WORLD TRADE ORGANIZATION

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Committee on Import Licensing Original: English

REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES

NOTIFICATION UNDER ARTICLE 7.3 OF THE AGREEMENT ON IMPORT LICENSING PROCEDURES

MONTENEGRO

The following communication, dated 30 January 2015, is being circulated at the request of the delegation of Montenegro.

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1 MINISTRY OF ECONOMY

Outline of System

1. Import licensing system is regulated by the Foreign Trade Law (RM OG No. 28/04 and 37/07) and the Law on Foreign Trade in Weapons, Military Equipment and Dual-Use Items (OG MNE No. 80/08). Import licenses are required for weapons and military equipment, non-military ordnance and other goods from National Control List for export and import.

Purposes and coverage of licensing

2. Imports of:

- weapons and military equipment – specific tariff lines from Chapters 27, 28, 29, 31, 36, 38, 71, 88, 89, 93;
- non-military ordnance – Chapters 36, 93;
- other goods from National Control List for export and import – Chapter 31 -1 tariff line (ammonite)/ Chapter 39 – 1 tariff line (polyacetals)/ Chapter 71 – 26 tariff lines (precious metals)/ Chapter 84 – 1 tariff line (machines for processing rubber).

are subject to licensing.

3. The import licensing system applies to goods originating in and coming from all countries.

4. Licenses are not intended to restrict the quantity or value of imports. In accordance with the Foreign Trade Law (RM OG No. 28/04 and OG MNE No. 37/07) government may require import licenses only when it is necessary to:

- protect human, animal or plant life or health;
- protect national security;
- protect environment or exhaustible natural resources;
- protect public morals;
- protect intellectual property rights; or
- enforce any special rules related to gold and silver.

5. The following laws and legal acts regulate issuance of licenses by the Ministry of Economy:

- The Foreign Trade Law (RM OG No. 28/04 and 37/07);
- The Law on Foreign Trade in Weapons, Military Equipment and Dual-Use Items (OG MNE No. 80/08);
- The Law on Optical Discs (RM OG No. 2/07 and OG MNE No. 53/11);
- The Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 32/11);
- The Law on Administrative Dispute (OG MNE No. 32/11);
- National Control list for export and import (OG MNE No. 25/13);
- National Control List of Weapons and Military Equipment (OG MNE No. 43/13).

Procedures

6. Not applicable.

7. (a) Licenses are issued in a period not exceeding 30 days, except for weapons and military equipment where licenses are issued in a period not exceeding 90 days, provided all required documents are submitted. Licenses could be obtained in a shorter period.

(b) Yes.

(c) There are no limitations as to the period of the year during which application for licence and/or importation may be made.

(d) Generally, consideration of application for import licence is effected by only one administrative body, Licensing Chamber. In case of the permission consideration of permission applications is carried out by the respective issuing body.

8. None, except in cases prescribed by international regulations including international sanctions, recommendations of OEBS, etc.

The reasons for any refusal are given to the applicant in writing. In the event of refusal to issue a licence, the applicant has a right of appeal to the Administrative Court of Montenegro, as prescribed by the Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 32/11) and the Law on Administrative Dispute (OG MNE No. 32/11).

Eligibility of importers to apply for licence

9. According to the Law on Foreign Trade in Arms, Military Equipment and Dual Use Goods OG MNE No. 80/08) in order to be engaged in importation of arms, military equipment and dual use goods, natural and legal persons have to be registered within the Ministry of Economy. In other cases, all persons having the right to engage in import activities are eligible to apply for licenses which are issued by the Ministry of Economy. There is no published list of importers, with exception of the register of importers of weapon kept within the Ministry of Economy.

Documentation and other requirements for application for licence

10. Please see Exhibit I[1].

11. The importer must only provide a copy of a license or approval upon actual importation along with other required customs documents (declaration, invoice, bill of lading, certificates and, where required, other certificates - origin, conformity, veterinary, health, quality, phytosanitary).

