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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 communication, dated 30 October 2012, is being circulated at the request of the delegation of Albania.

I. IMPORT LICENSING PROCEDURES ON MILITARY GOODS

Outline of system

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

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 April 2007.

AKSHE's work is focused on the state control of exports, imports, transits, 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 aiming prevention of use of such goods for unlawful purposes.

[1] See document G/LIC/3.

Purpose and coverage of licensing

2. The licensing system for military goods and dual use goods and technology function as one, concentrated in the State Export Control Authority mentioned in the previous question.

The products that are covered are listed in the national list according to the Decision of the Council of Ministers No. 106 of 9 February 2011, "On approving the updated list of military goods and dual use goods and technology which undergo state control of import-exports".

This list is based on 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 values of imports. In the Albanian legislation for the import of military and dual use goods there is no restriction in value or quantity.

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

- Priority of national interest – political, economic and military, of which protection is necessary for guaranteeing national security;
- Protection of political, economic and military interest of the country;
- 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;
- Legality;
- Conduct of export control to the extent required to achieve its purpose only;
- Harmonisation of state export control procedures and regulations with international legal norms and practices;
- 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 5 April 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 April 2007;
- Decision of the Council of Ministers No. 43, of 16 January 2008, "On Organizing, functioning and the status of the State Export Control Authority", Official Gazette: Year 2008, No. 8, Page 240; publishing date: 30 January 2008;
- Decision of the Council of Ministers No. 106, of 9 February 2011, "On approving the updated list of military goods and dual use goods and technology which undergo state control of import-exports";
- Decision of the Council of Ministers No. 305, of 25 March 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 April 2009;

- Decision of the Council of Ministers No. 304, of 25 March 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 April 2009;
- Decision of the Council of Ministers No. 604, of 28 August 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 April 2009, "On determining tariffs for the issuance of legal documents".

Any import of military and dual use goods need to be licensed by the State Export Control Authority. An import license 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 of 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 license quotas. Also according to the Albanian legislation there cannot be derogations from the licensing requirement.

II. There are no such as size of quotas. A license can be issued with the validity from 1-3 year with the extend option if there is a contract betwen the entities envolved.

III. There is no restriction in the Albanian legislation related this matter. An import license 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 license. Also to obtain an import license is needed an end-user statement or certificate which is filled by the importer or any other who is the end user.

IV. Not applicable.

V. If issuance of licences and authorisations does not call for coordination of work 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 transfers of goods.

VI. There is no such provisions in the Albanian legislation. After that the import license is granted it the importation can be done at any time during is validity period.

VII. A license application is proceeded 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 consulting of 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 licenses cannot be fully satisfied, the license cannot be granted. There is no exeptions.

The new importers that want to deal with international trade of military goods need to be registred by the State Export Control Authority. After they get the Registration Certificate they can demand for an import license. This registration is not required for the trade of dual use goods and technologies.

IX. In the Republic of Albania for the import of military goods and dual use goods and technology, always is required an import license even when there is an export license issued by the exporting countries.

Also in this case the import license 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 to import the goods. This time-limit is the maximum to proceed an import license. If the importer submit all the necessary documents and satisfy all the requirements, the license 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 is procceded by the State Export Control. Trade activities with foreigners take place on the basis of licences and authorizations issued by the Authority, following if required the consulting of 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 circumstances under which the license can be refused are:

- The application for obtaining 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 for obtaining 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 taking of the relevant decision, laying down the explanations of and reasons behind failure to consider it or its rejection.

The decision made by the State Export Control Authority to revoke licence, authorisation and international import certificate, or to remove from the rolls the name of an entity involved in economic activities with foreign countries for international transfers of goods, may be appealed against to the court of appeal, in accordance with the general rules of appeal. Appeal against decision does suspend its execution.

Eligibility of importers to apply for licence

9. A person or a firm or institution that wants to deal with the import of military goods has first to be registered by the State Export Control Authority. This provision is not required for the import of dual use goods. The registration certificate fee for military goods is 30 USD.

