FRENCH REPUBLIC

Ministry of Labour, Health, Solidarity and Families

Order of

laying down the technical arrangements for the holding, cultivation, import, export, transport and storage of the cannabis plant for medical purposes on national territory

NOR: XXX

The Minister for the Interior, the Minister for Labour, Health, Solidarity and Families, the Minister for the Economy, Finance and Industrial and Digital Sovereignty and the Minister for Agriculture and Food Sovereignty,

Having regard to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;

Having regard to Law No 2023-1250 of 26 December 2023 on Social Security financing for 2024, notably Article 78 thereof;

Having regard to the Public Health Code, in particular Articles L5124-1 and L5138-1 and Articles R5132-75 to R5132-78 and R5132-86 thereof;

Having regard to Decree No 2022-194 of 17 February 2022 on cannabis for medical use;

Having regard to Decree XXX of XXX on cannabis for medical use;

Having regard to notification No XXX of XXX to the European Commission;

Hereby order:

Article 1

As regards the cultivation and production of cannabis for medical purposes, only the establishments referred to in Articles L5124-1 and L5138-1 of the Public Health Code may apply to the Director-General of the National Agency for the Safety of Medicines and Health Products for the authorisation referred to in Article R5132-86 II and III of that Code and, where applicable, for the import or export authorisation provided for in Article R5132-78 of that Code.

Only a grower that is contractually bound to supply their production to one of the establishments mentioned in the preceding paragraph may hold and grow cannabis plants

(species *Cannabis sativa L.*). The contract between them shall be concluded for a maximum term of 5 years and shall include at least the items set out in Annex 3 to this Order.

Article 2

The authorisation application referred to in Article R5132-86 II and III of the Public Health Code shall state:

1° the name and address of the applicant for authorisation;

2° the address of the premises intended for production, including cultivation.

The application shall be accompanied by a file including:

- the administrative identification of the grower and a presentation of their business and their competence in the various stages of production;

- a presentation of the production premises, describing the exact location (GPS coordinates), the means employed to comply with the requirements referred to in Annex 1, including, where appropriate, the recommendations made in the context of the safety study referred to in Article 6;

- the administrative identification of the undertaking responsible for the transport;

- a copy of the contract between the grower of cannabis for medical use and the pharmaceutical establishment referred to in Articles L5124-1 and L5138-1 of the Public Health Code;

- a copy of the document (or protection plan) provided for in Annex 2.

Article 3

Cannabis plants (species *Cannabis sativa L.*) for medical purposes shall be cultivated in an enclosed building with opaque walls or an opaque enclosure meeting the requirements laid down in Annex 1.

Rooms dedicated to cultivation or flower handling shall be equipped with mechanical ventilation and an air filtration system that prevents pollen from spreading into the outdoor environment.

Cultivation in open fields or flexible greenhouses is prohibited.

Growers of cannabis for medical use and all persons for whom they are responsible, including their employees and transporters, are subject to an obligation of discretion for all operations relating to that activity. It is prohibited to identify or promote the cultivation premises.

Article 4

It is prohibited to remove and transport plants or parts of plants, or propagation equipment, from the cultivation premises, except for the purposes of transport to one of the establishments referred to in Articles L5124-1 and L5138-1 of the Public Health Code.

Article 5

All facts relating to intrusions into the plant, pharmaceutical raw materials or medicinal product production site, or incident during transport, as well as damage to or theft of plants or reproductive material, shall be reported without delay to the police services or national gendarmerie units in accordance with the procedures set out in Annex 4.

The establishment holding the authorisation referred to in Article 1 shall inform the Regional Health Agency as well as the National Agency for the Safety of Medicines and Health Products thereof.

Article 6

The person responsible for the plant production site is required to draw up a protection plan in accordance with Annex 2 to this Order.

For each plant, pharmaceutical raw materials or medicinal product production site, the police or gendarmerie safety coordinator may be requested to carry out a security study.

They shall set out recommendations corresponding to the production site, its immediate and wider environment (location, security context in connection with delinquency), response times and possible malicious scenarios. These recommendations, if written, shall be attached to the authorisation application referred to in Article 2 of this Order.

Article 7

The National Agency for the Safety of Medicines and Health Products shall keep the list of operators in the supply chain (growers, transporters, establishments producing raw materials for pharmaceutical use, or pharmaceutical establishments) available to the Director-General of the National Police, the Director-General of the National Gendarmerie and the Director-General of Customs and Indirect Taxes (DGDDI).

Article 8

This Order shall be recorded in the *Official Journal* of the French Republic.

Done on

The Minister for the Interior,

For the Minister and by delegation

The Minister of Labour, Health, Solidarity and Families,

For the Minister and by delegation

The Minister for the Economy, Finance and Industrial and Digital Sovereignty,

For the Minister and by delegation (DGDDI)

The Minister for the Economy, Finance and Industrial and Digital Sovereignty,

For the Minister and by delegation (Directorate-General of Enterprise [DGE])

The Minister for Agriculture and Food Sovereignty,

For the Minister and by delegation

Annex 1: Characteristics of buildings for the cultivation of cannabis for medical use with a view to ensuring their safety and preventing malicious acts.

