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Committee on Import Licensing

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REPLIES TO THE QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES[1]

NOTIFICATION UNDER ARTICLE 7.3 OF THE AGREEMENT ON IMPORT LICENSING PROCEDURES (2015)

CUBA

The following communication, dated 21 September 2015, is being circulated at the request of the delegation of Cuba.

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[1] See G/LIC/3, Annex, for the Questionnaire.

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1 MINISTRY OF SCIENCE, TECHNOLOGY AND THE ENVIRONMENT (CITMA)

1.1 Centre for Environmental Inspection and Control (CICA)

1.1.1 Ozone-depleting substances

Outline of systems

1. A licence is required to import substances that have the potential to deplete the ozone layer (otherwise known as ozone-depleting substances or ODS), and products, equipment and technologies that use these substances. The purpose of this requirement is to ensure that emissions and the use of these substances at national level are maintained at the levels and within the ranges that are authorized under international commitments.

Purposes and coverage of licensing

2. The system covers any substance pertaining to the hydrochlorofluorocarbons (HCFCs) group, and mixtures thereof; R-401A (chlorodifluoromethane, difluoroethane and chlorotetrafluoroethane), R-409A (chlorodifluoromethane, chlorotetrafluoroethane and chlorodifluoroethane) and R-408A (chlorodifluoromethane, trifluoroethane and pentafluoroethane), etc. Also included are products and equipment containing these substances (e.g. refrigerated and/or air-conditioned transport units, portable extinguishers, refrigerators, freezers, heat-pumps, and aerosol products). The latter will only be allowed entry into the country until 31 December 2014.

3. The licensing system applies to all the above substances, regardless of the countries they originate in or come from.

4. Licensing is intended to restrict the quantity of imports through the use of a nationally established maximum quota for each substance, with a view to progressively reducing the substances in question until they are totally eliminated, in compliance with Cuba's obligations as signatory to the Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer.

5. Law No. 81 on the environment, Article 12(g) and (i); and Ministry of Science, Technology and the Environment (CITMA) Resolution No. 116/2005. Import licensing is mandatory. The legislation specifies the substances covered by this licensing system.

Procedures

6. In the fourth quarter of the year, the CITMA, through the Technical Ozone Office (**OTOZ**), establishes and notifies all interested parties of the following year's annual maximum import quota for each controlled substance, in accordance with the national schedule for the elimination of these substances. This quota cannot be carried over from one year to the next.

The authorized importers of controlled substances are Empresa Cubana Importadora-Exportadora de Productos Químicos (QUIMIMPORT), Grupo Empresarial Comercializadora ITH and Empresa Importadora-Exportadora TECNOTEX. Authorization is conferred under Resolution No. 9 of 2013 specifically for methyl bromide for quarantine and preshipment (QPS) purposes. QUIMIMPORT is also covered by this Resolution.

These importers submit their applications to the OTOZ twice a year, at the beginning of the first and the second half of the year, along with the requests from the central government agencies (OACE). Once the import quota has been allocated, sales proceed in accordance with a distribution procedure based on needs and availability. This information is not published and is supplied only to the interested parties (OTOZ, importer, Centre for Environmental Inspection and Control (CICA), and entities concerned), as explained above. The approved figure is the overall amount and is set regardless of the country of origin. The legislation does not provide for any exceptions or derogations from the licensing requirement.

I. Quota size is determined on a yearly basis (calendar year). Quotas cannot be carried over from one year to the next, and they remain in effect only for the period of validity of the import licence (until 31 December of the year in question). Import licences are valid for only one shipment. If the anticipated amount is too large for a single shipment, a new licence must be requested for the excess within the same calendar year.

II. Importing entities are required to keep a permanent inventory of imports of these substances and their destinations. In July and December each year, they must notify the Technical Ozone Office, by means of an official communication signed by their most senior executive, of all imports and sales of ozone-depleting substances, and products, equipment, and technologies containing such substances. Every three months, the Customs General of the Republic notifies promptly to the Technical Ozone Office the data relating to actual imports into Cuba of all regulated and controlled ozone-depleting substances, and products, equipment and technologies. The environmental authority (CICA) is free to order a State Environmental Inspection to monitor compliance with the requirements set in the licences granted.

III. Applications must be submitted in the year for which the quota is assigned, at any period of the year, 60 working days before the scheduled shipment date. Licences remain valid until 31 December of the year in which they are granted.

IV. Import licences are granted within a maximum period of 30 working days.

V. 25 working days.

VI. Applications are submitted to the CICA, which is based at the Office for Environmental Regulation and Nuclear Safety (ORASEN) of the CITMA. It is not necessary to approach any other administrative body.

VII. Applications are always submitted by the importer and must specify the entities the substances are for and the quantities of substance to be imported for each of those entities, in accordance with the amounts allocated in advance by the OTOZ (HCFCs) in the case of methyl bromide. The OTOZ allocates these amounts on the basis of the requests that the entities have made, and the overall amount that the country can allow without affecting its international phase-out commitments. Under no circumstances does the CICA have any influence over this decision.

VIII. Applications are examined and, once approved in the same order, they are notified to the CICA, thus ensuring that any importer to which a quota has been allocated can apply for the necessary licence.

IX. Import licences are also required. The processing procedure is the same.

X. Not applicable.

XI. No.

7. (a) 60 working days prior to the scheduled date of importation.

(b) Licences cannot be extended. A new licence may be requested, within the same calendar year, if all of the anticipated amount is not imported.

(c) There are no limitations.

(d) In such cases, environmental licences are granted solely by the CICA.

8. An application for an import licence may be refused if any of the requirements set forth in the legislation is not met; the applicant is notified in writing of the grounds for the refusal. No appeal lies from a refusal.

Eligibility of importers to apply for licence

9. The importation and exportation of the substances in question and products, equipment and technologies that use these substances must be authorized by the Ministry of Foreign Trade by means of a resolution defining the substance type or group.

Documentational and other requirements for application for licence

10. Form issued by the authority.

11. The relevant licence must be presented to Customs.

12. There is a fee of 62 Cuban pesos.

13. Not applicable.

Conditions of licensing

14. Licences are valid for the year in progress. They cannot be extended.

15. No.

16. Licences are not transferable.

17. Not applicable.

Other procedural requirements

18. There are no other procedures.

19. Not applicable.

1.1.2 Biological diversity

Outline of systems

1. Biological Diversity Import Permits (CITMA Resolution No. 111/96 - "Regulations on Biodiversity") are required for all plant and animal species and parts and derivatives thereof, except for species considered to be exotic, at risk or genetically modified and those listed in the three appendices to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Also excluded from the scope of the above Resolution are the biological resources evoked by the agricultural, livestock and fish production of the Ministry of Agriculture, the Ministry of the Sugar Industry, the Ministry of Fisheries and other state, cooperative and private producers, which are duly authorized by the competent authority, destined for human and animal consumption, and traditionally used in the country for these purposes. These import permits are granted to national or foreign natural persons and legal persons.

Purposes and coverage of licensing

2. Species entering the country as various animal or plant specimens, in the form of holotypes, genotypes, products or derivatives of species and non-exotic specimens.

3. This procedure applies to goods from any country in the world.

4. These permits do not restrict quantity.

5. The Ministry of Science, Technology and the Environment (CITMA) was established in April 1994 pursuant to Decree-Law No. 147 of the Republic of Cuba. By means of Resolution No. 111 of 1996, the CITMA appointed the Centre for Environmental Inspection and Control (CICA) to establish, in coordination with the competent bodies, checks aimed at ensuring effective compliance with the measures needed to preserve and ensure the sustainable use of the country's natural resources.

Procedures

6. Not applicable.

7. (a) Applications for import permits must be submitted 30 working days in advance.

(b) Extension is possible; requests must be addressed to the CICA.

(c) Not applicable.

(d) The CICA is the only institution in the country authorized to review and assess applications (with the assistance of experts from legally appointed competent scientific bodies).

8. Applications for permits may be refused if the information therein is not approved. The applicant must be notified of this decision in writing.

Eligibility of importers to apply for licence

9. Importers must be registered in the National Register for Exporters and Importers of the Chamber of Commerce of the Republic of Cuba.

Documentational and other requirements for application for licence

10. Permit requests must be set forth in a document addressed to the CICA and an application form must be completed with the required information.

11. Not applicable.

12. The following fees are payable pursuant to Resolution No. 181/2004.

13. Not applicable.

Conditions of licensing

14. An import permit is valid for six calendar months and may be extended before its expiry date through a request made to the CICA.

15. Permits are subject only to expiry.

16. Permits are not transferable.

17. Not applicable.

Other procedural requirements

18. No other procedures are required prior to importation.

19. Not applicable.

1.2 National Centre for Biological Safety (CNSB)

Outline of systems

1. The National Centre for Biological Safety (CNSB), as the regulatory centre of the Ministry of Science, Technology and the Environment (CITMA), is responsible for granting licences for the use, testing, production, release, importation and exportation of, and research into, biological agents and their products, and organisms and parts thereof containing genetic information, in the national territory, and at the various stages of the construction of facilities posing a biological risk. This procedure is in conformity with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

Purposes and coverage of licensing

2. Biological safety authorization is a form of environmental licence, through which the CITMA, after having carried out a risk assessment, authorizes a natural or legal person to conduct certain activities in accordance with a number of conditions and requirements. Authorization can be granted in the form of a licence, permit, notification or report.

Licences are the form of biological safety authorization used for activities posing the highest level of risk which include the importation of biological agents and their products, and organisms and parts thereof containing genetic information. For the importation of parts of biological agents containing genetic information, which is a lower risk activity, a biological safety notification is required.

For these purposes, biological agents are defined as viable micro-organisms or their products, priors and other organisms which cause or may cause disease in humans, animals and plants; organisms are defined as any biological entity that is genetically modified or exotic to the country, capable of reproduction or transferring genetic material.

3. The Biological Safety Authorization System is applicable to goods originating in any country.

4. The system does not provide for a limit to the quantity or value of imports; this depends instead on the risk analysis carried out in each case.

5. The legal instruments under which the Biological Safety Authorization System is maintained are the following:

- Resolution No. 67/96 on the creation of the CNSB and its functions and responsibilities, which include organizing and implementing procedures for granting licences for the importation of biological agents and their products, and organisms and parts thereof containing genetic information.
- Decree-Law No. 190 on biological safety, Section 1, Article 4(c). Establishes the responsibilities of the CITMA, which include granting, suspending and withdrawing licences for activities relating to the use, testing, production, release, importation and exportation of, and research into, biological agents and their products, and organisms and parts thereof containing genetic information.
- Resolution No 180/2007 - Regulations for the Granting of Biological Safety Authorization, Chapter 1, Article 6(e). Provides that prior biological safety authorization must be obtained in order to import and export biological agents and their products, and organisms and parts thereof containing genetic information.

