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REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES[1]

Notification under Article 7.3 of the Agreement on Import Licensing Procedures

ALBANIA

The following notification, dated 6 December 2010, is being circulated at the request of the delegation of Albania.

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I. LIVE ANIMALS, LEATHER, FEED BIOLOGIC MATERIAL ON ANIMAL INSEMINATION AND VETERINARY DRUGS AND VACCINES

Outline of system

1. The licensing procedure in Albania has recently changed. Activities for production are licensed according to Law "On licensing", No. 10081, dated 23.02.2009, as well as sub-legal acts for law implementation. The legislation on licensing defines the activities according to fields (categories and sub categories) and special criteria for licensing; required documentation and any other accompanying documents for each activity. Licensing requests for activities included in such categories or sub categories are verified by the National Licensing Center (NLC) at the Ministry of Economy, Trade and Energy (METE).

Assessment on fulfillment of criteria for licensing (approval) is done through an intermediate decision of the institution that covers the respective field of activity. The decision of the Food Competent Authority is based on the evaluation of the submitted documents and on site inspection to

[1] See document G/LIC/3.

assess that the requirements and mandatory standards defined in the legislation have been fulfilled. Approval or refusal is published in the register within the deadline, otherwise it is considered as tacit approval.

The final decision of the NLC is published in the register and the title is submitted on the website of the NLC.

The CCA (MAFCP) suspends or revokes a licence in cases where, during verification, the technical-technological and sanitary-veterinary requirements are not fulfilled according to the law.

Purpose and coverage of licensing

2. The import licensing system covers these groups of products:

(a) Live animals;
(b) Biological material on animal insemination;
(c) Veterinary drugs and vaccines.

3. Imports are carried out based on bilateral trade agreements that Albania has signed with various countries where the products are imported from (or even from other countries that meet the requirements of the legislation in force).

4. The licensing system does not intend to restrict the quantity and the value of the imports. There is no alternative method. The MAFCP does not determine quotas for import licences.

5. Licensing is a legal request, and the licensing system is based on the following legal framework:

- Law No.10081, dated 23.2.2009 "On licences, authorization and permission in Republic of Albania";
- Decision, No.538, dated 26.5.2009 "On licences and authorization that are verified through the NCL and the same other common sub-legal regulations";
- Law "On Food", No. 9863, dated 28.01.2008;
- Law, No.10 137, dated 11.5.2009 "On same amendments in current legislation on licences, authorization and permission in Republic of Albania";
- Decision, No.1295, dated 29.12.2009, "On same amendments in Decision", No.538, dated 26.5.2009 "On licences and authorization that are verified through the NCL and the same other common sub-legal regulations";
- Law No.9426 dated 06.10.2005 "Animal Breeding" - changed.

Licensing is authorized by the Law No. 10081, dated 23.2.2009 "On licences, authorization and permission in the Republic of Albania" and the system cannot be abolished without legislative approval. The legislation does not leave designation of products to administrative discretion.

Procedures

6.I. Not applicable.

II. Not applicable.

III. For goods and import entities which meet the criteria and conditions defined in the relevant legislation, licences are without limitations.

In order to ensure that licences are used for import issues, the steps are as follows:

- The approved list of importers is sent to the Regional Directory of Agriculture, Food and Consumer Protection of each district, municipalities and Border Inspection Points responsible for licence control of import usage;
- The list of approved importers is published on the NLC's website.

IV. As there are no quotas for imports of such goods, the application can be submitted at any time.

V. The maximum time to process the application for import licences is:

(a) ten days for live animals;
(b) fifteen days for biological materials on animal insemination;
(c) fifteen days for veterinary drugs and vaccines.

Decision, No.1295, dated 29.12.2009, "On some amendments in Decision" and No.538, dated 26.5.2009 "On licences and authorization that are verified through the NCL and some other common sub-legal regulations".

VI. No time limit. The importer has the right to start the import activity from the moment they attain the licence.

VII. The NLC is the only entity where the applicant, (each importer), needs to apply and present all the documentation. Documents are then sent online (from the NLC office), for approval to the Ministry of Agriculture Food and Consumer Protection (MAFCP). After this process, the NLC issues the import licence to the applicant.

VIII. There are no limits on licensing numbers. There are no restrictions on timing and ranking of applications in order to get a licence. The licence is issued based on the fulfillment of the conditions determined by the Albanian law.

Applications which do not meet the requirements are refused until a second period, determined by a competent inspection authority. The refusal is published on the NLC's website.

The examination of the application, from the date of the submission, takes 10 days for the import of live animals and within 15 days for the trading of biological material and veterinary medicine.

There is no specific legislation for new importers.

IX. Not applicable since there are no quotas and licences are not issued automatically.

X. The import of goods is permitted based on the legislation cited below, and in any case only based on export permits:

- Law No. 10081, dated 23.2.2009 "On licences, authorization and permission in Republic of Albania";
- Decision, No. 538, dated 26.5.2009 "On licences and authorization that are checked over through the NCL and the same other common sub-legal regulations";
- Annex I: Permission and licensing categories which are followed by/or through the NLC;

- Annex I, Section II: Food and Health. Category II.2, Code II.2, B; Category II.3: Breeding or animal trading with Code II.3, C; Category II.7, Code II 7B;
- Drugs' Trading.

XI. No, such conditions are associated with the issuance of the licence.

7.(a) No. Imports can be carried out only after issuance of the import licence. Goods cannot arrive at the port without a licence. Importation can only occur after the NLC has issued the licence to the importer.

(b) No, because the licensing authority must examine the documentation required. The time taken to issue a licence is 10-15 days.

(c) No limitations for the time of application.

(d) The NLC is the only entity where the applicant (each importer), needs to apply and present all the documentation. Documents are then sent online (from the NLC office), for approval to the Ministry of Agriculture Food and Consumer Protection (MAFCP). After this process, the NLC issues the import licence to the applicant.

8. The licence can be refused in cases where the importer does not meet the requirements set forth in the law and regulations.

The applicant is officially informed by the NLC for reasons of a refusal. This information is automatically published on the NLC's website. Any interested party has the right to appeal on an administrative process to the NLC or the MAFCP for cases of licences with preliminary inspections. Administrative complaints are analyzed by the representatives of the NLC, except cases of licences with preliminary inspection which are analyzed by the MAFCP.

In the cases of preliminary inspection, the MAFCP is informed by the NLC when a complaint is presented to their office. In both cases, complaints addressed to the NLC or the MAFCP are published in the National Registry of Permits and Licences. For administrative issues, after reviewing the administrative complaint, a decision given may be directly appealed to the competent court. The above mentioned issues are being followed by the terms specified in section 6, of the Code of Administrative Procedures on administrative complaints within one month.

Eligibility of importers to apply for licence

9.(a) There are no restrictive systems.

(b) All persons, firms and institutions that satisfy the criteria set forth in the current legislation have the right to apply for licensing.

(c) No, there is not such a system. A list of fees exists and this is based on the Order of the Minister of Agriculture, Food and Consumer Protection, No. 8 dated 08.05.2007 "On the fees and secondary revenues applicable by institutions of the agriculture and food system".

Yes, the list of authorized importers published on the website of the NLC is sent to all central institutions, districts, municipalities and border inspection points.

Documentation and other requirements for application for licence

10. The necessary information and documentation to be filled by the applicant are provided by the NLC.

11. The required documents are those issued by the National Licensing Centre (NLC).

12. Fees depend on the type of licence. The fee for import licences of live animals is 10.000 lek, for trading of biological material is 300 All, and 100.000 All for veterinary medicine trade.

13. No, an advance payment or a deposit is required.

Conditions of licensing

14. All licences are indefinite based on the Article 11, Law No.10081, dated 23.2.2009 "On licences, authorization and permission in the Republic of Albania". In order to check if the conditions are fulfilled by the applicant, the MOAFCP frequently performs in site controls. If some conditions are not fulfilled then the MOAFCP presents the proposal to the NLC for the refusal of this licence.

15. No.

16. No, licences are not transferable.

17.(a) Not applicable. There are no quantity restrictions for products.

