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ARTICLE 1. DEFINITIONS

For the purposes of these specifications:

Agency or ANRAC: the National Agency for the Regulation of Activities relating to Cannabis, created under the provisions of Dahir No. 1-21-59 of 3 doulhijja 1442 (July 14, 2021) promulgating Law No. 13-21 on the legal uses of cannabis;

Good manufacturing practices (GMP): the rules of quality, safety and efficacy to be respected in the transformation of cannabis plants for medical and pharmaceutical purposes, enacted by the Competent Authority, after consultation with the government departments and concerned professional bodies;

Cannabis: any plant of the genus cannabis as defined in Article 2 of Law No. 13-21 on the legal uses of cannabis mentioned above;

Inputs: the plant raw material containing cannabis and used for the manufacture of medical and pharmaceutical products;

ONSSA: the National Office for Food Safety created under the provisions of Dahir No. 1-09-20 of 22 Safar 1430 (18 February 2009) promulgating Law No. 25-08 establishing the National Office for Food Safety;

Harmful organisms: any species, strain or biotype of plant, animal or pathogen likely to cause damage to plants or plant products;

Cannabis products: products resulting from the transformation of cannabis for medical and pharmaceutical purposes;

TRANSFORMER: any legal person under Moroccan law holding an authorization to transform and manufacture cannabis for medical and pharmaceutical purposes, in accordance with the provisions of the aforementioned Law No. 13-21;

Transformation: the transformation and manufacture of cannabis products for medical and pharmaceutical purposes;

Carrier: any legal person,, authorized by ANRAC, which uses for road transport, one or more vehicles, belonging to it or rented, complying with the regulations and standards in force in this area and meeting the specifications of the Specifications relating to the activity of Transport of cannabis and its products;

Data register: the data register held by the Transformer for the recording of stock movements of cannabis and its products, under the provisions of the aforementioned Law No. 13-21 and in accordance with model 2.5 set out in Annex 2 of Order No. 1296-22 of 11 choul 1443 (May 12, 2022) setting the model registers and the modalities for their keeping by the National Agency for the Regulation of Cannabis-Related Activities and by holders of authorizations to carry out activities relating to cannabis;

Cannabis residues: any residual material remaining during or after cannabis transformation and not intended for marketing.

ARTICLE2. SCOPE OF APPLICATION

These specifications define the conditions for the transformation of cannabis for medical and pharmaceutical purposes, the technical standards and those relating to the quality control of the products, their method of conditioning and preservation of their quality, the conditions and measures to be taken for the protection of the environment, the obligations in terms of safety, the traceability procedures, as well as the procedures for monitoring compliance with the various clauses of these specifications.

It applies to any legal person wishing to be authorized to operate a transformation unit from the date of its coming into force.

ARTICLE3. LEGAL REFERENCES

These specifications are drawn up by ANRAC, after consulting the ministries and institutions concerned.

Without prejudice to other laws and regulations in force in this area, these specifications are subject to the provisions of the following legal texts:

- Dahir No. 1-21-59 of 3 doulhijja 1442 (14 July 2021) promulgating Law No. 13-21 on the legal uses of cannabis;
- Dahir No. 1-21-66 of 3 doulhijja 1442 (14 July 2021) promulgating Law No. 76-17 on plant protection;
- Dahir No. 1-06-151 of 30 choul 1427 (22 November 2006) promulgating Law No. 17-04 on the Code of Medicines and Pharmacy and its implementing texts;
- Dahir on Law No. 1-73-282 of 28 Rabii II 1394 (21 May 1974) on the suppression of drug addiction and the prevention of drug addicts and amending the Dahir of 12 Rabii II 1341 (2 December 1922) on the Regulation on the Importation, Trade and possession and use of poisonous substances as well as the Dahir of 20 chaabane 1373 (24 April 1354) prohibiting hemp in Kif, as supplemented or amended;
- Dahir of 12 rabii II 1341 (2 December 1922) regulating the import, trade, possession and use of poisonous substances as amended and supplemented;
- Joint Order of the Minister of the Interior, the Minister of Health and Social Protection, the Minister of Agriculture, Maritime Fisheries, Rural Development and Water and Forests and the Minister of Industry and Trade No. 1293-22 of 11 choul 1443 (12 May 2022) setting the procedures for issuing authorizations for the exercise of activities relating to cannabis;
- Joint Order of the Minister of the Interior, the Minister of Health and Social Protection, the Minister of Agriculture, Maritime Fisheries, Rural Development and Water and Forests, and the Minister of Industry and Trade No. 1297-22 of 11 choul 1443 (12 May 2022) setting the tetrahydrocannabinol (THC) levels provided for in Articles 6 and 17 of Law No. 13-21 on the legal uses of cannabis;
- Joint Order of the Minister of the Interior, the Minister of Agriculture, Maritime Fisheries, Rural Development and Water and Forests and the Minister of Industry and Trade, No. 1294-22 of 11 choul

