ENTERPRISE GREECE

Licensing procedures.

Sector of manufacturing and related activities.





GENERAL SECRETARIAT FOR INDUSTRY

GENERAL DIRECTORATE FOR INDUSTRY AND BUSINESS ENVIRONMENT



DEFINITIONS

MANUFACTURING ACTIVITIES: activities that take place in specific facilities and which, with the use of mechanical, chemical or other means, modify the form or quality of raw materials or products, in order to make them suitable for their intended use.

with machinery, as defined in the relevant JMD 2219/146 / Φ .15 / 2012 toxic substances, liquid or gaseous fuels and industrial or medical gases.

ing out specific activity.

MODERNIZATION / EXPANSION: replacement or addition of machinery, building facilities and the change or addition of the activity.

intended purpose, provided that the unit meets all the requirements listed below: out.

Change.

APPROVAL: Issuance of an administrative act accompanied by an inspection before the establishment and operation of the activity.

regime of the approval, it is not accompanied by issuance of an administrative act.

- **RELATED ACTIVITIES:** service providing activities to third parties without manufacturing of new products
- (Government Gazette B' 584), as well as activities related to storage facilities for flammable, corrosive, oxidizing or
- **ESTABLISHMENT:** first time installation of mechanical equipment at a specific location with a view to carry-

- **PROFESSIONAL WORKSHOP:** a techno-economic plant which uses mechanical, chemical or other equipment to modify the form or properties of raw materials or products, in order to make them suitable for their
- a) It has mechanical installations, with an installed driving power of not more than 37KW, or a thermal power of not more than 70 KW. These limits do not include the power that is not directly related to the production process, as well as the power of a mechanical installation intended solely to protect the environment from the activity carried
- b) It is classified as a low nuisance activity according to the provisions of the relevant 3137/191 0.15/2012 (B' 1048) decision of the Ministers of Development, Competitiveness and Shipping and Environment, Energy and Climate

NOTIFICATION: The body carrying out the activity submits to the information system www.notifybusiness.gov.gr notification of establishment or operation which is accompanied by an expost inspection and contrary to the licensing

COMPETENT AUTHORITY

 MINISTRY OF DEVELOPMENT AND INVESTMENTS **GENERAL SECRETARIAT FOR INDUSTRY** GENERAL DIRECTORATE FOR INDUSTRY AND BUSINESS ENVIRONMENT DIRECTORATE OF LICENSING FOR BUSINESSES AND BUSINESS PARKS DEPARTMENT OF SUPPORT TO REGIONS, REGISTRY OF INSPECTORS AND INDUSTRIAL AND BUSINESS REGIS-TRIES AND INDUSTRIAL AND COMMERCIAL REGISTERS

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The competent service for the institutional framework of manufacturing and related activities facilities licensing is the Directorate of Licensing of Businesses and Business Parks (Department of Regional Support, Inspectors' Register and Industrial and Business Registers).

• DIRECTORATES FOR DEVELOPMENT OF THE REGIONAL UNITS

https://www.enpe.gr/el/perifereies

Competent services for the manufacturing and related activities facilities licensing are the Directorates for development of the Regional Units.

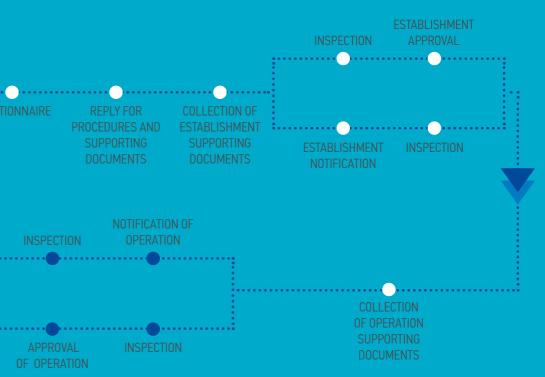
Department of Authorisations, Development and Natural Resources.

