Agência Nacional
de Vigilância Sanitária

RESOLUTION - RDC Nº. 90, OF DECEMBER 27, 2007.

Governs the registration of identification data for tobacco derivative smoking products.

The Collegial Directorate of the National Agency of Health Oversight [*Agência Nacional de Vigilância Sanitária, ANVISA*], in the exercise of the authority conferred upon it by Article 11, Section IV of the Regulation approved by Decree nº 3.029, of April 16, 1999, and having before it the provisions of Section II and §§ 1º and 3º of Art. 54 of the Internal Regimen approved pursuant to Annex I of Edict nº. 354 of ANVISA, of August 11, 2006, republished in the DOU official bulletin on August 21, 2006, at a meeting held on December 20, 2007, and

In light of the provisions of Law n.º 9.782, January 26, 1999, amended by Provisional Measure nº 2190-34 of August 23, 2001, which determines the regulation, oversight and inspection of products and services involving a risk to public health;

In light of the provisions of Art. 8º, section X and paragraph 4º, of Law n.º 9.782, of 1999, amended by MP nº. 2.190-34, of 2001;

In light of the provisions of Law nº. 9.782, of 1999, amended by MP nº. 2.190-34, of 2001, with regard to the phrase “registration, revalidation or renewal of the registration of smoking products"

In light of the need for revision of RDC 346/ 2003 on the registration of smoking products, as well as the adoption of the new electronic system for application;

In light of the risks to health inherent in tobacco derivatives and their particularities, setting them apart from other products subject to a regime of sanitary oversight;

Adopts the following Regulation that governs the established procedures that are applicable to tobacco leaf and smoking products that are processed, manufactured, sold and/or stored in the national territory, imported or exported and I, Director-President, require its publication:

CHAPTER I

Initial Provisions

Art. 1º This Resolution concerns rules and procedures to be observed in applications for registration and renewal of registration of identification data for smoking products.

CHAPTER II

Definitions

Art. 2º For the purposes of this Resolution, the following definitions apply:

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I - Smoking Product: a manufactured product, whether it is a tobacco derivative or not, that uses leaves or extracts of leaves or other parts of plants in its composition, that is intended to be smoked, chewed or inhaled;

II – Tobacco derivative: any product manufactured for consumption that uses in its composition tobacco leaves, intended for smoking, inhalation or chewing, even if it is only partially composed of tobacco;

III - Product: result of the transformation of raw materials into a material of saleable, added economic value;

IV – Brand Name: name, whether or not it is accompanied by any descriptor, applied to a product, that will be recognized by the consumer as a way to distinguish the product from others of the same character. Sub-brands shall be considered brands;

V – Descriptor: words, numbers and colors of packaging.

VI – Registration of smoking products – Identification data: as provided in Law 9.782/99, Annex II, registration is understood to refer to the approval of an application for the registration of a brand of smoking product, based on analysis of the documentation and the Identification data that must, by requirement, be passed along to ANVISA;

VII – Renewal of registration of smoking products – Identification data: as provided in Law 9782/99, renewal of registration is understood to refer to the act of renewal of Identification data of the brand of a smoking product, before its validity has expired, observing the period specified in this Resolution;

VIII – Processed tobacco: raw material consisting of tobacco leaves that has passed through a processing operation, used in the obtaining of other tobacco derivatives;

IX – Registration of Processed Tobacco: electronic application submitted by the processing company to register the quantity and origin of the types of tobacco processed by the company in the year immediately prior to that of the application, intended for use as raw materials for the obtaining of tobacco derivatives;

X - Additive: any substance or compound that is not tobacco or water, used for the processing, manufacture and packaging of a smoking product;

XI – Wrapping of tobacco derivatives: material that is wrapped around the column of tobacco to form the cylinder of the product;

XII – Wrapping of filter: paper that is directly wrapped around the filter;

XIII – Paper Tip: paper that is wrapped around the filter and extends to the cylinder of the cigarette. It is the material that connects the filter to the cylinder of the cigarette;

XIV - Filter: placed at the end of the cylinder of the cigarette to retain part of the particulate matter and nicotine that accompany the smoke;

XV – Primary smoke stream: also called the principal smoke, it is the smoke that comes out of the end and goes into the mouth and is inhaled by the smoker during the process of smoking;

XVI – Secondary smoke stream: also called lateral smoke, it is all the smoke emitted during the burning of the smoking product, except for the part that goes out of the end and enters the mouth and is inhaled by the smoker ;

