



REPLIES TO THE QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES<sup>1</sup>

NOTIFICATION UNDER ARTICLE 7.3 OF THE AGREEMENT ON IMPORT LICENSING PROCEDURES (2018)

CUBA

The following communication, dated 4 September 2018, is being circulated at the request of the delegation of Cuba.

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<sup>1</sup> 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 Biological diversity**

##### **Outline of systems**

1. Export and import permits are required for all species listed in the Appendices to CITMA Resolution No. 160/11 - "Regulations for the control and protection of species of special significance for biological diversity in the country" as well as species included in the three appendices of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). CITMA Resolution No. 111/96 - "Regulations on Biodiversity" governs the conservation of national biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the use of genetic resources, all plant and animal species and parts and derivatives thereof except for species considered exotic or transgenic. 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 Food Industry, the State sugar enterprise Azcuba, 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 Cuban and non-Cuban natural persons and legal persons.

### **Purposes and coverage of licensing**

2. Species entering the country as animal or plant variety specimens, in the form of holotypes, genotypes, products or derivatives of species and specimens of species.
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, and by means of Resolution No. 16 of 1999, 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. There are no penalties, since no legal instrument contains any provisions to that effect. 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, *inter alia*, 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 and the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction.

### 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 and 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 of 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.
- Resolution No. 2/2004, Regulations governing the accounting and control of biological materials, equipment and technology. Chapter IV, Article 26 establishes the safeguards report as an essential requirement for activities relating to the transfer of biological agents, organisms, equipment and technology.

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 to 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. The timeframe and procedures for the safeguards report are the same as for the biological safety import licence for biological materials, equipment or technology.

(b) In Cuba's 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 appropriate. 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 to the planned activity are needed 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 10 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, e-mail 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 Cuban and non-Cuban 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 a 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, an application for a 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 for conducting 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 a licence to import ionizing radiation sources and attaches the report setting out 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 10 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 licences 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, e-mail 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)**

### **1.4.1 Substances that deplete the ozone layer**

#### **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. ORASEN, together with Cubaenergía, 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), Group Empresarial Comercializadora ITH and Empresa Importadora-Exportadora TECNOTEX.

These importers submit their applications to the CNSQ 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 (Technical Ozone Office, the CNSQ, 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

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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 out 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. Upon receiving the application, ORASEN reviews the documentation supplied and determines within a period of five working days following receipt whether or not to issue the environmental license. The period for issuing a licence concludes within 30 working days as from the date of acceptance of the application by ORASEN. Within that period, ORASEN informs the applicant in writing whether the licence has been awarded or refused.
  - 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 CNSQ (HCFCs). The CNSQ 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.
  - 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. Not applicable
  - 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) No
  - (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 are 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.

### **1.4.2 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 (Res. 96/2004), pentachlorophenol (Res. 96/2004) and ethylene dichloride (Res. 96/2004) are prohibited, as is the industrial use in textile production of polybrominated biphenyls (only polybrominated) and tris (2,3 dibromopropyl) phosphate (Res. 96/2004). The use of polybrominated biphenyls and tris (2,3 dibromopropyl) phosphate for purposes other than textile production is subject to licensing (by the CICA, Res. 96/2004). The industrial use of ethylene oxide for sterilization purposes (Res. 96/2004) 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 (Res. 96/2004), as is the importation of anthophyllite, tremolite, actinolite and amosite (Res. 96/2004).

Any natural or legal person, whether a Cuban national or a foreigner, that possesses in whatever quantity or form any of the pesticides that are prohibited under the first clause of this Resolution shall immediately notify the Director of the municipal hygiene and epidemiology centre or unit in the territory concerned, who shall send a state health inspector within a period of 24 hours from receipt of the notification to guarantee compliance with the current legislation governing pesticides (Res. 268/1990).

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 (Res. 96/2004).

All 192 States Parties to the CWC may market the controlled substances of Schedules 1 and 2 (According to Article V, paragraph 1 of the Convention, "[e]ach State Party has the right, subject to the provisions of this Convention, to develop, produce, otherwise acquire, retain, transfer and use toxic chemicals and their precursors for purposes not prohibited under this Convention"). 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 (according to Article VI, Part VIII C).

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 CWC, 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.

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## 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. Decree-Law No. 202/99 and Resolution No. 32/2003 designate the Secretariat of the National Authority for the Prohibition of Chemical Weapons (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 authorization being 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 must be accompanied by the following:

- 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 issue 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 National Bureau of Standards (ONN)

### Outline of systems

1. Technical authorization is granted by the National Bureau of Standards (ONN), in its capacity as the competent national authority, following verification that the goods being imported comply with the mandatory technical requirements.

### Purposes and coverage of licensing

2. This procedure applies to all importing companies that market products classified as follows pursuant to Resolution No. 30/2018 of the Ministry of Foreign trade and Investment:

**GROUP A:** Measuring instruments and equipment which are subject to metrological control under Cuban Standard NC-OIML-D19:94 "Pattern evaluation and approval" and for which the ONN is the competent national authority for evaluation, approval and registration.

3. All countries.

4. Licensing is not intended to restrict the quantity or value of imports.

5. Decree-Law No. 183 of 23 February 1998 and its regulatory decrees Nos. 270 and 271 of 10 January 2001, and Resolution No. 148 of 23 September 2014 of the Director-General of the National Bureau of Standards.

### Procedures

6. Not applicable.

7.(a) Prior to entering into a contract for the goods with the supplier.

(b) No, because the documents and information provided have to be examined by specialists.

(c) There are no limitations as to when applications may be made.

(d) Consideration of applications is effected by a single body, the ONN.

8. Applicants are informed of the criteria for the approval or refusal of a licence. They have the right to file a written complaint, with attached supporting documentation, in respect of any breach of terms of the contract established with the ONN or the consequences thereof, within 30 calendar days of the breach. The ONN must examine the complaint and respond within 10 days of receipt.

A complaint-response extension of up to 10 working days may be granted. The Parties are bound to settle any dispute regarding the interpretation, implementation, amendment or cancellation of the established contract amicably and in good faith. If no agreement is reached, the dispute must be referred to the Economic Division of the competent People's Provincial Court, as stipulated in Decree-Law No. 241 of 26 September 2006.

### 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. For **Group A** products:

Companies importing and exporting measuring instruments and equipment subject to pattern evaluation and approval must apply to the ONN's Directorate of Metrology for a pattern approval certificate, as established in the "Procedure for the pattern evaluation and approval of measuring instruments". Once they have obtained this certificate, they then have to apply for technical authorization from the ONN's Marketing and Investment Department (DCI) for each contract, which



must be presented to the Customs General of the Republic (AGR) to secure the release of the goods. The ONN, through its accredited inspection bodies, can check compliance with the established pattern evaluation and approval requirements.

For **Group B** products:

Companies importing and exporting products covered by mandatory Cuban standards must apply to the ONN's Marketing and Investment Department (DCI) for technical authorization for each contract.

Applications for technical authorization are submitted to the DCI on the official application form and must be accompanied by the following documents:

- registration certificate issued by the competent national authority for products subject to this requirement;
- certificates of tests carried out on the product in accordance with the corresponding standard;
- management system certificate, if obtained;
- European Conformity (*Conformité Européenne*, CE) mark certificate, if obtained;
- China Compulsory Certification (CCC) mark certificate for products from China;
- certificate of product conformity issued by a certification body;
- any other document demonstrating compliance with international or regional standards.

If need be, agreement must be reached as to any additional documents or information that must be submitted for analysis and subsequent approval or rejection.

The DCI reserves the right to make acceptance of the application conditional upon submission by the applicant of all the technical information required for evaluation. The contract is signed at the time of filing of the application. Applicants importing products that do not have a certificate of conformity demonstrating compliance with the relevant mandatory Cuban standard must apply at least 30 calendar days ahead of time to the Conformity Assessment Directorate of the ONN for batch certification in accordance with the established procedures. Once these steps have been completed, the corresponding technical authorization can be issued.

11. The technical authorization, which must be presented to the Customs General of the Republic (AGR) to secure the release of the goods.

