



REGULATORY FRAMEWORK FOR THE DEVELOPMENT OF THE MEDICAL CANNABIS AND INDUSTRIAL HEMP INDUSTRY

Decree 405/2023

DCTO-2023-405-APN-PTE - Approve the Regulation of Law No. 27.669.

City of Buenos Aires, 04/08/2023

HAVING REGARD TO File No. EX-2023-36943337-APN-DGDA#MEC, Laws Nos. 27.350 and 27.669, Decree No. 30 of 20 January 2023, and

WHEREAS:

That Law No. 27.669 - "REGULATORY FRAMEWORK FOR THE DEVELOPMENT OF THE CANNABIS INDUSTRY". MEDICINAL AND INDUSTRIAL HEMP" aims to establish the chain of production and national marketing and/or for export of the Cannabis plant, its seeds and derived products for medicinal use, including scientific research, and for industrial use, thus promoting the national development of the sectoral production chain.

That the aforementioned law governs the entire territory of the ARGENTINEAN REPUBLIC with the character of public order, the activities regulated therein are subject to federal jurisdiction, and any incidence that may directly or indirectly arise or derive from the same shall be under the jurisdiction of the Federal Contentious-Administrative Court.

The ARGENTINE REPUBLIC has duly acceded to the 1961 SINGLE CONVENTION ON DRUGS, the 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES and the UNITED NATIONS CONVENTION AGAINST ILLICIT TRAFFICKING IN DRUGS AND SUBSTANCES.

SICOTRÓPICAS OF 1988, issuing the regulations for internal adaptation to the objectives agreed within the framework of these treaties.

That the aforementioned Law No. 27.669 falls within the aforementioned regulatory context, by regulating a production system that guarantees the availability of psychotropic substances for use for health and scientific research.

That, in the same way, in accordance with the provisions of the aforementioned 1961 SINGLE CONVENTION ON DRUGS, which establishes that it shall not apply to the cultivation of the cannabis plant exclusively for industrial (fibre and seeds) or horticultural purposes, the aforementioned law promotes the production chain of this variety of the non-psychoactive Cannabis plant intended for industrial purposes.



That the aforementioned Law No. 27.669 is the result of legislative consensus, based on an initiative presented by the NATIONAL EXECUTIVE BRANCH which, among other objectives, sought to channel society's demands related to the benefits attributed to the use of cannabis for medicinal purposes, in order to improve access to health care for the population.

That the gradual move towards the legalisation of the medicinal, therapeutic and palliative use of Cannabis, as well as the reconsideration of the potential of Industrial Hemp has led to the emergence of a dynamic industry involving initiatives from the public and private sector and civil society organisations.

That our country has clear comparative advantages for the development of Medicinal and Industrial Cannabis, due to the scientific and technological capacities in agricultural and industrial matters, as well as the favourable climatic and soil conditions of the national territory.

That the development of a local production chain promoted, regulated and controlled by the NATIONAL STATE favours the fulfilment of the objectives defined in Law N° 27.350 and makes possible the generation of a supply of quality controlled and certified products.

That crops authorised within the regulatory framework of Law N° 27.350 and Law N° 27.669 shall not be considered narcotic drugs for the purposes of Law N° 23.737, its amendments and its corresponding Regulatory Decree.

That among the changes established by the aforementioned Law No. 27.669, the foundational fact of creating a specific, appropriate and updated legal and institutional framework to regulate the emerging Hemp and Medical Cannabis industry stands out, with the aim of promoting the development of productive capacities, boosting regional economies, contributing to the reconversion of existing agricultural activities, replacing imports and promoting the generation of quality jobs in the development of the sector.

That the national production and industrialisation of Cannabis will guarantee universal access to its medicinal derivatives for the beneficiaries of the National Programme for the Study and Research of the Medicinal Use of the Cannabis Plant, its derivatives and non-conventional treatments created by article 2 of Law No. 27.350.

Article 4 of Law No. 27.669 created the REGULATORY AGENCY FOR THE MEDICINAL HEMP AND CANNABIS INDUSTRY (ARICCAME) and Article 7 established its functions, among which is the regulation of the import, export, cultivation, industrial production, manufacture, marketing and acquisition, by any title, of seeds of the Cannabis Plant, Cannabis and its derivative products for medicinal or industrial purposes.

That Decree No. 30/23 established the missions of the various bodies that make up the REGULATORY AGENCY FOR THE HEMP AND MEDICINAL CANNABIS INDUSTRY (ARICCAME), its
The formation and determination of the rules of operation, with the aim of ensuring the start-up of its activities.



By virtue of the aforementioned regulation, the President, Vice-President and members of the Board of Directors were appointed and it was determined that until the REGULATORY AGENCY FOR THE HEMP AND MEDICINAL CANNABIS INDUSTRY (ARICCAME) is fully operational, the MINISTRY OF ECONOMY will provide technical, administrative, financial, budgetary and legal assistance.

That, in this sense, it is imperative that the CHAIRMAN OF MINISTERS' OFFICE make the necessary budgetary readjustments to comply with the provisions of this decree.

