# WORLD TRADE ORGANIZATION

**G/LIC/N/3/CUB/3**
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**Committee on Import Licensing** Original: Spanish


## REPLIES TO THE QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES[1]

Notification under Article 7.3 of the Agreement on Import Licensing Procedures

CUBA

The following communication, dated 14 January 2009, is being circulated at the request of the delegation of the Republic of Cuba.

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## I. MINISTRY OF SCIENCE, TECHNOLOGY AND THE ENVIRONMENT (CITMA)

### A. CENTRE FOR ENVIRONMENTAL INSPECTION AND CONTROL (CICA)

### 1. Ozone Depleting Substances

**Outline of systems**

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

**Purposes and coverage of licensing**

2. Any substance pertaining to the chlorofluorocarbons (CFC) group, and mixtures thereof; bromochlorodifluoromethane, bromotrifluoromethane and dibromotetrafluoromethane; and carbon tetrachloride, trichloroethane, and methyl bromide. Also covered 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, other than medical aerosols).

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

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

Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer.

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

**Procedures**

6. In the fourth quarter of the year, the CITMA, through the Technical Ozone Office, 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 entities responsible for allocating quotas for each type or group of controlled substances are the Ministry of Domestic Trade (MINCIN) (for CFC substances) and the Ministry of Agriculture (MINAGRI) (for methyl bromide). Once the annual maximum import quota has been received, these entities distribute, in the fourth quarter of the year, the amounts of controlled substance allocated to each consumer for the following year, 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, allocating entities, entities, importers and the Centre for Environmental Inspection and Control (CICA)), as explained above. The approved figure is an overall amount and does not take into account the country of origin. The legislation does not provide for any exceptions or derogations from the licensing requirement.

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

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

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

IV. Import licences are granted within a maximum period of 35 working days.

V. 25 working days.

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

VII. Applications are always submitted by the importer and must specify the entities the substances are for and the quantities of substance to be imported to each of those entities, in accordance with the amounts allocated in advance by the MINCIN (CFCs), the MINAGRI (methyl bromide) or the Technical Ozone Office directly (other controlled substances). These amounts are allocated by each of the aforementioned authorities on the basis of the consumption of each entity, the requests the entities have made, and the overall amount the country can allow without affecting its international phase-out commitments. Under no circumstances does the CICA have any influence over this decision.

VIII. Applications are examined in the order in which they are submitted to the CICA (on a first come, first served basis), and any entity allocated a quota can apply (through the corresponding importer) for the necessary licence.

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

X. Not applicable.

XI. No.

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

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

(c) 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 is not met; the applicant is notified in writing of the grounds for the refusal. No appeal lies from a refusal.

**Eligibility of importers to apply for licence**

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

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

10. See form attached (Annex I).[2]

11. The relevant licence must be presented to Customs.

12. There is a fee of 44 Cuban pesos.

13. Not applicable.

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

**Conditions of licensing**

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

15. No.

16. They are not transferable.

17. Not applicable.

**Other procedural requirements**

18. There are no other procedures.

19. Not applicable.

**2. Biological Diversity**

**Outline of systems**

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

These import permits are granted to national or foreign natural persons and legal persons.

**Purposes and coverage of licensing**

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

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

4. These permits do not restrict quantity, but ensure coordination with the competent bodies.

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

**Procedures**

6. Not applicable.

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

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

(c) Not applicable.

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

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

**Eligibility of importers to apply for licence**

9. Importers must be registered in the National Register of 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:

National natural persons and national institutions - 43 Cuban pesos
National trading institutions - 91 Cuban pesos
Foreign persons - 43 Cuban convertible pesos
National trading institutions - 91 Cuban convertible pesos

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.

B. SECRETARIAT OF THE NATIONAL AUTHORITY FOR THE PROHIBITION OF CHEMICAL WEAPONS (CEANPAQ)

## 1. Chemical Weapons

### Outline of systems

1. The importation into Cuba of the substances listed in Schedules 1, 2 and 3 of the Chemical Weapons Convention (CWC) is subject to an import licensing system which ensures that these substances are used for purposes not prohibited by the CWC and that Schedule 1 and 2 substances are traded only with States Parties. 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 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.

3. All 184 States Parties to the CWC may engage in trade in the controlled substances listed in Schedules 1 and 2. Any State Party and State not party to the CWC may engage in trade in Schedule 3 substances, provided that the latter issues a certificate stating the final destination of the substances.

4. 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.

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

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

The controlled substances are listed in the Annex to Decree Law No. 202/99, which reproduces the CWC's "Annex on Chemicals".

The Council of State (the legislature) has made licensing a statutory requirement and empowers the CITMA (the executive) to establish the terms and conditions for each system.

**Procedures**

6.I. The legislation does not provide for quotas to ensure that the quantity of a 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 relating to Schedule 1 substances and products containing Schedule 1 substances 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 Secretariat of the National Authority for the Prohibition of Chemical Weapons (CEANPAQ) 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 CEANPAQ as the competent authority and specify that in cases where another type of authorization is required for the importation, manufacture or other uses of chemical substances, the processing and granting of licences will be contingent upon the authorization issued by that authority.