(b) No.

Other procedural requirements

18. No, there are not any other administrative procedures.

19. Foreign exchange is provided automatically by banking authorities, every day.

II. IMPORT LICENSING PROCEDURES OF PLANT PROTECTION PRODUCTS (PPP)

Outline of system

1. The licensing procedure in Albania has recently changed. Activities for production are licenced according to the Law 10081, dated 23.02.2009. Import of products for plant protection in Albania is conducted through permissions issued by the NLC, based on preliminary criteria to be fulfilled by the interested parties. The entities are inspected by the District Inspectorate of plant protection. This licence is issued through the NLC. In Albania only registered products can be imported for plant protection.

Purpose and coverage of licensing

2. The licensing system covers plant protection products such as insecticides, fungicides, herbicides, disinfectants and similar products. These products fall under code 3808 of the Combined Nomenclature.

3. The control system for Plant Protection Products (PPP) is being applied to those registered in countries of the European Union. PPP from all countries are accepted without limitations.

4. This licensing system does not intend to restrict the quantity or value of imports coming into Albania. The purpose of issuing the import licence of PPP is to strictly control the products. Since these are poisonous products, their careless utilization can affect plants, animals, human beings and environment. In the international legislation on plant protection there does not exist any other alternative known method.

5. The Albanian legislation that regulates this licensing system includes:

- Law No. 10081, dated 23.02.2009 "On Licensing, Authorizations and Permissions in the Republic of Albania";
- Law No. 9362, dated 24.03.2005 "On the plant protection services" – changed;
- Decision of the Council of the Ministers No. 1555, dated 11.12.2008, "For the determination of registration rules and evaluation criteria of Plant Protection Products (PPP)".

The decision of Council of Ministers No. 1555, dated 12.11.2008, "On the determination of registration rules and evaluation criteria of PPP", provides that only registered Plant Protection Products can be imported.

Procedures

6.I. Not applicable.

II. Not applicable.

III. Not applicable.

IV. Not applicable.

V. Based on the Law No. 10081, dated 23.02.2009 "On Licensing, Authorizations and Permissions in the Republic of Albania" the maximum time for processing the applications is 15 days.

VI. No time remains.

VII. The applicant presents required documentation at the National Licensing Center. This is the only administrative organ that an importer has to approach to get the licence.

VIII. Not applicable.

IX. Not applicable.

X. Not applicable.

XI. There are no such conditions associated with the licence.

7.(a) The importer can import the product at the time when he judges it appropriate. The time limit to get a licence is 10-15 days and the licence cannot be obtained for goods arriving at the port without a licence.

(b) The licence is granted after the examination of the required documentation, within the time limits set forth in the legislation. Up to now, no emergency applications for licences are deposited in the National Licence Center.

(c) No limitations related to the period of the year during which applications for licences can be made.

(d) Applications for import licences are affected only by one administrative organ, which is the National Licensing Center.

8. The licence can be refused when the importer fails to meet the appropriate conditions on storage and preservation of the plant protection products, as required by the legislation (including the necessary documentation).

The applicant is officially informed by the NLC, for the reasons of a refusal. This information is automatically published on the NLC's website.

According to the legislation on plant protection, in the case of a refusal of a licence, the applicant has the right to appeal at the higher administrative bodies and at the court of first instance.

Eligibility of importers to apply for licence

9.(a) There are no restrictive systems.

(b) All persons, firms and institutions that satisfy the criteria set forth in the current legislation have the right to apply for licensing.

(c) No, there is not such a system.

All persons that have import licences are eligible to import plant protection products. All importers are on a published list by the Ministry of Agriculture, Food and Consumer Protection. The list is sent to the cross – border points where phyto-sanitary and quarantine inspection service is established. According to Order No. 9 dated 12.7.2010 "On fees and secondary revenues applicable by agriculture and food institutions in the MAFCP".

Documentation and other requirements for application for licence

10. The applicant presents the required documents to the Directory of the NLC. The whole set of documents is available at the NLC office.

11. The import licence of plant protection products is presented at the quarantine inspectorate office at the cross-border points. After the control by the quarantine inspectorate is carried out, the customs authorities accomplish customs procedures.

12. Licensing fee is 2000 lekë.

13. No deposit or advance payment is required.

Conditions of licensing

14. The licence is permanent.

15. No penalty.

16. The licence is not transferable.

17. No conditions are attached to the issuance of the licence.

Other procedural requirements

18. Yes, there is the procedure of the "State Commission of PPP" for the PPP registration in the Republic of Albania.

19. Foreign exchange is provided automatically by banking authorities, every day.

III. IMPORT LICENSING PROCEDURES OF FAUNA AND FLORA

Outline of system

1. Import permits are issued in the framework of the CITES Environmental Convention on "International Trade on Endangered Species of Wild Flora and Fauna" to which Albania is a Party from September 2003.

CITES works by subjecting international trade in specimens of selected species to certain controls. All import, export, re-exports and introduction from the sea of species covered by the Convention has to be authorized through a licensing system. Each Party to the Convention must designate one or more Management Authorities in charge of administering that licensing system and one or more Scientific Authorities to advise them on the effects of trade on the status of the species. The designated management Authority for Albania is the Biodiversity Directorate in the Ministry of Environment, Forests and Water Administration.

The species covered by CITES are listed in three Appendices of the Convention, according to the degree of protection they need. (www.cites.org/appendices).

Purpose and coverage of licensing

2. CITES import permit (certificate) covers all wild animal and plant species listed in the Appendices of the CITES Convention.

Appendix I includes species threatened with extinction. Trade in specimens of these species is permitted only in exceptional circumstances. Appendix II includes species not necessarily threatened with extinction, but in which trade must be controlled in order to avoid utilization incompatible with their survival.

3. The system applies to goods originating in and coming from countries that are Parties to CITES Convention.

4. The licensing is intended to restrict the number of species, wild animals and plants listed in the Appendices of the Convention in order to improve their conservation and comply with the obligations and requirements of the Convention; this, according to the management plans for individual species and/or quotas are established by Parties at the beginning of each calendar year by Parties and notified to the Secretariat. These quotas are published by the Secretariat through Notifications to the Parties and posted on the Convention's web page at www.cites.org/notifications.

5. The Law No. 9021, dated 06.03.2003 "On the accession of the Republic of Albania in the Convention "On the International Trade of Endangered Species of Wild Flora and Fauna" (CITES)";

The Law No.9867, dated 31.1.2010 "On the rules and procedures on international trade of endangered species of wild fauna and flora". This Law sets up the required infrastructure for the implementation of the CITES Convention in Albania.

Letter of the Minister of Environment for the establishment of Scientific and Management Authorities for the implementation of CITES Convention in Albania addressed to CITES Secretariat, dated 30.01.2004 and revised by letter of the Minister of Environment, Forests and Water Administration of 12.04.2006 reflecting changes of organization following the re-structuring of some Ministries in early 2006.

Procedures

6.I. For products under restrictions as to the quantity, the information is published on CITES Convention website concerning annual quotas and information on national authorities in charge of the Convention implementation and permit issuing authorities.

II. See 4 above.

III. Licences are allotted only to species subject to the CITES Convention.

IV. The applications may be submitted at any time of the year.

V. Processing applications may vary between one to four weeks, depending largely on the consultation time with the scientific authority of CITES for Albania, defined in the draft law quoted in paragraph V. According to Article 18 of the draft law, within 5 working days from the day the application is received, the Management Authority requires, in writing, the opinion of the Scientific Authority. This authority must give its written opinion within 10 days.

CITES permits or certificates are issued within 15 working days after the application is received. In cases when advice of the Scientific Authority is needed, the permit or certificate is issued within 5 working days of advice being received.

VI. It depends on the time available before the importation takes place.

VII. The consideration of a permit or certificate application is effected by the Ministry of Environment, Forests and Water Administration as the nominated management authority of CITES. However, before granting the permit, the Ministry has to consult the scientific authority (namely the Museum of Natural Sciences – respectively Flora and Fauna Sections for wild fauna and flora species).