All the 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 for licence

10.
(1) Certificate of registration (only for military goods).
(2) License 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).
(3) Brief summary of current commercial activity, which reflects the entity's ability to perform activities in the area of transfer of military goods (only private commercial entities).
(4) A natural person who seeks to obtain a license 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 offense that constitutes grounds for denial of license, the illegal activities during the last 10 years from the date of the application for license;
  - Certificate of tax authorities and the bank where the money transfer will be performed;

- Taxpayer Personal Identification Number (allowed for import-export);
- Extract the simple and historical taken by the National Registration Center.

(5) Legal person who seeks to obtain a license must submit the following documents:
- Confirmation that the company is trial (Civil and Criminal Section) issued by the judicial district in which the company is 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);
- The act of establishment (notarized copy);
- Decision of the court to establish the company;
- Taxpayer Personal Identification Number;
- Extract the simple and historical taken by the National Registration Center.

(6) International import certificate or end-user.

(7) 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.

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

(9) Bill of goods.

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

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

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

(13) 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 license with the validity of one year is 30 USD. The licensing fee for an import license with the validity of three years is 60 USD.

13. There is not other deposit or advance payment except that paid for licensing fee.

Conditions of licensing

14. The validity of the license is from 1-3 year, According to the type of the license required. The validity of the license can be extended, but not after the term of validity of the economic agreement, which refers to this license.

15. There are not penalty for non-utilization of the licenses.

16. Licenses are not transferable.

17. There are not other conditions attached to the issue of the license.

Other procedural requirements

18. No, there are not other procedures prior importations.

19. All banks provide foreign exchange automatically.

II. IMPORT LICENSING PROCEDURES ON HEALTH

Outline of system

1. Due to the amendments on licensing procedures, only for some of medicinal products is required to provide an import license, before placing them on the market. Medicinal products, according to their use and technical capacities that authorities have, are divided in groups as per below:

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

Among the above mentioned groups, the import authorization is required for medicines, DDD-s (disinfectants, disinsectants and deratizing substances) and dental equipments in case they are source of ionized radiation. Every subject, before starting the activity on import/export or place on the market of these substances, has to be licensed nearby the National Licensing Center (NLC). In some of licensing procedures, is needed the statement of the charge d'affaires structure at the Ministry of Health. The decision need to be fulfill within 15 days of work, after that it come published by the National Licensing Center in the National Licensing Register, as a authorized subject on these activities. There after, import authorizations are granted for every concrete importation according to regulation in force:

(1) All the pharmaceutical products circulating in the Albania market should be registered, except certain case (such as pharmaceuticals prepared in pharmacy or facing the emergency cases). The registered drugs are imported by juridical subjects licensed on this activity by the National Licensing Center (NLC), under the written statement of the Ministry of Health, prior to the licensing approval by the NLC. Only for the medicines under patent protection, the importers need to be assigned by the Representative Offices established in Albania or by regional ones; in case of generics there's no need for such assignment. Licensed subjects on the import of medicines carry out their imports, based on the published 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.
(2) In case of import of unregistered drugs (in case of emergency such as natural catastrophes, epidemics, or drug's unique alternatives for hospital/ambulatory service), the application is to be submitted near by the Pharmaceutical Department (Ministry of Health). After evaluation on needs for these drugs by the specialized structures within the Ministry of Health, the Minister of Health authorizes the importation. This authorization has validation for 2 (two) months.
(3) The import of narcotic drugs and psychotropic substances is regulated separately, because importation process is more restricted and under control of Albanian and international authorities. Licensed 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 at the Pharmaceutical Department the request on authorization import. If the required quantity doesn't exceed the allowed quantities, the authorization signed by the Minister of Health is granted, with validation for 3 (three) months from its issuing date. 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 near the Pharmaceutical Department, the request for import authorization followed by the

export-authorization of the exporting country. After that, the Pharmaceutical Department proceeds with procedure of granting of the authorization, valid for a period of 2 (two) months. Finally, provision of this authorization means allowing entry into Albania of narcotic or psychotropic substances.