The legislation specifies which organisms are subject to control, i.e. biological agents that affect humans, animals and plants; genetically modified organisms; exotic species; and parts of any of these containing genetic information. These products constitute the converge of biological safety regulation and the scope of risk control.

Any change needed to the current system – which would mean amending the Decree-Law – would be made by the Council of State at the proposal of the CITMA. Any amendment of Resolution No. 180, which gives effect to the authorization system, would be the responsibility of the issuing authority, in this case the CITMA, which is in charge of biological safety.

Procedures

6. Not applicable.

7. (a) The application assessment process can vary from 30 (notification) to 90 (licences other than for the importation of genetically modified organisms intended for release into the environment) or 270 (importation of genetically modified organisms intended for release into the environment) working days from the date of receipt of the application, provided that the information submitted is complete. Should further information be required, the process will be suspended until the relevant information has been received. Authorization must be requested in accordance with the established time-limits.

(b) In our case, it is not possible to grant authorization immediately except under very exceptional circumstances, as the products concerned pose a risk to those handling them, to the community and to the environment. Enough time is therefore needed to carry out a risk analysis that includes bibliographical consultation, consultation with experts and the application of risk identification techniques.

(c) There are no limitations as to the period of the year during which an application may be made.

(d) Examination of biological safety licence applications is the job of the CNSB. However, in the course of its examination, it may need to call on experts from other administrative bodies to assist in reaching a final decision. Applications are also submitted to the Centre for Environmental Inspection and Control (CICA) for an opinion on whether or not the activities are proper. The technical report of the Centre is binding for the granting of a biological safety licence.

8. In general, applications for biological safety import licences may be refused for two reasons:

- The activity's adverse effects on human, animal and plant health or the environment are so evident that authorization is inadvisable in the light of the conditions in the country.

- The anticipated benefits are not worth the risks involved.

In addition to the granting or refusal of a licence, other decisions may be taken:

- The granting of a licence with certain conditions attached to its validity: the competent authority may approve a planned activity and issue a licence with the rider that the holder will make the requisite changes or improvements within the specified time-limit or else the licence will lose its validity.

- Deferral: issue of the licence is deferred when changes or improvements are needed in the planned activity in order to remedy safety defects and so forestall any adverse effects.

In the event of refusal or deferral, the competent authority must state the grounds in writing, accounting for the decision in detail.

Appeal against the competent authority's decision lies within ten working days of the date of notification, as appropriate, to:

- The Director-General of the Office for Environmental Regulation and Nuclear Safety; or

- the Minister of the CITMA when the impugned decision is upheld by the Director-General of the Office for Environmental Regulation and Nuclear Safety.

The authority concerned must rule within 15 working days of the date on which the appeal was filed.

All the above procedures are described in and regulated by Resolution No. 180/2007 - Regulations for the Granting of Biological Safety Authorization.

Eligibility of importers to apply for licence

9. Importers must be registered in the National Register for Exporters and Importers of the Chamber of Commerce of the Republic of Cuba.

Documentational and other requirements for application for licence

10. In order to obtain an import licence, the applicant must submit a technical file, accompanied by a written application for a biological safety licence, to the competent authority. The following information must be included:

- Name of the facility or release area.
- Body or organization to which it belongs.
- Date of application.
- Legal domicile, telephone and fax numbers, email address.
- Description of the proposed activity.
- Risk assessment carried out for each activity.
- Name, surname and signature of the entity's legal representative.
- Official stamp of the entity.
- Certified copy of the requesting entity's charter.
- Certified copy of the document officially appointing the owner of the requesting entity.

The technical file must also contain the general information referred to in Annexes 5, 6, 11, 12 and 13 to Resolution No. 180/2007 pertaining to the specific product to be imported.

11. Upon importation, the relevant biological safety licence is required.

12. Import licences cost between 345 and 3,979 Cuban pesos.

13. Not applicable.

Conditions of licensing

14. The period of validity of a licence depends on the assessment made by the specialist in charge of the process. To renew a licence upon its expiry, a new letter of application must be submitted to the CNSB.

15. Penalties are imposed only if importation takes place without biological safety authorization or after the licence expiry date.

16. Licences are not transferable between importers.

17. The issuing of a licence is subject to the conditions laid down in the legislation on biological safety.

Other procedural requirements

18. Not applicable.

19. Not applicable.

1.3 National Centre for Nuclear Safety (CNSN)

Outline of systems

1. Authorization is required to import ionizing radiation sources (radioactive sources and ionizing radiation-generating equipment). This provides a means of controlling the sources entering the country and ensuring that the use to which they will be put is proper and safe. Authorization is also required to import nuclear materials and significant components so as to verify that they are being imported for peaceful and authorized purposes, in accordance with the safeguards regime for such materials.

Licences are granted to national legal persons or foreign legal persons based or represented in the Republic of Cuba.

These procedures are in conformity with the Code of Conduct on the Safety and Security of Radioactive Sources and supplementary Guidance on the Import and Export of Radioactive Sources, of the International Atomic Energy Agency (IAEA), and with the nuclear non-proliferation commitments under the treaties on non-proliferation and prohibition of nuclear weapons in Latin America and the Caribbean.

Purposes and coverage of licensing

2. The authorization described above is granted in the form of:

- import licences;
- authorization to transfer nuclear material or significant components (or both), insofar as the importation is considered an international transfer.

Ionizing radiation source: Anything that produces ionizing radiation and might cause exposure to such radiation.

Nuclear material: Uranium containing the mixture of isotopes occurring in nature; uranium depleted in the isotope 235; thorium; any of the foregoing in the form of metal, alloy, chemical compound, or concentrate. Plutonium-239; uranium-233; uranium enriched in the isotopes 235 or 233; and any material containing one or more of the foregoing.

Significant components: Equipment or components for nuclear installations or those of the type used in such installations, specially designed or developed for the treatment, utilization or production of nuclear material.

3. The licensing system applies to goods from any country.

4. In this case, licensing is not intended to restrict the quantity of imports; its purpose is to assess the radioactive sources or ionizing radiation-emitting equipment which enter the country in terms of radioactivity-related risks, bearing in mind that justification for the import of these goods hinges on the use to be made of them in Cuba and the safety requirements to be met during use. With regard to nuclear material or significant components, transfer authorization is required in order to control the nuclear material imported into the country, both quantitatively and qualitatively, ensuring that it is destined for peaceful use, and preventing any unauthorized use, waste or movement, in accordance with the safeguards agreements concluded between the Republic of Cuba and the IAEA.

5. Decree-Law No. 207 of 14 February 2000 on the use of nuclear energy.

CITMA Resolution No. 334 of 29 December 2011 - "Regulations governing the notification and authorization of practices and activities associated with the use of ionizing radiation sources".

Import licensing is mandatory. The legislation specifies the products that are subject to licensing in each case.

The Council of State (the legislature) has made licensing a statutory requirement and empowers the CITMA (the executive) to establish the terms and conditions for each system. Parliamentary approval would be required to abolish the current system.

Procedures

6. Not applicable.

7. (a) Under current legislation, an import licence must be obtained from the National Centre for Nuclear Safety (CNSN) prior to the introduction of ionizing radiation sources into the country. It is provided that the CNSN must respond to a licence application within 30 working days of its receipt.

(b) For the transfer of nuclear material or significant components, applications must be submitted 90 days before the scheduled date of importation.

(c) Given that an assessment is required, a licence can never be granted immediately.

(d) There are no limitations as to the period of the year during which an application for licence may be made. The CNSN is the sole body responsible for considering licence applications.

8. Under Article 20 of CITMA Resolution No. 334/2011, applications for licence to import ionizing radiation sources may be rejected on the following grounds:

- The documents and information provided by the applicant are incomplete or have not been prepared in accordance with the requirements of CITMA Resolution No. 334/2011.
- The application has not been signed by the entity's legal representative.
- The documents and information are confusing, incomplete or contradictory.
- The activity for which authorization is requested is not justified for the purposes of radiological protection.
- The applicant does not meet the regulatory and safety requirements to conduct the activity.

Authorization to transfer nuclear material or significant components is not granted unless the requesting entity is authorized to use such material or components.

The CNSN notifies the requesting entity in writing of the rejection of the application for licence to import ionizing radiation sources and informs it of the grounds for the decision.

Appeal to the Director-General of CITMA's Office for Environmental Regulation and Nuclear Safety against the decision rejecting the application lies within ten working days of the date of notification of the decision.

Eligibility of importers to apply for licence

9. Importers must be registered in the National Register for Exporters and Importers of the Chamber of Commerce of the Republic of Cuba.

Documentational and other requirements for application for licence

10. Applications for licence to import ionizing radiation sources must be submitted by the legal representative of the interested entity, using the form contained in Annex 2 to CITMA Resolution No. 334/2011. The application form must be signed by the legal representative, stamped by the entity, and include data such as the name and address of the requesting entity, the name and surname of the entity's legal representative, and the type of authorization requested.

Applications to transfer nuclear material or significant components must be submitted using the forms contained in Annexes 2 and 4 to CITMA Resolution No. 62/1996, as appropriate.

11. Applicants for licences to import ionizing radiation sources must submit the following documents and information:

- Legal document certifying that the entity is authorized to import.
- Tariff heading(s).
- Details of the sources to be imported, pursuant to Annex 7 to CITMA Resolution No. 334/2011, which specifies the information to be submitted, such as the name of the radioactive source and whether or not it is sealed, or in the case of ionizing radiation-generating equipment, details that include the following: source activity and category, radionuclide activity, source serial number, equipment model, use and voltage, and type of radiation emitted.
- Entity for which the imported source is destined, including: name, legal domicile, fax number, email address, and consent to receive the source.
- Expected date of arrival in national territory.
- Entity responsible for transportation of the source to the receiving entity (except for radiation-generating equipment).
- Air or maritime terminal at which the source is expected to arrive.
- In the case of sealed sources, certification of leak-tightness testing in accordance with ISO-9978 or another internationally recognized standard.
- Certification of special form radioactive material under current regulations on the transport of radioactive material.
- In the case of ionizing radiation-emitting equipment, detailed information on the equipment's safety characteristics, provided by the manufacturer, and certification from the regulatory authority in the country of origin concerning the approval of the design.
- Production certificate for sealed sources.
- Certification of ISO-2919 classification of the source.
- Package design approval certificate for the transportation of Type B packages in accordance with the regulations in force on the transport of radioactive material.

12. A fee of 1,263 Cuban pesos is charged for the issue of an import licence, as laid down in Resolution No. 347/2012 of the Ministry of Finance and Prices.

There is no charge for the authorization to transfer nuclear materials or significant components.

13. There is no deposit or advance payment requirement. The only payment required is the fee referred to in point 12 above. If authorization is refused, the applicant is not required to make any payment.

Conditions of licensing

14. The period of validity of an import licence is specified by the CNSN on a case-by-case basis according to the prevailing circumstances. When an import licence expires, a new one must be requested, which will have a new period of validity.