VIII. Not applicable. A CITES licensing system is special and the phrase "the fact that the application can be submitted at any time of the year" does not mean "first come first serve basis". As from previous explanations one can understand that this is a situation in which the licence is issued only if the application fulfils the requirements of the Convention. If not, the licence is not issued, nor allocated to someone else.

IX. Import licences are applicable only if the country of intended import is an EU country, in compliance with the EU wildlife trade Regulation No. 338/97.

X. Management authorities of CITES are in continuous cooperation and are in constant communication with each other. In the above mentioned case usually an e-mail from the issuing authority is sent in notification of the respective permit.

XI. Yes, for species of Annex 1 of CITES, which can only be used for scientific research purposes.

7.(a) Ideally one month in advance.

(b) A licence cannot be granted immediately on request.

(c) No there are no limitations as to the period of the year.

(d) See VII above.

8. An application may be refused in cases where the export certificate from the country of origin is false or if there are any doubts on the determination of the species i.e. the so called "look alike" species. However, in any case, the Management Authority will first be advised by the Scientific Authority and later decide on the refusal of a permit or certificate.

Eligibility of importers to apply for licence

9. All persons, subjects and institutions are eligible to apply for CITES permits or certificates.

Documentation and other requirements for application for licence

10. A sample form is required. The importer is required to supply a document certifying the species name and origin, and the purpose he/she is asking for the given species to be imported, as well as the purpose of bringing the species into the country.

11. Export permit from the Management Authority of the country of origin, or from the country from where the species is coming.

12. No, currently there is no licensing fee or administrative charge since the by-law on these tariffs is not yet elaborated.

13. No for the moment. The Law quoted above foresees that the Minister responsible for wildlife issues, will, by Government Decree, determine tariffs and payment methods.

Conditions of licensing

14. According to the law that will be approved by the end of the year and to the provisions of the European Council Regulation 338/97 for the implementation of CITES in the EU, validity of CITES export and re-export permits or certificates is 6 months from the issuance date, whilst the import permits for live specimens included in Annexes I and II of the Convention is 12 months from the issuance date.

15. If the permit or certificate has been issued previously, for a long time, a new one might be required in order to reflect any changes that might have occurred in the species status in respect to the placement in the CITES Appendices.

16. No, licences are not transferable between importers.

17. Conditions attached to the issuance of a licence in terms of quantitative restrictions apply only in cases where there is a quota determined in a Notification to the Parties by the CITES Secretariat. Besides quotas given in the Notifications published by the Secretariat, other conditions are set-up only for live animals for which the licence is valid, only in the cases where transportation conditions comply with the Regulation of the Transport for live animals or the IATA Regulation for live animals.

Other procedural requirement

18. No.

19. All banks provide foreign exchange automatically.

IV. WASTE IMPORT LICENSING PROCEDURES

Outline of system

1. No answer was provided.

Purpose and coverage of licensing

2. The Ministry of Environment, Forests and Water Management (MEFWM) is involved in the process of cross-border of waste: importation, exportation and transition.

- The MEFWM issues licences for exportation and transition of waste;
- The MEFWM prepares the required documents for issuing the import licence of waste, which is approved by the Decision of the Council of Ministers.

3. The system applies to goods originating from all countries. Albania does not have any bilateral agreement with any other country.

4. The limitations for importation of waste are defined by environmental legislation and the conditions of the technology, laboratories and managing capacities which aim to protect the environment from pollution and damage.

5. Importation, exportation and transition of waste is administered by:

- Law No. 8934 dated 05.09.2002 "On protection of the environment";
- Law No. 9010, dated 13.02.2003 "On environmental administration of solid waste";
- Decision of Council of Ministers No. 806, dated 4.12.2003 "On approval of rules and procedures for importation of utilization waste, processing and recycling";
- Rule No.4 dated 15.10.2003 "On checking and approval of exportation licences and transition of waste";
- Decision of Council of Ministers No.835, dated 28.12.2005 "On approval of the list of danger waste, other waste and other remains, that are not allowed to be imported, with the aim to preserve, deposit and exterminate";
- Decision of Council of Ministers, year 1994, "On danger waste and residues";
- Law No.9537, dated 18.5.2006 "On administration of hazardous waste".

Licensing is done according to the defined above-mentioned procedures and also for waste and residues mentioned above.

Procedures

6.I. The relevant legislation is published in the official gazette and on the webpage of the MEFWM.

- Importers are informed in detail at the MEFWM or the Environmental Regional Agencies.

- Other exporting countries can take the information from the reports which the ministry presents at the Secretariat of the Basel Convention "On cross border of waste and danger waste and their extermination".
- Interested foreign parties can be informed directly at the MEFWM.
- There is no definition of a maximum and minimum limit for imported waste. The limitations depend only on the type of waste and the activity for which they are planned (processing and recycling).
- There cannot be any exception or derogation from the licensing requirement.

II. There is no application of quotas.

III. Importation is only allowed for waste which can be used for the purpose of reusing, processing and recycling. Similar activities cannot be limited. Every activity is able to obtain a licence. The importers of waste are defined by the Decision of the Council of Ministers.

IV. Not applicable.

V. The process of approval of a licence for importation of waste is made by the Decision of Council of Ministers. The process is long, but the ministry prepares the required file within a period of 1 month.

VI. In general there are no limitations. It is defined only by the maximum deadline of the validity of the licence.

VII. For issuance of a licence of importation of waste, the following approvals should be obtained:

- A licence of exportation from the competent authority of the country of origin and the relevant licences from the transit countries;
- An environment licence issued before by the Ministry of Environment, Forestry, and Water Management;
- A licence of the exercising activity by the relevant Ministry;
- A relevant licence issued by the Ministry of Heath;
- An approval by the community from where the activity is taking place.

VIII. The licence is examined according to the rank of application at the MEFWM. The procedures for preparing the draft decision of the Council of Ministers to grant an import licence is defined by the environmental legislation (meaning the type of activity for which the residue will be used and the type of residue that is going to be imported). Past performance is taken into consideration relating to the impact on the environment (meaning if there is any penalty for polluting the environment, or complaints by citizens etc). There is no distinction for new applicants. The applications are continually examined, immediately after the request is done. The information is sent to the applicant for further completion of documentation necessary for the preparation of the draft Decision of the Council of Ministers. This draft Decision is then circulated for the opinion of the Ministry of Economy, Trade and Energy, Ministry of Finances, Ministry of Public Works and Transport, and Ministry of Agriculture, Food and Consumer Protection. The Council of Ministers decides on granting the licence, on the conditions of imported waste and on the deadlines of the licence.

IX. Not applicable.

X. To issue the licence, the applicant must attach the export licence issued by the competent authority of the country of exportation.

XI. No.

7.(a) No.

(b) No.

(c) No.

(d)
- Handling the documents and preparing the file for an import licence is done at the Ministry of Environment, Forestry and Water Management.
- The Ministry of Economy, Trade and Energy, Ministry of Finances, Ministry of Public Works and Transport, and Ministry of Agriculture, Food and Consumer Protection, send their opinions.
- The Council of Ministers approves the import licence of waste.

8. The Ministry of Environment, Forestry and Water Management prepares the draft Decision of the Council of Ministers in case of refusal of applications. The applicant has the right to appeal within 30 days in the Court.

Eligibility of importers to apply for licence

9.(a) Legislation only allows the importation of non dangerous waste, which should only be used for the purposes of processing, reusing or recycling, if certain conditions are satisfied:

- Utilization, processing and recycling of waste is carried out with a contemporary technology that guarantees the protection of public health and protection of the environment;
- Stuffs or useful materials are obtained from the by-waste; expensive raw materials are saved;
- Their transportation does not negatively affect human health and environment.

The rules and procedures for obtaining the import licence are defined in the Decision of the Council of Ministers No. 806, dated 4.12.2004 "On approval of rules and procedures for importation of waste with the aim to process, use and recycle". Only the waste which is listed in Annex I of the decision of the Council of Ministers No. 26, dated 31.01.1994 "On dangerous waste and residues" can actually be imported.