(4) In order to facilitate the import procedures, after the month of May of 2008, according to the order of Minister No. 215 dated 27 May 2008, has been avoid the obligation of granting and submitting in the custom authorities, the import authorization for medical equipments, dental equipments and consumables. If medical equipments are sources of ionizing radiation, an approval is issued by the Commission on Radiation Protection in the Institute of Public Health. This approval takes into account the quality certificate, data on the device model/batch No.; maximal tension, manufacturing date and the quality certificate of the two last years from the importing date, invoice No.; the approximate date to be imported.

(5) Related to importation of disinfectant, disinsectant and deratizing substances (DDD), the subject after being licensed by the National Licensing Center on the activity of intercessory services hygienic-sanitarian, he/she submits the request for import authorization near by the Hygienic and Epidemiologic Sector (MoH). The requirement comes verified by the charged specialist of the Hygienic and Epidemiologic Sector if it fulfills all the requirements of the list of DDD substances, approved every year by the Minister of Health. Also, on the issuing of the import authorization related to DDD substances, is required the opinion of specialists from Public Health Institute (PHI), regarding the samples for the concrete import to be first tested. PHI has to express its official opinion within 10 days of work. Based on all effectuated verification, 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 product covered by the above mentioned licensing systems are:

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

3. Pharmaceuticals to be registered in Albania and later imported, should be registered and circulate in one of the European countries, Switzerland, USA, Canada, Japan and Australia. With regard to the pharmaceuticals manufactured within the Balkan area, they can be registered and later imported, only if these goods circulate in their country at least since 2 years.

4. Licensing system generally is 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 to the market. Even though, health care is mainly covered by imported products, is aiming on the stimulation of the domestic production by increasing the number of qualitative medicinal products manufactured in Albania. Normally, adoption of proper legislation, setting up of structures and equipping with necessary technology, creates the condition and opportunities to use other alternatives, which consist on control of imported drugs at several stages, at the border by custom authorities, during wholesale distribution, during dispensing by pharmacies and their use. The adoption of 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 June 1993 "On regimen of export-import and medicines production";
- Joint Guideline of Ministry of Health and Ministry of Finance No. 180 of 13 August 1993 "On co-operation for the regimen of import-export of medicines and their clearance";
- Law No. 7975 of 26 July 1995 "On narcotic drugs and psychotropic substances, amended with:
  (a) Law No. 9271 of 9 September 2004;
  (b) Law No. 9559 of 8 June 2006.
- Decision of Council of Ministers No. 415 of 17 August 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 August 2000;
- Order of Minister of Health No. 104 of 5 March 2004, "For a change in the Guideline No. 180 of 13 August 1993 on co-operation for the regimen of import-export of medicines and their clearance";
- Order of Minister of Health No. 245 of 29 June 2006 "For a change in the Guideline No. 180 of 13 August 1993 on co-operation for the regimen of import-export of medicines and their clearance";
- Law No. 9323, of 25 November 2004 "On medicines and pharmaceutical service" amended with:
  (a) Law No. 9523 of 25 April 2006;
  (b) Law No. 9644 of 20 November 2006;
  (c) Law No. 10008 of 27 October 2008.
- Law No. 9928 9 June 2008 "On dental health service in the Republic of Albania";
- Order of Minister of Health No. 162 of 16 April 2008 "On abrogation of the Order of Minister No. 214 of 22 April 2004";
- Law No. 10081 of 23 February 2009 "On licenses, authorizations and permits in the Republic of Albania";
- Law No. 10137 of 11 May 2009 "On some addenda to the current legislation on licenses, authorizations and permits in the Republic of Albania";
- Decision of Council of Ministers No. 538 of 26 May 2009 "On licenses and permits handeled by or through the National Licensing Center (NLC) and on some sublegal common regulations";
- Decision No. 1295 of 9 December 2009 "On some amendments to Decision of Council of Ministers No. 538 of 26 May 2009 On licenses and permits handeled by or through the National Licensing Center (NLC) and on some sublegal common regulations";
- Law No. 10138 of 11 May 2009 "On Public Health";
- Order of Minister of Health No. 102 of 22 February 2010 "On the issuing of the authorization on the import-export, wholesale and retail trade of the DDD substances (disinfectant, disinsectant and deratizing substances)";
- Order of Minister of Health No. 365 of 3 August 2012 "On the approval of the List and usage of the DDD substances (disinfectant, disinsectant and deratizing substances) in the Public Health";
- Law on Protection from ionized radiation No. 8025 of 9 November 1995, amended by the Law No. 9973 of 28 July 2008;
- Decision of Council of Ministers No. 158 of 13 February 2008 "On import-export of ionized radiation source in the Republic of Albania";
- Regulation No. 3918/4 of 3 November 2004 "On Import, export and trasit of radioactive sources";
- Guidance No. 4756/1 of 21 December 2006 "On import-export of radiation materials in Albania";
- Categorization of Radioactive Sources No. 9 of 7 January 2010;

