



REPUBLIC OF ALBANIA
MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT
MINISTER

NO. 451/8 prot.

Tirana, on. 20.01. 2025

INSTRUCTION

No. 2, dated 20.01. 2025

ON

**APPROVAL OF STANDARDS FOR EACH PHASE OF THE PROCESS RELATED
TO THE CULTIVATION OF CANNABIS PLANT**

Pursuant to Article 102, paragraph 4, of the Constitution, letter 'b' of paragraph 3, Article 9, 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,' with the proposal of the National Agency for *Cannabis* Control (hereinafter referred to as *the Agency*):

INSTRUCT:

Article 1

Scope

This guideline aims to define the standards and procedures that must be followed throughout all phases of *cannabis* plant cultivation for medical and industrial purposes.

Article 2

Definitions

All terms defined in this guideline shall have the same meaning as those defined in Law No. 61/2023, "On the Control of *Cannabis* Cultivation and Processing and the Production of Its By-products for Medical and Industrial Purposes."

For the purposes of this guideline, the following additional definitions apply:

1. "Good Agricultural and Collecting Practices (EU-GACP)" are a set of standards for the collection, cultivation, harvesting, and initial processing of plant materials for use in

plant-based medicines, published by the European Medicines Agency (EMA) according to Annex 2, attached and an integral part of this instruction.

2. "Standard Operating Procedures (SOP)" are guidelines for performing tasks or operational activities, designed to increase performance, improve efficiency, and ensure product quality. In the context of this guideline, SOP refers to cultivation process SOPs that are specific to each variety to be cultivated.
3. "Mother Plant" refers to a *cannabis* plant selected and cultivated specifically 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 to produce plant materials but is kept in a stable vegetative phase (18-24 hours of light per day to prevent flowering) to continuously produce clones.
4. "Clone" refers to a plant individual genetically identical to the mother plant, produced without sexual reproductive processes, maintaining all characteristics of the original mother plant, including: genetic profile, cannabinoid and terpene production, growth cycle, and yield. A clone is considered as such from the moment the branch is cut from the mother plant until it has developed a stable root system but has not yet entered an independent growth phase, relying on the cultivation environment (substrate and high humidity) to survive, and has not begun active independent growth (new leaf production or significant development), typically 2-3 weeks after cutting.
5. "Seedling" refers to the plant individual created from a seed through sexual propagation and may have genetic variations compared to its parents. A seedling is considered as such after the seed has germinated until it has passed the first growth phase (cotyledons and 4-6 sets of the first true leaves) and has gained independence from the water and nutrient supply.
6. "Plant Protection Products (PPP)" refers to a product that contains one or more active substances and is used to protect plants and plant products from pests, or to prevent their action, influencing the life processes of plants, but with effects distinct from chemical fertilizers, such as growth regulators, products to destroy undesirable plants or plant parts, and to control or prevent the growth of unwanted plant parts.
7. "Monoecious" refers to a *cannabis* plant where both male and female flowers are found on the same plant.
8. "Dioecious" refers to a *cannabis* plant where male and female flowers are found on different plants.
9. "Consumption" refers to the use or intake of *cannabis* by-products or products through food, supplements, or beverages, inhalation via vapor or smoking, and sublingual application.
10. "Protected Variety" refers to the variety of seed, seedling, clone, or mother plant that grants the subject who protected the variety the exclusive right to use it.
11. "Register" refers to the National Register of licensed and authorized *cannabis* activity, as provided under Article 13 of Law No. 61/2023.

Article 3

General Standards Applicable During Cultivation Phases

1. Seed/Seedling/ Clones/ Mother Plant Varieties used for the cultivation of *cannabis* for medical/industrial purposes are registered in the National Catalog (NC) of species and varieties or in the Common European Catalog of Agricultural Plant Varieties, updated, and are not genetically modified products. Registration in the NC is done by the Seed

and Seedling Authority itself or by a licensed or permitted entity. In cases where the entity registers a protected variety, this variety cannot be cultivated by other entities.