(b) Not applicable.

(c) There is not yet any list of importers.

Documentation and other requirements for application for licence

10. They are defined in chapter I.4 and chapters II.2 and 3 of the Decision of the Council of Ministers No. 806, dated 4.12.2004 "On approval of rules and procedures for importation of waste with the aim to use process and recycle".

11. They are defined in chapters II.2 and 3, of the Decision of the Council of Ministers No. 806, dated 4.12.2004 "On approval of rules and procedures for importation of waste with the aim to use process and recycle".

12. Yes, 30.000 leke, Albanian currency.

13. No.

Conditions of licensing

14. The validity is defined in the Decision of the Council of Ministers and can be different due to the request made by the applicant and on environmental policies in the field of waste. The maximum validity is 5 years.

15. No.

16. This transfer is not specified for import licences. In the case of changing the ownership of the activity, according to Article 42 of the law "On protection of environment", the new owner maintains the rights of the environmental licence and implements the conditions foreseen in it.

17. Not applicable.

Other procedural requirements

18. They are mentioned in the question VII of this questionnaire.

19. The exchange rate is provided automatically by banking authority, every day.

V. IMPORT LICENSING PROCEDURES FOR MEDICINAL PRODUCTS

Outline of system

1. Due to the amendments on licensing procedures, only some medicinal products are required to provide an import licence, before placing them on the market. Medicinal products, according to their use and technical capacities that authorities have, are divided into groups as follows:

(a) Medicines (drugs).
(b) Dental equipment.
(c) Medical devices (consumables).
(d) Disinfectants, disinsectants and deratizing substances (DDD-s).

Among the above-mentioned groups, the import authorization is required only for the first group (medicines) and the fourth group (disinfectants, disinsectants and deratizing substances). Every subject, before starting the activity on import/export or placing these substances on the market, has to be licenced by the National Licensing Center (NLC). In some of the licensing procedures, a statement is required by the charge d'affaires at the Ministry of Health. The decision has to be fulfilled within 15 working days, after this it is published by the National Licensing Center in the National Licensing Register, as an authorized subject on these activities. Thereafter, import authorizations are granted for every concrete importation according to the regulation in force:

- The registered drugs are imported by marketing authorization holders (MAH) or manufacturing ones, based on the register of drugs, published and updated by the National Center of Drugs Control. Import procedures are performed at the entry customs offices, in the presence of the pharmaceutical inspector.

- In case of importation of unregistered drugs (in case of an emergency such as natural catastrophes, epidemics, or the unique alternatives of a drug for hospital/ambulatory service), the application is submitted by the Pharmaceutical Department (Ministry of Health). After a requirement evaluation for these drugs by the specialized structures within the Ministry of

Health (in rare cases an official opinion is required by the National Center of Drug Control), the Minister of Health authorizes the importation. This authorization has a 2 (two) months validity.

- The importation of narcotic drugs and psychotropic substances is separately regulated, because the importation process is more restricted and under control of the Albanian and international authorities. Licenced subjects by the National Licensing Center on wholesale trade of drugs, also need to be authorized by the Pharmaceutical Department, related to their activity on importation and distribution of narcotic drugs and psychotropic substances. When the importer wants to import narcotics and psychotropic, he/she submits the request for an authorization import at the Pharmaceutical Department. If the required quantity doesn't exceed the allowed quantities, the authorization, signed by the Minister of Health, is granted, with a validity of 3 (three) months from its issuance. This authorization is used as an international control instrument. When the authorization has reached the destination (control authorities of exporting country), these authorities grant export authorization for their exporter. Therefore, within these three months, the Albanian importer resubmits the request for import authorization followed by the export-authorization of the exporting country to the Pharmaceutical Department. After that, the Pharmaceutical Department grants the authorization, valid for a period of 2 (two) months. Finally, authorization is provided which means the allowance of narcotic or psychotropic substances into Albania.

- In order to facilitate import procedures, since May 2008, according to the order of Minister No. 215 dated 27.05.2008, the obligation of granting and submitting in the custom authorities, the import authorization for medical equipments, dental equipments and consumables has been avoided. If medical equipment is sources of ionizing radiation, a special permission is issued by the Commission on Radiation Protection in the Institute of Public Health. This Commission only gives permission on the specific activity that the importer will carry out.

- Regarding the importation of disinfectant, disinsectant and deratizing substances (DDD), the applicant, after being granted a licence by the National Licensing Center on the activity of intercessory services hygienic-sanitarian, submits the request for import authorization from the Hygienic and Epidemiologic Sector (MoH). The requirement is verified by the specialist of the Hygienic and Epidemiologic Sector to see if it fulfills all the requirements of the list of DDD substances, approved every year by the Minister of Health. Also, on the issuance of import licences related to DDD substances, an opinion of the specialists from the Public Health Institute (PHI) is required. The PHI has to express its official opinion within 10 working days. Once the verification is completed, the National Sanitary Head-Inspector (Director of Public Health Department) approves the import authorization.

Purpose and coverage of licensing

2. Importation licensing systems are:

(i) Licensing of medicines (drugs);
(ii) Licensing of disinfectant, disinsectant and deratizing substances;
(iii) Licensing of ionized radiation sources.

The products covered by the above mentioned licensing systems are:

- Narcotic Drugs and Psychotropic Substances referred to in the list in accordance with Single Conventions of 1961 and 1971;
- Pharmaceutical Products of chapter 30 of the Combined Nomenclature of Goods.
- Disinfectant, disinsectant and deratizing substances, chapters 28, 29 of the CNG.

3. The systems apply to all medicinal products, in spite of their origin.

4. Generally, licensing systems are used to control products that will enter the country. Licensing is seen as a tool to control what products, in what quantity and with what quality, are entering into the market. Although health care is mainly covered by imported products, its aim is on the stimulation of domestic production by increasing the number of qualitative medicinal products manufactured in Albania. Normally, adoption of a proper legislation, setting up of structures and the equipping of necessary technologies, creates the conditions and opportunities to use other alternatives, which consist of controls of several stages of imported drugs, at the border by custom authorities, during wholesale distribution, during dispensing by pharmacies and their use. The adoption of a new legislation and structures relating to the control system is under way.

5. Legal framework that regulates the procedures of import licensing includes:

- Council of Ministers Decision No. 325, of 14.06.1993 "On regimen of export-import and medicines production";
- Joint Guideline of Ministry of Health and Ministry of Finance No. 180 of 13.08.1993 "On co-operation for the regimen of import-export of medicines and their clearance";
- Law No. 7975 of 26.07.1995 "On narcotic drugs and psychotropic substances, amended with:
  (a) Law No. 9271 of 9.09.2004;
  (b) Law No. 9559 of 8.06.2006.
- Decision of Council of Ministers No. 415 of 17.08.1993 "On import, export, wholesale and retail trade licensing of disinfectant, disinsectant and deratizing substances" and related Order of Minister of Health No. 361 of 18.08.2000;
- Order of Minister of Health No. 104 of 5.03.2004, For a change in the Guideline No. 180 of 13.08.1993 "On co-operation for the regimen of import-export of medicines and their clearance";
- Order of Minister of Health No. 245 of 29.06.2006, For a change in the Guideline No. 180 of 13.08.1993 "On co-operation for the regimen of import-export of medicines and their clearance";
- Law No. 9323, of 25.11.2004 "On medicines and pharmaceutical service" amended with:
  (a) Law No. 9523 of 25.04.2006;
  (b) Law No. 9644 of 20.11.2006;
  (c) Law No. 10008 of 27.10.2008.
- Law No. 9928 9.06.2008 "On dental health service in the Republic of Albania";
- Order of Minister of Health No. 162 of 16.04.2008 "On abrogation of the Order of Minister no. 214 of 22.04.2004";
- Law No. 10081 of 23.02.2009 "On licences, authorizations and permits in the Republic of Albania";
- Law No. 10137 of 11.05.2009 "On some addenda to the current legislation on licences, authorizations and permits in the Republic of Albania";
- Decision of Council of Ministers No. 538 of 26.05.2009 "On licences and permits handeled by or through the National Licensing Center (NLC) and on some sub-legal common regulations";
- Decision No. 1295 of 29.12.2009 "On some amendments to Decision of Council of Ministers No. 538 of 26.05.2009 "On licences and permits handeled by or through the National Licensing Center (NLC) and on some sub-legal common regulations";
- Law No. 10138 of 11.05.2009 "On Public Health";
- Order of Minister of Health No. 102 of 22.02.2010 "On the issuing of the authorization on the import-export, wholesale and retail trade of the DDD substances (disinfectant, disinsectant and deratizing substances)";
- Law on Protection from ionized radiation No. 8025 of 9.11.1995, amended by the Law No. 9973 of 28 July 2008;

- Decision of Council of Ministers No. 158 of 13.02.2008 "On import-export of ionized radiation source in the Republic of Albania";
- Regulation No. 3918/4 of 3.11.2004 "On import, export and transit of radioactive sources";
- Guidance No. 4756/1 of 21.12.2006 "On import-export of radiation materials in Albania";
- Categorization of Radioactive Sources No. 9 of 7.01.2010;
- Regulation No. 10 of 2010 "On licensing and inspection of ionized radiation sources".

