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 (2019)

MONTENEGRO

The following communication, dated 7 July 2020, is being circulated at the request of the delegation of Montenegro.

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1 MINISTRY OF ECONOMY

1.1 Arms and military equipment

Outline of system

1. Import licensing system is regulated by the Law on Foreign Trade in arms and military equipment (OG MNE No. 40/16). Import licenses are required for weapons and military equipment listed in the 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

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 the Government may require import licenses only when it is necessary to:

- Protect national security.

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

- The Law on Foreign Trade in Arms and Military Equipment (OG MNE No.40/16);
- The National Control List of Weapons and Military Equipment (OG MNE No.69/18);
- The Law on Administrative Procedure (RM OG No.60/03 and OG MNE No.56/14; 20/15; 40/16 and 37/17).

Procedures

6. Not applicable.

7.a) Licenses are issued in a period not exceeding 15 days, except for weapons and military equipment where licenses are issued in a period not exceeding 30 days, provided that 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) An importer has to approach only one administrative organ as regards the application. Ministry of Economy has to obtain positive opinion from the Ministry of Foreign Affairs, the Ministry of Defence and the Ministry of Internal Affairs in accordance with the Law on Foreign Trade in Arms and Military Equipment (OG MNE No.40/16).

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.56/14; 20/15; 40/16 and 37/17) and the Law on Administrative Dispute (OG MNE No.54/16).

Eligibility of importers to apply for licence

9. According to the Law on Foreign Trade in Arms and Military Equipment in order to be engaged in importation of arms and military equipment, natural and legal persons have to be registered within 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 No.18/19) the Ministry of Economy charges 100 € for issuing licenses for weapons and military equipment from the National Control List for export and import.

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

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. 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.

1.2 Other goods

Outline of system

1. Import licensing system is regulated by the Foreign Trade Law (RM OG No.28/04; 37/07 and OG MNE No.73/10; 01/14; 14/14 and 57/14). Import licenses are required for other goods listed in the National Control List for export and import.

Purposes and coverage of licensing

2. Imports of:

- Other goods from National Control List for export and import Chapter 29 – 19 tariff lines (polyacetals)/ Chapter 30 – 60 tariff lines Chapter 31 - 1 tariff line, Chapter 33 -1 tariff line, Chapter 34 -1 tariff line, Chapter 36 - 20 tariff lines, Chapter 37 -1 tariff line, Chapter 38 - 2 tariff lines, Chapter 39 - 3 tariff lines, Chapter 40 - 2 tariff lines, Chapter 48 -1 tariff line, Chapter 50 -1 tariff line, Chapter 61 -1 tariff line Chapter 63 - 4 tariff line, Chapter 65 – 2 tariff lines, Chapter 70 -1 tariff line Chapter 71 - 5 tariff lines, Chapter 83 - 1 tariff line, Chapter 84 - 9 tariff lines, Chapter 85 - 5 tariff lines, Chapter 88 - 6 tariff lines, Chapter 90 - 53 tariff lines, Chapter 93 - 24 tariff lines, Chapter 95 - 2 tariff lines, Chapter 96 – 1 tariff line

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

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 the Government may require import licenses only when it is necessary to:

- Protect human, animal or plant life or health;
- 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; 37/07 and OG MNE No.73/10; 01/14; 14/14 and 57/14);
- The Law on Optical Discs (RM OG No. 2/07 and OG MNE No.53/11);
- The National Control list for export and import (OG MNE No.40/20);
- Decision to amend National Control list for export and import (OG MNE No.40/20);
- The Law on Administrative Procedure (RM OG No.60/03 and OG MNE No.56/14; 20/15; 40/16 and 37/17).

Procedures

6. Not applicable.

7.a) Licenses are issued in a period not exceeding 15 days, provided that 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) An importer has to approach only one administrative organ as regards the application. Ministry of Economy has to obtain positive opinion from the Ministry of Internal Affairs (explosives, civil aircrafts, arms for sport and hunting ext.) Civil aircraft agency (civil aircrafts, drones) in accordance with the Foreign Trade Law (RM OG No.28/04; 37/07 and OG MNE No.73/10; 01/14; 14/14 and 57/14).

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.56/14; 20/15; 40/16 and 37/17) and the Law on Administrative Dispute (OG MNE No.54/16).

Eligibility of importers to apply for licence

9. 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.

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 No.18/19) the Ministry of Economy charges 10 € for goods from the National Control List for export and import.

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

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. 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.

1.3 Goods which may be used for the execution of a death penalty and whose application may be subject to torture

Outline of system

1. Import licensing system is regulated by the Law on foreign trade of goods and services which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment (OG MNE No.2/18).

Purposes and coverage of licensing

2. Imports of:

- goods which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment – specific tariff lines from Chapters 29, 30, 33, 38, 39, 42, 62, 62, 84, 93

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 the Government may require import licenses only when it is necessary to:

- Protect national security.

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

- Law on foreign trade of goods and services which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment (OG MNE No.2/18);
- The Law on Administrative Procedure (RM OG No.60/03 and OG MNE No.56/14; 20/15; 40/16 and 37/17).