- Regulation No. 10 of 7 January 2010 "On licensing and inspection of ionized radiation sources";
- Approval No. 494/6 of 7 February 2011 "Approval on import-export for X-rays generators";
- Guidance No. 134 of 12 April 2011 "On import – export and transit of radioactive sources of first and second category in the Republic of Albania".

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 of 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 International Narcotic Control Board and are published in its special publication. Practically the authority does not apply the allocation of quotas among importers. There is a yearly quota, which is divided among importers by agreement based on the supplying contracts that importers have signed with public or private health institutions, or due to medicines inclusion in the reimbursement scheme etc. There is not any limitation for the quantities imported from any country. Importers import the quantity they think it is reasonable or according to the supply contracts, they have signed, always within yearly quota and the agreement done with other importers. As we are taking into consideration a very restricted control, no request for exception or derogations from the licensing requirement is accepted.

With regard to DDD substances, each year come approve by the Minster the list of substances according to the WHO recommendations and Directive 98/8/EC regarding the biocide products to be used in the public health. Only these substances specified in this list can be import.

II. The quota size for each narcotic drug is determined for a year period and covering all the country. Importation licenses are granted every time that importer will import a quantity within the quota. Because of, the import authorizations are valid for 3 months, after one importation within 3 months can be done the next importation from the same importer.

Related to ionized radiation sources the import authorization are for single use and valid for 2 weeks.

III. Licenses are allotted for the quantity of a certain narcotic drug that is imported by a certain manufacturer and a certain country (this is not defined by authority, but from the fact that 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 supervises especially license usage, because no utilization would result in the lack of drugs in health institutions and pharmaceutical market. In the case of no utilization of the license, the importer notifies the responsible authority and if he does not, the authority based on the data received in the pharmaceutical market, communicates with importer to solve any possible problems or to make possible the importation from another importer if the first has not possibility to do it. The primary concern of authorities is that the market not to suffer the lack of medicines.

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

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 with the start of a calendar year begins even the importing periods, so they begins their procedures after that date.

Related to radiation sources this period is two weeks and two months.

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

- Related to disinfectant, disinsectant and deratizing substances, is required the official opinion of Public Health Institute;
- The same situation occurs with the ionized radiation sources, where the importer has to approach more than one administrative organ.

The positive answer (approved import license) or negative one (along with all explanations) is given to importer in the Ministry of Health.

VIII. There are several ways to act in the case of not satisfied license demand. If the medicine is for ambulatory use and it is not the first alternative in the reimbursement list, it is served the first to come. It is enough to submit the application with all necessary data and the license will be granted to him. If the drug is intended for hospital use (according to contracts importer has with hospitals), or is first alternative in the reimbursement list (with the highest coverage level) it is served first the importer that fulfill these conditions and then the others according to the agreements among themselves, take the difference of quotas. If the importer submits an application for narcotic import authorization in the end of the year, knowing that the period of authorization approval obliges importer to bring the cargo/shipment in the following year, which is not allowed by international control authorities, usually is decided that procedures must be done the next year when the new quotas are open. It is not examined the importer performance. The maximal 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 in Albania and there is a very small number of importers, sometimes even only one). There is not any provision for new importer, they are considered in the same way like the old ones. The applications are examined immediately.

Related to ionized radiation sources, new applicants have to be assessed through licensing process for each approval import.

IX. In the case of narcotic drugs we have the case of bilateral quotas. According to regulatory framework and practically together with the application for exportation it is submitted even the importation authorization from the importing country (granted to importer). The export authorizations the only issued for this case are granted immediately.