XVII - Analytical Report: technical report issued by a laboratory containing the results of the physical and chemical analyses of smoking products;

XVIII – Processing Company: this refers to the company that engages in activities involving any kind of processing of tobacco leaf used for smoking products;

XIX – Manufacturing Company: company that produces any tobacco derivative;

XX – Total Tobacco: blend of the different types of tobacco that go into the final composition of smoking products;

XXI - Electronic Application: procedure undertaken by the interested party to fill in the Identification data required by this rule, sending of electronic documentation and printing of the Unique Guide for Collection of the Inspection Fee for Sanitary Oversight, using the Electronic System for Application and Fee Collection available at the ANVISA website;

XXII - Primary application: application containing all documentation concerning the subject that will lead to the opening of the process;

XXIII- Secondary application: application containing all documentation concerning the subject that is linked to the primary process that is already existing;

XXIV – Form for Application for Smoking Product: standardized document made available in the Electronic Application containing spaces to be filled in electronically for the Identification data required by this rule;

XXV – Mail Protocol: administrative document proving receipt by mail of the documents required by this rule;

XXVI – On-line Protocol: administrative document proving receipt of the Identification data filled in and sent to ANVISA through the Electronic System for Service and Fee Collection;

XXVII - Website: this is the Internet location of ANVISA, where services for application, fee collection and publication of the Situation Report on Brands of Smoking Products, established by this Resolution, identified as http://www.anvisa.gov.br;

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CHAPTER III

Formulation of the request, compilation of the process and public notification of the act

On the Registration of the Tobacco Derivative Smoking Product - Identification data

Art. 3º It is required to register the Identification data of all brands of smoking tobacco derivatives, manufactured in the national territory, imported or exported.

Sole paragraph. The Identification data and information contained in applications do not generate a registration number, with any disclosure, publicity or promotion associated with the registration process of ANVISA being prohibited.

Art. 4º National manufacturing companies and importing companies of tobacco derivative smoking products must send to ANVISA the primary application for the Registration of Identification Data for each brand that is to be sold, imported or exported.

§ 1º The primary application for the registration of identification data must be done individually, by product brand, and must be accompanied by the following documentation:

I – Original of the Receipt for Payment of the Inspection Fee for Sanitary Oversight, generated by the Electronic System for Service and Fee Collection, available at the ANVISA website;

II - CD-ROM containing the electronic file of the packaging showing all the surfaces available to the public or the proof of submission of packaging through the Electronic Application System;

III – A sample of the packaging as it is used for sale;

IV – Copy of the Executive Declaration (Portuguese acronym, ADE) of the granting of the Special Registration of the Manufacturer or importer, when dealing with cigarette products, issued by the Secretary of Federal Revenue of Brazil - SRF/MF, pursuant to the regulations in force;

V - Copy of the Executive Declaration (ADE) of Tax Status for the brand of cigarette on file with the Secretary of Federal Revenue of Brazil - SRF/MF, pursuant to the regulations in force, or an authenticated copy of the stamped communication on file with the SRF if the ADE has not yet been published in the official bulletin of the DOU.

VI – Original Analytical Report of the quantifications required in §2º of this article concerning the composition of the smoke and the total tobacco;

VII - CD-Rom containing the description of the methods used, when they are different from the methods officially accepted for the quantification of the compounds in the primary stream, secondary stream and the total tobacco;

VIII – Original of the proof of transmission of the data provided for the Electronic Application;

IX – Printed copy of data provided through the Electronic Application System.

§ 2º Data to be provided through the Electronic Application System for the registration of the brand Identification data are as follows:

I – Brand characteristics: brand name, product type, origin, purpose and types of packaging;

II – List of the types of tobaccos used;

III – List of the Additives used;

IV - Specifications and Physical Characteristics of filter and wrappings;

V - Parameters and Compounds present in the primary stream, in accordance with Annex I;

VI - Parameters and Compounds present in the secondary stream in accordance with Annex I;

VII - Parameters and Compounds present in the total tobacco in accordance with Annex I.

§ 3º Analytical data concerning sections V, VI and VII must be obtained through laboratory analysis and specifically for the brand that is to be registered.

§ 4º The laboratory analyses used for quantification of the compounds must adhere to internationally accepted methods or those adopted on the basis of an agreement or international convention ratified and internalized by Brazil, in accordance with Annex I of this Resolution.