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

16. Import licences are not transferable.

17. No other conditions are attached to the issuing of these licences. The licence holder must adhere to the licensing requirements.

Other procedural requirements

18. No other procedures are required prior to importation.

19. Not applicable.

1.4 National Centre for Chemical Safety (CNSQ)

Chemical substances

Outline of systems

1. Importation into Cuba of the substances listed in Schedules 1, 2 and 3 of the Chemical Weapons Convention (CWC) and those regulated by the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, 1998, to which Cuba is party, is subject to an import licensing system which ensures that these substances are used for purposes not prohibited by the CWC or the Rotterdam Convention. Such licences are granted only to properly established legal persons.

Purposes and coverage of licensing

2. Parties that are interested in importing any of the substances listed in Schedules 1, 2 and 3 of the CWC or those restricted under the Rotterdam Convention must apply for an import licence. Applications must indicate the following: chemical name of the substance, quantity, Schedule to which the substance belongs, name of director of the entity, owner, legal domicile, import licence number (as certified by the certificate of registration with the National Register of Exporters and Importers of the Chamber of Commerce of the Republic of Cuba), commercial invoice, name and address of the exporter, country of origin and country of provenance.

Licences are valid for only one import transaction.

The import and industrial use of crocidolite (blue asbestos), polychlorinated terphenyls, pentachlorophenol and ethylene dichloride are prohibited, as is the industrial use in textile production of polybrominated biphenyls and tris(2,3 dibromopropyl) phosphate. The use of polybrominated biphenyls and tris(2,3 dibromopropyl) phosphate for purposes other than textile production is subject to licensing. The industrial use of ethylene oxide for sterilization purposes in the national health system and procedures ensuring its operation is restricted. The import and domestic marketing of polychlorinated biphenyls (askarels) and electrical equipment containing more than 50 ppm PCBs is prohibited, as is the importation of anthophyllite, tremolite, actinolite and amosite.

3. The decisions in the preceding paragraph apply to all countries of origin of these chemicals but do not cover imports thereof for the purposes of research or analysis or their use as reference standards, in which case a licence issued by the CNSQ is compulsory.

All 190 States Parties to the CWC may market the controlled substances of Schedules 1 and 2. Any State Party and State not party to the CWC may market Schedule 3 substances, provided that the latter issues a certificate stating the final destination of the substances.

The purpose of the system is to ensure that Schedule 1, 2 and 3 substances, and products containing such substances in the percentages established, are imported only for purposes not prohibited under the CWC. The procedure limits the quantity of Schedule 1 substances in the country at any given time, which cannot exceed one tonne, and ensures that transfers of Schedule 1 and 2 substances and the products containing them take place only between States Parties. With regard to Schedule 3 substances, if they are transferred to a State not party to the CWC, that State must issue a certificate stating their end use and confirming that they are to be used for non-prohibited purposes.

4. The procedure is designed to limit the volume of imports and reflects the country's determination to support all actions aimed at the non-proliferation of weapons of mass destruction and hence at destroying those in existence in any part of the world, in the light of the disastrous consequences of the use of CWC-controlled substances for mankind and the future of our planet. As to the substances covered by the Rotterdam Convention, it is considered of the utmost importance, in view of the relevance of this instrument and the growing risks and hazards posed by increased production and trade in chemical substances, to prohibit the use of certain toxic chemicals and to expand the scope of the Convention to other products of this nature, thus preventing the introduction into Cuba of unwanted chemicals.

5. Decree-Law No. 202 on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and the Destruction Thereof of 24 December 1999 refers in Chapter III, entitled "Licences and Permits", to the general rules concerning the procedure for the granting of licences and permits for activities involving the chemical substances listed in the CWC.

Resolution No. 32/2005 implements the supplementary regulations to Decree-Law No. 202 entitled "Regulations for the Implementation of the National System for the Control of the Chemical Substances Listed in the Chemical Weapons Convention, the Granting of Licences and Permits, and Information Processing", Chapter III of which, including the first and second sections thereof, is devoted to explaining the procedures for the granting and refusal of licences, appeals, the responsibilities of the competent authority, and the time-frames and deadlines for processing the licences and permits to be obtained by entities conducting activities involving the substances listed in the CWC.

Resolution No. 159/1995 and Resolution No. 96/2004 provide for the domestic implementation of activities relating to the Rotterdam Convention and prohibit or restrict the importation and industrial use of various chemicals.

Under the above-mentioned legal instruments, licensing is compulsory for activities involving the use of substances listed therein.

The controlled substances are listed in the Annexes to these instruments. The Council of State (the legislature) has made licensing a statutory requirement and empowers the CITMA (the executive) to establish the terms and conditions for each system.

Procedures

6.I. The legislation does not provide for quotas to ensure that the quantity of a CWC Schedule 1 substance in the country does not exceed one tonne at any given time. This is instead controlled through licence applications for any activity involving these substances, including importation. In the event of a risk of the above quantity being exceeded, licence applications, whether or not relating to importation, would be rejected in accordance with the established procedure.

No activities have been conducted in the country using Schedule 1 substances.

II. Not applicable.

III. Not applicable.

IV. The deadline for the submission of applications is 60 days prior to the start of the activity (importation/exportation).

This deadline does not apply to applications for the importation or exportation of saxitoxin in quantities of 5 mg or less. In these cases a licence may be requested up until the time of entry into or departure from the country, provided that the transfer is for medical or diagnostic purposes.

V. The processing period for applications is 30 days, though it is shorter for both imports and exports, when the **CNSQ** receives the commercial invoice.

VI. Licences are issued for the date of importation indicated on the commercial invoice.

VII. Decree-Law No. 202/99 and Resolution No. 32/2003 designate the CNSQ as the competent authority and specify that in cases where another type of authorization is required for the importation, manufacture or other uses of chemical substances, the processing and granting of licences will be contingent upon the authorization issued by that authority.

VIII. On a first-come, first-served basis.

IX. Not applicable.

X. Not applicable.

XI. Not applicable.

7. There are no quantitative limits on the importation of CWC Schedule 2 and 3 substances and products containing such substances in the percentages set forth in the CWC, if they are used for non-prohibited purposes.

(a) Licence applications must be submitted 30 days prior to the scheduled date of importation.

(b) In exceptional circumstances, the Director of the **CNSQ** may authorize the granting of a licence even when the application has not been submitted within the established time-frame.

(c) Import licences cannot be granted immediately. They are issued for only one substance, one import transaction, and when the importer presents the commercial invoice.

(d) There are no limitations as to the period of the year during which the licence application may be submitted or the importation effected.

(e) Decree-Law No. 202/99 and Resolution No. 32/2003 designate the CEANPAQ as the competent authority and specify that in cases where another type of authorization is required for the importation, manufacture or other uses of chemical substances, the processing and granting of licences will be contingent upon the authorization issued by that authority.

8. Licence applications may be refused on the grounds of failure to meet the above criteria or other criteria set forth in current legislation. The reasons for refusal are set forth in a licence refusal letter, in accordance with the "Procedure for Processing Applications for **CNSQ** Authorization".

Applicants have the right to appeal to the Director of the Office for Environmental Regulation and Nuclear Security within 30 working days of the date on which they receive the communication notifying them of the refusal.

Should the appeal be turned down by the Director of the Office for Environmental Regulation and Nuclear Security, application for a Special Review Procedure may be made within 180 days of that decision to the Minister of Science, Technology and the Environment if there is evidence of a blatant flaw in the taking of the decision or if there is information that the authority that refused authorization did not have or was not aware of at the time. A ruling must be issued within 30 working days of the receipt of the review application.

Eligibility of importers to apply for licence

9. Importers must be registered in the National Register for Exporters and Importers of the Chamber of Commerce of the Republic of Cuba.

Documentational and other requirements for application for licence

10. An application form for authorization to import chemical substances listed in the CWC.

The importer must submit the following documents with the application:

- Photocopies of the decision appointing the director of the entity and the entity's charter.
- Photocopy of the certificate of registration with the National Register of Exporters and Importers of the Chamber of Commerce.
- Photocopy of the commercial invoice.

11. Other documents required by the Customs General of the Republic include the importer's licence to import chemical substances listed in the CWC.

12. Each import licence costs 897 Cuban pesos.

13. The issuing of licences is not associated with any deposit or advance payment requirement apart from the application fee.

Conditions of licensing

14. Import licences are valid for only one import or export transaction. They cannot be extended.

15. Yes. Entities which conduct activities involving CWC substances without the relevant authorization are committing an administrative offence sanctioned by Agreement No. 5517, adopted by the Executive Committee of the Council of Ministers on 26 August 2005, without prejudice to any civil and criminal liability incurred.

16. Import licences are not transferable between importers.

17. No conditions are attached to the issuing of a licence other than the requirements set forth in current legislation.

Other procedural requirements

18. Yes, there are some other prior administrative procedures of this sort.

19. Not applicable.

1.5 Technical Ozone Office (OTOZ)

Outline of system

1. The import, export and consumption licensing system is regulated under Resolution No. 116/2005 on the National Schedule for the Control of Ozone-Depleting Substances which lays down in annex the substances and products subject to import and export licensing together with control measures. The authorization system is administered by the Regulations Department of the Technical Ozone Office and the environmental licence system by the Centre for Environmental Inspection and Control (CICA) which is based at the Office for Environmental Regulation and Nuclear Safety (ORASEN) of the Ministry of Science, Technology and the Environment (CITMA).

Purposes and coverage of licensing

2. The system covers imports and exports of substances, equipment and technologies listed in the Annexes to Resolution No. 116/2005 on the National Schedule for the Control of Ozone-Depleting Substances are subject to controls and regulations. These range from a ban on import, export and consumption, to the granting of licences, a quota system, and authorizations.

The substances listed in Annexes 1, 2, 3, 4, 7, 8 and 9 are subject to a ban on import, export and consumption in accordance with the time-limits laid down in prevailing legislation and the Montreal Protocol.

The substances listed in Annex 5 are subject to a licence-based regulatory system and quotas until 1 January 2013, from which date their import, export and consumption will be prohibited; similarly as of 1 January 2013, a licence-based regulatory system will be in force, in conjunction with quotas, for the substances listed in Annex 6, as will an import ban on the technologies listed in Annex 10 that use or contain those substances.

Importers and exporters applying to the OTOZ for an environmental licence may state in their application that their imports and exports of substances, equipment and technologies listed in Annex 10 are free of controlled substances. The OTOZ will assess the documentation and decide:

if there are no controlled substances, to authorize the import or export by issuing the appropriate notice for the Customs Clearance Office;

if there are controlled substances in the import or export, to refer the matter to the CICA for the appropriate measures to be taken in accordance with the legislation in force.

3. The system applies to products originating in and coming from the signatory countries to the Montreal Protocol (197 members).