Nearly the same happens with the ionized radiation sources, where, to provide the export approval from the exporting country, is needed the confirmation from importing country.

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

Related to ionized radiation sources, two counties are informed between them through their contact points.

XI. Related to 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.

Related to ionized radiation source: Yes.

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

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

(c) No, there is not any limitation.

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

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

- National Center of Drugs Control is informed that the drug does not meet the necessary quality, safety standards; information is received by homologues authorities or by the results of NCDC own tests (testing of samples in the market);
- Manufacturer or control authorities informs for the starting of withdrawal procedures of the product from market, meanwhile the importer submits the application for import licence;
- The registration validity of the medicine has expired and the manufacturer has not begun the re-registration procedures.

On each case, there is an explanation for refusal. The applicants can make the appeal to the Ministry of Health, the supervising levels of Pharmaceutical Department and of 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 case of 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 licenses 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) which has a

professional license (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 e second registration only for this kind of activity.
Related to ionized radiation sources, all the physics or legal persons are eligible to apply for license, under restrictive licensing system too.

(b) In health services there are not non-restrictive systems.

(c) There is a system of professional licensing (registration) for importation, exportation, and wholesale distribution of medicinal products. Eligible are those firms that have proper facilities, according to criteria defined for this purpose and specialized staff to perform this 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. 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 to the authorities and begin the procedure. In the different systems is submitted different documentation depending on groups of products that will be imported.

(a) To import registered medicines, registered importer submits an application for import authorization that include a) importer's data, b) a table with medicines that will be imported where is detailed 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. Submission is done to the National Center of Drugs Control where the import license is granted.
(b) To import unregistered medicines, the application for import authorization has the same data as above is submitted to the Pharmaceutical Department of the Ministry of Health, where the import authorization signed by Minister of Health is granted.
(c) To import narcotic and psychotropic drugs, the importer has to submit the application to the Pharmaceutical Department in the Ministry of Health, including abovementioned data, and full address of manufacturer. When the importer submits the Ministry of Health, first he requires the granting of import authorization. When he/she receives even the confirmation that exporter has received the export authorization in the originating country the importer applies for the import license when the cargo is ready.
(d) To import medical devices, dental equipments and consumables, has been avoid the obligation of granting and submitting in the custom authorities, the import authorization for medical equipments, dental equipments and consumables. If the medical devices are sources of ionizing radiation the application must be accompanied by an approval for that activity.
(e) To import disinfectant, disinsectants, deratizing substances the applicant submits an application that contains the following information: i) importer's data, ii) Taxpayer Personal Identification Number and iii) certificate of origin of the goods iv) custom office v) storage address of these products.
(f) To import ionized radiation source the licensed applicant on this field should be provided by:
- a copy of registration to the court;
- technical data for radiation sources;
- certification for sealed sources;
- data on exporter country;
- clarification on the purpose of the use of sources;
- declaration for the source in the end of the use;
- clarification of transport of the sources.

11. When the cargo/shipment arrives in Albania this must be supplemented generally 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 type of the product that is imported.

Related to ionized radiation sources, for upon actual importation is required an official request for approval of import, quality certificate, data on the device model/batch No.; maximal tension, manufacturing date and the quality certificate of the two last years from the importing date, invoice, the approximate date to be imported.

12. The fees are different depending on type of license:
- The fee for import of unregistered medicines is 1000 Leks for each medicine;
- The fee for import of raw materials is 500 Leks for each item;
- The fee for import of registered medicines is 200 Leks for each authorization;
- The fee for import of narcotics and psychotropic substances is 200 Leks for each authorization;
- The fee for import for packages is 200 Leks for each authorization;
- The fee for import of disinfectants, disinsectants and deratising substances the fee is 2000 Leks for each authorization;
- The fee for import of 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 licenses:

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

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

16. Import licenses are not transferable between importers.

17 (a) For narcotic drugs and psychotropic substances, there is condition that the total quantity of the imported medicine, from each importer, will not be more than the annual quantity approved for the country.

Related to ionized radiation source there's any other condition. The same for the point (b) of this question.

(b) There are not other conditions.

