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HELLENIC REPUBLIC

MINSTRY OF ECONOMY & DEVELOPMENT

GENERAL SECRETARIAT OF INDUSTRY

II DIRECTORATE GENERAL FOR IMPLEMENTATION OF REGULATIONS, INFRASTRUCTURE & CONTROL

DIRECTORATE FOR LICENSING OF UNDERTAKINGS & INDUSTRIAL PARKS

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Prot. No. 51483/700/Φ.63

Digitally signed by EIRINI PITTARA Date: 2018.05.14 14:50:27 EEST

DECISION

RE: “Terms and conditions for cultivating and processing pharmaceutical cannabis”

The Ministers for

Justice, Transparency and Human Rights

Health

Rural Development and Food

the Alternate Ministers for

Interior Economy and Development

and

the Deputy Minister for Rural Development and Food

Having regard to:

1. Law 4139/2013 “Concerning addictive substances and other provisions” (Government Gazette, Series I, No. 74) and in particular Article 2A, as it was added by Article 1 of Law 4523/2018 “Concerning the production of final products of pharmaceutical cannabis and other provisions” (Government Gazette, Series I, No. 41);
2. Law 3982/2011 “Simplification of the authorization procedure for technical professional and processing activities and business parks, and other provisions” (Government Gazette, Series I, No. 143);
3. Law 4442/2016 “New institutional framework for the exercise of financial activities and other provisions” (Government Gazette, Series I, No. 230);
4. Law 4512/2018 “Provisions for the implementation of Structural Reforms of the Economic Adjustment Program and other provisions” (Government Gazette, Series I, No. 5) and in particular Section D of Part B thereof;
5. Law 3325/2005 “Establishment and operation of industrial-craft plants as part of the sustainable development framework, and other provisions” (Government Gazette, Series I, No. 68);
6. Law 3938/2011 “Establishment of an Office for the Handling of Arbitrariness Incidents in the Ministry of Citizen Protection and other provisions” (Government Gazette, Series I, No. 61) and in particular Article 22 as amended by subparagraph C.5 of the first article of Law 4254/2014 (Government Gazette, Series I, No. 85);
7. Law 4235/2014 “Administrative measures, procedures and sanctions in respect of the implementation of EU and national legislation in the sectors of food, animal feed and the health and protection of animals and other provisions falling within the mandate of the Ministry of Rural Development and Food” (Government Gazette, Series I, No. 32) and in particular para. 1 of Article 62;
8. Law 4258/2014 “Procedure for the delimitation and regulation of issues on water streams - provisions of Urban Planning legislation and other provisions” (Government Gazette, Series I, No. 94) and, in particular, cases 2a and 2b of para. 6 of Article 11;
9. Law 1599/1986 “Citizen-State Relations, introduction of new identity cards and other provisions” (Government Gazette, Series I, No. 75);
10. Presidential Decree 63/2005 “Codification of legislation on Government and Government bodies” (Government Gazette, Series I, No. 98);
11. Presidential Decree 70/2015 on the “Re-establishment of the Ministries of Culture and Sport, Infrastructure, Transport and Networks, Rural Development and Food. Re-establishment of the Ministry of Shipping and the Aegean and renaming thereof as the Ministry of Shipping and Island Policy. Renaming of the Ministry of Culture, Education and Religious Affairs as the Ministry of Education, Research and Religious Affairs, the Ministry of Economy, Infrastructure, Shipping and Tourism as the Ministry of Economy, Development and Tourism, and the Ministry of Reconstruction of Production, Environment and Energy as the Ministry of Environment and Energy. Transfer of the General Secretariat for Industry to the Ministry of Economy, Development and Tourism” (Government Gazette, Series I, No. 114);
12. Presidential Decree 123/2016 “Re-establishment and renaming of the Ministry of Administrative Reform and E-Governance, re-establishment of the Ministry of Tourism, establishment of the Ministry of Immigration Policy and the Ministry of Digital Policy, Telecommunications and Media, renaming of the Ministry of Interior and Administrative Reconstruction, the Ministry of Economy, Development and Tourism and Infrastructure, Transport and Networks” (Government Gazette, Series I, No. 208);
13. Presidential Decree 96/2017 “Internal Regulation of the Ministry of Justice, Transparency and Human Rights” (Government Gazette, Series I, No. 136);
14. Presidential Decree 97/2017 “Internal Regulation of the Ministry of Rural Development & Food” (Government Gazette, Series I, No. 138);
15. Presidential Decree 121/2017 “Internal Regulation of the Ministry of Health” (Government Gazette, Series I, No. 148);
16. Presidential Decree 141/2017 “Internal Regulation of the Ministry of Internal Affairs” (Government Gazette, Series I, No. 180);
17. Presidential Decree 147/2017 “Internal Regulation of the Ministry of Economy and Development” (Government Gazette, Series I, No. 192);
18. Presidential Decree 73/2015 “Appointment of a Deputy Prime Minister, Ministers, Alternate Ministers and Deputy Ministers”(Government Gazette, Series I, No. 116);
19. Presidential Decree 125/2016 “Appointment of Ministers, Alternate Ministers and Deputy Ministers” (Government Gazette, Series I, No. 210);
20. Decision No. οικ. 483/35/Φ.15/2012 of the Alternate Minister for Development, Competitiveness and Shipping “Designation of form, supporting documents and procedure for the installation and operation of processing activities under Law 3982/2011 (Government Gazette, Series I, No. 143), the amendment and renewal of licenses and the deadline for the transfer or technical reorganization” (Government Gazette, Series II, No. 158);
21. Decision οικ. 5540/71/Φ15/2018 “Amendment to Decision of the Alternate Minister for Development, Competitiveness and Shipping No. οικ. 483/35/Φ.15/2012 (Government Gazette, Series II, No. 158) ‘Designation of form, supporting documents and procedure for the installation and operation of processing activities under Law 3982/2011 (Government Gazette, Series I, No. 143), the amendment and renewal of licenses and the deadline for the transfer or technical reorganization’ and amendment to the decision of the Alternate Minister for Economy and Development no. οικ. 32790/392/Φ.15/2017 (Government Gazette, Series II, No. 1061) ‘Simplification of the framework for the exercise of processing activities and other activities related to food and drinks and standardization of the administrative procedures for the notification of the operation thereof’” (Government Gazette, Series II, No. 60);
22. Decision no. 484/36/Φ.15/2012 of the Alternate Minister for Development, Competitiveness and Shipping “Designation, scales and procedure for the imposition of fines under Article 29, para. 8 of Law 3982/2011 (Government Gazette, Series I, No. 143)” (Government Gazette, Series II, No. 230);
23. Decision no. 8004/21/2/2012 of the Minister for Finance and the Minister for Citizen Protection “Service provision by the Hellenic Police to third parties against consideration” (Government Gazette, Series II, No. 888);
24. Decision no. Υ197/2016 of the Prime Minister “Assignment of competences to the Alternate Minister for Economy and Development, Mr. Alexandros Charitsis” (Government Gazette, Series II, No. 3722);
25. Decision no. 11226/133908/2016 of the Prime Minister and the Minister for Rural Development and Food “Assignment of competences to the Deputy Minister for Rural Development and Food, Mr. Vasileios Kokkalis” (Government Gazette, Series II, No. 3903), as amended by Decision no. 638/128269/2017 of the Prime Minister and the Minister for Rural Development and Food “Amendment to the decision for the Assignment of competences to the Deputy Minister for Rural Development and Food, Mr. Vasileios Kokkalis” (Government Gazette, Series II, No. 4250);
26. The fact that no expense for the State Budget arises herefrom.

