



**REPUBLIC OF ALBANIA
COUNCIL OF MINISTERS
DRAFT DECISION**

No.748, dated 2.10.2026

**“ON THE DETERMINATION OF DETAILED RULES FOR THE SUPERVISION OF
LICENSED AND AUTHORIZED ACTIVITIES OF THE CANNABIS PLANT AND THE
PRODUCTION OF ITS BY-PRODUCTS FOR MEDICAL AND INDUSTRIAL
PURPOSES”**

Pursuant to Article 100 of the Constitution and point 5 of article 36 of Law No. 61/2023, “On the control of the cultivation and processing of the cannabis plant and the production of its byproducts for medical and industrial purposes”, upon the proposal of the Minister of Health and Social Welfare, the Minister of Agriculture and Rural Development, and the Minister of the Interior, the Council of Ministers,

HAS DECIDED:

CHAPTER I

GENERAL PROVISIONS

Article 1

Purpose

This decision establishes the detailed rules for the supervision, control and inspection of licensed or authorized entities, as well as of the activities carried out by them in the field of the import, cultivation, processing, production, storage, safekeeping, transportation, circulation, export, seizure, confiscation and destruction of the cannabis plant, as well as of its by-products and products for medical or industrial purposes, pursuant to Law No. 61/2023, “On the control of the cultivation and processing of the cannabis plant and the production of its by-products for medical and industrial purposes” (hereinafter referred to as “Law No. 61/2023”).

Article 2

Purpose

The purpose of this decision is:

- a) to ensure the implementation of Law No. 61/2023 and the bylaws issued pursuant thereto;
- b) to ensure compliance with and continued maintenance of the conditions of the license or permit by each entity;
- c) to prevent, record and address violations of the legal provisions in force;
- ç) to enable the application of the measures and sanctions provided for under Law No. 61/2023 in the event of violations of the conditions of the license or permit;
- d) to ensure public safety, public health, full traceability of the material and the integrity of the lawful market;
- dh) to ensure continuous, effective and risk-based supervision of licensed or authorized entities, as well as of all stages of their activities;
- e) to ensure clear standards for safeguarding public safety, public health, the rule of law and full traceability of the material throughout the entire cycle of activities provided by law;
- ë) to ensure the coordination of the activities of the responsible state institutions (hereinafter referred to as the competent authorities), avoiding overlapping controls and increasing transparency in the exercise of their powers;
- f) to ensure the immediate recording and handling of critical incidents, material discrepancies and deviations from the conditions of the permit or license, in accordance with the legislation in force.

Article 3

Scope of Application

1. This decision shall apply to:
 - a) all stages of the activities of licensed or authorized entities, including the import of seeds, seedlings, clones and mother plants; cultivation, harvesting, drying, processing, production, packaging, labelling, storage, safekeeping, transportation, circulation, export, seizure, confiscation and destruction of cannabis for medical or industrial purposes, as well as of the respective by-products and final products;
 - b) the Agency and other competent public authorities exercising supervisory, control or inspection functions pursuant to Law No. 61/2023 and the sector-specific legislation in force, according to the scope of activity of each respective institution.
2. The provisions of this decision shall also apply to other ancillary or supporting activities related to licensed and authorized entities, as expressly provided for in Law No. 61/2023 and the bylaws issued pursuant thereto.

3. The Agency shall authorize and coordinate, in accordance with Law No. 61/2023, the conduct of controls or inspections by other competent authorities at licensed or authorized entities, without prejudice to the powers exercised by such authorities under their respective legislation.

Article 4 **Definitions**

For the purposes of this decision, the following terms shall have the following meanings:

- a) “Agency” means the National Cannabis Control Agency, established pursuant to Law No. 61/2023;
- b) “Critical incident” means any event or circumstance that compromises or is likely to compromise public safety, public health, the integrity of the traceability system, the lawfulness of the activity or the safeguarding of the material, including loss, theft, diversion, unauthorized access, data manipulation, failure of security systems, or material discrepancies between the actual situation and official records;
- c) “Inspection” means the procedure for conducting checks on-site or remotely, carried out by authorized employees, in accordance with the legislation in force;
- ç) “Quarantine” means the temporary status of physical and administrative isolation of a plot, material or lot, until the completion of the relevant verifications, analyses or decisionmaking;
- d) “Control” means the administrative, documentary, technical, physical or electronic verification of elements of the entity’s activity, with the purpose of establishing compliance or non-compliance with the legislation in force;
- dh) “Combined control” means a control that combines on-site physical verification with remote supervision;
- e) “Lot” means an identifiable quantity of material, plant, by-product or product, associated with a specific origin, stage, plot, premises or process, which is subject to separate registration and traceability;
- ë) “Non-conforming material” means any material, by-product or product that does not comply with the legal requirements, the conditions of the permit or license, the applicable technical standards, the required analytical results, or the data recorded in the System and Register;
- f) “Supervision” means the continuous administrative, technical and operational activity carried out by the Agency, independently or in coordination with other competent authorities, for the purpose of verifying compliance with the conditions of the permit or license and the legal requirements at every stage of the activity;
- g) “Remote supervision” means a form of supervision carried out through technological means, including electronic systems, cameras, sensors, unmanned aerial vehicles, satellite imagery and other approved means, in accordance with the legislation in force;

- gj) “Stage-based supervision” means supervision carried out in a differentiated manner according to the stages of the activity, including, as applicable, import, cultivation, harvesting, processing, production, storage, transportation, export and destruction;
- h) “Material change” means any change to essential elements of the entity or its activity that may affect the validity or conditions of the permit or license, including a change in beneficial ownership, administrator, technical director, security plan, infrastructure, critical contracts, traceability system or standard operating procedures;
- i) “Register” means the National Register of licensed and authorized activity involving the cannabis plant, as provided for under Law No. 61/2023;
- j) “Seizure” means the administrative measure of taking material under the control and custody of the competent authority where reasonable grounds exist to ensure the preservation of evidence, the lawfulness of the procedure and the prevention of the further use or diversion of the material;
- k) “System” means the traceability system that ensures tracking in accordance with the provisions of Law No. 61/2023 and the bylaws in force;
- l) “Chain of custody and traceability” means the uninterrupted documentation of the identity, location, status, movement, storage, sampling, analysis, transfer, seizure, confiscation or destruction of the material.