BRIEF FLOW CHART

LICENSING PROCEDURE OF MANUFACTURING ACTIVITIES

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ESTABLISHMENT PROCEDURE **OPERATION PROCEDURE**





LICENSING STAGES

Stage 1: Establishment

At this stage the operator of the manufacturing (or related) activity is in the planning phase and should know before starting any works if there are spatial and urban planning conditions (land uses, industrial legislation and other characteristics of the area) that allow its installation/establishment. The establishment stage is probably the most critical one for the implementation of an investment, since various urban planning regulations regarding the siting of a specific manufacturing facility are examined and interpreted. Establishment approval is generally required at this stage, except in the specific cases detailed below, where an establishment notification is required. Requirements for approval of establishment or notification of establishment &
 requirements for no approval of establishment or notification of establishment

a. Establishment approval is required for setting up and modernization/expansion of:

i) manufacturing units established in areas for which no "industrial/craft establishments" land uses **have been designated by urban planning;**

ii) establishments falling under the scope of:
a) Joint Ministerial Decision 172058/2016
(Government Gazette B' 354), (it concerns facilities with dangerous substances that can cause large-scale accidents);

b) Law 4409/2016 (Government Gazette A' 136) (offshore Safety) (it concerns offshore hydrocarbon exploration and exploitation works):

c) Ministerial Decision $\Delta 3/A/o\iota\kappa$. 4303 TE 26510/2012 (Government Gazette B' 603) ("Technical Regulation" Natural gas transmission systems with a maximum operating pressure of more than 16 bars ") (it refers to land-based natural gas transmission systems with a maximum operating pressure of more than 16 bars); **iii)** establishments carrying out activities consisting in the processing of flammable, explosive, corrosive, oxidizing, toxic or other hazardous substances and pressurized gases, irrespective of the quantity being processed;

iV) establishments carrying out activities consisting in the storage of flammable, explosive, corrosive, oxidizing, toxic or other hazardous substances in quantities greater than 100 kg.,

V) establishments carrying out activities consisting in the storage of explosives, where the quantity of the stored explosives exceeds the limits provided by law (par. 2 of Article 1 of 3329/15.2.89 joint decision of the Ministers of National Defence, Public Order and Transport and Communications and the Deputy Ministers of Environment, Spatial Planning and Public Works and Industry, Energy and Technology (B' 132); and

vi) establishments carrying out activities consisting in the storage of pressurized gases in quantities greater than 200 kg.





b. Establishment notification is required for setting up and modernization/expansion of:

i) professional workshop establishments, mechanical low nuisance service facilities and warehouse facilities of low nuisance flammable, oxidizing and explosive products, provided that the motive or thermal power of their machinery does not exceed that of

the professional laboratory, regardless of the area in which they are located and are not subject to any of the above cases.

ii) manufacturing units, if they are built in areas where land uses for industrial activities **have been designated by urban planning** and are not subject to any of the cases of the paragraph above.

iii) facilities of cases a (iii), a (iv), a (v), a (vi) above,
 when land uses for industrial-manufacturing activities have
 been designated by urban planning.

c. No approval of establishment or notification of establishment is required:

 i) for modernization of machinery/expansion (not addition or change of activity) of a unit that has been provided with an approval of establishment, if it does not fall under the case A (ii) above and this is done within the existing degree of nuisance of the unit and within the time period indicated by the approval of establishment (20 years from the date of issue of the approval of establishment in areas with designated land uses and 10 in areas without designated land uses).

ii) ii) for establishment and modernization/expansion of manufacturing and related activities units within Industrial Areas that have been organized according to Law 4458/1965, in Industrial and Business Areas, which have been organized according to Law 2545/1997, as well as in Business Parks, which are organized according to part C of Law 3982/2011

iii) for modernization of machinery/expansion of legally operating units if the operator does not wish for the said modernization to be subject to notification or approval of establishment and if from the modernization of machinery/expansion:
a) the degree of nuisance does not change for professional laboratories, warehouses and low nuisance units unless an amendment to the environmental conditions is required; and

b) there is no increase in the installed power, laid down in the operating license of the medium and high nuisance units, by more than 20% every three years from the start of operation or the previous expansion or modernization. This increase, provided that there is no change in the degree of nuisance in the unit, may not, in any case, exceed 600 kW of motive and thermal power.

2 Establishment Process Steps

a) Submission of the Questionnaire by the interested party to the Directorates for Development of the Regional Units (Annex I of the MD published in Government Gazette B' 158.2012 - 7.6.2019).

b) Response of the service which, based on the above questionnaire, determines the procedures and supporting documents required for both the establishment and the operation stages.

