

REPUBLIC OF ALBANIA
MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

No. Prot. 451/31

Tirana, on.05.03.2025

INSTRUCTION

No.10, Date 05.03.2025

ON

**DETERMINING THE FORMAT OF THE PERMIT FOR THE EXERCISE OF ACTIVITIES RELATED TO
THE PRODUCTION OF CANNABIS FOR INDUSTRIAL PURPOSES AND THE CRITERIA FOR THE
ACTIVITIES INCLUDED IN THE PERMIT**

In support of Article 102, point 4, of the Constitution, point 3, of Article 22 of Law No. 61, dated 21.7.2023, "On the control of the cultivation and processing of the cannabis plant and the production of its by-products for medical and industrial purposes":

I HEREBY INSTRUCT:

Article 1
Object

1. Determining the format of the permit for the exercise of the activity of importing seeds, seedlings, clones or mother plants, storage, cultivation, production and processing, transport, as well as export of cannabis by-products and final products for industrial purposes.
2. The definition of criteria that the entity must meet to be granted a permit.

Article 2
Definitions

All terms defined in this Instruction have the same meaning as those defined in 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".

For the purposes of this Instruction, the additional definitions have the following meanings:

1. “Mother plant” refers to cannabis plant specifically selected and cultivated to serve as a source of genetic material for the creation of clones through vegetative propagation. The mother plant may be imported as such and is not used for producing plant materials but is kept in a stable vegetative state (exposed to 18–24 hours of light per day to prevent flowering) to continuously produce clones.
2. “Primary processing” is the process that involves drying, cleaning and separating the harvested cannabis plant.
3. “Standard Operating Procedure (SOP)” is a detailed document that describes the specific steps that must be followed to perform a task or process consistently and in compliance with established standards.
4. “European Good Agricultural and Collection Practices (EU-GACP)” are a set of standards for the collection, cultivation, harvesting and initial processing of plant materials, published by the European Medicines Agency (EMA).
5. “Hazard Analysis and Critical Control Points (HACCP)” is a management system that identifies, evaluates and controls biological, chemical and physical hazards at all stages of processing, manufacturing and distribution of the final product.
6. “ISO” refers to a set of international standards that guarantee safety, reliability and high quality of final products, published by the International Organization for Standardization.
7. “EU-GMP” refers to European Good Manufacturing Practices.

Article 3

Activities covered by the permit

1. The permit for the exercise of the activity of cannabis production for industrial purposes is granted for the following activities:
 - a) Import of cannabis seeds, clones, seedlings or mother plants of cannabis for industrial purposes, their storage and transportation.
 - b) Cultivation of the cannabis plant for industrial purposes with the aim of obtaining the flower, including initial processing, storage, transportation and export of its by-products.
 - c) Cultivation of the cannabis plant for industrial purposes with the aim of obtaining the seed and fiber, including initial processing, storage, transportation and export of its by-products.

ç) Cultivation of the cannabis plant with the aim of obtaining the flower, including initial processing, production, storage, transportation and export of the by-products and final products.

d) Cultivation of the cannabis plant for the purpose of obtaining seeds and fiber, including initial processing, production, storage, transportation and export of its by-products and final products.

2. The permit is granted for one or several of the activities specified in point 1 of this article.

3. The entity may contract a third party for transportation activities, provided that the third party meets all security conditions set forth in the decision “On the determination of the rules and fees for the storage and physical security of permitted entities”, and must be specified in the permit. In cases where the transport is envisaged to be carried out by a third party contracted by the permitted entity according to the provisions in the permitted, the permitted entity is responsible for ensuring compliance with applicable security standards and conditions in accordance with the legal framework in force.

4. To obtain a permitted, the entity must meet the criteria for each activity included in the relevant permitted according to this Instruction.

Article 4 Permit Format

The format of the permit for conducting cannabis production activities for industrial purposes is as specified in Annex 1, which is attached and forms an integral part of this Instruction.

Article 5 Criteria for Activities Covered by the Permit

1. The entity applying for a permit to conduct activities under Article 3 of this Instruction must meet the conditions specified in point 2 of Article 22 and point 1 of Article 23 of Law No.

