REPUBLIKA E SHQIPËRISË
KUVENDI

LAW

No. 61/2023

FOR THE CONTROL OF THE CULTIVATION AND PROCESSING OF THE *CANNABIS* PLANT AND PRODUCTION OF ITS BY-PRODUCTS FOR MEDICINAL PURPOSES AND INDUSTRIAL

In support of Articles 78 and 83, point 1, of the Constitution, with the proposal of the Council of Ministers,

ASSEMBLY

OF THE REPUBLIC OF ALBANIA

DECIDE:

CHAPTER I

GENERAL PROVISIONS

Article 1

object

The object of this law is to determine the rules for the cultivation, production and controlled circulation of the *cannabis plant,* its by-products and final products for medical and industrial use.

Article 2

Purpose

The purpose of this law is to regulate and guarantee the process of control and supervision of cultivation, production and circulation, as well as the export of the *cannabis plant,* its by-products and final products for medical and industrial purposes.

Article 3

Definitions

In terms of this law, the following terms mean:

1. "Licensed activity" is any activity of a commercial, economic and professional nature that is carried out by licensed entities for the import of seeds or seedlings of the cannabis plant, cultivation, production, transportation, as well as the export of by-products and products of cannabis for medical purposes.

2. "Permitted activity" is any activity of a commercial, economic and professional nature, which is carried out by the entities allowed for the importation of seeds or seedlings of the cannabis plant, cultivation, production, transportation, as well as the export of by-products and final cannabis products for industrial purposes.

3. "Cannabis plant for industrial purposes" is the cannabis plant, including all fresh or dried parts of the plant and seeds of the cannabis sativa and cannabis ruderalis varieties containing not more than 0.8% THC , which is cultivated for industrial purposes.

4. "Cannabis plants for medical purposes" are plants of different varieties, variations and subspecies of cannabis sativa, cannabisindica and cannabis ruderalis, obtained from cultivation for medical purposes and scientific research under controlled conditions, according to the rules provided for in this law.

5. "Cannabis" are the flowering and fruiting tops of plants of the genus cannabis, excluding seeds and leaves when these are not associated with the tops from which the resin has not been removed, regardless of the name they may have.

6. "Traceability" is the process of tracking and tracing seeds, seedlings, substances, plants, materials and preparations, which are the subject of this law, in all stages of planting, cultivation, production of by-products and final product, marketing and supply to the end user.

7. "Cultivation" is the process from planting seeds or seedlings to harvesting the cannabis plant.

8. "Cannabis plant residues" are parts of the cannabis plant cultivated for the purposes medical or their waste after production and processing, which are treated as unnecessary.

9. "Industrial by-product" means the materials obtained from the entire cannabis plant, including the stem, flower and seed, which is produced for industrial purposes, which include, but are not limited to uses for the construction, textile sector , cosmetics, energy production, paper production, etc.

10. "By-products for medical purposes" are substances and preparations extracted from the cannabis plant, used for the preparation of final products, which include drugs and cosmetic products.

11. "Production unit" is: a)

an area of land from 5 to 10 hectares, fenced, in which the cultivation of the cannabis plant for medical purposes is allowed, including warehouses and other special premises, in function of the processes related to the cultivation of the cannabis plant and the production of by-products for medicinal purposes;

b) a land area of not less than 1 hectare in which the cultivation of the cannabis plant is allowed for industrial purposes, including warehouses and other special premises, in function of the processes related to the cultivation of the cannabis plant and the production of by-products of the cannabis plant for industrial purposes.

12. "Preparation" is the extract, mixture or raw plant material obtained from the cannabis plant, in a solid or liquid state or in any other state, which contains a narcotic drug or psychotropic substance.

13. "Production" is the process involved in the preparation, processing, mixing, purification and any other activity intended to obtain the products and by-products of the cannabis plant for medicinal purposes and for industrial purposes.

14. "Final product for medical purposes of the cannabis plant" is the narcotic drug, psychotropic substances and cosmetic products.

15. "Final product for industrial purposes of the cannabis plant" is any product that contains cannabis plants for industrial purposes.

16. "Trafficking" is any way of passing into civil circulation the *cannabis plant,* its by-products and final product for remuneration, including import, export, transit, supply, purchase, sale, exchange, storage and storage.

17. "Marking" is the process of placing a unique mark in the form of a code, stamp, label or any other unique form of marking on *cannabis* seeds, seedlings, substances, plants, by-products or final products thereof, proving that cultivation was carried out according to the rules defined in this law, in order to identify and trace it.

18. "Employee Cleanliness Verification" is a process of verification, review and evaluation, which refers to the performance of a preliminary, careful and critical check on the suitability of the person who is employed by the National Cannabis Control Agency *or* by the entity licensed under this law.

Article 4

Scope of application

1. This law applies to every entity that carries out licensed activities for:

a) importing seeds or seedlings or their reproduction;

b) the cultivation of the medical or industrial *cannabis* plant;

c) the production of the by-product or final product; ç)

circulation of the *cannabis plant,* by-product or final product.

2. This law also applies to any state structure that performs supervision, control and inspection of the implementation of this law.

Article 5

General prohibitions

In the Republic of Albania it is prohibited:

a) the cultivation of the medical *cannabis* plant and the production of its by-products and final products in excess of the provisions of this law;

b) the cultivation of the *cannabis* plant and the production of its by-products and final products for medicinal purposes, their trading and possession if they are not marked and traceable according to the provisions of this law;

c) possession of tools, equipment and instruments for the production of the medical *cannabis* plant and its by-products and final products, except for the cases declared by the entity equipped with a license, provided for in this law;

ç) the use of by-products and final products of the *cannabis plant,* except for the cases provided for in this law and in the special legislation in force;

d) retail or wholesale sale and distribution, acquisition or consumption in the territory of of the Republic of Albania of by-products or final products for medical purposes;

dh) advertising made directly or indirectly or in any other way, regardless of the medium of publication, of the activity of importing cannabis seeds or seedlings *and* the cultivation, production, sale, possession and use of the *cannabis* plant- *it* medical.

Article 6

Image purity verification process

1. Only persons who pass the process of verifying the purity of the image may be employed as an employee of the Agency or in entities licensed or permitted according to the provisions of this law.

2. To carry out the process of verifying the purity of the image of the Agency's employees, as well as of the persons involved as employees of the entities licensed or permitted according to the provisions of this law, the Agency cooperates with the State Police and the responsible authorities or institutions that hold or administer the data for this purpose.

3. The process of verifying the purity of the image includes the criterion of moral integrity, as well as the criteria special ethical-professional for specific work positions.

