowing the medical and recreational use of cannabis and cannabinoids in Colombia. On one hand, as previously mentioned in this document, there are social, political, cultural and historic conditions of the Colombian society that must be overcome.

Colombia has been one of the epicentres of the "war on drugs" and, paradoxically, one of their major producers. This has created a complicated scenario that requires a shift in the approach towards cannabis and other cannabinoids, conceiving them as a medicinal product and a raw material with a high potential for the manufacturing of various products (such as paper, bricks and fuel, among others) and as an alternative to pharmaceuticals, rather than as an illicit and harmful drug.

In addition to the above social, political, cultural and historical challenge, the so-called "green gold" boom has led to other practical issues. For instance, there has been an

avalanche of requests and applications for licences, which has led to the authorisation processes taking longer than expected.

Furthermore, companies are facing challenges in obtaining the quality certification required for the industry. Indeed, manufacturers of products for human use or consumption must comply with a series of rules and procedures to guarantee the high quality standards that will prevent harm to consumers. These procedures are called Good Manufacturing Practices (GMP) and they are an essential condition for meeting the standards recommended by the agencies that control authorisation and licensing for the manufacture and sale of products such as food, drinks, dietary supplements, medicinal products, active pharmaceutical ingredients and medical devices.

Additionally, the industry has encountered significant difficulties with the financial sector. Indeed, difficulties in opening bank accounts, access to credit and monetising funds has been another obstacle in taking the medicinal cannabis business forward. To the extent that there are significant federal restrictions on the transfer of funds associated with the cannabis business, as well as the fact that some Colombian banks hold securities in the United States, where the trade and distribution of cannabis is still prohibited, they fear that the US Government could take reprisals, and this has brought several corporate investment initiatives to a halt.

Finally, there have been challenges faced by small and medium growers, who see the arrival of large corporations as a threat to their local businesses. The main obstacle that small and medium producers have faced comes from the legislation itself, as it appears to aim to create a pharmaceutical industry, which necessarily implies complying with certain production standards and protocols, and this in turn requires investing considerable sums that are unaffordable for small businesses wishing to compete on a level playing field.

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

Decree 613 establishes the different types of cannabis licences (and modalities) that may be requested by growers, producers and sellers in Colombia, as well as the obligations that each of the licence holders must fulfil.

With regards to such type of licences, article 2.8.11.2.1.2 of Decree 613 establishes the following licences, each of which has different modalities:

Licence	Modalities	Activities	Issuing Authority
Licence for the cultivation of psychoactive cannabis plants (Licencia de cultivo de cannabis psicoactivo).	• To produce seeds for planting • To produce buds/grain • To produce derivatives (Under this modality, the applicant must already have a licence for the manufacturing of cannabis derivatives or have it in process) • For scientific purposes • For storage • For final disposal	Cultivation of psychoactive cannabis that includes the sowing or planting, acquisition and production of seeds, storage, marketing, distribution and final disposal, as well as export and use for medical and scientific purposes	Ministry of Justice and Law
Licence for the cultivation of non–psychoactive cannabis (Licencia de cultivo de cannabis no psicoactivo)	• To produce seeds for planting • To produce buds/grain • To produce derivatives • For scientific purposes • For storage • For final disposal	Allows holders to carry out activities of cultivation of plants whose THC percentage is less than 1% in dry weight, which may include sowing, procurement and production of seeds; storage, marketing, distribution and final disposal of plants, as well as export and use for medical and scientific purposes.	Ministry of Justice and Law

Licence	Modalities	Activities	Issuing Authority
Licence for the manufacturing of cannabis derivatives or by-products (Licencia de fabricación de derivados de cannabis)	• Production of derivatives for use within Colombia • Production of derivatives for scientific research • Production of psychoactive cannabis derivatives • Manufacture of derivatives for export	For the processing of cannabis for medical and scientific purposes, which may include the manufacture, acquisition on any terms, import, export, storage, transport, marketing and distribution of psychoactive and non-psychoactive cannabis derivatives	INVIMA (formerly by the Ministry of Health and Social Protection)
Licence for the use of cannabis seeds for sowing or planting (Licencia de uso de semillas para siembra)	• For sale or supply • For scientific purposes	This licence may include acquisition on any title, import, storage, marketing, distribution, possession and final disposal, as well as export and use for medical and scientific purposes.	Ministry of Justice and Law

As mentioned above, the recreational use of cannabis in Colombia is prohibited.