Procedures

6. Not applicable.

7.a) Licenses are issued in a period not exceeding 30 days, except in case the additional checks are to be performed in a period not exceeding 45 days, provided that 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) An importer has to approach only one administrative organ as regards the application. Ministry of Economy has to obtain positive opinion from the Ministry of Foreign Affairs, the Ministry of Internal Affairs Ministry of Culture in cases where these goods will be used for exposure to museums in accordance with the Law on foreign trade of goods and services which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment (OG MNE No.2/18).

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.56/14; 20/15; 40/16 and 37/17) and the Law on Administrative Dispute (OG MNE No.54/16).

Eligibility of importers to apply for licence

9. According to the Law on foreign trade of goods and services which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment (OG MNE No.2/18), natural and legal persons. There is no published list of importers.

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 No.18/19) the Ministry of Economy charges 100 € for issuing licenses goods which may be used for the execution of a death penalty, torture or other cruel, inhuman or humiliating treatment or punishment.

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

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 one year.

15. 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 AGENCY FOR MEDICINES AND MEDICAL DEVICES

2.1 Drugs

Outline of system

1. Agency for Medicines and Medical Devices (hereinafter: Agency) issues authorisations for the import of: medicines classified as drugs (hereinafter: drugs). Authorisations are issued in accordance with the following legislation:

- Law on control of manufacture and trade of substances that can be used in the manufacture of narcotic drugs and psychotropic substances ("Official Gazette of Montenegro", No.83/09 and No.40/11);
- Law about preventing of drug abuse ("Official Gazette of Montenegro", No.28/11 and No.35/13);
- Decision to amend National Control list for export and import (OG MNE No.40/20);
- Law on administrative procedure ("Official Gazette of Montenegro", No.056/14; 020/15; 040/16 and 037/17).

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

Purposes and coverage of licensing

2. Agency issues import licences for the following products:

- Drugs, precursors and medicines containing precursors.

3. The system is related to the goods originating/coming from any country.

4. 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. Issuance of import licences is conducted in accordance with:

- Law on control of manufacture and trade of substances that can be used in the manufacture of narcotic drugs and psychotropic substances ("Official Gazette of Montenegro", No.83/09 and No.40/11);
- Law about preventing of drug abuse ("Official Gazette of Montenegro", No.28/11 and No.35/13);
- Law on administrative procedure ("Official Gazette of Montenegro", No.056/14; 020/15; 040/16 and 037/17).

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

Procedures

6.I. Information on permitted annual quotas for import of drugs are published on the website of the International Narcotics Control Board (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 are 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 licence for drugs to the Customs Administration, and after customs clearance of the goods, Customs returns this copy of the licence 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 authorisations, 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 licences for the import of drugs is up to 30 days but usually 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 (which requires a special export licence).

7.a)-d) Not applicable.

8. An application for licence may be rejected due to inadequate documentation on the product or the applicant and in other cases in accordance with relevant laws. 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 ministry in charge, in accordance with:

- The Law on control of manufacture and trade of substances that can be used in the manufacture of narcotic drugs and psychotropic substances ("Official Gazette of Montenegro", No.83/09 and No.40/11);
- The Law about preventing of drug abuse ("Official Gazette of Montenegro", No.28/11 and No.35/13);
- The Law on administrative procedure ("Official Gazette of Montenegro", No.056/14; 020/15; 040/16 and 037/17).

Eligibility of importers to apply for licence

9. There is a system of registration of legal persons that may perform import and marketing. Legal persons that import and market drugs and precursors additionally require a separate authorisation for wholesale of drugs or precursors.

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].

The portal Agency http://calims.me/ contains all the data that must be listed on the application for import all product groups.

- Documentation required for obtaining authorisation for import, export and transit of narcotic drugs:

A. **The applicant for issuance of the import authorisation for narcotic drugs** shall submit the documentation consisted of the following

1) Cover letter;
2) Completed application form;
3) User's statement on purpose;
4) Pro forma invoice.

A1. **Unauthorised medicines**

In addition to the documentation referred to in point A (paragraphs 1, 2, 3 and 4), the following documentation shall also be submitted:

1) Certificate of analysis of the batch of the medicine;
2) Certificate of compliance of the batch of the medicine with the EU GMP Annex 16;
3) Certificate from the competent regulatory authority of one of the EU Member States that the medicine has been manufactured in accordance with the Good Manufacturing Practice Guidelines - EU GMP Certificate. (only for medicines that have not previously been granted import authorisation);
4) Confirmation by the competent regulatory authority that the medicine is authorised for marketing in the country of the manufacturer, or the European Union, or in countries that have the same marketing authorization requirements (marketing authorization, or CPP certificate in English, or translated into Montenegrin) (only for medicines that have not previously been granted import authorisation);
5) Approved Summary of Product Characteristics and the Patient Information Leaflet from one of the countries listed in paragraph 3 (in English, or translated into Montenegrin). Also, it is necessary to provide a mock-up of the packaging approved along with the SmPC and PIL, or developed according to the approved packaging labelling (only for medicines that have not previously been granted import authorisation).