4. The procedures, deadlines, criteria and documentation necessary for the verification of the purity of the picture are determined by a joint instruction of the minister responsible for health, the minister responsible for agriculture and the minister responsible for internal affairs and security, with the proposal of the General Director of the Agency .

CHAPTER II

CREATION, ORGANIZATION, FUNCTIONING AND COMPETENCES OF THE AGENCY

Article 7

Establishment, status and financing of the Agency

1. The National Cannabis Control Agency, hereinafter referred to as the Agency, is a public budget legal entity subordinate to the minister responsible for health, whose mission is the supervision, control and inspection of the cultivation and processing of the cannabis plant and of the production of its by-products for medical and industrial purposes and monitoring the implementation of this law.

2. The agency is organized and operates at the central level, with headquarters in Tirana, and extends its activity throughout the territory of the Republic of Albania.

3. The funding sources of the Agency are the income from the state budget and the income generated by its activity based on and for the implementation of this law. The procedure and way of using the income are determined by the decision of the Council of Ministers.

4. The agency has the official coat of arms, logo and seal. The coat of arms consists of the coat of arms of the Republic of Albania, with the notes: "Republic of Albania, Ministry of Health and Social Protection, National Cannabis Control Agency".

5. The seal of the Agency has the form and constituent elements, determined according to the legislation in force for the production, administration, control and storage of official seals.

Article 8

Direction and organization

1. The Agency is headed by the General Director, who organizes and directs everyone the activity of the institution and answers to the minister responsible for health.

2. The Licenses Commission is created and operates under the Agency, with the aim of supporting it in the exercise of powers in accordance with the role and duties it has according to the provisions of this law.

3. The structure and organization of the Agency are approved by order of the Prime Minister, with the proposal of the minister responsible for health.

4. The working relations of the Agency's employees are regulated according to the Labor Code.

5. The employee of the Agency must have integrity and a clean moral image. He must not have been convicted by a final court decision for a criminal offense committed in the field of narcotics.

6. Persons employed at the National Cannabis Control Agency, in addition to the general requirements, must also meet the criteria for clean image, as well as special professional criteria for specific job positions.

7. The verification of the criteria of the purity of the image is applied to the person seeking to be employed in the Agency, as well as to his connections with family members or outside it. Persons who do not meet the criterion of image purity, cannot connect or continue to have a working relationship with the Agency.

8. The professional criteria for the employees of the Agency, as well as for the verification of the image of the employees of the licensed entities, are determined by a joint instruction of the minister responsible for internal affairs and security, the minister responsible for agriculture and the minister responsible for health, with the proposal of the director General of the Agency.

Article 9

Competences of the Agency

1. The Agency exercises its powers based on the principles of legality, professionalism, responsibility, accountability, efficiency and transparency and in accordance with the legislation in force.

2. The Agency, in exercising its activity at the administrative level, has the following powers:

a) organizes the procedures for granting the license according to the rules defined in this law and the rules defined by the minister responsible for health;

b) supervises the activity of licensed and permitted entities in accordance with the conditions and criteria defined in the license and permit for the cultivation of the cannabis plant for medical and industrial purposes;

c) drafts the standards for areas and plots of land in which the cultivation of the cannabis plant for medical and industrial purposes will be allowed, which are approved by decision of the Council of Ministers, with the proposal of the ministry responsible for agriculture;

ç) drafts every 3 years the report regarding the fulfillment of the conditions for granting licenses and permits and recommends, as the case may be, the fulfillment of the conditions or the suspension or cancellation of licenses and permits;

d) cooperates with other competent bodies in order to achieve objectives and obligations deriving from international agreements to which the Republic of Albania is a party;

dh) presents reports to the competent international organizations on the import and export of the cannabis plant and its by-products or final products, in accordance with the obligations arising from the international conventions for the control of narcotic and psychotropic substances; e) continuously cooperates with the European Center for Monitoring Drugs and Addiction to them and the International Narcotics Control Board;

ë) performs the verification of the purity of the image of every employee of the Agency and of the licensed or permitted entities, according to the provisions of this law, in cooperation with the responsible authorities or institutions that keep or administer the data for this purpose. The verification of the figure is carried out at the time of the person's engagement, as well as periodically according to the provisions of the joint instruction, mentioned in Article 8 of this law;

f) cooperates with law enforcement agencies and state structures to maintain the purity of the image of employees of licensed or permitted entities, as well as the prevention of criminal offenses;

g) maintains and administers registers, databases and statistics at the national level according to the provisions of this law;

gj) issues the export authorization for industrial cannabis and cannabis products for industrial purposes;

h) drafts regulations, instructions and methodologies for the unification of the processes and work standards of the Agency's employees and proposes it to the minister responsible for health for approval;

i) proposes the areas to the minister responsible for agriculture and the minister responsible for the environment cadastral where *cannabis* will be cultivated for industrial purposes;

j) issues administrative measures with fines and bans on the exercise of activity against licensed subjects and permitted subjects, according to this law;

k) evaluates requests for the sale of shares of partners of license or permit holding entities and proposes for approval, after the approval of the Licenses Commission, the minister responsible for health for licenses and the minister responsible for agriculture for permits.

3. The Agency, in exercising its activity, at the technical level, has the following powers:

a) supervises the use and planting by licensed subjects of seeds and seedlings imported or produced in the Republic of Albania, in accordance with the legislation in force for planting and propagating plant material, as well as registered in the national catalog;

b) designs the standards for each stage of the process related to the cultivation of the *cannabis* plant , which are approved with the instructions of the minister responsible for agriculture.

c) coordinates the work with the responsible state authorities for the registration and immediate inclusion in the national catalog of seeds and seedlings, which are accompanied by distinctiveness-uniformity-stability (DUS) testing;

ç) supervises and monitors the planting and cultivation of the *cannabis* plant and its by-products, which are used for medical and industrial purposes, and, if it finds that the subject has planted or cultivated quantities different from those provided for in the permit or license, decides their destruction and proposes the corresponding sanctions;

d) controls and inspects all the cultivation processes of the *cannabis* plant at every stage planting, harvesting, drying, preservation and storage, production of plant raw material;

dh) controls and inspects, based on the license, the premises and headquarters where the processing of by-products and final products for medical purposes takes place;

e) takes measures for the seizure and destruction of *cannabis* plants or its by-products, according to the provisions of this law;

ë) cooperates with the structures responsible for customs to monitor the regime of import of seeds and seedlings, as well as the regime of export of by-products or final products of medical and industrial *cannabis ;*

f) performs any other activity provided by other laws or by-laws pursuant to this law.