The systems of import licensing are based on laws, government decisions or other administrative acts. None of the licensing systems can be abolished without any legislative approval. None of the legislation leaves designation of product to be subjected to administrative discretion.

Procedures

6.I. The only case of implementing quantity limitation is the importation of narcotic drugs and psychotropic substances. Yearly quantities are approved by the International Narcotic Control Board and are published in its special publication. The authority does not apply the allocation of quotas among importers. There is an agreement of a yearly quota, which is divided among importers based on the supplying contracts that importers have signed with public or private health institutions, or due to medicines included in the reimbursement scheme etc. There is no limitation for the quantities imported from any country. Importers import the quantity they think is reasonable or according to the supply contracts they have signed, always within a yearly quota and the agreement done with other importers. Taking into consideration that this is a very restricted control, no request for exception or derogations from the licensing requirements is accepted.

II. The quota size for each narcotic drug is determined for a period of a year and covers all the country. Importation licences are granted every time the importer imports a quantity within the quota. As import authorizations are valid for 3 months, only one importation within the 3 months can be done until the next importation from the same importer.

The import authorization relating to ionized radiation sources are for single use and valid for 2 weeks.

III. Licences are allotted for the quantity of a certain narcotic drug that is imported by a certain manufacturer and from a certain country (this is not defined by authority, but from the fact that the drug is registered and the registration is done by a manufacturer that is established in a certain country. After this, the importer begins his/ her procedures).

Because this is a process of reciprocal control among several authorities, its continuity is supervised by these authorities. Pharmaceutical Authorities particularly supervise licence usage, because no utilization would result in the lack of drugs in health institutions and the pharmaceutical market. In the case of a licence not being used, the importer notifies the responsible authority and if he does not, the authority, based on the data received in the pharmaceutical market, communicates with the importer to solve any possible problems. The Pharmaceutical Authorities are also able to make the importation possible from another importer if the first has not the possibility to do so. The primary concern of authorities is that the market does not suffer from lack of medicines.

The Radiation Protecting Commission has the right to approve authorization imports, only to licence holders on this purpose. Unused allocations are not added to the coming periods. Every year begins with new quotas for such medicines for one year that are equal to the needs of that country.

IV. There is not any defined period.

V. There is not any defined period, but usually the applications are processed within a working day.

VI. There is not any defined period. The authority and the importer are informed that the importing period begins at the start of a calendar year, so they are able to begin their procedures after that date.

In the case of radiation sources this period is two weeks and two months. Two weeks is for the approval of import export and two months is for licences.

VII. The only cases where the application for import licensing is examined by two authorities are those of unregistered medicines, of disinfectant, disinsectant and deratizing substances and of ionized radiation sources:

- In some cases relating to unregistered medicines, the official opinion of the National Center of Drugs Control is required.
- The official opinion of the Public Health Institute is required relating to disinfectant, disinsectant and deratizing substances,
- The same situation occurs with ionized radiation sources, where the importer has to approach more than one administrative organ.

The positive answer (approved import licence) or negative one (along with all explanations) is given to importers by the Ministry of Health.

VIII. There are several ways to act in the case of an unsatisfied demand for a licence. If the medicine is for ambulatory use and is not the first alternative in the reimbursement list, then the basis is first come, first served. A licence will be granted provided that all the necessary data is submitted. If the drug is intended for hospital use (according to contracts the importer has with the hospitals), or is the first alternative in the reimbursement list (with the highest coverage level) the importer is served first so that he fulfills these conditions; then the others are considered according to the agreements among themselves, taking the difference of quotas. If the importer submits an application for narcotic import authorization at the end of the year, knowing that the period of authorization approval obliges the importer to bring the cargo/shipment in the following year, which is not allowed by international control authorities, usually it is decided that procedures must be done the next year when the new quotas are open. The importer's performance is not examined. The maximum quantities for each importer are determined by the agreements they reach with each other based on contracts or market studies (it must be stressed that there is a small number of narcotic drugs imported into Albania and there is a very small number of importers, sometimes even only one). There is no provision for new importers, they are given the same considerations as the previous importers. The applications are examined immediately.

In the case of ionized radiation sources, new applicants have to be assessed through a licensing process for each import approval.

IX. In the case of narcotic drugs these are cases of bilateral quotas. According to a regulatory framework, the submitted application for exportation grants the importation authorization from the importing country (granted to importer). Only the issued export authorizations for this case are granted immediately.

These are the same procedures with ionized radiation sources, where confirmation is required from the importing country to provide the export approval from the exporting country.

X. In the case of importing narcotic drugs and psychotropic substances, when import and export authorization are granted, the authority of the exporting country, after granting export authorization, based on application and import authorization, sends a copy of export authorization to the authority of the importing country.

In the case of ionized radiation sources, the two countries are informed by their contact points.

XI. In the case of medicines: No. The exported products, mainly of Albanian manufacturers, are the same that are sold in the domestic market. So far, such a limiting procedure does not exist.

In the case of ionized radiation sources: Yes.

7.(a) The import authorization validity is for 1 to 2 months, respectively, for medicines, registered or not; 3 months for narcotics and psychotropic and ionized radiation sources. However relating to DDD the validity varies from 6 months for disinsectant and deratizing substances, to 1 year for disinfectants of the potable water.

The approval is valid for two weeks for ionizing radiations.

(b) Yes, the licences are granted immediately on request, despite unregistered medicines, where in some cases an examination from the Ministry of Health and the National Center of Drug Control is required. The procedure for the examination is up to 3 working days.

(c) No, there is no limitation.

(d) There are cases where the application needs to be passed onto other administrative organs such as import of unregistered medicines (the application passes to the NCDC); import of DDD substances (the application passes to the PHI); and, import of ionized radiation sources. The organs cooperate with each other and the importer has to approach only the Ministry of Health, when the importer receives the answer.

8. The application for a licence (import authorization) on medicines can be refused when the importer fails to meet the defined criteria and in some other cases, specifically when:

(a) The National Center of Drugs Control is informed that the drug does not meet the necessary quality and safety standards; information is received by homologue authorities or by the results of the NCDC's own tests (testing of samples on the market).

(b) Manufacturer or control authorities inform the starting of withdrawal procedures of the product from the market, meanwhile the importer submits the application for an import licence.

(c) The registration validity of the medicine has expired and the manufacturer has not begun the re-registration procedures.

In each case, there is an explanation for refusal. The applicants can make an appeal to the Ministry of Health, the supervising levels of the Pharmaceutical Department and to the National Center of Drugs Control. The other body for appeal is the Court, if they think that the authority has violated the law.

Related to ionized radiation sources, the application for import authorization may be refused, but as mentioned above, in the case of a refusal there is an explanation. The applicant has the right to appeal.

