RESOLUTION RDC no. 13, JANUARY 27TH, 2004

The Collegiate Board of Directors of the Brazilian National Health Surveillance Agency, in the exercise of the powers vested by Article 11, subsection IV, of ANVISA Regulation approved by Decree no. 3,029, of April 16th, 1999, as well as by Article 111, subsection I, item b, and its Paragraph 1 of the Internal Statute approved by Ordinance no. 593, of August 25th, 2000, republished on December 22nd, 2000, in meeting held on September 11th, 2003,

considering the need to define duties and obligations to persons of public or private rights involved in the import, consumption and export of products subject to health surveillance, not registered within the Brazilian Health Surveillance System, and intended for exhibition, demonstration or distribution in fairs or events;

considering the need to align health surveillance inspection procedures for import, consumption and export of products subject to health surveillance, not registered within the Brazilian Health Surveillance System, and intended for exhibition or distribution in fairs or events, hereby adopts the following Resolution and I, Director-President, determine its publication;

Article 1. The Technical Regulation on the health surveillance of import, consumption and export of products subject to health surveillance, not registered within the Brazilian Health Surveillance System, and intended for exhibition, demonstration or distribution in fairs and events is hereby approved, as attached.

Article 2. Failure to observe or to comply with the provisions hereof shall constitute sanitary violation, being the offenders hereby subject to the penalties addressed in Law no. 6,437, of August 20th, 1977, and its modifications, notwithstanding other applicable civil and criminal sanctions.

Article 3. This Resolution shall come into force on the date of its publication on the Official Gazette and all provisions to the contrary are hereby revoked.

CLAUDIO MAIEROVITCH PEESANHA HENRIQUES

ANNEX

Technical Regulation on the health surveillance of import, consumption and export of products subject to health surveillance, not registered within the Brazilian Health Surveillance System, and intended for exhibition, demonstration or distribution in fairs or events

CHAPTER I

Import of medical devices and in-vitro diagnostic products not registered at the Brazilian Health Surveillance Agency and solely intended for exhibition in fairs or events.

Article 1. Import of medical devices and in-vitro diagnostic products not registered at Anvisa and solely intended for exhibition in fairs or events shall be clearly authorized by the competent health surveillance authority of Anvisa prior to their customs clearance in national territory.

Paragraph 1. All products addressed in this Article shall be returned to their origin and the legal entity responsible for their import shall communicate the effective return date, with five business days in advance, to the health surveillance authority in exercise in the location where
the products thereof will leave the country.

Paragraph 2. Prior to embarkation to be returned, the products addressed in the previous paragraph shall be subject to physical inspection conducted by the health surveillance authority in exercise in the location where the products will leave the country.

Paragraph 3. The proper document that proves that the products have left the country shall be submitted to the health surveillance authority in exercise in the location of customs clearance, within five business days after embarkation.

Article 2. The products addressed in this Chapter shall solely be imported after their mandatory registration at the Integrated System of Foreign Trade - SISCOMEX, being the legal entity responsible for such import hereby exempt from requesting Anvisa’s health surveillance authority for the authorization for embarkation overseas.

Article 3. When imported by legal entities that hold the product registration overseas and that are regularized at Anvisa as to the operating permit (AFE) for importing and exporting medical devices or in-vitro diagnostic products, the import of the products addressed in this Chapter shall be authorized and/or cleared by the health surveillance authority in exercise in the location of customs clearance after submission of the pertinent Application Form for Sanitary Inspection and Clearance and of the Liability Statement (Annex I), as well as after compliance with all other requirements hereof.

Sole Paragraph. Import applications referring to the products addressed in this Article shall be submitted to the competent health surveillance in exercise in the location of customs clearance.

Article 4. When imported by legal entities not regularized at Anvisa, the import of the products addressed in this Chapter shall be approved by the competent technical department of Anvisa in Brasilia, prior to the sanitary authorization and clearance to be provided by the health surveillance authority in exercise in the location of customs clearance after submission of the pertinent Application Form for Sanitary Inspection and Clearance and of the Liability Statement (Annex II), as well as after compliance with all other requirements hereof.

Paragraph 1. The legal entities addressed in this Article shall have sanitary, civil and criminal liability for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import.

Paragraph 2. The legal entities addressed in this Article are hereby exempt from submitting to the health surveillance authority in exercise in the location of customs clearance the operating permit (AFE) for importing and exporting medical devices and in-vitro diagnostic products (healthcare products).

Paragraph 3. A technical manager shall be liable for the products addressed in this Article during their stay in national territory.

