

January 19, 2021

MEXICO CANNABIS UPDATE

Mexico Issues Rules for Medical Cannabis Use

January 12, 2021 marked yet another historic milestone for Mexican cannabis as the secondary rules for medical cannabis in Mexico were published by the Secretary of Health (SSA) in the Federal Official Gazette. The rules, titled Rules for the Sanitary Control of the Production, Research and Use of Medical Cannabis and its Pharmacological Derivatives (*Reglamento en Materia de Control Sanitario para la Producción, Investigación y Uso Medicinal de la Cannabis y sus Derivados Farmacológicos*), and successively referred to as the “Rules”), come after more than three and a half years after the 2017 amendments that legalized such use.

These Rules are only intended for medical and research purposes and come separate from the ongoing legislative process for recreational marihuana and industrial hemp.

General Provisions

The stated purpose of the Rules is to establish the “...*regulation, control, promotion and sanitary oversight of raw material, molecular compounds, pharmacological derivatives and medications with production, scientific, industrial and medical purposes.*”

The contemplated research activities only include those for pharmacological and agronomic purposes. As for “industrial” use, the term is set with the connotation of production of molecular compounds, pharmacological derivatives and medications; not as industrial hemp in the broader sense that contemplates its multiple uses. This is different from the definition set in the general cannabis legalization bill approved by the Senate last November and sitting on the Chamber of Deputies for approval.

There are some definitions worth noting, some of which have generated feedback from industry advocates suggesting improvement, namely:



LEGAL

Corral, Arzola, Armendáriz & Máynez

- Cannabinoids: Defined as “organic compounds pertaining to the terpenophenolic group, which include CBD and THC” (which, by the way, are the only cannabinoids identified and defined in these rules).
- Cannabis: “Cannabis sativa, indica and americana or marihuana, its resin, preparations and seeds.”
- CBD: “Cannabidiol and its acid forms, cannabinoid compound that lacks psychoactive properties.”

The Federal Commission Against the Protection against Sanitary Risks (COFEPRIS) will oversee implementing and managing the traceability system which shall organize the use of specialized technical tools. This may appear strange to those expecting that it be the Secretary of Agriculture (or the tax revenue service, for that matter), who would normally have the best resources and knowledge to manage this area.

In addition to the SSA through COFEPRIS, the following government agencies will be involved in the application and enforcement of the Rules:

- National Service for Agro-food Sanitation, Innocuity and Quality (SENASICA): oversee and promote cannabis sanitation, as well as managing systems to prevent or reduce contamination at the primary production stage in accordance with the Mexican Law of Vegetal Sanitation;
- National Service for Seed Inspection and Qualification (SNICS): regulate the production of certified seeds, qualification of seeds and sale of cannabis seeds in accordance with the Federal Law for the Seed Production, Certification and Commerce;
- Secretary of Agriculture (SADER): involved in the review of permits for importation of seeds, through its various agencies that are under its jurisdictional and operative umbrella;
- COFEPRIS: sanitary oversight and control of scientific, industrial and medical use of cannabis in accordance with the General Health Law;
- Mexican Tax Revenue Service (SAT): verify compliance with applicable tax provisions, including but not limited to the import and export taxes, and customs procedures, in accordance with the Customs Law, the Health Law, among others; and
- Secretary of Economy (SE): intervene in the determination of applicable tariffs that shall be applied to the import and export of cannabis.

Generally speaking, the Rules insert the medical use and scientific research of cannabis into the Mexican health, sanitary and agricultural legal framework, depending on the stage in the value chain of a medical cannabis product. Thus, existing requirements and guidelines to carry out research in general for healthcare purposes, operate pharmacies or drug stores, register medical products, import a plant or register a seed, will be applicable as it pertains.

Each of the existing government agencies mentioned above are assigned with responsibilities that, depending on its nature, will now cover the respective stages of production, processing, preparation, importation or exportation, sale and prescription for the allowed uses. In other words, no new agencies are created, as opposed to the recreational cannabis legalization bill which currently contemplates the creation of a new institute for cannabis regulation and control.

Research

- A research protocol shall be authorized by COFEPRIS for those parties intending to carry out cannabis research. Existing secondary rules for health care research will be applicable, which for example, set forth the requirements and credentials that research professionals must meet.
- Research done on human beings shall not only follow applicable laws and regulations, but also “good clinical practices” adopted internationally, which are not clearly defined or identified.
- The SSA, through COFEPRIS who will issue research protocol authorizations, will lead coordination efforts to maintain a national cannabis research.

Production

- A permit shall be obtained from SENASICA for cultivation with either research or medicine production purposes. SENASICA will keep a National Registry of Cultivation Permits (*Registro Nacional de Permisos de Siembra*). The list of requirements is provided in the Rules and include an approved research protocol.
- Cultivation permits may be granted for **(a)** cultivation, growth and harvest; **(b)** health research; **(c)** production of molecular compounds, pharmacological derivatives and medication; or **(d)** production of SNICS-certified seed.