Article 10

Functions of the Agency

1. The Agency supervises the licensed and permitted activity at each stage and for each production cycle to ensure that the activity:

a) is carried out in accordance with the legal provisions and by-laws issued based on and for their implementation, with the stipulations made in the license or permit, as well as with the stipulations in the approved production plan;

b) is not carried out contrary to the purposes of the law and the international obligations of the Republic of Albania.

2. The agency carries out supervision, controls and inspections according to this law and, when necessary, coordinates the process in cooperation with other institutions.

3. In fulfillment of its tasks of control, inspection and monitoring according to the provisions of this law, the Agency exchanges information with the prosecution offices of general jurisdiction, the Special Prosecutor's Office/National Bureau of Investigation, the State Police, as well as other competent authorities pursuant to this law, and may sign bilateral or multilateral cooperation agreements with them.

4. The agency, mainly or upon request, performs verifications in accordance with the provisions of this law. After carrying out the verification, if the Agency assesses the taking of measures for the suspension or cancellation of the license, it will be forwarded to the License Commission for consideration.

5. The agency cooperates and exchanges information with the State Police and other national or international institutions, with which Albania has agreements in the field of the fight against the use and trafficking of narcotics and psychotropic substances and against the laundering of proceeds from illegal activity.

6. The agency collects and administers data necessary for the exercise of its functions on the licensed and permitted activity, as well as on the holder of the license or permit. The primary and secondary data are determined by the decision of the Council of Ministers, according to the provisions in point 6 of article 13 of this law.

7. The agency presents a 6-month work report to the ministry responsible for health, which i
the ministry responsible for order and security is also informed.

8. The agency exercises any other function defined in the law or in the regulation for its operation. The rules for the internal organization of the Agency are approved by the minister responsible for health.

9. The Agency approves the activity regulations of the licensed entities.

Article 11

Licensing Commission

1. The Licensing Commission is set up under the Agency for the review and assessment of requests submitted for obtaining a license for the cultivation of *cannabis* for medical purposes, according to the provisions of this law.

2. The commission has 7 members and has the following composition:

a) 3 representatives from the ministry responsible for health;

b) 1 representative from the ministry responsible for public order and security; c) 2
representatives from the ministry responsible for agriculture;

ç) 1 representative from the ministry responsible for the economy.

3. The chairman of the Commission is one of the representatives of the ministry responsible for health.
The nominal names of the members of the License Commission are determined by order of the relevant ministers.

4. Ministers, according to the provisions of point 2, may appoint as members persons who exercise public functions related to the function and duties of this Commission and have no less than 5 years of work experience. The members of the Commission are appointed for a period of up to 4 years.

5. The members of the Commission have an obligation and sign the declaration of confidentiality, the declaration of the absence of conflict of interest, and must be equipped with the security certificate from the Directorate of Security of Classified Information.

6. The Licensing Commission has the following

duties: a) administers and verifies the documentation submitted by the entities that have applied for a license, according to the provisions of Article 16 of this law, made available by the Agency;

b) evaluates the fulfillment of the conditions regarding the premises, equipment and personnel for obtaining the license;

ç) draws up the list and the relevant relation regarding the requesting entities, as well as prepares the proposal for granting or refusing the license;

c) in case of detection of violations, according to the provisions of this law, propose to the minister responsible for health to take the administrative measure of suspension or revocation of the license.

7. The functions of assistance and logistical support of the License Commission are performed by the Agency through employees appointed by the General Director, who serve as the technical secretariat for the meetings of the Commission.

8. The organization of the work and activity of the Commission is done by order of the minister responsible for health. The members of the Commission exercise their activity against remuneration. The amount of remuneration for the chairman and members of the Commission is determined according to the decision of the Council of Ministers for determining the amount of remuneration for the members of the councils, boards or permanent commissions of the central government units.

Article 12

Units monitoring the cultivation, production and trade of *cannabis* for medical and industrial purposes

1. The specialized unit for the supervision, control and inspection of the cultivation, production and circulation of *cannabis* for industrial purposes and the unit for the supervision, control and inspection of the cultivation, production and circulation of *cannabis* for medical purposes are established and operate in the Agency. .

2. The units direct and coordinate the supervisory, control and inspection activity in cooperation with the structures of the ministry responsible for agriculture for *cannabis* for industrial purposes and the ministries responsible for health and order for *cannabis* for medical purposes.

3. The unit for monitoring *cannabis* for industrial purposes and the structures of the ministry responsible for agriculture draw up the report on the lands that meet the standards for the cultivation of *cannabis* for industrial purposes. The joint report is submitted to the minister responsible for agriculture.
The Council of Ministers by November 30 of each calendar year approves the cadastral areas in which starting from January 1 of the following year, the cultivation of *cannabis* for industrial purposes is allowed.

4. The medical *cannabis* monitoring unit proposes to the minister responsible for health the report on the lands requested by the licensed entities, which meet the standards for the cultivation of *cannabis* for medical purposes, for approval in the Council of Ministers.

5. The units monitor the process to guarantee the cultivation of only seeds and seedlings registered in the institution responsible for the registration of seeds and seedlings, as well as importation only by subjects equipped with import licenses and authorizations.

6. The unit monitors the process of importing seeds and seedlings that are varieties of *cannabis* cultivation for medical and industrial purposes, included in the Common European Catalog of Plant Varieties in Agroculture, as well as the process of their reproduction.

Article 13

National Register of Licensed and Permitted *Cannabis* Plant Activity

1. All licensed and permitted entities in terms of this law are registered in the National Register of licensed and permitted entities.

2. The register is established in the form of a state database, administered by the Agency and contains all information on licensing application, licensing decision-making, authorization application, authorization decision-making, permit application, permit decision-making, tracking, supervision and control, administrative measures related to all stages of cannabis *cultivation ,* starting from the moment of granting the license, permit and authorization until their revocation and seizure or destruction of plants or its by-products, according to the provisions of this law.

3. The following are recorded in the register:

a) subjects licensed and permitted for the cultivation of *cannabis* and authorized for importation of seeds and seedlings;

b) data on licenses, permits for the cultivation of *cannabis* and authorizations for the importation of seeds and seedlings, as well as their suspension or cancellation;

c) types of seeds and seedlings, which are cultivated by subjects according to the European list of *cannabis* seeds for medical and industrial purposes; ç) the imported amount,

the produced amount, the buyer of the raw material, the fertilizer products used; d) data in the export authorization of by-products or final products

cannabis for industrial and medical purposes according to the provisions of this law;

dh) type and quantity of *cannabis plant,* by-products or final products disposed of. In the case of industrial *cannabis,* these data are recorded according to the subject's self-declaration;

e) placing unique signs and following all stages of securing seeds and seedlings, cultivation, production, marketing, supply, transport that serve to identify the cannabis plant, by-products and final *product .* Unique marks in the case of industrial *cannabis* are not placed for marketing to the end user for export;

ë) administrative measures taken against cultivation subjects.