We hereby decide as follows:

The following provisions shall apply for the cultivation and processing of cannabis within the meaning of the provisions of Article 2A of Law 4139/2013 and shall prevail over any other relevant general or special provision:

Article 1

Grant of approval of establishment and installation

The approval for the production, possession, transport, and procurement of raw materials and substances of cannabis varieties of the Cannabis sativa L. species with a tetrahydrocannabinol (THC) content exceeding 0.2%, the production, import and trade in propagation material, as well as the installation and operation of a manufacturing unit for the processing and manufacture of medical final cannabis products, with the exclusive purpose of either supplying them to the state monopoly for distribution for medical purposes, or exporting them, shall be subject to a single approval under the following terms and conditions:

A) Supporting documents for the issue of the installation approval

* 1. Land use certificate by the competent Building Agency, accompanied by the topographical chart that was submitted for the issue thereof. Where this topographical chart does not indicate the surface area of the area where all activities are to be performed, or the facilities or infrastructure neighboring the particular area and which could possibly affect the location of the activities, a separate topographical chart shall be submitted, to an appropriate scale, indicating the foregoing.
	2. Environmental Impact Assessment (EIA) and Decision on the Approval of Environmental Conditions (DAEC).
	3. Technical report by the entity documenting that the capacity of the manufacturing unit for the processing of cannabis is sufficient for the utilization/management of the quantity of cannabis produced and cultivated in the facility. The technical report shall contain a top view of the area occupied by the manufacturing unit, with an indicative location of the machinery.
	4. A copy of the police identity card or valid passport of the applicant natural persons or the natural persons participating in the management or administration of the applicant legal entities. Where the applicant is a legal entity, the aforementioned supporting document shall be produced: a) for Sociétés Anonymes, in respect of all members of the BoD, b) for General Partnerships, Limited Partnerships and Limited Liability Companies or Private Companies, in respect of all partners, c) for Joint Ventures without legal personality, in respect of all joint-venturing members.
	5. A certificate that all applicant natural persons or the natural persons participating in the management or administration of the applicant legal entities,as defined in case 4 above, are not under guardianship.
	6. A copy of a general use criminal record of the applicant natural persons or the natural persons participating in the management or administration of the applicant legal entities, as defined in case 4 above.
	7. A Solemn Statement stating that no final indictment has been issued in respect of the crimes of para. 5 of Article 2A of Law 4139/2013 for all applicant natural persons or the natural persons participating in the management or administration of the applicant legal entities,as defined in case 4 above.
	8. A Solemn Statement regarding compliance with the requirements of para. 5 of Article 2A of Law 4139/2013 of the applicant natural persons or the natural persons participating in the management or administration of the applicant legal entities, as defined in case 4 above.
	9. A certificate that the legal entity has not been declared bankrupt, that no application has been filed for declaring the legal entity bankrupt, that no application for conciliation-consolidation has been filed, that no application for dissolution has been filed and a certificate that the legal entity has not been dissolved.
	10. Tax and social insurance clearance certificates for the applicant natural person or the legal entity, which have been issued at the earliest one month before the application submission date.
	11. A permanent residence certificate for the persons set forth in the last section of para. 2a of Article 2A of Law 4139/2013.
	12. A tax and procedural representative statement, where the applicant has its registered office abroad.
	13. Opinions by the entities referred to in field B.3.7 of the questionnaire, if required.
	14. A Solemn Statement of the applicant natural person or the legal representative of the applicant legal entity that no school operates within a distance of less than 1,000 meters from the boundaries of the land plot of the unit to be licensed.
	15. A ten thousand (10,000) euro fee, deposited in KAE 3741 in favor of the General Secretariat for Industry (Ministry of Economy & Development).

Without prejudice to urban planning legislation, any architectural diagrams (topographical chart, coverage chart, top view, sections) or certifications thereof shall not be required for the grant of the installation approval. Where the urban legislation requires a certification of the architectural charts, the Directorate for Licensing of Undertakings & Industrial Parks of the General Secretariat of Industry, which grants the installation approval pursuant to the provision of para. B, shall certify them, provided that the installation approval can be granted.

B) Procedure for the issue of the installation approval

* + 1. For the grant of the installation approval, the entity of the unit being licensed (henceforth the entity) must submit to the Directorate for Licensing of Undertakings & Industrial Parks of the General Secretariat for Industry (hereinafter Licensing Directorate of the GSI) the questionnaire of Annex I filed in.
		2. The Licensing Directorate of the GSI shall grant to the entity, within three (3) working days, a response which shall list the required supporting documents laid down in paras A and C for the installation and operation approval, respectively. The supporting documents listed under A13 and 14 shall not be produced by the entity, but shall be sought through administrative channels by the Licensing Directorate of the GSI.
		3. The entity shall submit the designated supporting documents in five copies, of which one (1) in printed form and the remaining four (4) in digital form.
		4. The Licensing Directorate of the GSI shall transmit to the competent Agencies of the Ministry of Rural Development and Food, of the Ministry of Health/National Organization for Medicines, and the Hellenic Police, one of the digital copies, respectively, accompanied by the submitted questionnaire.
		5. The installation approval shall be granted by means of a decision of the Minister for Economy and Development, the Minister for Health, and the Minister for Rural Development & Food within 30 days from the submission of a complete dossier and shall be valid for five (5) years.
		6. Within fifteen (15) days from the grant of the installation approval, the Licensing Directorate of the GSI shall perform an on-site inspection, aiming at verifying the correctness of the questionnaire, the suitability of the area, if pre-existing, as well as the conditions prevailing in the area where the unit will be installed. Where the inspection discovers deviations from the contents of the questionnaire or unsuitability of the area or incompatibility of the conditions prevailing in the area, within ten (10) days the entity shall be notified in writing and/or electronically in respect of such discoveries, of the deadline for correcting the discovered deviations, if possible, as well as in respect of the sanctions should such deviations are not corrected. If the correction of the deviations is impossible, the installation approval shall be revoked.