§ 5º The report of the laboratory analysis must contain, in addition to the quantifications, the name and address of the laboratory, the name, title and signature of the person responsible for the analyses, indication of the methods used, brand name analyzed and data of the conclusion of the analyses.

§ 6º For purposes of registration of identification data, only the report of the laboratory analysis issued within a period no greater than 06 (six) months prior to the date of the protocol of the application will be accepted.

§ 7º For purposes of registration the brand name contained in the initial application will be used, and any change of the brand name applied for must be undertaken in an application for Renewal of Brand Registration.

Art. 5º Any alteration to be made by the company in the packaging submitted for the registration of identification data, except for an alteration of the brand name, must be submitted for analysis by ANVISA, through an Amendment, that will be analyzed within a period of up to 30 days.

§ 1º The request for an amendment must be accompanied by a sample of the packaging as it will be used for sale;

§ 2º The request cited in the heading of this article seeking the alteration of the packaging can be submitted at any time by the company, and the packaging containing the alteration can only be sold after the approval of the amendment has been sent to the company.

Art. 6º Once the analysis is concluded, and if there is no further requirement to be fulfilled, the application for the registration of identification data shall be approved, and the public notification of this act will be provided in the *Diário Oficial da União*, the official bulletin, of the specific brand, the company name and the CNPJ number.

Sole paragraph. Any alteration in the composition declared by the company in filing for registration of the brand must be reported to Anvisa through a request for an Amendment, within a period of up to 30 days after the alteration.

Renewal of the Registration of Tobacco Derivative Smoking Products - Identification data

Art. 7º National companies that manufacture and companies that import tobacco derivatives must submit to ANVISA an application for the Renewal of the Registration of Identification Data of Tobacco Derivative Smoking Products each year, adhering to the deadlines set forth in this Resolution.

§ 1º The application for the Renewal of the Registration of Identification Data for the brand must contain, as required, the following documentation:

I – Original of the Receipt for Payment of the Inspection Fee for Sanitary Oversight, generated by the Electronic System for Service and Fee Collection, available at the ANVISA website;

II - CD-ROM containing the electronic file of the packaging showing all the surfaces available to the public or the proof of submission of packaging through the Electronic Application System;

III – A sample of the packaging as it is used for sale;

IV – Copy of the Executive Declaration (Portuguese acronym, ADE) of the granting of the Special Registration of the Manufacturer or importer, when dealing with cigarette products, issued by the Secretary of Federal Revenue of Brazil - SRF/MF, pursuant to the regulations in force;

V - Copy of the Executive Declaration (ADE) of the Tax Status for the brand of cigarette on file with the Secretary of Federal Revenue of Brazil - SRF/MF, pursuant to the regulations in force, or an authenticated copy of the stamped communication on file with the SRF if the ADE has not yet been published in the official bulletin of the DOU.

VI – Updated original Analytical Report of the quantifications required in Annex I of this rule concerning the composition of the smoke and the total tobacco;

VII – Original of the proof of transmission of the data provided for the Electronic Application;

VIII – Printed copy of data provided through the Electronic Application System.

§ 2º Data to be provided through the Electronic Application System for the Renewal of the Registration of Identification Data of the brand are as follows:

I – Brand characteristics: brand name, product type, origin, purpose and types of packaging;

II – List of the types of tobaccos used and their origins;

III – List of the Additives used;

IV - Specifications and Physical Characteristics of filter and wrappings;

V - Parameters and Compounds present in the primary stream, in accordance with Annex I;

VI - Parameters and Compounds present in the secondary stream in accordance with Annex I;

VII - Parameters and Compounds present in the total tobacco in accordance with Annex I.

§ 3º The determinations contained in paragraphs 3º, 4º, 5º and 6º of article 4º, must be observed, with respect to the analytical report.

§ 4º If there is an alteration in the methods used for quantification of the compounds in the primary stream, the secondary stream or the total tobacco, a CD-Rom must be submitted containing the description of the new methods, together with the documentation required for the renewal.

§ 5º If there is an alteration in the brand name, an authenticated copy must be submitted of the stamped communication with the SRF if the ADE has not yet been published in the DOU.

§ 6º For an application for Renewal of the Filing of Tobacco Derivative Smoking Products - Identification Data – the company must have satisfied all the requirements in previous years for the specific brand.