1 - Facilities at which cultivation and related storage activities take place must have conditional restricted access and a physical and electronic security system that includes the following minimum requirements:

a) a video surveillance system with coverage of the perimeter of the premises and access zones, using video cameras for capturing and recording images;

b) an intrusion detection system.

2 - The retention period for video surveillance system images shall be 30 days.

3 - The intrusion detection system referred to in paragraph 1b) shall have at least a grade 3 classification in accordance with EN 50131-1 or equivalent and shall control all points of access to the cultivation or support areas of the facilities.

4 - Events detected by the security systems provided for in paragraph 1 must be handled and recorded in accordance with the legal provisions relating to the monitoring and reception of alarms.

5 - Access to facilities at which cultivation and related storage activities take place must be limited to persons whose functions and responsibilities require them to be present and must include a record of entries and exits including dates and times.

6 - Vehicles transporting cannabis plants for medical purposes intended for cultivation must be equipped with a global positioning system that records and tracks their route, enabling the vehicle to be identified and located immediately by the internal security forces.

7 - Police and national gendarmerie security representatives may carry out security studies whose objective is to formulate recommendations of a human, organisational and technical nature that make it possible to establish a security strategy aimed at deterring crime, delaying or blocking malicious action, reducing its effects and alerting and facilitating the action of police and gendarmerie services. Growers shall draw up a security plan that, as far as possible, incorporates the recommendations of the security coordinator. This security plan shall be communicated to the authorised establishment and to the police services or national gendarmerie units with jurisdiction.

8 - Recourse to a private security company (remote monitoring, physical presence on site) is possible.

9 - The crop must not be visible from places accessible to the public (only the roof and the upper part of the walls may be transparent, provided that the crop itself is neither visible nor accessible).

Annex 2 – Security organisation procedures

The person responsible for the medical cannabis cultivation structure is required to draw up a document (protection plan) including the following elements:

- presentation of the site (including the nature of the activity, staff, timetables, its immediate and wider environment)
- security devices in place or planned
- human resources (including person in charge of security matters and contact with law enforcement) and organisational resources
- physical protection devices
- flow management (staff, visitors, service providers, mail)
- information system security
- alerting and crisis management procedure
- penalty payments
- alerting system
- alerting tools
- crisis organisation
- business continuity (particularly in the case of degraded mode operation).

The drafting of this document may, where appropriate, be based on the recommendations of the security coordinator.

Annex 3: Mandatory items that must be included in the contract between the grower of cannabis for medical use and the establishment referred to in Articles L5124-1 and L5138-1 of the Public Health Code

The contract between the grower of cannabis plants for medical use and an establishment referred to in Articles L5124-1 and L5138-1 of the Public Health Code shall include at least the following items:

1e) complete administrative identification of the contractors;
2e) a copy of the grower's criminal record (part 3), dated less than 3 months before the contract was signed;
3e) Compliance with the following general principles:

- the obligation of the grower of cannabis for medical use to ensure cultivation under the conditions laid down in the good practices referred to in the European Guideline on Good Agricultural and Collection Practice (GACP);
- given the sensitivity of the crop, the obligation of the grower of cannabis for medical use to ensure, in its own name and that of its staff and by the carrier, respect for the confidential nature of this crop and the operations relating thereto;
- a prohibition on the grower using the cannabis produced for any reason other than sale to the authorised establishment co-signing the contract.

4e) Cultivation conditions:

- the cultivation premises (GPS coordinates), surface area and number of plants concerned;
- the quantity covered by the contract and in particular the total mass of cannabis that may be produced;
- the variety planted and the part of the plant harvested, supplemented by a more precise identification of the plant material where appropriate;
- the nature and origin of the reproductive material used to initiate the cultivation.

5e) The term of the contract, which is concluded only for a maximum of 5 years, expressly renewable for the same duration.
6°) Pursuant to the regulations on narcotics:

- after harvesting, the cannabis plants must be stored on the grower's premises in dedicated lockable rooms that do not contain anything else, with an enhanced warning or security system against attempted burglary in accordance with Article R5132-80 of the Public Health Code and the Order of 22 February 1990 on the conditions for holding substances and preparations classified as narcotic drugs;
- the operations carried out, the quantities used and obtained and the losses resulting from these operations must be subject to strict traceability in a dedicated register in accordance with Article R5132-82 of the aforementioned Code;
- an annual statement of the stocks and operations carried out must be sent to the holder of the authorisation referred to in Article R5132-86 of the Public Health Code, in order to comply with the provisions of Article R5132-83 of the aforementioned Code;
- the destruction procedures must be carried out in accordance with the provisions of R5132-82 of the aforementioned Code, in the presence of the authorisation holder and under the supervision of a bailiff.