A2. Authorised medicines

In addition to the documentation referred to in point A (paragraphs 1, 2, 3 and 4), the following documentation shall also be submitted:

1) Certificate of compliance of the batch of the medicine with the EU GMP Annex 16.

B. The applicant for issuance of the export and transit authorisation for narcotic drugs shall submit the documentation consisted of the following:

DOCUMENTATION REQUIRED FOR OBTAINING AUTHORISATION FOR IMPORT, EXPORT AND TRANSIT OF NARCOTIC DRUGS AND INSTRUCTION FOR COMPLETING THE APPLICATION FORM (Exhibit II[1])

1) Cover letter;
2) Completed application form;
3) User's statement on purpose;
4) Pro forma invoice;
5) Import authorisation issued by the competent institution of the importing country (in the case of export/transit from/through Montenegro) and export authorisation issued by the competent institution of the exporting country (in case of transit through Montenegro).

B1. Unauthorised medicines

In addition to the documentation referred to in point B (paragraphs 1, 2, 3, 4 and 5), the following documentation shall also be submitted:

1) Certificate of analysis of the batch of the medicine;
2) Certificate of compliance of the batch of the medicine with the EU GMP Annex16.

B2. Authorised medicines

In addition to the documentation referred to in point B (paragraphs 1, 2, 3, 4 and 5), the following documentation shall also be submitted:

1) Certificate of compliance of the batch of the medicine with the EU GMP Annex16

- Documentation required for obtaining authorisation for import, export and transit of precursors and medicines containing precursors:

    1) Cover letter;
    2) Application for authorisation with information on imported/exported drugs;
    3) Statement on purpose signed by the user;
    4) Invoice or pro-forma invoice from a supplier;
    5) Import authorisation issued by the competent authority in the importing country (in case of export from Montenegro) and export authorisation of the issued by the competent authority of the exporting country (in case of transit through Montenegro) – at the request of the Agency only;
    6) Certificate of analysis of a batch of a medicine;
    7) End user's statement on purpose of precursors;
    8) Proof of payment of prescribed fees.

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.

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 line with these 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.

13. No.

Conditions of licensing

14. The period of validity of an import licence for drugs is 6 months and is valid for a single import. Licences cannot be extended, but a request for a new licence can be submitted.

15. No, there is not a 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) No other conditions attached.

Other procedural requirements

18. No.

19. N/A.

2.2 Human and veterinary medicines, precursors and medicines containing precursors and medical devices

Outline of system

1. Agency for Medicines and Medical Devices (hereinafter: Agency) issues authorisations for the import of: human and veterinary medicines, medical devices, and precursors and medicines containing precursors. Authorisations are issued in accordance with the following legislation:

- Law on Medicines ("Official Gazette of Montenegro", No.56/11 and No,06/13);
- Law on Medical Devices ("Official Gazette of Montenegro", No.024/19);
- Decision to amend National Control list for export and import (OG MNE No.40/20); Law on administrative procedure ("Official Gazette of Montenegro", No.056/14; 020/15; 040/16 and 037/17).

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 ("Official Gazette of Montenegro", No.56/11 and No.06/13) envisages that Government of Montenegro may determine alternative procedure and conditions for the issuance of marketing authorisation for a medicine.

Purposes and coverage of licensing

2. Agency issues import licences for the following products:

- Human and veterinary medicines;
- Precursors and medicines containing precursors; and

- Medical devices.

3. The system is related to the goods originating/coming from any country.

4. The purpose of issuing authorisations for the import of medicines, medical devices and precursors is not to limit the quantity or value of the import, but to check the documentation on the quality, safety and efficacy of products imported. Alternative methods for meeting the goals are not considered, because issuance of import licences is in accordance with the national legislation which is to a great extent harmonized with the EU legislation in the area.

5. Issuance of import licences is conducted in accordance with:

- Law on Medicines ("Official Gazette of Montenegro", No.56/11 and No.06/13);
- Law on Medical Devices ("Official Gazette of Montenegro", No.024/19);
- Law on administrative procedure ("Official Gazette of Montenegro", No.056/14; 020/15; 040/16 and 037/17).

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

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

Procedures

6. Not applicable.

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 according to the opinion of the importer. 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) In case of emergency, if the documentation is correct, the licence may be issued in less than 30 days or shorter than the average period (see answer to question a).

c) There are no limitations regarding the period of the year during which the application may be submitted and / or import be done.

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

8. An application for licence may be rejected due to inadequate documentation on the product or the applicant and in other cases in accordance with relevant laws. 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 ministry in charge, in accordance with:

- The Law on Medicines ("Official Gazette of Montenegro", No.56/11 and No.06/13);
- The Law on Medical Devices ("Official Gazette of Montenegro", No.024/19);
- The Law on administrative procedure ("Official Gazette of Montenegro", No.056/14; 020/15; 040/16 and 037/17).

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 authorisation (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 registered in accordance with decision on wholesale registration 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].