Paragraph 4. The professional formation of the technical manager addressed in the previous paragraph shall comply with the requirements established in the pertinent sanitary legislation in force.

Paragraph 5. Import applications referring to the products addressed in this Article may be submitted directly to the competent technical department of Anvisa in Brasilia or to the
Article 5. The liability statements in Annex I and II hereof shall be submitted undersigned by the legal representative and technical manager.

Sole Paragraph. The aforementioned documents shall have the signatures thereof notarized by a notary office.

Article 6. Commercialization and change in the intended purpose of import of the products addressed in this Section are hereby prohibited.

Article 7. It is hereby prohibited to use the products addressed in this Chapter in human beings.

CHAPTER II

Import and consumption of medical devices and in-vitro diagnostic products not registered at the Brazilian Health Surveillance Agency and intended for exhibition and demonstration in fairs or events.

Article 8. Import of medical devices and in-vitro diagnostic products not registered at Anvisa and intended for exhibition and demonstration in fairs or events shall be clearly authorized by the competent health surveillance authority of Anvisa prior to their customs clearance in national territory.

Article 9. The products addressed in this Chapter shall solely be imported after their mandatory registration at the Integrated System of Foreign Trade - SISCOMEX, being the legal entity responsible for such import hereby exempt from requesting Anvisa's health surveillance authority for the authorization for embarkation overseas.

Article 10. When imported by legal entities that hold the product registration overseas and that are regularized at Anvisa as to the operating permit (AFE) for importing and exporting medical devices or in-vitro diagnostic products, the import of the products addressed in this Chapter shall be approved by the competent technical department of Anvisa in Brasilia, prior to the sanitary authorization and clearance to be provided by the health surveillance authority in exercise in the location of customs clearance after submission of the pertinent Application Form for Sanitary Inspection and Clearance and of the Liability Statement (Annex III), as well as after compliance with all other requirements hereof.

Article 11. When imported by legal entities not regularized at Anvisa, the import of the products addressed in this Chapter shall be approved by the competent technical department of Anvisa in Brasilia, prior to the sanitary authorization and clearance to be provided by the health surveillance authority in exercise in the location of customs clearance after submission of the pertinent Application Form for Sanitary Inspection and Clearance and of the Liability Statement (Annex IV), as well as after compliance with all other requirements hereof.

Paragraph 1. The legal entities addressed in this Article shall have sanitary, civil and criminal liability for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product demonstration provided by the health surveillance authority.
Paragraph 2. The legal entities addressed in this Article are hereby exempt from submitting to the health surveillance authority in exercise in the location of customs clearance the operating permit (AFE) for importing and exporting medical devices and in-vitro diagnostic products (healthcare products).

Paragraph 3. A technical manager shall be liable for the products addressed in this Article during their stay in national territory.

Paragraph 4. The professional formation of the technical manager addressed in the previous paragraph shall comply with the requirements established in the pertinent sanitary legislation in force.

Article 12. Import applications referring to the products addressed in Articles 10 and 11 hereof may be submitted directly to the competent technical department of Anvisa in Brasilia or to the competent health surveillance authority in exercise in the location of customs clearance, at the discretion of the legal entity responsible for such import.

Article 13. In the case of technical opinions issued by the competent department of Anvisa not approving the import application for product exhibition and demonstration along with consumption or direct exposure to human beings, or in the case of technical opinions approving such application with technical conditions, the health surveillance authority in exercise in the location of customs clearance shall be responsible for sending such technical opinion, by the use of the proper administrative instrument, to the competent health surveillance authority of the Brazilian Unified Health System in exercise in the location of the fair or event for complementary health surveillance measures.

Paragraph 1. In the case of mandatory return of all products to their origin, the legal entity responsible for their import shall communicate the effective return date, with five business days in advance, to the health surveillance authority in exercise in the location where the products thereof will leave the country.

Paragraph 2. Prior to embarkation to be returned, the products addressed in the previous paragraph shall be subject to physical inspection conducted by the health surveillance authority in exercise in the location where the products will leave the country.

Paragraph 3. The proper document that proves that the products have left the country shall be submitted to the health surveillance authority in exercise in the location of customs clearance, within five business days after embarkation.

Article 14. The liability statements in Annex III and IV hereof shall be submitted undersigned by the legal representative and technical manager.

Sole Paragraph. The aforementioned documents shall have the signatures thereof notarized by a notary office.

Article 15. Commercialization and change in the intended purpose of import of the products addressed in this Section are hereby prohibited.