Other procedural requirements

18. With regard to narcotics prior to the importation, the Minister of Health issues an authorization on import, based on requirement of the licensed company (taking into account that the required quantity doesn't exceed the yearly allowed quantities). 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.

19. All banks provide foreign exchange automatically.

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

Outline of system

1. The procedure of licensing in Albania has recently changed. Activities for production are licensed according to the Law 10081, dated 23 February 2009 – Import of products for plant protection in Albania is conducted through permissions issued by NLC, based on some preliminary criteria to be fulfilled by the interested parties. The entities are being inspected from the District Inspectorate of the plant protection. This license is issued through NLC. In Albania could be imported only registered products 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 is being applied to those that are registered in countries of European Union. PPP are accepted without limitations coming from all countries.

4. This licensing system does not intend to restrict the quantity or value of imports coming into Albania. The purpose of issuing the import license 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 does not exist other alternative known method

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

- Law No. 10081, dated 23 February 2009 "On Licensing, Authorizations and Permissions in the Republic of Albania";
- Law No. 9362, dated 24 March 2005 "On the plant protection services" – changed;
- Decision of the Council of the Ministers No. 1555, dated 11 December 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 November 2008, "On the determination of registration rules and evaluation criteria of PPP", provides that only registered Plant Protection Products could be imported.

Procedures

6.I.-IV Not applicable.

V. Based on the Law No. 10081, dated 23 February 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 importer has to approach to get the licence.

VIII. Not applicable.

IX. Not applicable.

X. Not applicable.

XI. There are not such conditions associated with the license.

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

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

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

(d) Application for import licenses are affected only by one administrative organ, which is National Licensing Center.

8. The license can be refused when the importer failure 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 informed officially by NLC, for the reasons of licence's refusal. This information is published automatically on the NLC's website.

According to the legislation on plant protection in the case of the refusal of the license, 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 not 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 license are eligible to import plant protection products. All importers are listed in the Ministry of Agriculture, Food and Consumer Protection and the list is published. The list is sent to the cross – border point where phyto-sanitary and quarantine inspection service is established.

According to the Order No. 9 dated 12 July 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 required documents at the Directory of the NLC. The whole set of documents is available at NLC office.

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

12. Licensing fee is 2000 lekë.

13. No deposit or advance payment requirement.

Conditions of licensing

14. The license is permanent.

15. No penalty.

16. The license is not transferable.

17. No conditions are attached to the issuing of the license.

Other procedural requirement

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.

IV. LIVE ANIMALS, BIOLOGIC MATERIAL ON ANIMAL INSEMINATION AND VETERINARY DRUGS AND VACCINES

Outline of system

1. The procedure of licensing in Albania has recently changed. Activities for production are licensed according to Law "On licensing", No. 10081, dated 23 February 2009, as well as according to sublegal acts for Law implementation. The legislation on licensing defines the activities according to fields (categories and sub categories) and special criteria for licensing; evincive documentation and any other accompanying documents for each activity.

Requests for licensing of activities included in such categories or sub categories are checked over 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 Food Competent Authority is based on the evaluation of submitted documents and on site inspection to assess fulfillment of requirements and mandatory standards defined in the legislation. Approval or refusal is published in the register within deadline, otherwise it is considered as approval in silence.

The final decision of NLC is published in the register and the title is submitted at the wickets of NLC.

CCA (MAFCP) suspends or revokes the license in cases when during checking it results that technical-technological and sanitary-veterinary requirements are not fulfilled according to the Law.

Purpose and coverage of licensing

2. Import licensing system is covering these groups of products:
   (a) live animal;
   (b) biologic material on animal insemination;
   (c) veterinary drugs and vaccines.

3. Import is 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 imports. There is not any alternative method. MAFCP does not determine quotes for import licenses.

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

- Law No. 10 081, dated 23 February 2009 "On licenses, authorization and permission in Republic of Albania";
- Decision, No. 538, dated 26 May 2009 "On licenses and authorization that are checked over through NCL and same other common sub-legal regulations";
- Law "On Food", No. 9863, dated 28 January 2008;
- Law, No. 10 137, dated 11 May 2009 "On same amendments in current legislation on licenses, authorization and permission in Republic of Albania";
- Decision, No. 1295, dated 29 December 2009, "On same amendments in Decision, No. 538, dated 26 May 2009 On licenses and authorization that are checked over through NCL and same other common sub-legal regulations";
- Law No. 9426 dated 6 October 2005 "Animal Breeding" changed.