Other terms used in this decision shall have the meaning assigned to them by Law No. 61/2023 and the sector-specific legislation in force.

CHAPTER II

SUPERVISION SYSTEM

Article 5

Continuous Supervision and Planning of Controls and Inspections

1. Supervision shall be carried out by the Agency on a continuous basis, according to the stages and processes of the activity, based on risk analysis, the data administered in the Register and System, the entity’s periodic reports, critical incidents and its compliance history.
2. Controls and inspections shall be planned and carried out based on risk analysis and the annual program approved by the Agency.
3. In addition to scheduled controls and inspections, the Agency and as applicable, other competent authorities, shall carry out controls or inspections outside the program in cases where:

- a) there are indications or reasonable grounds for suspicion, or violations are identified;
 - b) a request is submitted by judicial bodies or other competent authorities;
 - c) a discrepancy is identified between the actual situation and the data in the Register or System;
 - ç) the entity fails to fulfil its reporting obligations or submits incomplete or inaccurate data;
 - d) a critical incident or failure of security, traceability or monitoring systems is identified;
 - dh) continuous verification of processes according to the stages of the activity provided for under Law No. 61/2023 is required.
4. Supervision, control and inspection shall be carried out, according to the nature of the relevant stage or process and within the limits of the powers established by law, as follows:
- a) supervision shall be carried out continuously, pursuant to Law No. 61/2023 and the sector specific legislation in force;
 - b) control and inspection shall be carried out pursuant to Law No. 61/2023, the sector specific legislation in force and the legislation on inspection.
5. Supervision, control and inspection shall be carried out in the following ways:
- a) on-site, through direct verification at the production unit, other premises related to the entity's activity, means of transport, or any other location where the licensed or authorized activity is carried out;
 - b) jointly between institutions;
 - c) remotely, through the System, Register, monitoring cameras, sensors, unmanned aerial vehicles, satellite imagery, digital platforms and other authorized technological means;
 - ç) in combination, by combining physical presence on-site with remote control or verification.

Article 6

Control and Inspection Program Procedure

1. The Agency shall prepare and approve the annual control and inspection program for licensed or authorized entities, based on risk analysis and the need for stage-based supervision of the activity.
2. The annual program shall be prepared taking into consideration:
 - a) the risk profile of each entity;
 - b) the information and documentation administered by the Agency;
 - c) the data contained in the Register and System;
 - ç) the periodic reports and critical incidents notified by the entity;
 - d) findings, corrective measures, violations and the entity's previous compliance history;
 - dh) information received from other public authorities, foreign counterpart authorities or international organizations;
 - e) the need for joint inter-institutional controls or inspections.

3. Entities shall be subject to controls and inspections in accordance with the approved program and shall be subject to continuous supervision according to the stages and processes of their activity.
4. Controls and inspections outside the program shall be authorized by the Agency, on its own initiative or based on a reasoned request from other competent authorities.
5. Controls and inspections outside the program shall be authorized, in particular, where:
 - a) there are indications or reasonable grounds for suspicion of violations;
 - b) a violation is identified during remote control or the need for on-site verification arises;
 - c) the entity fails to fulfil its reporting obligations, submits incomplete information, or reasonable grounds arise to question its accuracy;
 - ç) information made available by domestic or foreign authorities gives rise to reasonable grounds for suspicion of violations;
 - d) verification of the implementation of measures or tasks assigned during previous controls is required;
 - dh) a reasoned request is submitted by the minister responsible for health or the minister responsible for agriculture, or by the Commission;
 - e) a critical incident or a risk to public safety, public health or the integrity of the traceability system is identified.

Article 7

Authorized Employees

1. Supervision, control and inspection shall be carried out by the authorized employees of the Agency. Where a control or inspection is carried out in cooperation with other competent authorities, it shall also be carried out by the authorized employees of those authorities, in coordination with the Agency.
2. The replacement of an authorized employee shall be made by a specific order of the respective head of the institution and, where the control or inspection is scheduled, the entity shall be notified thereof before the commencement of the activities by the new employee.
3. Before the commencement of the supervision, control and inspection procedure at the production unit, each authorized employee shall identify themselves by presenting the official identification document of the institution.
4. Upon completion of the procedure, the authorized employees shall prepare the relevant procedural documentation and shall bear individual responsibility for the actions carried out and the decisions taken by them during the process.
5. Authorized employees shall perform their duties impartially, avoid conflicts of interest and maintain confidentiality of information, in accordance with the legislation in force.

Article 8

Rights of the Entity

The entity shall enjoy the rights provided for under the legislation in force on inspection and, in particular, shall have the right:

- a) to be informed in advance of the authorization for supervision, control or inspection, except in cases of unplanned inspection or where otherwise provided for by the legislation in force;
- b) to request the identification of the authorized employees by means of their official identification document;
- c) to receive information on the subject matter, purpose, legal basis and procedure of the supervision, control and inspection;
- ç) to be present during the conduct of supervision, control and inspection activities, personally or through its legal representative or an authorized representative;
- d) to submit explanations, documents, evidence and objections concerning the facts, circumstances and findings identified;
- dh) to be informed of the official record and other acts issued during the procedure, as well as to receive copies thereof, in accordance with the legislation in force;
- e) to request the protection of the confidentiality of commercial, technical and financial data, in accordance with the legislation in force;
- ë) to submit objections to the results of the control and inspection within the time limits prescribed by the legislation in force;
- f) to request retesting of a sample where provided by this decision;
- g) to appeal against decisions of the competent authority, in accordance with the procedures and time limits provided for under Law No. 61/2023 and the legislation in force.