CHAPTER III

Import of cosmetics, perfumes and personal hygiene products not registered at the Brazilian Health Surveillance Agency and intended for exhibition in fairs or events.
Article 16. Import of personal hygiene products, perfumes and cosmetics not registered at Anvisa and intended for exhibition in fairs or events shall be clearly authorized by the competent health surveillance authority of Anvisa prior to their customs clearance in national territory.

Paragraph 1. All products addressed in this Article shall be returned to their origin and the legal entity responsible for their import shall communicate the effective return date, with five business days in advance, to the health surveillance authority in exercise in the location of customs clearance.

Paragraph 2. Prior to embarkation to be returned, the products addressed in the previous paragraph shall be subject to physical inspection conducted by the health surveillance authority in exercise in the location where the products will leave the country.

Paragraph 3. The proper document that proves that the products have left the country shall be submitted to the health surveillance authority in exercise in the location of customs clearance, within five business days after embarkation.

Article 17. The products addressed in this Chapter shall solely be imported after their mandatory registration at the Integrated System of Foreign Trade - SISCOMEX, being the legal entity responsible for such import hereby exempt from requesting Anvisa's health surveillance authority for the authorization for embarkation overseas.

Article 18. When imported by legal entities regularized at Anvisa as to the operating permit (AFE) for importing and exporting cosmetics, perfumes and personal hygiene products, the import of the products addressed in this Chapter shall be authorized and/or cleared by the health surveillance authority in exercise in the location of customs clearance, after submission of the pertinent Application Form for Sanitary Inspection and Clearance and of the Liability Statement (Annex V), as well as after compliance with all other requirements hereof.

Article 19. When imported by legal entities not regularized at Anvisa, the import of the products addressed in this Chapter shall be authorized and/or cleared by the health surveillance authority in exercise in the location of customs clearance, after submission of the pertinent Application Form for Sanitary Inspection and Clearance and of the Liability Statement (Annex VI), as well as after compliance with all other requirements hereof.

Paragraph 1. The legal entities addressed in this Article shall have sanitary, civil and criminal liability for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product demonstration provided by the health surveillance authority.

Paragraph 2. The legal entities addressed in this Article are hereby exempt from submitting to the health surveillance authority in exercise in the location of customs clearance the operating permit (AFE) for importing and exporting cosmetics, perfumes or personal hygiene products.

Paragraph 3. A technical manager shall be liable for the products addressed in this Article during their stay in national territory.

Paragraph 4. The professional formation of the technical manager addressed in the previous paragraph shall comply with the requirements established in the pertinent sanitary legislation in force.
Article 20. Import applications referring to the products addressed in Articles 18 and 19 hereof shall be submitted to the competent health surveillance authority in exercise in the location of customs clearance.

Article 21. The liability statements in Annex V and VI hereof shall be submitted undersigned by the legal representative and technical manager.

Sole Paragraph. The aforementioned documents shall have the signatures thereof notarized by a notary office.

Article 22. Distribution, commercialization and change in the intended purpose of import of the products addressed in this Chapter are hereby prohibited.

CHAPTER IV

Import of cosmetics, perfumes and personal hygiene products not registered at the Brazilian Health Surveillance Agency and intended for exhibition with demonstration in fairs or events.

Article 23. Import of personal hygiene products, perfumes and cosmetics not registered at Anvisa and intended for exhibition with demonstration in fairs or events shall be clearly authorized by the competent health surveillance authority of Anvisa prior to their customs clearance in national territory.

Article 24. The products addressed in this Chapter shall solely be imported after their mandatory registration at the Integrated System of Foreign Trade - SISCOMEX, being the legal entity responsible for such import hereby exempt from requesting Anvisa's health surveillance authority for the authorization for embarkation overseas.

Article 25. When imported by legal entities regularized at Anvisa as to the operating permit (AFE) for importing and exporting personal hygiene products, perfumes and cosmetics, the import of the products addressed in this Chapter shall be authorized and/or cleared by the health surveillance authority in exercise in the location of customs clearance, after submission of the pertinent Application Form for Sanitary Inspection and Clearance and of the Liability Statement (Annex VII), as well as after compliance with all other requirements hereof.

Paragraph 1. Import applications referring to the products addressed in this Article shall be submitted to the competent health surveillance in exercise in the location of customs clearance.

Paragraph 2. A technical manager shall have technical liability for the import, transportation and stay of the product in national territory, as well as for the product demonstration.

Article 26. When imported by legal entities not regularized at Anvisa, the import of the products addressed in this Chapter shall be approved by the competent technical department of Anvisa in Brasilia, prior to the sanitary authorization and clearance to be provided by the health surveillance authority after submission of the pertinent Application Form for Sanitary Inspection and Clearance and of the Liability Statement (Annex VIII), as well as after compliance with all other requirements hereof.