2. The licensed/permitted entity, for each *cannabis* variety, and for each stage of their cultivation process, must develop and update the relevant SOPs in accordance with EU-GACP, and implement them after approval by the Agency. The SOPs should include, but not be limited to, specifications according to the provisions in Annex No. 1, attached and an integral part of this guideline.
3. Each cultivation phase must meet the standards in accordance with EU-GACP, and be certified for them, as well as the requirements and standards of the importing country.
4. During *cannabis* cultivation, an irrigation system, temperature, humidity, and nutrition should be used in accordance with the approved SOPs.
5. The licensed/permitted entity must implement and monitor the cultivation phases of seeds/seedlings/clones/mother plants of *cannabis*, in accordance with the SOP specifications of the respective variety, documenting their implementation and monitoring.
6. The use of PPPs (Plant Protection Products) is prohibited during all phases of cultivation for *cannabis* for medical purposes, as well as for *cannabis* for industrial purposes when it is intended for human and animal consumption.
7. All personnel employed by the entity who are engaged in the cultivation processes must be informed and trained on the approved SOPs.
8. The licensed/permitted entity must guarantee a separate and secure environment for the temporary storage of any plant material classified as waste, a separate and dedicated space for material blocked for analysis purposes, in order to minimize contamination from microorganisms, insects, and chemical pollutants, as well as a separate environment for seized materials.
9. In the case of cultivation in closed or protected environments, all areas must be kept clean and organized to prevent microbial contamination of the *cannabis* plant.
10. All auxiliary tools used in the cultivation process must be cleaned and disinfected according to standard procedures.
11. Scales used in the *cannabis* cultivation process must be regularly calibrated.
12. In the case of cultivation in closed or protected environments, employees engaged in the cultivation process must follow hygiene protocols, including handwashing and avoiding contact with plant material if they are sick.
13. The entity monitors during all phases of cultivation to ensure that the standard for the THC level, not exceeding 0.8%, for each part of the *cannabis* plant for industrial purposes, is applied.
14. For *cannabis* cultivated for use in the cosmetics sector, additional regulations of the applicable legislation for cosmetic products, as well as the standards of the importing country for this category, apply.
15. For *cannabis* cultivated for human and animal consumption, additional regulations in accordance with the applicable legislation for products for human and animal consumption, based on the type of consumption, as well as the relevant standards of the importing country for these categories, apply, in accordance with the data uploaded in the Registry before the cultivation process by the licensed/permitted entity.
16. The entity uploads to the Registry additional regulations of the applicable legislation and relevant standards of the importing country when *cannabis* is cultivated for final use in the cosmetics sector or for human and animal consumption, based on the type of consumption.
17. The entity implements the standards, for each cultivated lot, for uploading to the Registry, the data related to:

- a) quantities of imported seeds/seedlings/clones/mother plants;
- b) origin and type/variety of seeds/seedlings/clones/mother plants used;
- c) traceability code;
- d) number of plants cultivated;
- e) intended final use of the *cannabis* plant, its by-products, and products such as cosmetic products, products for human/animal consumption (food, inhalation, etc.), textile products, construction, etc.

18. The entity implements standards for uploading to the Registry, on the day it occurs, and throughout the cultivation phases, from planting to harvest, including:

- a) date of import of seeds/seedlings/clones/mother plants;
- b) date of planting/propagation/cloning;
- c) date of harvest;
- d) amount harvested;
- e) date of initial processing and any subsequent processing;
- f) amount of waste for disposal;
- g) amounts of product disposed of.

Article 4

Specific standards according to cultivation phases

1. Specific standards according to cultivation phases are as follows:

1.1 Sowing and Propagation Phase:

a) The sowing and propagation phase is carried out on soil or in a growing medium in accordance with the specifications of the relevant variety SOPs, which, after approval by the Agency, are uploaded to the Register by the subject before the cultivation process begins.

b) Sowing and propagation is carried out by one of the following methods:

- i. through seeds;
- ii. through seedlings;
- iii. through clones obtained from the mother plant.

c) In the case of sowing and propagation for the production of *cannabis* flowers for medicinal purposes, female dioecious seeds/seedlings/mother plants are used.

d) In the case of sowing and propagation for the production of *cannabis* for industrial purposes, seeds/seedlings/mother plants are used, which are expected to develop *cannabis* plants with low THC content(<0.8%).

e) In cases where propagation is done through clones obtained from the mother plant:

- i. The mother plant can be imported as such.
- ii. The propagation process through the mother plant is carried out and controlled in accordance with the conditions specified in the relevant variety SOPs, to keep the

plant healthy and in a vegetative state, without reaching the flowering stage.

iii. The process of sowing clones obtained from the mother plant is carried out and controlled in accordance with the conditions specified in the relevant variety SOPs, to ensure their healthy growth.

f) In every case of sowing and propagation of *cannabis* plants, the licensed/authorized subject follows the procedures for labeling and traceability according to the provisions in the law and the implementing sub-legal acts for seeds/seedlings/clones/mother plants.