4. The register interacts with other databases, which serve the process of granting licenses, permits and authorizations, as well as the supervision of the process of cultivation of cannabis *for* medical purposes and for industrial purposes.

5. The corresponding structures of the ministries responsible for health, finance, public order and security and agriculture have access to this register.

6. Determining in detail the primary and secondary data, the determination of the concrete databases with which this register interacts, the level of its access by interested subjects or the public, the determination of the data that will be public, as well as the way of recording and storing the data and documents contained in the register are determined by the decision of the Council of Ministers, with the joint proposal of the minister responsible for health, the minister responsible for agriculture and the minister responsible for public order and security.

CHAPTER III

PROCEDURE OF DEVICE WITH LICENSE FOR EXERCISE OF RELATED ACTIVITIES WITH THE PRODUCTION OF *CANNABIS* FOR MEDICINAL PURPOSES

Article 14

License to exercise activity

1. The license for the production of *cannabis* for medical purposes may include the following activities:

a) cultivation, production of the *cannabis* plant for medicinal purposes; b)

transportation of seeds, plants and *cannabis* by-products for medical purposes in the territory of the Republic of Albania;

c) export of *cannabis* plants, products and by-products for medical purposes.

2. The license is granted for one or several activities, according to the provisions of point 1 of this article, for a period of 15 years, with the right of renewal upon request for each of the activities and based on the selection procedure organized by the Agency. The format of the license for exercising activities related to the production of *cannabis* for medical purposes is approved by order of the minister responsible for health.

3. The license is granted only to the entity that meets the conditions and criteria defined in this law, as well as only for the units and activity required and defined in its development plan, determining the coordinates of the location of the units and the relationship of the entity with the land.

4. The license is granted only in the name of the subject and is non-transferable and inalienable.
The license has as its integral part the activities for which the subject is licensed, with the fulfillment of the requirements defined in this law.

5. If the license stipulates that certain activities, provided for in the license, can be carried out in whole or in part by other entities, these entities will be verified in relation to meeting the condition of image purity, as well as expressly defined in the license . Changes related to the alienation of the ownership of these entities require the prior written approval of the Licensing Commission. The Commission grants or rejects the preliminary approval within 3 months from the complete submission of the request, based on the documentation defined in relation to the verification of the purity of the picture.

6. The license defines one or several units for which the subject has met the criteria. If the subject is licensed for more than one unit, they must be adjacent to each other and, in any case, no more than 4 units in the same license.

7. The license for cultivation activity is granted only on open, covered surfaces or greenhouses.
The area of the activity license unit for cultivation of cannabis for medical purposes cannot be less than 5 hectares and not more than 10 hectares.

8. The total area allowed for the cultivation of the cannabis plant for medical purposes cannot be greater than 200 hectares at the national level.

9. The applicant, in order to be provided with a license, pays at the time of submitting the application a fee in the amount of 100,000 (one hundred thousand) ALL, which is non-refundable. The fee payment procedure and the way of using this fee are determined by a joint instruction of the minister responsible for finance and the minister responsible for health.

10. The license granting conditions, defined in point 2 of article 15, must be respected by the licensed entity throughout the duration of its validity. Every 3 years the license conditions are re-evaluated by the Agency, which, if it finds non-fulfillment of the conditions and criteria, proposes, as the case may be, the suspension or cancellation of the license or asks the subject to fulfill the conditions within a 30-day period.

11. No later than 6 months before the end of the validity period of the license, the entity may request its renewal when it proves that it meets the conditions of the licensed device according to the provisions of this law.

Article 15

Licensed Device Terms

1. Every legal entity, which seeks to be provided with a license, must fulfill the following conditions for each activity required for licensing:

a) have 3 years of experience in at least 3 of the main activities, such as: production, cultivation and circulation of the cannabis plant for medicinal purposes;

b) the entity or one of its shareholders, who owns 51% of the company's shares, must:

i. to be engaged in the activity of producing by-products of the cannabis plant in one of countries of the Organization for Economic Cooperation and Development for at least 5 years;

ii. be a holder of good manufacturing practices, issued by the European Medicines Agency or the American Food and Drug Administration for at least 3 years;

iii. to have company capital of not less than 100,000,000 (one hundred million) ALL;

iv. to have shown positive financial performance in the last financial year;

c. of this administrative, organizational capacity and appropriate reliability to engage successfully in the main activities required for licensing;

vi. not be included in the lists of persons registered or announced as financiers of terrorism.

2. The legal entity, which submits an application for a license for the production of medical cannabis, must among others:

a) to determine in a tax manner the activity or activities for which it seeks to be licensed;

b) to present the units in which the activity will be developed with coordinates, as well as the legal relationship with the land;

c) submit the business development plan, identifying the cultivation model and the purpose of cultivation, as well as the minimum and maximum area of the development unit;

ç) to present the processing plan of the drying, cutting and storage facilities, equipped in accordance with the production capacity, foreseen in advance in the production development plan;

d) to submit the security plan for the surface for cultivation and processing, defining the elements of protection, fencing, security with cameras and physical security for 24 hours, barrier elements before the entrance and barbed wire on the fence, according to the standards determined by the decision of Council of Ministers;

dh) submit a self-declaration for the employment of at least 10 people for each unit, 2 of whom must be qualified employees in the field of pharmacy and agro-engineering, with work experience of no less than 3 years in the relevant field;

e) submit a self-declaration on the readiness to conclude an agreement with the responsible structure of the ministry responsible for public order and security to guarantee access for inspection to the private physical security company that supervises the cultivation environments of the cannabis plant and its by-products, as well as the movement of vehicles dedicated to trading raw materials and products, according to the rules and tariffs determined by the Council of Ministers;

ë) submit a self-declaration for the start of the activities described in the license within 12 months of its approval;

f) submit a self-declaration that after the third year he will pay an annual fee equal to 1.5% of the annual turnover, but, in any case, not less than 10,000,000 (ten million) ALL;

g) submit a bank guarantee in the amount of 10% of the investment value;

gj) submit a self-declaration that he will meet all requirements for traceability according to the provisions of this law;

h) submit a self-declaration about the processes carried out by third parties and their identification with accurate data in order to evaluate and verify them;

i) submit a self-declaration about the availability of payment of tracking system fees.