C) Supporting documents for the issue of the operation approval

* + - 1. A certified property deed or a lease agreement or an assignment of use free of charge, certified by the competent Tax Office, covering the entire area of the unit being licensed. The duration of the lease agreement or the assignment of use free of charge must correspond to the duration for which the interested party applies for the operation approval.
			2. A top view of the area, with an indicative location of the machinery inside said area, including an indication of its power, signed by a competent engineer under the law.
			3. A certificate by the respective Security Sub-division or Security Department regarding compliance with the terms and conditions for the safe guarding of the cultivation areas, the facilities of the manufacturing unit, the storage areas of raw materials, substances and final products of pharmaceutical cannabis, pursuant to Article 3.
			4. A greenhouse type approval, where required.
			5. A Solemn Statement of the entity regarding compliance with the requirements of para. 5 of Article 2A of Law 4139/2013 in respect of any person that has a relationship of any kind of employment status with the unit.
			6. A Solemn Declaration by the competent engineer under the law, in respect of the structural sufficiency, the installation of the mechanical equipment in the primary (not auxiliary or jointly-used) area, the number of the existing building permit and the fact that no additional permit is required.
			7. A solemn statement by the entity indicating the number and the specialty of technicians it will occupy under the law.
			8. A solemn statement by engineers of a respective specialty, as the case may be, certifying that the installation was performed in accordance with the installation approval granted and that the foreseen works were implemented in accordance with the approved designs.
			9. A solemn statement for the assignment - undertaking of the supervision, operation and maintenance of the installation by its owner and the competent engineer under the law, respectively, where the total power exceeds 59 kW.
			10. A copy of the building permit, if the activity is to be performed in a newly constructed building.
			11. A Solemn statement as per Law 1599/1986 by the competent engineer under the law certifying that the fire protection measures and means, as foreseen in Joint Ministerial Decision Φ15/οικ.1589/104/2006 (Government Gazette, Series II, No. 90), as in force at each time, in respect of the installation of the manufacturing unit for the production of pharmaceutical cannabis, have been implemented and are in good order.
			12. An acceptance certificate and a valid control certificate for the steam boilers of the installation, in accordance with Articles 5 and 9 of Ministerial Decision No. 10735/651/2012 (Government Gazette, Series II, No. 2656), where the unit is equipped with steam boilers.
			13. A valid control certificate of liquid propane gas tanks, in accordance with Ministerial Decision No. Δ3/14858/1993 (Government Gazette, Series II, No. 477), Article 3.3.13, where the unit is equipped with a liquid propane gas installation.
			14. A solemn statement by a competent engineer under the law that the traffic connection of the installation has been performed in accordance with the approved designs.
			15. Water usage license, where required.
			16. License for the construction of port works and use of shoreline and beach, where required.
			17. Power generator license, where one exists and/or is used.
			18. A ten thousand euro (€ 10,000) fee, deposited in KAE 3741 in favor of the General Secretariat for Industry (Ministry of Economy & Development).

D) Procedure for the issue of the operation approval

For the grant of the operation approval, the entity must submit to the Licensing Directorate of the GSI the supporting documents set forth in the reply document determining the supporting documents that were sent upon submission of the questionnaire at the installation stage. The supporting documents shall be submitted in five copies, of which one (1) in printed form and the remaining four (4) in digital form. The supporting document listed under C 18 shall not be produced by the entity, but shall be sought through administrative channels by the Licensing Directorate of the GSI.

The Licensing Directorate of the GSI shall transmit to the competent Agencies of the Ministry of Rural Development and Food, of the Ministry of Health/National Organization for Medicines, and the Hellenic Police, one of the digital copies, respectively.

The operation approval shall be granted by means of a decision of the Minister for Economy and Development, the Minister for Health, and the Minister for Rural Development & Food within 30 days from the submission of a complete dossier and shall be valid for ten (10) years.

Within two (2) months from the operation approval, the Licensing Directorate of the GSI shall perform an on-site inspection in order to verify compliance with the terms for the grant of the operation approval.

Throughout the duration of the operation of the unit, the Licensing Directorate of the GSI shall perform on-site inspections on at least an annual basis to verify compliance with the terms for the grant of the installation and operation approvals. Where breaches are discovered, the inspection findings shall be promptly notified to the competent Agencies of the Hellenic Police, as such are defined in Article 4, and to the competent agencies of the Ministry of Rural Development and Food, as such are defined in Article 6.

E) Update of supporting documents

The entity shall be obliged to re-submit to the Licensing Directorate of the GSI updated versions of the installation approval supporting documents set forth under A 4-11, as well as of the operation approval supporting documents set forth under C 3 and C 5, by 31 December of each year, as from the year following the year of the approval. This obligation shall apply, in respect of installation approval supporting documents (A 4-11), throughout the validity term of the installation approval and, in respect of the operation approval supporting documents (C3 and C5), throughout the validity term of the operation approval.

The Licensing Directorate of the GSI shall review the updated supporting documents and, where they do not meet the statutory requirements, it shall notify the entity and the agencies of the co-competent Ministries and shall impose the sanctions provided for in case b of para. 2 of Article 9. The same sanctions shall be imposed in case of omission to submit the updated supporting documents.

Other installation and operation approval supporting documents that have a determined validity (e.g. DAEC), as well as updated versions of supporting documents the content of which may be changed (e.g. Statement of tax and procedural representative or Solemn Statement of assignment -undertaking of the supervision, operation and maintenance of the installation) shall be submitted to the Licensing Directorate of the GSI before the expiry thereof, or within ten (10) days from the amendment thereto, respectively.