4. Automatic import licences are used for statistical purposes. Non-automatic import licences are used to administer the import restrictions applied in accordance with Resolution No. 116/2005 on the National Schedule for the Control of Ozone-Depleting Substances and the Montreal Protocol.

5. The licensing system is statutorily required. The system may be suspended when deemed appropriate. A notice to that effect is published in the Official Journal and the regulatory bulletin for importers and exporters.

Procedures

6. For products under restrictions:

I. The specialized regulatory bulletin "Legislation in force to protect the ozone layer in Cuba" publishes information on quotas and formalities of filing applications for licences, exceptions and derogations.

II. Quotas are determined on a yearly basis.

III. The licences are allocated to authorized importers, whether Cuban or non-Cuban.

IV. A minimum period of 60 days prior to the scheduled date of shipment is allowed for the submission of applications for licences from the time of announcing the opening of quotas.

V. Licence applications are processed in three weeks.

VI. The period for issuing a licence concludes within 30 working days counted from the date of acceptance of the application by the Centre for Environmental Inspection and Control (CICA), which is based at the Office for Environmental Regulation and Nuclear Safety (ORASEN) of the CITMA.

VII. The licence applications are considered by the Centre for Environmental Inspection and Control (CICA) which is based at the Office for Environmental Regulation and Nuclear Safety (ORASEN) of the CITMA and the OTOZ.

VIII. The main criterion for allocating licences is according to need and the equipment to be imported in accordance with the legislation in force. Applications are considered on a first-come, first-served basis.

IX. There are no bilateral quotas or export restraint arrangements.

X. Export permits are not required from exporting countries.

XI. Licences are not issued on condition that the goods should be exported and not sold in the domestic market.

7. When there is no quantitative limit on importation of a product or on imports from a particular country:

(a) Applications for licences must be made at least 60 days prior to the scheduled shipment date and one week before importation for authorizations. Authorizations can be obtained within a shorter time-limit for goods that have arrived at port.

(b) In such circumstances, a licence can be granted immediately on request.

(c) There are no limitations as to the period of the year during which the application for a licence or authorization may be submitted or the importation effected.

(d) The importer only has to approach one administrative body about an application.

8. None. The applicant is notified in writing of the reasons for the refusal. In the event of refusal to issue a licence, the applicant has the right of appeal to the Office for Environmental Regulation and Nuclear Safety (ORASEN).

Eligibility of importers to apply for licence

9. All persons, firms and institutions are eligible to apply for a quota and recognized importers are eligible to apply for an environmental import or export licence.

Documentational and other requirements for application for licence

10. An environmental licence application form is available at the Centre for Environmental Inspection and Control (CICA) which is based at the Office for Environmental Regulation and Nuclear Safety (ORASEN) of the CITMA; an application form for an authorization is available at the Technical Ozone Office. The importer is required to supply the following documents with an application for an authorization from the OTOZ:

- A letter requesting a permit stating the goods that are the subject of the application, the supplier, the shipping document and invoice, and a declaration that the goods do not contain any ozone-depleting substances.
- Copy of the BL or AW shipping document or in their absence the contract number with a copy of the annex listing the goods subject to OTOZ controls.
- Copy of the invoice (not necessary if the contract is submitted).
- Technical specifications of the product, equipment and technology.

11. Upon importation or exportation, the importer or exporter must present either the environmental licence approved by the Centre for Environmental Inspection and Control (CICA), which is based at the Office for Environmental Regulation and Nuclear Safety (ORASEN) of the CITMA or the authorization issued by the OTOZ to the Customs Clearance Office.

12. There is no licensing fee or administrative charge.

13. No deposit or advance payment requirement is associated with the issue of licences.

Conditions of licensing

14. The licence is valid for one calendar year from its date of issue. Validity cannot be extended beyond that calendar year.

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. The issue of a licence is subject to the presentation of documents, intended uses and approved quota; the issue of authorizations is subject to presentation of documents.

Other procedural requirements

18. No other administrative procedures, apart from environmental import and export licensing, are required prior to importation.

19. The banking authorities automatically provide foreign exchange for goods to be imported. There is no link with applications for environmental licences or authorizations.

2 MINISTRY OF AGRICULTURE

2.1 National Centre for Plant Health (CNSV)

Outline of systems

1. Licences are required to import the materials subject to quarantine listed in Decree-Law No. 153 (regulated items).

Licences are granted to companies, unions and other State organizations, State bodies and agencies, budgeted entities, joint ventures, and commercial corporations legally established in national territory, and to national or foreign natural or legal persons expressly authorized by law to engage in international trade in goods and registered in the National Register of Exporters and Importers of the Chamber of Commerce of Cuba and the Central Register of the Customs General of the Republic. This procedure is in conformity with the International Plant Protection Convention (IPPC) under the FAO.

Purposes and coverage of licensing

2. Import licences are granted for materials subject to quarantine (regulated items) that do not represent a danger to Cuban agriculture, in particular those intended for sowing, and fresh fruits and vegetables originating in areas free of fruit flies. This includes materials relating to those materials subject to quarantine (regulated items), for any use.

3. The licensing system applies to all materials subject to quarantine (regulated items) originating in and coming from any country.

4. Licensing is not intended to restrict the quantity of imports, but to prevent the introduction of pests.

5. Decree-Law No. 153, Articles 3(2), 18(a), 25 and 30; and Ministry of Agriculture Resolution No. 435 of 1994. Phytosanitary import licensing is mandatory and the legislation establishes which products are subject to these procedures. Parliamentary approval would be required to abolish the current system.

Procedures

6. Not applicable.

7. (a) Article 8 of Resolution No. 435/94 provides that import licences must be requested 60 days prior to the shipment of the goods from their country of origin. The approval or refusal of the application is notified within 30 days of the date on which it was submitted, although this period may vary under certain circumstances. If goods arrive in the country without a permit or a licence, Decree No. 169/1992 on infringements will be applied.

   (b) No.

   (c) Applications for licences may be made during any period of the year. The period during which importation is authorized, however, is specified on the licence granted.

   (d) Pursuant to Decree-Law No. 190/99 on biological safety for exotic plants, the interested party must first present the licence granted by the National Centre for Biological Safety (CNSB), the Centre for Environmental Management and Inspection, or the Institute of Ecology and Systematics, to the National Centre for Plant Health (CNSV).

8. Licence applications may be refused if pest risk analysis shows that the product to be imported represents a danger to the country. The interested party is notified of this and informed of the technical considerations relating to the refusal. No appeal lies from a refusal.

Eligibility of importers to apply for licence

9. Importers must be registered in the National Register for Exporters and Importers of the Chamber of Commerce of the Republic of Cuba.

Documentational and other requirements for application for licence

10. The importer must complete the application form set forth in Annex III.[2]

11. The importer or its representative must be in possession of an import licence and the certificates specified therein.

12. All licences granted must be paid for. The fee is determined beforehand in the services contract between the importer and the CNSV in accordance with the rate established in Ministry of Agriculture Resolution No. 2669/2005.

13. No deposit or advance payment requirement is associated with the issuing of licences.

Conditions of licensing

14. A licence may be valid for up to one year. Validity may be extended by following the same procedure as for the previous application. It speeds formalities up to provide the number of the previous phytosanitary licence.

15. There are no penalties.

16. No, licences are not transferable between importers.

17. Not applicable.

18. Other procedural requirements

19. Not applicable.

2.2 Institute of Soils (IIS)

Outline of systems

1. A licence is required to import fertilizers to ensure that the use of these substances at national level is maintained at the levels and within the ranges that are authorized.

Purposes and coverage of licensing

2. The following products are subject to registration with the Central Registration Authority for Fertilizers. Registration is a precondition for them to enter and be used in Cuba:

- Chemical fertilizers.
- Organic fertilizers.
- Biological fertilizers.
- Biostimulating fertilizers.

3. They can originate in and come from any country.

4. Licensing is not intended to restrict the quantity and/or value of imports; instead its purpose is to ensure control of use in Cuba of substances that may be hazardous to life or have a pollutant effect on the environment.

[2] A sample form is available for consultation in the Secretariat (Market Access Division) (in Spanish only).

5.

- Decree No. 179/1993 "Protection, Use and Conservation of Soils and Infringements thereof", which lays down the parameters and obligations governing the use and conservation of Cuban soil; Ministry of Justice Resolution No. 7/2001 authorizing the establishment of the Central Registration Authority for Fertilizers; and Ministry of Agriculture Resolution No. 322/2001 implementing the Central Registration Authority for Fertilizers, sets out the documents to be submitted with an application for registration, the statutory procedures to be followed and the assessments that the Committee of Experts will conduct.
- Registration is statutorily required under the legislative instruments referred to above.
- The legislation that forms the legal framework for the control system provides that all products referred to in point 2 of this questionnaire are subject to licensing.
- Since the legal basis is Decree No. 179/1993 "Protection, Use and Conservation of Soil and Infringements thereof", legislative approval must be obtained for its abolition.

Procedures

6. Not applicable as there are no restrictions as to quantity or value.

I. In view of point 6 above, the matter of publication of information concerning allocation of quotas does not apply. Information concerning formalities of filing and therefore authorization to use in Cuba is published in the document "Official List of Authorized Fertilizers" (LOFA), see the Chapter "Central Registration Authority for Fertilizers" which gives the authority's address and contact details. In view of the information given above, the matters of publication of the overall amount of quotas, the amount allocated to goods from each country, and the means of requesting exceptions or derogations from the licensing requirement do not apply.

II. Not applicable because there are no restrictions on quantities, as noted above; authorizations are permanent provided that the registered products remain within the parameters under which they were approved by the Committee of Experts at the Central Registration Authority for Fertilizers.

III. As stated above, all the products described are subject to the registration requirement regardless of their origin or nationality.

The National Customs Administration, together with the Ministry of Foreign Affairs (MINREX) and the State Control System at the Institute of Soils, lay down the control procedures that oversee the entry into and use in Cuba of registered products only.

No direct request has been made to our organization in that regard.

IV. Not applicable.

V. There are no minimum or maximum lengths of time; the time taken to process an application for a fertilizer before registration on the Central Register varies depending on how complex the fertilizer in question is. The potential dangers that a fertilizer poses to life and the environment are assessed by field tests and trials.

VI. See above.

VII. The importer has to approach the Central Registration Authority for Fertilizers only.

VIII. Not applicable as there is capacity to respond to the applications submitted.

IX. Not applicable.

X. Approval or refusal to license the products described is notified to the applicant importer or national producer and published officially in the LOFA.

XI. Not applicable in view of the second part of point 5, before the section on "procedures".

7. Where there is no quantitative limit on the importation of a product or on imports from a particular country:

(a) See point V.

(b) This is the importer's responsibility; see the first and second parts of point III.

(c) No, the process must run its full course before registration is possible.

(d) There are no limitations as to the period of the year.

(e) See point VII.

8.