Paragraph 1. Import applications referring to the products addressed in this Article may be submitted directly to the competent technical department of Anvisa in Brasilia or to the
Paragraph 2. The legal entities addressed in this Article shall have sanitary, civil and criminal liability for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product demonstration provided by the health surveillance authority.

Paragraph 3. The legal entities addressed in this Article are hereby exempt from submitting to the health surveillance authority in exercise in the location of customs clearance the operating permit (AFE) for importing and exporting cosmetics, perfumes or personal hygiene products.

Paragraph 4. A technical manager shall be liable for the products addressed in this Article during their stay in national territory.

Paragraph 5. The professional formation of the technical manager shall comply with the requirements established in the pertinent sanitary legislation in force.

Article 27. The liability statements in Annex VII and VIII hereof shall be submitted undersigned by the legal representative and technical manager.

Sole Paragraph. The aforementioned documents shall have the signatures thereof notarized by a notary office.

Article 28. The products addressed in this Chapter shall comply with the Positive Lists of Dyes, Preservatives and Sun Blocks and with the Restrictive List of Substances established in Anvisa Resolution no. 79/2000, and its updates.

Article 29. All products addressed in this Chapter that may contain, in their composition, substances included in the List of Prohibited Substances established in Anvisa Resolution no. 79/2000 and its updates are hereby prohibited to be imported into national territory.

Article 30. Distribution, commercialization and change in the intended purpose of import of the products addressed in this Chapter are hereby prohibited.

CHAPTER IV

Import of sanitizing products not registered at the Brazilian Health Surveillance Agency and intended for exhibition and/or demonstration in fairs or events.

Article 31. Import of sanitizing products not registered at Anvisa and intended for exhibition and demonstration in fairs or events shall be clearly authorized by the competent health surveillance authority of Anvisa prior to their customs clearance in national territory.

Paragraph 1. All sanitizing products solely imported for exhibition in fairs or events shall be returned to their origin and the legal entity responsible for their import shall communicate the effective return date, with five business days in advance, to the health surveillance authority in exercise in the location of customs clearance.

Paragraph 2. Prior to embarkation to be returned, the products addressed in the previous paragraph shall be subject to physical inspection conducted by the health surveillance authority in exercise in the location where the products will leave the country.
Paragraph 3. The proper document that proves that the products have left the country shall be submitted to the health surveillance authority in exercise in the location of customs clearance, within five business days after embarkation.

Article 32. The products addressed in this Chapter shall solely be imported after their mandatory registration at the Integrated System of Foreign Trade - SISCOMEX, being the legal entity responsible for such import hereby exempt from requesting Anvisa's health surveillance authority for the authorization for embarkation overseas.

Article 33. When imported by legal entities that hold the product registration overseas and that are regularized at Anvisa as to the operating permit (AFE) for importing and exporting sanitizing products, the import of the products addressed in this Chapter shall be approved by the competent technical department of Anvisa in Brasilia, prior to the sanitary authorization and clearance to be provided by the health surveillance authority in exercise in the location of customs clearance after submission of the pertinent Application Form for Sanitary Inspection and Clearance and of the Liability Statement (Annex IX), as well as after compliance with all other requirements hereof.

Paragraph 1. The legal entities addressed in this Article shall have sanitary, civil and criminal liability for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product demonstration provided by the health surveillance authority.

Paragraph 2. The legal entities addressed in this Article are hereby exempt from submitting to the health surveillance authority in exercise in the location of customs clearance the operating permit (AFE) for importing and exporting sanitizing products.

Paragraph 3. A technical manager shall be liable for the products addressed in this Article during their stay in national territory.

Paragraph 4. The professional formation of the technical manager addressed in the previous paragraph shall comply with the requirements established in the pertinent sanitary legislation in force.

Article 35. Import applications referring to the products addressed in Articles 33 and 34 hereof may be submitted directly to the competent technical department of Anvisa in Brasilia or to the competent health surveillance authority in exercise in the location of customs clearance, at the discretion of the legal entity responsible for such import.

Article 36. In the case of technical opinions issued by the competent department of Anvisa not approving the import application for product exhibition and demonstration along with consumption or direct exposure to human beings, or in the case of technical opinions approving such application with technical conditions, the health surveillance authority in...
exercise in the location of customs clearance shall be responsible for sending such technical
opinion, by the use of the proper administrative instrument, to the competent health
surveillance authority of the Brazilian Unified Health System in exercise in the location of the
fair or event for complementary health surveillance actions.