Eligibility of importers to apply for licence

9.(a) Under restrictive licensing systems, application for licences is done only by operators that fulfill the conditions of such systems. In health services the application is submitted by a subject (importer or medical clinic that uses the products for its own activity) who has a professional licence (registration) issued by the Ministry of Health. If the subject applies to import narcotic and psychotropic drugs, or medicinal products that are source of ionizing radiation, it must have a second registration only for this kind of activity. Related to ionized radiation sources, all the physics or legal persons are eligible to apply for a licence, under the restrictive licensing system too.

(b) In health services there are no non-restrictive systems.

(c) There is a system of professional licensing (registration) for importation, exportation, and wholesale distribution of medicinal products. Eligible firms must have proper facilities, according to criteria defined for this purpose, and specialized staff to perform the activity. This registration has a fee, which is published with all other requests. So far, there are importers' lists that can be given to the interested parties. The National Center of Drugs Control already has its online list of pharmaceutical importers and distributors (www.qkkb.gov.al).

Documentation and other requirements for application for licence

10. There is not any application form, importers receive necessary information from the authorities and begin the procedure. Different systems are required to submit different documentation depending on the groups of products that will be imported.

(a) To import registered medicines, registered importers submit an application for import authorization that include a) importer's data, b) a table with medicines that will be imported detailing brand name, generic name of the medicine, quantity, manufacturing and expiry date, batch number, CIF price, manufacturer name and the country from which the import is done. An invoice is attached to the application. It is submitted to the National Center of Drugs Control where the import licence is granted.

(b) To import unregistered medicines, the application for import authorization has the same data as above and is submitted to the Pharmaceutical Department of the Ministry of Health, where the licence is signed and granted by the Minister of Health.

(c) To import narcotic and psychotropic drugs, the importer has to submit the application to the Pharmaceutical Department in the Ministry of Health, including the above-mentioned data, and full address of the manufacturer. When the importer submits to the Ministry of Health, he first requires the granting of an import authorization. When he/she receives the confirmation that the exporter has received the export authorization in the originating country, the importer applies for the import licence when the cargo is ready.

(d) The import authorization has been abolished. If the medical devices are sources of ionizing radiation the application must be accompanied by a special licence (registration) for that activity.

(e) To import disinfectant, disinsectants, deratizing substances the application shall contain the following information: i) importer's data, ii) Taxpayer Personal Identification Number and iii) certificate of origin of the goods.

(f) To import ionized radiation sources the licenced applicant in this field should provide:

- A copy of a registration to the Court;
- Technical data for radiation sources;
- Certification for sealed sources;
- Data on the exporting country;
- Clarification on the purpose of the use of sources;
- Declaration of the source of the end use;
- Clarification of transport of the sources.

11. When the cargo/shipment arrives in Albania this must be generally supplemented by these types of documents i) invoices, ii) packing list, iii) certificate of analyses, iv) certificate of quality, v) certificate of conformity, vi) certificate of product origin. The number of documents depends on the type of product that is imported.

In the case of ionized radiation sources, only an official request for approval of import and a copy of Proforma Invoice is required.

12. The fees are different depending on the type of licence:

- The fee to import unregistered medicines is 1000 Leks for each medicine;
- The fee to import raw materials is 500 Leks for each item;
- The fee to import registered medicines is 200 Leks for each authorization;
- The fee to import narcotics and psychotropic substances is 200 Leks for each authorization;
- The fee to import packages is 200 Leks for each authorization;
- The fee to import disinfectants, disinsectants and deratizing substances is 2000 Leks for each authorization;
- The fee to import ionized radiation sources vary from 1000 Leks to 20.000 Leks.

13. No, it is not required.

Conditions of licensing

14. There are different validity periods for import licences:

- Import authorizations for registered medicines have a 1-month validity;
- Import authorizations for unregistered medicines, have 2 months validity;
- Import authorizations for disinfectants, disinsectants and deratizing substances have 6 months validity and exceptional import licences for water disinfectants have a 1-year validity;
- Import authorizations for narcotic drugs and psychotropic substances have 3 months validity;
- Import authorizations for ionized radiation sources are for single use and valid for 2 weeks.

When the validity of a licence is over, the importer must submit an application to extend the validity.

15. The only case of penalty for non-utilization of the licence or the partial use of it occurs in the import of ionized radiation sources.

16. Import licences are not transferable between importers.

17.(a) For narcotic drugs and psychotropic substances, the total volume of the imported medicine, from all importers, shall not be more than the annual quantity approved for the country.

In the case of ionized radiation sources there are no other conditions. The same, for point (b) of this question.

(b) There are no other conditions.

Other procedural requirements

18. No, there are no other procedures prior to importations.

19. All banks provide foreign exchange automatically.

VI. IMPORT LICENSING PROCEDURES FOR EXPLOSIVE, PYROTECHNIC AND FIREWORK MATERIALS FOR CIVILIAN USE

Outline of system

1. To issue licences to import, export and manufacture explosives, fireworks and pyrotechnic materials to civilians, the Ministry of Defence has established the Commission of Granting the Licences for Explosives, Fireworks and Pyrotechnic Materials for Civilian Use, which is an ad hoc Commission established at the State Export Control Authority (AKSHE). This commission is composed of five persons.

Purpose and coverage of licensing

2. The licensing system is a single one managed by the Ministry of Defence with the Commission of Granting the Licences which is in place at the State Export Control Authority.

Products subject to an import licence by this Commission are explosives, fireworks and pyrotechnic materials for civilian use. Pyrotechnical materials, fireworks that are allowed to be imported, exported or produced in the Republic of Albania for civilian use, whose transformation is done only by burning, at a rate of 1-10m/sec, that shine and blaze in different colors, are defined in part II, class I, groups 3 and 4, in the commune "G", (1.3G or IAG), of the law No. 9272, dated 16.9.2004, "For the adherence of the Republic of Albania in the European Agreement "For the overland international transportation of dangerous ADR goods" and "the protocol of endorsement".

Explosive materials for civilian use are not grouped or listed but they can be imported in the Republic of Albania if they meet the EU standards and have the conformity certificates attached.

3. The licensing system does not discriminate any country.

4. The licensing system is not intended to restrict the quantity or values of imports. There is no restriction in value or quantity in the Albanian legislation to import explosive and pyrotechnic materials for civilian use.

The licensing system defines the procedures, rules and responsibilities of the Administration for the production, storage, use, control, getting rid of, transfer and way of selling explosive materials for civilian use, to protect and secure life, human and animal health, material values and environment from risks that these materials may cause.

5. Law No. 9126, dated 29.07.2003 "On the civilian use of explosive materials in the Republic of Albania";

Council of Ministers Decision No. 853, dated 17.12.2004 "On the procedure of issuing permission for importing, exporting and producing pyrotechnical materials, firecrackers, for civilian use";

Council of Ministers Decision No. 597, dated 10.09.2004 "On the procedure of issuing permission for importing, exporting and producing explosive materials, for civilian use";

Order of the Minister of Defence No. 315, dated 15.3.2007 "On the approval of the regulation on the criteria and procedures for issuing permits of import, export and production of explosives, pyrotechnic substances, fireworks, for civilian use and the operating of the granting permits commission";

Order of the Minister of Defence No. 525, dated 30.7.2004 "For the application procedures for the registration of explosive substances in the state register of explosive substances for civilian us"

Common Order of the Minister of Defence No. 107 Prot, on 23.02.2005 and the Minister of Finance No.471/3 Prot, on 2005 "On financial rates for permission to import, export and produce explosives for civil use";

Order of the Minister of Defence No. 155 dated 2.03.2005 "On the financial tariffs for the granting of the permits of the importation, exportations and manufacturing of the pyrotechnical materials, fireworks for civilian use";

Order of the Minister of Defence No 1106 dated 10.08.2009 "For registration of the explosives for the civil use in the state registry of the explosives, by the State exports Control Authority";

Any import of explosive and pyrotechnic materials for civilian use need to be licenced. An import licence is always required. An exception from this is made only in the following cases:

- For explosives, used by the Armed and Public Order Forces, whose use is regulated by special law;
- The licensing system in Albania which cannot be abolished without legislative approval.

