



Ministry of Health
BRAZILIAN HEALTH SURVEILLANCE
AGENCY
COLLEGIATE BOARD OF GOVERNORS
RESOLUTION – RDC # 172, OF SEPTEMBER
8, 2017

Provides for procedures for the import and export of goods and products intended for scientific or technological research and for research involving human beings, and provides other measures.

The Collegiate Board of Governors of the Brazilian Health Surveillance Agency, in the use of the attribution conferred by art. 15, III and IV allied to art. 7, III, and IV, of Law # 9,782, of January 26, 1999, art. 53, V, §§ 1 and 3 of the Internal Regulations approved in accordance with Annex I of the Collegial Board of Governors' Resolution - RDC # 61 of February 3, 2016, resolves to adopt the following Collegial Board of Governors' Resolution, as resolved at a meeting held on September 5, 2017, and I, the Chairman, determined its publication.

CHAPTER I - DEFINITIONS

Art. 1 For the purposes of this Resolution, it is considered:

I - Export Authorization (AEX): document issued by Anvisa authorizing the export of substances from the lists A1, A2, A3, B1, B2, C3, D1, F1, F2, F3 and F4 and from list E or plants that may originate substances subject to special control, of Ordinance SVS/MS # 344 of May 12, 1998, and its updates, as well as of the medicines containing them;

II - Import Authorization (AI): document issued by Anvisa authorizing the import of substances from lists A1, A2, A3, B1, B2, C3, D1, F1, F2, F3 and F4 and from list E or plants that may originate substances subject to special control, of Ordinance SVS/MS # 344 of 1998, and its updates, as well as of the medicines containing them;

III - Simplified Special Authorization (APE) - Authorization granted by Anvisa to educational and research institutions to acquire and use the substances listed in Ordinance SVS/MS # 344/98 and its updates;

IV - Bill of Lading: document issued on the date of shipment of the good or product, by the carrier or consolidator, constituting the contract of international transport and proof of disposition of the good or product to the importer (airborne cargo - Air Waybill/AWB, waterborne cargo - Bill Landing/BL and land cargo - Knowledge of International Transport by Highway/CTR);

V- Accreditation: is the act by which the Brazilian Council of Scientific and Technological Development (CNPq) authorizes the scientist, researcher or scientific, technological and innovation institution to import under the protection of Law # 8,010, of March 29, 1990;

VI - Simplified Import Declaration (DSI): it is the simplified import procedure, made through the Brazilian Revenue Service's own form, for the entry and regular stay of the product in Brazil;

VII - Exportation: shipment to other countries of material intended for scientific and/or technological research;

VIII - Intermediated Import: import by legal entity that promotes, in its name, foreign trade operation of import of goods and products under health surveillance acquired for the purpose of supply for exclusive use in scientific and/or technological research;

IX - Scientific, Technological and Innovation Institution: body or entity of direct or indirect public administration or non-profit private legal entity legally constituted under the Brazilian laws, with headquarters and forum in the Country, including in its institutional mission or in its social or statutory objective the basic or applied scientific or technological research or the development of new products, services or processes;

X - Import Licensing (LI): electronic application with SISCOMEX (Import Module), by the importer or its legal representative, for procedures to verify compliance with requirements for import of goods and products under health surveillance;

XI - NOVOEX: SISCOMEX module intended for export;

XII - Scientific or Technological Research: research whose results are applied in the health sector and aimed, ultimately, to improve the health of individuals and population groups;

XIII - Scientific or technological research involving human beings: research that, individually or collectively, directly interacts with the human being, without registration of the product under research;

XIV - Researcher: a natural person mandatorily bound to a scientific and/or technological institution, responsible for coordinating and carrying out basic or applied research, of scientific or technological nature;

XV - Export Register (RE): is the set of information of commercial, financial, currency and fiscal nature that characterizes the operation of export of a commodity and defines its framework;

XVI - Express Shipment: international document or order transported by air, by Courier Company, which requires fast transfer and immediate receipt by the recipient;

XVII - International Postal Shipment: goods and products under health surveillance transported through international order by the Brazilian Postal and Telegraph Company (ECT);

XVIII - Integrated Foreign Trade System (SISCOMEX): administrative instrument that integrates the activities of registration, monitoring and control of foreign trade operations, through a single and computerized flow of information; and

XIX - Term of Responsibility: document signed by the importer or exporter that declares the sole and exclusive destination for scientific or technological research of the material to be imported or exported.