Article 16

Application submission and necessary documentation

The request for licensed equipment is submitted to the Agency together with the following documentation and data: a) certificate of

registration at the National Business Center;

b) the historical extract of the legal entity and, as the case may be, the founding act and the company's statute and the list of beneficial owners, if any; c) data of the legal

representative or the person authorized to follow the licensing procedure;

ç) certificates issued by competent bodies, such as: i. the

security certificate of the subject, issued by the Directorate of Security of Classified Information for Albanian citizens, and the certificate unified with it for foreign citizens, issued by the competent authorities of the country where they are resident;

ii. certificate issued by the prosecution body that proves that the subject, administrator, members of management bodies, partners or shareholders are not under criminal prosecution; iii. certificate

issued by the judicial body proving that the subject, administrator, members of management bodies, partners or shareholders are not under trial for any criminal offence;

iv. the certificate of judicial status that proves that the subject, administrator, members of the management bodies, partners or shareholders are not criminally convicted by a final court decision;

c. certification from the executive body proving that the subject is not in the process of execution liable for unpaid property obligations;

vi. certification proving that the requesting entity, partners or shareholders of the requesting entity are not in bankruptcy proceedings;

vii. the financial statements of the requesting entity, as well as of its shareholders for the last 3 years before submission of the request;

viii. documents certifying experience in relevant activities according to the requirements set forth in this law;

ix. certification by the tax authorities for the settlement of tax obligations both by the entity and by any legal entity in the event of a merger of companies; x. certification on the availability of qualified personnel in the exercise of the activity according to the requirements of this law;

d) the relevant regulation for the rules and way of functioning of the activity or activities for which it seeks to be licensed;

dh) the self-declaration for the conclusion of the preliminary agreement for storage and physical security according to the provisions of this law; e) the self-declaration for the payment of the bank guarantee according to the provisions of this law.

Article 17

Notice of Competition for Licensed Equipment

1. The Agency announces the notice of competition for equipment with a license for medical purposes for all its activities, licensed according to the provisions of this law.

2. The notification contains:

a) list of necessary documentation; b) place and deadline for submitting the request and documentation; c) the language and manner of presentation of documents; ç) the place, date and time of the review of the documentation.

Article 18

The procedure for the selection of the winning subject

1. The selection of the subject is made according to a competition procedure organized by the Agency in accordance with the conditions defined in this law, after receiving the evaluation from the License Commission.

2. Members of the Licensing Commission declare under their own responsibility that participation in this commission does not constitute a cause for the emergence of a conflict of interest with the entities participating in the competition. In case of non-declaration, the measures provided for in the legislation in force for the prevention of conflict of interests in the exercise of public functions shall be applied.

3. The Licensing Commission, after verifying the documentation, after evaluating the fulfillment of the conditions and criteria provided by this law, draws up a final list ranking the participants in the competition according to the points obtained in accordance with the scoring scheme approved by the Commission. The candidate ranked first on the list is considered the winner.

4. The commission ranks the participants in the competition according to the assessment of experience or experience in exercising the activity and professional experience, referring to: a) first, the results of the assessment of experience in the main activities for which the license is granted, according to the provisions of the letter "a" of point 1 of article 15;

b) secondly, in cases of the same results of the assessment of experience, years of experience or professional experience, according to the provisions of letter "b" of point 1 of article 15.

5. The Commission drafts, approves and publishes more detailed rules, which determine:

a) criteria for evaluating experience in the exercise of the main activities for which the license is granted between participants in the competition with equal assessment points; b) criteria for evaluating the required professional experience; c) the procedure followed in the case of equal points.

6. The entities listed under point 3 have the right to submit a complaint to the minister responsible for health within 10 days from the publication of the notice. The minister's order can be appealed to the court according to the provisions of the legislation in force for the adjudication of administrative disputes.

7. At the end of the deadline for submitting complaints and their examination and after the applicant declared winner has fulfilled within 30 days the fulfillment of the criteria related to the guarantee fund, the Agency submits the proposal for granting the license to the minister responsible for health.

Article 19

License approval

1. The Minister responsible for health, upon receipt of the proposal for the winning entity according to provisions of Article 18 of this law, approves the license within 3 months.

2. The order for the granting of the license determines the name of the subject, the development of the activity, the deadline, the area expressed in coordinates, a description of the activity licensed under this license, as well as the activities or processes that are allowed to be carried out by third parties for account of the license holder. The minister's order is published in the National Register of licensed entities.

3. If the minister does not express himself within 90 days from the presentation of the proposal by the Agency, then the request is considered rejected.

4. The subject is considered as the holder of the license for exercising the activity or activities, in meaning of this law, on the date of the minister's order for the licensed device.

Article 20

Changing license data

1. During the exercise of the activity, the license holder is obliged to notify the Agency of all changes and deviations from the previously planned measures in the business development plan, changes in the documentation submitted at the time of submitting the request for licensed equipment and the change of data related to the change of third parties or the termination of the agreement regarding the activities that will be exercised partially or completely by third parties.

2. The licensed subject addresses the Agency with a written information within 10 working days from the moment the change occurred, describing every fact and circumstance that has brought about changes or deviations from the planning.

3. The Agency gives or rejects the approval for these changes within 1 month from the complete submission of information, based on the documentation defined by the by-law by the Agency and proposes concrete measures to the minister responsible for health.

4. The minister responsible for health, upon receiving the Agency's proposal, if he finds that the changes are related to the activities defined in the license, approves the license changes, which are published in the same way as the license publication.

Article 21

Suspension and revocation of license

1. The minister responsible for health may suspend the license if the subject:

a) does not implement the legislation in force and the by-laws issued for the exercise of activities for which it is licensed;

b) violates the terms of the license; c) does not appear within the deadline for changing the license data.

2. The minister responsible for health decides to cancel the license if the subject:

a) repeatedly violates the terms of the license; b) repeatedly violates the legislation in force for exercising the activities for which he is licensed;

c) requests the cancellation of the license; ç) does not start the development of the activity within a period of 12 months from the approval of the license; d) obtained the license through fraud;

dh) is declared bankrupt and is not able to fulfill the obligations according to the conditions of this license;

e) upon termination of the legal entity, holder of the license.

3. The verification and ascertainment of violations, defined in points 1 and 2 of this article, is done by The Licensing Commission after listening to the explanations of the subject, holder of the license.

4. The minister responsible for health, with the proposal of the Licensing Commission, decides on the suspension or cancellation of the license.

5. Submission procedure, deadlines and consideration of the proposal for the suspension or repeal of licenses are approved with the instructions of the minister responsible for health.

6. The decision to suspend or revoke the license is taken regardless of the administrative and criminal sanctions that may be applied and is published in the same way as the publication of the license.