Paragraph 1. In the case of mandatory return of all products to their origin, the legal entity
responsible for their import shall communicate the effective return date, with five business
days in advance, to the health surveillance authority in exercise in the location where the
products thereof will leave the country.

Paragraph 2. Prior to embarkation to be returned, the products addressed in the previous
paragraph shall be subject to physical inspection conducted by the health surveillance
authority in exercise in the location where the products will leave the country.

Paragraph 3. The proper document that proves that the products have left the country shall be
submitted to the health surveillance authority in exercise in the location of customs clearance,
within five business days after embarkation.

Article 37. The liability statements in Annex IX and X hereof shall be submitted undersigned by
the legal representative and technical manager.

Sole Paragraph. The aforementioned documents shall have the signatures thereof notarized by
a notary office.

Article 38. Distribution, commercialization and change in the intended purpose of import of
the products addressed in this Chapter are hereby prohibited.

CHAPTER V

Import and consumption of food intended for exhibition, demonstration and/or distribution in
fairs or events.

Article 39. Import of food intended for exhibition and demonstration in fairs or events shall be
clearly authorized by the competent health surveillance authority of Anvisa prior to their
customs clearance in national territory.

Article 40. Import of food intended for exhibition, demonstration and/or distribution in event
or fairs shall be analyzed, approved and have their sanitary clearance provided by the
competent health surveillance authority of Anvisa in exercise in the location of customs
clearance, after submission of the pertinent Application Form for Sanitary Inspection and
Clearance and of the Liability Statement (Annex XI), as well as after compliance with all other
requirements hereof.

Paragraph 1. The products addressed in this Chapter shall solely be imported after their
mandatory registration at the Integrated System of Foreign Trade - SISCOMEX.

Paragraph 2. Import applications referring to the products addressed in this Article shall be
submitted to the competent health surveillance in exercise in the location of customs
clearance, except those addressed in Paragraph 3 of this Article.

Paragraph 3. Food that does not have any regulation approved in Brazil is hereby precluded
from the provision of this Article.
Paragraph 4. In compliance with the provision of the previous paragraph, legal entities responsible for the import hereof shall submit the following documentation to the competent health surveillance authority of Anvisa in Brasilia, in addition to complying with other requirements hereof:

I - Pertinent Application Form for Sanitary Inspection and Clearance;
II - Liability Statement (Annex XI);
III - evidence of product use or commercialization, as it is presented, in other countries, economic blocks, CODEX ALIMENTARIUS, and other acknowledged international bodies;
IV - description of ingredients, additives and technology coadjuvants used in the product formulation;
V - product technical specifications; VI - product’s validity period;

Paragraph 5. The requirement made by the previous paragraph shall not depend on the condition of product registration being mandatory or not.

Article 41. The legal entities responsible for the import of the products addressed in this Chapter shall have sanitary, civil and criminal liability for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product demonstration provided by the health surveillance authority.

Article 42. The legal entity responsible for the import of the products addressed in this Chapter shall have a technical manager in their personnel board, who shall have technical liability for the import, transportation and stay of the product in national territory, as well as for the product return to its origin and for its demonstration, along with product consumption and its direct exposure to human beings.

Article 43. The liability statement in Annex XI hereof shall be undersigned by the legal representative and technical manager.

Sole Paragraph. The aforementioned document shall have the signatures thereof notarized by a notary office.

Article 44. Commercialization and change in the intended import purpose are hereby prohibited.

CHAPTER VI GENERAL PROVISIONS

Article 45. Legal entities responsible for the import of medical devices, in-vitro diagnostic products and sanitizing products intended for exhibition or demonstration in fairs or events shall attach, to the pertinent Application Form for Sanitary Inspection and Clearance, document undersigned by the importer's legal representative and technical manager containing the following information:

I - name and address of the legal entity that will exhibit and/or demonstrate the product;
II - name of the technical manager responsible for the product exhibition and/or demonstration while the event is taking place;
III - type of event;
IV - full address of the fair or event;
V - name and date of the fair or event;
VI - justified amount of the product;
VII - qualitative and quantitative formula of the product, except if medical device;
VIII - product technical specifications;
IX - product's validity period;
X - legal or physical person responsible for the event;
XI - place of product storage before and after the fair or event;
XII - copy of product label, in the case of sanitizing product.

Sole Paragraph. The documents addressed in subsections VII, VIII and XII hereof shall be exclusively submitted to the technical department of sanitizing products at Anvisa, in Portuguese, and sworn translated.