F) Renewal of operation approval

For the renewal of the operation approval, the entity shall submit the questionnaire of Annex I. The Licensing Directorate of the GSI shall review the dossier of the supporting documents and shall determine the supporting documents which it deems that the entity must submit again.

Article 2

Amendment - Transfer of approvals

The approvals granted under Article 1 shall not be transferable. Any change to the shareholding composition of a legal entity shall be notified in writing to the Licensing Directorate of the GSI. Any new natural person or legal entity entering the legal entity shall submit all supporting documents relating to the management of the legal entity laid down in Article 1.

Any expansion or modernization under Article 17, para. 9 and 10 of Law 3982/2011, and in particular any amendment to the total surface area of the cultivation area, the mechanical equipment (addition, removal or change of machinery), storage areas, building facilities, and safety measures shall require a new installation approval and amendment to the operation approval, subject to the deposit of a € 5,000 fee for the installation approval and a € 5,000 fee for the amendment to the operation approval. For the issue of the new approvals, the entity shall submit the questionnaire of Annex I and the Licensing Directorate of the GSI shall determine which of the supporting documents of para. A are required for the new installation approval and which of the supporting documents of para. B are required for the issue of the amended operation permit, having regard to the nature of the amendment and the update of the supporting documents performed in accordance with para. E of Article 1.

Article 3

Safety and guarding specifications

* + - * 1. All cultivation and processing activities shall be performed within a fenced area, where the storage areas shall also be located. The cultivation area shall be closed.
				2. In respect of the protection of the perimeter, the following shall be at least implemented:

a) The area shall be fenced with a permanent mesh grid and/or wall, with a height of at least 3 m. Inside the fence, a free - empty zone of at least 3 m shall be constructed.

b) Lighting, from the sunset until the sunrise, with adequate sufficiency that renders any movement for the approach of the fence visible, both from the inside and the outside thereof.

c) Safety alarm system, operating continuously, with external motion detectors which shall report every attempt to breach the fence.

d) The fence shall be equipped with an integrated, 24/7 operational, supervision system, with the use of cameras, that will cover the perimeter and the free - empty zone, with no blind spots. The cameras must be able to record under any visibility conditions. The system must be equipped with a back-up battery to ensure uninterrupted operation. Recordings shall be kept for at least 90 days.

e) Guarding duties shall be performed by uniformed personnel and trained private guards in accordance with the provisions of Law 2518/1997, on a 24-hour basis, who shall continuously monitor the fencing, the empty zone and the safety systems. At least one moving guard per shift along the internal free-empty zone. For surface areas exceeding 10,000 m2, the moving guards shall be at least two. Upon change of shifts, the guards shall verify, on the log specially kept to this end, the proper operation of the cameras and of the electronic center.

f) A central outpost shall be located at the main entrance, to guard the entry-exit and to check the persons entering-leaving the facility. It shall be manned by at least two guards. At the same time, the gates shall be equipped with an integrated monitoring system, operating 24/7, with the use of cameras, which shall record under any visibility conditions equipped with a back-up battery to ensure uninterrupted operation.

* + - * 1. In order to protect the cultivation, the manufacturing unit and the storage areas, the following shall be mandatory:

a) Sufficient lighting, from sunset to sunrise, in order to ensure that any entry or exit, to or from the cultivation area, the manufacturing unit and the storage areas is visible.

b) Operation of a safety alarm system, with exterior motion detectors that will sound the alarm when anyone tries to violate the doors of these spaces.

c) The integrated monitoring system that operates 24/7, with the use of cameras, shall cover the entries and the interior of said spaces, without any blind spots. The cameras shall record under any visibility conditions. The system shall be equipped with a back-up battery to ensure uninterrupted operation. Recordings shall be kept for at least 90 days.

* + - * 1. Only specially authorized persons may enter the spaces of the aforementioned area, who shall be logged electronically. The electronic logs of entry-exit shall be kept for ten years and shall be made available to all and any inspections by the Hellenic Police, both routine and non-routine.
				2. In addition to the aforementioned security measures, the undertaking must ensure the adoption of any additional measure that is deemed necessary, in order to prevent any risk of destruction, damage, theft or loss, excluding the possibility that the above elements end up in the hands of any third person, in any manner. Moreover, the operation of the security measures must be continuous, constant, and uninterrupted; any damage or fault must be promptly restored. Damages, faults, destructions, losses and any need for maintenance shall be promptly taken care of on the same day.

Article 4

Monitoring of compliance with the guarding and security terms

The Public Security Division of the Hellenic Police Headquarters (PSD/HPH) is hereby designated as the competent authority for the monitoring and coordination of the other co-competent Agencies of the Hellenic Police, for the implementation of the provisions of Article 2A of Law 4139/2013, as it was added by Law 4523/2018, in respect of compliance with security terms, both of the facilities of the units and the transport of the final products.

The respective Security Police Sub-divisions, the respective Security Departments and, where no such departments exist, the respective Police Precincts (respective Police Authorities) are hereby designated as the competent authorities for the on-site inspections provided herein and for the preparation of the certificate provided for in paragraph C 3 of Article 1 hereof.

The respective Policy Authority shall perform on-site inspections of the facilities of any approved unit at least in the following cases:

a) Where the entity, after receiving the installation approval and after taking the security measures foreseen, requests a certificate, under paragraph C 3, for the compliance with the security terms, in order to submit it to the Licensing Directorate of the GIS, for the issue of the operation approval.

b) Where the entity requests the update of the certificate, under paragraph C 3, for the compliance with the security terms, pursuant to para. E of Article 1.

c) Six months after the issue of the aforementioned certificate.

d) Where the final product is transported.

e) In any emergency situation, the respective Police Authority may perform an inspection of the compliance with the security terms.

Where the law or the security terms are breached, the findings of the inspection shall be forthwith notified to the Licensing Directorate of the GIS and the competent agencies of the Ministry of Rural Development and Food, as such are defined in Article 6.

Article 5

Specifications for the transport of the final product

1. For the transport of the final products of pharmaceutical cannabis, the entity shall request a transport approval from the Public Security Division of the Hellenic Police Headquarters (PSD/HPH), promptly submitting, at least ten days prior to the transport date, a relevant application to the respective Police Agency of the place of manufacture, indicating:

a) The exact date and time of departure.

b) The following identity details of the carrier and the recipient:

Where a natural person is concerned: Full name, date and place of birth, home address, professional capacity and passport or identity card number, as well as their phone number, fax number and e-mail address, if available.