- There are no circumstances other than those described above under which a licence application can be refused.
- The applicant is always informed of the reasons for any refusal.
- No appeal is possible because the decision is the opinion of a Committee of Experts composed of trained specialists representing a range of bodies.

Eligibility of importers to apply for licence

9. Entities and institutions may apply subject to presentation of accreditation in Cuba by the appropriate bodies; persons may apply subject to presentation of powers confirming their accreditation by the entity they represent.

There is no restrictive licensing register for registration applications.

Documentational and other requirements for application for licence

10.

- Powers confirming the credentials of the person applying for registration.
- An official application form (the original and one copy).
- Technical information about the commercial product.
- Draft labelling.
- List of countries where the product is authorized indicating the registration number and recommended uses.
- Product patent, where appropriate.
- A sample of the product commensurate with the quantities required for the tests and trials that will be conducted.

11. Documents attesting to approval and registration with the Central Registration Authority for Fertilizers.

12. There is no set fee or charge. The amount charged depends on product type and the analyses and tests conducted on it in the light of its features. The amount charged is based on the official price list drawn up for such activities.

13. The issue of a licence is subject to payment of the analyses and tests conducted. The amount charged is not refundable and is based on the criteria referred to in 12 above.

Conditions of licensing

14. Licences do not expire provided that the composition and formulation of the fertilizer are the same as when the licence application was made.

15. The penalties are those provided for in Decree No. 179/1993 "Protection, use and Conservation of the Soil and Contraventions thereof".

16. Licences are not transferable.

17. Not applicable.

Other procedural requirements

18. As far as we are concerned, those laid down in relation to registration in the Central Registration Authority for Fertilizers.

19. Not applicable.

3 MINISTRY OF THE ARMED FORCES (MINFAR)

3.1 National Office of Hydrography and Geodesy (ONHG)

Outline of systems

1. Licences for the importation and extraction of satellite global positioning systems (GPS).

Purposes and coverage of licensing

2. Satellite global positioning systems (GPS) used for geodesic and hydrographic purposes and other similar activities.

3. It applies to imports from any country.

4. Licensing does not restrict either the quantity or the value of imports. Its purposes are described in the fourth and fifth Whereas paragraphs of Decree No. 269 of 9 March 2000 on space radio communications services.

5. Decree No. 269, mentioned above, and Resolution No. 90 of the Minister of the Revolutionary Armed Forces (MINFAR) of 13 February 2001 "to implement Decree No. 269". Licensing is mandatory, except for natural persons who import the products for personal use, e.g. clocks and watches, pagers, and outdoor orientation devices, in which case the goods must be declared at customs upon arrival in the country. Licences are required for high precision equipment imported for use in geodesic and hydrographic activities requiring the determination of precise coordinates. Changes cannot be made to the current system without parliamentary approval.

Procedures

6. Not applicable. Imports of GPS equipment are not subject to any restrictions in terms of quantity or value.

7. When the equipment is not used in activities to determine high precision coordinates.

(a) Three months before importation. In cases where imports have been effected and have arrived in port owing to inadvertency, the matter is examined on a case-by-case basis, every effort being made to ensure that the economic implications for the importer are kept to a minimum.

(b) Yes, wherever possible. In cases where it is known in advance that the licence will not be used within the set time, we recommend that a request for its renewal be made to the ONHG.

(c) There are no limitations of this sort.

(d) Licence applications are processed solely by the ONHG, which, if necessary, consults the MININT, the MINFAR and other central government agencies (OACE) before issuing or refusing the import licence.

8. Licence applications may be refused if the GPS equipment involved is to be used to measure coordinates in areas for which the recipients of the equipment do not have authorization.

Applications may also be refused if they have been submitted by an importer whose corporate purpose does not justify the use of GPS technology. In all cases, applicants are notified of the reasons for the refusal. Decree No. 269 and Resolution No. 90 do not provide for a right of appeal.

Eligibility of importers to apply for licence

9. Legal persons are eligible to apply for an import licence. In the case of natural persons, the justification given for importing the technology is analysed on a case-by-case basis.

Documentational and other requirements for application for licence

10. Applications must be addressed to the Director of the ONHG and must contain the following information:

- Date.
- Name of requesting entity.
- Body to which it belongs.
- Address of requesting entity.
- Resolution establishing the requesting entity.
- Corporate purpose of the requesting entity.
- Person responsible for importation (natural person accountable to the entity requesting the licence).
- Geographical area in which the equipment will be used.
- Technical tactical data concerning the equipment (including photos, wherever possible).
- Importing entity.
- Applicant details (name, surname and position) and signature.

11. The import licence, signed by the Director of the ONHG.

12. Import licences are free of charge.

13. No deposit or advance payment requirement is associated with the issue of licences.

Conditions of licensing

14. Licences are valid for 90 calendar days and may be extended by submitting a new application to the ONHG explaining the reasons why the importation did not take place in the period approved under the first licence issued.

15. There is no penalty for non-utilization.

16. Licences are not transferable.

17. There are no other conditions.

Other procedural requirements

18. No other administrative procedures are required prior to importation.

19. Not applicable.

4 MINISTRY OF THE INTERIOR (MININT)

4.1 Protection Directorate

Outline of systems

1. Import licences are required to show that the security devices used to ensure the safety and protection of goods and people have been examined by means of appropriate procedures and that

their quality meets the requirements of both the manufacturer and the body that governs their use.

Licences are granted to properly established national legal persons.

Purposes and coverage of licensing

2. Analogue and digital closed circuit television (CCTV), cameras, lenses, sequencers, movement controllers, quads, multiplexers, matrices, video and audio signal transmitting equipment, accessories, components and parts, and image processing and management software.

Access control systems (ACS) of the following types: magnetic card, proximity, code, voice recognition, hand geometry, fingerprint, and retina scanner; accessories, components and parts, and information processing and management software.

Intruder alarm systems. Central alarm units; intruder detectors of the following types: magnetic contact, electrical contact, capacitive, radio frequency, infra-red, passive infra-red, ultrasonic, pressure, vibration, seismic, temperature, and laser; acoustic and visual signalling apparatus.

Central alarm receiving units and remote security system management platforms. Mechanical push button security locks; mechanical security locks; electronic security locks; time control locks; high security padlocks; time locks; reinforced doors; reinforced vault doors; fireproof vault doors; emergency vault doors; explosion-resistant doors; fire doors; reinforced windows and glass; bullet-proof steel armour-plating; day and night deposit boxes; ATMs; panel-reinforced rooms or vaults; data storage safes; security doors; value transfers; counter safes and anti-theft boxes; gun racks; safety deposit boxes for bank vaults; code-reading key copying machines; master key systems including codifiers and decodifiers with software programme; skeleton keys; European Standard high security safes, grades 1, 2, 3 and 4; high security safes, grades TL15, TL30, TL15X6, TL30X6, TRTL15X6, TRTL30X6 and TXTL60; high security coded locks and keys; mechanical combination locks, groups 1, 1R and 2, for use with safes and vault doors; electronic combination locks; electro-mechanical locks and keys; electronically controlled code-operated safes; encoded electro-mechanic transponder systems for motor vehicle security; non-copiable security cylinders.

3. The licensing system applies to goods from any country.

4. Licensing is not intended to restrict the quantity of imports; its purpose is to prevent the entry of security technologies of dubious quality which do not meet the requirements for their use and which are incompatible with the systems used in the country.

5. Decree-Law No. 186/98 on the Security and Physical Protection System, Chapter II, Section 1, concerning the competent authority, Article 3(e), (g), (h) and (j); Resolution No. 2/2001 - Regulations to Decree-Law No. 186/98, Articles 124, 125, 126, 127 and 128. Import licensing is mandatory. Parliamentary approval would be required to abolish the current system.

Procedures

6. Not applicable.

7. (a) There is no requirement as to how far in advance a licence must be requested, but the Protection Directorate has 15 working days from the receipt of the application within which to issue its decision. Under exceptional circumstances, the period for examining the application may be shortened at the Directorate's discretion.

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

   (c) No.

   (d) Consideration of licences is effected only by the Protection Directorate of the Ministry of the Interior (MININT).

8. An application for an import licence may be refused in the event of infringement of Article 124 of Resolution No. 2/2001. The applicant is notified of the reasons for the refusal. Applicants have no right of appeal to the Protection Directorate of the MININT. Licences for non-approved technologies can be issued only when the import is to be used as a sample for the type approval process.

Eligibility of importers to apply for licence

9. Importers must be registered in the National Register for Exporters and Importers of the Chamber of Commerce of the Republic of Cuba.

Documentational and other requirements for application for licence

10. The information required in applications is that specified in Article 128 of Resolution No. 2/2001:

- Importer details.
- Security devices to be imported.
- Make and model.
- Supplier.
- Import destination.

11. Import licence.

12. There is no fee or charge.

13. Not applicable.

Conditions of licensing

14. The period of validity of a licence is not determined.

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

16. Import licences are not transferable between importers.

17. The product must be approved by the accredited national entity (ACERPROT) on the basis of compliance with the technical and environmental standards in force in the country.

Other procedural requirements

18. No other administrative procedures are required prior to importation.

19. Not applicable.

5 MINISTRY OF PUBLIC HEALTH (MINSAP)

5.1 National Pharmaceutical and Optical Directorate (DNFO)

Outline of systems

1. Cuba is party to the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic Substances, 1971, and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. By virtue of the implementation of the international trade control-related provisions of these Conventions, in Cuba imports and exports of narcotic drugs, psychotropic substances, precursors and basic chemicals are subject to an import licensing system which is supplemented by a planning system covering medical, scientific and other legitimate needs, and a group of administrative measures aimed at preventing the possible diversion of these substances towards unlawful channels at any stage of their transit.

All national entities (legal persons) operating with these substances are registered in a central register at the Narcotic Drug and Psychotropic Substance Administration, which is the drug control department of the National Pharmaceutical Directorate of the Ministry of Public Health (MINSAP). They must already have registered in the National Register of Exporters and Importers of the Chamber of Commerce of Cuba and the Central Register of the Customs General of the Republic.

Purposes and coverage of licensing

2.

- Narcotic drugs regulated by the Single Convention on Narcotic Drugs, 1961.
- Psychotropic Substances regulated by the Convention on Psychotropic Substances, 1971.
- Precursors and basic chemicals regulated by the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

Purposes of licensing: Compliance with the obligations deriving from the above-mentioned international conventions, prevention of the diversion of these substances from their lawful circulation channels, and ensuring that medical and scientific needs are met.

3. The import licensing system is applied on the basis of the above-mentioned classification to goods from all countries without exception.

4. Licensing is not intended to restrict the quantity or value of imports. Limits on quantities for import are consistent with the estimates system established by the international treaties in which all member States participate. The estimates system is administered by the International Narcotics Control Board (INCB) and aims to meet legitimate needs for these substances while preventing illicit trafficking and diversion from lawful international trade channels.