12. Applicants must pay 100% of the total value of the service by cheque or bank transfer once the corresponding pre-invoices, established in line with the current regulations and rates, have been issued.

13. Where no payment is forthcoming, the ONN sends the corresponding trade complaint to the applicant, who is required to review the contents and respond within 10 days of receipt. In the event of the failure of the applicant to make payment, the competent authority will charge a penalty of 0.011% for each day of delay, in line with the maximum default interest rates established pursuant to Decision No. 41 of 14 May 2008 of the Monetary Policy Committee of the Central Bank of Cuba, namely 4% per year in Cuban pesos.

### **Conditions of licensing**

14. A licence is valid for one year. Its validity may be extended by following the same procedure as for the initial application. If an applicant fails to submit the required technical documentation within 30 working days of the date on which the application was filed, the application will be cancelled. If an applicant fails to make payment within 30 days of the date of issue of the pre-invoice, the technical authorization will be cancelled.

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. No.

**Other procedural requirements**

18. Not applicable.

19. Not applicable.

**2 MINISTRY OF AGRICULTURE (MINAG)****2.1 Directorate of Plant Health (DSV)****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 Importers and Exporters of the Chamber of Commerce of the Republic of Cuba. 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 fruit and vegetables originating in fruit fly-free areas, but including those for other uses.

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, rather 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 shipment of the goods from their country of origin. The approval or rejection 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 a 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 in Annex III.

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 is valid for up to one year. Validity may be extended by following the same procedure as for the initial application; indicating the number of the previous phytosanitary licence speeds up the formalities.

15. There are no penalties.

16. No, licences are not transferable between importers.

17. Not applicable.

### **Other procedural requirements**

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 mandatory registration with the Central Registration Authority for Fertilizers in order 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; rather, its purpose is to ensure control of the use in Cuba of substances that may be hazardous to life or have a pollutant effect on the environment.

- 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, which sets out the documents to be submitted with an application for registration, the statutory procedures to be followed and the assessments to be conducted by the Committee of Experts.
  - 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.
7. Where there is no quantitative limit on the importation of a product or on imports from a particular country:
- (a) There are no minimum or maximum lengths of time; the time taken to process an application for a fertilizer before registration in 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.
  - (b) No, the process must run its full course before registration is possible.
  - (c) There are no limitations as to the period of the year.
  - (d) The importer only has to approach the Central Registration Authority for Fertilizers.
8. There are no circumstances other than those described above under which a licence application may 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 are eligible to apply subject to presentation of accreditation in Cuba by the appropriate bodies; natural persons are eligible to apply subject to presentation of a power 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. Applications must contain the following information:
- 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 point 12 above.

### **Conditions of licensing**

14. Licences do not expire provided that the composition and formulation of the fertilizer remain 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 Cuba is concerned, those laid down in relation to registration with the Central Registration Authority for Fertilizers.

19. Not applicable.

## **2.3 Directorate of Animal Health (DSA)**

### **Outline of systems**

1. Sanitary-veterinary regulations governing the importation of animals, animal products, biological products and materials of any origin which are liable to harm animal health and which arrive in national territory by sea or by air.

### **Purposes and coverage of licensing**

2. The purposes of licensing are protection of national territory from the introduction of exotic diseases; prevention and control of animal diseases, including zoonoses; epizootiological monitoring; veterinary drug registration; and sanitary/hygienic control of food of animal origin intended for human consumption or animal feed. The established regulations cover imports of the following:

- (a) live domestic and wild animals of protected species;
- (b) products of animal origin for consumption or for industrial, decorative, experimental or research purposes;
- (c) microbial and parasitic agents that affect animal health;
- (d) vaccines, strains and other similar products used in veterinary medicine;
- (e) culture and diagnostic media with components of animal origin; and
- (f) elements, products and packaging of any origin capable of transmitting or carrying animal diseases.

3. All countries.

4. There is no restriction as to the value or quantity of imports; licensing is solely for sanitary purposes.

5. Law No. 1224, Decree-Law No. 137 and Resolution No. 121 of 1993 of the Ministry of Agriculture (MINAG). Licensing is mandatory.

### **Procedures**

6. There is no restriction as to the value or quantity of imports.

7.(a) Prior to signing the contract with the supplier.

(b) A licence cannot be granted immediately given that the established procedure must be followed.

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

(d) Consideration of applications is effected solely by the Directorate of Animal Health.

8. Without prejudice to whether or not an infringement of the provisions on veterinary medicine has been established, preventive, counter-epizootic, therapeutic and any other measures required may be imposed in respect of ships, aircraft and land transport vehicles of any class deemed to contain organisms, micro-organisms or other animal-disease-carrying or animal-disease-causing agents.

Where required, the preventive detention for further examination of animals, products of animal origin, means of transport and equipment may also be ordered.

The State inspection and sanitary control of food and products of animal origin for human consumption is conducted in the facilities where they are processed or stored or in their means of transport by the Ministry of Agriculture in conjunction with, and under the direction of, the Ministry of Public Health.

The Ministry of Agriculture, in conjunction with the Ministry of Finance, will establish the regulations governing the compensation, where applicable, due to owners in the event of sanitary slaughter under the infectious and contagious disease control programme.

Biological and pharmaceutical preparations produced in Cuba for farming and veterinary activities or for foreign trade are subject to the corresponding controls, in accordance with the standards established by the Ministry of Agriculture. Imported biological and pharmaceutical preparations are subject to controls prior to their use in national territory, in accordance with the quality certification provided by the manufacturer.

### **Eligibility of importers to apply for licence**

9. Entities and institutions are eligible to apply subject to presentation of accreditation in Cuba by the appropriate bodies; natural persons are eligible to apply subject to presentation of a power confirming their accreditation by the entity they represent.

### **Documentational and other requirements for application for licence**

10. All applications for authorization to import animals must be accompanied by the certification issued by the competent authorities of the exporting country, authenticated and certified by the Cuban consular authority, where appropriate.

Applications are granted or refused on the basis of a health risk analysis.

11. The import licence issued by the DSA is required.

12. Yes; the amount charged depends on the type of product.

13. There is no deposit requirement associated with the issue of licences.

#### **Conditions of licensing**

14. Licences are valid for one year; their validity may be extended.

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

16. Licences are not transferable.

17. No.

#### **Other procedural requirements**

18. Before filing an application for an import licence, importers are required to apply to the competent authority for an inspection and sanitary certification visit of the establishments wishing to export to Cuba (MINAG, Directorate of Animal Health) and for registration of the products in question (MINSAP, INHEM Food Register).

19. Not applicable.

### **3 MINISTRY OF THE ARMED FORCES**

#### **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 implementing 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, it is recommended 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:

- (a) date;
- (b) name of requesting entity;
- (c) body to which it belongs;
- (d) address of requesting entity;
- (e) resolution establishing the requesting entity;
- (f) corporate purpose of the requesting entity;
- (g) person responsible for importation (natural person accountable to the entity requesting the licence);
- (h) geographical area in which the equipment will be used;
- (i) technical tactical data concerning the equipment (including photos, wherever possible);
- (j) importing entity;
- (k) 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 regulates their use.

Licences are granted to properly established Cuban 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 decoders 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:

- (a) importer details;
- (b) security devices to be imported;
- (c) make and mode;
- (d) supplier;
- (e) 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.

### **4.2 Fire Protection Agency (APCI)**

#### **Outline of systems**

1. The Fire Protection Agency (APCI) was created pursuant to Resolution No. 5 of August 2003 of the Minister of the Interior with exclusive responsibility to conduct the certification and homologation, in accordance with the relevant technical requirements, of fire protection equipment manufactured in, imported into and/or marketed in Cuba. The APCI is responsible for organizing and implementing, as appropriate, all activities relating to the evaluation of equipment of this type intended for distribution for use in Cuba. The agency's services activity is rooted in its corporate purpose, as updated in Resolution No. 244 of March 2014 of the Ministry of the Economy and Planning.

This procedure seeks to ascertain that fire protection equipment complies with the technical requirements set forth in the national and international rules in force. To our knowledge, no other country has an import licensing system with this objective, with all the flexibility that such a process requires.