12. Yes, there is a license fee. In accordance with the Law on Administrative Fees (RM OG Nos. 55/03, 81/05, 2/06 and OG MNE 22/08 and 77/08) the Ministry of Economy charges 100€ for issuing licenses for weapons and military equipment; 50€ for non-military ordnance; and 5€ for goods from National Control List for export and import.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

[1] Available for consultation in the Secretariat (Market Access Division)(English only).

Conditions of licensing

14. Licenses are valid for one year from the date of issuance. If the realization of the activities related to foreign trade lasts longer than a year, the Ministry may determine the validity of the license until the deadline for completion of the work specified in the contract, but not longer than three years.

15. No, there is no penalty for non-utilization of a license or a portion of a license.

16. Licences are not transferable between importers.

17. There are no conditions attached to the issuance of a licence.

Other procedural requirements

18. There are no other administrative procedures, apart from import licensing required prior to importation.

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.

2 MINISTRY OF HEALTH - AGENCY FOR MEDICINES AND MEDICAL DEVICES

Outline of System

1. Agency for Medicines and Medical Devices (hereinafter: Agency) issues licenses for the import of: human and veterinary medicines, medical devices, medicines classified as drugs (hereinafter: drugs), precursors and medicines containing precursors. Licenses are issued in accordance with the Law on Medicines (OG MNE No. 56/11 and No. 06/13), the Law on Medical Devices OG MNE No. 79/04, 53/09 and 40/11), the Law on the control of manufacture and marketing of substances that can be used in the manufacture of narcotic drugs and psychotropic substances (OG MNE No. 83/09 and 40/11), the Law on the Prevention of Drug Abuse (OG MNE No. 28/11 and 35/13) and the Decision on the control list for export and import of goods (OG MNE No. 22/14).

Purposes and coverage of licensing

2. Agency issues import licences for the following products:

- human and veterinary medicines - specific tariff lines from chapter 30;
- drugs, precursors and medicines containing precursors;
- medical devices – specific tariff lines from chapters 30, 33, 34, 37, 38, 39, 40, 42, 48, 50, 61, 63, 70, 84, 90, 94, 96.

3. The system is related to the goods originating in and coming from all countries.

4. Licenses are not intended to restrict the quantity or value of the import (except for drugs, the explanation is below), but to check the documentation on the quality, safety and efficacy of products imported. There is an annual quota for drugs in terms of quantity at the national level that cannot be exceeded. This quota, for each calendar year, is determined by the International Narcotics Control Board in Vienna (INCB), and authorisations for the import of drugs are issued according to it.

5. The following laws and legal acts regulate issuance if licenses by the Agency for Medicines and Medical Devices:

- The Foreign Trade Law (RM OG No. 28/04 and OG MNE 37/07);
- The Law on Medicines (OG MNE No. 56/11 and 06/13);
- The Law on Medical Devices (RM OG No. 79/04, and OG MNE No. 53/09 and 40/11);
- The Law on the control of manufacture and marketing of substances that can be used in the manufacture of narcotic drugs and psychotropic substances (OG MNE No. 83/09 and 40/11);
- The Law on the Prevention of Drug Abuse (OG MNE No. 28/11 and 35/13);
- The Decision on the control list for export and import of goods (OG MNE No. 22/14);

- The Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 32/11);
- The Law on Administrative Dispute (OG MNE No. 32/11).

Issuance of import licences is obligatory and there is no possibility not to issue the licence based on administrative discretion.

The Article 5 of Law on Medicines (OG MNE No. 56/11 and 06/13) envisages that Government of Montenegro may determine alternative procedure and conditions for the issuance of marketing authorisation for a medicine.

Procedures

6.