1443 (May 12, 2022) setting the model contract for the sale of cannabis crops, the delivery report of said crops and the minutes of destruction of surplus cannabis production, its seeds, plants, crops and products;

- Joint Order of the Minister of the Interior, the Minister of Health and Social Protection, the Minister of Agriculture, Maritime Fisheries, Rural Development and Water and Forests, and the Minister of Industry and Trade No. 1296-22 of 11 choul 1443 (12 May 2022) setting the model registers and the modalities of their keeping by the Regulatory Agency for Cannabis-related Activities and by the holders of authorizations carrying out activities relating to cannabis.

ARTICLE 4. AUTHORISATIONS, DECLARATIONS AND REGISTRATION

The Transformer is required to comply with all the obligations provided for by the regulations applicable to his activity, in particular those provided for by Law No. 76-17 above, Decree No. 2-22-243 of 21 doulhijja 1443 (July 21, 2022) taken for the application of certain provisions of Law No. 76-17 on plant protection as well as other texts adopted for its application as they are published, make the necessary declarations, hold all related authorizations and send supporting documents and copies to ANRAC.

4.1 Authorization to establish a pharmaceutical establishment

For the transformation and manufacture of cannabis for medical and pharmaceutical purposes, the Transformer is required to set himself up as an industrial pharmaceutical establishment in accordance with the provisions of Dahir No. 1-06-151 of 30 choul 1427 (22 November 2006) promulgating Law No. 17-04 on the Medicines and Pharmacy Code, and to submit to all the legislative and regulatory provisions applicable to this type of establishment.

4.2 Authorization to Transform and Manufacture Cannabis

Any legal person wishing to carry out an activity of transformation and manufacture of Cannabis for medical and pharmaceutical purposes, must file, with ANRAC, against acknowledgment of receipt, an application for authorization accompanied by the documents referred to in Article 4 of Joint Order No. 1293-22 of 11 choul 1443 (May 12, 2022) setting the procedures for issuing authorizations for the exercise of activities relating to cannabis.

The applicant must send ANRAC these specifications initialed on all pages and signed on the last page, prior to the issuance of the authorization to engage in the activity of transformation cannabis for medical purposes. The signature must be preceded by the handwritten mention “read and approved, I undertake to strictly respect all the clauses of these specifications”.

The exercise of the activities of transformation and manufacture of Cannabis Products is authorized only after obtaining the official document of authorization to exercise said activity, issued by ANRAC.

The Transformer is required to commence the transformation and manufacturing of cannabis for medical use before the expiry of a period of three (3) years from the date of issuance by ANRAC of the authorization in question.

ARTICLE5. DOMICILIATION OF THE TRANSFORMER

The Transformer is considered domiciled at the address of its registered office which appears in his extract from the Trade Register.

ARTICLE6. INSURANCE

The Transformer is required to subscribe to insurance companies approved by the Insurance and Social Security Supervisory Authority (ACAPS), and without prejudice to other insurances in force in this area, the following insurances:

- Insurance of all personnel on duty against accidents at work and occupational diseases;
- The insurance of the civil liability of the Transformer.

The certificates relating to the above-mentioned insurance must be valid at all times.

Copies of these certificates shall be sent to ANRAC, in accordance with the procedures provided by it for this purpose.

ARTICLE7. SOCIAL CONDITIONS OF STAFF

The Processor is required to provide his staff with all the social services provided for by the laws and regulations in force, in particular those of the Labor Code and the Social Security Organisms.

ARTICLE8. TRANSFORMATION, QUALITY AND PERFORMANCE RULES

8.1 Transformation rules

The Transformer is required to comply with transformation standards, quality requirements and performance monitoring procedures as well as Good Manufacturing Practices, in accordance with the regulations in force relating to products for medical and pharmaceutical uses.

The Transformer is responsible for all processes of transformation of the raw material.

The Transformer must have internal transformation procedures, which he will make available to ANRAC.

8.2 Control of product quality and effectiveness

The transformer is required to carry out the tests and analyses necessary to control the quality and effectiveness of the products in accordance with the provisions of the Regulations specific to the activity.

He is required, in particular, to control the THC (Delta 9-tetrahydrocannabinol) content at all stages of cannabis transformation.

The analyses of this content are carried out according to the method described in Annex C to Commission Regulation (EC) No 1177/2000 of 31 May 2000 amending Regulation (EEC) No 1164/89 laying down detailed aid modalities for fiber flax and hemp (Community method for the quantitative determination of Δ -9-THC in hemp varieties); the size of the samples to be taken for the purposes of that control is fixed by ANRAC.