Article 9

Obligations of the Entity

The entity shall be obliged to:

- a) cooperate and not obstruct the conduct of the supervision, control and inspection procedure;
- b) provide the information, documentation, records and explanations requested by the authorized employees;
- c) ensure full and immediate access to the premises, equipment, materials, means of transport, documentation and electronic systems related to the licensed or authorized activity;
- ç) not manipulate, conceal, move, replace or alter documents, data, samples, evidence, materials or records;
- d) keep internal documents up to date and accessible, including emergency plans, risk assessments, security plans, standard operating procedures and relevant records;
- dh) make available to the Agency and, as applicable, to the State Police a 24/7 contact number for the administrator, technical director or person responsible;

- e) make available specialized technical personnel where required for the verification of equipment, technological processes or electronic systems;
- ë) ensure the preservation of evidence, samples and material subject to control, in accordance with the instructions of the authorized employees, until completion of the procedure;
- f) provide personal protective equipment for the authorized employees and inform them of the risks present in the workplace;
- g) provide separate and access-restricted premises for the storage of materials temporarily blocked, seized, confiscated or intended for destruction;
- gj) implement corrective measures within the prescribed time limits and report on their implementation in the Register and System;
- h) immediately notify the Agency and, as applicable, the competent authorities of any critical incident, any breach of physical security or of the traceability system, as well as any circumstance giving rise to reasonable grounds for suspicion that the cannabis plant, its byproducts or products have been used or may be used for the production of narcotic or psychotropic substances.

Article 10

Right of Entry, Control and Inspection at the Production Unit

1. Authorized employees have the right of entry, control and inspection at the production unit, in means of transport and on any other premises related to the entity's activity, in accordance with Law No. 61/2023, Law No. 99/2024 and this decision.
2. For the purpose of verifying compliance with legal requirements, authorized employees have the right, in particular, to:
 - a) access and verify data in the Register and System, the entity's internal electronic platforms, as well as records from security systems and cameras;
 - b) carry out the necessary measurements, photographs, filming and recordings;
 - c) take samples in accordance with the procedures established by this decision;
 - ç) require the provision of specialized technical personnel where necessary for the verification of equipment, technological processes or electronic systems.
3. In the event of obstruction, entry for the purpose of conducting supervision, control and inspection shall be carried out with the assistance of the State Police, at the request of the Agency, in accordance with the legislation in force.
4. All procedural actions carried out during the control or inspection shall be recorded in the relevant official record and uploaded to the Register.

Article 11

Preparation and Notification of the Official Record

1. Upon completion of each supervision, control or inspection activity, the authorized employees shall prepare the relevant official record, which shall contain at least the following information:
 - a) the date, time and place where the activities were carried out;
 - b) the identity of the authorized employees and the persons present;
 - c) the subject matter and legal basis of the control or inspection;
 - ç) the actions carried out and the documentation reviewed;
 - d) the factual findings and discrepancies identified; dh) the samples taken and the materials blocked, seized or placed in quarantine, as applicable;
 - e) the statements, explanations and objections of the entity;
 - ë) the measures imposed, the time limits and the respective obligations, where applicable.
2. The official record shall be signed by the authorized employees and by the legal representative of the entity or an authorized representative thereof, where present.
3. In the event of refusal by the entity or its representative to sign, this fact shall be recorded in the official record, without affecting its validity.
4. The official record shall be uploaded to the Register and notified to the entity within 2 (two) working days from the completion of the relevant activities.
5. In the case of remote supervision, the official record shall be prepared by the authorized employee and officially notified to the entity through the Register or by other official means of communication.
6. The entity shall have the right to submit written explanations or objections concerning the findings recorded in the official record within 8 (eight) working days from the date of its notification.

CHAPTER III

STAGE-BASED SUPERVISION

SECTION I PRELIMINARY SUPERVISION

Article 12

Verification of the Conditions of the Permit and License

1. The Agency, through its authorized employees, shall verify compliance with the conditions of the permit and license:
 - a) prior to the commencement of the entity's operational activity, with regard to the essential conditions related to security, infrastructure, traceability and the organization of the activity;
 - b) during the conduct of the activity, periodically and whenever the need for reassessment arises;

- c) following any material change notified by the entity or identified by the Agency.
- 2. The verification process shall include the review of the relevant documentation and the key elements of the entity's infrastructure and operations, as follows:
 - a) the site layout and compliance of the facility's infrastructure with the approved documentation;
 - b) the physical security scheme and elements of the facility;
 - c) agreements with the structures responsible for public order and public security, as applicable;
 - ç) the contract with the Private Physical Security Company (SHPSF), where required;
 - d) the contract with the entity responsible for carrying out destruction procedures, where required; dh) contracts with other third-party entities directly related to the conduct of the activity; e) the agreement or documentation for the use of the traceability system;
 - ë) the personnel engaged, including the list of employees, employment contracts and documentation concerning their qualifications; f) staff training plans;
 - g) standard operating procedures (SOPs) for each stage of the activity.
- 3. The entity shall be obliged to notify the Agency in writing of any material change within 10 (ten) working days from the date on which the change occurred, describing the facts and circumstances that caused it, in accordance with point 2 of Article 20 of Law No. 61/2023.
- 4. Where the verification establishes that the entity has not fully complied with the specified conditions, the Agency shall set a time limit for their fulfilment and notify the entity of the obligations and corrective measures to be undertaken.
- 5. Where it is established that the entity does not comply with the essential conditions of the permit or license or fails to implement the corrective measures within the prescribed time limit, the Agency shall propose the suspension or revocation of the permit or license, in accordance with the legislation in force.
- 6. The results of the verification shall be documented in the relevant official record and uploaded to the Register.
- 7. The Agency shall reassess the conditions of the license and permit periodically, at least once every 3 (three) years, as well as whenever necessary due to material changes, control findings or critical incidents.
- 8. The entity shall be obliged to submit to the Agency the periodic reports, information and documentation required for the supervision of compliance with the conditions of the permit or license, within the time limits and in the formats and in accordance with the requirements established by the legislation in force and by the acts issued by the Agency pursuant thereto.