### **Purposes and coverage of licensing**

2. The homologation of fire safety products encompasses all of the theoretical and practical evaluation activities that enable compliance with the fire protection requirements laid down in national and international technical standards to be determined and/or the recognition, on the basis of an evaluation of documentation and/or practical testing, of the certification and/or test report issued by a recognized body.

Products are categorized by specialized function.

Categories:

- A. Electrical equipment.
- B. Ventilation equipment, heating equipment, flammable liquids and combustible gases.
- C. Fire alarm systems and similar products.
- D. Fire protection equipment.
- E. Fire barriers.
- F. Construction materials.
- G. Fire resistance.

An applicant who presents a product that corresponds to one that has already been homologated by the APCI (same producer, brand and characteristics, but a different supplier if the applicant is not the manufacturer) must still demonstrate, by means of documentation, samples, etc., that it is indeed the exact same product. An official certificate will then be issued and the new product recognized and included in the list of homologated and approved products. The period of validity will correspond to that of a new product.

Where the product presented has the same trademark as a product that has already been homologated but was produced in another country, it will be subject to the homologation and approval process in accordance with the corresponding specific characteristics.

### **LIST OF PRODUCTS SUBJECT TO HOMOLOGATION AND APPROVAL AND REQUIRING ASSESSMENT IN ACCORDANCE WITH THEIR CATEGORY CLASSIFICATION**

#### **Fire resistance**

- Floor-ceiling designs - Concrete with cellular steel floor units (S-Deck).
- Floor-ceiling designs - Concrete with steel floor units.
- Floor-ceiling designs - Concrete and steel joists.
- Floor-ceiling designs - Reinforced concrete.
- Floor-ceiling designs - Wood joist assemblies.
- Beam designs for floor-ceiling assemblies.
- Roof-ceiling designs.
- Beam designs for roof-ceiling assemblies.
- Wall and partition designs.
- Column designs.
- Interior wall system designs.
- Exterior wall system designs.

#### **Construction materials**

- Air-conditioning systems and components thereof: ducts, filters, connectors, dampers, acoustic material, sealants, adhesives.
- Construction materials: mineral wool and insulation blankets, laminated wall panels, composite wall panels, floor boards, wall coatings and finishes, floor coatings and finishes, fire-retardant coatings, spray-applied mineral wool, insulation, pipes, cladding materials, doors and gates, fittings and hardware for escape route doors, fire doors and emergency exit doors, fittings and hardware for fire-resistant lift doors, fire-resistant windows, glass blocks, decorative fabrics for other purposes, decorative false ceilings, etc.

**Fire barrier systems and components thereof**

- Intumescent paint (primer, undercoat and topcoat) for metal.
- Fire-retardant paints and varnishes (primary stain, varnish finish coat) for wood.
- Fire-resistant mortar.
- Fire-resistant filler.
- Spray-applied mineral wool.
- Ceramic tiles.
- Fire-resistant silicone.
- Fire-resistant clamps.
- Fire-resistant grilles.
- Fire dampers.
- Fire doors.
- Fire-resistant windows.
- Fire-resistant drywall panels.
- Mineral wool panels.

**Fire protection equipment**

- Portable fire extinguishers: water, water with additives, foam, gas, powder, etc.
- Manually transportable fire extinguishers: water, water with additives, foam, gas, powder, etc.
- Automatic fire extinguishers: water with additives, foam, gas, powder, etc.
- Fire extinguishers. Spare charges, fire extinguisher cabinets, boxes and covers.
- Fire-extinguishing systems with dry extinguishing agents: powder, etc.
- Fire-extinguishing systems with wet extinguishing agents: water with additives, potassium acetate and potassium chloride, etc.
- Gaseous fire-extinguishing systems: CO<sub>2</sub>, argon, nitrogen, FM-200, FE-13, NOVEC 1230, etc.
- Water-mist and water-spray extinguishing systems.
- Low-, medium- and high-expansion foam extinguishing systems.
- Compressed air foam extinguishing systems.
- Fittings, components and spare charges for the above systems. Nozzles and diffusers. Support brackets and fasteners.
- Fire-fighting pumps and pump units.
- Pipes for supply networks and water-based fire protection systems.
- Control instruments and accessories for fire protection systems.
- Hydrants, equipment cabinets, fire hose reels (FHRs), hoses, nozzles, foam generators, proportioners, mixers, monitors.
- Sprinklers, fittings and components for sprinkler systems. Nozzles and diffusers. Support assemblies and fasteners, etc.
- Valves: check valves for sprinkler systems, non-return, with actuator, etc.
- Personal protective equipment: jackets, helmets, boots, vests, blankets.
- Extinguishing agents.

**Fire alarm systems and similar products**

- Intruder detection and alarm systems with fire-detection capability.
- Fire detection and alarm systems: conventional, addressable, analogue, extinguishing, gas, etc.
- Remote supervision and monitoring devices.
- Notification and alarm devices: audible alarms, visual alarms, visual and audible alarms, loudspeakers, other accessories.
- Initiating devices and accessories therefor: flame, heat, smoke and combined detectors, detector bases, manual pull stations/call points.
- Flame detectors, heat detectors, manual pull stations/call points and other devices for classified zones. Anti-explosion equipment (explosion-proof, intrinsic safety, increased safety, oil-immersion).
- Gas detectors.
- Monitoring devices: pressure switches, flow switches, position sensors, level sensors, flow sensors, etc.
- Control and activation devices: relay bases, relay outputs, etc.
- Remote modules: monitor modules, control modules, isolator modules, etc.

- System integration computer programmes.
- Computer programmes for in-system device programming.
- Electrical cables for detection systems.

**Electrical equipment**

- Electric conductors: cables, wires, braided wires, strip, etc.
- Conduits and fittings: tubing, cable trays, inspection chambers, covers, seals, etc.
- Emergency lighting and signage: independent light sources with or without signage, safety decals, pictograms, etc., whether or not photoluminescent.
- Overcurrent protection: thermal, magnetic, fuses, combined, etc.
- Surge protection: data surge protectors, AC surge protectors.
- Arc striking devices.
- Passive protection system devices: Franklin lightning rods, Faraday cages, down conductors, electrodes, fasteners, lightning-strike counters, etc.

3. The system applies to both domestically produced and imported goods. Imported goods come from any country where they are produced and marketed by suppliers with which Cuba has trade relations.

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, and of materials and substances that pose a fire safety risk.

5. Technical Communications Nos. 1 and 4 of 2012 and No. 2 of 2013 of the Head of the Fire and Rescue Service of the Republic of Cuba. Licensing is mandatory.

**Procedures**

6. Not applicable.

7.(a) There is no requirement as to how far in advance certification must be requested, but the APCI has 30 working days from the receipt of the application within which to issue its decision, provided that the certification requirements are clearly defined, substantiated and understood. An application for certification by the importing entities is a pre-requisite for entering into a purchase contract.

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

(c) There are no such limitations.

(d) Consideration of applications and granting of certification are effected solely by the Fire Protection Agency of the Ministry of the Interior.

8. A licence application may be refused where:

- the equipment in question is not fire protection 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.

**Eligibility of importers to apply for licence**

9. Legal persons, such as the importers, producers, marketers and suppliers of such equipment in national territory, as well as the Cuban, joint or foreign enterprises that use the equipment and are authorized to import it for their own use, are eligible to engage in these procedures.

**Documentational and other requirements for application for licence**

10. Applications must be submitted in writing and include a list of products, contact information for the manufacturers, full contact details of the supplier for Cuba, and the full contact details of the

certification applicant if other than the supplier. The documentation listed hereunder is also required in the context of the application process.

An evaluation requires submission of the following documents, irrespective of the nature or destination of the product:

- technical specifications of the product;
- official certificate issued by a recognized body attesting to the fire protection and safety characteristics and/or rating of the product;
- report on the tests and trials conducted on the product by the aforementioned body, or by an accredited laboratory and the results of which are recognized by the said body;
- physical samples of the product (a minimum of one). In the case of certain products that, for the above reasons, require additional tests or trials, the supplier will be specifically requested to provide the requisite number of samples;
- other supplementary documentation that provides further information on the product and the manufacturer (depending on the product type).