Art. 8º Once the analysis is concluded, and if there is no further requirement to be fulfilled, the application for the Registration of Identification Data shall be approved, and the public notification of this act will be provided in the *Diário Oficial da União*, the official bulletin, of the specific brand, the company name and the CNPJ number.

Sole paragraph. Any alteration of the composition declared by the company in the application for renewal of the brand must be reported to ANVISA, through a request for an Amendment, within a period of up to 30 days after such alteration.

CHAPTER IV

The Registration of Processed Tobacco

Art. 9º Tobacco processing companies must register each year with ANVISA all the tobacco that they processed in the previous year.

Art. 10 A new procedure is hereby established which is totally electronic, for the annual application for Registration of Processed Tobacco.

§ 1º Applications must be made through Electronic Application and after filling in all the required data concerning the processed tobaccos, must be submitted to ANVISA in electronic format, through the On-Line Protocol, which is available in the Electronic System for Service and Fee Collection, exclusively for the Registration of Processed Tobacco and subsequent renewals.

§ 2º The necessary instructions for the electronic procedure are available at the ANVISA website.

CHAPTER V

Exceptions

Art. 11 For the registration of brand identification data for tobacco derivative smoking products other than cigarettes, and their renewals, information concerning the sections below will not be required:

I - Specifications and Physical Characteristics of filter and wrappings;

II - Parameters and Compounds present in the primary stream;

III - Parameters and Compounds present in the secondary stream;

Sole paragraph. For the products mentioned in the heading of this article, the filling out of the fields for the listing of Parameters and Compounds present in the Total Tobacco are maintained, in accordance with the list contained in Annex I of this resolution.

Art. 12 Tobacco derivatives, whether they are for smoking or not, including cigarettes, manufactured in the national territory exclusively for export, shall be exempt from having to submit the information called for in Annex I of this resolution.

Sole paragraph. Applications for products mentioned in the heading can contain differences in packaging, in accordance with the requirements of the countries of destination, and must be submitted in the application for registration of identification data or renewal.

CHAPTER VI

Deadlines

Art. 13 Requests for registration of brand identification data of tobacco derivative smoking products can be processed with Anvisa at any time of year.

§ 1º The application for registration mentioned in the heading will be analyzed in up to 45 days after submission to Anvisa, and if there is no further requirement to be fulfilled by the company, the analysis will be concluded, the application for registration granted and published in the *Diário Oficial da União*, the official bulletin.

§ 2º Sale of the brand can only commence after the granting of the application for registration and the publication in the *Diário Oficial da União* of the specific brand name, the company name and CNPJ number.

§ 3º After the publication of the granting of the application in the *Diário Oficial da União*, the brand name will be included in the List of Brands of Smoking Products available at the Anvisa website.

Art. 14 The Registration of Identification Data is valid for 12 months, counting from the date of publication in the *Diário Oficial da União* of the resolution granting the initial application for registration, and its validity must be renewed annually.

§ 1º The application for a Renewal of the Registration of Identification Data must be processed annually by the company within 90 days prior to the date of expiration of the registration.

§ 2º In the event that the application for Renewal of the Registration of Identification Data is not processed within the stipulated deadline, the Registration will be cancelled due to expiration or lapsing of the deadline, with publication of the Resolution in the *Diário Oficial da União*, and the brand will be removed from the Situation Report on Brands of Smoking Products, available at the available at the ANVISA website.

§ 3º When the Registration is cancelled, the company must submit a new application for Registration of Identification Data, in accordance with the terms of this Resolution, even if a new brand is not involved, for purposes of regularization.

§ 4º The company can cancel its registration at any time, through a secondary application for the Cancellation of Registration, available in the Electronic Application.

CHAPTER VII

General Provisions

The Protocol

Art. 15 To access the ANVISA Electronic System for Service and Fee Collection for purposes of application and processing, it is required to register the company electronically, in keeping with the Resolutions for Processing and Application that are in force.

Sole paragraph. Instructions for the filling out of electronic forms of the Electronic Application System can be found at the ANVISA website.

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Art. 16 The protocol for documentation exclusively concerning processes or applications relating to smoking products, must be carried out with the Protocol Sector - UNIAP at the main office of ANVISA, in Brasilia.

§ 1º Any document intended to fulfill technical and/or administrative requirements to be attached to the process or application, will only be analyzed after its protocol in the Protocol sector - UNIAP at the main office of ANVISA, in Brasilia.

