



LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

ECUADOR

Communicated by the Government of Ecuador

NOTE BY THE SECRETARIAT

- (a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [] have been added or changed by the Secretariat.
- (b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

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*Note by the Secretariat: This document is a direct copy of the texts communicated to the Secretariat.

No. 003-CD

THE BOARD OF DIRECTORS OF CONSEP

CONSIDERING

THAT there is a need to establish regulations in application of article 3 of Law No.108, the Narcotic Drugs and Psychotropic Substances Act¹,

THAT paragraph 15 of article 13 assigns to the Board of Directors of CONSEP the function of approving individuals and corporations which may be authorized by the Executive Secretary to import, export, manufacture, sell and use controlled substances;

THAT under agreement 052 of 3 June 1991², published in the Official Gazette (Registro Oficial) No. 722 of 9 July of that year, CONSEP's internal procedures were issued for the accreditation of individuals and corporations as importers, exporters, manufacturers, sellers and users of controlled substances;

THAT on the basis of experience of its application there is a need to amend some of the requirements and procedures laid down in those Rules of Procedure; and,

In exercise of its legal powers,

HEREBY DECIDES

TO ISSUE THE FOLLOWING REGULATIONS ON REQUIREMENTS AND PROCEDURES TO BE FULFILLED BY INDIVIDUALS AND CORPORATIONS WISHING TO USE AND SELL CONTROLLED CHEMICAL SUBSTANCES

I. OBJECTIVE AND SCOPE OF APPLICATION

Article 1. The objective of this regulation is to determine the requirements and procedures to be fulfilled by individuals and corporations wishing to obtain legal approval to import, export, manufacture, sell or buy locally controlled substances, or use them in industrial processes.

II. REQUIREMENTS TO BE FULFILLED BY INDIVIDUALS

Article 2. An individual wishing to obtain the approval to which the foregoing article refers shall submit the following documents:

- a. A written application addressed to the Executive Secretary of CONSEP on the form provided by CONSEP;
- b. Photocopy of identity card;

¹E/NL.1991/1

²E/NL.1993/21

- c. Photocopy of the personal tax registration (RUC);
- d. Copy of the commercial registration entry in the relevant Trade Register.
- e. Up-to-date certification of membership of the relevant Chamber of Commerce, if applicable; and
- f. The information requested in Annex III.

III. REQUIREMENTS TO BE FULFILLED BY CORPORATIONS

Article 3. A corporation wishing to be approved for import, export, manufacture, selling, buying locally and using controlled substances shall submit the following documents:

- a. A written application addressed to the Executive Secretary of CONSEP, signed by its legal representative, on the form provided for the purpose by CONSEP;
- b. Certified copy of the deed of incorporation of the corporation and any changes thereto;
- c. Certification of the appointment of the legal representative, registered in proper form;
- d. Certification of the appointment of the relevant technical representative, registered in proper form;
- e. Certificate of fulfilment of obligations vis-a-vis the Office of the Superintendent of Companies, relating to the last financial period;
- f. Certified copy of the balance sheets submitted to the Office of the Superintendent of Companies, relating to the last financial period;
- g. Certified copy of the commercial registration entry in the relevant Trade Register;
- h. Up-to-date certification of membership of the relevant Chamber of Commerce; and,
- i. The information requested in Annexes II or III, as applicable.

All the documents must be duly legalized and up-to-date.

Article 4. Before granting approval, CONSEP officials in the relevant district, shall inspect pharmaceutical laboratories, pharmacies, clinics, hospitals, industrial or commercial enterprises, and places used to warehouse and store the controlled substances covered by these Regulations, and shall submit a report thereof to the Director-General for Inspection and Control.

Article 5. The above-mentioned report shall include, inter alia, the type, quality and quantity of the controlled substance or substances required by the applicant for a period of one calendar year, and the storage, handling, transport and security facilities available.