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 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.

In exceptional circumstances, the Director of the CEANPAQ may authorize the granting of a licence even when the application has not been submitted within the established time frame.

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

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

8. Licence applications may be refused on the grounds of failure to meet the above criteria or other criteria set forth in current legislation. The reasons for refusal are set forth in a licence refusal letter, in accordance with the "Procedure for Processing Applications for CEANPAQ 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 of 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 is attached (Annex II).[3]

The importer must submit the following documents with the application:

- Photocopies of the decision appointing the director of the entity and the entity's charter;
- photocopy of the certificate of registration with the National Register of Exporters and Importers of the Chamber of Commerce;

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

- 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 416 Cuban pesos or 416 Cuban convertible pesos, depending on the currency in which the importing entity operates.

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

**Conditions of licensing**

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

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

16. Import licences are not transferable between importers.

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

**Other procedural requirements**

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

19. Not applicable.

C. NATIONAL CENTRE FOR NUCLEAR SAFETY (CNSN)

**Outline of systems**

1. Authorization is required to import radioactive sources and ionizing radiation emitting equipment. This provides a means of controlling the sources and equipment 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.

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

**Purposes and coverage of licensing**

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

- Import licences for radioactive sources and ionizing radiation emitting equipment;

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

Radioactive source: Anything that might cause exposure to radiation, whether by emitting ionizing radiation or releasing radioactive substances or materials.

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 International Atomic Energy Agency.

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

CITMA Resolution No. 62 of 12 July 1996 - "Regulations for the National Nuclear Materials Accounting and Control System".

CITMA Resolution No. 25 of 9 June 1998 - "Regulations concerning the Authorization of Practices Associated with the Use of Ionizing Radiation".

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. Legislative approval would be required to abolish the current system.

**Procedures**

6. Not applicable.

7. (a) Under current legislation, a licence must be obtained prior to the importation of ionizing radiation equipment and sources. In this respect, it is provided that the National Centre for Nuclear Safety (CNSN) must respond to a licence application within 30 working days of its receipt.

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

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

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

(d) The CNSN is the sole body responsible for considering licence applications.

8. After having considered the information submitted, the competent authority may refuse an application for authorization to import ionizing radiation emitting equipment or radioactive sources on the following grounds:

(a) The information is inaccurate, unclear or contradictory;

(b) the data provided is incomplete;

(c) the device or equipment is not appropriate for the specific use for which it is intended;

(d) the person nominated to be responsible for radiological protection does not meet the relevant requirements;

(e) authorization previously given to the entity was suspended or withdrawn for reasons that continue to exist or where there is no evidence to suggest that the reasons for the suspension or withdrawal no longer exist;

(f) the results of the inspections conducted to verify the existence of the required technical conditions show that it is advisable to refuse the application;

(g) staff do not meet the relevant requirements.

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 applicant that authorization has been refused and provides a report setting forth the grounds for this decision.

Applicants have no right of appeal.

**Eligibility of importers to apply for licence**

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

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

10. For the importation of radioactive sources and ionizing radiation emitting equipment, a formal application must be submitted by the legal representative of the interested entity. Applications must specify the type of authorization requested and contain the following general information:

1. Name of the entity
2. State administration body to which the entity belongs
3. Address
4. Telephone number
5. Telex number
6. Fax number

7. Name of legal representative
8. Activity for which licence is required

Where authorization is required to transfer nuclear material or significant components, an application form is used.

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

1. Certification of the legal status of the requesting entity
2. Details of the ionizing radiation sources to be imported[4]
3. Reference to the user entity for which the goods are destined
4. Selling entity
5. Expected date of arrival in national territory
6. Company responsible for distribution or transportation of the source
7. Air or maritime terminal at which the radioactive material is expected to arrive
8. Production certificate for sealed sources
9. Certification of ISO 2919 classification of sealed sources or certification of special form radioactive material under current regulations on the transport of radioactive material.
10. In the case of ionizing radiation emitting devices, detailed information on the device's safety characteristics, provided by the manufacturer, must be submitted, together with certification from the regulatory authority in the country of origin concerning the approval of the design.
11. Package design approval certificate for the transportation of Type B packages in accordance with current regulations on the transport of radioactive material.

12. A state service fee of 2098 Cuban pesos is charged for a licence to import radioactive sources and ionizing radiation emitting equipment.

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

13. There is no deposit or advance payment requirement. The only payment required is the authorization 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 for radioactive sources or ionizing radiation emitting equipment is established on a case-by-case basis by the CNSN. A licence is normally granted for three months. The validity of a licence cannot be extended; instead, a new licence 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.

[4] Depending on the name of the radioactive source and whether or not it is sealed, or in the case of emitting equipment, the information to be submitted, such as that pertaining to source and radionuclide activity, concentration of activity, source serial number, and equipment voltage, is determined by law.