C Collection by the operator of the supporting documents required for the establishment stage either through the Licensing Authority or by the interested party.

d) On the spot inspection and issuance of Approval of Establishment or submission of Notification of establishment through **www.notifybusiness.gov.gr** and ex-post on the spot inspection.





3 Establishment Documents

i) A Certificate of land use from the competent Building Service, accompanied by the site plan submitted for its issuance. In case that in the site plan no facilities or infrastructures, adjacent to the specific area, which potentially affect the siting of the activity, are indicated, a separate site plan shall be submitted at an appropriate scale to capture the above.

ii) a) An Environmental Terms Approval Decision (AE Π O), if the activity belongs to category A in an area without designated land uses or **b)** a Decision of inclusion in Standard Environmental Commitments ($\Pi\Pi\Delta$), if the activity belongs to Category B.*

iii) In case of operation of the activity in a multi-storey building, according to the provisions of article 4 of law 3741/1929 (Government Gazette A' 4) "About ownership per floors", a solemn declaration of the operator that there is a joint ownership regulation with reference to its number and that the regulation does not prohibit the activity. In case there is no joint ownership regulation, a solemn declaration by the facility owner that there is no joint ownership regulation and that he agrees with the installation of the activity. **IV** In case the activity falls within the scope of JMD 172058/2016 (B' 354) (SEVESO), the notification file or safety study, at the discretion of the above JMD.

V) v) An Opinion of the agencies (APPENDIX TO ANNEX I JMD published in Government Gazette B 158.2012 - 7.6.2019), if it is required for the area or for the specific activity, as well as a declaration by the operator or the engineer of the above site plan to the effect that the mandatory distances from specific establishments and areas, as required by the legislation in force, have been observed.

It is noted that the required supporting documents are the same for both the establishment approval and the establishment notification

The only difference is that in the approval the supporting documents are presented to the licensing authority, an on site inspection is performed and the establishment approval is issued, while in the notification the supporting documents are kept in a relevant file in the unit and are presented to the competent authority during the inspection after the submission of notification.



Stage 2: Operation

At the stage of operation, the operator has completed the implementation of the business plan and the construction of the plant, having taken into account all the technical specifications and conditions and the relevant approvals required by law, and the activity is ready to operate. As the operator has been informed by the competent authority of the requirements to be met during the operation of the plant and given the risk level associated with the activity in this phase, it is generally required to submit an operation notification, except in the specific cases detailed below, where an operation approval is required.

a. Operation Approval is required:

I) with Business Activity Code (KAD) 49.50, Pipeline Transport Services

a) with Business Activity Code (KAD) 49.50, Pipeline Transport Services

- KAD 49.50.11 Pipeline Transport Services of crude or refined oil and petroleum products -KAD 49.50.12 Pipeline Transport Services of Natural Gas -KAD 49.50. 19 Pipeline Transport Services of Other Goods

b) carrying out the activities referred to in Law 3982/2011 falling within the scope of JMD No 172058/11.2.2016 (B' 354) (Seveso Directive) and

c) those referred to in Law 4409/2016 (A' 36), ie offshore hydrocarbon prospecting operations.

ii) a) for the set up of establishments carrying out the activities falling under law 3982/2011 that are classified as category A1 according to ministerial decision ΔΙΠΑ (DIRECTORATE OF ENVIRONMENTAL LICENSING)/37674 (B' 471)

b) for establishments carrying out activities that due to addition of activity are classified as category A1 for the first time

c) for facilities of activities that due to modernization of their machinery switch from category B' to category A1, according to the aforementioned decision.

b. Notification of Operation is required:

I) In all cases of establishment, modernization / expansion not referred to in the previous paragraph A.



Z Operation Procedure Steps

a) Submission of the Questionnaire by the interested party, (Annex I of the MD published in Government Gazette B 158.2012 -

7.6.2019), if not submitted at an earlier stage. b) Response of the agency, which, based on the above guestionnaire, is setting out the procedures and supporting documents required for the operation stage. C Collection of the supporting documents required for the Operation stage either through the Licensing Authority or by the interested party.

d) On the spot inspection and issuance of Approval of Operation or submission of Notification of Operation through http://www.notifybusiness.gov.gr.

i) A Brief technical description of the facility signed by the competent engineer (Site plan showing the building facilities and traffic signs). A description of the activity with a floor plan with indicative placement of the machinery inside it and a list of the machinery with an indication of their power.

ii) A Solemn Declaration by the competent engineer certifying the static equilibrium and the industrial-manufacturing use of the building, that no new building permit or settlement or legalization of the building facility is required, that the installation of the machinery took place in a main use area (not in ancillary or shared areas) and that it is in accordance with the technical description of the supporting document 1.