Article 46. Legal entities responsible for the import of cosmetics, perfumes and personal hygiene products shall attach, to the pertinent Application Form for Sanitary Inspection and Clearance, document undersigned by the legal representative and technical manager containing the following information:

I - name and address of the legal entity that will exhibit and/or demonstrate the product;
II - name of the technical manager responsible for the product exhibition and/or demonstration while the event is taking place;
III - type of event;
IV - full address of the fair or event;
V - name and date of the fair or event;
VI - justified amount of the product;
VII - qualitative and quantitative formula of the product, in Portuguese or in international nomenclature (INCI);
VIII - legal or physical person responsible for the event;
IX - place of product storage before and after the fair or event.

Article 47. Legal entities responsible for the import of food intended for exhibition or demonstration and distribution in fairs or events shall attach, to the pertinent Application Form for Sanitary Inspection and Clearance, document undersigned by the importer's legal representative and technical manager containing the following information:

I - name and address of the legal entity that will exhibit and/or demonstrate the product;
II - name of the technical manager responsible for the product exhibition and/or demonstration while the event is taking place;
III - type of event;
IV - full address of the fair or event;
V - name and date of the fair or event;
VI - justified amount of the product;
VII - legal or physical person responsible for the event;
VIII - place of product storage before and after the fair or event;
IX - copy of the product label, in the case of food.

Sole Paragraph. For the purpose of technical analysis, the health surveillance authority may require, at their own discretion, the submission of the label addressed in subsection XI translated into Portuguese, undersigned by the legal representative and technical manager of the legal entity responsible for the import of the product.
Article 48. Medications not registered at Anvisa are hereby prohibited to be imported for distribution, exhibition or demonstration in fairs and events in national territory.

Sole Paragraph. Distribution, exhibition or demonstration in fairs and events of medications not registered at Anvisa are hereby prohibited.

Article 49. The health surveillance control of the imported products herein addressed shall be complemented by the competent health surveillance authority in exercise in the state where the event or fair is taking place.

Article 50. The health surveillance authority may require, at their own discretion, complementary technical information, by the use of a proper legal instrument, in order to draw the conclusion as to the approval of the import of the products herein addressed.

Article 51. The authorization for importing products subject to health surveillance solely intended for international fairs and events is hereby established and approved.

Sole Paragraph. The authorization addressed in this Article shall be provided for each import license registered at SISCOMEX - Import Module.

Article 52. Legal entities authorized according to the pertinent regulatory norms of the Brazilian Federal Public Administration and responsible, in national territory, for the fair or event that proposes the exhibition, demonstration and/or distribution of products subject to health surveillance with international origin shall communicate Anvisa’s technical department in Brasilia with 90 days in advance.

Article 53. Products not regularized by the Brazilian Health Surveillance System that have not been used in fairs or events, as well as the residues that resulted from the demonstration thereof, shall be under control and intervention of Anvisa’s competent health surveillance authority in exercise in the state the fair or event took place in order to define their final destination together with the legal entity responsible for their import.

Paragraph 1. It is the responsibility of the legal entity responsible for the import of the products addressed in this Article to meet all expenses related to the product return to its origin or to its destruction in national territory.

Paragraph 2. Intermediate and final technical procedures related to the aforementioned destruction shall be carried out in the presence of Anvisa’s competent health surveillance authority in exercise in the state where the products will be treated and discarded.

Article 54. Import applications related to the products herein addressed shall be submitted to the competent health surveillance authority by 10 business days before the event.

Sole Paragraph. The health surveillance authority shall provide a response to the application addressed in this Article within seven business days after the date of application submission or receipt at Anvisa’s Customer Service or at Health Surveillance Offices in Ports, Airports and Borders of states.

ANNEX I

LIABILITY STATEMENT
IMPORT OF MEDICAL DEVICES AND IN-VITRO DIAGNOSTIC PRODUCTS NOT REGISTERED AT ANVISA AND INTENDED FOR EXHIBITION IN FAIRS OR EVENTS.

Legal entity

duly regularized at Anvisa as to Operating Permit (AFE) number for importing medical devices and/or in-vitro diagnostic products, herein represented by its legal representative and technical manager, hereby declares that the products listed below will be exhibited, in national territory, in fairs and events, and the probable return date to their origin is: (month) (day), (year).

The undersigned parties take full sanitary, civil and criminal responsibility before this body for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product exhibition provided by the health surveillance authority.

Date:

ANNEX II

LIABILITY STATEMENT

IMPORT OF MEDICAL DEVICES AND IN-VITRO DIAGNOSTIC PRODUCTS NOT REGISTERED AT ANVISA AND INTENDED FOR EXHIBITION IN FAIRS OR EVENTS.