The estimates system administered by the INCB works well and obtains excellent results, and therefore does not affect imports: on the contrary, it contributes to orderly import activity at international level.

5.

- Ministerial Resolution No. 58 of 1967, Standards and Procedures for the Control of Narcotic Drugs, in accordance with the provisions of the Single Convention on Narcotic Drugs, 1961.
- Ministerial Resolution No. 72 of 1990, which implements the provisions of the Convention on Psychotropic Substances, 1971.
- Ministerial Resolution No. 67 of 1996 - Regulations for the Control of Precursors and Basic or Essential Chemicals, which implements the provisions of the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

Import licensing is mandatory and is governed by specific legislation.

Procedures

6.I. Once officially registered, the importer is automatically notified of the formalities to be completed when submitting an application for an import licence, and of the statutory rules and procedures.

Information relating to the approved estimates for the country is officially published by the INCB and distributed to each country in printed form. It is also available on the INCB website. Once the estimates are known, the quotas are allocated and the importers so informed as of January each year.

There are no exceptions or derogations from the licensing requirement. Anyone operating with the above-mentioned substances is required to obtain an import licence.

II. Import quota size is determined on a yearly basis. The approved quotas are officially published by the INCB. Licences are valid from their date of issue until 31 December each year.

III. In the case of the above-mentioned substances which we are responsible for controlling, their final destination and end use must be stated each time an import licence is requested. There are also various levels of State supervision which make it possible to ascertain the lawfulness of these transactions.

IV. At any time of the year, although it is recommended that import licence applications be submitted, preferably, during the first quarter of the year.

V. The processing period for import licence applications is 15 working days as of the date when the application is submitted.

VI. Not applicable. This depends on the period of time established by the exporting country's competent authority for the granting of the export licence once the corresponding import licence has been received.

VII. Import licence applications are considered solely by the Narcotic Drug and Psychotropic Substance Administration of the National Pharmaceutical Directorate of the MINSAP, which is registered with the United Nations as the competent national authority for the purposes of the implementation of the above-mentioned international treaties regarding the monitoring and control of drugs for medical and scientific use and chemical precursors.

VIII. All applications are dealt with on a first come, first served basis and in accordance with established priorities. New importers are directly incorporated into the control system once the established legal requirements have been met.

IX. This is not applicable in the case of narcotic drugs, psychotropic substances and precursors. The licensing system applies to imports and exports alike and is mandatory both for the countries in which the goods originate and for those for which the goods are destined.

X. Under the above-mentioned treaties, export permits must be endorsed by the competent national authority of the importing country and subsequently returned to the competent national authority of the exporting country. Cuba is also party to the pre-export notification mechanism, which is applied to products classified as precursors and basic chemicals.

XI. Not applicable.

7. (a) Applications must be submitted at least 15 days before the imports arrive in the country.

(b) Yes, it can, provided that the request is duly justified and the established requirements have been met.

(c) Not applicable.

(d) Import licence applications are considered solely by the Narcotic Drug and Psychotropic Substance Administration of the National Pharmaceutical Directorate of the MINSAP, which is registered with the United Nations as the competent national authority for the purpose of implementation of the above-mentioned international treaties in respect of the monitoring and control of drugs for medical and scientific use and chemical precursors.

8. An import licence application may be refused if it is shown to fall short of the established legal formalities and technical requirements, or if there is any indication of a risk to the country. Wherever possible, the applicant is directly notified of the reasons for the refusal.

Eligibility of importers to apply for licence

9. Importers must be registered in the Central Register for Importers and Exporters at the Pharmaceutical and Optical Directorate of the MINSAP.

Any legal entity may register provided that it is already registered in the National Register of Exporters and Importers of the Chamber of Commerce of Cuba and the Central Customs Register of the Customs General of the Republic.

Documentational and other requirements for application for licence

10. Applications for import licences must contain the following information:

- Name and legal domicile of the importer and exporter.
- The entity's registration number in the National Register for the Monitoring of Controlled Substances.
- Telephone number, fax number and email address of the importer and exporter.
- Generic name of the narcotic drug, psychotropic substance or substance with similar effect.
- International Non-proprietary Name (INN), if any.
- Harmonized system code.
- Quantity of product with measurement units expressed in letters and numbers.
- Product description: presentation, packaging, pharmaceutical form and dose of the product in the case of pharmaceutical preparations.
- International sales contract number, where appropriate.
- Declaration as to the use and final destination of the substance, identifying the client or the user of the substance.
- In the case of imports of pharmaceutical preparations, the registration number issued by the Centre for State Control of Medicinal Product Quality.
- Anticipated date of arrival of goods in the case of imports or anticipated date of departure in the case of exports.
- Authorized customs points where the goods declaration will be presented upon arrival in or departure from the country. In the case of exports, the customs entry point in the importing country must be stated.
- Date of application.
- Signature of the director or manager of the requesting entity and official stamp.

In the case of exports, the import permit issued by the importing country's competent national authority for drug control must also be presented.

11. The export permit issued by the exporting country's competent national authority for drug control.

12. Not applicable.

13. Not applicable.

Conditions of licensing

14. Licences are valid from the date on which they are issued until the 31 December of each year. They cannot be extended. In the event of expiry, a new application must be submitted.

15. There are no penalties for the non-utilization of a licence or a portion of licence, or if the licence expires or is suspended, as a licence is required for each individual transaction.

16. Licences are not transferable.

17. No other conditions are attached to the issuing of a licence, unless an official investigation or official supervision is required.

Other procedural requirements

18. No other administrative procedures are required prior to importation.

19. Not applicable.

5.2 Institute of Hygiene, Epidemiology and Microbiology (INHEM)

Outline of systems

1. Health Registration of foodstuffs, raw materials, food additives, materials, equipment or utensils in contact with food, cosmetics, products for personal hygiene or use, toys, products manufactured from tobacco, products and technologies to treat water for consumption, industry or recreation.

A licence is required to import raw materials, foodstuffs, food additives, materials, equipment or utensils in contact with food, cosmetics, products for personal hygiene or use, toys, products manufactured from tobacco, products and technologies to treat water for consumption, industry or recreation, equipment and utensils for food use that incorporate these items. The purpose of this requirement is to ensure that commercial certainty, the hygiene status and use of these items at national level are maintained at the levels and within the ranges that are authorized under international commitments.

Purposes and coverage of licensing

2. The purpose of the system is to use Health Registration to control the health-related aspects of products marketed and distributed in Cuba.

3. The licensing system applies to all raw materials, ingredients, food products, materials in contact with food, food additives, equipment and utensils for food use, regardless of the countries they originate in or come from.

4. The purpose is to assess and monitor with a view to approving or not approving a foodstuff as fit for human consumption or human use; the assessment ascertains physical, chemical, biological and toxicologic properties using laboratory analyses in accordance with the health standards in force. Health or other certificates issued by the competent authorities must be submitted prior to such analyses, enabling Cuba to comply with its obligations as a signatory to the WTO SPS Agreement on food safety based on the Codex Alimentarius standards.

5. Law No. 41 on "Public Health"; MINSAP Resolution No. 64/1997. Import licensing is mandatory. The legislation specifies the products covered by this licensing system.

Procedures

6. Not applicable.

7. Where there is no quantitative limit on the importation of a product or on imports from a particular country:

(a) Licence applications must be submitted before importation.

(b) Goods arriving in port without a licence must hold approval from the State Health Inspectorate which by way of exception will determine the methodology to use on a case-by-case basis.

(c) A licence cannot be granted immediately upon request.

(d) There are no limitations as to the period of the year during which the licence application may be submitted or the importation effected.

8. Importing entities are required to register their products and their destinations with the Health Registration Authority prior to importation.

The Health Registration Authority is supported in the performance of its duties by a Committee of Expert Advisers, specialist Technical Committees and test laboratories accredited by the Cuban National Institute of Hygiene, Epidemiology and Microbiology and Nutrition and Food Hygiene Institute (INHEM-INHA).

The Committee of Experts analyses the products submitted to it for consideration and makes a decision on each one, as follows:

Authorized: Indicates that the product satisfies all the requirements laid down by the health authority.

Provisionally authorized: Indicates that the product, its packaging and/or labelling has failed to satisfy one of the non-essential requirements laid down by the competent health authority and lays down a time-limit for compliance. If the product fails to satisfy the requirements upon the expiry of the time-limit, it will be classed as prohibited.

Prohibited: Indicates that the product does not satisfy the conditions relating to nutrition, hygiene and/or presentation required for distribution in Cuba.

Products deemed by the Committee of Experts to be "Pending" will have a maximum of 30 days from the date they are declared "Pending" for the client to supplement the information required or to comply with any other stipulation laid down by the committee. If the requirement is not complied with in the allotted time-frame then the product in question will be discontinued and removed from the Health Registration procedure.

The maximum period allowed for a technical opinion on the product will be 20 working days counted from the submission of the sample with documentation until the date of the final decision, depending on the type of analysis required.

Issuance of a Health Certificate:

Once a product has been approved, a Health Certificate for it will be drawn up and issued. It will be valid for three years unless the product proves to be harmful to health or the certificate is withdrawn at the request of the party concerned.

An application for an import licence may be refused if any of the requirements set forth in the legislation is not met; the applicant is notified in writing of the grounds for the refusal. No appeal lies from a refusal.

Eligibility of importers to apply for licence

9. Those eligible to apply are Cuban or non-Cuban legal person that takes on certain powers under contract from a manufacturer or owner of raw materials, foodstuffs, cosmetics, items for personal or domestic use, toys, products and technologies to treat water for consumption, industry or recreation and products manufactured from tobacco in Cuban territory.

Documentational and other requirements for application for licence

10. In order to submit an application for Health Registration, a producer, importer and/or marketing business must be registered with the Health Registration Authority, a process that requires them to submit:

- A list of general information.
- Photocopies of the licences from the National Register of Foreign Representations and the Chamber of Commerce of the Republic of Cuba for the authorized activity, or a Ministry of Foreign Trade Resolution for products for import or a Health Licence from the producing establishment and the corporate purpose of the entity for domestic products.
- Each registered entity must keep the information upon which accreditation is based up to date, and modify it in line with any changes.
- Only a business or entity that is in compliance with these requirements can make an application to the Registration Authority in respect of its products.

11. The documents required are the certificate of registration with the Health Registration Authority and a Health Import Permit.

12. The system requires advance payment for Health Registration and the cost of laboratory analyses conducted on the samples that applicants are required to submit. The amount varies according to the tariff applicable to the product.

13. Not applicable.

Conditions of licensing

14. Licences are valid for three years. They must be renewed three months before they expire via the submission of technical files, certification and samples but the fee is half that for the initial application. After that time, the licence expires and the product is regarded as a new product.