Licensing is authorized by the Law No. 10 081, dated 23 February 2009 "On licenses, authorization and permission in the Republic of Albania" and the system can not be abolished without legislative approval. The legislation does not leave designation of products to administrative discretion. Additional legal requirements on licensing is Law No. 10465 dated 29 September 2011 "On veterinary service in the Republic of Albania", Article 137.

Procedures

6.I.-II Not applicable.

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

The steps in order to ensure that licenses are used for import issues 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 body for control of license of import usage;
- List of approved importers is published on the NLC's website.

IV. As there are not quotas for imports of such goods, the application can be submitted at any time.

V. The maximum time to process the application for license to import to:
- Live animals is 10 days;
- Biologic material on animal insemination is 15 days;
- Veterinary drugs and vaccines is 15 days.

Decision, No. 1295, dated 29 December 2009, "On some amendments in Decision No.538, dated 26 May 2009 On licenses and authorization that are checked over through NCL and some other common sub-legal regulations".

VI. No time limit. The importer has the right to start the import activity, since the moment they get the license.

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

VIII. There are no limits on licensing numbers. There are no restrictions on timing and ranking of the applications in order to get a license. The license is issued based on the fulfillment of the conditions determined by the Albanian law.
In cases that the applicant does not meet the requirements, the application is refused until a second period, determined in the act of competent inspection authority. The act of refusal is published on the NLC's website.
The examination of the applicant's request, from the date that has deposited the application, is performed within 10 days for the import of live animals and within 15 days for the trading of racial material and veterinary medicine.

IX. Not applicable since we do not have quotas and we do not issue licenses automatically.

X. The import is not permitted only based on export permissions.
- The import of goods is made only based on:
- Law No.10081, dated 23 February 2009 "On licenses, authorization and permission in Republic of Albania";
- Decision, No.538, dated 26 May 2009 "On licenses and authorization that are checked over through NCL and same other common sub-legal regulations";
- Annex I: Permission and licensing categories which are followed by/or through 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 issuing of the license.

7.(a) No.

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

(c) No limitations for the time of application.

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

8. The license can be refused in case when the importer does not meet the requirements set forth in the law and regulations.

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

Any interested party has the right to appeal on an administrative way to the NLC or MAFCP for cases of licenses with preliminary inspections. Administrative complains are being analyzed by the representatives of NLC, except cases of licenses with preliminary inspection which are analyzed by the MAFCP.

In the cases of preliminary inspection, MAFCP is informed by NLC when a complaint is presented to their office.

In both cases, complaints addressed to NLC or MAFCP, it is published in the National Registry of Permits and Licenses.

For administrative issues, a decision given after reviewing the administrative complaint maybe appealed directly to the competent court.

Regarding the above mentioned issues, are being followed 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 not 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 that is based on the Order of the Minister of Agriculture, Food and Consumer Protection, No. 8 dated 8 May 2007 "On the fees and secondary revenues applicable by institutions of the agriculture and food system".

Yes, the list of the authorized importers published on the website 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 the documentation to be filled by the applicant are provided by NLC.

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

12. Depends on the type of license, there is different fee for different license. The fee for import license of live animals is 10.000 lek, for trading of racial material is 300 All, and 100.000 All for veterinary medicine trade.

13. No, advance payment or deposit is required.

Conditions of licensing

14. All licenses are indefinite based on the article 11, Law No. 10 081, dated 23 February 2009 "On licenses, authorization and permission in the Republic of Albania".

In order to check if the conditions are fulfilled by the applicant, the MOAFCP performs frequent in site controls. If some conditions are not fulfilled than the MOAFCP presents the proposal to the NLC for the refusal of this license.