11. A valid certificate and the evaluation report for each product imported.

12. Certification application costs are established in accordance with the product and its technical characteristics.

13. Not applicable.

### **Conditions of licensing**

14. The period of validity of certificates is as follows:

- homologated products: 5 years;
- approved products: 5 years;
- approved products for exclusive one-time use: without a period of validity.

The holder will receive a renewal notice three months prior to the end of the aforementioned period of validity and the expiry of the certificate. The certificate may be renewed by following a similar procedure as for the initial application.

15. No, but the certificate issued only accredits the specific product that was subject to the process and under no circumstances may endorse another product even if it does possess similar characteristics. Inappropriate use of a certificate could result in its withdrawal.

Similarly, a product may also lose its homologated or approved status if, during its period of validity, non-compliant features are detected and make the withdrawal of certification advisable. The certificate issued validates the technical guarantee and endorses the product for use and marketing in the country.

16. Certificates are not transferable between suppliers in the country.

17. No.

### **Other procedural requirements**

18. No.

19. Not applicable.

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## **5 MINISTRY OF PUBLIC HEALTH (MINSAP)**

### **5.1 National Directorate of Medicines and Medical Technologies, Pharmaceutical Services Department, Control Unit for Narcotic Drugs, Psychotropic Substances and Other Similar Substances (DNMTM)**

#### **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 entered in a central register at the Control Unit for Narcotic Drugs, Psychotropic Substances and Other Similar Substances, which is the drug control department of the National Directorate of Medicines and Medical Technologies. These entities must comply with the following requirements: be entered in the Register of Importers and Exporters of the Chamber of Commerce of Cuba and the Central Register of the Customs General of the Republic, be legally constituted, with a corporate purpose covering import and/or export activities, and be registered with the Ministry of Foreign Trade and Foreign Investment; and the substances with which they operate must be included in the list of goods approved for the entity.

#### **Purposes and coverage of licensing**

- 2.(a) Narcotic drugs regulated by the Single Convention on Narcotic Drugs, 1961.
- (b) Psychotropic substances regulated by the Convention on Psychotropic Substances, 1971.
- (c) Precursors and basic chemicals regulated by the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

Purposes of licensing: to comply with the obligations deriving from the above-mentioned international conventions, to prevent the diversion of these substances from their lawful circulation channels, and to ensure 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.(a) 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.
- (b) Ministerial Resolution No. 72 of 1990, which implements the provisions of the Convention on Psychotropic Substances, 1971.
- (c) 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 such transactions.
- IV. At any time of the year, although it is recommended that import licence applications be submitted, preferably, during the first, second and third quarters 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. Consideration of import licence applications is effected by the Control Unit for Narcotic Drugs, Psychotropic Substances and Other Similar Substances 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. Where there is any suspicion of illegal activities and a more in-depth investigation is required, the competent authorities are notified so that the applications can be examined by the National Counter-Narcotics Directorate of the Ministry of the Interior.
- 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 and are issued licences once they have met the established legal requirements.
- 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, in accordance with the requirements of the above-mentioned conventions.
- 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) Consideration of import licence applications is effected solely by the Control Unit for Narcotic Drugs, Psychotropic Substances and Other Similar Substances of the MINSAP, which is registered with the United Nations as the competent national authority for the purpose of the 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 entered in the Central Register for Importers and Exporters at the Control Unit for Narcotic Drugs, Psychotropic Substances and Other Similar Substances of the MINSAP.

Any legal entity may register provided that it is already registered in the National Register of Importers and Exporters 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:

- (a) name and legal domicile of the importer and exporter;
- (b) the entity's registration number in the National Register for the Monitoring of Controlled Substances;
- (c) telephone number, fax number and e-mail address of the importer and exporter;
- (d) generic name of the narcotic drug, psychotropic substance or substance with similar effect;
- (e) International Non-proprietary Name (INN), if any;
- (f) harmonized system code;
- (g) quantity of product with measurement units expressed in letters and numbers;
- (h) product description: presentation, packaging, pharmaceutical form and dose of the product in the case of pharmaceutical preparations;
- (i) international sales contract number, where appropriate;
- (j) declaration as to the use and final destination of the substance, identifying the client or the user of the substance;
- (k) in the case of imports of pharmaceutical preparations, the registration number issued by the Centre for State Control of Medicinal Product Quality;
- (l) anticipated date of arrival of goods in the case of imports or anticipated date of departure in the case of exports;
- (m) 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;
- (n) date of application;
- (o) 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 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, i.e. each time goods cross the border.

16. Import licences are not transferable.

17. No other conditions are attached to the issue 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 National Institute of Hygiene, Epidemiology and Microbiology (INHEM)

### Outline of systems

1. The import licensing system is regulated by Ministry of Public Health (MINSAP) Resolutions Nos. 64/97, 128/98 and 275/2003 and the relevant Regulations and Indicators Handbook, which establishes the list of goods subject to import licensing. The licensing system is administered by the Department of Sanitary Registration and Control of the National Institute of Hygiene, Epidemiology and Microbiology (INHEM).

### Purposes and coverage of licensing

2. Imports of all registered products are subject to automatic licensing during the three years of their certification; imports of new products applying for first-time sanitary registration are subject to non-automatic licensing.

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

4. Automatic import licences are used for statistical purposes while non-automatic import licenses are used to administer the import restrictions applied in accordance with current sanitary legislation.

5. The sanitary licensing and sanitary registration systems are statutorily required. The systems may be suspended when deemed appropriate. A notice to that effect is published in the Official Journal.

### Procedures

6. Not applicable.

7.(a) Licence applications must be submitted at least one week prior to importation. Licences may be obtained within a shorter time-limit as well as for goods arriving at port without a licence.

(b) In certain circumstances, a pre-arranged licence can be granted immediately on request subject to detention of the goods at destination.

(c) There are no limitations as to the period of the year during which the licence application 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 competent authority.

### **Eligibility of importers to apply for licence**

9. All persons, firms and institutions are eligible to apply for licences.

### **Documentational and other requirements for application for licence**

10. A sample application form is available for consultation in the Secretariat. Importers are required to submit the following documents with their applications: contract with the supplier, technical specifications of the product, required product certifications, sample of no commercial value of each product for the required laboratory analyses, and product labels.

11. Upon actual importation, an importer is required to submit the approved import licence or a copy thereof.

12. Payment is required both for sanitary registration and for laboratory analyses of the samples that applicants are required to submit. The amount varies according to the tariff applicable to the product.

13. There is an advance payment requirement associated with the issue of licences in accordance with the established rate.

### **Conditions of licensing**

14. A licence is valid for three years from the date of issue. The period of validity may be extended by submitting a new application for the product, together with the related documentation.

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

### **Other procedural requirements**

18. The Health Registration Authority reserves the right, where it deems it relevant and always in conjunction with the State Health Inspectorate, to conduct a technical visit to the producer, marketer or controlling entity prior to issuing the licence or during the period of validity of registration in order 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 and 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 employed 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, and 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, and 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.cecmecmed.cu>.

7.(a) An application for an import certificate for medicines for human use may be filed before or after the shipment of 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 working 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, a certificate is delivered for each individual shipment.

(d) 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 current requirements governing applications for entry in and renewal of and amendments to entries in the Register of medicines for human use.

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.(a) Import certificate application on the relevant official form (original and two copies);

(b) 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;

(c) 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);

(d) Copy(ies) of the letter(s) in which the receiving establishment(s) accept the import of medicine(s) for human use the expiry date of which is less than one year upon 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 possess the documents referred to in point 2 of this response, import may be authorized subject to the retention of the goods. The documents will need to be submitted at a later date as part of an application for clearance of the batches so that the goods can be distributed.

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. An import certificate is issued for each shipment and covers the 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 relevant regulations, when medicines for human use covered by a contract are received in two or more separate shipments, a new import certificate must be requested for each shipment of the amount outstanding given that 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 cross-border movement of samples of biological material**

### **Outline of systems**

1. The control of cross-border movement of samples of biological material is the means employed 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), micro-organisms and other elements 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.

(a) MINSAP Ministerial Resolution No. 132 of 2004.