Article 6. The Department of Inspection and Control shall analyze the required application and supporting documents submitted by the applicants and shall submit a report thereof to the Board of Directors of CONSEP within six (6) days. For this purpose, it may request any information it considers relevant from INTERPOL, the Criminal Investigation Department (OID), the applicant and other public bodies. The above-mentioned time limit shall be suspended until the applicant has submitted any information requested of him.

Article 7. The Board of Directors of CONSEP, at its meeting immediately following the submission of the report to which the foregoing article refers, shall decide on the application for approval, in the form of a resolution (signed by the Executive Secretary) in one original and three copies. The original shall be issued to the applicant and the copies filed in the Office of the Executive Secretary.

Article 8. The approval granted by the Board of Directors of CONSEP to individuals and corporations shall be of indefinite duration, but shall be revoked or suspended if the holders commit any offences laid down in the Narcotic Drugs and Psychotropic Substances Act and the Regulations in application thereof.

Article 9. If the Board of Directors of CONSEP decides to refuse an application for approval, the applicant may submit a further request, which satisfies the requirement or requirements whose absence were the grounds for refusal.

In the case of small traders or occasional buyers, Directive 003 shall be applied by the Executive Secretary.

IV. GENERAL PROVISIONS

Article 10. The documentation required for approval shall be submitted in the forms prepared for the purpose by CONSEP, on payment of the applicable fee, in one original and one copy, the pages of which shall be numbered and initialled by the Secretary-General of CONSEP. The original shall be retained in the Office of the Executive Secretary and the copy returned to the applicant, with acknowledgement of submission. The applicant may submit the documentation to the applicable district office of CONSEP, where the date of presentation shall be fixed.

Article 11. Individuals or corporations approved by the Board of Directors of CONSEP shall immediately inform the Office of the Executive Secretary of any changes of address, telephone number, post office box, fax, stores, legal representative, shareholders, technical representative, amendments to articles of association or change of name, cessation of activity and other information concerning the activities of such persons.

V. FINAL PROVISION

Article 12. Decision No.052 issued by the Board of Directors of CONSEP on 3 June 1991, published in Official Gazette No.722 of 9 July 1991 is hereby revoked.

These Regulations shall come into force on their publication in the Official Gazette.

Done in the Board Room of CONSEP, in Quito on the twenty-ninth day of July one thousand nine hundred and ninety-three.

(Signed) Dr. Carlos Larreátegui, State Attorney-General, Chairman of the Board of Directors of CONSEP.

(Signed) Franklin Zambrano Llor, Executive Secretary of CONSEP.

This is a certified true copy of the foregoing original document, as attested by myself, with my seal and signature, in Quito, on 25 August 1993.

(Signed) Franklin Zambrano Llor, Executive Secretary of CONSEP, Secretary to the Board of Directors of CONSEP.

ANNEX 1

APPROVAL OF CORPORATIONS OF A COMMERCIAL NATURE

GENERAL FEATURES OF THE ENTERPRISE

[...]

ANNEX 2

APPROVAL OF INDUSTRIAL CORPORATIONS

[...]

No. 015-CD

THE BOARD OF DIRECTORS OF CONSEP

CONSIDERING

THAT on 22 July 1993, it issued the REGULATIONS ON THE IMPORT OR EXPORT OF CHEMICAL PRECURSORS AND OTHER SPECIFIC CHEMICALS SUBJECT TO CONTROL BY CONSEP;

THAT there is a need to reform the Regulations in force, incorporating the internal procedures of the Commercial Section of the Office of the Executive Secretary;

In exercise of the power granted in paragraph 5 of article 13 of Law No.108, the Narcotic Drugs and Psychotropic Substances Act,¹

HEREBY DECIDES:

TO ISSUE THE REGULATIONS ON THE IMPORT OR EXPORT OF CHEMICALS SUBJECT TO CONTROL BY CONSEP.