**Other procedural requirements**

18. No other procedures are required prior to importation.

19. Not applicable.

D. NATIONAL CENTRE FOR BIOLOGICAL SAFETY (CNSB)

**Outline of systems**

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

**Purposes and coverage of licensing**

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

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

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

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

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

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

- Resolution No. 67/96 on the creation of the CNSB and its functions and responsibilities, which include organizing and implementing procedures for granting licences for the importation of biological agents and their products, and organisms and parts thereof containing genetic information.

- Decree Law No. 190 on biological safety, Section 1, Article 4(c). Establishes the responsibilities of the CITMA, which include granting, suspending and withdrawing licences for activities relating to the use, testing, production, release, importation and exportation of, and research into, biological agents and their products, and organisms and parts thereof containing genetic information.

- Resolution No. 180/2007 - Regulations for the Granting of Biological Safety Authorization, Chapter 1, Article 6(e). Provides that prior biological safety authorization must be obtained in order to import and export biological agents and their products, and organisms and parts thereof containing genetic information.

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

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

**Procedures**

6. Not applicable.

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

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

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

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

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

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

- The anticipated benefits are not worth the risks involved.

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

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

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

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

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

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

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

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

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

**Eligibility of importers to apply for licence**

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

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

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

- Name of the facility or release area

- Body or organization to which it belongs

- Date of application

- Legal domicile, telephone and fax numbers, 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 of 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 3979 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.

## II. MINISTRY OF AGRICULTURE

### A. NATIONAL CENTRE FOR PLANT HEALTH (CNSV) AND PLANT QUARANTINE

**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.

**Purposes and coverage of licensing**

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

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

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

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

**Procedures**

6. Not applicable.

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

   (b) No.

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

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

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

**Eligibility of importers to apply for licence**

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

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

10. The importer must complete the application form set forth in Annex III.[5]

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

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

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

**Conditions of licensing**

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

15. There are no penalties.

16. No, licences are not transferable between importers.

17. Not applicable.

**Other procedural requirements**

18. Not applicable.

19. Not applicable.

## III. MINISTRY OF THE INTERIOR (MININT)

### A. PROTECTION DIRECTORATE

**Outline of systems**

1. Import licences are required to show that the security devices used to ensure the safety and protection of goods and people have been examined by means of appropriate procedures and that their quality meets the requirements of both the manufacturer and the body that governs their use.

Licences are granted to properly established national legal persons.

**Purposes and coverage of licensing**

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

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

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

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

Central alarm receiving units and remote security system management platforms.

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

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

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

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

**Procedures**

6. Not applicable.

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

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

(c) There are no limitations.

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

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

**Eligibility of importers to apply for licence**

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

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

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

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

11. Import licence.

12. There is no fee or charge.

13. Not applicable.

**Conditions of licensing**

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

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

16. Import licences are not transferable between importers.

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

**Other procedural requirements**

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

19. Not applicable.

## IV. MINISTRY OF THE ARMED FORCES (MINFAR)

### A. 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 radiocommunications services.

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

**Procedures**

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

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

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

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

(c) There are no limitations of this sort.

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

8. Licence applications may be refused if the GPS equipment involved is to be used to measure coordinates in areas for which the recipients of the equipment do not have authorization. Applications may also be refused if they have been submitted by an importer whose corporate purpose does not

justify the use of GPS technology. In all cases, applicants are notified of the reasons for the refusal. Decree No. 269 and Resolution No. 90 do not provide for a right of appeal.

**Eligibility of importers to apply for licence**

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

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

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

(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.

## V. MINISTRY OF PUBLIC HEALTH (MINSAP)

### A. NATIONAL PHARMACEUTICAL AND OPTICAL DIRECTORATE

**Outline of systems**

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

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

**Purposes and coverage of licensing**

2. - Narcotic drugs regulated by the Single Convention on Narcotic Drugs, 1961.

- Psychotropic Substances regulated by the Convention on Psychotropic Substances, 1971.

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

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

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

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

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

5. Ministerial Resolution No. 58 of 1967, Standards and Procedures for the Control of Narcotic Drugs, in accordance with the provisions of the Single Convention on Narcotic Drugs, 1961.

Ministerial Resolution No. 72 of 1990, which implements the provisions of the Convention on Psychotropic Substances, 1971.

Ministerial Resolution No. 67 of 1996 - Regulations for the Control of Precursors and Basic or Essential Chemicals, which implements the provisions of the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

Import licensing is mandatory and is governed by specific legislation.

**Procedures**

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

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

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

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

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

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

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

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

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

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

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

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

XI. Not applicable.

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

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

(c) Not applicable.

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

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

**Eligibility of importers to apply for licence**

9. (a) Importers must be registered in the Central Register for Importers and Exporters at the Pharmaceutical and Optical Directorate of the MINSAP. Any legal entity may register provided that it is already registered in the National Register of Exporters and Importers of the Chamber of Commerce of Cuba and the Central Customs Register of the Customs General of the Republic.

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

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

(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 Nonproprietary 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 the 31 December of each year. They cannot be extended. In the event of expiry, a new application must be submitted.

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

16. Licences are not transferable.

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

**Other procedural requirements**

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

19. Not applicable.