61/2023, as well as the following general criteria:

a) Be registered in the commercial register with the business activity covered by the permit.

b) Have a five-year business plan aligned with the activities specified in the permit.

c) Have a regulation for internal administrative processes.

ç) Have a training plan for employees based on the respective activities.

d) Have a positive financial performance in the last financial year.

dh) Have no unpaid obligations to the tax administration, local government units, as well as for electricity and water supply.

e) Provide legal documentation proving ownership or lease of the land where the activity will

be conducted, covering the entire validity period of the permit.

ë) Employee staff in compliance with Law No. 61/2023 and Instruction No. 274, dated 16.05.2024, "On the determination of procedures, deadlines, criteria, and necessary documentation for verifying the integrity of employees of the National Agency for Cannabis Control or permitted/permitted entities, as well as ethical-professional criteria."

f) Comply with security and transportation standards and conditions in accordance with the Council of Ministers' decision determining the rules and fees for storage and physical security for permitted entities.

2. For activities specified in point 1, letter "a" of Article 3, in addition to the general criteria, the entity must also meet the following:
 - a) Have a preliminary sales agreement for the sale of seeds, clones, seedlings, or mother plants with the permitted entity that will purchase them for cannabis cultivation.
 - b) Have documented storage facilities with the corresponding layout plan.
3. For activities specified in letters "b" and "c" of point 1 of Article 3, in addition to the general criteria, the entity must also meet the following criteria:
 - a) Have a pre-established development and production plan.
 - b) For each variety of cannabis plant, and each phase of the cultivation and processing process, relevant SOPs (Standard Operating Procedures) must be drawn up in accordance with EU-GACP (European Good Agricultural and Collection Practice), as specified in Annex 2 attached and forming an integral part of this instruction.
 - c) Have warehouses and dedicated facilities based on the production unit's capacity, documented with the corresponding layout plan.
 - ç) Be equipped with the necessary and suitable tools and equipment for cultivation, processing, and storage.
 - d) Be equipped with a preliminary sales agreement with the receiving entity for the processing of raw materials, who will purchase it.
4. For activities specified in letters "ç" and "d" of point 1 of Article 3, in addition to the general criteria, the entity must also meet the following criteria:
 - a) Have a pre-established development and production plan.
 - b) Have drafted the relevant SOPs for each variety of the cannabis plant and each phase of the cultivation and processing process, based on EU-GACP, as well as production and packaging of final products in compliance with HACCP/ISO and EU-GMP standards for cosmetic and food products, as outlined in Annex 2.
 - c) Have the necessary and suitable tools and equipment for cultivation, processing, storage, and production.
 - ç) Have warehouses and dedicated facilities based on the production unit's capacity,

documented with the corresponding layout plan.

d) Have a preliminary sales agreement with the receiving entity for the purchase of final cannabis products for industrial purposes.

Article 6
Final Provisions

1. All institutions and entities mentioned in this Instruction are responsible for its implementation.
2. Guideline No. 14, dated 21.05.2024, of the Minister of Agriculture and Rural Development, "On the approval of the permit format for the exercise of activities related to the production of industrial cannabis and the criteria for the activities included in the permit," is repealed.

This Instruction enters into force upon publication in the Official Gazette.

MINISTER

Anila Denaj

Annex No. 1

MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

PERMITTE

No. _____, Date _____

FOR THE CONDUCT OF ACTIVITIES

Pursuant to Law No. 61/2023, "On the control of cannabis plant cultivation and processing and the production of its by-products for medical and industrial purposes," the permit is granted to the entity with the following details:

Entity Name: _____

Headquarters Address: _____

Entity NUIS/NIPT: _____

Geographical Coordinates of Each Production Unit: _____

Location of Production Units (Region/Municipality/Administrative Unit/Cadastral Zone):

Number of Production Units: _____

Area of Each Production Unit / Total Area of Production Units: _____

Permission is granted to carry out the following activities:

- Import of cannabis seeds, clones, seedlings, or mother plants for industrial purposes, including their storage and transportation.
- Cultivation of the cannabis plant for industrial purposes to obtain the flower, including primary processing, storage, transportation, and export of its by-products.
- Cultivation of the cannabis plant for industrial purposes to obtain seeds and fiber, including initial processing, storage, transportation, and export of its by-products.
- Cultivation of the cannabis plant for the purpose of obtaining the flower, including primary processing, production, storage, transportation, and export of its by-products and final products.
- Cultivation of the cannabis plant for the purpose of obtaining seed and fiber, including primary processing, production, storage, transportation, and export of its by-products and final products.