LEGAL

Corral, Arzola, Armendáriz & Máynez

- Cultivation activities shall be carried out in “confined sites” within “physical barriers” that limit contact with “people or environment”.
- The registration or production of qualified cannabis seeds may be requested into the National Catalogue of Vegetal Varietals (*Catalogo Nacional de Variedades Vegetales*), provided the requirements set forth in the Rules are met. Expert opinions may be sought in order to verify the varietal’s distinctiveness, homogeneity and stability.
- A varietal may be registered into a National Program for the Production of Certified Seeds (*Programa Nacional de Produccion de Semillas Calificadas*) by the SNICS. The list of requirements is provided in the Rules.

Medical Use

- Medical cannabis can only be prescribed by duly licensed medical, homeopathic and dentist professionals. Their prescriptions must carry a barcode to be obtained by COFEPRIS and the prescription books will be subject to strict control and patient information recording practices.
- International travel passengers (Mexican nationals or foreigners) who require cannabis medication use shall carry and present the special, barcode-bearing prescription with signature by the medical professional, or such be the case, the permit or authorization by the foreign nation’s authority.
- Pharmacies, drug stores and establishments that provide diagnosis and treatment services will be subject to strict compliance requirements, starting with those set for by the existing sanitary control and health care regulations.

Industrial Use

- As indicated above, cannabis raw material is defined as “...*cannabis seeds, seedlings, propagative vegetative material, stem, leaves or inflorescences, necessary for the production of molecular compounds, pharmacological derivatives or medication*”.
- Establishments who process, import, export or use raw material shall keep control books authorized by COFEPRIS and integrate a Custody and Safeguard Security System.
- Production facilities, processing laboratories or storage organizations who handle cannabis as raw material, molecular compounds or medication can only sell it to establishments that hold the corresponding sanitary licenses,



LEGAL

Corral, Arzola, Armendáriz & Máynez

such as hospitals, pharmacies and distributors, obtained in accordance with other applicable secondary regulations.

- Cannabis in homeopathic medications will only be allowed if presented diluted and dynamized.
- Cannabis (natural or synthetic) is not allowed in herbal remedies. This provision confirms that herbal remedies or supplements are not allowed under these Rules and will be left to the above-mentioned general legalization bill.

Import and Export of Raw Material and Medication

- Raw material, molecular compounds, pharmacological derivatives and medications can be imported. Establishments seeking to import cannabis as raw material shall prove to COFEPRIS that such material is legally allowed in the country of origin.
- On the other hand, only pharmacological derivatives and medications can be exported - not raw material.
- In order to obtain a permit for seed import with research and industrial purposes under the Rules, SADER will publish the mandatory phytosanitary requirements.
- The Rules provide in this corresponding section the detailed requirements and logistics that will apply to the importation process of molecular compounds, pharmacological derivatives and medications. The process includes prior notices to the port of entry customs office, sampling, import documents to be delivered, and storage facility requirements.
- For the importation of medication intended for personal use, COFEPRIS will be the agency with authority to issue the corresponding permit. Applicants will submit the current medical prescription that includes the medical professional's license number and details the product and quantity.

Import Authorizations

- SENASICA will issue the phytosanitary import certificates for botanic seed for cultivation, seedlings for cultivation and vegetative propagative material. Such certificates will be issued under guidelines aimed at preventing entry of plagues or other similar hazards.



LEGAL

Corral, Arzola, Armendáriz & Máynez

- Once raw material enters the country, it shall be mobilized to facilities where confined cultivation is allowed under strict custody and control responsibilities.

Establishments for Medical Attention

- Medical care services that result in the supply or prescription of cannabis medications can be provided in establishments that meet the corresponding requirements for operation.
- For purposes of this summary and consistent with the terminology used in the Rules, an “establishment” shall be deemed any of the commercial establishments that are mentioned by Mexico’s General Health Law, the existing Medical Supplies Secondary Regulations (*Reglamento de Insumos para la Salud*) or the -also existing- Secondary Regulations for Healthcare Research (*Reglamento de la Ley General de Salud en Materia de Investigacion para la Salud*). These include medication production facilities or laboratories, pharmacies, drugstores, storage facilities, clinics and hospitals, among others.
- Each such establishment shall have a responsible individual who will be in charge of maintaining compliance with a list of reporting, safety, control and record keeping obligations.
- Licenses granted by COFEPRIS for these establishments shall have a duration of 2 years.

Advertisement and Sale

- The General Health Law provides for two types of advertisement: that targeted to healthcare professionals or for the public in general. Cannabis medications can only be advertised to healthcare professionals and not to the public pursuant to guidelines approved by the SSA.
- Establishments that sell pharmacological derivatives in cannabis medications shall meet sanitary requirements and qualifications before COFEPRIS.

It is worth reminding that these Rules are separate and developed in a parallel process to the deadline set also by the nation's highest court for April 30, 2021 to



LEGAL

Corral, Arzola, Armendáriz & Máynez

legalize recreational use and which will allow for cultivation, import and export of industrial hemp.

If you would like an English translation of these Rules or the recreational cannabis legalization bill at a discounted price, please reply to this message.

If you would like to consult our previous Mexico Cannabis Updates, please click [here](#).

If you're interested in learning more about the Mexican legalization process and what you or your clients can start doing to enter the Mexican market, please contact us at larmendariz@caamlegal.mx.

Luis Armendariz

LinkedIn: [luisarmendariz](#)