CHAPTER II - IMPORT

Section I - Import for Scientific or Technological Research

Article 2. The import of goods and products under health surveillance, intended to scientific or technological research, carried out by researchers or Scientific, Technological and

Innovation Institutions duly accredited by CNPq, under the terms of Law # 8,010/90 and its amendments, will have the automatic deferment of import licensing in SISCOMEX.

Sole paragraph. Imports of human biological samples and products subject to special control, as provided for in Ordinance SVS/MS # 344, of 1998, and its updates are excluded from the above provisions, for which the procedures established in the respective Sections of this Resolution shall apply.

Article 3. The import of goods and products under health surveillance intended for scientific or technological research, carried out by researchers or Scientific, Technological and Innovation Institutions duly accredited by CNPq, will take place by means of SISCOMEX, Express Shipment and International Postal Shipment.

Article 4. The import of goods and products under health surveillance intended for scientific or technological research carried out by researchers or Scientific, Technological and Innovation Institutions not accredited by CNPq, will have non-automatic deferment of import licensing and shall submit to the express and favorable opinion of the competent health authority of Anvisa.

§ 1 - The import referred to in the caput shall be analyzed within 48 (forty-eight) hours after the arrival of the product in the national territory and compliance with the pertinent legal requirements.

§ 2. The import referred to in the caput shall be given by the modalities SISCOMEX, Express Shipment, International Postal Shipment or non-electronic ISD.

Section II - Import for Scientific or Technological Research Involving Human Beings

Article 5. The import of goods and products under health surveillance intended for research involving human beings shall be submitted to the express and favorable manifestation of the competent health authority of Anvisa prior to its clearance in the national territory.

§ 1 - The import will have its analysis within 48 (forty-eight) hours after the arrival of the product in the national territory and the fulfillment of the pertinent legal requirements.

§ 2. The import made by researchers or Scientific, Technological and Innovation Institutions duly accredited by CNPq, whose tax regime is exempt from the Federal Revenue, will have automatic deferment of import licensing in SISCOMEX.

§ 3. The imports referred to in the caput shall be in the modalities SISCOMEX, Express Shipment and International Post Shipment.

§ 4 - The import by physical person of products under health surveillance that are subject to regularization before Anvisa and that do not yet have such regularization, intended to research involving human beings, is prohibited.

Article 6. The import, by legal entity, of goods and products that can be regularized before Anvisa and which do not yet have such regularization, intended to research involving human beings, must be preceded by mandatory



evaluation and approval of the research by the Research Ethics Committee (REC) and, when applicable, by the Brazilian Commission for Research Ethics (CONEP).

Article 7. The provisions of this section do not apply to research involving human beings whose purpose is to register or change the registration of the product in Brazil, or market research.

Section III - Import of Human Biological Samples

Article 8. The import of human biological samples intended for research in general shall have non-automatic deferment of import licensing and shall be submitted to the express and favorable manifestation of the competent health authority of Anvisa.

§ 1 - The import referred to in the caput shall be analyzed within 48 (forty-eight) hours after the arrival of the product in the national territory and compliance with the pertinent legal requirements.

§ 2. The import referred to in the caput shall be by the modalities SISCOMEX, Express Shipment and International Postal Shipment.

Section IV - Import of Goods and Products Subject to Special Control

Article 9. The import of substances, plants, medicines and products subject to special control contained in Ordinance SVS/MS # 344, of 1998, and its updates, intended to the scientific or technological research and the investigation involving human beings will have non-automatic Import Licensing registered in SISCOMEX.