(b) Health Protection Regulation Bureau (BRPS) Resolution No. 8 of 2007.

### **Procedures**

6. Not applicable, there is no restriction as to 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 at Customs the person concerned can liaise with CECMED 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. Form issued by the authority.

- (a) Approval of the MINSAP CITMA Committee for research projects. For research projects that involve the movement on separate occasions of samples of biological material that have received prior approval, the initial licence granted must be referred to (licence number).
- (b) Technical report from the Haematology and Immunology Institute for samples of bone marrow.
- (c) Notification from the Vice-Ministry of Health Care for samples for clinical diagnostic purposes.
- (d) 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, which requires a number 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. 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 cannot be imported without the corresponding import licence issued by the Centre for State Control of Medicinal Product Quality or the Health Registration, Control and Quality Department, as appropriate.

#### **Purposes and coverage of licensing**

2. The licensing system 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 Health Protection Regulation Bureau (BRPS) Resolution No. 8 of 2007. The procedure is mandatory for the covered products.

#### **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.cecmecmed.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 import certificate for medicines for human use may be filed before the shipment of 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, a certificate is delivered for each individual shipment.
- (d) No. Depending on the product, applications are considered by CECMED or, in the case of cosmetics, by 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 a refusal.

No appeal is provided for in the regulations. However, 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.(a) Import certificate application on the relevant official form (original and two copies).

(b) Certificates from the official veterinary services of the country of origin containing the information set out in the Third Paragraph of and in Annex 2 to Ministry of Agriculture and Ministry of Public Health Joint Resolution No. 2/2001.

(c) Copies of the analysis certificates for each of the product batches included in the application.

(d) 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 specifications or technical standard applicable to 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:

a. Product data:

- generic name;
- trade name;
- physical state;
- presentation;
- manufacturer;
- country;
- marketing entity.

b. Quality specifications or technical standard applicable to the product.

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

d. 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 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 goods covered by a contract are received in two or more separate shipments, a new authorization must be requested for each shipment of the amount outstanding given that 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. This administrative procedure seeks to ascertain that the personal protective equipment used by workers complies with the technical requirements set forth in the national and international rules in force.

The purpose of the procedure is to assess, approve and register personal protective equipment on the basis of an examination of the technical documentation, a physical examination of the equipment and its marking in accordance with the applicable standards, and certain tests when the country has the competent laboratories.

Based on the examination, a technical authorization is issued certifying that the equipment satisfies the requirements, and stating the category and period of validity of the authorization.

#### **Purposes and coverage of licensing**

2. The goods covered by this system are personal protective equipment, meaning devices or items worn by workers to protect them against one or more risks to their safety or health at their work station, and the parts, components or interchangeable accessories needed to ensure their proper functioning and used exclusively therewith, including:

- (a) protective headgear for motorcycle, motorbike and moped riders and equipment for underwater work (diving), essential to many economic activities even if they are not used exclusively by workers;
- (b) personal protective equipment acquired in connection with different technology projects, for example protective clothing that comes with refrigerating equipment, protective devices for welding equipment, etc. to test their protective characteristics;

- (c) surgical gloves and lead aprons for x-ray exposure used in public health.

The following are not included: protective equipment designed exclusively for use by the armed forces, fire services, sporting activities, public transport (ships and aircraft), and rescue activities. However, other personal protective equipment used in such activities, but not designed exclusively for such use, are subject to registration. These include:

- respirators used by the fire services;
- motorcycle helmets and goggles used for sporting activities.

While the importation of equipment that has been donated is not subject to technical authorization, it must nevertheless undergo the relevant technical analysis before it can be used.

3. All countries.

4. The procedure seeks to ensure compliance with the protective requirements of the equipment marketed in the country for use by workers, and is in no way intended to restrict the quantity of imports. The process is efficient enough to avoid any unnecessary delays that could impede the marketing of the equipment.

The analysis method used is essentially documentary. Tests could possibly also be conducted to achieve the desired result, but the necessary laboratories are not always available.

5. The basic laws or regulations that provide the legal basis for the procedure are:

Paragraph 2.2 of Agreement 8332 of 23 March 2018, which states that "the functions of the MTSS include proposing, directing and controlling policies in the areas of occupational protection, safety and hygiene and checking the protective characteristics of personal protective equipment".

Article 36 of the Basic Regulations of the MTSS, adopted on 10 January 2015 by Resolution No. 2 of the President of the Council of State and the Council of Ministers, Army General Raúl Castro Ruz, which states that the functions of the Centre shall be to register and approve personal protective equipment produced or marketed in the country.

Article 141 of Law No. 116 containing the Labour Code, which 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, which specifies that the Centre for the Certification of Personal Protective Equipment 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.

## Procedures

6. Not applicable.

7. 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) Not limited in time. 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.
- (b) Certification is not possible unless accompanied by the relevant analysis. The process may, however, be quicker for renewals of previously registered and approved equipment.
- (c) There are no limitations of that kind.

- (d) There is only one administrative body.
8. An application for registration may be refused where:
- (a) the equipment in question is not the workers' personal protective equipment under the criteria referred to above;
  - (b) the documents or samples delivered by the applicant do not satisfy the requirements or when there are discrepancies between them;
  - (c) the documentation presented 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 MTSS as stipulated in the contract concluded between the parties.

### **Eligibility of importers to apply for licence**

9. MTSS Resolution No. 7 of 2013 provides that legal personality to engage in registration procedures is vested in importers, producers and marketers of personal protective equipment; and in any 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. For registration of the entity:
- (a) the information requested in Form 1 delivered by the authority;
  - (b) for foreign commercial branches, a copy of the trading licence issued by the Chamber of Commerce of the Republic of Cuba and the list of equipment must be attached;
  - (c) 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;
  - (d) 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:

- (a) the information listed in Form 2;
  - (b) declaration of conformity by the equipment's manufacturer;
  - (c) approval certificate issued by an accredited independent laboratory in the country of origin or a third country;
  - (d) technical fact sheet on the equipment;
  - (e) physical sample of the equipment with minimum marking for the purposes of identification (trademark, model and reference number).
11. The technical report attesting to its approval.
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:
- (a) equipment in Category I: 5 years;
  - (b) equipment in Category II: 4 years;
  - (c) equipment in Category III: 3 years.

Upon expiry of the above period, the holder may renew the registration certificate once only.

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

16. The rights conferred upon a licence-holder by the registration of equipment are not transferable 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. Agreement No. 3954 on Administrative Control, adopted by the Executive Committee of the Council of Ministers on 26 March 2001, confers duties and powers on the National Institute of Hydraulic Resources (INRH) that include the planning, regulation and control of hydraulic resources and the operation, technical oversight and maintenance of hydraulic works and installations.

Agreement No. 5 of 9 July 2005 of the Drought Task Force encharges the INRH with promulgating regulations prohibiting the importation of water-intensive sanitation equipment, fittings and furnishings, in line with worldwide trends and existing legislation.

Resolution No. 28 of 28 February 2006 of the President of the INRH lays down the water consumption standards for water-intensive sanitation equipment, fittings and furnishings and the energy efficiency ratings required for electric pumps. It further provides that technical approval must be obtained from the Institute prior to the importation into Cuba or production in Cuba of such products. These rules will have to be refined in line with technical and technological developments.

##### **Purposes and coverage of licensing**

2. The purpose of licensing is to lay 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. Not applicable.

7.(a) Applications must be submitted at least 72 hours prior to the 10<sup>th</sup>, 20<sup>th</sup> and 30<sup>th</sup> of each month.

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

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:

- (a) the importation of pumps;
- (b) 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.

### **8 MINISTRY OF INDUSTRY (MINDUS)**

#### **8.1 National Lift Group (GNA)**

##### **Outline of systems**

1. Regulations on lifts, escalators and moving walkways, which govern the design, manufacture, installation, operation, maintenance, repair, periodical inspection and importation of this type of equipment.

##### **Purposes and coverage of licensing**

2. The licensing system covers lifts for transporting people and goods (HS 84281000), and escalators and moving walkways for transporting people (HS 84284000), regardless of speed of movement and subject to the exceptions indicated in the regulations.