SECTION II

IMPORT OF SEEDS, SEEDLINGS, CLONES OR MOTHER PLANTS

Article 13

Import Procedures and Supervision

1. The procedure for the import of seeds, seedlings, clones and mother plants shall be carried out in the following stages:
 - a) authorization of the import;
 - b) prior notification of the competent institutions;
 - c) control at customs point;
 - ç) post-import verification at the production unit.
2. About the prior notification stage:
 - a) the entity shall notify the authority responsible within the ministry responsible for agriculture at least 15 (fifteen) working days prior to the arrival of the consignment;
 - b) the notification shall be accompanied, as applicable, by the relevant documentation, including the phytosanitary certificate, the contract or agreement with the foreign entity, and the documents or labels for the plant propagation material registered in the European Union Common Catalogue;
 - c) the entity shall notify the customs authority no later than 24 (twenty-four) hours prior to the arrival of the consignment.
3. Regarding the control stage at the customs point:
 - a) the customs authority shall verify the conformity of the quantity, value and tariff code with the documentation declared pursuant to the permit or license, as well as the physical presence of the consignment;
 - b) the authority responsible within the ministry responsible for agriculture shall carry out the relevant control, verifying the origin, health status and accompanying documentation of the imported material.
4. Upon completion of the import procedures, the Agency shall supervise, control and inspect the entity at the production unit for the purpose of verifying the conformity of the imported consignment with the relevant authorizations and compliance with the conditions of the permit or license.
5. In the event of a discrepancy, missing documentation or a breach of traceability, the Agency shall impose the relevant measures pursuant to Article 40 of Law No. 61/2023 and, in the event of concerns regarding the health status of the imported material, shall report the matter to the authority responsible within the ministry responsible for agriculture.

SECTION III

CULTIVATION

Article 14

Supervision, control, and inspection according to cultivation stages

1. The Agency shall exercise supervision, control and inspection over the cultivation activity of the cannabis plant for medical and industrial purposes at all its stages, ensuring compliance with legal requirements, traceability of the process, compliance with the conditions of the permit or license, and the integrity of the data recorded in the Register and System. For this purpose, the authorized employees of the Agency shall:
 - a) verify that the cultivation of the cannabis plant is carried out only on areas previously approved by the competent authorities, in accordance with the conditions of the permit or license;
 - b) supervise all stages of the cultivation of the cannabis plant, including planting, the vegetative stage and the flowering stage, for the purpose of verifying compliance with EU-GACP standards and the approved SOPs for each variety and cultivation stage, in accordance with the legal framework in force;
 - c) supervise the process of planting seeds, seedlings, clones and mother plants, in accordance with the notification submitted by the entity, verifying that the materials used are authorized, registered and accompanied by the relevant documentation, and that they have been recorded in the System and Register prior to their use;
 - ç) verify the marking, identification and traceability of plants, plots, cultivation areas and movements of material at each stage of cultivation;
 - d) verify, during the vegetative stage, the development of plants in accordance with the approved SOPs for each variety, as well as compliance between the actual situation and the recorded data;
 - dh) verify, during the flowering stage, the compliance of the cultivated varieties, environmental conditions, compliance with the technical and legal requirements relating to the quality and safety of production and, where necessary, take samples for the relevant analyses;
 - e) supervise the implementation of security standards in accordance with the approved security plan, as well as monitor the activity in real time through the System and visual monitoring means (CCTV);
 - ë) carry out periodic and unannounced inspections, as well as combined controls that combine physical presence on-site with remote monitoring, for the purpose of verifying the compliance of the activity with the conditions of the permit or license;
 - f) verify the recording and updating of data for each cultivation stage in the Register and System;
 - g) verify the existence of separate premises, as well as a quarantine area for the temporary storage of materials (waste, samples for analysis and seized materials), for the purpose of preventing microbial contamination.
2. The institution responsible for plant health shall carry out periodic inspections, monitoring and supervision for the identification of pests in cannabis crops and the use of plant protection products (PPPs), in cooperation with the Agency.

3. The State Police shall control the private physical security companies contracted by the entity for the protection of the cultivation premises of the cannabis plant and the processing premises for its by-products and products, as well as the vehicles dedicated to the transportation of by-products and products.
4. Findings related to the cultivation of unmarked, undeclared, unjustified, or unlicensed material are documented in the official record and handled in accordance with specific rules regarding seizure, confiscation, and destruction.

SECTION IV

HARVESTING, DRYING AND PROCESSING

Article 15

Control of Harvesting and Formation of the Lot

1. The Agency shall supervise and verify the harvesting process through the System, Register, visual monitoring means and, where necessary, on-site.
2. The entity shall notify the Agency of the scheduled harvesting date no later than 15 (fifteen) days prior to its commencement.
3. Upon receipt of the notification, the Agency shall carry out the relevant verifications and, as applicable, notify the other competent authorities.
4. The authorized employees shall verify that:
 - a) harvesting is carried out in accordance with the notification and the declared time limits;
 - b) the harvested material corresponds to the data recorded for the plot, stage, quantity and relevant identifiers;
 - c) during the period from harvesting until the formation of the lot, no unauthorized movement or transfer of the harvested material takes place;
 - ç) organic waste and unusable materials are handled in accordance with the legislation in force.
5. Upon completion of harvesting, the entity shall immediately record in the System and Register the quantity of harvested material and the formation of the relevant lot.
6. The lot formed following harvesting may not proceed to the drying, processing, production, sale or export stage unless it has been registered and, where required, has undergone the relevant verifications or analyses.
7. In the event of discrepancy, the Agency shall impose the relevant measures pursuant to Article 40 of Law No. 61/2023.