Procedures

6.I. The licensing procedures and formalities are published on the official website of the State Export Control Authority: www.akshe.gov.al. In the Albanian legislation there is no restriction to the value, quantity or licence quotas. Also according to the Albanian legislation there cannot be derogations from the licensing requirements.

II. There is no such thing as size of quotas. A licence can be issued with 1 year of validity.

III. There is no restriction in the Albanian legislation related to this matter.

An import licence is issued only when there is an application for it, which fulfills the requirements of the Albanian legislation. For each import performed by a licenced entity an AKSHE official is present at the customs point where the import will take place. If there is a request from governments and export promotion bodies of exporting countries about the names of importers who deal in this area, there are no restrictions to provide them such a list.

IV. Not applicable.

V. The processing period, if the application fulfills all the required documentation has a maximum of 30 days of processing.

VI. There is no such provision in the Albanian legislation. Once the import licence is granted, the importation can be done at any time during its validity period.

VII. A licence application for an import licence is processed by the Commission of Granting the Licences. However, this application must be completed before with the necessary documentation that is issued by the Ministry of Interior and National Licensing Center, (this document would be explained in the questions below).

VIII. If the demand for licences cannot be fully satisfied, the licence cannot be granted. There are no exceptions. Also there are no amounts for granting the licences to an importer.

IX. An import licence is always required to import explosive and pyrotechnic materials for civilian use, even when there is an export licence issued by the exporting countries. Also in this case the import licence is not issued automatically but the application is subject to controls.

X. Not applicable.

XI. Not applicable.

7.(a) The application must be done 30 days before the importation of the goods. This time limit is the maximum to process an import licence. If the importer submits all the necessary documents and satisfies all the requirements, the licence can be obtained within a shorter time. But this is considered case by case.

(b) No. It has to be revised step by step.

(c) No.

(d) An application for an import licence is processed by the Commission of Granting the Licences. However, the application which is issued by the Ministry of Interior and National Licensing Center, must be completed with the necessary documentation before submission. (This document would be explained in the questions below).

8. No answer was provided.

Eligibility of importers to apply for licence

9.(a-b) Yes, if the object of their activity is the import of explosive and pyrotechnic materials for civilian use.

(c) Not applicable.

Documentation and other requirements for application for licence

10. An importer who wants to import pyrotechnic, fireworks materials for civilian use has to submit an application to the Commission of Granting Licences at the State Export Control Authority. The application needs to be completed with the following documents:

(i) Registration in the law-court as a physical or legal person for importation and firecrackers business;
(ii) Registration certificate in the taxing office;
(iii) Certificate of the identification number as a taxable person;
(iv) List composed by the firecrackers' manufacturer, with the code number, firecrackers labeling, way of packaging, quantity, weight, financial value, translated to Albanian and duly notarized;

(v) Permission issued by the Ministry of Environment, for the safety and protection of the environment, (currently this is issued by the National Licensing Center);

(vi) Copy of the importer's previous permission, in the case of renovation.

Documents must be original or notarized photocopies. The interested subject, before duty-payment, makes a bank deposit in order "To pay a draft to get the permission to import firecrackers", from the Ministry of Defence.

An importer wanting to import explosive materials for civilian use has to submit an application to the Commission of Granting Licences at the State Export Control Authority. The application needs to be complete with the following documents:

(i) Registration in the law-court as a physical or legal person
(ii) Necessary documentation for the types and quantities of explosives from the manufacturing factory.
(iii) Conformity assessment document and documentation of technical data of the composition of explosives, associated with pictures.
(iv) Permission issued by the Ministry of Environment, for the safety and protection of the environment. (Now issued by the National Licensing Center)
(v) Service contract for physical storage and transportation with the third party, when there is no licence for these services.
(vi) Permission from the Ministry of Public Order for storage and transfer of explosives, to be imported.
(vii) Copy of the previous import permit (if any), invoices and a list of explosives, which have previously been used, a statement of storage conditions of the explosives and of the quality of these materials.

11. The documents required upon importation are the documents mentioned in the previous question.

12. The licensing fee for an import licence with the validity of one year is 100 US$.

13. There is no other deposit or advance payment except that paid for the licensing fee.

Conditions of licensing

14. The validity of the import licence is 1 year. The validity of the licence cannot be extended, and the importer has to submit another application.

15. There are no penalties for non-utilization of the licences.

16. Licences are not transferable.

17. The conditions attached to the issue of the licence are that the importer has to notify the Commission before importing the licensed materials.

Other procedural requirements

18. No, there are no other procedures prior to importation.

19. All banks provide foreign exchange automatically.

VII. IMPORT LICENSING PROCEDURES FOR MILITARY GOODS

Outline of system

1. The import of military goods and dual use goods and technology is managed by the Albanian State Export Control Authority (AKSHE) under the Minister of Defence. Trade with foreign parties is performed based on licences and authorizations issued by this authority, after consultations with the relevant institutions if needed.

This permission is issued based on Law No. 9707 "On State Exports Control of Military Goods and Dual Use Goods and Technology" Official Journal No. 48, Page 1237; Publishing date: 24.04.2007).

The AKSHE's work is focused on the state control of exports, imports, transit, transfers and intermediary activities for military goods and dual use goods and technology, to ensure the interests of the Republic of Albania, to supervise its commitment to international treaties of non-proliferation of weapons of mass destruction and their launching systems, the transfer of conventional weapons, as well as the implementation of measures aimed at preventing the of use of such goods for unlawful purposes.

Purpose and coverage of licensing

2. The licensing system for military goods and dual use goods and technology function is a single one, concentrated in the State Export Control Authority. The products that are covered are listed in the national list according to the Decision of the Council of Ministers No.1569, of 19.11.2008, "On approving the list of military goods and dual use goods and technology which undergo state control of import-exports", Official Gazette: Year 2008, No. 195, Page 10481; Publishing date: 06.01.2009. This list is based on the European Union published list on military goods and dual-use goods and technology.

3. The system does not discriminate any country.

4. The licensing system is not intended to restrict the quantity or value of imports. There is no restriction in value or quantity in the Albanian legislation to import military and dual use goods.

The state export – import control policy is built on the following principles:

(a) Priority of national interest – political, economic and military, of which protection is necessary for guaranteeing national security.
(b) Protection of political, economic and military interest of the country.
(c) Obligation to observe the international commitments made by the Republic of Albania to non-proliferation of weapons of mass destruction, the ways for their proliferation, and to ensure state control over international transfer of goods designed for military purposes, and dual-use goods, as well as to prevent these goods from being used for terrorist acts and other illegal purposes.
(d) Legality.
(e) The export control over military items has to be done only in line with the national policies mentioned in this paragraph without interfere on the free trade of this goods
(f) Harmonisation of state export control procedures and regulations with international legal norms and practices.
(g) Ensuring interaction with international organisations and foreign countries in the state export control area so as to reinforce international security and stability, including countervailing of weapons of mass destruction and the system for their proliferation.

5. The Albanian legislation for the import-export military goods and technology of dual use is as follows.

- Law No. 9707, of 05.04.2007, "On State Control over the import-export of military goods and dual use goods and technology" Official Gazette No. 48, Page 1237; Publishing date: 24.04.2007.

- Decision of the Council of Ministers No. 43, of 16.01.2008, "On Organizing, functioning and the status of the State Export Control Authority", Official Gazette: Year 2008, No. 8, Page 240; publishing date: 30.01.2008.

- Decision of the Council of Ministers No.1569, of 19.11.2008**,** "On approving the list of military goods and dual use goods and technology which undergo state control of import-exports", Official Gazette: Year 2008, No. 195, Page 10481; Publishing date: 06.01.2009.

- Decision of the Council of Ministers No. 305, of 25.3.2009, "On determining the procedure of issuing legal documents, in the framework of state control over the import-export of military goods and dual use goods and technology"**,** Official Gazette: Year 2009, No. 51, Page 2468; Publishing date: 29.04.2009.

- Decision of the Council of Ministers **N**o. 304, of 25.3.2009, "On determining the procedure on expertise and control by the State Export Control Authority", Official Gazette: Year 2009, No. 51, Page 2466; Publishing date: 29.04.2009.