3. No distinction is made between countries. The licensing system applies to all imported equipment.

4. The regulations do not restrict quantity by country of origin or provenance. Their purpose is to ensure the necessary safety requirements for the transportation of passengers and goods.

5. Resolution No. 137 of 2004 of the Ministry of Metallurgical, Mechanical and Electronics Industries (SIME) and Joint Resolution SIME-MINCEX No. 1 of 2005. Licensing is mandatory for all regulated products. Given the highly technical nature of the subject matter concerned, the Government is in charge of implementation and empowered by law in this respect. A central government agency (OACE) has been designated as the body responsible for this type of technology in Cuba.

### **Procedures**

6. Not applicable.

7.(a) The import approval notification is issued before the importer signs the supply contract.

(b) The import approval notification does not expire.

(c) Applications for import approval notifications may be made at any time.

(d) The importer is only required to approach the competent national authority, in this case the National Lift Authority attached to the Ministry of Industry.

8. Import applications may be refused if they do not comply with the regulations on lifts, escalators and moving walkways, or if they concern the replacement of existing equipment that is still operational and usable in accordance with safety requirements. In such cases, the applicant will be notified of the reasons for refusal and of the possibility of appealing this decision before the General Directorate of the Ministry of Industry.

9. All importing entities are eligible to apply for authorization, provided that they have been given approval to market these products.

### **Documentational and other requirements for application for licence**

10. The application shall be addressed to the head of the National Lift Group with the following information attached:

- Technical project and descriptive report, in duplicate, containing: a description of the type element concerned and the operation thereof; the relevant calculations, characteristics and technical descriptions; details of the electrical equipment concerned; and installation and assembly plans. The project must be signed by a duly authorized engineer and the owner or investor.

The application must include the following:

#### For lifts:

- The name of the investor in charge of the works, and the address, telephone number, fax number and/or email address where they can be contacted.
- A copy of the Resolution specifying the person authorized to sign the contract, with the address, telephone number, fax number and/or email address where they can be contacted.
- Details of the place where the project will be carried out, including the address of the building.
- A traffic study.
- A general ground plan of the building, showing the position of the lift and the building's compliance with the manufacturer's requirements.
- A cross-section diagram of the lift shaft, showing the various floors, the lift car and how it is suspended.
- A cross-section diagram of the machine room, showing the transmission mechanisms and lift motor.
- A ground plan of the machine room, showing the lift motor and base.
- A ground plan of the lift pit, showing the devices it contains.
- A table showing the operating magnitudes assigned to the motor.
- Electrical circuit diagrams.
- Safety device details.

- Adjustment and maintenance manuals.\*
- A spare parts catalogue.\*
- Assembly manuals.\*
- Details of at least three different suppliers from registered trading enterprises.
- The name of the authorized company that is to assemble the lift, and its economic valuation.
- Any other information that the investor considers of interest.

Note: \* It is not necessary to submit these documents if the equipment has been registered.

**For escalators and moving walkways, the following must be provided in addition to the information required for lifts:**

- An analysis of the static tension of the supporting structure or an equivalent certificate from an accredited static-tension analyst.
- Details of breakage-resistance tests conducted by an accredited body on direct-action components of steps, pallets or belts, such as chains and racks.
- Calculations of breaking distance, together with adjustment data for loaded moving walkways.
- Details of step or pallet tests.
- Details of belt breakage-resistance tests.
- Handrail breakage-resistance certificate.
- Registration certificate, in duplicate, as endorsed by the registration body, stating that the type element is registered and in compliance with all the required specifications.
- Construction licence, in duplicate, as issued by the competent authorities, certifying that the construction of the building has been approved.

11. The procedure is completely free of charge.

12. Not applicable.

13. Not applicable.

### Conditions of licensing

14. The import approval notification does not expire.

15. Not applicable.

16. Not applicable.

17. Not applicable.

### Other procedural requirements

18. Not applicable.

19. Not applicable.

## 9 MINISTRY OF ENERGY AND MINING (MINEM)

### 9.1 National Office for the Control of the Rational Use of Electricity (ONURE)

#### Outline of systems

1. Technical authorization to import electrical end-use equipment. Electrical end-use equipment not imported for marketing purposes must meet the voltage requirements for the installations in which it is to be used. Where the equipment is to be used at exhibitions and fairs or in field trials, the authority in charge will grant technical authorization for three months. Where the equipment is to be marketed, the authority in charge will grant technical authorization for two years, provided that the equipment is registered by the authority responsible and the technical acceptance is valid.

## Purposes and coverage of licensing

2. Licensing seeks to establish and control technical requirements relating to the energy efficiency, electrical safety and tropicalization of electrical end-use equipment that is imported, manufactured or assembled in Cuba by national or foreign legal persons, with a view to promoting the rational and efficient use of electricity and ensuring consumer protection through the use of highly energy-efficient and good quality equipment.

It covers the following electrical end-use equipment:

- Household refrigerating appliances classified under tariff subheadings 8418.10, 8418.21, 8418.22, 8418.29, 8418.30 and 8418.40.
- Household electric fans, classified under tariff subheadings 8414.51 and 8414.59.
- Compact fluorescent lamps (CFLs) classified under tariff subheading 8539.31.10.
- Electric smoothing irons classified under tariff subheading 8516.40.
- Air-conditioning machines classified under tariff subheadings 8415.10 (window or wall types); 8415.82 and 8415.83 (split systems).
- Microwave ovens classified under tariff subheading 8516.50.
- Electric rice cookers classified under tariff subheading 8516.79.
- Electric pressure cookers classified under tariff subheading 8516.79.
- Electric coffee makers classified under tariff subheading 8516.71.
- Household electric washing machines classified under tariff subheadings 8450.11, 8450.12, 8450.19 and 8450.90.

3. All countries.

4. Licensing does not restrict the quantity or value of imports. It seeks to contribute to Cuba's policy on electricity saving.

5. Ministry of Basic Industry (MINBAS) Resolution No. 136 of 2009. Licensing is required for all entities that import the equipment described above.

## Procedures

6. Not applicable.

7.(a) Prior to signing the contract of sale with the supplier.

(b) The authority in charge will have a maximum of five working days to consider the application and issue the corresponding technical authorization.

(c) There are no limitations.

(d) Consideration of applications is effected solely by the authority in charge.

8. The following constitute general violations to this regulation:

- Arrival at a Cuban port or airport of electrical end-use equipment that has not received valid technical acceptance from the authority in charge.
- Non-compliance with the obligations undertaken, as set forth in existing legislation in this area.

In the event of either of the above-mentioned violations, the authority in charge will apply one or more of the following penalties:

- Warning notification.
- Suspension of technical authorization for one year.
- Withdrawal of technical authorization.
- Refused entry or destruction of the equipment.

The authority in charge will have 30 working days from when it becomes aware of a violation to apply the above-mentioned penalties.



### **Eligibility of importers to apply for licence**

9. Companies listed in the National Register of Exporters and Importers of the Chamber of Trade of the Republic of Cuba that are authorized by the Ministry of Foreign Trade to import products under these subheadings.

### **Documentational and other requirements for application for licence**

10. Entities interested in beginning the technical acceptance process for any of the electrical end-use equipment described, shall complete the relevant form and email it to the authority in charge.

11. The technical authorization document issued by the competent authority.

12. Yes, the administrative charge corresponds to the type of equipment concerned and the validation tests carried out on this equipment in laboratories recognized by the competent authority.

13. Not applicable.

### **Conditions of licensing**

14. Technical acceptance is valid for two years, provided that there is no change to the equipment's technical specifications or the product model. At least 45 days before the technical acceptance expires, the holding entities may request an extension of two years, provided that the equipment's technical specifications or the product model have not changed. The authority in charge will have five working days to consider the extension request and make a decision thereon, after which the applicant will be notified.

15. Not applicable.

16. Equipment for which an importer already has technical authorization may be imported by other importers, provided that the product model and its technical specifications do not change.

17. Not applicable.

### **Other procedural requirements**

18. Not applicable.

19. Not applicable.

## **10 MINISTRY OF INFORMATICS AND COMMUNICATIONS (MINCOM)**

### **10.1 General Directorate of Communications (DGC)**

#### **Outline of systems**

1. Technical authorization issued by the Ministry of Informatics and Communications for imports of telecommunications equipment and devices, which must be approved by the customs authority for the purposes of importation.