Legal entity
	herein represented by its technical manager and legal representative, hereby declares to the Brazilian Health Surveillance Agency that the products listed below will be exhibited, in national territory, in fairs and events, and the probable return date to their origin is: (month) (day), (year).

The undersigned parties take full sanitary, civil and criminal responsibility, before this body, for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product exhibition provided by the health surveillance authority.

Date:
Date: _____/____/20____.

ANNEX III

LIABILITY STATEMENT

IMPORT OF MEDICAL DEVICES AND IN-VITRO DIAGNOSTIC PRODUCTS NOT REGISTERED AT ANVISA AND INTENDED FOR EXHIBITION AND DEMONSTRATION IN FAIRS OR EVENTS.

Legal entity

____________________, duly regularized at Anvisa as to Operating Permit (AFE) number________________ for importing medical devices and/or in-vitro diagnostic products, herein represented by its legal representative and technical manager, hereby declares that the products listed below will be exhibited and demonstrated (please, complement with information as to the demonstration of the products along with their consumption or direct exposure to human beings), in national territory, in fairs and events.

The probable return date to their origin is: (month) (day), (year). (please, include this paragraph in the case of mandatory product return).

The undersigned parties take full sanitary, civil and criminal responsibility, before this body, for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product exhibition and demonstration provided by the health surveillance authority.

____________________       ________________________
RESPONSABIL. TECNICO       REPRESENTANTE LEGAL

Date: _____/____/20____.

ANNEX IV

LIABILITY STATEMENT

IMPORT OF MEDICAL DEVICES AND IN-VITRO DIAGNOSTIC PRODUCTS NOT REGISTERED AT ANVISA AND INTENDED FOR EXHIBITION AND DEMONSTRATION IN FAIRS OR EVENTS.

Legal entity

_____________________, herein represented by its technical manager and legal representative, hereby declares to the Brazilian Health Surveillance Agency that the products listed below
will be exhibited and demonstrated (please, complement with information as to the
demonstration of the products along with their consumption or direct exposure to human
beings), in national territory, in fairs and events.

The probable return date to their origin is: (month) (day), (year). (please, include this
paragraph in the case of mandatory product return).

Date: _____/____/20__.

ANNEX V

LIABILITY STATEMENT

IMPORT OF PERSONAL HYGIENE PRODUCTS, PERFUMES AND COSMETICS NOT REGISTERED AT
ANVISA AND INTENDED FOR EXHIBITION IN FAIRS OR EVENTS.

Legal entity

________________________________________, duly regularized
at Anvisa as to Operating Permit (AFE) number___________________________for importing
personal hygiene products, perfumes and cosmetics, herein represented by its legal
representative and technical manager, hereby declares that the products listed below

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will be exhibited in national territory, in fairs and events.

The probable return date to their origin is: (month) (day), (year).

The undersigned parties take full sanitary, civil and criminal responsibility before this body for
individual or collective health damages, as well as for damages to the environment, that result
from change in the intended purpose of product import or from non-compliance with the
orientations on product exhibition provided by the health surveillance authority.

_______/____/20__.

ANNEX VI

LIABILITY STATEMENT

IMPORT OF PERSONAL HYGIENE PRODUCTS, PERFUMES AND COSMETICS NOT REGISTERED AT
ANVISA AND INTENDED FOR EXHIBITION IN FAIRS OR EVENTS.

Legal entity

__________________________________________________________________________________________, herein represented by its technical manager and legal representative, hereby declares to the Brazilian Health Surveillance Agency that the products listed below will be exhibited in national territory, in fairs and events.

The probable return date to their origin is: (month) (day), (year).

Date: ______/____/ 20___.

ANNEX VII

LIABILITY STATEMENT

IMPORT OF PERSONAL HYGIENE PRODUCTS, PERFUMES AND COSMETICS NOT REGISTERED AT ANVISA AND INTENDED FOR EXHIBITION WITH DEMONSTRATION IN FAIRS OR EVENTS.

Legal entity

__________________________________________________________________________________________, duly regularized at Anvisa as to Operating Permit (AFE) number________________________ for importing medical devices and/or in-vitro diagnostic products, herein represented by its legal representative and technical manager, hereby declares that the products listed below will be exhibited and demonstrated (please, complement with information as to the demonstration of the products), in national territory, in fairs and events.

We also declare that we have data that prove the safety of product use and that the product does not pose any risk to health when used according to its instructions for use and other statements in its label.