CHAPTER I

DEFINITIONS

Article 1. For the purposes of these Regulations:

- a. "Controlled chemicals" means chemical precursors of other specific chemicals, as defined in Annex IV, Tables I and II of the Narcotic Drugs and Psychotropic Substances Act² as updated by the Board of Directors of CONSEP.
- b. "Commercial importer" means an individual or corporation approved by CONSEP who imports controlled chemicals solely for the purposes of selling them, without subjecting them to any industrial process.
- c. "Industrial importer" means an individual or corporation approved by CONSEP who imports controlled chemicals for the purposes of industrial processing which results in a recognized commercial product distinct from the substances used.
- d. "Exporter" means an individual or corporation approved by CONSEP who exports controlled chemicals.

¹E/NL.1991/1

²E/NL.1992/41

CHAPTER II

SCOPE OF APPROVAL AND AUTHORIZATION

Article 2. Importers or exporters approved by the Board of Directors of CONSEP may import or export controlled chemicals.

In each case, the Office of the Executive Secretary of CONSEP shall grant the applicable authorization pursuant to Law No.108, the Regulations in application thereof and these Regulations.

Article 3. The Office of the Executive Secretary may authorize the import or export of controlled chemicals by a number of importers or exporters approved by the Board of Directors of CONSEP, jointly or in partnership solely for such purpose, in order to reduce freight and transport costs, take advantage of cargo capacity or to obtain better terms of purchase or sale.

Article 4. The authorization to import or export controlled chemicals issued by the Office of the Executive Secretary shall permit:

- a. Processing of the import or export declaration by the Central Bank of Ecuador; and
- b. Release from Customs of the controlled substances listed in the approved import declaration.

CHAPTER III

COMMERCIAL IMPORTERS

Article 5. CONSEP shall authorize new imports by applicants who fulfil the following requirements:

- a. Timely submission of the monthly reports required under articles 40 and 41 of the Regulations for the application of the Narcotic and Psychotropic Substances Act³, in compliance with the annexes to these Regulations;
- b. On the date of submission of the new application, the balances of controlled chemicals are fully justified and permit a maximum supply of three months. In special cases, CONSEP may authorize imports when existing stocks represent a supply exceeding the above-mentioned period; and,
- c. Any other information required by the Department of Inspection and Control.

³E/NL.1991/63

CHAPTER IV

INDUSTRIAL IMPORTERS

Article 6. *CONSEP shall authorize new imports by applicants who fulfil the following requirements:*

- a. Timely submission of the monthly reports required under article 40 of the Regulations for the application of Law No. 108;
- b. Provide the Office of the Executive Secretary with the information indicated in Annexes 1 to 6 of these Regulations. The finished products to which the Annexes refer are those in the production of which one or more controlled substances are used; and,
- c. Any other information required by the Department of Inspection and Control.

CHAPTER V

EXPORTERS

Article 7. *CONSEP shall authorize new exports by applicants who fulfil the following requirements:*

- a. Timely submission of the monthly reports required under article 40 of the Regulations for the application of Law No. 108;
- b. Submit the import authorization issued by the destination country for the export from Ecuador; and,
- c. Any other information required by the Department of Inspection and Control.

CHAPTER VI

INTERNAL PROCEDURES FOR AUTHORIZING IMPORTS OR EXPORTS

Article 8. *The Executive Secretary shall authorize the import or export of controlled chemicals in accordance with the following procedure:*

- a. As soon as the applicant submits the relevant application and supporting documentation, an official of the Commercial Section shall determine whether it is admissible within 8 working hours from its submission.

If all prescribed requirements are satisfied, the official shall certify that fact on the application. Otherwise, his immediate superior shall return the application and other documents to the applicant, indicating in writing the reasons for returning them, so that the applicant may complete or correct the documentation as the case may be.

- b. Once the certification referred to in the foregoing paragraph has been given, the Director-General of Inspection and Control or his deputy shall examine the application and supporting documents, and arrange that within the next six working days the technical staff of the Inspection and Control Department shall check the information and issue a report thereon.

If appropriate, the applicants may be requested to provide additional information, and the previously established time limit shall be suspended. Such information must be submitted within a maximum of sixty calendar days from the date of the application.