#### **Purposes and coverage of licensing**

2. Licensing seeks to maintain control of the use of the radio frequency spectrum and regulate the manufacturing and importation of radiocommunications equipment and the compatibility, manufacturing and importation of information and communication technology (ICT) equipment.

It covers the following types of equipment:

- Electrical apparatus for line telephony or line telegraphy, including line telephone sets with cordless handsets and telecommunication apparatus for carrier-current line systems or for digital line systems; videophones (HS 85.17).
- Microphones and stands therefor (wireless microphones only) (HS 8518.10).
- Transmission apparatus for radiotelephony, radiotelegraphy, radiobroadcasting or television, whether or not incorporating reception apparatus or sound recording or reproducing apparatus; television cameras; still image video cameras and other video camera recorders; digital cameras (wireless only) (HS 85.25).
- Radar apparatus, radio navigational aid apparatus and radio remote control apparatus (HS 85.26).
- Reception apparatus for radiotelephony, radiotelegraphy or radiobroadcasting, whether or not combined, in the same housing, with sound recording or reproducing apparatus or a clock (HS 85.27).
- Parts suitable for use solely or principally with the apparatus of headings 85.25 to 85.28 (HS 85.29).
- Electric sound or visual signalling apparatus (for example, bells, sirens, indicator panels, burglar or fire alarms), other than those of heading 85.12 or 85.30 (wireless only) (HS 85.31).

3. All countries.

4. There is no restriction as to the quantity or value of imports. Its purpose is to maintain technical compatibility with networks.

5. Joint Resolution MINCEX-MIC No. 1 of 2003 and MINCOM Resolution No. 272 of 2015.

#### **Procedures**

6. Not applicable.

7.(a) Prior to signing the contract of sale with the supplier.

(b) No, an expert evaluation is necessary.

(c) There are no limitations.

(d) Consideration of applications is effected solely by the authority in charge.

8. The following constitute general violations to these regulations:

- Arrival at a Cuban port or airport of telecommunications equipment that has not received valid technical acceptance from MINCOM.
- Non-compliance with the obligations undertaken, as set forth in existing legislation in this area.

#### **Eligibility of importers to apply for licence**

9. Companies listed in the National Register of Exporters and Importers of the Chamber of Trade of the Republic of Cuba that are authorized by the Ministry of Foreign Trade to import products under these subheadings.

#### **Documentational and other requirements for application for licence**

10. Entities interested in beginning the technical acceptance process for the above-mentioned telecommunications equipment shall send a request to the authority in charge.

11. The technical authorization document issued by the competent authority.

12. No.

13. Not applicable.

#### **Conditions of licensing**

14. Technical acceptance is valid for one year.

15. Not applicable.

16. They are not transferable.

17. Not applicable.

#### **Other procedural requirements**

18. Not applicable.

19. Not applicable.

### **11 MINISTRY OF CONSTRUCTION**

#### **11.1 Directorate of Standardization**

##### **Outline of systems**

1. Directive No. 1 for assessing the technical suitability of non-traditional products and construction systems, and its regulations, and Directive No. 2 for the conformity certification of traditional construction products and systems. The technical suitability document (DITEC) is the official document issued for a construction product or system once it has successfully undergone the evaluation process.

##### **Purposes and coverage of licensing**

2. The aim is to ensure that constructions designed and built in national territory do not compromise the safety of human beings, animals, property or the environment, or other aspects of society in general. To this end, constructions must meet certain requirements that can reliably ensure an adequate level of safety.

The DITEC can only be granted for the following non-traditional construction products and systems (new products or the new use of a traditional product):

- Industrially manufactured products and systems.
- Perfectly identifiable products and systems.
- Products and systems intended for a specific and unequivocal use.

For the purposes of these regulations, "non-traditional" shall be understood to mean products and systems which, having not been used sufficiently in practice by the time the application is filed, are not covered by Cuban rules or regulations that make it possible to verify whether they meet key requirements.

3. All countries.

4. There is no restriction as to the quantity or value of imports. Licensing seeks to contribute to Cuba's policy on electricity saving.

5. Ministry of Construction Resolution No. 933 of 1999. Licensing is mandatory for all entities that import the products or systems described above.

##### **Procedures**

6. Not applicable.

7.(a) Prior to signing the contract of sale with the supplier.

- (b) No, an evaluation will be conducted by the Technical Centre for the Development of Construction Materials. Other institutions may be contracted if necessary. This work includes visits to production centres and construction sites, testing, user surveys, the preparation of a preliminary draft of the technical suitability document (DITEC), and consideration of the opinions of the rapporteur and the committee of experts.
- (c) There are no limitations.
- (d) Consideration of applications is effected solely by the authority in charge.

8. The DITEC may be provisionally suspended or invalidated where:

- (a) The product or system is defective;
- (b) The holder does not comply with the regulations or meet the conditions established in the DITEC;
- (c) The original text is misused;
- (d) The holder promotes or agrees to the use of the product or system for a purpose other than that for which the DITEC was granted;
- (e) Other products are marketed under the DITEC.

If any of the above-mentioned circumstances are detected in the use and circulation of the DITEC, the Directorate of Standardization will, with a view to the temporary suspension or invalidation of the document, notify the holder of the infringements observed and request that he present his case within 30 days. Any decision to suspend or invalidate the DITEC will be made known to the parties concerned.

#### **Eligibility of importers to apply for licence**

9. The DITEC is available to producers, importers and traders of the products and systems concerned.

#### **Documentational and other requirements for application for licence**

10. Applications shall be made in writing and must contain the express commitment to respect the obligations deriving from the regulations, particularly as regards any necessary controls, sampling, testing or experiments carried out in the factory or laboratory, or on the work site. Applications must be accompanied by the following information:

- (a) Name and identification of the product or system.
- (b) Name and distinctive mark of the manufacturer.
- (c) Main characteristics of the product or system that determine its suitability for use (in accordance with essential construction requirements).
- (d) Scope.
- (e) Packing, packaging, labelling and marking requirements.
- (f) Handling, transportation and storage requirements.
- (g) Rules on maintenance and repair.
- (h) Technical information regarding usage.
- (i) Results of tests conducted by accredited entities and of in-factory testing, which should at least cover aspects relating to the essential construction requirements.
- (j) Documents concerning the relevant quality system.
- (k) Characteristics of production, processing and manufacturing control centres.
- (l) References to use in works that are completed or under construction.
- (m) Certificates issued by authorized institutions and any other information considered useful.

Where a DITEC is requested for a product or system produced in various factories, the report shall indicate any fundamental differences that may exist in the manufacturing characteristics of the various establishments. Where deemed necessary, a specific report shall be requested for each production centre.

11. The DITEC.

12. Not applicable.

13. Not applicable.

### **Conditions of licensing**

14. The DITEC is valid for five years, unless the relevant file specifies a different period of time or the object of the DITEC has been provided for in domestic standards or regulations during this period. The DITEC can be invalidated, reviewed or renewed where there are grounds for doing so. The renewal of the DITEC must be requested six months before its validity expires, by following the same application procedure.

15. Not applicable.

16. In the event of the transfer of the property or right concerned, the use of the DITEC will require authorization from the Directorate of Standardization.

17. Not applicable.

### **Other procedural requirements**

18. Not applicable.

19. Not applicable.

## **12 MINISTRY OF TRANSPORT**

### **12.1 Cuban Ship Registry (RCB)**

#### **Outline of systems**

1. Approval or certification of assemblies, accessories and parts for motor vehicles, railway vehicles, ships and boats, and of workshops, laboratories and other installations engaged in production and in the provision of services in the various transport sectors and in port activities, in accordance with the provisions in force and the international agreements to which the Republic of Cuba is party.

#### **Purposes and coverage of licensing**

2. Its purpose is to ensure that assemblies, accessories and parts for motor vehicles, railway vehicles, ships and boats, and workshops, laboratories and other installations engaged in production and in the provision of services in the various transport sectors and in port activities do not compromise the safety of human beings, animals, property or the environment, or other aspects of society in general. To this end, products must meet certain requirements that can reliably ensure an adequate level of safety.