§ 2º It is prohibited to send documentation addressed directly to the ANVISA server.

§ 3º To expedite the analysis, the application should contain the required documents, arranged according to the sequence of the sections, separated by sheets of different colors or weight, and pages that are sequentially numbered.

Art. 17 Applications processed without the receipt for payment of the Inspection Fee for Sanitary Oversight relating to the matter subject to application or with a transaction number already used in another application, will be immediately denied by the sector that processed the application.

Art. 18 Applications submitted with the receipt for payment of the Inspection Fee for Sanitary Oversight, but which are not accompanied by the complete documentation required by this Resolution, will be processed on a provisional basis and forwarded to the technical area, pursuant to the resolution in force on the document analysis of processed applications.

§ 1º Applications processed on a provisional basis must be supplemented with the missing documentation, by means of an Amendment, which is available from the electronic application service, which must be processed with ANVISA before the technical analysis is completed.

§ 2º The technical area will formulate the Technical Requirement only for requests of information or clarification regarding the documentation processed.

§ 3º A failure to provide the complete documentation required by this Resolution for the registration of identification data, or renewal, or completion of the technical analysis with an unsatisfactory result will result in the denial of the application.

Approval

Art. 19 Approval of the application for Registration of Identification Data or for its Renewal will be granted to brands of smoking products that satisfy the requirements of this resolution, and public notification of this act will be provided through publication in the *Diário Oficial da União* of the specific brand name, name of the company and CNPJ number.

Art. 20 A specific brand can only be sold after the publication of approval of the application for Registration of Identification Data, in the *Diário Oficial da União*.

§ 1º It is prohibited to import, export or sell in the national territory any brand of smoking product that is not duly regularized in accordance with this Resolution even if the brand is intended for research in the consumer market.

§ 2º It is prohibited to sell on the Brazilian domestic market brands of smoking products registered exclusively for export.

Art. 21 It is prohibited to use any number generated on an application for registration of identification data for any purposes that are not in strict adherence to the ANVISA process.

Cautionary Suspension

Art. 22 Applications for registration of identification data or renewal of a cigarette brand will only be granted by ANVISA if the situation of the brand is in order with the Secretary of Federal Revenue of Brazil - SRF/MF.

§ 1º Cancellation of the Special Registration of a national manufacturer or importer of cigarettes, established by Executive Declaration issued by Secretary of Federal Revenue of Brazil - SRF/MF shall entail a cautionary suspensions of all brands of that company through publication in the *Diário Oficial da União*, its removal from the ANVISA website and the prohibition of the specific brands in question.

§ 2º The situation of brands subject to cautionary suspension will be regularized at the ANVISA website after submission of a copy of the Executive Declaration (ADE) issued by the Secretary of Federal Revenue of Brazil - SRF/MF, re-establishing the Special Registration for the national manufacturer or importer of cigarettes.

§ 3º The brand name of the cigarette appearing in the application for Registration or Renewal must be the same as that appearing on the Executive Declaration (ADE) of Tax Status of the cigarette brand with the Secretary of Federal Revenue of Brazil - SRF/MF.

§ 4º Cancellation of the Tax Status of the cigarette brand by the Secretary of Federal Revenue shall result in a cautionary suspension of the brand through publication in the *Diário Oficial da União*, its removal from the ANVISA website and the prohibition of its sale.

Denial

Art. 23 The application for Registration of Identification Data or its Renewal will be denied when:

I – It does not meet the requirements set forth in this Resolution;

II – It does not meet the technical requirements.

§ 1º Public notification of the denial of the application will be given via publication of the resolution in the *Diário Oficial da União*.

§ 2º It shall be possible to appeal to the authority that issued a decision of denial of an application for Registration of Identification Data or its Renewal, and the agent subject to regulation shall make inquiry of the legislation in force to ascertain the procedures adopted by ANVISA.

Cancellation

Art. 24. The registration of identification data will be cancelled when:

I – Its Renewal is not applied for within the deadline stipulated by this regulation;

II – The application for Renewal of Registration is denied;

III – At the request of the company, through an electronic application for Cancellation of Registration;

§ 1º Application for the cancellation of registration of identification data of the brand by the company holding the registration must be processed with the Protocol Sector - UNIAP at the main office of ANVISA, in Brasilia, and must include the justification for the application and the signature of the person legally in charge of the company.