The portal Agency http://calims.me/ contains all the data that must be listed on the application for import all product groups.

- Documentation required for obtaining authorisation for import, export and transit of precursors and medicines containing precursors:
    1) Cover letter;
    2) Application for authorisation with information on imported/exported drugs;
    3) Statement on purpose signed by the user;
    4) Invoice or pro-forma invoice from a supplier;
    5) Import authorisation issued by the competent authority in the importing country (in case of export from Montenegro) and export authorisation of the issued by the competent authority of the exporting country (in case of transit through Montenegro) – at the request of the Agency only;
    6) Certificate of analysis of a batch of a medicine;
    7) End user's statement on purpose of precursors;
    8) Proof of payment of prescribed fees.

- Documentation required for obtaining authorisation for import of medicines for human and veterinary use:

    1) Cover letter;
    2) Table containing list of medicines to be imported/exported;
    3) Invoice or pro-forma invoice from a supplier;
    4) Evidence that a medicine has been granted marketing authorization in the country of a manufacturer, in countries of European Union or in countries that have same standards for issuing marketing authorization (marketing authorisation, or CPP certificate in English language, or translated into Montenegrin) – for the first import or at the request of the Agency;
    5) Evidence from the competent authority from European Union Member States that a medicine has been manufactured in accordance with Guidelines on Good Manufacturing

Practice – GMP certificate issued by one of the EU Member States – for the first import or at the request of the Agency;
6) Summary of Product Characteristics (SmPC) and Package Leaflet (PL) approved in one of the countries referred to in point 4 (in English, or translated into Montenegrin). It is also necessary to submit Mock-up, approved along with the SmPC and PL or developed in line with the approved labelling for immediate and outer packaging – for the first import or at the request of the Agency;
7) Certificate of analysis for each batch(es) of medicines to be imported;
8) Agreement/statement of the manufacturer/MAH from EU on the appointment of authorised distributors for Montenegro – for the first import or at the request of the Agency;
9) In case of import/export of blood products and immunological products a certificate of analysis for every batch is required, from a manufacturer and from one of the laboratories that are OMCL members, or from the National laboratory of the Agency for Medicines and Medical Devices of Serbia (ALIMS);
10) Manufacturing and control summary protocol (for vaccines only), for batch(es) for which certificates are submitted;
11) Justified request of the health institution, i.e. opinion of medical specialist on the need for import of the particular medicine – for the first import or at the request of the Agency;
12) Proof of payment of prescribed fees.

- Documentation required for obtaining authorisation for import of medical devices:

1) Cover letter;
2) Application for authorisation with information on imported medical devices;
3) Letterheaded statement of the applicant for import of medical devices justifying the reason for not submitting application for entry into the register of medical devices kept by the Agency; in case that the application has been submitted, please state the date of submission of the documentation for entry into the register and number under which it is filed in the Agency;
4) Letterheaded statement of the healthcare institution (healthcare professional) justifying the import of specific medical devices. If a similar medical device is entered in the Agency's register, the reason why the medical device that has already been entered into the register cannot be used shall be given;
5) Supporting certificates for each product from the list:
   - Manufacturer's Declaration of Conformity (DoC);
   - EC certificates, except for medical devices of Class I and In Vitro – Others;
6) Invoice or pro-forma invoice from a supplier;
7) Proof of payment of prescribed fees.

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.

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 line with those decision 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 line with the Decisions, fees for import/export/transit of precursors is 50 euros.

13. No.

Conditions of licensing

14. The period of validity of an import licence for medicines and medical devices is 3 months from the date of issuance and is valid for a multiple import. The period of validity of an import licence for precursors is 30 days and is valid for a single import.

Licences cannot be extended, but a request for a new licence can be submitted.

15. No, there is not a 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) No other conditions attached.

Other procedural requirements

18. No.

19. N/A.

3 NATURE AND ENVIRONMENTAL PROTECTION AGENCY

3.1 Waste

Outline of System

1. Licenses for the transboundary movement of waste (import, export and transit) are issued in accordance with the Law on waste management (OG MNE, No.64/11; 39/16) and Basel Convention on the Control of Transboundary movements of hazardous waste and their disposal (OG FRY-International agreements, No.2/99). 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.

Purposes and coverage of licensing

2. Import licenses are required for:

- Transboundary movement of waste (import, export and transit of waste);

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

4. The issue of licenses is not intended to limit the quantities or value of imports, but exclusively with the purpose of adequate monitoring of the imported goods. For waste management the licensing intends to control the quantity of imports because it is related to the protection of the environment and fulfilling the obligation in accordance with the international agreement: Basel Convention.
No alternative methods were considered.

5. The licensing is maintained in accordance with:

- The Law on waste management ("OG MNE", No.64/11; 39/16);
- The Law on Confirmation of the Basel Convention on the Control of Transboundary Movements of Dangerous Waste and Their Disposal ("OG FRY"-International agreements, No.2/99);
- The Rulebook on the content of documentation submitted in support of the application for the permit for import, export and transit of waste, as well as lists of waste classification and the content and manner of keeping a register of issued licenses ("OG MNE", No.83/16; 76/16).