III) An Environmental Terms Approval Decision (AE Π O) or Decision of inclusion in Standard Environmental Commitments ($\Pi\Pi\Delta$)).*

IV) The Building Permit, with all the accompanying studies and designs, including any settlements, arrangements or legalizations of arbitrary constructions, as well as the relevant fine payment certificates.

V) A solemn declaration by the owner of the plant and the competent engineer under the law, respectively, to the effect that the supervision, operation and maintenance of the plant has been assigned and undertaken, if the total driving power of the plant exceeds 59 kW (80 HP), or a maintenance contract from the manufacturer for the mechanical equipment to the effect that the latter is responsible for the proper functioning of the mechanical equipment.

VI) A Fire Safety Certificate of the competent Fire Department according to JMD 136860/1673 / Φ 15 (B' 6210), if required. In case of installations of petroleum products (liquid fuels) or LPG for the operational needs of the units the provisions of MD (B' 578/1991) and MD Δ 3/14858/1993 (B' 477) apply respectively.

VII) A valid inspection certificate for the plant's liquefied gas tanks, according to MD Δ 3 / 14858/1993 (B' 477), article 3.3.13, if required.

Viii) Valid acceptance and inspection certificates for the plant's steam boilers, on the basis of Articles 5 and 9 of MD 10735/651/2012 (B' 2656), if required.





IX] An Approval for food manufacturing activities and other products of animal origin, pursuant to Regulations 853/2004 (L 139) or 183/2005 (L 35) or 1069/2009 (L 300), if required.

X) A Water use permit, in case of borehole water for manufacturing purposes, if required.

Xi) A Solemn Declaration according to Ministerial Decision no. Y Π E/ Δ H E/ 89003/443 (B' 5674/2018) for the backup power generating pairs of the unit, if required.

XII) An Approval of pavement leveling-lowering or approval of traffic connection or approval of entry-exit by the agency in charge for the maintenance of the road (or roads) in front of the unit, accompanied by a solemn declaration by the competent engineer under the law, that the traffic connection or the entry-exit of the facility was implemented according to the approved plans, if required.

XIII) Permission for the construction of a port project or the use of a seashore and beach, if required

xiv) Permission to use natural gas, if required.

It is noted that the required supporting documents are the same for both the operation approval and the operation notification

The only difference is that in the approval the supporting documents are presented to the licensing authority, an onsite control is performed and the approval of operation is issued, while in the notification the supporting documents are kept in a relevant file in the unit and are presented to the competent authority during the inspection after the submission of notification.

For the cases of activities that are subject to the approval regime for both the establishment and operation stages, applies the deadline of sixty (60) days from the submission of the complete file to the agency.



* GENERAL INFORMATION FOR ENVIRONMENTAL LICENSING

A. Environmental Terms Approval Decision (AEIIO)

For manufacturing and related activities facilities that environmentally belong to category A (Law 4014, JMD 92108/1045/Φ.15/2020 (B' 3833)) an environmental impact study is required along with an Environmental Terms Approval Decision (ΑΕΠΟ). -For projects and activities of an environmental subcategory A1, the ΑΕΠΟ is issued by the Ministry of Environment and Energy.

-For projects and activities of an environmental category A2, the AENO is issued by the relevant Decentralized Administration.

B. Standard Environmental Commitment Procedure ($\Pi\Pi\Delta$)

In the cases of projects and activities that fall under environmental category B, no AEIIO is required as they are automatically subject to Standard Environmental Commitments. Under responsibility of the competent authority that has issued the license of operation, the manufacturing and related activities projects and activities are automatically subject to $\Pi\Pi\Delta$ in accordance with the provisions of no. $\Phi.15/4187/266$ (B' 2012).

C. Urban categorization

Since the issuance of JMD 92108/1045/0.15 any reference in the current legislation to high, medium and low nuisance has been respectively replaced by the A1, A2 and B environmental classification categories.



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IN COOPERATION



GENERAL SECRETARIAT FOR INDUSTRY

GENERAL DIRECTORATE FOR INDUSTRY AND BUSINESS ENVIRONMENT