§ 2º Brands that have their registration of identification data cancelled must be withdrawn by the manufacturer or importers from all commerce and points of sale within a period of 30 days after the date of cancellation.

CHAPTER VIII

On Final and Transitory Provisions

Art. 25 Within a period of 12 months after the date of publication of this resolution, the analyses appearing in Annex I with the observation "filling out optional only in the first year that this Resolution is in effect" shall not be required for cigarettes.

Sole paragraph. At the end of the period stipulated in the heading of this article, these compounds will become subject to required filling in of information.

Art. 26 Within a period of 12 months after the date of publication of this resolution, the analyses appearing in Annex I, concerning the list of Parameters and Compounds Present in the Total Tobacco, with the indication “filling out optional for products other than cigarettes only in the 1st year that this Resolution is in effect” shall not be required for other smoking products, other than cigarettes.

Sole paragraph. At the end of the period stipulated in the heading of this article, these compounds will become subject to required filling in of information.

Art. 27 For registration of identification data obtained while RDC 346, of December 2, 2003 is in force, and that were published on the page of Anvisa in the first six months of 2007, and for registrations renewed in 2007, a deadline of June 30, 2008 is set to apply for Renewal.

Sole paragraph. For successive renewals of the registrations mentioned in the heading, the annual deadline of June 30 is set.

Art. 28 For registration of identification data obtained while RDC 346, of December 2, 2003 is in force, and that were published on the page of Anvisa in the second six-month period of 2007, a deadline of March 31, 2009 is set to apply for Renewal.

Sole paragraph. For successive renewals of the registrations mentioned in the heading, the annual deadline of March 31 is set.

Art. 29 Non-compliance with the terms of this Resolution constitutes a health infraction, subjecting the offender to the penalties of Law nº 6.437, of August 20, 1977 and other applicable provisions.

Art. 30 In cases of doubt, or incidents that call for additional evaluations, ANVISA may, at its discretion, demand addition information concerning the documents and data provided in the application for Registration or Renewal of Registration of Identification Data.

Art. 31 The National Agency of Health Oversight – ANVISA can publish regulatory instructions to regulate situations not provided for in this Resolution.

Art. 32 Resolution RDC nº. 346, of December 2, 2003, is hereby revoked.

Art. 33 This Resolution enters into effect on the date of its publication.

DIRCEU RAPOSO DE MELLO

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ANNEX I

I - Parameters and Compounds Present in the Primary stream

	Compounds	Unit
1.	Tar[1]	mg/cig
2.	Nicotine[1]	mg/cig
3.	Carbon monoxide[1]	mg/cig
4.	Benzopyrene	ng/cig
5.	Formaldehyde	µg/cig
6.	Acetaldehyde	µg/cig
7.	Acetone	µg/cig
8.	Acrolein	µg/cig
9.	Propinaldehyde	µg/cig
10.	Crotonaldehyde	µg/cig
11.	Methylethylcetone	µg/cig
12.	Butanaldehyde	µg/cig
13.	Hydroquinone	µg/cig
14.	Resorcinol	µg/cig
15.	Catechol	µg/cig
16.	Phenol	µg/cig
17.	meta-Cresol	µg/cig
18.	para-Cresol	µg/cig
19.	ortho-Cresol	µg/cig
20.	Ammonia	µg/cig
21.	Hydrogen Cyanide	µg/cig
22.	Pyridine	µg/cig
23.	Quinoline	µg/cig
24.	1, 3-butadiene	µg/cig
25.	Isoprene	µg/cig
26.	Acrylonitrile	µg/cig
27.	Benzene	µg/cig
28.	Toluene	µg/cig
29.	Styrene	µg/cig
30.	NNN: N´nitrosonornicotine	ng/cig
31.	NAT: N´nitrosoanatabine	ng/cig
32.	NAB: N´nitrosoanabasine	ng/cig
33.	NNK : 4-(methylnitrosoamine) 1- (3-piridil)-1-butanona	ng/cig
34.	3-aminobiphenyl	ng/cig
35.	4-aminobiphenyl	ng/cig
36.	1-aminonaphtalene	ng/cig
37.	2-aminophtalene	ng/cig
38.	Nox	µg/cig
39.	Eugenol[2]	mg/cig
40.	pH	Unit
41.	Efficiency of filter for nicotine	%
42.	Mercury[3]	ng/cig
43.	Nickel[3]	ng/cig
44.	Lead[3]	ng/cig
45.	Selenium[3]	ng/cig
46.	Cadmium[3]	ng/cig
47.	Chrome[3]	ng/cig
48.	Arsenic[3]	ng/cig
49.	Menthol [2, 4]	mg/cig

[1] The lab analyses used for quantification of compounds must follow ISO methods;

[2] Required to fill out if applicable.