The legislation does not leave designation of products to be subjected to licensing to administrative discretion.

It is possible for the government (or the executive branch) to abolish the system without legislative approval.

Procedures

6. Not applicable.

7.a) There is no fixed time-limit for submitting an application before importation. In accordance with the Law on Administrative Procedure length of time for processing application is 30 day from the day of receipt of the official request. License could be obtained in a shorter period than 30 days if all required documents are submitted.

b) There is no such possibility.

c) There are no such limitations.

d) NEPA is a Single administrative body in charge of consideration of licence applications.

8. In addition to non-fulfilling of the criteria prescribed by relevant legislation, application could be rejected in the case when applicant submits application for the goods that are not allowed for import. Reasons for rejection of any form are given by NEPA to the applicant in a separate administrative act. Decision may be appealed to the Ministry of Sustainable Development and Tourism in accordance with the Law on Administrative Procedure.

Eligibility of importers to apply for licence

9. All legal persons or entrepreneurs registered in the Central Registry of the Commercial Court are eligible to apply for licences. Regarding permits for chemical, besides above, a legal person must meet the requirements in terms of personnel, facilities and equipment.

All persons and companies that fulfil the conditions envisaged by the Law are eligible to apply for licenses.

- There is no registration fee.
- There is no published list of authorized operators.

Documentation and other requirements for application for licence

10. Please see Exhibit III[1].

The application for permit for import of non-hazardous waste, only for the purpose of its processing, must contain the following:

- Documentation of signs and types of waste from the list of non-hazardous waste;
- An agreement between importers and exporters of waste with validity period until the completion of delivery of waste and with financial guarantees or insurance policy or other form of insurance in the case of return in the country of export;
- An agreement between importers and processors of waste, in case that the importer is not the waste processor;
- Proof that the importer of waste is registered for import activities;

- Information on methods for transport and shipment of waste (at once or in several shipments);
- Information on the border crossing point on which imports will be made, the time of arrival of waste on border crossing point, route of waste movement from the border customs office to processors; and,
- Proof of the administrative fee payment.

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

12. There are administrative fees as follows:

- Administrative fee in the amount of 2 EUR for non-hazardous waste;

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

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year.

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

16. The licenses are not transferable between importers.

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

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.

3.2 Ozone depleted substances and alternative substances

Outline of System

1. Permits for import/export of ozone depleted substances and alternative substances are issued in accordance with the Law on the Protection against Adverse Impacts of Climate Change (Official Gazette of MNE, No.073/19, dated 27.12.2019) and the Decree on ozone depleted substances and alternative substances (OG MNE, No.5/11). Also, on 23 October 2006 Montenegro ratified by means of succession the Vienna Convention on ozone layer protection, the Montreal Protocol on ozone depleted substances and the Amendments to the Montreal Protocol. One of the obligations under the Montreal protocol was to establish import/export licences to control consumption of ozone depleted substances. Montenegro operated under Article 5 of Montreal protocol and it is in compliance with the provisions of the Protocol.

Purposes and coverage of licensing

2. Import licenses are required for:

- Ozone depleting substances and alternative substances;

3. The system applies to goods originating and coming from all countries. Import is forbidden for countries that are not parties to the Montreal protocol on ozone depleted substances.

4. The issue of licenses is not intended to limit the quantities or value of imports, but exclusively with the purpose of adequate monitoring of the imported goods. In the case of ozone depleted substances, the licensing intends to control the quantity of imports because it is related to the protection of the environment and fulfilling the obligation in accordance with the international agreements: the Vienna Convention and the Montreal Protocol. No alternative methods were considered.

5. The licensing is maintained in accordance with:

- Law on the Protection against Adverse Impacts of Climate Change (Official Gazette of MNE, No.073/19, dated 27.12.2019);
- The Decree on ozone depleted substances and alternative substances ("OG MNE", No.5/11);
- The Law on ratification of The Vienna Convention for the Protection of the Ozone Layer with Annexes I and II ("Official Gazette of SFRJ" – International agreements, No.1/90);
- The Law on ratification of The Montreal Protocol on Substances that Deplete the Ozone Layer ("Official Gazette of SFRJ" – International agreements, No.16/90);
- The Law on ratification of the Amendments to The Montreal Protocol on Substances that Deplete the Ozone Layer ("Official Gazette of Serbia and Montenegro"-International agreements, No.24/04).

The legislation does not leave designation of products to be subjected to licensing to administrative discretion.

It is possible for the government (or the executive branch) to abolish the system without legislative approval.

Procedures

6.I. Imports of ozone depleted substances (ODS) are under the quota system. Procedure for quota system for import of the ozone depleted substances are prescribed by the Decree on ozone depleted substances and alternative substances ("OG MNE", No.5/11).

II. A quota for import of ozone depleting substances is determined on an annual basis and written application of importer for setting annual quota have to be submitted to the NEPA not later than 1st December of the current year for the following year. The licences for import are issued for each import separately.