Samples are taken according to specific methods and under hygienic conditions.

8.3 Inputs

The transformer is required to obtain supplies exclusively from the cooperatives of authorized producers referred to in Law No. 13-21, through sales contracts concluded in accordance with the provisions of Article 10 of the said Law No. 13-21.

Before using each input, the Transformer must confirm their identity and obtain assurance that the raw materials have the characteristics necessary to provide the quality, quantity or yield expected during a given manufacturing process.

ARTICLE 9. TRANSFORMATION RESIDUE

The Transformer must keep a record of the quantities of Cannabis Residues generated at each stage of the transformation process.

The Transformer must have internal procedures for the traceability of Cannabis Residues, which he will make available to ANRAC.

The Cannabis Residues are destroyed by the transformer in accordance with the provisions of Articles 10 and 15 of the aforementioned Law No. 13-21.

The minutes and any supporting documents relating to the destruction operations must be made available to ANRAC.

Each step of the transformation process generating Cannabis Residues must be documented and reported to ANRAC.

ARTICLE 10. OBLIGATIONS OF TRANSFORMERS

10.1 General obligations

The Transformer is required to apply all the clauses of these specifications and to comply with all legislative and regulatory obligations applicable to him and for which it assumes full responsibility.

The Transformer is required to have facilities and equipment, in good working order and meeting the requirements of the Regulations specific to the activity.

10.2 Obligation to report harmful organisms

The Transformer is required to declare, without delay, to the ONSSA any finding of the presence of a harmful organism within the transformation unit or in the crops purchased, or any reason to suspect such a presence in accordance with the provisions of the aforementioned law n ° 76-17 and its implementing texts. A copy of this declaration must be immediately transmitted to ANRAC by any means.

10.3 Obligation to inform, advice and warn

ANRAC reserves the right to request at any time the transmission of the various documents relating to the data specific to the Products (characteristics, composition) or their method of obtaining (cultivation, manufacture, transformation, delivery, etc.).

In the event that the Transformer is unable to transmit, refuses or opposes the transmission of the requested elements within the deadlines set by ANRAC, he is given formal notice under the conditions set out in Article 19 of these specifications.

ARTICLE 11. CONDITIONING, PACKAGING AND LABELLING

The Transformer must imperatively ensure that the Products resulting from the transformation of cannabis are contained in packaging or in regulatory containers, and labelled in accordance with the regulatory provisions in force and in particular those relating to Articles 46, 47 and 48 of the aforementioned Law No. 13-21.

ARTICLE 12. TRANSPORT

For the transportation of Cannabis Products, the Transformer must use exclusively a Carrier duly authorized by ANRAC for this purpose.

The transport of Cannabis Products must be ensured under conditions that maintain their quality and performance, and prevent their deterioration and in compliance with the rules of Good Practice issued by the Competent Authority. The Transformer is thus obliged to communicate to the Carrier the necessary instructions and information and to record them in the contract between the two parties.

The Transformer must ensure that the Carrier has the necessary and adequate equipment means to respect the pharmaceutical circuits and preserve the cold chain.

In the event that the Transformer is himself the consignee of a transport operation, he is obliged to acknowledge receipt of the merchandise and to refrain from deferring their acceptance without valid reason. If he refuses to accept the merchandise in question, the Transformer must notify ANRAC without delay and comply with the terms of storage of the merchandise provided for in the sales contract.

ARTICLE 13. NOTIFICATION OF CHANGES CONCERNING THE TRANSFORMER

The Transformer is required to notify ANRAC and any competent administration of any change affecting his establishment, including his corporate officers, shareholders, the composition of the board of directors (managers) or on his activity, which is likely to modify his situation compared to that declared for obtaining the authorization of Transformer or when registering it in the Trade Register.

Notification of the change must be made within a period not exceeding thirty (30) days from the date of occurrence of the change, and must be made by any secure means.

The implementation of the change can only take place after obtaining the corresponding authorizations by the Transformer.

ARTICLE 14. GENERAL HYGIENE AND SAFETY OBLIGATIONS

The Transformer is required to comply with the Regulations specific to his activity with regard to hygiene and safety rules.

The Transformer is required to communicate to ANRAC all the hygiene and safety rules applicable to him and the system he has put in place to ensure compliance with them within his establishment.

ARTICLE 15. STORAGE

Cannabis and Cannabis Products must be stored in secure and monitored warehouses owned by the Transformer.

The Transformer must register all storage warehouses for Cannabis and Cannabis Products with ANRAC.

The Transformer is required to comply with the modalities and conditions of storage provided for by the standards and regulations in force and to take all necessary measures to preserve and maintain the quality and performance of the Cannabis and the Cannabis Products, under penalty of being held liable.