Article 16

Supervision, Control and Inspection of Drying and Processing Processes

During the supervision of the drying and processing stage, the authorized employees of the Agency shall verify, in particular, that:

- a) the drying and processing of the cannabis plant are carried out in premises specifically designated and approved for this purpose, under controlled environmental conditions, in separate areas and in accordance with the relevant SOPs;
- b) the entity has recorded every movement of the material from the commencement of the drying process until the completion of processing;
- c) the material entering the drying and processing stage is identified according to the relevant lot and has been recorded in the System and Register;
- ç) environmental conditions, such as temperature, humidity and air circulation, are monitored and documented in the relevant records;
- d) the calibration of recording equipment and its maintenance are documented and carried out in accordance with the approved procedures;
- dh) hygiene measures are implemented during the drying and processing processes to prevent microbial, physical and chemical contamination, and the rules governing entry into and exit from controlled areas are complied with;
- e) remote monitoring through the System, Register and camera system are used to verify every movement of the raw material from the commencement of the drying process until the completion of the processing process;
- ë) any deviation, loss, damage, contamination or discrepancy during the drying and processing stage is documented, reported and handled in accordance with the legislation in force.

SECTION V

PRODUCTION OF BY-PRODUCTS AND PRODUCTS, THEIR STORAGE AND SAFEKEEPING

Article 17

Supervision and Control of Compliance with Standards for Quality, Form, Packaging and Labelling

1. Supervision of compliance with quality standards throughout the entire production cycle, from the cultivation of the cannabis plant to the production of its by-products and final products, including the criteria for form, packaging and labelling, shall be carried out by the authorized employees of the Agency.
2. In exercising their functions, the authorized employees of the Agency shall verify that:

- a) the entity has a functional quality control system and the relevant technical documentation;
 - b) laboratory testing is carried out in accordance with the legal requirements and applicable standards;
 - c) analytical results, certificates of analysis and supporting documentation are retained and made available for verification;
 - ç) corrective and preventive actions are documented and implemented in accordance with the approved procedures;
 - d) packaging premises, materials used and storage conditions comply with the applicable standards; dh) labelling and packaging comply with the legal and technical requirements in force; e) the real-time recording in the System of data relating to the processing, formulation, packaging, movement and storage of the material corresponds to the actual situation.
3. Any lot intended for circulation, sale or export shall proceed to the subsequent stage only after completion of the relevant analyses and verification of its compliance with the legal and technical requirements.
 4. Violations identified in relation to the standards for quality, form, packaging and labelling shall be documented in the official record and handled in accordance with the procedures provided for under the legislation in force.
 5. Where the violations concern specific sectoral legislation on medicinal products, pharmaceutical services, cosmetic products, food or feed, the Agency shall refer the matter to the competent authorities for the adoption of the relevant measures.

Article 18

Supervision, Control and Inspection of Storage and Safekeeping Premises

1. The authorized employees of the Agency shall carry out inspections and controls in warehouse areas to verify:
 - a) the compliance of the warehouse capacity with the relevant layout;
 - b) the clear separation of premises and stored materials according to their status, identification, lot and intended purpose, including:
 - i. raw materials; ii. materials placed in the quarantine area, with restricted access; iii. by-products and final products; iv. waste generated during the cultivation, processing and production processes; v. expired or damaged materials; vi. materials intended for destruction;
 - vii. areas dedicated to the storage of equipment and auxiliary materials;
 - c) the compliance of the labelling of each package with the legislation in force;
 - ç) the recording of every entry, exit, movement, transfer, quarantine, reclassification or change in the status of the material in the System and Register;

d) the recording and documentation of storage condition parameters for each category of material, in accordance with the approved SOPs and EU-GACP and EU-GMP standards, including temperature, humidity, ventilation, lighting and measures to prevent contamination, damage or loss of quality; dh) the functionality and maintenance of security elements in each premises, including access

control, surveillance systems, alarm systems and the security of loading and unloading points;

e) the availability of the necessary and appropriate means and equipment for storage;

ë) the organization of the premises in a manner that ensures the accurate identification of materials and prevents cross-contamination, mixing, diversion or unauthorized access.

2. Supervision of storage and safekeeping shall be carried out through on-site control and remote monitoring of the Register, System and security cameras, in order to ensure that the movements of products and their status are fully reflected and correspond to the actual situation in the warehouse.

SECTION VI SAMPLING, ANALYSIS AND RETESTING

Article 19

Sampling for Testing by an Authorized Employee of the Agency

1. The Agency, through its authorized employees, shall have the right to take samples for testing of the cannabis plant, its by-products and products, at any stage of the activity, where necessary to verify compliance with the legislation in force.
2. Sampling shall, as a rule, be carried out in the presence of the legal representative of the entity or an authorized representative thereof and shall be documented in the official record.
3. The authorized employee shall ensure that the sample:
 - a) is taken in accordance with the applicable methodology and standards;
 - b) is identifiable, traceable and protected against contamination, loss or replacement;
 - c) is divided into portions in accordance with the requirements of the testing, retesting and reserve storage procedure;
 - ç) is transported and stored under conditions that guarantee its integrity and quality. The sampling, division, storage, transportation and handling of samples shall be carried out in accordance with the relevant sampling guidelines and the approved procedures.
4. From the moment the sample is taken, the lot from which it was taken shall be placed in quarantine where required by this decision or by the nature of the analysis to be carried out.
5. Where the sample is taken during the vegetative or flowering stage, the Agency may order the isolation of the relevant plot or area until the final results are issued.
6. Reserve samples shall be stored at the Agency's designated premises or in accordance with the procedures approved for this purpose.
7. The results of the analysis shall be uploaded to the Register and notified to the entity, while ensuring its right to retesting in accordance with this decision.