III. The licenses are not allotted for certain goods partly or only to domestic procedures of like goods. Legal person or entrepreneur performing the imports of ODS are obligated to submit proof to the NEPA Unified Customs Document of imported or exported amounts of ODS for each issued permit, not later than three days after the performed import or export of such substances. Unused allocations are not added to quotas for the next year. Also, all issued licences are published on the NEPA web site.

IV. Written application of importer for setting annual quota for ODS imports, have to be submitted to the NEPA not later than 1st December of the current year for the following year. An application for obtaining import permit for import of ODS could be submitted as soon as quotas are allocated for the year for which the quota is allocated.

V. Length of time for processing application is prescribed by the Law on Administrative Procedure. Processing time is up to 30 days.

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

VII. NEPA is a Single administrative body for consideration of licence applications.

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

IX. Not applicable.

X. Through the communication between country authorities in charge of the implementation of the Montreal protocol.

XI. There are no such products.

7.a)-d) Not applicable.

Eligibility of importers to apply for licence

9. All legal persons or entrepreneurs registered in the Central Registry of the Commercial Court are eligible to apply for licences. Regarding permits for chemical, besides above, a legal person must meet the requirements in terms of personnel, facilities and equipment.

All persons and companies that fulfil the conditions envisaged by the Law are eligible to apply for licenses.

- There is no registration fee.
- There is no published list of authorized operators.

Documentation and other requirements for application for licence

10. Please see Exhibit III[1].

The application for import of ozone depleted substances and alternatives substances must contain the following:

- Written request for permits for import/export of ozone depleted substances and alternatives substances which contains the following information: name and type of goods; heading tag or label of goods tariff; the amount of goods in units of measure; information about the person who imports and exports the goods (name, address, registration, and registration number); indication of the state of origin of goods; the name of the company that supplied the goods and the country from which goods are supplied; border crossing;
- A copy of the invoice or pro-invoice companies that supplied goods; and,
- Evidence that the importer / exporter is registered to carry out these activities;
- Proof of the administrative fee payment.

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

12. There are administrative fees as follows:

- Administrative fee in the amount of 40 EUR for each imported consignment of ozone depleted substances;

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

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year. In case of import of chemicals and ozone depleted substances and alternative substances the license is valid for the period specified in the license, or until the end of the current year.

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

16. The licenses are not transferable between importers.

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

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.

3.3 Endangered and protected species of flora and fauna

Outline of System

1. Permits for import of species and their products and derivates are issued in accordance with the Law on nature protection (OG MNE, No.054/16) and the CITES Convention. By means of succession, on 3 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.

Purposes and coverage of licensing

2. Import licenses are required for:

- Endangered and protected species of wild flora and fauna their products and derivates;
- Endangered and protected species of wild flora and fauna their products and derivates in accordance with the CITES convention and protected 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) in accordance with the Law of Nature Protection.

3. The system applies to goods originating and coming from all countries. Import is forbidden for countries that are not parties to the CITES Convention.

4. The issue of licenses is not intended to limit the quantities or value of imports, but exclusively with the purpose of adequate monitoring of the imported goods. In case of CITES, the licensing intends to control the quantity of imports because it is related to the protection of the environment and fulfilling the obligation in accordance with the international agreements: CITES Convention.
No alternative methods were considered.

5. The licensing is maintained in accordance with:

- The Law on Confirmation of the CITES Convention on International Trade of Endangered Species of Wild Fauna and Flora ("OG FRY", International agreements, No.11/01);
- The Nature Protection Act ("OG MNE", No.054/16);
- The Ordinance on closer conditions for the trade in protected wild species of plants, animals and fungi ("OG MNE", No.109/17).

The legislation does not leave designation of products to be subjected to licensing to administrative discretion.

It is possible for the government (or the executive branch) to abolish the system without legislative approval.

Procedures

6.I Information regarding CITES species quotas can be found at CITES website (http://www.cites.org/) and formalities of filing applications for licences can be found at Nature and Environment Protection Agency (NEPA) website (http://www.epa.org.me/). Information regarding other questions is not applicable.

II. System of quotas for CITES permits is not established in Montenegro.

III. The licenses are not allotted for certain goods partly or only to domestic procedures of like goods. Also, all issued licences are published on the NEPA web site. The copy of the CITES licence with Customs Administration signature and seal.

IV. Not applicable.

V. Length of time for processing application is prescribed by the Law on Administrative Procedure. Processing time is up to 30 days.

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

VII. NEPA is a Single administrative body for consideration of licence applications.

VIII. Not applicable.

IX. Not applicable.

X. Through the communication between country authorities in charge of the implementation of the CITES Convention.

XI. There are no such products.

7.a)-d) Not applicable.

8. In addition to non-fulfilling of the criteria prescribed by relevant legislation, application could be rejected in the case when applicant submits application for the goods that are not allowed for import. Reasons for rejection of any form are given by NEPA to the applicant in a separate administrative act. Decision may be appealed to the Ministry of Sustainable Development and Tourism in accordance with the Law on Administrative Procedure.