Approval is considered to be the action, with all the effects thereof, that is taken by a competent authority to recognize officially, through a document issued for this purpose, that:

- (a) certain assemblies, accessories and parts for motor vehicles, railway equipment, ships and boats, or materials for the repair thereof, or for means and equipment used to transport freight or goods, meet the quality requirements and characteristics stipulated for their use;
- (b) the workshops, laboratories and other installations engaged in production and in the provision of services meet the necessary technical and technological requirements, which together with the knowledge and professional skills of their employees, make it possible to ensure that such establishments are suitably qualified to carry out their work and provide the necessary quality and guarantees.

Entities engaged in importation, marketing, production and the provision of services are required to ensure the submission for approval of the products and services described, and to use, produce, import and market only those that have received approval.

The system applies to new or retreaded tyres, welding electrodes, lifting devices and port fenders, with a view to standardizing the requirements to be met by these products. Technical import authorization (ATI) will be granted on the basis of an analysis of the necessary requirements.

3. All countries that wish to export the said products to Cuba.
4. The licensing procedure does not restrict the quantity or value of imports: its purpose is to ensure the quality of the products and compliance with domestic technical regulations. No alternative methods were considered, since those used were effective in meeting the objectives pursued.
5. MINTRANS Resolution No. 90-1992  
MINCEX Resolution No. 307-2004  
MINTRANS Resolution No. 293-2014

Licensing is required for all entities that import the equipment described in the answer to question 2 above.

### **Procedures**

6. Not applicable.
  - 7.(a) Prior to signing the contract of sale with the supplier. In the case of goods arriving at the port without a licence, the approval formalities can take place at the border.
  - (b) No, as it is necessary at least to examine the required documentation.
  - (c) There are no limitations.
  - (d) Consideration of applications is effected solely by the authority in charge, although in the case of tyres, the approved brands are registered with the Tyres Committee.
8. The applicant is informed of the reasons for the refusal. There is no right of appeal.

### **Eligibility of importers to apply for licence**

9. Importers authorized to import these products in accordance with a list approved by MINCEX may apply for technical authorization.

### **Documentational and other requirements for application for licence**

10. Applications shall be made in writing and must contain the following information:
  - (a) Product name and identification.
  - (b) Name and distinctive mark of the manufacturer.
  - (c) Main characteristics of the product or system that determine its suitability for use (in accordance with essential requirements).
  - (d) Scope.
  - (e) Technical information regarding usage.
  - (f) Results of tests conducted by accredited entities and of in-factory testing, which should at least cover aspects relating to key requirements.
  - (g) Documents concerning the relevant quality system.
  - (h) Characteristics of production, processing and manufacturing control centres.
  - (i) Certificates issued by authorized institutions and any other information considered useful.
11. The certificate of approval issued by the competent authority.
12. Not applicable.
13. Not applicable.

### Conditions of licensing

14. The certificate of approval is valid for three years, subject to annual supervision and confirmation that the conditions under which it was issued have been maintained.

The certificate of approval may also be invalidated, reviewed or renewed where there are grounds for doing so. Renewal must be requested three months before expiry, following the same procedure as for the initial application.

15. Not applicable.

16. The certificate of approval is transferable and may be used by other importers provided that the product specifications and characteristics do not change.

17. Not applicable.

### Other procedural requirements

18. Not applicable.

19. Not applicable.

## 13 MINISTRY OF CULTURE

### 13.1 National Registry of Cultural Property (RNBC)

#### Outline of systems

1. For the purposes of the international movement of cultural property, the National Registry of Cultural Property of the Republic of Cuba (RNBC) applies and administers a cultural property import system, under which importers may obtain a numbered document that constitutes an import certificate.

#### Purposes and coverage of licensing

2. Licensing seeks to control cultural heritage with a view to its preservation, and to prevent the illegal trafficking of cultural property, in accordance with the legislation in force in Cuba and the international agreements to which our country is party. The following items are subject to import licensing:

- Documents and other property relating to history, including the history of science and technology, and to the life of the founders of nationality and independence, leaders and eminent figures, and events of national and international importance.
- Collections or objects of scientific interest.
- Products of archaeological excavations and archaeological discoveries.
- Elements of artistic or historical monuments or archaeological sites which have been dismembered.
- Property of artistic interest, such as original objects and works, and reproductions or copies of plastic and decorative art works and of works of applied art and popular art.
- Ethnological or folkloric objects and documents.
- Rare manuscripts and incunabula, books, documents and publications.
- Archives, including photographic, sound and cinematographic archives.
- Maps and other cartographical materials, original and printed scores, special editions and sound recordings.
- Items of numismatic, philatelic and vitophilic interest, including revenue and similar stamps, single or in collections.
- Ethnographic objects and musical instruments.
- Any element or part of any urban historical centre, construction or site, whether or not declared a national or local monument.

3. The system applies to cultural and/or heritage property originating in and coming from any country.

4. There is no restriction as to the quantity or value of imports. Licensing seeks to ensure protection and control.

5. Import licensing for cultural property is maintained under Law No. 1 of 4 August 1977, "Law on the Protection of Cultural Property", implemented by Decree No. 118 of 23 September 1983, and Resolution No. 57 of 26 October 1994 of the Minister of Culture, which establishes the importation procedure. This legislation implements the following conventions:

- Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property.
- Convention concerning the Protection of the World Cultural and Natural Heritage, Paris, November 1972.
- Convention for the Safeguarding of the Intangible Cultural Heritage, Paris, 17 October 2003.
- Convention on the Protection of the Underwater Cultural Heritage, Paris, 2 November 2001.

On this basis, the licensing system is statutorily required. The designation of products to be subjected to licensing is provided for in the above-mentioned international conventions and in Law No. 1 and its supplementary legislation. The granting of these licences for goods that require them cannot be suspended, as the law does not provide for any exceptions.

### **Procedures**

6. Not applicable.

7.(a) Import licence applications are processed within 48 hours.

(b) No, as it is necessary to assess the product concerned.

(c) There are no limitations.

(d) Generally speaking, licence applications are considered by a technical administrative body. For the importation of heritage property, property the composition of which includes any of the species protected under the CITES Convention, property of outstanding significance, or property of uncertain origin, the matter is put to the consideration of the CITES authority of the Ministry of Science, Technology and the Environment (CITMA), the Chair of the National Cultural Heritage Council, and the relevant bodies of the Ministry of the Interior.

8. Not applicable.

### **Eligibility of importers to apply for licence**

9. Licences are assigned to any natural or legal person interested in importing, on a temporary or permanent basis, any of the cultural or heritage property referred to in the Law. Applications are expressly made beforehand, and importers notify the Registry of the date so that the requested import can be verified and the corresponding certificate validated.

### **Documentational and other requirements for application for licence**

10. Applicants must provide the following information, in document form or by email:

- The particulars of the applicant.
- The technical data sheet for each of the items to be imported.
- Details of the type of regime under which importation is requested, i.e. permanent or temporary; in the case of the latter, an indication of the period of time during which importation will take place and the origin of the imported item.
- The nature of the import transaction, e.g. institutional, private, diplomatic.
- The purpose of importation.
- The particulars of the carrier, including their passport number.
- The country of origin and the authorization issued by that country where required.
- Mode of importation.



- Place, date and time of arrival.
- For unaccompanied freight imports, the date and time when the containers will be opened.

11. Upon importation, the specialist from the National Cultural Property Registry must present the import licence that has been issued and verify it.

12. The applicable administrative charge is in the process of being approved.

13. Not applicable.

#### **Conditions of licensing**

14. Import licences are valid for 60 days from the date of issue. The period of validity may be extended at the request of the applicant.

15. There is no penalty for the non-utilization of a licence or portion of a licence. The document issued is simply invalidated.

16. Licences are transferable between importers, provided that the change of carrier is requested beforehand; where property is detained pending compliance with import formalities, the carrier may endorse the document only once.

17. Not applicable.

#### **Other procedural requirements**

18. Not applicable.

19. Not applicable.

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