In order to comply with the provisions of Law No. 27.669, it is necessary to issue the regulations that allow for the effective operation of the REGULATORY AGENCY FOR THE HEMP AND MEDICINAL CANNABIS INDUSTRY (ARICCAME), the FEDERAL COUNCIL FOR THE DEVELOPMENT OF THE HEMP AND MEDICINAL CANNABIS INDUSTRY and the HONORARY CONSULTATIVE COUNCIL.

It is also provided for the integration of the HONORARY CONSULTATIVE COUNCIL, which will operate under the aforementioned REGULATORY AGENCY FOR THE HEMP AND MEDICINAL CANNABIS INDUSTRY (ARICCAME) and will be made up of TWENTY (20) full members and an equal number of substitutes, acting "ad honorem", in which institutions from the scientific-technological areas of the NATIONAL STATE, specialised technical bodies and civil society organisations will participate.

That in order to ensure the operational and administrative coordination of the FEDERAL HEMP AND MEDICINAL CANNABIS INDUSTRY COUNCIL, the Board of Directors shall appoint ONE (1) official of the REGULATORY AGENCY OF THE HEMP AND MEDICINAL CANNABIS INDUSTRY (ARICCAME), who will shall act simultaneously with his functions and on an ad honorem basis as its Administrative Secretary.

In order to implement the licensing and authorisation system, the "ONE STOP SHOP FOR THE HEMP AND MEDICINAL CANNABIS INDUSTRY" system is adopted for the management of procedures related to the issuance of authorisations, licences and certifications required.

The main objective of this system is to provide greater efficiency in procedures and formalities, unify administrative procedures and files, give intervention to the bodies with specific competences involved and facilitate access and dissemination of information in a homologated, standardised, updated and integrated manner.

That in accordance with international regulations ratified by the ARGENTINEAN REPUBLIC, Law No. 27.669 establishes differentiated procedures for Cannabis and psychoactive Cannabis, on the one hand, and for Industrial and/or horticultural Hemp, on the other.

The International Conventions on the control and monitoring of narcotic drugs and psychotropic substances include Cannabis and psychoactive Cannabis as substances subject to the strict control of the States Parties and provide that their production can only be authorised by means of a licensing regime.



That, in line with these rules, a licensing regime is established with the scope indicated in the preceding recital, organised by criteria of activity on the basis of the different links in the Cannabis and psychoactive Cannabis production chain.

On the other hand, industrial and/or horticultural hemp is excluded from the conventional system and, consequently, the granting of administrative authorisations for the different production activities linked to it is foreseen, thus establishing a simplified differential regime.

Whereas, furthermore, the said REGULATORY AGENCY OF THE HEMP AND CANNABIS INDUSTRY MEDICINAL (ARICCAME) is competent to control and issue administrative authorisations with regard to the use of the Cannabis plant, Cannabis seeds, Cannabis and its derivative products, with particular regard to the aim of contributing to the development of cooperative activity and small-scale agricultural and industrial production and, in this, to gender and diversity perspectives.

The relevant legal advisory services have taken the appropriate action.

That the present measure is dictated by virtue of the powers arising from Article 99, sections 1 and 2 of the NATIONAL CONSTITUTION.

For this reason,

THE PRESIDENT OF THE ARGENTINE NATION

DECREES:

ARTICLE 1 - Approve the Regulations of Law No. 27.669 - "REGULATORY FRAMEWORK FOR THE DEVELOPMENT OF THE MEDICINAL CANNABIS AND INDUSTRIAL HEMP INDUSTRY", which, as ANNEX, shall be as follows I (IF-2023-87002696-APN-ARICCAME#MEC) forms an integral part hereof.

ARTICLE 2.- The REGULATORY AGENCY FOR THE HEMP AND MEDICINAL CANNABIS INDUSTRY shall (ARICCAME), a decentralised body under the auspices of the SECRETARIAT OF INDUSTRY AND PRODUCTIVE DEVELOPMENT of the MINISTRY OF ECONOMY, shall be the Authority for the Application of Law No 27.669 of the Regulations approved by this Decree.

ARTICLE 3.- The REGULATORY AGENCY OF THE HEMP AND HEMP INDUSTRY is hereby empowered to CANNABIS MEDICINAL (ARICCAME) to issue, within the scope of their respective competences, the clarifying or complementary rules for the effective application of the Regulation approved by the present decree.

ARTICLE 4: The Head of the Cabinet of Ministers shall make the necessary budgetary reallocations to meet the expenditures required for the fulfilment hereof.

ARTICLE 5.- This decree shall enter into force from the date of its publication in the OFFICIAL BULLETIN.



ARTICLE 6. Communicate, publish, send to the NATIONAL OFFICIAL REGISTRY and file.

FERNÁNDEZ - Agustín Oscar Rossi - Sergio Tomás Massa - Carla Vizzotti

NOTE: The Annex(es) to this Decree are published in the web edition of the BORA.

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