CHAPTER IV

DEVICE WITH PERMISSION FOR EXERCISE OF ACTIVITIES RELATED TO PRODUCTION OF INDUSTRIAL *CANNABIS*

Article 22

Permission to exercise the activity

1. The permit for the exercise of the activity of producing *cannabis* for industrial purposes, hereafter the "permit", allows the activity of importing seeds or seedlings or their reproduction for the purposes of use as seeds/seedlings, cultivation, production and processing, transportation, and export of by-products and final products of *cannabis* for industrial purposes.

2. The permit is granted for a period of 5 years, with the right of renewal, for areas not smaller than 1 hectare.

3. The format of the permit and the criteria for the activities included in it are approved by instruction of the minister responsible for agriculture.

4. The permit is approved by order of the minister responsible for agriculture, based on the selection procedures organized by the responsible structure in the ministry responsible for agriculture, and is published in the relevant register.

5. The activities included in this license cannot be transferred to third parties, except for those permitted in the permit description.

6. A copy of each approved permit and the practice, based on which the permit review and approval procedure was followed, is submitted to the Agency within 5 days from the issuing of the minister's order for permit approval.

Article 23

Licensed Device Terms

1. The request for the equipment with a production permit is submitted to the ministry responsible for agriculture and accompanied by the following documentation:

a) the registration document of the farmer, natural or legal person; b) the list of

personnel employed or subcontracted to manage the cultivation process, from i which is no less than 1 agronomist, accompanied by:

i. the certificate issued by the prosecution body proving that the subject is not under criminal prosecution; ii. the

certificate issued by the judicial body that proves that the subject is not under trial for any criminal offense; iii. the certificate of

judicial status that proves that the subject is not criminally convicted by a final court decision;

iv. the statement for granting the approval in order to carry out the control by the competent authorities of the purity of the image of the employees; c) self-declaration

about the source of financing the expenses;

ç) the self-declaration that there are no tax obligations towards the tax administration and local units; d) the self-

declaration for the conclusion of the preliminary agreement for storage and physical security, according to the rules and fees determined by the decision of the Council of Ministers;

dh) the preliminary sales agreement for the entity licensed to process the raw material, which will purchase it;

e) ownership documentation, copy of land registration card and indicative map or lease contract if the land is not owned by the requesting subject, located in the cadastral areas, approved for cultivation. If the land is not equipped with a final ownership document, the deed of taking ownership of the land and the survey plan are presented.

ë) self-declaration for payment of tracking system fees.

2. After the verification of the documentation by the responsible structure in the ministry responsible for agriculture, a copy of the practice is forwarded to the ministry responsible for order and public security, which within 10 days gives the assessment for approving or rejecting the request.

3. The responsible structure in the ministry responsible for agriculture after receiving the assessment from the ministry responsible for order and security, within 10 days submits a report to the minister responsible for agriculture for the equipment with permission or the rejection of the request.

4. The minister responsible for agriculture, upon receiving the report of the unit according to the provision of point 3 of this article, approves the permit. If the minister does not express himself within 30 days from the presentation of the report, the request is considered rejected.

5. The subject is considered as a permit holder, in the sense of this law, on the date of the minister's order for the equipment with permit.

6. The production permit is revoked if during the exercise of the activity it is established:

a) carrying out the activity contrary to the criteria of the law;

b) carrying out the activity contrary to the conditions of the permit;

c) non-payment of fees for the tracking and marking system; ç) violation of

other legal provisions related to the activity of the licensed subject.

7. During the phase of verifications carried out according to the provisions of point 6 of this article, the minister may to decide the suspension of the cultivation permit until the final decision is made.

HEAD V

DEVELOPMENT OF LICENSED OR PERMITTED ACTIVITIES

Article 24

Production unit

1. The activities specified in the license or permit, according to the provisions of this law, are carried out only in production facility environments with limited access and monitored.

2. The production unit is the area of land from 5 to 10 hectares, limited, which also includes warehouses and other premises dedicated only to the processes related to the cultivation of the cannabis plant and the production of by-products for purposes medical and the area not less than 1 hectare, which also includes warehouses and other premises dedicated only to the processes related to the cultivation of the cannabis plant and the production of by-products of the cannabis plant for industrial purposes.

3. The number, area and location of the production units are determined in order to detailed in the license or permit.

4. The license allows the production of up to 4 border production units. For unlimited units, the device with a separate license is required.

5. The capacity of the unit for processing and storage must correspond to its capacity for cultivation.

Article 25

Importation of seeds and seedlings of the cannabis plant

The import of seeds and seedlings of the cannabis plant is carried out by the entity equipped with a license or permit after the authorization given by the State Entity of Seeds and Saplings, according to the provisions of law no. 10 416, dated 7.4.2011, "On planting and plant propagation material".

Article 26

Planting the plant

1. The entity equipped with a license or permit for planting activity is allowed to plant only seeds and seedlings registered in the institution responsible for the registration of seeds and seedlings.

2. The entity equipped with a license to plant cannabis for medical purposes or a permit to cultivate cannabis for industrial purposes, not later than 10 days before the start of planting cannabis seeds, is obliged to notify The agency or regional unit of the ministry responsible for agriculture, asking them to be present in the planting process.

3. After the supervision of the planting process, in the presence of the subject's representative, the relevant minutes are kept, a copy of which is deposited with the Agency.

4. Data on the planting process are recorded in the relevant register.

Article 27

Plant harvesting supervision

1. The grower of the *cannabis plant,* no later than 15 days before the day of the start of harvesting the *cannabis plant,* is obliged to notify the Agency, requesting that the representative of this agency be present in the process of harvest. The agency notifies the responsible ministries according to the purpose of cultivation of the *cannabis plant.*

2. After the supervision of the collection process, in the presence of the subject's representative, the relevant minutes are kept, a copy of which is deposited with the Agency.

3. After the end of the process of harvesting *cannabis* for medical purposes, the Agency carries out checks on the quantities of the harvest carried out and of the material produced and records in the record the number of seedlings collected and the amount by weight of the wet mass.

4. Data on the harvesting process are recorded in the relevant register.

Article 28

Processing and raw material

1. The material produced by the *cannabis plant is* dried, cleaned, separated, packaged and labeled.

2. After the harvest is completed, the collected above-ground part of the *cannabis plant is* dried in a specially arranged space.

3. The *cannabis* grower keeps a special record in 3 copies for the quantity produced, in the presence of Agency employees. One copy is sent to the ministry responsible for public order and security, one copy is kept by the growing entity, while one copy is kept by the Agency.

4. The *cannabis* grower submits a report to the responsible structure of the ministry responsible for public order and security and the Agency for the completion of the process of production, cultivation and dry mass obtained within 10 days from the date of completion of the process.