The undersigned parties take full sanitary, civil and criminal responsibility, before this body, for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product exhibition and demonstration provided by the health surveillance authority.

__________________________________________________________________________________________

RESPONSÁVEL TÉCNICO REPRESENTANTE LEGAL

Date: ______/____/ 20___.

Date:

/ / 20____.
ANNEX VIII

LIABILITY STATEMENT

IMPORT OF PERSONAL HYGIENE PRODUCTS, PERFUMES AND COSMETICS NOT REGISTERED AT ANVISA AND INTENDED FOR EXHIBITION WITH DEMONSTRATION IN FAIRS OR EVENTS.

Legal entity ____________________________, herein represented by its technical manager and legal representative, hereby declares to the Brazilian Health Surveillance Agency that the products listed below will be exhibited and demonstrated (please, complement with information as to the demonstration of the products), in national territory, in fairs and events.

We also declare that we have data that prove the safety of product use and that the product does not pose any risk to health when used according to its instructions for use and other statements in its label.

The undersigned parties take full sanitary, civil and criminal responsibility, before this body, for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product exhibition and demonstration provided by the health surveillance authority.

Date: _____/____/20___.

ANNEX IX

LIABILITY STATEMENT

IMPORT OF SANITIZING PRODUCTS NOT REGISTERED AT ANVISA AND INTENDED FOR EXHIBITION AND DEMONSTRATION IN FAIRS OR EVENTS.

Legal entity ____________________________, duly regularized at Anvisa as to Operating Permit (AFE) number ____________ for importing sanitizing products, herein represented by its legal representative and technical manager, hereby declares that the products listed below will be exhibited and/or demonstrated (please, complement with information as to the
demonstration of the products along with their consumption or direct exposure to human beings), in national territory, in fairs and events.

The probable return date to their origin is: (month) (day), (year). (please, include this paragraph in the case of mandatory product return to their origin).

The undersigned parties take full sanitary, civil and criminal responsibility, before this body, for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product exhibition and demonstration provided by the health surveillance authority.

Date:

ANNEX X

LIABILITY STATEMENT

IMPORT OF SANITIZING PRODUCTS NOT REGISTERED AT ANVISA AND INTENDED FOR EXHIBITION AND DEMONSTRATION IN FAIRS OR EVENTS.

Legal entity

represented by its technical manager and legal representative, hereby declares to the Brazilian Health Surveillance Agency that the products listed below will be exhibited and/or demonstrated (please, complement with information as to the demonstration of the products along with their consumption or direct exposure to human beings), in national territory, in fairs and events.

The probable return date to their origin is: (month) (day), (year). (please, include this paragraph in the case of mandatory product return to their origin).

The undersigned parties take full sanitary, civil and criminal responsibility, before this body, for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product exhibition and demonstration provided by the health surveillance authority.

Date:

ANNEX XI
LIABILITY STATEMENT

IMPORT OF FOOD INTENDED FOR EXHIBITION, DEMONSTRATION OR DISTRIBUTION IN FAIRS OR EVENTS

The undersigned parties take full sanitary, civil and criminal responsibility, before this body, for individual or collective health damages, as well as for damages to the environment, that result from change in the intended purpose of product import or from non-compliance with the orientations on product exhibition, demonstration and distribution provided by the health surveillance authority.

We also certify that the products in question:

a) are classified as one of the categories addressed in Annexes I or II of the technical regulation on the manual of basic procedures for registration and exemption of registration of products deemed as food;

b) meet their respective requirements for quality and identity or comply with their specific technical regulation; comply with other requirements established in the sanitary legislation in force.

Date: ____/____/20__.

ANNEX XII
FEDERATIVE REPUBLIC OF BRAZIL
MINISTRY OF HEALTH
BRAZILIAN HEALTH SURVEILLANCE AGENCY

AUTHORIZATION no. ____________________ FOR IMPORT OF PRODUCTS SUBJECT TO HEALTH SURVEILLANCE SOLELY INTENDED FOR INTERNATIONAL FAIRS AND EVENTS.

According to Article 51 of Anvisa RDC no. __, of December, 2003,

the Coordinator of Health Surveillance in Ports, Airports and Borders hereby authorizes company_____________________________________________________________________
Brazilian Registry of Legal Entities (CNPJ)______________, located on_________________________
________________________________________ number ________________, to import the products listed below for the purpose of______________________________________________,
identify the authorized activity
in fair or event
identify the name of the event
that will take place on dates__________, at establishment_________________________
located on______________________________________________.
identify the address of the event

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City and date:
COORDINATOR OF PORTS, AIRPORTS AND BORDERS OF THE STATE OF __________________________