ARTICLE 16. SAFETY OF THE TRANSFORMATION SITE

The Transformer must take all necessary precautions and appropriate measures to avoid the occurrence of an incident or accident and to minimize its effects. Where appropriate, he must notify the competent authorities without delay and make available the information at his disposal to them.

The Transformer must have secure and monitored warehouses to store the cannabis crops he purchases from cooperatives. ANRAC reserves the right to inspect these warehouses and transformation units, at any time and without notice, by agents commissioned by it for this purpose and sworn in accordance with the legislation in force.

The Transformer must therefore put in place physical security systems and corresponding facilities for the cannabis transformation site, as well as documented procedures to detect and respond to intrusions or unauthorized access, theft or loss of Cannabis or Cannabis Products, and more generally any incident that may contravene the proper functioning of the site.

The means used may in particular consist of material, human or electronic means, permanent or temporary, fixed or mobile, without prejudice to the prerogatives and means of control provided for by ANRAC, in accordance with Article 49 of the aforementioned Law No. 13-21.

The means of remote control set up by the Transformer under his own security device, must be able to be freely consulted by ANRAC in addition to his own prerogatives and means.

The Transformer is required to put in place procedures to ensure that Cannabis Residues and all or part of the production that cannot be sold, are eliminated or destroyed in a safe and secure manner.

The Transformer must provide details on the method of destruction of the Cannabis and his compliance with the provisions of Article 15 of the aforementioned Law No. 13-21.

ARTICLE 17. TRACEABILITY PROCEDURES

In accordance with Article 45 of Law No. 13-21 on the legal uses of cannabis, the transformer must keep a Data Register recording all cannabis harvest entries as well as cannabis products in, out and in stock.

Each time a quantity of cannabis harvest is used as an input to the production chain, the Transformer enters a new entry on his Data Register by designating himself as a “customer”. For each crop variety used in this operation, the Transformer enters the variety and quantity in the output column (S) as well as the remaining stock for that variety (former stock minus the quantity used at the input of the production chain).

At the exit of the production chain, the transformer enters a new entry on his Data Register by designating himself as “recipient”. For each variety of the product recovered, the Transformer enters the name of the variety and the quantity in the column of entries (E) as well as the new stock for this variety (old stock plus the quantity recovered at the exit of the production chain).

The Transformer is required to keep his Data Register for a period of ten (10) years and to present it at each inspection.

ARTICLE 18. ENVIRONMENT

The Transformer is required to comply with regulations relating to the protection of the environment, particularly those concerning waste management, emissions management and flows, discharges, direct or indirect deposits into surface or groundwater, as well as good environmental practices that ANRAC reserves the right to enact.

The guide to these good practices will be published by ANRAC before it is required of Transformers, under the provisions of Article 33 of the aforementioned Law No. 13-21.

ARTICLE 19. PROCEDURES FOR MONITORING COMPLIANCE WITH THESE SPECIFICATIONS

In addition to the control exercised by the inspectors provided for in Article 131 of Law No. 17-04 on the Medicines and Pharmacy Code, judicial police officers, customs officers, commissioned agents under ANRAC for this purpose and sworn in accordance with the legislation in force, may access the Transformer’s head office and transformation units to examine documents relating to the activity of cannabis transformation, and to verify compliance with the various clauses of these specifications.

To this end, the Transformer is required to receive the above-mentioned agents, to facilitate their performance of their task and to make all the information and documentation requested available to them.

In the event of non-compliance with the legislative and regulatory provisions on Cannabis and the provisions of these specifications in terms of transformation, and without prejudice to the Regulations specific to his activity, the Transformer is required to submit, within a period which may not exceed seven (07) days following the sending of the report of finding of infringements as established by the commissioned agents by ANRAC, his explanations on the violations found.

In the absence of a response, or if the justifications given by the Transformer are unfounded, ANRAC gives formal notice, by registered letter with acknowledgment of receipt or by bailiff, to put an end to the violations found within a period it fixes and which may not be less than one (1) month.

Without prejudice to the application of Article 30 of the aforementioned Law No. 13-21, if the Transformer does not comply with the above-mentioned formal notice addressed to him, the authorization to transform cannabis for medical use may be suspended for a period of six (6) months and no request to carry out an activity related to Cannabis and its products may be filed with ANRAC by the Transformer during the period of suspension.

The suspension is lifted as soon as the infringements found within the abovementioned period are terminated.

If the violation persists at the end of the aforementioned period, ANRAC may refer all necessary sanctions, including the closure of the transformation site, to the Wali or the Governor of the province or municipality to which the Transformer depends.

The decision to suspend, or withdraw the authorization under the conditions provided for by the aforementioned Law No. 13-21, is notified to the interested party in the same forms as those of the notification of the formal notice.

Read and approved, I undertake to strictly respect all the clauses of these specifications.