§ 1 The import referred to in the caput shall be analyzed within 48 (forty-eight) hours after the arrival of the product in the national territory and compliance with the pertinent legal requirements.

§ 2 The import referred to in the caput requires prior authorization of shipment of Anvisa, and then is submitted to inspection by the health authority before its customs clearance.

§ 3 The substances in list C of SVS/MS # 344, 1998, and its updates, except substances in list C3, shall be exempt from prior authorization.

§ 4 The import referred to in the caput will be given only by legal entities and by the modalities SISCOMEX and Express Shipment.

§ 5. The import of substances, plants, medicines and products subject to special control contained in Ordinance SVS/MS n° 344, of 1998, and its updates, that can be regularized before Anvisa and that do not yet have such regularization, intended to the research involving human beings, must be preceded by mandatory evaluation and approval of the research by CEP and, when applicable, by CONEP.

Article 10. In addition to the provisions of this Section, the import of substances, plants, medicines and products subject to special control shall comply with all the requirements of Ordinance SVS/MS n° 344, of 1998, its updates and other pertinent legislation.

Section V - Intermediated Import

Article 11. The import of goods and products subject to health control for use in scientific or technological research and research involving human beings by intermediary juridical person of the researcher or the Scientific, Technological and Innovation Institution shall be allowed.

Article 12. For the import of products that can be regularized before Anvisa, the intermediary importer must be regularized, as regards the Operating Permit and the Special Authorization for the activity and product class, as well as to present a Statement of Responsibility established in the Annex I of this Resolution, signed by the researcher responsible for the research and by the Scientific, Technological and Innovation Institution.

Sole paragraph. Imports made directly by researchers or Scientific, Technological and Innovation Institutions are exempt from the requirement set forth in the caput.

Section VI - Import Procedures for Non-Automatic Licensing

Article 13. For imports through SISCOMEX (LI), the following documents must be presented:

I - Petition for inspection and health release, available on the ANVISA website;

II - Commercial invoice;

III - Bill of lading;

IV - Term of Responsibility - Annex I, except for products subject to special control contained in Ordinance SVS/MS # 344, of 1998, and its updates;

V - AEP in the case of products subject to special control contained in Ordinance SVS/MS n° 344, of 1998, and in its updates;

VI - AI issued by Anvisa in the case of substances listed in lists A1, A2, A3, B1, B2, C3, D1 and F1, F2, F3 and F4 and plants in list E plants or plants capable of producing substances subject to special control of SVS Ordinance # 344, of 1998, its updates, as well as the medicines containing them;

VII - AEX or similar document issued by the health authority of the exporting country, in the case of substances listed in lists A1, A2, A3, B1, B2, C3, D1, F1, F2, F3 and F4, plants in list E or plants that may originate substances subject to special control, of Ordinance SVS/MS # 344, of 1998, and its updates, as well as the medicines containing them; and

VIII - REC CONEP opinion, when dealing with research involving human beings.

Article 14. For the import by the modality Express Shipment, the following documents must be presented:

I - Petition for inspection and health release, available on Anvisa's website;

II - Term of Responsibility - Annex I, except for products subject to special control contained in Ordinance SVS/MS # 344, of 1998, and its updates;

III - Union Recollection Guide - GRU;

IV - Proof of payment of the Union Collection Guide - GRU, in case of import, by legal entity, of human biological samples;

V - Commercial invoice;

VI - Bill of lading;

VII - REC or CONEP opinion, when dealing with research involving human beings;

VIII - AEP in the case of products subject to special control contained in Ordinance SVS/MS # 344, of 1998, and its updates;

IX - Import Authorization for substances listed in lists A1, A2, A3, B1, B2, C3, D1, F1, F2, F3 and F4 and plants in list E plants or plants which may give rise to substances subject to special control, of Ordinance SVS/MS # 344, of 1998, and its updates, as well as the medicines containing them; and

X - AEX or similar document issued by the health authority of the exporting country, in the case of substances listed in lists A1, A2, A3, B1, B2, C3, D1, F1, F2, F3 and F4, and plants in list E or plants that may originate substances subject to special control, of Ordinance SVS/MS # 344, of 1998, and their updates, as well as of the medicinal products containing them.