Eligibility of importers to apply for licence

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

All persons and companies that fulfil the conditions envisaged by the Law are eligible to apply for licenses.

- There is no registration fee.
- There is no published list of authorized operators.

Documentation and other requirements for application for licence

10. Please see Exhibit III[1].

The application for import of CITES listed species and their products and derivates has to contain the following:

- Application for issuance of CITES import permit;
- Copy of CITES export permit;
- Positive opinion of Montenegrin scientific authorities that import of species will not jeopardize survival of that species and sustainability of biodiversity in Montenegro;
- Positive opinion of Montenegrin scientific authorities that imported species will be properly accommodated;
- Statement by the importer regarding the mode of species transport and using purposes;
- Proof of administrative fee payment;
- Additional documents according to Law on nature protection and Law on foreign trade.

Written request for permits for plant, animal and fungus species has to contain the following information:

- Name and seat, or the name and address of the importer;
- The name of the input border crossing;
- Day and start time of importation;
- Quantity;
- Provider/supplier (quantity);
- A court certificate; and
- Proof of the administrative fee payment.

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

12. There are administrative fees as follows:

- Administrative fee in the amount of 50 EUR for each imported consignment of CITES species/products/derivates (1 CITES import permit).

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

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year.

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

16. The licenses are not transferable between importers.

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

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.

3.4 Hazardous chemicals

Outline of System

1. Permits for free movement of hazardous chemicals and adding biocide into a temporary list of biocides are issued in accordance with the Law on chemicals (OG MNE, No.51/17) and the Law on biocidal products ("OG MNE", No.54/16).

Purposes and coverage of licensing

2. Import licenses are required for:

- Free movement of hazardous chemicals and adding biocide into a temporary list of biocides.

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

4. The issue of licenses is not intended to limit the quantities or value of imports, but exclusively with the purpose of adequate monitoring of the imported goods. No alternative methods were considered.

5. The licensing is maintained in accordance with:

- The Law on chemicals ("OG MNE", No.51/17);
- The Law on biocidal products ("OG MNE", No.54/16);
- The Rulebook on detailed conditions for storage and measures for safe keeping and use of hazardous chemicals ("OG MNE", No.61/18);
- The Decree on prohibition and restriction of the use, placing on the market and production of chemicals that presenting an unacceptable risk to human health and the environment ("OG MNE", No.70/18);
- The Rulebook on detailed contents of prior notification for export of chemicals ("OG of MNE", No.061/17);
- The Rulebook on list of dangerous chemicals and products which export is prohibited ("OG of MNE", No.071/18);
- The Rulebook on conditions for placing biocidal products on the market and use ("OG MNE", No.059/16);

- The Rulebook on content of the application for issuing permit for biocides ("OG MNE", -No.017/17);
- The Rulebook on the contents of the technical dossier and the basic data for biocides ("OG MNE", No.005/17; 9/18);
- The Foreign Trade Law ("Official Gazette of Republic Montenegro (OG RMNE)", No.28/04; 37/07 and "OG MNE", No.57/14);
- Decision to amend National Control list for export and import (OG MNE No.40/20);
- The Law on Administrative Procedure ("OG MNE", No.56/14; 20/15; 40/16; 37/17);
- The Decree on the implementation of the Foreign Trade Law ("OG RMNE", No.52/04; 44/07 and ("OG MNE", No.78/2017).

The legislation does not leave designation of products to be subjected to licensing to administrative discretion.

It is possible for the government (or the executive branch) to abolish the system without legislative approval.

Procedures

6. Not applicable.

7.a) There is no fixed time-limit for submitting an application before importation. In accordance with the Law on Administrative Procedure length of time for processing application is 30 day from the day of receipt of the official request. License could be obtained in a shorter period than 30 days if all required documents are submitted.

b) There is no such possibility.

c) There are no such limitations.

d) NEPA is a Single administrative body in charge of consideration of licence applications.

8. In addition to non-fulfilling of the criteria prescribed by relevant legislation, application could be rejected in the case when applicant submits application for the goods that are not allowed for import. Reasons for rejection of any form are given by NEPA to the applicant in a separate administrative act. Decision may be appealed to the Ministry of Sustainable Development and Tourism in accordance with the Law on Administrative Procedure.

Eligibility of importers to apply for licence

9. All legal persons or entrepreneurs registered in the Central Registry of the Commercial Court are eligible to apply for licences. Regarding permits for chemical, besides above, a legal person must meet the requirements in terms of personnel, facilities and equipment.

All persons and companies that fulfil the conditions envisaged by the Law are eligible to apply for licenses.

- There is no registration fee.
- There is no published list of authorized operators.

Documentation and other requirements for application for licence

10. Please see Exhibit III[1].

Written request for permits for free movement of hazardous chemicals has to contain the following information:

- Name and seat, or the name and address of the supplier, trade name and chemical name and address of the manufacturers of chemicals;
- Information on the method of packaging and labelling of chemicals;

- Information on the purpose and use of chemicals;
- Data on the quantity of chemicals;
- Information on the method of storage (location, description of facilities);
- Measures to be implemented for the safe keeping and storage of chemicals;
- Other information requested by the NEPA;
- Contract of insurance against liability for any damage that may result from the use of chemicals;
- Proof of the administrative fee payment.