5. Before the dry material is packed, the Agency performs quality control in certified and accredited laboratories according to the provisions of the relevant legislation for the accreditation of conformity assessment bodies. Method for quality control related to component content of cannabinoid and tetrahydrocannabinol, as well as physico-chemical and microbiological control for the way of packaging, form and quantity is determined by the instruction of the minister responsible for agriculture.

6. The packaging of the dry plant contains the following information:

a) the name and seat of the cultivating entity; b) the day, month and year of harvest and production; c) the name of the raw material;

ç) net and gross amount of dry mass; d) the shape of the plant, whether it is a leaf, flower, plant, whole or cut;

dh) packaging date and expiration date;

e) the unique identification mark.

Article 29

Products and by-products produced from the medical *cannabis* plant

1. Products and by-products intended for medical use, produced from the *cannabis* plant by the licensed producer, are subject to all the provisions provided for in the legislation in force on drugs and pharmaceutical services, the legislation on narcotic drugs and psychotropic substances and the legislation for cosmetic products before their release into circulation.

2. All by-products and products produced in the country according to point 1 are intended only for export, according to the provisions of this law.

Article 30

Transportation

Possession, movement, accompanying and transportation of seeds, seedlings, raw material, medical *cannabis* plant and its by-products from one country to another are done by the entity licensed for this activity, after notifying the Agency in advance. In any case, the transport is carried out by escorting a security and physical security company according to the contract with the licensed entity.

Article 31

Safety

The storage and security of the unit, transportation and trading are done by the entity that has concluded the contract of storage and security of the unit with the licensed entity.

Article 32

Export of by-products of the *cannabis* plant

1. The export of by-products or final products of the *cannabis plant is* carried out by the entity equipped with a license, according to the provisions of this law.

2. The export of by-products or final products of *cannabis* for medical purposes is done according to the legislation in force for drugs and the legislation for narcotic drugs and psychotropic substances and for cosmetic products.

3. The export of by-products or final products of *cannabis* for industrial purposes is done by the Agency according to the provisions of the joint instruction of the minister responsible for agriculture and the minister responsible for the economy.

4. The export of by-products or final products of the *cannabis* plant must be carried out with a special authorization for export, which contains the following data:

a) the name of the product, the international name of the owner, if any, the quantity to be exported;

b) the name and address of the importer and the exporter and must specify the period within to which the import or export must be carried out;

c) if the importer's country stipulates the obligation to be provided with an import certificate or other document analogous to this certificate, the number and date of the import certificate and the authority that issued it.

5. Before issuing the export authorization, in countries that provide for the obligation to be provided with an import certificate or other similar document, the Agency must request the subject to present an import certificate issued by the competent authorities of the importing country or territory.

CHAPTER VI

MARKING AND TRACKING

Article 33

TRANSMISSION

1. The Agency administers the National Register of permitted and licensed entities and supervises the placement of unique signs for identification and tracking at all stages of cultivation, production, marketing, supply, transport of the cannabis plant, by-products and final *products* until the end user according to the provisions of this law.

2. Licensed and permitted entities, according to the meaning of this law, have the obligation to dispose of data in this registry.

3. For the purposes of control and inspection of licensed and permitted activities in this register, the following have access:

a) the ministry responsible for health;

b) the ministry responsible for agriculture;

c) the ministry responsible for finance;

ç) the ministry responsible for order and security;

d) National Agency of Medicines and Medical Devices;

dh) institutions or entities permitted by order of the minister responsible for health.

Article 34

Marking and tracking

1. Marking is done through a unique sign in the form of a code, stamp, label or any other type of marking and is mandatory at all stages, including importation, cultivation, production, processing, storage, preservation of the medical and industrial cannabis plant , its by-products and final products, the export and use of by-products or final products of the medical and industrial *cannabis* plant in order to facilitate traceability.

2. Traceability is an identification method for the precise location of the medical and industrial *cannabis* plant , its by-products and final products at all stages from planting to final use, as well as its owner at all the stages. Tracking does not apply to industrial *cannabis* for trade to the end user.

3. All holders of a license, according to the provisions of this law, are obliged to mark the plant, seed, substance, preparation, product, which is the object of their activity, and to implement all legislation related to marking and tracking.

4. The cost of marking and tracking is borne by the entities licensed and permitted under this law. Fees and payment procedures are determined by the decision of the Council of Ministers, with the proposal of the minister responsible for finance, the minister responsible for health and the minister responsible for agriculture.

5. The requirements for traceability, as well as the rules for the unique marking elements, label or stamp or other forms of marking, the procedure and method of marking and tracing, as well as the authority or party authorized to carry out the marking and traceability are determined by decision of of the Council of Ministers, with the proposal of the minister responsible for health and the minister responsible for agriculture.

CHAPTER VII

Oversight

Article 35

Responsible bodies

1. For the inspection of the implementation of the provisions of this law, the Agency, the structures responsible for the registration of seeds and seedlings and the health of plants and the National Agency are charged

of Medicines and Medical Devices, according to the duties provided in this law and in accordance with their legal powers.

2. The agency coordinates the supervision process with other institutions.

Article 36

Supervision and control

1. Supervision of the implementation of the provisions of this law and the rules adopted on its basis in relation to the licensed activities is carried out by the Agency through its employees.

2. Fulfillment of obligations under the drug law is supervised and monitored by structure responsible for pharmaceutical inspection.

3. Fulfillment of obligations for the process of registration of seeds and seedlings and their control plant health is carried out by the responsible structures of the ministry responsible for agriculture.

4. Supervision during the process of disposal of the cannabis plant and its by-products or final products is done by the Agency in cooperation with the responsible structure of the ministry responsible for public order and security.

5. More detailed rules for supervision are determined by decision of the Council of Ministers, based on the general rules of the legislation in force for inspection.

Article 37

Taking samples and samples

1. Sampling is carried out through the Agency in cooperation with the responsible institutions for supervision, according to this law.

2. The minister responsible for health and the minister responsible for agriculture determine with a joint instruction the method, quantity of sampling and the laboratory for performing analyzes with accredited methods for quality control, inside or outside the country.

CHAPTER VIII

SEIZURE AND FORfeiture

Article 38

Confiscation of the medicinal cannabis plant, its by-products and final products

1. The cannabis plant for medical purposes, its by-products and final products are confiscated by order of the minister responsible for health, with the proposal of the Agency if it is established that:

a) are cultivated, processed, circulated or possessed by an unlicensed entity;

b) are not marked and traceable according to the provisions of this law.

2. The cannabis plant for medical purposes, its by-products and final products, confiscated according to this law, are subject, as far as it is applicable, to the regulation of the administration of confiscated drugs, according to the legislation in force on drugs and the service pharmaceutical.