15. No.

16. No, licenses are not transferable.

17. Not applicable. We don't have quantity restriction for products.

Other procedural requirements

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

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

V. IMPORT LICENSING PROCEDURES FOR WASTE

Outline of system

1. The system is maintained to protect the life and health of the population, and to protect the environment. Importation is allowed only for that type of waste which can be used for the purpose of reusing, processing and recycling them. The Ministry of Environment, Forestry and Water Administration (MoEFWA) is the responsible institution for the process of cross-border of waste: importation, exportation and their transition. MoEFWA issues exportation license and the permission for transition of the wastes. MoEFWA is responsible for preparation of the necessary documents to be presented to the Council of Ministers which approves the Decision on the import license of the wastes.

Purpose and coverage of licensing

2. The products covered are waste from social and economic activities and physically consumed products that are not included in the definition of non-dangerous waste.

3. The system applies to all wastes coming from all countries, regardless of their origin.

4. The limitations for importation of waste are defined by the environmental legislation establishing the conditions for technology, laboratories and managing capacities; its aim is to protect the environment.

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

(1) Law No. 8934 dated 5 September 2002 "On protection of environment";
(2) Law No. 10463, dated 22 September 2011 "On integrated waste management";
(3) Decision of Council of Ministers No. 806, dated 4 December 2003 "On approval of rules and procedures for importation of utilization waste, processing and recycling";
(4) Rule No. 4 dated 15 October 2003 "On checking and approval of exportation licenses and transition of waste";
(5) Decision of Council of Ministers No. 835, dated 28 December 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, to deposit and to exterminate";
(6) Decision of Council of Ministers, year 1994, "On danger waste and remains".

The system cannot be abolished without legislative approval.

Procedures

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

- Importers are informed in details in MoEFWA;
- Other exporting countries can take the information by the reports which the Ministry presents to the Secretariat of the Basel Convention "On cross border of waste and danger waste and their extermination";
- No exception or derogation from the licensing requirement.

II.-IV. Not applicable.

V. The MoEFWA prepares the necessary documentations for government approval within one month.

VI. Not applicable.

VII. The following institutions must be approached for prior approval:

- The Ministry of Environment, Forestry and Water Administration, which issue the environmental permit;
- The relevant Ministry which issue the license for exercising the activity in the relevant field;
- The Ministry of Health;
- The community of the district where the activity will be placed.

VIII. Not applicable.

- First come first served;
- Past performance is taken into consideration relating to the impact on the environment (existence of any penalty for polluting the environment during previous activities, complains by citizens, etc.);
- No;
- No distinction between new applicants and experienced one.

IX. Not applicable.

X. The export license from the competent authority of country of origin is a prior condition to issuing the import license.

XI. No.

7.(a) No.

(b) No.

(c) No.

(d) See 6.VII.

8. When an application is refused, MoEFWA prepares the Draft Decision of the Council of Ministers that refused the application. The applicant has the right to appeal within 30 days in Court.

Eligibility of importers to apply for licence

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

- Utilization, processing and recycling of the waste are carried out by a contemporary technology that guarantees the protection of public health and protection of the environment;
- Through waste processing are obtained stuffs or useful materials; and to save raw material which are expensive;
- Their transportation does not negatively affect human health and environment.

Rules and procedures to obtain the import license are defined in the Decision of the Council of Ministers No. 806 dated 4 December 2004 "On approval of rules and procedures for importation of waste with the aim to process, to use and to recycle". Only the type of wastes listed in Annex I of the Decision of the Council of Ministers No. 26, dated 31 January 1994 "On dangerous waste and remains" can be imported.

Documentation and other requirements for application for licence

10. The documents are defined in Chapter I, point 4 and chapter II points 2 and 3 of the decision of the Council of Ministers No. 806, dated 4 December 2004 "On approval of rules and procedures for importation of waste with the aim to use, to process and to recycle".

11. They are defined in Chapter II, points 2 and 3, of the Decision of the Council of Ministers No. 806, dated 4 December 2004 "On approval of rules and procedures for importation of waste with the aim to use, to process and to recycle".

12. Yes, 30.000 leks, Albanian currency.

13. No.

Conditions of licensing

14. The maximal validity is 1 year.

15. No.

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

17. Not applicable.

Other procedural requirements

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

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