I. Information on permitted annual quotas for import of drugs are published on the website of the International Narcotics Control Board (http://www.incb.com/). Quotas are formed on the basis of needs that importers submit to the Agency for each drug individually on annual level. After processing these data, the Agency sends data to the Ministry of Health, which sends these data for the approval to the International Narcotics Control Board Authority in Vienna (INCB). In the event that there is increased needs in relation to the required annual quota, Agency through the Ministry of Health may, with an explanation, ask for an increase in quotas for certain drugs.

   All the information needed to obtain import authorisation for drugs (regulations, instructions and forms) the importer can find on the website of the Agency http://calims.me/

II. Amount of quotas is determined annually by the International Narcotics Control Board. Application for import may be submitted by necessity, with the condition not to exceed the quota, and the validity period is 6 months and it applies to a single import.

III. The Agency sends one copy of the import license for drugs to the Customs Administration, and after customs clearance of the goods, Customs returns this copy of the license to the Agency, which contain details of the realisation of imported products. The amount that has not been imported is not counted into the allowed quota. The importer receives two copies of import license, one of which must be sent to the competent authority of the exporting country.

IV. Applications may be submitted immediately after publishing quotas.

V. The period needed for processing applications and issuing license for the import of drugs is up to 30 days. Processing is usually done within 7 days.

VI. Import can be done immediately after obtaining import licence (date of issuance of the licence is stated on the licence).

VII. Processing of applications for import of drugs is performed only by one administrative body - Agency for Medicines and Medical Devices.

VIII. If the demand for licences cannot be completely fulfilled i.e. if a small amount is missing for fulfilling an annual quota, the applicant which did not import his stated year demand takes precedence over others for obtaining import licence for a certain drug (see answer to question I). Applications for import are processed according to the date of receipt, chronologically. The new importer who obtained wholesale licence for marketing of drugs, must submit annual demand for drugs before submitting an application for import.

IX. Import licences are always needed, regardless of the fact that exporting countries issues export licences. Import licences are not issued automatically.

X. Not applicable.

XI. There have been no such cases so far. Legal provisions provide that the procedure for approving the import of drugs is identical regardless of whether the product will be marketed in Montenegro or exported to other countries (what requires a special export licence).

7. (a) Products that are not subjected to the limitation in quantitative terms are medicines (for human and veterinary use), precursors and medical devices.
The application for import for these products may be submitted at any time. The time-limit for issuing licence is 30 days. This term is most often 7 days, or if the goods have already arrived at the customs and at the request of the importer, it may be even shorter, i.e. be done by priority (providing all necessary documentation is still obligatory).

(b) Yes.

(c) There are no limitations as to the period of the year during which application for licence and/or importation may be made.

(d) Processing of applications for import is performed only by one administrative body - Agency for Medicines and Medical Devices.

8. None. Reasons for rejection of any kind are given to the applicant in the form of an appropriate legal act. In case of rejection, the applicants have the right to appeal to the competent ministry, in accordance with:

- Law on Medicines (OG MNE No. 56/11 and 06/13);
- Law on Medical Devices (RM OG No. 79/04 and OG MNE No. 53/09 and 40/11);
- Law on the control of manufacture and marketing of substances that can be used in the manufacture of narcotic drugs and psychotropic substances (OG MNE No. 83/09 and 40/11);
- Law on the Prevention of Drug Abuse (OG MNE No. 28/11 and 35/13);
- Law on General Administrative Procedure (RM OG No. 60/03 and OG MNE No. 32/11).

Eligibility of importers to apply for licence

9. There is a system of registration of legal persons that may perform import and marketing. Import or marketing of medicines may be performed by legal persons seated in Montenegro, which possess wholesale license (wholesalers), issued by the Agency or authority in charge of veterinary affairs for veterinary medicines. Legal persons that import and market drugs and precursors additionally require a separate authorisation for wholesale of drugs or precursors.

Wholesale of medical devices may be performed by legal persons seated in Montenegro, which are entered in the register kept by the Agency.