VALID UNTIL: _____

The permitted entity is authorized to conduct transportation through the following subcontracted entity (if applicable):

Subcontracted Transportation Entity (if any): _____

NUIS/NIPT of Subcontracted Entity: _____

Headquarters of Subcontracted Entity: _____

MINISTER

(NAME, SURNAME)

(SIGNATURE)

Annex No. 2

SOP Structure

Minimum Elements Included in an SOP:

1. Key Information

- **Title:** [Name of the SOP]
- **SOP Identification Number :** [Unique Identifier]
- **Update Number:** [Version Number]
- **Effective Date:** [Date of SOP Implementation]
- **Prepared By:** [Name/Role]
- **Approved By:** [Name/Role]
- **Distribution List:** [Names/Departments Receiving the SOP]

2. Purpose

- A clear and concise statement describing the purpose of the SOP, outlining the process and its significance.

3. Scope of Application

- Boundaries of the SOP, specifying applicable departments, roles, and processes.
- Potential exclusions.

4. Definitions

- All abbreviations or technical terms used in the SOP.

5. Responsibilities

- Defining roles and responsibilities for each step in the procedure.

6. Materials, Equipment, and Necessary Tools

- A list of all equipment, materials, and tools necessary to perform the procedure.

7. Procedure

- Detailed, step-by-step instructions for process implementation, arranged in a logical sequence.

7.1 Preparation

- Preliminary actions required, including equipment setup and calibration.

7.2 Implementation

- Key process steps, ensuring clarity and logical flow, with diagrams or schematics if needed.

7.3 Completion

- Closing activities such as equipment cleaning or data recording.

8. Quality Control (Self-Inspection)

- Sampling or testing steps to ensure compliance with quality standards.

9. Safety and Health Protection Measures

- Required personal protective equipment (PPE) and protocols for handling chemical solvents.

10. Marking and Tracking

- Procedures followed for labeling and tracking.

11. Documentation and Record Keeping

- All documents and records to be completed during the process and the procedure for their storage.

11. References

- All reference documents, applicable laws, and instructions used in SOP development.

12. Update History

- Tracking changes made to the SOP over time, integrating updates such as:
- Version 1.0: Initial creation of the SOP, including the basic structure.
- Version 1.1 and further ones: Reflecting improvements and protocol additions.

13. Procedures Requiring SOP in the Processing and Production of Cannabis plant for Industrial Purposes include but are not limited to:

13.1 Processing

- Cleaning and decortication of stems for fiber extraction and separation.
- Drying, cleaning, and separation of flowers.

13.2 Product Manufacturing

- Fabrication of textiles, ropes, paper, bioplastics, construction materials, energy sources, etc.
- Production of cannabis-based products for human or animal consumption (oils, proteins, edible seeds, etc.).
- Formulation of oils, tinctures, topical, and cosmetic products.
- Infusion of CBD into cosmetics, food, beverages, and inhalable products.
- Extraction of cannabinoids using various methods (CO₂, ethanol, cold pressing, etc.).
- Other processes envisaged for the production of products not included in the above categories.

13.3 Packaging and Distribution

- Packaging process.
- Labeling as per regulatory requirements.
- Storage and transportation protocols.

13.4 Waste Management

- Waste storage.
- Disposal of plant materials and solvent residues.
- Recycling and reuse of biomass.

13.5 Safety and Health Protection Measures

- PPE usage protocols.
- Emergency measures for fires, chemical accidents, or natural disasters.

13.6 Marking and Tracking

- Procedures followed for marking and tracking at every stage.

13.7 Training

- Staff orientation for compliance with EU-GACP, EU-GMP, and HACCP/ISO standards.
- Regular training on equipment use and safety.