Where a legal entity is concerned: Name or trade name and registered office, as well as the surname, first name, date and place of birth, home address, passport or identity card number of the legal representative of the legal entity, as well as their phone number, fax number and e-mail address.

c) The exact quantity and type of the final product transported.

d) The required licenses or approvals for the producer, the carrier and the recipient.

f) The application provided for in Article 7, ANNEX A of the Joint Ministerial Decision No. 8004/21/2/2012 (Government Gazette, Series II, No. 888) for the provision of services by the Hellenic Police to third parties against consideration, completed in respect of the product’s transport.

The PSD/HPH shall issue the approval, unless the public security requirements for the transport are not met. In the latter case, it shall notify the transport applicant in a timely manner, through the respective Police Authority regarding the postponement or the modification of the route.

The PSD/HPH shall notify a) the respective Police Authority of the place of manufacture, b) the Financial Division of the Hellenic Police Headquarters, c) the Ministry of Rural Development and Food, d) the Ministry of Health of the upcoming transport.

The respective Police Authority shall review:

a) the lawful registration of the transport vehicle, and

b) whether the terms and conditions of the transport approval are complied with, in respect of the details of the driver and the vehicle.

The PSD/HPH shall coordinate the transport escort and shall issue an order to all, as the case may be, Police Authorities involved, notifying such order to the co-competent Authorities.

Subsequently, the transport of the final products of pharmaceutical cannabis from the place of manufacture a) to the place of delivery, if it is located within Greece or b) to the competent Customs Office, if the destination is outside of the European Union, shall be performed with the due diligence and with the escort of police authorities.

To this end, the provisions of Article 22 for the “service provision by the Hellenic Police to third parties against consideration” of Law 3938/2011 shall apply.

In any event, the transported quantities of final product must be packaged and sealed in a manner that excludes the unsealing thereof, in any manner, during transport.

The transport approval shall apply only for the type, the quantities, the time, the route and the place of departure and arrival indicated therein and may be used only once. If it is not used during its validity term, the holder must promptly submit to the PSD/HPH, through the respective Police Authority, the original approval and a relevant solemn statement certifying the lack of use, the reasons and any new, planned date under the same terms and conditions.

Anyone performing any transport without the foreseen approval shall be punished pursuant to the provisions of Law 4139/2013.

Article 6

Specifications for the import of propagation material and cultivation

1. The Directorate of Cultivation Systems and Plant Production Products of the Ministry of Rural Development and Food shall be the competent Directorate for all matters concerning the approvals or revocations of Article 1 and for cultivation until the drying stage of the unprocessed raw materials of the cannabis varieties of the Cannabis sativa L. species with a tetrahydrocannabinol (THC) content exceeding 0.2%.

The Directorate of Propagation Material of Cultivated Plant Species and Plant Genetic Resources of the Directorate General for Agriculture of the Ministry of Rural Development and Food (MRDF) is hereby designated as the competent authority for the supervision of the compliance with the procedures for the import of seeds of cannabis varieties and the controls related thereto.

The performance of the inspections provided for herein shall be performed by the departments of Rural Development and Inspections (DRDI) of the Directorates of the Decentralized Agencies of the MRDF.

The quantity of imported seeds shall not exceed three (3) kilograms of seeds per thousand square meters of cultivated area, and shall be imported for covering the needs of seeding of the approved cultivation area.

The mandatory labelling of the imported propagation material shall include at least the following details:

a) The name or the trade name of the shipping company.

b) The plant species.

c) The net weight (in kilograms), where seeds are concerned, or the number of planting material (number of plates / number of tissue culture micro-containers), where planting material is concerned.

d) The country of origin.

The entity, which has been granted an operation approval under Article 1, shall declare, two working days before the arrival of the seeds, to the local Department of Rural Development and Inspections of the Directorates of the Decentralized Agencies of the MRDF (DRDI), the arrival of the shipment at the entry-points of the Greek territory. The declaration shall be made by filling in a solemn statement under Article 8 of Law 1599/1986, signed, bearing a certification of the authenticity of the signature of the natural person or the legal representatives of the legal entity, accompanied by an official copy of the purchase invoice. The competent agencies, immediately upon receipt of the solemn statement and the accompanying documents, shall inspect the propagation material that has arrived in respect of sealing and labelling.

The entity which has been granted an operation approval under Article 1, shall be obliged:

a) To implement distinct marking of the cultivated parts - plots of land, with a codified system (traceability) that shall follow all stages of the manufacturing process.

b) To keep a record with every purchase - import supporting document for the original cannabis propagation material it has procured.

c) To keep a record with the final number of plants that were produced.

d) To notify the local Department of Rural Development and Inspections of the Directorates of the Decentralized Agencies of the MRDF (DRDI), one working day before the performance:

1. of seeding, the weight of the seed to be used;
2. of planting, the number of planting material;
3. of destruction of plants, the number of plants to be destroyed and the manner of destruction;
4. of harvesting, the number of the harvested inflorescences;
5. of destruction of cultivation remnants, the weight of the plant tissue to be destroyed;
6. of drying, the weight of the dried raw materials.

d) To notify the local Department of Rural Development and Inspections of the Directorates of the Decentralized Agencies of the MRDF (DRDI) every month of the stored amounts of inflorescences or raw materials.

Article 7

Supervision falling within the competence of the Ministry of Rural Development and Food

1. The departments of Rural Development and Inspections (DRDI) of the Directorates of the Decentralized Agencies of the MRDF must perform administrative inspections in order to verify the submitted information.

They shall also be obliged, at least every quarter, to perform on-site inspections of the approved unit.

1. Its inspections shall concern the lawful import of seeds, the quantity of seeds stored, between their import until seeding, the quantity of seeds destroyed, the quantity of harvested inflorescences, the number of destroyed plants, compliance with notifications, compliance with the obligations of the unit, in general, and the remaining obligations falling within the competence of the MRDF.
2. Following every inspection, the competent bodies shall prepare an inspection report, which shall be signed by the competent inspection organ and shall be received by the entity or its agents, who shall be present during the inspection. In case of refusal of reception, the inspection report shall be notified to the interested party by any lawful means. If breaches are discovered, the inspection finding shall be promptly notified to the Licensing Directorate of the GSI, to the competent Agencies of the Hellenic Police, as such are designated in Article 4, and to the competent Directorates of the MRDF.
3. In any event and at every stage of the procedure, the entity must notify, review and provide the inspection mechanism with the possibility of direct and easily identifiable access to the cultivation, processing, possession and storage of the product.