For the request to adding the biocide into a temporary list of biocides, the applicant has to submit the basic information about the biocide:

- The name of the biocide's manufacturer;
- Authorized representative of the biocide's manufacturer;
- Identity of biocides and active substances in the biocide;
- Effectiveness of biocides;
- The content of the declaration;
- The method of use;
- Classification, packaging and labelling of biocides;
- Annex 4 of Rulebook on the contents of the technical dossier and the basic data for the biocide; and
- Proof of the administrative fee payment.

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

12. There are administrative fees as follows:

- Administrative fee in in the amount of 40 EUR for chemicals.

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

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year. In case of import of chemicals and ozone depleted substances and alternative substances the license is valid for the period specified in the license, or until the end of the current year.

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

16. The licenses are not transferable between importers.

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

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.

3.5 Ionizing radiation generators and radioactive sources for spare parts for devices that produce ionizing radiation

Outline of System

1. Permits for importing ionizing radiation generators, for radioactive sources for spare parts for devices that produce ionizing radiation are issued in accordance with the Law on ionizing radiation protection and radiation safety (OG MNE, No.56/09; 58/09).

Purposes and coverage of licensing

2. Import licenses are required for:

- Generators of ionizing radiation, radioactive sources and spare parts for devices that produce ionizing radiation.

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

4. The issue of licenses is not intended to limit the quantities or value of imports, but exclusively with the purpose of adequate monitoring of the imported goods. No alternative methods were considered.

5. The licensing is maintained in accordance with:
- The Law on ionizing radiation protection and radiation safety ("OG RMNE", No.56/09; 58/09);
- The Foreign Trade Law ("Official Gazette of Republic Montenegro (OG RMNE)", No.28/04; 37/07 and "OG MNE", No.57/14);
- Decision to amend National Control list for export and import (OG MNE No.40/20);
- The Decree on the implementation of the Foreign Trade Law ("OG RMNE", No.52/04; 44/07 and ("OG MNE", No.78/2017);
- The Law on Administrative Procedure ("OG MNE", No.56/14; 20/15; 40/16; 37/17).

The legislation does not leave designation of products to be subjected to licensing to administrative discretion.

It is possible for the government (or the executive branch) to abolish the system without legislative approval.

Procedures

6. Not applicable.

7.a) There is no fixed time-limit for submitting an application before importation. In accordance with the Law on Administrative Procedure length of time for processing application is 30 day from the day of receipt of the official request. License could be obtained in a shorter period than 30 days if all required documents are submitted.

b) There is no such possibility.

c) There are no such limitations.

d) NEPA is a Single administrative body in charge of consideration of licence applications.

8. In addition to non-fulfilling of the criteria prescribed by relevant legislation, application could be rejected in the case when applicant submits application for the goods that are not allowed for import. Reasons for rejection of any form are given by NEPA to the applicant in a separate administrative act. Decision may be appealed to the Ministry of Sustainable Development and Tourism in accordance with the Law on Administrative Procedure.

Eligibility of importers to apply for licence

9. All legal persons or entrepreneurs registered in the Central Registry of the Commercial Court are eligible to apply for licences. Regarding permits for chemical, besides above, a legal person must meet the requirements in terms of personnel, facilities and equipment.

All persons and companies that fulfil the conditions envisaged by the Law are eligible to apply for licenses.

- There is no registration fee.
- There is no published list of authorized operators.

Documentation and other requirements for application for licence

10. Please see Exhibit III[1].

As regards the ionizing radiation, the request has to include basic information about the goods to be imported; a general application form does not exist. The importer must submit the following:

- Proof that the facilities and rooms where trading in ionizing radiation sources or radioactive material is performed in comply with technical, secure, safe, sanitary and other prescribed requirements ensuring health and protection of people and the environment against ionizing radiation;
- Proof that there is an employee in charge for protection against ionizing radiation;
- Proof that persons operating ionizing radiation sources are provided with adequate ionizing radiation protection equipment, as well as equipment for radiation measurements;
- Proof that all persons operating ionizing radiation sources have professional qualification required and satisfy prescribed health requirements for work with ionizing radiation sources;
- Certificate on technical/technological integrity of ionizing radiation source, obtained by the competent authority;
- Instruction for action in case of radiation accident;
- Proof that radioactive materials x-ray devices or other devices producing ionizing radiation are secured in accordance with prescribed requirements for their trading.

11. Importer must present valid license issued by NEPA along with standard customs documentation. When it comes to ionising radiation, in addition to above mentioned, complete technical documentation of the device is required.

12. There are administrative fees as follows:

- Administrative fee in the amount of 100 EUR for ionising radiation.

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

Conditions of licensing

14. The license is valid for the period specified in the license, but not longer than one year. When it comes to ionising radiation, the license is valid up to one year and cannot be extended.

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

16. The licenses are not transferable between importers.

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

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.