

**CHANGES IN THE
CANABIS REGIME
FOR INDUSTRIAL
PURPOSES**

Health Law Legislation
and Regulations

P. 1-4



LIFE SCIENCES AND HEALTHCARE

HIGHLIGHT

Changes to the legislation and regulation on Cannabis for industrial and medicinal purposes

- **Clarification of the legal regime for cannabis for industrial purposes including for food use or animal feed**
- **Technical regulation on waste management from the production of cannabis for medical purposes**

In January and February, two relevant amendments to the cannabis regime were published. The first, published in January, clarifies and regulates the regime for the cultivation of cannabis for industrial purposes, where the DGAV is responsible for the authorization. The second is a joint technical regulation between APA and Infarmed on “Cannabis waste management, within the scope of activities that produce cannabis for medical purposes”.

► **[Ordinance 14/2022 of 5 January](#)**

<https://files.dre.pt/1s/2022/01/00300/0002000023.pdf>

Ordinance 14/2022 of 5 January clarifies the regulation on cannabis cultivation for industrial purposes.

The first amendment to Ordinance 83/2021, of 15 April, defines the requirements for processing requests and procedures for granting authorizations to carry out activities related to the cultivation, manufacturing, wholesale trade, transport, circulation, import and export of medicines, preparations and substances based on the cannabis plant.

According to the changes introduced:

- the **[cultivation of the cannabis plant for industrial purposes](#)** by obtaining fiber and seeds not intended for sowing, including for food or animal feed or for the manufacture of food or compound feed, or for experimental purposes for the same purposes, **[must be compliant with the following requirements:](#)**

- (i) Individual producers must submit the respective authorization request to the Directorate-General for Food and Veterinary Medicine (DGAV), by 31 July of each year of cultivation, and at least 20 days before the scheduled date for sowing, in accordance with the model available on the DGAV website;
 - (ii) The above notification must be accompanied by the Characterization of the Agricultural Exploration of a beneficiary (iE) document and the document containing graphic information on the limits of the beneficiary's plots, with photographic background (P3), as registered in the Parcel Identification System (iSIP), referring to the place where the cultivation activity will be carried out;
 - (iii) Only varieties registered in the Common Catalogue of Varieties of Agricultural Species and containing a tetrahydrocannabinol (THC) content of less than 0.2 % may be grown;
 - (iv) To the respective notification, the producer must attach an official declaration from the country of registration of the variety, or from the country of production of the certified seed, attesting to the THC content of each variety that is intended to be grown;
 - (v) The seeds to be used annually for sowing, of the varieties mentioned in the above paragraph, must be certified and correctly packaged in properly closed packages and with the appropriate identification of their content, in accordance with the provisions of article 42 of Decree-Law no. 42/2017, of 6 April, which regulates the production, control, certification and marketing of seeds of agricultural and horticultural species;
 - (vi) Producers must keep the seed purchase invoices and the official packaging labels used in sowing for at least 1 year;
 - (vii) The recipients of the production must be indicated and as well as the products to be produced;
 - (viii) The full identification and address of the farmer, farmers or corporate headquarters, in the event of not being the applicant, must be provided;
 - (ix) The stages of development of the plant must be identified, including the forecast of dates and indication of the origin of the product and the destination of the product;
 - (x) The quantity to be sown or to be planted, for each variety sown or planted, must be identified;
 - (xi) The complete address and geographic location by coordinates of the facilities where the product is stored must be indicated.
- Ordinance 14/2022 of 5 January introduces a change to the previous regime in relation to the requirements for the cultivation for industrial purposes, which are different from those for the cultivation for medicinal purposes.
- Thus, the technical requirements applicable to the cultivation of the cannabis plant for industrial purposes are as follows:
- The cultivation of the cannabis plant for industrial purposes must be carried out under suitable agronomic conditions for these purposes, and in accordance with the provisions of the following paragraphs:
 - (i) It can only be carried out outdoors, by sowing, plants may not be transplanted, and no stage of plant development can occur in greenhouses, shelters or similar structures;

- (ii) The minimum area allowed, for the sum of the plots of a given agricultural holding, is 0.5 ha;
- (iii) The sowing density must be adequate for the purpose, and cannot be less than 30 kg of seed per hectare.
- Flowers with or without seeds are not permitted to be transported off the farm.
- Opened seed packages containing leftover seeds not used in sowing in the agricultural season for which they were purchased cannot be used in the following year, and the farmer must keep documentary evidence of the destination of such.
- Seed packages that have been purchased and associated with [rejected authorization applications](#) must be kept with their original seal and can only have the following destinations:
 - a) If the rejection was not for reasons associated with the packaging, the applicant may keep the packages, as long as they are kept in their original form, and they may be presented in another authorization application process;
 - b) If the rejection is for reasons associated with the packaging, they can be returned to their origin, or destroyed, or sent for animal or human consumption, in case they are not treated with plant protection products, and the farmer must keep documentary proof of the destination for at least for three years.

The new regime came into force on 6 January, and applies to authorization procedures in progress on that date.

- **Informed - Technical Note "Management of Cannabis Waste, within the scope of activities that produce cannabis for medicinal purposes" - APA / INFARMED, IP**

https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/5649247

Technical Note nº 012/CD/100.20.200 Date: 08/02/2022 To: Organizations for the cultivation, manufacture and distribution of preparations based on the cannabis plant for medicinal purposes, Portuguese Pharmacists' Association

APA - The Portuguese Environment Agency and INFARMED - The National Authority for Medicines and Health Products, as the National Waste Authority and licensing entity and regulator of activities related to the production and distribution chain of cannabis products respectively, prepared the **Technical Note "Cannabis Waste Management, within the scope of activities that produce cannabis for Medicinal purposes"**

<https://www.infarmed.pt/documents/15786/1559752/Nota+T%C3%A9cnica+%27%27Gest%C3%A3o+de+Res%C3%ADduos+de+Can%C3%A1bis%2C+no+%C3%A2mbito+de+atividades+que+produzem+can%C3%A1bis+para+ fins+medicinas%27%27C2%A0%2%A0/19e7d27a-aa0d-a9a9-062a-ef83115280de>

This Technical Note aims to clarify the procedure that must be adopted with regard to the management of cannabis waste, namely its classification, transport and treatment, in accordance with the legislation in force on waste and registration in the field of controlled substances, and the specifics of the activity itself and characteristics of the product.

CONTACTS

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