

Voluntary Report – Voluntary - Public Distribution

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Report Name: Industrial Hemp Report

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Report Highlights:

After five years of negotiations, Ecuador continues the process to approve the production of hemp for industrial and medicinal purposes. The Ministry of Agriculture is currently developing the regulations for planting. The Ministry of Health is modifying their regulations to allow the use and consumption of hemp and hemp products.

Section I – Hemp

After the movement to legalize the production and trade of industrial/medicinal hemp began in 2015, the Ecuadorian population has begun to differentiate between recreational and industrial hemp.

Section II – Hemp Production:

Currently, the production of hemp is not legal in Ecuador, but the Ministry of Agriculture (MAG) has been working since June 21, 2020 to issue regulations for the planting, cultivation, and harvesting of hemp and have 120 days to issue them.

Three production types will be allowed: industrial hemp, open-air cannabidiol (CBD), and greenhouse CBD for medicinal purposes, whose production costs, risks, and profitability are ranked as low, high, and very high, respectively. In addition, production cycles in the Coastal region are shorter than in the Highlands, but CBD content is higher in the latter.

In order to be able to plant hemp, MAG will issue production licenses, but those won't be issued to natural persons and will only be granted to private companies, public entities, cooperatives, or small and medium producers associations, domiciled in Ecuador. To get a license the interested parties will need to provide documents on investments and financial statements that demonstrate the legality of the resources that will be used in the business.

The legal representatives, the directors, and shareholders who have 6 percent or more of participation of the businesses must present criminal records for the license process. The cost of this license, which may not be transferable, will be related to the cultivation area, although the criteria for establishing the costs are not yet defined. Self-cultivation will not be allowed to avoid further informality.

One of the requirements to obtain a license will be to have a form of purchase guarantees or promises for the product, either from the internal or external market.

The regulation and control over planting, cultivation, and harvesting will be overseen by the National Animal and Plant Health Authority (AGROCALIDAD). There is still no specific definition of competencies.

Section III – Labeling Requirements

Not Applicable

Section IV – Packaging and container Regulations

Not Applicable

Section V – Hemp / Cannabinoid Regulations

On October 26, 2015 the Government of Ecuador issued the Organic Law for the Comprehensive Prevention of the Socio-economic Phenomenon of Drugs and for the Regulation and Control of the Use of Listed Controlled Substances, which establishes the way in which the government will regulate the activities and medicinal and industrial use of cannabis. In this standard, cannabis was classified in a general way, as a controlled substance, and therefore required authorization for its handling. However, a disagreement arose between this law and the Comprehensive Organic Criminal Code (COIP), published

in February 2014. That disagreement consists in that on one hand there is a law that conceived the possibility of obtaining authorizations for the handling of cataloged substances and, on the other hand, one that establishes a prison sentence of one to three years for those who sow, grow, or harvest plants from which these substances are produced for their commercialization.

This meant that the private sector initiative to undertake in the cannabis industry was truncated due to the response given by the government authorities who warned that it could not materialize due to the impossibility of authorizing what another rule classified as illegal.

After five years of work by pro-cannabis groups and professionals interested in this new industry, the Ecuadorian National Assembly approved on September 17, 2019, with 85 votes in favor, the reforms to the articles of the COIP Organic Penal Code on substances subject to control.

This reform decriminalizes the sowing, cultivation, and harvesting of cannabis, considering that it must have the authorization of the competent authority for therapeutic or medical-scientific research purposes and for non-pharmaceutical industrial use, non-medical scientific research, or training, within the framework of the provisions of the 2015 Organic Law of Comprehensive Prevention of the Socio-economic Phenomenon of Drugs and Regulation and Control of the Use of Listed Substances Subject to Control.

On the other hand, the COIP reform recognizes hemp as a different crop from the rest of cannabis, understanding that the purpose is to differentiate it from the rest of the *Cannabis* species (recreational hemp) if it has less than 1 percent tetrahydrocannabinol (THC) content, ordering its removal from the list of listed substances subject to control.

The National Assembly sent the new COIP reforms to the President of the Republic, who made a partial veto to it, without objecting or modifying the articles related to the substances listed. The process was then delayed by the referral of the bill to the Constitutional Court for the analysis of four constitutional observations made by the President. It should be noted that none of these observations were related to cannabis cultivation.

The Constitutional Court completed the analysis at the end of November 2019 and the National Assembly on December 24, 2019 decriminalized the cultivation and production of hemp with a content of less than 1 percent THC, which has industrial properties and is non-recreational.

With this approval, the law entered into force on June 21, 2020, the date from which MAG would have 120 days to develop the regulations for planting. The law excludes hemp from the list of substances subject to control, including the possession of products for medicinal or therapeutic use that contain the active ingredient non-psychoactive (CBD), as long as there is a diagnosis of a disease or condition that supports its use. As well, THC, the ingredient in cannabis that produces the psychotropic effect, remains as a controlled substance if it is not within the parameters.

Section VI – Regulatory Source

The Ministry of Agriculture (<https://www.agricultura.gob.ec>) will be the leading agency to control the planting and production of hemp in Ecuador. The Ministry of Health (www.salud.gob.ec) will be in charge of the issuance of health certificates for the trade of imported and locally produced hemp products.

Section VII – Other Requirements, Regulations and Registration Measures

At the moment and based on decisions issued by the Andean Community of Nations (CAN), only cosmetic products for topical use that contain CBD are authorized to obtain a health certificate. These products are part of an international lists of ingredients that may or may not be incorporated into cosmetics and their corresponding restrictions or conditions of use. Products for human consumption are not allowed.

Likewise, it will be necessary to know the final text of the Organic Health Code, which will also incorporate provisions on the regulation of the medicinal and therapeutic use of cannabis and its derivatives. To date, it awaits a second debate in Ecuador's National Assembly.

From the perspective of intellectual property, it is worth remembering that the law does not define precisely the use of the word *cannabis* in the registration of a trademark. However, it is very important to bear in mind that Article 134 of Decision 486 of the Andean Community of Nations, in its final part, provides that the nature of the product or service to which a trademark is to be applied shall not be an obstacle to its registration.

This may result in the acceptance or refusal of a trademark registration application that includes the term *cannabis* in its name or list of products or services to be registered. Any derivative or referential expression will be subject to the criteria of the examiner of the Competent National Office in charge of the registration file, since, being a restricted product, objections could be generated.

To date, different opinions have been given, without there being a defined position in this regard. In any case, the number of trademark applications that have been granted is much higher than those that have received official objections or oppositions by third parties.

The presentation of the denomination and the elements that make up the graphic part of the label will also be very important, without forgetting that they should not be considered among those that determine absolute illegality (in the terms of article 135 of Decision 486), due to the impossibility of registering trademarks that are contrary to the law, morality, public order ,or good customs.

Until the beginning of this year, the National Service for Intellectual Rights (SENADI) processed a limited number of trademark applications and a more restricted number of patent applications. It is estimated, since there are no exact official statistics, that a high percentage of registration of these marks has been granted, something different from what happens with patents, the processing of which is quite slow.

It is important to note that several associations of producers of hemp and its derivatives have been created, as well as groups that advocate for the therapeutic use of cannabis in Ecuador, including some with the support of the Public Defender's Office. The arguments focus on considering the product as an alternative for people suffering from catastrophic and chronic diseases, as a palliative against pain, epilepsy, and other oncological problems or brain disabilities.

Section VIII – Other Regulatory and Import Contacts

Not applicable

Attachments:

No Attachments.