Fees for issuance of licences for the import and wholesale of all these products are defined by:

- Decision on the manner of payment and amount of fees for issuance of authorisations, certificates and approvals for manufacture and marketing of medicines ("Official Gazette of Montenegro", No. 22/13 from 17 May 2013) and
- Decision on the mode of payment and amount of fees for entering and removing medical devices, manufacturers and legal persons that market and import medical devices into and from the Register, as well as keeping the Register. (Official Gazette of Montenegro No. 78/2009).

A list of all legal persons that are authorised to perform import and marketing on the basis of authorisations issued by the Agency, is published on the website of the Agency http://calims.me/ and is regularly updated.

Documentation and other requirements for application for licence

10. Please see Exhibit II[1].

11. Upon actual importation, additional documentation is required only for the products belonging to the group of controlled substances i.e. drugs and precursors. Documents required are related to the quantity of the imported products and the date of the import.

For other group of products (medicines and medical devices) no additional documentation upon import is not required.

Also, upon actual importation other customs documents (declaration, invoice, bill of lading, certificates and, where required, other certificates - origin, conformity, veterinary, health, quality, phytosanitary) are required as well.

12. The fees for issuing import licences are defined by Decisions adopted by the Government:

- Decision on the manner of payment and amount of fees for issuance of authorisations, certificates and approvals for manufacture and marketing of medicines ("Official Gazette of Montenegro", No. 22/13 from 17 May 2013) and
- Decision on the mode of payment and amount of fees for entering and removing medical devices, manufacturers and legal persons that market and import medical devices into and from the Register, as well as keeping the Register. (Official Gazette of Montenegro No. 78/2009).

In reference to the abovementioned decisions fees for import licences for medicines and medical devices are determined based on the total value of the requested import:

Import value	Fees (EUR)
up to 5 000 EUR	60
from 5 000 up to 50 000 EUR	125
from 50 000 up to 250 000 EUR	250
from 250 000 up to 500 000 EUR	500
from 500 000 up to 1.000 000 EUR	1.000

In reference to the abovementioned decisions, fees for import licences for import/export/transit for drugs and psychotropic substances in line with the international conventions is 1% of the total import/export/transit value.

In reference to the abovementioned decisions, fees for import/export/transit of precursors is 50 euros.

13. No.

Conditions of licensing

14. Period of validity of an import licence for medicines and medical devices is 3 months from the date of issuance and not later than the end of a calendar year and is valid for a multiple import. Period of validity of an import licence for drugs is 6 months and is valid for a single import. Period of validity of an import licence for precursors is 30 days and is valid for a single import.

Licences could not be extended but request for a new licence can be submitted.

15. There is no penalty for the non-utilization of a licence or a portion of a licence.

16. Licences are not transferable between importers.

17.(a) No other conditions attached.

(b) There are no other conditions attached to the issuance of a licence.

Other procedural requirements

18. There are no other administrative procedures, apart from import licensing required prior to importation.

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.

3 MINISTRY OF SUSTAINABLE DEVELOPMENT AND TOURISM - ENVIRONMENTAL PROTECTION AGENCY

Outline of System

1. Import of CITES listed species and their products and derivates is partially regulated by the Law on nature protection (OG MNE No. 51/08 from the 22nd of August 2008, No. 21/09 from the 20th of March 2009, No. 40/11 from 08th of August 2011 and 62/13 from 31st December 2013). By means of succession, on 3rd June 2007, Montenegro ratified the CITES Convention. Montenegro operates under Articles 1 to 25 of the CITES Convention and it is in compliance with the CITES provisions.

Transboundary movement of waste is, in accordance with the Law on waste management (OG MNE No. 64/2011) and Basel Convention on the Control of Transboundary movements of hazardous waste and their disposal, defined as import of waste on the territory of Montenegro, transit of foreign origin waste through the territory of Montenegro and export of waste from the territory of Montenegro. The import of hazardous waste is forbidden. The import of non-hazardous waste to remove and use as fuel or other means to generate energy is forbidden as well.