3. The agency records in the register the type and quantity of the confiscated cannabis plant.

4. In the case of the confiscation of the cannabis plant, its by-products and final products, the Agency and state supervisory institutions have the obligation to notify the structures responsible for order and security, as well as to apply the relevant sanctions for all those actions that come contrary to the provisions of this law.

Article 39

Destruction of cultivated plants

1. Medical *cannabis* plants , regardless of the purpose of use, if they have germinated by themselves, as well as the remains of the medical *cannabis* plant on the surface of the earth, specified in the license or permit, are destroyed according to the manner and provisions of this law by the licensed or permitted entity, in the presence of the Agency's representative. For the performance of this process, the relevant minutes are kept according to the legislation in force.

2. If the subject does not fulfill the obligation of point 1, the destruction is carried out by the Agency with the expenses of the subject, against whom an administrative measure is taken for non-fulfillment of this obligation.

3. The entity authorized for the cultivation of industrial *cannabis* carries out the destruction of plants that are not used for trading purposes or of plant waste and reports to the Agency on the amount of plants destroyed.

4. The agency keeps a separate register for the type and quantity of the disposed *cannabis* plant.

5. The detailed method of disposal of self-grown plants and the remains of plants harvested or destroyed according to points 1, 2 and 3 of this article, is determined by a joint instruction of the minister responsible for health, the minister responsible for agriculture and the minister responsible for public order and security.

CHAPTER IX

sanctions

Article 40

Administrative offenses

1. The following violations, when they do not constitute a criminal offense, constitute an administrative misdemeanor and are punished

as follows: a) with a fine from 500,000 (five hundred thousand) to 1,000,000 (one million) lek if the subject licensed or permitted:

i. uses narcotic drugs and psychotropic substances contrary to the conditions established by this law; ii. advertises

directly or indirectly all activities related to the *cannabis* plant
it for medical purposes;

iii. performs sales in the territory of the Republic of Albania of the medical *cannabis* plant ,
its by-products or final products;

iv. does not apply the measures given by the Agency regarding the exercise of the licensed or permitted activity; c. hinders

the sampling process according to the provisions of Article 37 of this law; vi. exceeds the deadline set

for the collection of the produced quantities of the obtained dry mass
cannabis for medical purposes;

vii. does not fulfill the obligations regarding the notification of the ministry responsible for public order and security, the ministry responsible for agriculture and the ministry responsible for health of any situation indicating suspicion that cannabis or parts of *its* plants have been used or may be are used for the production of narcotic and psychotropic substances;

viii. does not fulfill the obligations related to keeping the register for the amount of *cannabis* produced and purchased for medical and/or industrial purposes or does not submit the report within the legal deadlines to the supervisory authorities;

b) with a fine from 1,000,000 (one million) to 3,000,000 (three million) ALL if the subject licensed or permitted:

i. does not apply the conditions related to the transport of the *cannabis* plant for medicinal purposes during transport or the conditions for the storage of the original packaging;

ii. does not comply with the rules regarding the processing and production development plan; iii. does not comply with the rules regarding the security plan, including the definition of its elements protection, fencing, camera security and physical security;

iv. does not respect the rules regarding marking or tracking.

c) with a fine from 3,000,000 (three million) to 5,000,000 (five million) ALL if the subject licensed or permitted:

i. hides or falsifies documents by planting and managing larger areas with medical or industrial *cannabis* or when the registration of the areas has not been completed within the stipulated period; ii. does not declare the areas on which it cultivates *cannabis* for medicinal purposes and/or *cannabis* for industrial purposes;

iii. exports by-products or final products in quantities other than those declared, according to the provisions of this law;

iv. falsely reports the data, for the purpose of completing the registers, provided for in this law;

c. performs processes for which it is not licensed, permitted or authorized;

vi. continues the activity even after the expiration of the license or permit;

vii. impedes, avoids surveillance or verification in relation to marking and tracking;

viii. cultivates, produces, processes, supplies, trades, keeps, transports unmarked plants, seeds, narcotic or psychotropic products according to the provisions made in Article 34 for marking and tracking.

2. In addition to the fine provided for in point 1 of this article, the legal person may also be sanctioned with a temporary ban on carrying out the activity for a period from 6 months to 3 years.

3. Administrative offenses, according to the provisions of this law, are ascertained and sanctioned by the Agency.

4. In the conditions of finding violations of the Criminal Code, the Agency reports, in accordance with the provisions of the Criminal Code, to the relevant authorities according to the provisions of the Code of Criminal Procedure.

5. Revenues from fines are paid 100% to the state budget.

Article 41

complaint

Regarding the administrative measures taken by the Agency, as well as any other administrative action carried out in violation of the Code of Administrative Procedures and this law, the subjects can submit an appeal to the Administrative Court of First Instance in Tirana within 45 days of being informed.

CHAPTER X

TRANSITIONAL AND FINAL PROVISIONS

Article 42

Transitional provisions

1. Entities, which at the time of entry into force of this law, exercise the activity of cultivation and production of cannabis for industrial purposes, according to the legislation in force on narcotic drugs and psychotropic substances within 8 months from the entry into force of this law, have the right to adapt the allowed activity to be equipped with a permit, in accordance with the provisions of this law.

2. Exercising the activity by the entities defined in point 1, without obtaining a permit according to provisions of this law, after this period is considered illegal.

3. The National Cannabis Control Agency is established within 3 months from the entry into force of this law.

Article 43

Bylaws

1. The Council of Ministers is instructed to approve by-laws in implementation of articles 7 point 3 within 9 months from the entry into force of this law; 9, item 2; 13, item 6; 15, item 2; 23, item 1; 34, points 4 and 5, and 36, point 5.

2. The minister responsible for health shall be appointed within 3 months from the entry into force of this the law to issue by-laws in implementation of articles 11, point 8, and 14, point 2.

3. The minister responsible for agriculture is instructed to issue the by-law in implementation of article 9, point 3 within 3 months from the entry into force of this law.

4. Ministers are charged according to their area of responsibility to issue by-laws in implementation of articles 6, point 4 within 9 months from the entry into force of this law; 8, item 8; 14, point 9; 32, point 3; 37, point 2, and 39, point 5.

Article 44

repeal

With the entry into force of this law, the provisions of law no. 7975, dated 26.7.1995, "On narcotic drugs and psychotropic substances", as amended, and other legal and by-laws, which contradict the provisions of this law, are repealed.

Article 45

Entry into force

This law enters into force 15 days after its publication in the Official Gazette.

SPEAKER

NIKOLA was born

Approved on 20.7.2023