

DECISION
No. 50, dated 22.01.2025

**ON THE APPROVAL OF STANDARDS FOR AREAS AND LAND PARCELS WHERE
THE CULTIVATION OF THE PLANT FOR MEDICAL AND INDUSTRIAL PURPOSES
SHALL BE PERMITTED**

Pursuant to Article 100 of the Constitution, article 9, paragraph 2, subparagraphs “c” of 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”, upon the proposal of the Minister of Agriculture and Rural Development, the Council of Ministers

DECIDED:

1. In this Decision, the following terms shall have the following meanings:

a) **“Standards”** shall mean the entirety of requirements and criteria that areas and land parcels must meet for the cultivation of *cannabis* for medical and industrial purposes;

b) **“Land parcel”** shall mean a defined area of land acquired through an ownership acquisition act, which shall be used for the cultivation of the *cannabis* plant for medical or industrial purposes, in implementation of the provisions of 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”;

c) **“Protected environment”** shall mean a covered cultivation environment designed to create favorable conditions for plant growth by protecting plants from external atmospheric factors, including extreme temperature variations, wind and rainfall. This environment allows the penetration of solar radiation and generally includes structures such as greenhouses or plastic tunnels, which provide a certain degree of control over temperature, humidity and light, in accordance with the good agricultural and collection practices (GACP) guidelines of the European Medicines Agency;

ç) **“Closed environment”** shall mean a fully cultivated, covered and isolated environment from external atmospheric influences, which provides favorable conditions for plant growth without the penetration of natural solar radiation. This type of environment uses artificial lighting and cultivation systems to control parameters such as light, humidity, temperature, ventilation, and other external factors, ensuring optimal conditions for cultivation, in accordance with the good agricultural and collection practices (GACP) guidelines of the European Medicines Agency;

d) **“Area”** shall mean the entirety of land parcels where the *cannabis* plant is cultivated for medical or industrial purposes;

dh) **“Cultivation medium or cultivation substrate”** shall mean a material or mixture of materials, natural or manufactured, that provides physical support and nutrient supply for plant growth, which may include natural soil, peat, perlite, vermiculite, coconut fibers, or other

substrates that create suitable conditions for plant growth in a cultivation environment, allowing regulation of moisture, aeration and nutrients.

2. The standards for areas and land parcels for the cultivation of the *cannabis* plant for medical purposes shall be as follows:

- a) land parcels forming part of the production unit shall not be located within the boundaries of:
 - i. protected areas and areas designated as having priority for tourism development, declared as such by a decision of the Council of Ministers;
 - ii. forests, pastures and meadows;
 - iii. military areas;
 - iv. areas designated as urban systems in local territorial planning documents.
- b) land parcels forming part of the production unit shall be located at a minimum aerial distance of 3 (three) km from apiaries approved in accordance with beekeeping legislation;
- c) land parcels forming part of the production unit shall be located at a minimum aerial distance of 3 km from military areas and assets/properties under the administrative responsibility of the Ministry of Defense;
- ç) the concentration of heavy metals in soil or cultivation media (cultivation substrates) where *cannabis* is cultivated for medical purposes shall not exceed the maximum values specified in annex 1, attached to this decision and forming an integral part thereof;
- d) the soil or cultivation media (cultivation substrates) where medical *cannabis* is cultivated shall comply with the standards provided for in the good agricultural and collection practices guidelines of the European Medicines Agency and the World Health Organization, as well as with the standards established by the International Organization for Standardization (ISO).

3. The standards applicable to areas and land parcels for the cultivation of the *cannabis* plant for industrial purposes shall be as follows:

- a) land parcels forming part of a production unit shall not be located within the boundaries of:
 - i. protected areas and areas designated as priority tourism development areas, as declared by a decision of the Council of Ministers;
 - ii. forests, pastures and meadows;
 - iii. military areas;
 - iv. areas designated as urban systems under local territorial planning documents.
- b) land parcels forming part of the production unit shall be located at a minimum aerial distance of 3 (three) km from apiaries approved in accordance with beekeeping legislation;
- c) land parcels forming part of the production unit shall be located at a minimum aerial distance of 3 km from military areas and assets/properties under the administrative responsibility of the Ministry of Defense;

4. Where the conduct of the licensed activity requires construction works to be carried out on a land parcel forming part of the production unit, such works shall be undertaken in accordance with the legislation governing territorial planning and development.

5. Where a land parcel is used for the cultivation of *cannabis* for medical or industrial purposes, it shall be supported by a valid title of ownership, in accordance with the provisions of the Civil Code and law no. 111/2018, “For the cadaster.”

6. The standards set out in paragraph 2, letter “a”, subparagraph “iv” and letter “b” and in paragraph 3, letter “a”, subparagraph “iv” and letter “b”, of this decision shall not apply where cultivation is carried out in closed environments.

7. The Ministry of Agriculture and Rural Development, the Ministry of Health and Social Protection, the National *Cannabis* Control Agency and licensed and duly authorized entities shall be responsible for the implementation of this decision.

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

DEPUTY PRIME MINISTER
Belinda Balluku

ANNEX No. 1

Maximum concentration limits for elements in cultivation media or cultivation substrates

(expressed in mg/kg of dry matter, based on a representative soil sample)

Metal and chemical symbol	Maximum value (in mg/kg)
Antimony (Sb)	2
Arsenic (As)	5
Mercury (Hg)	0.5
Cadmium (Cd)	1
Cobalt (Co)	20
Chromium (Cr)	100
Copper (Cu)	100
Lead (Pb)	60
Nickel (Ni)	50
Zinc (Zn)	200
Vanadium (V)	100