Article 20

Measures following the receipt of test results

1. Where the analysis results comply with the requirements of the legislation in force, the Agency shall remove the quarantine status of the relevant lot or plot and allow the continuation of the subsequent processes.
2. Where the analysis results do not comply with the requirements of the legislation in force, the relevant lot or plot shall remain in quarantine until a final decision is taken in accordance with this decision.
3. Regarding the total THC level of cannabis for industrial purposes, the lot shall be considered non-conforming where the measured value, assessed together with the upper limit of measurement uncertainty, exceeds the maximum permitted limit of 0.8% pursuant to Law No. 61/2023.
4. In the event of a non-conforming result, the entity may submit one of the following requests:
 - a) retesting;
 - b) correction of the parameters that deviate from the requirements, where technically feasible and permitted;
 - c) change of the intended use of the lot, where permitted by the legislation in force and where this does not compromise user safety; otherwise, the procedure for the destruction of the lot shall proceed.
5. A non-conforming lot shall not be permitted to be placed into circulation, sold, exported or used at another stage of the activity until completion of the procedures provided for under this decision.
6. If the entity does not submit a request pursuant to point 4 of this Article within the time limits established in the guideline approved pursuant to point 5 of Article 28 of Law No. 61/2023, the Agency shall order the continuation of the relevant procedure in accordance with the legislation in force.
7. Any decision taken pursuant to this Article shall be documented in the official record and uploaded to the Register.

Article 21

Retesting Samples

1. The entity shall have the right to request retesting of the sample within 2 (two) working days from receipt of notification of the analysis result. The request shall be submitted through the Register and by official letter addressed to the Agency.
2. The Agency shall review the request for retesting and decide whether to accept or reject it within 5 (five) working days from receipt of the request. In the event of rejection, the entity shall be notified to proceed with the relevant measures in accordance with this decision. In

the event of acceptance, the retesting shall be carried out by the laboratory that conducted the initial analysis, using the reserve sample stored in accordance with the approved procedure and under the same analytical conditions. Retesting and final analysis shall be carried out in accordance with the relevant guidelines and the list of laboratories approved pursuant to the legislation in force. An appeal against the rejection of a request for retesting shall be submitted by the licensed or authorized entity pursuant to the Code of Administrative Procedures.

3. Where the retesting confirms the initial result, the lot shall be handled in accordance with one of the provisions under letters (b) or (c) of point 4 of Article 20 of this decision; otherwise, the procedure for the destruction of the lot shall proceed. Where the retesting does not confirm the initial result, the analysis shall be carried out by a second approved laboratory, different from the first laboratory, using the reserve sample stored for this purpose. The result of the second laboratory shall be final for the purposes of this decision.
4. Where the retesting confirms the initial result, the entity shall have the right, at its own expense, to request that the sample also be analyzed by an accredited laboratory within or outside the country, in accordance with the legislation in force. The conduct of such analysis shall not automatically suspend the effects of the measures imposed by the Agency, unless the Agency decides otherwise on duly reasoned grounds.
5. Where the final analysis does not confirm the initial result, the Agency shall order the release of the lot from quarantine and the continuation of the relevant processes. Where repeated discrepancies or significant deviations between analyses are identified, the Agency shall notify the responsible authorities and take the actions provided for under the legislation in force against the approved laboratory.
6. The costs related to testing, retesting and final analysis shall be borne by the entity.

Article 22

Sampling for Testing by Other Competent Authorities

1. Where other competent authorities need to take samples related to the cannabis plant, its products or by-products for the purposes of control or inspection within their respective areas of activity, they shall notify the Agency in advance and coordinate with it the conduct of the relevant actions.
2. Sampling related to cannabis shall be carried out in the presence of an authorized employee of the Agency and documented in the relevant official record. The authority taking the sample shall ensure its identification, integrity, traceability and safekeeping, and shall maintain a material balance for each use, consumption, transfer or remaining quantity thereof.
3. The analysis results shall be notified to the Agency and the entity and uploaded to the Register immediately upon receipt, but no later than 24 (twenty-four) hours thereafter. If, following the completion of the analyses or examinations, a surplus of the sample remains,

it shall be handed over to the Agency, which shall follow the relevant procedure in accordance with the legislation in force.

4. The costs of sampling, transportation and analysis shall be prepaid by the competent authority conducting the control or inspection and shall be charged to the entity only where violations are identified, in accordance with the legislation in force.
5. Analyses of samples related to cannabis shall be carried out in laboratories approved pursuant to the legislation in force, whereas other analyses shall be carried out in competent laboratories designated pursuant to the relevant sector-specific legislation.

SECTION VII TRANSPORT AND CIRCULATION

Article 23

Supervision of Transport and Circulation

1. The Agency shall supervise the transport and circulation of the cannabis plant, its byproducts and products, for the purpose of ensuring physical security, uninterrupted traceability, and compliance with the conditions of the permit or license and with the legislation in force.
2. Transport shall be carried out only by suitable, enclosed and secure means of transport, in such a manner that the material is not visible or identifiable from outside and its integrity, quality and security are maintained throughout the entire route. Where required by the nature of the product, transport shall be carried out under conditions that ensure the maintenance of the parameters specified on the labelling, package leaflet or relevant technical documentation.
3. The entity shall provide prior notification and, where required by the legislation in force, obtain authorization from the Agency for the movement or transport. The notification shall contain information on the lot, quantity, route, date and time of departure, means of transport, accompanying personnel and destination.
4. The Agency shall verify the compliance of the accompanying documentation, route and security measures, and shall supervise the transport through the System, monitoring means and, where necessary, on-site control. Any deviation from the route, unjustified interruption, missing documentation or breach of security measures shall be documented and handled in accordance with the legislation in force.
5. The State Police shall cooperate with the Agency to ensure security during transport and shall intervene where violations or risks to public safety are identified.