- Decision of the Council of Ministers No. 604, of 28.8.2003, "On approving, in principles, the European Union Code of Conduct regarding the export of weapons".

- Decision of the Council of Ministers No.341, of 8.4.2009**,** "On determining tariffs for the issuance of legal documents".

Any import of military and dual use goods needs to be licenced by the State Export Control Authority. An import licence is always required. An exception from this is made only in the cases that follow:

(a) transfer of goods in connection with events held by the Armed Forces, or other state security structures of the Republic of Albania outside its territory, or with events held by foreign military forces in the territory of the Republic of Albania, as part of international agreements laying down the mechanism of state control over the movement of these goods;
(b) international transfers of anaesthetics (medical anaesthetic gases), sports and hunting arms, gas-containing vessels, and exportation and importation of individual armament of military servicemen, and state law enforcement and internal security bodies, which, under law, are entitled to carry arms;
(c) state control procedures concerning international export transfers of goods, which aim at ensuring provision of military assistance in accordance with the terms contained in international agreements and treaties to which the Republic of Albania is a party, and the movement of goods outside of Albania with a view to offering emergency assistance to foreign countries, if this is established by law.

The licensing system in Albania cannot be abolished without legislative approval.

Procedures

6.I. The licensing procedures and formalities are published on the official website of the State Export Control Authority: www.akshe.gov.al. In the Albanian legislation there is no restriction in the value, quantity or licence quotas. There cannot be derogations from the licensing requirement.

II. There is no size of quotas. A licence can be issued with a validity from 1-3 years with an extend option if there is a contract betwen the entities involved.

III. There is no restriction. An import licence is issued only when there is an application for it, which fulfills the requirements of the Albanian legislation. Also the State Export Control Authority has the authority to do controls before, during, and after issuing the import licence. Also an end-user statement or certificate which is filled by the importer or any other who is the end user is needed to obtain an import licence.

IV. Not applicable.

V. If issuance of licences and authorisations does require coordination among the other institutions concerned, the time-limit for considering an application shall be determined in accordance with the categories of goods, but shall not exceed the following timescale as of the day of application:

- 15 days for importation or transhipment of goods, and temporary importation/exportation of goods for exhibitions, fairs, advertising, testing, and other similar purposes, if this does not call for transfer of ownership.

This time-limit does not include the time required for obtaining additional information from entities involved in international transfer of goods.

VI. There are no such provisions in the Albanian legislation. Once the import licence is granted the importation can take place at any time during its validity period.

VII. An application is dealt with by the State Export Control Authority. Trade activities with foreigners take place on the basis of licences and authorisations issued by this Authority, following, if required, the opinion of the institutions concerned. The concerned institutions are the Ministry of Defence, Ministry of Foreign Affairs, Intelligence Agencies, and Ministry of Interior.

VIII. If the demand for licences cannot be fully satisfied, the licence cannot be granted. There are no exceptions. The new importers who want to deal with international trade of military goods need to be registered by the State Export Control Authority. After they get the Registration Certificate they can demand an import licence. This registration is not required to trade dual use goods and technologies.

IX. In the Republic of Albania for the import of military goods and dual use goods and technology, an import licence is always required even when there is an export licence issued by the exporting countries. Also in this case the import licence is not issued automatically but the application is subject to controls.

X. Not applicable.

XI. Not applicable.

7.(a) The application must be done 15 days before importation of the goods. This time limit is the maximum allowed before an import licence procedure. If the importer submits all the necessary documents and satisfies all the requirements, the licence can be obtained within a shorter time. But this is to be considered case by case.

(b) No. It has to be revised step by step.

(c) No.

(d) A licence application procedure is done by the State Export Control. Trade activities with foreigners take place on the basis of licences and authorisations issued by this Authority, following, if required, the opinion of the institutions concerned. The concerned institutions are the Ministry of Defence, Ministry of Foreign Affairs, Intelligence Agencies, and Ministry of Interior.

8. The application to obtain licences, authorisations or international import certificates will not be taken into consideration if:

(a) It is deposited by a person who does not have the judicial capacity;
(b) Documents are missing, or they are formulated contrary to the requirements prescribed by the Law;
(c) There are other reasons running counter to Albanian legislation in force, or the ratified international agreements.

In the event that the application to obtain a licence, authorisation and international import certificate is not taken into account or rejected, the State Export Control Authority gives notice to the applicant and the state body responsible, within three days from the adoption of the relevant decision, provides the explanations of and reasons behind failure to consider it or its rejection. The decision made by the State Export Control Authority to revoke a licence, authorisation and international import certificate, or to remove from the list the name of an entity involved in economic activities with foreign countries for international transfers of goods, can be appealed to the court of appeal, in accordance with the general rules of appeal. An appeal against the decision suspends its execution.

Eligibility of importers to apply for licence

9. A person, firm or institution who wants to deal with the import of military goods, has to be first registered by the State Export Control Authority. This provision is not required to import dual use goods. The registration certificate fee for military goods is 30 US$. All persons or firms that are registered by the State Export Control Authority are in a list published on the website: www.akshe.gov.mod.al.

Documentation and other requirements for application of licence

10.(a) Certificate of registration (only for military goods).

(b) Licence application form completed by type, according to the guidelines set forth in this form, signed by the legal representative of the entity (notarized photocopy of the passport).

(c) Brief summary of the current commercial activity, which reflects the entity's ability to perform activities in the area of transfer of military goods (only private commercial entities)

(d) A natural person who seeks to obtain a licence must submit the following documents:

- Document that certifies expertise in the field of international transfers of military goods;
- Identification document (identity card, passport,);
- Proof that the judicial process is not (Section Civil and Criminal) issued by the judicial district in which the person resides;
- Certificate of prosecution that is not a criminal proceeding;
- Certificate of execution that no obligations to individuals or legal entities, private or state;
- Document that proves he is not convicted of any offence that constitutes grounds for denial of licence, the illegal activities during the last 10 years from the date of the application for licence;
- Certificate of tax authorities and the bank where the money transfer will be performed;
- Taxpayer Personal Identification Number (allowed for import-export);
- The historical Extract document issued by the National Registration Center regarding the changes that has been made during the years on the data mentioned above, in the simple extract.

(e) A legal person who seeks to obtain a licence must submit the following documents:

- Confirmation that the company is not on a trial neither in Civil or Criminal Section. This document is issued by the judicial district in which the company has the headquartered;
- Certificate of prosecution that is not a criminal proceeding;
- Certificate of execution that no obligations to individuals or legal entities, private or state;
- Proof of payment of taxes by the tax department;
- Certificate from the bank where the money transfer will be performed;
- Statute of the company (notarized copy);
- Act of establishment (notarized copy);
- Decision of the court to establish the company;
- Taxpayer Personal Identification Number;
- The historical extract mentioned above.

(f) International import certificate or end-user.

(g) Documents that provide information on the description of goods, conditions of delivery, quantity of goods, the value of goods, state transit transship, destination country and the last user, and country of origin of goods.

(h) Notarized copy of the contract or order, certified by the legal representative of the subject.

(i) Bill of goods.

(j) Documents that provide information on the description of goods, conditions of delivery, place of destination or origin of goods.

(k) Documents that provide information on the partner firm address, financial credibility, the bank account.

(l) Other valid documents to be considered as such by the State Export Control Authority.

(m) Warrant payment of the appropriate fee.

11. The documents required upon importation are the documents mentioned in the previous question.

12. The licensing fee for an import licence with a validity of one year is 30 US$. The licensing fee for an import licence with a validity of three years is 60 US$.

13. There is no other deposit or advance payment except that paid for the licensing fee.

Conditions of licensing

14. The validity of the licence is 1-3 years, according to the type of the licence required. The validity of the licence can be extended, but not upon the term of validity of the economic agreement, which refers to the licence.

15. There are no penalties for non-utilization of the licences.

16. Licences are not transferable.

17. There are no other conditions attached to the issue of the licence.

Other procedural requirements

18. No, there are no other procedures prior to importations.

19. All banks provide foreign exchange automatically.