On 23rd October 2006 Montenegro ratified by means of succession the Vienna Convention, the Montreal Protocol and the Amendments to the Montreal Protocol. Montenegro operated under the article 5 of Montreal protocol and it is in compliance with the provisions of Protocol.

Purposes and coverage of licensing

2. Import licenses are required for:

- Transboundary movement of waste;
- Endangered and protected species of wild flora and fauna theirs products and derivates;
- Plant, animal and fungus species (examples of wild plants, fungi and animals from free and their cultivated specimens; their development forms - eggs, seeds, fruits, mycelium, etc; their parts and derivatives; therefrom easily recognizable products)
- Ozone depleting substances and alternative substances, apparatus and their spare part based on the use of X-ray or of alpha, beta or gamma radiation and
- Chemicals.

3. The system applies to goods from originating in and coming from all countries, except for restrictions applying to trade with countries that are not parties to the CITES Convention and Montreal protocol on ozone depleted substances.

4. In case of CITES, ozone depleted substances and waste management the licensing intend to control the quantity of import. The purpose of licenses issued by the Environmental Protection Agency is related to environment protection.

No alternative methods.

5. Issuing of licenses by the Environmental Protection Agency is carried out in accordance with the following national and international legislations:

- The Law on waste management (OG MNE No. 61/11);
- The Law on Confirmation of the Basel Convention on the Control of Transboundary Movements of Dangerous Waste and Their Disposal (FRY OG, International agreements, No. 2/99);
- Rulebook on the content of documentation submitted in support of the application for the permit for import, export and transit of, as well as lists of waste classification (OG MNE No. 71/10);
- The Law on Confirmation of the CITES Convention on International Trade of Endangered Species of Wild Fauna and Flora (FRY OG, International agreements, No. 11/01);
- Nature Protection Act (OG MNE No. 51/08, 21/09, 40/11, 62/13, 06/14);
- Law on air protection (OG MNE, No. 25/10, 40/11);
- Decree on ozone depleted substances and alternative substances (OG MNE, No. 5/11);
- Law on chemicals (OG MNE, No. 18/12);

- Law on transport of dangerous substances (OG MNE, No. 33/2014);
- Rulebook of procedure prior notification and consent procedure on the basis of prior notification of export of chemicals);
- The Law on Ionizing Radiation Protection and Radiation Safety (RM OG No. 56/09);
- Rulebook on the requirements for trading and use radioactive materials, x-ray devices and other devices that generate ionizing radiation (FRY OG No. 32/98);
- The Foreign Trade Law (RM OD No. 28/04-37/07);
- Decision on Control List for Export and Import of Goods (Official Gazette of Montenegro, No. 22/2014);
- The Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 32/11).

Licensing is statutorily required.

It is not possible to abolish the system without legislative approval.

Procedures

6.

I. Ozone depleted substances and alternative substances are under restriction as to the quantity of imports. Decree on ozone depleted substances and alternative substances (OG MNE, No. 5/11) prescribes procedure for quota system for import of ODS.

   Information regarding quotas for CITES species can be found at CITES website (http://www.cites.org/) but Quotas for CITES are currently not established by the Management authority of Montenegro.

   Formalities of filing applications for licences can be found at Environmental Protection Agency website (http://www.epa.org.me/).

II. A quota is determined on a yearly basis and licences are issued for each import separately. Procedures for the size of the quotas are prescribed by the Decree on ozone depleted substances and alternative substances (OG MNE, No. 5/11). In reference to the mentioned Decree quota for ODS is allocated on the basis of past performance.

III. Legal person or entrepreneur performing the imports of these substances has to submit to the Agency proof of imported amounts of substances (Unified Customs Document) for each issued License not later than three days after the performed imports.

   In reference to CITES species, copy of used CITES licenses contain a stamp and signature of Customs Administration.

   Unused allocations are not added to quotas for the next year.