Article 15. For the import by the International Mail Shipment mode, the following documents must be presented:

I - Petition for inspection and health release, available on Anvisa's website;

II - Term of Responsibility - Annex I;

III - Commercial invoice; and

IV - REC or CONEP opinion, when dealing with research involving human beings.

Article 16. For import by DSI, the following documents must be presented:

I - Petition for inspection and health release, available on Anvisa's website;

II - Term of Responsibility - Annex I;

III - Commercial invoice; and

IV - REC or CONEP opinion, when dealing with research involving human beings.

CHAPTER III - EXPORT

Article 17. The export of goods and products under health surveillance, intended to scientific or technological research and research involving human beings shall take place through the modalities SISCOMEXNOVOEX, International Postal Shipment and Express Shipment.

Article 18. The export of the substances, plants, medicines and products subject to special control contained in Ordinance SVS/MS # 344, of 1998, and its updates, intended to the scientific or technological research and the research involving human beings will be given only by the modalities SISCOMEX-NOVOEX and Express Shipment.

Article 19. The following documents must be submitted for the export by SISCOMEXNOVOEX, Express Shipment or International Postal Shipment:

I. Petition for inspection and health release, available on the Anvisa website;

II. Term of Responsibility - Annex II;

III - Union Recollection Guide - GRU;



IV - Proof of payment of the Union Collection Guide - GRU, in case of import, by legal entity, of human biological samples;

V - AEX issued by Anvisa in the case of substances listed in lists A1, A2, A3, B1, B2, C3, D1, F1, F2, F3 and F4 and plants in list E plants or plants which may give rise to substances the special control of Ordinance SVS/MS # 344, of 1998, and its updates, as well as of the medicines that contain them.

CHAPTER IV - FINAL PROVISIONS

Article 20. Import and export of material under health surveillance intended to scientific or technological research and research involving human beings by the modalities accompanied and unaccompanied baggage shall not be allowed.

Article 21. Mandatory health requirements for sanctioning and health release of material for scientific or technological research or for research involving human beings shall be met regarding the packaging, transportation and storage standards informed by its manufacturer or supplier.

Article 22. For the import of regularized products in Brazil intended to scientific or technological research or research involving human beings, a declaration of the holder of the regularization must be presented, authorizing the import.

Sole paragraph. The authorization must be issued on behalf of the individual or legal entity that presents itself as an importer to Anvisa.

Article 23. When the scientific research is closed, the researcher or the Scientific, Technological and Innovation Institution shall give final destination to the materials in accordance with the legal provisions of environmental control.

Sole paragraph. The use of non-regularized medical equipment at Anvisa in health services after closing the research will be forbidden.

Article 24. This Resolution also applies to imports intended to research and laboratory analysis carried out by drug repression bodies in the conduct of their activities.

Article 25. Imports intended to programs of expanded access, compassionate use, post-study drugs supply and clinical trials whose objective is registration or alteration of product registration in Brazil will be analyzed within 5 (five) days after protocol and compliance with legal requirements.

Article 26. Failure to observe or comply with the provisions of this Resolution constitutes an infraction of a sanitary nature, subjecting the offender to the penalties of Law # 6,437, of August 20, 1977, without prejudice to other applicable civil or criminal sanctions.

Article 27. Chapter XIX of the Collegiate Board of Governors' Resolution - RDC # 81, of November 5, 2008, and the Collegiate Board of Governors' Resolution - RDC # 01, of January 22, 2008, are revoked.

Article 28. This Resolution shall enter into force thirty (30) days after its publication.

JARBAS BARBOSA DA SILVA JR.

Chairman