[3] Optional to fill out.

[4] Optional to fill out only during the first year that this Resolution is in effect.

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II - Parameters and Compounds Present in the Secondary Stream

Compounds		Unit
1.	Tar[1]	mg/cig
2.	Nicotine[1]	mg/cig
3.	Carbon monoxide[1]	mg/cig
4.	Benzopyrene	ng/cig
5.	Formaldehyde	µg/cig
6.	Acetaldehyde	µg/cig
7.	Acetone	µg/cig
8.	Acrolein	µg/cig
9.	Propinaldehyde	µg/cig
10.	Crotonaldehyde	µg/cig
11.	Methylethylcetone	µg/cig
12.	Butanaldehyde	µg/cig
13.	Hydroquinone	µg/cig
14.	Resorcinol	µg/cig
15.	Catechol	µg/cig
16.	Phenol	µg/cig
17.	meta-Cresol	µg/cig
18.	para-Cresol	µg/cig
19.	ortho-Cresol	µg/cig
20.	Ammonia	µg/cig
21.	Hydrogen Cyanide	µg/cig
22.	Pyridine	µg/cig
23.	Quinoline	µg/cig
24.	1, 3-butadiene	µg/cig
25.	Isoprene	µg/cig
26.	Acrylonitrile	µg/cig
27.	Benzene	µg/cig
28.	Toluene	µg/cig
29.	Styrene	µg/cig
30.	NNN: N´nitrosonornicotine	ng/cig
31.	NAT: N´nitrosoanatabine	ng/cig
32.	NAB: N´nitrosoanabasine	ng/cig
33.	NNK : 4-(methylnitrosoamine) 1- (3-piridil)-1-butanona	ng/cig
34.	3-aminobiphenyl	ng/cig
35.	4-aminobiphenyl	ng/cig
36.	1-aminonaphtalene	ng/cig
37.	2-aminophtalene	ng/cig
38.	Nox	µg/cig
39.	Eugenol[2]	mg/cig
40.	pH[4]	**Unit**
41.	Efficiency of filter for nicotine[4]	%
42.	Mercury[3]	ng/cig
43.	Nickel[3]	ng/cig
44.	Lead[3]	ng/cig
45.	Selenium[3]	ng/cig
46.	Cadmium[3]	ng/cig
47.	Chrome[3]	ng/cig
48.	Arsenic[3]	ng/cig

[1]The lab analyses used for quantification of compounds must follow ISO methods.

[2] Required to fill out if applicable.

[3] Optional to fill out.

[4] Not applicable.

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III - Parameters and Compounds Present in the Total Tobacco

Compounds	Unit
1. Ammonia	µg/g of tobacco
2. Nicotine	µg/g of tobacco
3. Nornicotine[3]	µg/g of tobacco
4. Myosmine[3]	µg/g of tobacco
5. Anabasine[3]	µg/g of tobacco
6. Anatabine[2,3]	µg/g of tobacco
7. NNN: N´nitrosonornicotine[3]	ng/g of tobacco
8. NAT: N´nitrosoanatabine[3]	ng/g of tobacco
9. NAB: N´nitrosoanabasine[3]	ng/g of tobacco
10. NNK: 4-(methylnitrosoamine) 1- (3-pyridyl)-1-butanone[3]	ng/g of tobacco
11. Lead[3]	ng/g of tobacco
12. Cadmium[3]	ng/g of tobacco
13. Mercury[3]	ng/g of tobacco
14. Nickel[3]	ng/g of tobacco
15. Selenium[3]	ng/g of tobacco
16. Chrome[3]	ng/g of tobacco
17. Arsenic[3]	ng/g of tobacco
18. Eugenol[1]	mg/g of tobacco
19. pH	Unit
20. Benzopyrene[2] [3]	ng/g of tobacco
21. Glycerol[2] [3]	mg/g of tobacco
22. Propylene Glycol[2] [3]	mg/g of tobacco
23. Triethylene Glycol[2] [3]	mg/g of tobacco
24. Nitrate[2] [3]	µg/g of tobacco
25. Triacetine[2] [3]	µg/g of tobacco
26. Sodium Propiontae[2] [3]	µg/g of tobacco
27. Sorbic Acid[2] [3]	µg/g of tobacco
28. Menthol[1] [2] [3]	mg/g of tobacco

[1]Required to fill out if applicable.