   The names of importers to whom licences have been allocated were not made known to governments and export promotion bodies of exporting countries upon request, as there were no such requests.

IV. Written application of importer for setting annual quota for ODS has to be submitted to the Agency by not later than 1 December of the current year for the following year. Quotas are allocated on the base of past performance. Importers have the right to submit applications for licences from the 1st January of the following year.

V. The deadline of issuance the decision on the application is 30 days and it is determined by the Law on General Administrative Procedure ("OG of the RMN", No. 60/03 and OG MNE No. 32/11).

VI. Import can be done immediately after obtaining import licence (date of issuance of the licence is stated on the licence).

VII. Environmental protection Agency as a Single administrative body is competent for consideration of licence applications, and it is the only organ importer has to approach.

VIII. Quotas usually satisfy demand, as they are referred to substances whose consumption is phasing out. In the case of new importers of ODS, they will be given 10% from total annual quota, on the basis of recommendation and experience from region countries. All applications are examined simultaneously.

IX. Not applicable.

X. When it comes to CITES species or substances controlled under the Montreal protocol (ODS) information is exchanged through the communication between countries CITES Management authorities or Montreal protocol management authorities.

XI. No.

7. (a) There is no fixed time-limit for submitting an application before importation. In accordance with the Foreign Trade Law, licenses are issued in a period not exceeding 15 days (Article 23) with provided that all required documents are submitted. License could be obtained in a shorter period than 15 days.

(b) Yes.

(c) No.

(d) Environmental protection Agency as a Single administrative body is competent for consideration of licence applications.

For chemicals licenes, request for the licence, has to be submitted to the Environmental Protection Agency, and in accordance with the provisions of the Law on transport of dangerous substances ("Off. Gazette of Montenegro", No. 33/2014) Agency submits application to the Ministry of interior affairs (Directorate of Emergency Situations) to obtain approval for the transport of dangerous substances.

Environmental Protection Agency informs the country to which Montenegro exports chemicals. Exports of chemicals based on the export permits are performed for the chemicals from the List of chemicals which are subject to the procedure of prior notification.

8. None. Reasons for rejection of any form are given to the applicant in a separate conclusion. When applicants do not meet the requirements of Article 42 of the Law on Ioning Radiation Protection and Radiation Safety and Article 3 of the Rulebook on the requirements for trading and use radioactive materials, x-ray devices and other devices that generate ionising radiation (FRY OG No. 32/98) applicants will not receive permission to import.

Decision may be appealed to the Ministry of Sustainable Development and Tourism through the Environmental protection Agency in accordance with the Law on Administrative Procedure (RM OG No. 60/03 and OG MNE No. 32/11).

Eligibility of importers to apply for licence

9. A legal person or entrepreneurs registered in the Central Registry of the Commercial Court are eligible to apply for licences.

Documentation and other requirements for application for licence

10. Please see Exhibit III[1].

11. Importer must present valid license issued by EPA along with standard customs documentation.

12. Administrative fee in the amount of 5€ is charged for each application. Administrative fee is 50 € for each imported consignment of CITES species/products/derivates (CITES import permit). Administrative fee is 50 € for each imported consignment of ozone depleted substances. Administrative fee is 50 € for each imported consignment chemicals. Administrative fee for import of radioactive materials is €200, and for import of devices that produce ionizing radiation is €100.

13. No.

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year (Law on Foreign Trade “OG RMNE, No. 28/04, 37/07”). Licenses for substances that deplete the ozone layer and alternative substances are issued for each delivery, separately and are valid for the period specified in the license, but not longer than one year.

15. No.

16. No.

17. It is prohibited to import and/or export cites listed species/products/derivates and ozone depleted substances from the countries or to the countries which are not parties to the CITES convention and Montreal protocol.

Other procedural requirements

18. No.

19. Foreign exchange is automatically provided by the banking authorities for goods to be imported.

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