The report shall be signed by the technical staff, the Head of Inspection and Control and the Director-General of Inspection and Control, or his deputy, and shall contain:

- General information, duly supported, on the import and export of controlled chemicals;
- The balance of receipts and disposals of controlled chemicals, showing the balances for the month immediately preceding;
- Analysis of the forecast use or sale of controlled chemicals, as applicable;
- Analysis of the period of supply of controlled chemicals which may not exceed four months for commercial importers; and
- The final recommendation to approve or refuse the requested import or export.

c. If the above-mentioned report recommends that approval should be granted, an official of the Commercial Section, after checking that all the legal and regulatory requirements have been satisfied, shall stamp and number the import or export permit.

If the report finds that certain legal or regulatory requirements have not been satisfied, the Commercial Section shall inform the applicant of the reasons for refusing permission to import or export.

d. On examining the documentation, the Executive Secretary or officials designated by the Board of Directors, shall approve or refuse the import or export of controlled chemicals.

All the documentation shall be filed at the Department of Inspection and Control of CONSEP.

Article 9. If the applicant does not submit any additional information requested, or does not withdraw the application for authorization to import or export within two months of submitting it, it shall lapse and the application shall be filed.

CHAPTER VII

GENERAL PROVISIONS

Article 10. The application to import or export shall be signed by the applicant, in the case of an individual, or its representative, in the case of a corporation, showing the CONSEP registration number, and shall contain the information required under article 39 of the Regulations in application of Law No.108.

Article 11. The rules under these Regulations shall also apply to controlled substances entering the territory of Ecuador, subject to arrangements for temporary admission, processing, free zones, public industrial or commercial bonded stores, as applicable.

Article 12. The technical staff of the Office of the Executive Secretary shall inspect the premises and periodically verify the information provided by importers or exporters, and the existence, storage and

destination of controlled chemicals imported pursuant to Law No.108, the Regulations for its application and these Regulations.

Article 13. The Executive Secretary of CONSEP shall inform the Central Bank of Ecuador, the Military Customs Police and the National Police of authorized imports and exports.

Article 14. The Office of the Executive Secretary shall fix the scale of maximum tolerance of losses of controlled chemicals pursuant to Law No. 108 and the Regulations for its application. For differences in imports, it shall be set at the level determined by the Monetary Board.

Article 15. Permits to import and export shall lapse one hundred and eighty and ninety days respectively from the date of issue and may not be extended. They may not be used to cover import or export of different substances.

Article 16. The forms for the import or export procedure shall be subject to a fee and may be obtained from CONSEP on payment of the prescribed fees.

Article 17. The decision issued by the Office of the Executive Secretary refusing authorization to import or export controlled chemicals may be appealed by the applicant at the Board of Directors, as laid down in article 13, paragraph 16 of Law No.108; and article 13, paragraph 5 of the Regulations for its application.

Article 18. In order to decentralize import or export procedures, the Board of Directors shall appoint regional, area or provincial CONSEP heads determined by the Executive Secretary as competent to approve or refuse applications.

Article 19. Persons approved by CONSEP to import controlled chemicals, subject to prior authorization by the Office of the Executive Secretary, may sell or lend part of their stocks to other individuals or corporations approved by CONSEP.

Article 20. The Office of the Executive Secretary shall maintain an up-to-date register of all imports and exports of controlled chemicals authorized or refused by CONSEP.

Article 21. Persons approved by CONSEP shall, in January of each year, submit to the Department of Inspection and Control an annual forecast of receipts and disposals of controlled chemicals.

Article 22. The REGULATIONS ON THE IMPORT OR EXPORT OF CHEMICAL PRECURSORS AND OTHER SPECIFIC CHEMICALS SUBJECT TO INSPECTION AND CONTROL BY CONSEP issued by the Board of Directors of CONSEP on 22 July 1993 are hereby revoked.

Done in the Board Room of CONSEP, in Quito on the sixteenth day of November one thousand nine hundred and ninety-three.

(Signed) Dr. Carlos Larreátegui, State Attorney-General, Chairman of the Board of Directors of CONSEP.

(Signed) Franklin Zambrano Loo, Executive Secretary of CONSEP.