Article 8

Personnel recruitment

Recruitment of personnel employed in the above approved activities, under any lawful relationship, without exception, shall be permitted only subject to the negative conditions laid down in Article 2A, para. 5 of Law 4139/2013. For the purposes of hiring, the personnel shall submit to the employer a copy of their criminal record, which shall be kept by the latter and shall be produced in any routine or non-routine inspection.

Article 9

Penalties

* 1. In case of refusal to submit details and information or in case of submission of false details or withholding of data and information or hampering, in any manner, with the performance of routine or non-routine inspections, the installation and/or operation approval shall be revoked, following an invitation to the entity to express its views within a 10-day deadline.
	2. a) Where any violation of the provisions of Articles 19-26 and 29 of Law 4139/2013 is discovered, the entity’s installation and/or operation approval shall be revoked without first hearing the entity’s views. A prior hearing of the entity’s views shall also not be required in case of repeat violation or a violation for a few days of the security terms under Article 3.

b) In any other event, a 10-day deadline shall be set for the entity to submit its views in writing. Five days after the expiry of the said deadline, the competent Agencies shall notify the entity in writing of the compliance issues, setting, at the same time, a deadline for compliance which may not exceed 30 days. Lack of compliance on the part of the entity within the deadline set as per the foregoing shall entail the revocation of the installation and/or operation approval.

* 1. In particular, if the violations concern matters of industrial legislation, the penalties of Article 29 of Law 3982/2011 and Ministerial Decision 484/36/Φ15/2012 ((Government Gazette, Series II, No. 230) shall be imposed.
	2. Where any inspection organ discovers a breach that concerns the competence of another inspection authority, it shall promptly notify said inspection authority, which shall take the aforementioned required actions. Installation and/or operation approvals shall be revoked by means of a decision by the Ministers for Economy and Development, for Health, and for Rural Development and Food, following a recommendation by the Licensing Directorate of the GSI, having first been notified by the competent inspection authority.
	3. The revocation decision shall order the sealing of the area, as well as the seizure of all cultivated plants and all products, at every stage of the process, under the responsibility of the Public Security Division. The destruction thereof may be also ordered.
	4. The cessation of the operation of the facility shall be prohibited, unless the Hellenic Police and the Ministries of Rural Development and Food, of Health, and of Economy and Development have been notified in advance. The abovementioned authorities shall be notified in writing 10 days prior to the cessation and at the same time they shall be invited to seal the entire area and to take delivery of all plants, seeds and final products.

In case of cessation of operation, without prior notification, the area shall be sealed forthwith and the products shall be seized at the orders of Hellenic Police.

ANNEX I

QUESTIONNAIRE TO THE LICENSING AUTHORITY

For the determination of the category and the supporting documents required for the exemption/issue of Installation and Operation Approvals for manufacturing units

General instructions for filling in by the interested investor

* + 1. All questionnaire fields pertaining to your activities must be fully and accurately filled in.
		2. Fields marked with (\*) shall be filled in by the Agency to which this Questionnaire shall be submitted.
		3. Where checkboxes are available, responses must be given by marking an X in the respective checkbox.
		4. The Questionnaire shall be filled in and signed under your exclusive responsibility. Inaccurate or untruthful filling in of the Questionnaire shall automatically entail the cancellation of the exemption, or the License that will have been, respectively, issued.

|  |  |
| --- | --- |
| To: | (\*) Reference No. |
| (To be filled in by the respective application submission center) |  |
| (\*) Cc: | (\*) Date |

A. GENERAL INFORMATION

|  |
| --- |
| A1. Details of Legal Representative |
| Name |  | Surname |  |
| Father’s full name |  |
| Mother’s full name |  |
| Identity Card Number (ID No.) |  | Issuing Authority |  |
| TIN |  | TAX OFFICE: |  |
| Date of birth |  | Place of birth |  |
| Address (Prefecture, Municipality, Street, Number, Postcode) |  |
| Telephone numbers |  |  |
| e-mail |  | Fax |
| Α2. Details of procedural representative |
| Name |  | Surname |  |
| Father’s full name |  |
| Mother’s full name |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Identity Card Number (ID No.) |  | Issuing Authority |  |
| TIN |  | TAX OFFICE: |  |
| Date of birth |  | Place of birth |  |
| Address (Prefecture, Municipality, Street, Number, Postcode) |  |
| Telephone numbers |  |  |
| e-mail |  | Fax |  |
| Α3. Details of tax representative |
| Name | Surname |
| Father’s full name |  |
| Mother’s full name |  |
| Identity Card Number (ID No.) |  | Issuing Authority |  |
| TIN |  | TAX OFFICE: |  |
| Date of birth |  | Place of birth |  |
| Address (Prefecture, Municipality, Street, Number, Postcode) |  |
| Telephone numbers |  |  |
| e-mail |  | Fax |  |
|  |
| Α4. Details on the manufacturing unit |
| A4.1 Details of unit |
| Trade name: |
| TIN: TAX OFFICE: |
| Year of establishment:  |
| Address/Location/Surface area: |
| Street: Number: P.C.:  |
| Location:  |
| Municipality:  |
| Prefecture:  |
| Regional Unit  |
| Surface area of the plot of land:  |
| Geographical coordinates for areas not included in the town plan |
| on the basis of GOOGLE MAP : □ on the basis of HGRS: □ |
| ο /.' / " N |
| ο / ' / " E |