15. Not applicable.

16. Yes, licences are transferable where authorized by the holder of the original import registration.

17. Not applicable.

Other procedural requirements

18. The Health Registration Authority reserves the right, where it deems it relevant, and in conjunction with the State Health Inspectorate, to conduct a technical visit to the producer, marketing or controlling entity prior to issuing or during the period of validity of registration to establish the degree to which the products comply with the requirements to which they are subject.

19. Not applicable.

5.3 Centre for State Control of Medicines, Medical Equipment and Devices (CECMED)

5.3.1 Control of imports of medicines for human use

Outline of systems

1. Regulation by Import Control is the means used by the Ministry of Public Health ("MINSAP") to prevent the commercial importation of medicines for human use that are of questionable quality or efficacy or that have been adulterated or tampered with, the use of which may pose a risk to people's health.

Purposes and coverage of licensing

2. Covers medicines for human use.

3. There are no country-based restrictions; all medicines for human use brought into Cuba are covered by the system regardless of their country of origin.

4. Licensing is intended to prevent the commercial importation of medicines for human use that are of questionable quality or efficacy or that have been adulterated or tampered with, the use of which may pose a risk to people's health.

5. MINSAP Ministerial Resolution No. 65 of 2003 and CECMED Resolution No. 83 of 2003. The procedure is mandatory for the products covered.

Procedures

6. Not applicable. There are no restrictions as to the quantity or value of the medicines; a licence is awarded strictly on health grounds. The regulations and procedures are published on the authority's website at http://www.cecmed.cu.

7. (a) The application for an Importation Certificate for medicines for human use may be made before or after shipment of the products covered by a contract, at the applicant's discretion, by submission of the appropriate form drawn up to that end listing one or more products, provided they are all part of the same contract and shipment; the CECMED has up to five days to issue the permit following receipt of the application.

(b) The prescribed processing time is short: a certificate is usually issued in less than five working days and where necessary or in a Health Service emergency the process can be speeded up.

(c) Not applicable, the certificate is delivered for each individual shipment.

(d) No.

(e) No.

8. An application for a licence may be refused if the products are not registered; if the expiry date or shelf-life of medicines for human use is less than one year following entry into Cuba; or if medicines for human use are not labelled as required in Spanish (including the patient information leaflet), regardless of whether or not the relevant information appears in another language, in accordance with the "Requirements for Applications for Registration, Renewal and Modification to the Register of medicines for human use" in force.

The applicant is notified of the reasons for the refusal.

Eligibility of importers to apply for licence

9. Authorized/accredited importers may import medicines.

Documentational and other requirements for application for licence

10. Form issued by the authority.

11.

- Import Certificate Application on the relevant official form (original and two copies).
- Document attesting to the quality of each of the batches of medicine included in the import application, such as: copy of Analysis Certificates from the original manufacturer or other national or foreign establishments or laboratories, Quality Certificate or other document in which the supplier assumes responsibility for the quality of the batches.
- Samples or photocopies of the labels on the packing materials for medicines for human use where the information is not in Spanish (including the patient information leaflet) for the exceptions provided for in Article 8(2).
- Copy(ies) of the letter(s) in which the receiving establishment(s) accept the import of medicine(s) for human use whose expiry date is less than one year at entry into the country and stating that they are aware of the shelf-life(ves) and that the remaining shelf life(ves) and quantity(ies) of product are such that they can be used prior to their expiry.

If at the time of submitting an import certificate application the applicant does not have the documents referred to in point 2 of this article, import may be authorized subject to the condition that the products covered by those documents are retained; the documents will need to be submitted at a later date as part of an application for clearance of batches for distribution.

The CECMED reserves the right to request additional information of any kind where it deems it relevant to do so.

12. The procedure costs 25 Cuban pesos.

13. Not applicable.

Conditions of licensing

14. The Import Certificate is issued for each shipment and covers those product(s) contained in the shipment in line with the properties and quantities specified in the certificate. The certificate is valid for up to six months.

No extension is possible; under the regulations when medicines for human use covered by a contract are received in two or more separate shipments a new Import Certificate must be applied for each shipment of the amount outstanding because the same document cannot be approved twice, nor can it be subject to corrections or clarifications that may interfere with its proper interpretation.

15. Not applicable.

16. Not applicable.

17. Not applicable.

Other procedural requirements

18. No administrative procedures are required prior to importation; however, as explained above, a medicine must be registered before it enters the country.

19. Not applicable.

5.3.2 Control of crossborder movement of samples of biological material

Outline of systems

1. The control of crossborder movement of samples of biological material is the means used by the Ministry of Public Health ("MINSAP") to ensure compliance with the national and international standards and provisions in force on the movement into or out of the country of samples of biological material with the aim of preventing risks to health.

Purposes and coverage of licensing

2. It covers any specimen or portion of cells and their components, tissues, organs and biological liquids (serum, plasma, blood, saliva, tears, urine, sweat, semen, nasopharyngeal and vaginal exudates, and cerebrospinal fluid), microorganisms and others that may pose a risk to human health.

3. The system applies to material originating in and coming from any country.

4. Not applicable.

5.

- MINSAP Ministerial Resolution No. 132 of 2004.
- Health Protection Regulation Bureau Resolution No. 8 of 2007.

Procedures

6. Not applicable, there is no restriction as to the quantity or value, this is a health monitoring system.

7. (a) The application must be made before the movement is under way and upon receipt of notification of shipment; however, if necessary, an application may be made with the product at Customs.

(b) Yes, as stated above, when the product is in Customs the person concerned can liaise with the centre to obtain a licence as quickly as possible provided that the requirements have been satisfied.

(c) No.

(d) Not under this system; however products of this type are subject to regulation by other bodies and sometimes a single product requires more than one licence (CITMA, IMV) before it can be removed from Customs.

8. The circumstances under which an application may be refused are within the ordinary criteria, if the product in question poses a risk to health or does not satisfy the conditions laid down for its transportation.

Eligibility of importers to apply for licence

9. In this case, a health licence can be applied for by natural or legal persons.

Documentational and other requirements for application for licence

10. Form issued by the authority.

11. Application on the relevant official form.

- Approval of the MINSAP CITMA Committee for research projects. For research projects that involve the movement of samples of biological material on separate occasions that have received prior approval, the initial licence granted will be declared and referred to (licence number).
- Technical report from the Haematology and Immunology Institute for samples of bone marrow.
- Notification from the Vice-Ministry of Health Care for samples for clinical diagnostic purposes.
- For human DNA samples, official notification from the CNGM stating that the control samples have been deposited.

12. Not applicable.

13. Not applicable.

Conditions of licensing

14. The period of validity is three months; if the material in question has not arrived within that time an application for an extension can be made by re-submitting the documentation (form).

15. Not applicable.

16. Not applicable.

17. Not applicable.

Other procedural requirements

18. If the samples are part of a research project then the project must have been approved by the MINSAP CITMA Committee and their methodology requires a set of licences from other bodies.

19. Not applicable.

5.3.3 Import of raw materials, medicines for human use, diagnostic devices, cosmetics and items for personal or domestic use of animal origin or containing components of animal origin

Outline of systems

1. The appropriate import licence issued by the Centre for State Control of Medicinal Product Quality or the Health Registration, Control and Quality Department, as appropriate, must be held in order to import raw materials, medicines for human use, diagnostic devices, cosmetics and items for personal or domestic use of animal origin or containing components of animal origin.

Purposes and coverage of licensing

2. Covers raw materials, medicines for human use, diagnostic devices, cosmetics and items for personal or domestic use of animal origin or containing components of animal origin.

3. There are no country-based restrictions; all medicines for human use brought into Cuba are covered by the system regardless of their country of origin.

4. Licensing is intended to prevent the entry into Cuban territory of raw materials, medicines for human use, diagnostic devices, cosmetics and items for personal or domestic use of animal origin or containing components of animal origin that are capable of infecting humans with transmissible animal diseases.

5. Ministry of Agriculture and Ministry of Public Health Joint Resolution No. 2/2001 and BRPS Resolution No. 8 of 2007. The procedure is mandatory for the products covered.

Procedures

6. Not applicable. There are no restrictions as to the quantity or value of the medicines; licences are awarded strictly on health grounds. The regulations and procedures are published on the authority's website at http://www.cecmed.cu.

7. Where there is no quantitative limit on the importation of a product or on imports from a particular country:

(a) The application for an Importation Certificate for medicines for human use may be filed before shipment of the products covered by a contract by submission of the appropriate official form drawn up to that end, listing one or more products, provided they are all part of the same contract and shipment; the CECMED has up to five days to issue the licence following receipt of the application.

(b) The prescribed processing time is short: a certificate is usually issued in less than five working days and where necessary or in a Health Service emergency the process can be speeded up.

(c) Not applicable, the certificate is delivered for each individual shipment.

(d) No.

(e) Depends on the product, CECMED, for cosmetics the Health Registration, Control and Quality Department at the INHA.

8. An application may be refused where products are deemed to pose a high health risk or are from high-risk countries.

The applicant is notified of the reasons for the refusal.

No appeal is provided for in the regulations but depending on the reasons for the refusal, the applicant must demonstrate that the product does not pose a risk to health.

Eligibility of importers to apply for licence

9. Authorized/accredited importers may import medicines.

Documentational and other requirements for application for licence

10. Form issued by the authority.

11.

- Import Certificate Application on the relevant official form (original and two copies).
- Certificates from the Official Veterinary Services of the country of origin containing the information set out in the Third Paragraph and in Annex 2 to Ministry of Agriculture and Ministry of Public Health Joint Resolution No. 2/2001.
- Copies of the Analysis Certificates for each of the product batches included in the application.
- Express permission or authorization from the Ministry of Public Health for medicines and cosmetics that are unregistered or for which no Provisional Marketing Licence has been issued.

In this case, the following information must also be submitted:

a. Product data:

   - Generic name.
   - Trade name.
   - Pharmaceutical form and strength (for medicines).
   - Product type (for cosmetics and items for personal or domestic use).
   - Presentation.
   - Manufacturer.
   - Country.
   - Marketing entity.

b. Quality specification or technical standard of the product.

c. Assessment of suppliers and reasoning behind the choice made.

d. Batch release certificate issued by the Regulatory Authority of the country of origin.

Express permission or authorization from the Ministry of Public Health for raw materials used in the manufacture of medicines or cosmetics that are unregistered or for which no Provisional Marketing Licence has been issued.

In this case, the following information must also be submitted:

e. Product data.

   - Generic name.
   - Trade name.
   - Physical state.
   - Presentation.
   - Manufacturer.
   - Country.
   - Marketing entity.

f. Quality specification or technical standard of the product.

g. Assessment of suppliers and reasoning behind the choice made.

h. Batch release certificate issued by the Medicines Regulatory Authority of the country of origin.

For products undergoing research and development the Import Licence application must be supplemented either upon submission or prior to submission by an explanation from the research entity as to the use of the raw materials or the product in question.