1.2 Vegetative Phase (includes the period of intensive growth of the *cannabis* plant where leaves and stems develop):

a) During the vegetative phase, when:

i. the purpose of cultivation is to obtain flowers, regardless of the intended use, if monoecious or male dioecious plants are observed, they must be immediately eliminated before flowering.

ii. the purpose of cultivation is to obtain seeds or fiber, the growth of female and male dioecious plants or monoecious ones is stimulated to achieve pollination of the flowers.

b) All pruned parts of the plants, including male dioecious plants or monoecious ones, are documented in terms of their quantity and type and treated as waste.

1.3 Flowering Phase:

During the flowering phase, *cannabis* plants are allowed to flower according to the deadlines specified in the relevant SOPs.

1.4 Harvesting Phase:

a) Indicators used to determine the precise time of harvesting the plant include, but are not limited to:

i. color of the pistils;

ii. opacity of the trichomes.

b) During the harvesting phase, the *cannabis* plant and/or its parts are collected according to the declared intended use.

c) During this phase when:

i. the purpose of cultivation is to obtain leaves or flowers, harvesting is done for the leaves or unpollinated flowers of female dioecious *cannabis* plants according to the SOPs for the relevant variety.

ii. the purpose of cultivation is to obtain seeds or fiber, harvesting is done after pollination of the flowers.

d) The harvested plant material undergoes a visual inspection to ensure that there is no mold, fungi, pests, rotting, or color degradation.

e) The freshly harvested plant material is immediately deposited in the environment where the subsequent phase takes place, to prevent thermal degradation and mold development.

Article 5
Final Provision

1. The Instruction No. 13, dated 21.05.2024, of the Minister of Agriculture and Rural Development "On the approval of standards for each phase of the process related to *cannabis* cultivation," is hereby repealed.
2. For the implementation of this instruction, all the institutions and subjects mentioned in this instruction are entrusted with the responsibility.

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

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Annex No. 1: Specifications to be Included in the SOPs

The SOPs must include, but are not limited to, the following specifications:

1. For cultivation in open, protected, and closed environments:
 - a) The pH range, heavy metal limits, and nutrient levels for the soil/cultivation substrate;
 - b) The duration in days/weeks for each phase of cultivation;
 - c) The distance between plants and between rows;
 - d) The plant age at the time of harvest;
 - e) The quantity and quality of irrigation water used, certified for cleanliness from chemical and biological pollutants;
 - f) The method for managing the characteristic odor of the *cannabis* plant;
 - g) The length of the day/night cycle (natural or simulated) for all cultivation phases;
 - h) The procedures and tools used during each phase of cultivation.

2. For cultivation in open environments, in addition to point 1 of this Annex, the SOPs must also include the following additional specifications:
 - a) The time of day when harvesting should be carried out (morning/noon/evening);
 - b) Soil management practices (techniques to prevent erosion);
 - c) Where allowed, the use of approved PPPs (Plant Protection Products) in accordance with the legal framework in force;
 - d) Measures for plant protection from insects, rodents, and other animals;
 - e) The control calendar for the presence or absence of production pests.

3. For cultivation in protected environments, in addition to point 1 of this Annex, the SOPs must also include the following additional specifications:
 - a) Additional lighting, in addition to natural light (frequency of use, color/wavelength of light used, and intensity of artificial light to support natural lighting);
 - b) Ambient temperature;
 - c) Air humidity within the environment;
 - d) Ventilation and air circulation;
 - e) CO₂ enrichment;
 - f) Protective equipment for the staff or visitors, such as clothing, gloves, masks, etc., used in all work phases.

4. For cultivation in closed environments, in addition to point 1 of this Annex, the SOPs must also include the following additional specifications:
 - a) Type of artificial lighting (frequency of use, color/wavelength of light used, and intensity of artificial light);
 - b) Ambient temperature;
 - c) Air humidity within the environment;
 - d) Ventilation and air circulation;
 - e) CO₂ enrichment;

- f) Protective equipment for the staff or visitors, such as clothing, gloves, masks, etc., used in all work phases;
- g) Monitoring procedures for the environment to guarantee conditions that protect against microbial contamination.