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| --- |
| A4.2 Characteristics of activity |
| 1. Type of activity (brief description) and main types of machinery to be used:  |  |
|  |
|  |
|  |
|  |
|  |
| 2. Activity code per the tax office classification: 21.20 |
| 3. The unit will be installed or is installed in an organized receiver of manufacturing and business activities under Article 41(4) of Law 3982/2011. | YES ο | NO ο |
|  |  |
|  |  |
| 4. Value of mechanical equipment |  |  |  € |
| 5. Raw and secondary materials used |
|  |
|  |
|  |
| 6. Production process |
|  |
|  |
|  |
| 7. Products manufactured |
|  |
|  |
|  |
| 8. General Commercial Registry (GEMI) Number: |  |
| The legalizing documents of the entity and its legal representative are registered with GEMI and I consent to the search thereof | YES ο | NO ο |
|  |  |
|  |  |

|  |
| --- |
| A5. Approval requested |
| Installation approval in existing building | □ | Grant of Operation Approval | □ |
| Installation Approval in a building under construction | □ | Renewal of Operation Approval | □ |

|  |  |  |  |
| --- | --- | --- | --- |
| Installation Approval for Expansion or Modernization of equipment | □ |  |  |
| Installation Approval for Expansion or Modernization of building | □ |  |  |
| Installation approval for modification to the cultivated area | □ |  |  |

|  |
| --- |
| B. SPECIFIC DETAILS |
| Β1. Classification of activity |
| Mechanical equipment power |
| 1. Total power of machinery directly related to the production process and which is going to be installed or is already installed: |  |  kW |
| 2. Total thermal power of machinery directly related to the production process and which is going to be installed or is already installed: |  |  kW |
| 3. Total driving and thermal power of environment protection machinery which is going to be installed or is already installed: |  kW |
| 4. Total driving and thermal power of the machinery that is not directly related to the production process (e.g. fire fighting, building service, air conditioning machinery, etc.) which is going to be installed or is already installed: |  kW |
| 5. Will a power generator be used YES ο | NO ο |  |  |
| backup ο / generation ο | quantity respectively |  |  |  |
| power (as the case may be) kVA MW. |  |  |
| B2. Classification of activity in nuisance categories and environmental impact |
| B2.1 Criteria/figures of nuisance of the unit on the basis of Joint Ministerial Decision 3137/191/Φ.15/2012 (Government Gazette, Series II, No. 1048), as in force at any time, and the criteria/figures of the environmental impact of the unit pursuant to Ministerial Decision ΔΙΠΑ/οικ./37674/2016 (Government Gazette, Series II, No. 2471), as in force at any time. |
| 1. kW  |
| 2. Tonnes/day  |
| 3. Tonnes/year  |
| 4. Other |
| B2.2 Criteria/figures of nuisance of the unit on the basis of Joint Ministerial Decision 3137/191/Φ.15/2012 (Government Gazette, Series II, No. 1048), as in force at any time, and the criteria/figures of the environmental impact of the unit pursuant to Ministerial Decision ΔΙΠΑ/οικ./37674/2016 (Government Gazette, Series II, No. 2471), as in force at any time, FOLLOWING MODERNIZATION OR EXPANSION |
| 1. Upon modernization, do the criteria/figures pertaining to nuisance caused by the unit change | YES ο | NO ο |

|  |  |  |  |
| --- | --- | --- | --- |
| 2. Upon modernization, do the criteria/figures pertaining | YES ο |  | NO ο |
| to the environmental impacts of the unit change |  |  |  |
| 3. Criteria / Figures |  | Current state | After modernization |
|  |  |
| 1. kW |  |  |  |  |
| 2. Tonnes/day |  |  |  |  |
| 3. Tonnes/year |  |  |  |  |
| 4. Other |  |  |  |  |
| B2.3 Waste |
| 1. The production process produces |
| Liquid waste | YES ο |  |  | NO ο |
| Gaseous waste | YES ο |  |  | NO ο |
| Solid waste | YES ο |  |  | NO ο |
| Hazardous waste | YES ο | NO ο |
| If yes, will the entity manage the hazardous waste? | YES ο |  |  | NO ο |
|  |  |  |  |
|  |  |  |  |
| 2. Liquid waste, if any, is disposed: |  |  |
| a. following processing with planned reuse pursuant to Joint Ministerial Decision 145116 (Government Gazette, Series II, No. 354/8-3-2011) and Joint Ministerial Decision ΚΥΑ 5673/400/97 (Government Gazette, Series II, No. 192/14.3.1997) □ |
| b. and/or in another manner: (please describe) |  |  |  |  |
|  |
|  |
|  |
|  |
|  |
| 3. After the modernization or the expansion, the waste will be increased (including liquid waste, hazardous, solid and non hazardous waste) | YES ο | NO ο |
|  |  |
|  |  |
| B2.4 Wastewater |
| 1. The wastewater from sanitation facilities will be driven to: |
| Network | YES ο |  |  | NO ο |
| Septic or absorbent tank | YES ο |  |  | NO ο |

|  |  |
| --- | --- |
| B3. Building |  |
| 1. The unit will be installed / modernized in already existing buildings | YES ο | NO ο |
| If yes, do the buildings have the appropriate construction permit | YES ο | NO ο |
| 2. The unit will be installed / modernized in buildings that will be constructed | YES ο | NO ο |
| If yes, the buildings will be constructed in one of the two following manners |  |
| In accordance with the applicable construction code without derogation | □ |
| With derogation from the applicable construction code |  | □ |
| 3. The installation will be performed in a main use area  | YES ο | NO ο |
| 4. Ownership status  |  |
| 5. Surface area of roofed activities area |  |  m2 |
| 6. Neighborhood conditions |  |  |
| The area surrounding the facility includes: |  |  |
| Residences ο Shops ο Laboratories ο |  |
| Plots of Land ο Open areas ο Warehouses ο |  |
| Workshops ο Streets ο ο |  |
| The plot of land is adjacent to |  |  |
| Residential buildings οStreet(s) ο |  |  |
| Plots of land ο |  |  |
| * 1. In respect of the area for the installation / modernization of the unit there are provisions which result in restrictions or prohibitions concerning the installation / modernization of the unit (please refer to Table in the Annex to this questionnaire).