SECTION VIII EXPORT

Article 24

Supervision of Export and Responsible Authorities

1. The Agency shall supervise, control and inspect the export process of by-products and products of the cannabis plant for medical and industrial purposes, verifying the compliance of the consignment with the relevant authorizations, the data in the Register and System, and the legal framework in force.
2. The Agency shall verify the accompanying documentation, the consistency of the declared data with the documentation submitted, compliance with the requirements for marking, traceability, packaging, labelling and transport security, and shall supervise the movement of the consignment to the customs point in accordance with the declared route. The Agency may participate in the physical inspection of the consignment at the customs point where notified by the customs authority or where there are indications of discrepancies.
3. The customs authority shall verify the compliance of the consignment with the customs declaration, the export authorization and the accompanying documentation, in accordance with point 4 of Article 13 of this decision. In the event of a deviation, discrepancy or suspicion of a violation, it shall immediately notify the Agency and, as applicable, the State Police and the authority that issued the export authorization and shall take the measures provided for under customs legislation.
4. The correction or cancellation of the customs declaration shall be carried out in accordance with the criteria and procedures established by the Customs Code and its implementing provisions.
5. The State Police shall intervene in cases of suspected violations, support on-site control and verification, and carry out the seizure or confiscation of the consignment, in accordance with the legislation in force.

SECTION IX SEIZURE, CONFISCATION AND DESTRUCTION

Article 25

Temporary Seizure Measure

1. Where, during supervision, control or inspection, circumstances are identified that require the preservation of evidence or the prevention of the movement, disposal, processing or disappearance of the material, the authorized employees of the Agency shall, pursuant to letter “e” of point 3 of Article 9 of Law No. 61/2023, impose the temporary seizure measure.
2. The measure shall be imposed by means of a reasoned interim act, which shall specify the legal basis, grounds, type, quantity, lot, location and identifiers of the seized material.
3. The material shall be inventoried, marked, secured and registered in the Register, ensuring its safekeeping and traceability.
4. The seizure shall remain in force only for as long as necessary to carry out the verifications. Where the grounds for imposing it cease to exist, the measure shall be lifted immediately.

Where the conditions set out in Article 38 of the Law are established, the Agency shall proceed with the proposal for confiscation.

5. Where necessary to ensure the physical security of the material, the Agency shall request the assistance of the State Police.

Article 26 **Confiscation**

1. Where, following completion of the verifications, it is established that the legal conditions for confiscation have been met, the Agency shall prepare and submit to the minister responsible for health a reasoned proposal for confiscation, accompanied by the official record of the findings and the relevant documentation.
2. The proposal for confiscation shall be prepared, in particular, where it is established that the material is cultivated, processed, circulated or possessed by unlicensed entities, or is not marked or traceable in accordance with the legislation in force.
3. In the case of the cannabis plant for medical purposes, by-products and final products, confiscation shall be carried out by order of the responsible minister, upon the proposal of the Agency, in the cases provided for under Law No. 61/2023.
4. The confiscation act shall specify the material to be confiscated, the legal basis, the quantity, the lot or relevant identifiers, and the measures for its administration, transfer or destruction. From the moment the confiscation act is issued, the material shall acquire the status of “confiscated” and shall be administered in accordance with this decision and the legislation in force until its final safekeeping, transfer or destruction.

Article 27 **Supervision, Control and Inspection of the Destruction Process**

1. The Agency shall exercise supervision, control and inspection over the process of destruction of plants, by-products, products, waste and any other material related to cannabis that, pursuant to the legislation in force, must be destroyed.
2. Destruction shall be carried out only by entities or structures authorized pursuant to the legislation in force and in accordance with approved methods, in such a manner that the material is rendered unusable and irreversible for any further use. Destruction shall be carried out in accordance with the methods and procedures established in the joint guideline on the detailed manner of destruction of cannabis plants and/or in the legislation in force.
3. Prior to destruction, the Agency shall verify the identity, quantity, status, accompanying documentation and chain of custody and traceability of the material to be destroyed. The destruction process shall be documented in the official record, which shall include at least the type of material, quantity, relevant identifiers, location, date, method used and persons present.

4. Upon completion of the destruction, the Agency shall record the relevant data in the Register and System and close the status of the destroyed material. Where necessary, the Agency shall request the participation or assistance of other competent authorities, including the State Police. The Agency shall also maintain a register of the type and quantity of material destroyed, in accordance with the legislation in force.

Article 28

Remote Supervision

1. The Agency shall exercise remote supervision over the activities of entities at every stage of the conduct of their activities, through real-time access to monitoring systems, security cameras and other authorized technological means, in accordance with the legislation in force and the relevant technical manuals.
2. Remote supervision, control and inspection shall be carried out, as applicable, through:
 - a) visual monitoring systems (CCTV) installed at the entity, to which the Agency has uninterrupted 24/7 access;
 - b) telemetry systems and environmental measurement devices installed at the entity;
 - c) alarm systems;
 - ç) unmanned aerial vehicles;
 - d) satellite platforms; dh) sensors and digital platforms;
 - e) any other device or technology enabling remote observation, recording, transmission or verification, in accordance with the provisions of the Agency's manuals.
3. Remote supervision shall ensure continuous observation and, where necessary, recording of the activity, documentation of the images and data obtained, as well as verification of the compliance between the transmitted data, the data uploaded to the Register and System, and the declarations made by the entity.
4. All images and data transmitted or obtained through remote monitoring means shall be documented in the official record and may be used as evidence in administrative, civil or criminal proceedings, in accordance with the legislation in force.
5. Where illegality, a critical incident or reasonable suspicion of a violation is identified during remote supervision, the Agency shall immediately take the relevant measures pursuant to this decision and, where necessary, notify the State Police and other competent authorities.

Article 29

Supervision, Control and Inspection of Traceability

1. The Agency shall supervise, control and inspect the implementation of the requirements for the marking, identification, labelling, registration and traceability of seeds, seedlings,

clones, mother plants, plants under cultivation, by-products, final products, consignments, blocked, seized and confiscated materials, and materials intended for destruction. Marking and traceability shall be carried out through the System and by the authorized entity pursuant to the bylaws in force.