12. Not applicable.

13. The procedure costs 25 Cuban pesos.

Conditions of licensing

14. Up to six months. When medicines for human use covered by a contract are received in two or more separate shipments, a new Import Certificate must be applied for each shipment of the amount outstanding because the same document cannot be approved twice, nor can it be subject to corrections or clarifications that may interfere with its proper interpretation. A licence cannot be extended.

15. No. The penalties provided for relate to the possibility of unlicensed hazardous products entering the country.

16. Not applicable.

17. Not applicable.

Other procedural requirements

18. Not applicable.

19. Not applicable.

6 MINISTRY OF LABOUR AND SOCIAL SECURITY (MTSS)

6.1 Centre for the Certification of Personal Protective Equipment

Outline of systems

1. Article 141 of Law No. 116 containing the Labour Code stipulates that "it is the duty of the Ministry of Labour and Social Security (MTSS) to propose general policy on labour protection and safety and to approve personal protective equipment that is produced or imported", in order to regulate this process. MTSS Resolution No. 7 of February 2013 specifies that the Centre for the Certification of Personal Protective Equipment attached to the Ministry is responsible for organizing and implementing, as appropriate, all activities relating to the validation of equipment of this type to be distributed and used by workers in Cuba.

It is an administrative procedure aimed at ascertaining compliance with the technical requirements for the equipment in accordance with the stipulations of the national or international rules in force. To our knowledge, no country has an established system of import licences with this objective, with all the flexibility the process requires.

Purposes and coverage of licensing

2. The purpose of the administrative procedure to which we refer is to assess, register and approve personal safety equipment on the basis of a paper-based check, physical examination of the equipment and its branding, and having regard to the standards that endorse them and performance in certain tests for which there are facilities in Cuban laboratories.

The analysis culminates in a technical report or certificate stating whether the equipment satisfies the requirements in each case. It also classifies the equipment into category I, II or III; there are differences between the categories as to the documentation and analytical rigour required, and variations in the period of validity of certification, all of which depend on the magnitude of the risks that the equipment protects against.

3. The system applies to goods produced domestically (mostly saddlery equipment) and imports and is restricted as noted above to workers' personal safety equipment, meaning devices or items worn by workers to protect them against one or more risks to their safety or health and the parts, components or accessories to such equipment, including protective equipment used in the health system. In line with international practice, the only exceptions from this procedure are items used by armed services, the fire and rescue service, sports people and means of transport.

The chief area of origin is Latin America, followed by Europe and Asia. A distinction must be drawn between "originating in" and "coming from", however. Where origin or place of manufacture is concerned, Europe is the main area.

4. The procedure is in no way intended to restrict the quantity or value of imports. Rather its aim is to ensure compliance with the protective characteristics of the equipment under assessment.

The method of analysis is mainly paper-based, as noted above. Consideration has been given to the idea of using technical tests on the various types of equipment, but the number of tests necessary for each type and their cost are high and only more developed countries have the resources to conduct them all. Nonetheless, a proposal has been made to conduct a set of basic checks on safety equipment for situations that arise most frequently or pose the greatest risk.

5. The basic laws or regulations that provide the legal basis for the procedure are Law No. 116 of 12 June 2014 containing the Labour Code and MTSS Resolution No. 7 of February 2013, which establishes the Centre for the Certification of Personal Protective Equipment as the body with responsibility for organizing and implementing all activities relating to the validation of equipment to be distributed and used by workers in Cuba.

Procedures

6.I. There are no restrictions on the import of products other than limits on finance and the resources available in Cuba for its acquisition. The legal basis underpinning the administrative procedure established for the registration and approval of personal protective equipment is published in the Official Journal and on the MTSS website.

II. There are no restrictions on the size of quotas, as noted above. The period of validity for approvals of equipment for import and marketing in Cuba varies between three and five years depending on the category of equipment involved.

III. No such restrictions exist.

IV. Not applicable.

V. Once the application has been received from the applicant with the samples and documentation required, the Centre has a maximum period of 20 days to complete the procedure, counted from the receipt of the application to raising an invoice for its services and notifying the applicant. The period is often less, however, and averages between 10 and 15 days.

VI. The Centre issues a certificate rather than a licence and the time available depends on the interested party's promptness in submitting the application and on whether the samples and documentation are delivered on time and in due form.

VII. The Centre for the Certification of Personal Protective Equipment is the competent body solely for the assessment, registration and approval of personal protective equipment to be imported or produced for distribution and use in the country. The applicant may have to undergo other procedures, but this process might be streamlined using the Single Window (VUCE) system that is currently under consideration in Cuba.

VIII. Not applicable.

IX. Not applicable.

X. Not applicable.

XI. Not applicable.

7. As stated in point VI, the time available to the licence holder to perform these procedures depends on how promptly the application is submitted and on whether the relevant documentation and samples are delivered on time and in due form.

(a) The approval of products arriving in port without the appropriate certification is contrary to the established rules and is only possible when authorized at a senior level in the MTSS.

(b) Certification is not possible unless accompanied by the relevant analysis. However, the process may be quicker for renewals of previously registered and approved equipment, and attracts a lower tariff than first-time approvals.

(c) There are no limitations of that kind.

(d) See point VII.

8. An application for registration may be refused where:

- The equipment in question is not personal protective equipment under the criteria referred to above.
- The documentation or samples delivered by the applicant do not satisfy the requirements.
- The equipment is shown to have been subject to fraud or alteration.

The applicant is notified of the report in such cases and may appeal to the next highest level of the Ministry of Labour and Social Security.

Eligibility of importers to apply for licence

9. MTSS Resolution No. 7 of 2013 deems that legal personality to engage in registration procedures is vested in importers, producers and marketers of personal protective equipment; and in any user entities that use such equipment and are authorized to import them for their own use, such as joint ventures, provided that they submit the evidence required to that end and satisfy the other requirements.

Documentational and other requirements for application for licence

10.

- The information listed in Form 1 delivered by the authority.
- For Foreign Commercial Field Offices, a copy of the Trading Licence from the Chamber of Commerce of the Republic of Cuba and the list of equipment must be attached.
- For entities operating from abroad, a copy of the Articles of Association of the entity in its country of origin notarized by the Consulate of Cuba in that country or at an International Notary's Office in Cuba.
- Cuban producers or trading entities must attach a copy of the MINCIN Central Commercial Registration to their application.

For registration and approval of the equipment:

- The information listed in Form 2 (attached).
- Declaration of Conformity by the equipment's manufacturer.
- Approval Certificate issued by an accredited independent laboratory in the country of origin.
- Technical fact sheet on the equipment.
- Physical sample of the equipment with minimum branding for the purposes of identification (trademark, model and reference number).

11. The Certificate or Technical Report attesting to its approval. It is drawn up at the end of the relevant assessment process and is valid for the period specified in paragraph 14 below.

12. The tariffs payable for the service are set out in Ministry of Finance and Prices Resolutions No. P-84 of 2001 and No. P-83 of 2005.

13. There are no requirements of this kind.

Conditions of licensing

14. The period of validity of registration certificates for equipment depends on the category of the equipment, as follows:

- Equipment in Category I: 5 years.
- Equipment in Category II: 4 years.
- Equipment in Category III: 3 years.

15. There are no penalties or charges of this kind.

16. The rights conferred by registration of equipment to a licence-holder cannot be transferred to another licence-holder unless the change is to the name of the commercial entity and evidence is produced to that end.

17. Not applicable.

Other procedural requirements

18. Not applicable.

19. There is no provision for mechanisms of this kind.

7 NATIONAL INSTITUTE OF HYDRAULIC RESOURCES (INRH)

7.1 National Hydraulic Works Directorate

Outline of systems

1. Executive Committee of the Council of Ministers Agreement No. 3954 on Administrative Control of 26 March 2001 states that the duties and powers of the National Institute of Hydraulic Resources include the planning, regulation and control of hydraulic resources and the operation, technical oversight and maintenance of hydraulic works and installations.

Agreement No. 5, adopted by the Drought Panel on 9 July 2005 confers responsibility upon the National Institute of Hydraulic Resources by promulgating a regulation prohibiting the importation of water-intensive sanitation equipment, fittings and furnishings, in line with worldwide trends and the legislation in place.

Resolution No. 28 of 28 February 2006 of the President of the National Institute of Hydraulic Resources laid down the water consumption standards for water-intensive sanitation equipment, fittings and furnishings and the energy efficiency ratings required for electric pumps. It further provided that technical approval had to be obtained from the Institute prior to the importation into Cuba or production in Cuba of such devices. These rules will have to be refined in line with the developments in technology.

Purposes and coverage of licensing

2. The purpose of licensing is to down water consumption standards for water-intensive sanitation equipment, fittings and furnishings and the energy efficiency ratings required for electric pumps.

3. The import licensing system is applied on the basis of the above-mentioned classification to goods from all countries without exception.

4. The licensing procedure is not intended to restrict the quantity or value of imports but to ensure that imported products comply with the standards laid down in respect of water-intensive equipment and quality and energy efficiency standards for electric pumps.

5. Ministry of Construction Resolution No. 655/2009.

Procedures

6.I. Resolution No. 655/2009 lays down the procedures for applications and technical import authorizations for the devices in question (attached hereto as Annexes 3, 4 and 5).

There are no exceptions or derogations from the licensing requirement. Anyone importing the above-mentioned devices is required to obtain an import licence.

II. Technical import authorization is delivered for each signed contract or commercial offer that includes the above-mentioned devices within its scope.

III. An application for authorization must be made for all devices, whether produced in Cuba or abroad.

IV. Applications must be submitted at least 72 hours prior to the dates specified in V below. Refusal will be notified in a document setting out the grounds for the refusal.

V. The 10th, 20th and 30th of each month.

VI. Not applicable.

VII. Applications for import licences are considered only by the National Hydraulic Works Directorate at the National Institute of Hydraulic Resources.

VIII. All applications are dealt with on a first-come, first-served basis.

IX. Not applicable.

X. Not applicable.

XI. Not applicable.

7. (a) Applications must be submitted at least 72 hours prior to the dates specified in V above.

(b) Yes, it can, provided that the established requirements have been met.

(c) Not applicable.

(d) Applications for import licences are considered only by the National Hydraulic Works Directorate at the National Institute of Hydraulic Resources.

8. An import licence application may be refused if it falls short of the established legal formalities and technical requirements.

Eligibility of importers to apply for licence

9. Not applicable.

Documentational and other requirements for application for licence

10. The forms issued by the authority are for:

- The importation of pumps.
- An application for tapware.

11. Technical Import Authorization (ATI).

12. Not applicable.

13. Not applicable.

Conditions of licensing

14. The technical authorization is valid until conclusion of the contract with the importing undertaking.

15. Not applicable.

16. Import licences are not transferable.

17. Not applicable.

Other procedural requirements

18. No other administrative procedures are required prior to importation.

19. Not applicable.

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