If YES, please list the ones you are aware of |  | NO ο |
| YES ο |
|  |  |
|  |  |
|  |  |

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| --- |
| B4. Water usage license, where water from drilling will be used for manufacturing processes |
| 1. The implementation of a water resources and water usage project is envisaged (e.g. Drilling) | YES ο | ΝΟ ο |
| 2. Water consumption |  |  m3 |

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| --- |
| Β5. License for the construction of port works and use of shoreline and beach |
| 1. The plot where the unit will be installed faces the shoreline: | YES ο | NO ο |
| If yes, is the execution of technical works on the shoreline and the beach envisaged | YES ο | NO ο |
| If works are to be performed in the shoreline and the beach at this location, is their construction permitted? | YES ο | NO ο |

|  |
| --- |
| Β6. Other issues |
| B6.1 Construction of road connection |
| 1. The plot where the unit will be installed has an entry or exit to a national road | YES ο | NO ο |
| B6.2 Liquid propane gas use |
| 1. Will LPG be used | YES ο | NO ο |
| B6.3 Steam boilers / Steam generator / Tanks / Bottles |
| 1. Are steam boilers / steam generators used YES ο | ΝΟ ο |  |
| Category Α ο |  B ο C ο |  |
| Inspection certificate:  |  |  |
| (state the number, the date, the validity term) |  |
| Acceptance Certificate:  |  |  |
| (state the number, date) |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 2. Are there tanks / bottles |  | YES ο | NO ο |  |
| Type and quantity Capacity for each one |  | portable ο fixed ο |  |
|  |  |  |  |
| Contents of each one |  |  |  |  |
|  |  |  |  |
| 3. Natural gas will be used: |  | YES ο | NO ο |  |
| B7. SEVESO |
| 1. The activity entails hazardous substances listed in Annex I to Joint Ministerial Decision 172058/2016 (Government Gazette, Series II, No. 354), columns 1 and 2, on the control of major-accident hazards, as in force at each time. | YES ο | NO ο |
| 2. The activity entails hazardous substances listed in Annex I to Joint Ministerial Decision 172058/2016 (Government Gazette, Series II, No. 354), columns 1 and 3, on the control of major-accident hazards, as in force at each time. | YES ο | NO ο |

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| --- |
| C. OTHER INFORMATION |
| C1. Statistical Data |
| 1. Total estimated investment account (mechanical equipment, buildings, plot of land, etc.)  |  | € |
| 2. Total number of persons that will be occupied / are already occupied in the unit |
| Technical staff  |
| Administrative staff  |
| Labor staff  |
| Other staff  |
| C2. Hazardous Substances |
| 1. Processing unit of flammable, explosive, corrosive, oxidant, toxic or other hazardous substances and pressurized gases | YES ο | NO ο |
|  |  |
|  |  |
| 2. Warehouse where quantities of flammable, corrosive, oxidant, toxic or other hazardous substances exceeding 100 kg are stored | YES ο | NO ο |
|  |  |
|  |  |

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| D. COMMUNICATION |
| D1. Selection of methods of communication |
| Mail |  | □ |
| Electronic Mail (e-mail) |  | □ |
| Fax |  | □ |
| Courier |  | □ |
| Telephone (invitation to the applicant to visit the Agency) | □ |
|  |  |  |
|  | Date:  |
| (\*) E. REMARKS |  |
| Remarks by the Agency |
|  |
|  | Date:  |

|  |
| --- |
| ANNEX TO QUESTIONNAIRE |
| LIST OF REQUIRED SUPPORTING DOCUMENTS AND MORE SPECIFIC REQUIREMENTS |
| POINT A. OPINIONS OF INSTITUTIONS |
| In respect of the area for the installation / modernization of the unit, or in respect of the specific activity, special supporting documents or opinions by Agencies or Institutions may be required, as the case may be, among the following exhaustive list (please state which ones you have already obtained or will obtain or you are aware that are required): |
| Opinion/other supporting document granted by IPTO, where medium and high voltage lines pass through | Government Gazette, Series IV, No. 101/13-04-1974, Government Gazette, Series IV, No. 110/20-05-1975 |
| Opinion/other supporting document of the respective water provision authority (e.g. EYDAP, etc.), where an open or closed water pipeline passes through the area | Hygiene Regulation A5/2280/1983 (Government Gazette, Series II, No. 720), as in force |
| Opinion/other supporting document from the competent agencies of the Ministry of Culture and Sport, where archaeological sites exist | Law 3028/2002 |
| Opinion/other supporting document of the Civil Aviation Authority, provided that the activity is located close to any facility that is operated under the responsibility of the CAA | Ministerial Decision Δ3/Δ/3271/2009 (Government Gazette, Series II, No. 191) |
| Opinion/other supporting document of the respective Agricultural Economy Directorate of the Region, where the activity is located in an agricultural area and where it may be located in a high productivity agricultural land | Article 56(2) of Law 2637/68, as amended by Article 37(24) of Law 2945/2001 |
| Opinion/other supporting document by the respective Forest Authority, provided that the installation area is subject to the provisions of forest legislation | Article 46 of Law 998/1979, as in force |
| Any opinion/other supporting document specifically required by the applicable legislation for the specific area or for the specific activity (e.g. Natura areas, NOM, etc.) | The Licensing Authority shall make reference to the specific legislation and shall provide justifications for requiring an opinion/supporting document on the basis thereof. |
| POINT B REVIEW OF DISTANCES |
| In respect of the area for the installation / modernization of the unit, or in respect of the specific activity compliance with minimum distances requirements is necessary: |
| From neighboring animal farming facilities | Law 4056/2012 |
| From areas classified as quarrying | Article 48 of Law 4512/2018 |
| For the establishment of production or storage plants for explosives | Article 2 of Joint Ministerial Decision 3329/21-2-1989 (Government Gazette, Series II, No. 132) |
| Distances from delimited water systems (streams, rivers) | The Licensing Authority shall make reference to the specific legislation and shall provide justifications for requiring an opinion/supporting document on the basis thereof. |
| Distances required under any special provisions (e.g. Yliki lake, healing springs, Holy Monasteries, foundations, nursing homes, etc.) | The Licensing Authority shall make reference to the specific legislation and shall provide justifications for requiring an opinion/supporting document on the basis thereof. |
| Distances from schools | At least 1,000 m |

Article 10

Entry into force

The provisions hereof shall prevail over any other special or general provision of law that regulates the above matters. The provisions hereof shall not exclude the application of provisions providing for criminal or administrative penalties.

This decision shall enter into force upon its publication in the Government Gazette. This decision must be published in the Government Gazette of the Hellenic Republic

Athens

The Minister for Minister for Health

Justice, Transparency and Human Rights

Charalampos Stavros Kontonis Andreas Xanthos

The Minister for Rural Development and Food The Alternate Minister for Interior

Evaggelos Apostolou Nikolaos Toskas

The Alternate Minister for Economy and Development The Deputy Minister for Rural Development and Food

Alexandros Charitsis Vasileios Kokkalis