2. In exercising this competence, the authorized employees of the Agency shall verify:
 - a) compliance with the requirements for the labelling and tracking of the material at every stage of the activity; b) the recording of data in the System within the prescribed time limits and their consistency with the information in the Register; c) consistency between the actual condition of the material, its identifiers and the declared data;
 - ç) implementation of the procedures approved pursuant to the legislation in force and the relevant technical manuals.
3. Every movement, transfer, opening, resealing, receipt, delivery for analysis, change of storage location or any other action concerning the material shall be recorded continuously in the chain of custody and traceability, in accordance with the format and rules approved by the Agency.
4. Where samples are taken from the material for analysis, the specific rules governing samples, laboratories and the quarantine of the lot shall also apply to their collection, delivery, storage and handling, in accordance with the legislation in force and the relevant bylaws.
5. Any discrepancy in traceability, failure to record data, interruption of the chain of custody or compromise of data integrity shall be documented in the official record and handled in accordance with this decision and the legislation in force.

Article 30

The Register and System

1. The Agency shall supervise the use, functioning and integrity of the Register and System by all entities, competent authorities, the party authorized to carry out marking and traceability, and any other institution that has access to or enters data into them, in accordance with Law No. 61/2023, the bylaws in force and the relevant technical manuals.
2. All entities and institutions that enter, process or administer data in the Register and System shall be responsible for the accuracy, completeness, integrity and timely updating of the data entered by them at every stage of the activity.
3. During supervision, control and inspection, verifications shall also be carried out based on the data in the Register and System, combined, where necessary, with remote control, documentary control and physical on-site control.
4. Every movement, change of status, taking into administration, placement in quarantine, seizure, confiscation, destruction, analysis result, interruption of activity or any other action

having a legal or material effect on the entity, lot or relevant material shall be recorded in the Register and System in accordance with the approved procedures and time limits.

5. The entity, competent authorities and any other institution having access to the Register and System shall immediately notify the Agency of any malfunction, interruption, defect, failure, loss of access, security breach or suspicion of data manipulation. Upon receipt of the notification, the Agency shall coordinate with the responsible institutions and take the necessary measures to restore functionality, ensure data integrity and document the incident.
6. Where a discrepancy is identified between the data in the Register or System and the actual situation, the Agency shall document the finding in the official record and take the relevant measures in accordance with the legislation in force.

Article 31

Supervision During Suspension and Following Revocation of the License or Permit

1. During the period of suspension and following the revocation of the license or permit, the Agency, through its authorized employees, shall exercise specific supervision over the entity to verify implementation of the relevant act, cessation of the activity, safekeeping of the material and compliance with legal obligations that continue to apply following suspension or revocation.
2. During the suspension, the authorized employees shall:
 - a) supervise compliance with the restrictions and prohibitions imposed by the suspension act through on-site control or remote supervision;
 - b) verify the maintenance of physical security, traceability and material management conditions for the material, by-products and products;
 - c) verify that the entity does not carry out any actions, movements, processing, sales, transportation, exports or other activities beyond the limits permitted by the suspension act;
 - ç) document any violation, take the relevant materials into custody where necessary and notify the competent authorities for the adoption of further measures.
3. Following the revocation of the license or permit, the authorized employees shall:
 - a) supervise the immediate and permanent cessation of the activity;
 - b) verify the complete inventory of materials, by-products, products, waste, labels and traceability elements;
 - c) verify the placement of materials in quarantine and, as applicable, propose or take measures for their seizure, confiscation and destruction, in accordance with the legislation in force;
 - ç) verify the surrender, deactivation or blocking of labels and other marking and traceability elements;

- d) verify the removal of the entity's access to the Register and System, as well as the closure of its user profiles;
 - dh) document and record every action in the Register.
4. The State Police, in cooperation with the Agency, shall:
- a) ensure security during the control and inspection of the entity;
 - b) assist in the cessation and physical blocking of the activity, where necessary;
 - c) carry out seizure in accordance with the legislation in force, support the confiscation process and participate in the destruction of materials, as applicable;
 - ç) act in accordance with the legislation in force where criminal offences or non-compliance with administrative decisions are identified.

CHAPTER IV FINAL PROVISIONS

Article 32

Remedying Identified Non-Compliance

1. Where, upon completion of supervision, control and inspection, non-compliance with the conditions of the permit or license or with the obligations established under this decision is identified, which does not constitute an administrative offence, the entity shall be sent the relevant report containing the respective recommendations and tasks to be fulfilled.
2. The entity shall be obliged to fulfil the assigned tasks within the time limit established by the Agency, which shall not exceed 30 (thirty) days, and shall notify the Agency of their fulfilment by submitting the relevant evidence.
3. The Agency shall carry out a follow-up inspection to verify the fulfilment of the assigned tasks.
4. Where the follow-up inspection establishes that the entity has not implemented the assigned tasks, the Agency shall proceed with the adoption of administrative measures pursuant to Law No. 61/2023.

Article 33

Technical Manuals and Implementing Institutions

1. For inspection procedures carried out by other institutions, in accordance with the provisions of this decision, the relevant manuals shall be proposed by those institutions and approved by the minister responsible following their prior review and approval by the Agency.
2. The manuals shall be prepared in accordance with Law No. 61/2023, this decision and other legislation and bylaws in force.
3. The Agency shall prepare the technical manuals for supervision and inspection, which shall be approved by order of the Director General, within the framework of the organization

and management of the institution's activities. The manuals shall be of an internal technical and organizational nature and shall aim to standardize working practices for the implementation of this decision, without creating new obligations, measures, conditions or procedures for entities.

4. The ministry responsible for health, the ministry responsible for agriculture, the ministry responsible for public order and security, the State Police, the Customs Administration, the National Cannabis Control Agency and the other institutions involved shall be responsible for the implementation of this decision.
5. Licensed and authorized entities shall be obliged to comply with this decision at all stages of their activities.

This decision shall enter into force upon publication in the Official Gazette.

PRIME MINISTER

EDI RAMA