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

INVIMA is the competent authority to issue licences for the manufacturing of cannabis derivatives or by-products. Before Decree 2106 of 2019, the competent authority was the Ministry of Health and Social Protection (Ministerio de Salud y Protección Social), through its Directorate of Drugs and Health Technologies (Dirección de Medicamentos y Tecnologías de la Salud). Once the licence has been issued, administrative and operational control of activities related to the handling of cannabis and its derivatives will be carried out through the National Narcotics Fund (Fondo Nacional de Estupefacientes), which is also the competent authority for the control of finished products derived from psychoactive cannabis (in which THC content is equal to or greater than 1% in dry weight).

On the other hand, the Ministry of Justice and Law, through its Directorate of Control and Inspection of Chemical Substances and Narcotics (Subdirección de Control y Fiscalización de Sustancias Químicas y Estupefacientes), is the competent authority for issuing licences for the use of seeds for sowing/planting and licences for the cultivation of psychoactive and non-psychoactive cannabis plants. It is also the entity in charge of the administrative and operational control over activities related to the management of seeds for sowing and the cultivation of psychoactive and non-psychoactive cannabis.

Finally, the Colombian Agricultural Institute (Instituto Colombiano Agropecuario (ICA)) is authority responsible for sanitary and phytosanitary matters applicable to products containing CBD.

AUTHORITY	ACTIVITY
National Institute of Food and Drug Surveillance – INVIMA	To issue the licence for the manufacturing of cannabis derivatives and to carry out control and evaluation visits.
Ministry of Justice and Law, through the Sub-directorate for the Control and Inspection of Chemical Substances and Narcotics	To issue the licence for the use of cannabis seeds for sowing and the licences for the cultivation of psychoactive and non-psychoactive cannabis plants and administrative and operative control of the activities related to the management of the seed for the planting and sowing of cannabis.
National Narcotics Fund	Administrative and operative control of activities related to the management of cannabis and its derivates and control and evaluation visits.
National Institute of Food and Drug Surveillance – INVIMA	Control of finished products from psychoactive cannabis, without prejudice to competence in sanitary and phytosanitary matters, once the licence is issued.
Colombian Agricultural Institute – ICA	
National Police	To support the authorities in the administrative and operational control, as well as in the visits that take place.

5. Currently is there any possibility to commercialise CBD products without a novel food approval or medicinal product marketing authorisation in Colombia?

Currently, there is no possibility of commercialising CBD products without novel food approval or medicinal product marketing authorisation in Colombia. According to national legislation, the commercialisation of CBD products requires the corresponding licences or registries before the authorised national entities.

Pursuant to article 85 of the Decree 2106 of 2019, the Licence for Manufacturing of Cannabis Derivatives or By-products (Licencia de Fabricacion de Derivados de Cannabis) is the authorisation granted by the INVIMA, through an administrative act, which allows the following modalities: import, export, production, manufacture, acquisition, storage, transport, marketing, distribution and use of cannabis derived products, as well as any products containing cannabis. This licence may be issued for one or more of the above-mentioned modalities according to the requirements and/or activities of the applicant.

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

The National Narcotics Fund is responsible for monitoring and controlling the content of cannabis in cannabis derived products. The licensees will have to carry out an analysis, by means of a valid analytical methodology, of the content of tetrahydrocannabinol (THC), cannabidiol (CBD) and cannabinol (CBN), in each property and lot, which will have to be registered before the National Narcotics Fund. Such methodology must comply with a protocol including the calibration curve, detection limit, quantification limit and all the analytical chemistry parameters. This measurement may also be made through the National Narcotics Fund. If necessary, the Ministry of Health and Social Protection may request changes or adjustments in the methodology in order to review comparable results.

Furthermore, the licensee must submit a bimonthly report regarding their production, within the first 10 days of the bimester, by means of the formats established for this purpose. The national entities have prepared the corresponding formats to submit the information and documentation for the compliance of the regulatory requirements.

In general terms, these formats specify information related to plantations, harvests, delivery of product to third parties, quantity of seeds at the end of the period, storage of seeds and losses in the crop, among others. If applicable, and in the event that the licensee has additional observations or comments, the corresponding documents must be specified and attached to the format.

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

Currently, the national regulation does not provide a limit for the purchase, sale, import or export of cannabis derived products.

However, the limitation set forth in the Colombian cannabis legislation refers only to the quotas that may be granted. Quotas are the maximum annual amount of (i) psychoactive cannabis plants that may be grown, or (ii) cannabis allowed to be acquired or received for cultivation, by those who have obtained the corresponding licences. This means that only those who aim to grow or cultivate psychoactive cannabis will have to apply for quotas.

The Sub-Directorate for the Control and Monitoring of Chemical and Narcotic Substances and the Directorate of Drugs and Health assign the quotas allocated by the Technical Group on Quotas, which in turn shall set the limits in accordance with the national quotas granted by the International Narcotics Control Board (INCB) (Junta Internacional de Fiscalización de Estupefacientes (JIFE)).

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