[2]Filling out optional for cigarettes only during the first year that this Resolution is in effect.

[3]Filling out optional for products other than cigarettes only during the first year that this Resolution is in effect.

Agência Nacional
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ANNEX II

Identification Data recorded in the Electronic Application

I - Electronic Application - Tobacco Processing Company - Identification data:
1. Origin of Types of Tobaccos Processed in the previous year:
- Type of Tobacco
- Quantity
- Country, State, City;

II - Electronic Application – Registration and Renewal of Registration of Tobacco Derivative Smoking Product - Identification data:
1. Characteristics of Brand:
- Brand Name
- Type of Product: Cigarette with filter, Cigarette without filter, Clove Cigarette, Cigar, Cigarillo, Bidis, Pipe or Hookah Tobacco, Rolling Tobacco, Chewing Tobacco, Corn Silk Cigarette, Inhalable Tobacco, Loose Tobacco, Tobacco for oral use and other manufactured tobacco derivative products intended for smoking, inhalation or chewing, even if only partially comprised of tobacco.
- Length (mm)
- Circumference (mm)

2. Origin:
- National Manufacture;
- Imported.

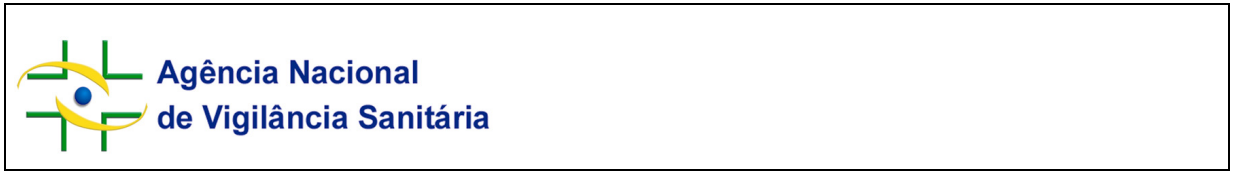
3. Purpose:
- Exclusively for sale on the domestic market;
- For sale on domestic and foreign markets .

4. Packaging:
- Types of Packages: pack, carton, can, pouch, box, shoulder box;
- Quantity of product per Package

5. List of Types of Tobacco used in the product:

- Types of Tobacco, Total Quantity of Tobacco used in the product;

6. List of Additives used in the product:
   - Names of Additives
   - Categories of additives: Sugar, Adhesive, Binding Agent, Combustion Agent, Ameliorant, Process Assistant, Flavoring, Fungicide, Preservative, Dye and Moistener;
   - Places of application: in the blend of Tobacco, in the paper wrapping, in the filter, in the Filter Paper, in the Tip Paper, in the packaging.
   - Maximum Quantity of use of Additives.
7. Specifications for Filter and Paper Wrappings:
   - Type of Filter
   - Characteristics of Filter: Total Ventilation (0-100%), Drop of Pressure with open vents; (mmH_2O), Drop of Pressure with closed vents (mmH_2O);
   - Composition of the Filtering Material: Substances, Quantities;
   - Physical Characteristics of Paper Wrapping for Filter:
     Grams (g/m^2);
     Permeability ($cm^3 . min^{-1} . cm^{-2}$) a 1 kPa; e
     Weight (mg/cig);
   - Physical Characteristics of Tip Paper:
     Grams (g/m^2);
     Permeability ($cm^3 . min^{-1} . cm^{-2}$) a 1 kPa; e
     Weight (mg/cig);
   - Physical Characteristics of Paper Wrapping of Product:
     Grams (g/m^2);
     Permeability ($cm^3 . min^{-1} . cm^{-2}$) a 1 kPa; e
     Weight (mg/cig);
8. Parameters and Compounds Present in the Primary stream:
   - Average Content, Standard Deviation and Methods Used;
9. Parameters and Compounds Present in the Secondary Stream:
   - Average Content, Standard Deviation and Methods Used;



10. Parameters and Compounds Present in the Total Tobacco: Average Content, Standard Deviation and Methods Used;
11. Attach electronic file of Packages reported (optional);

III - Electronic Application – Registration and Renewal of Registration of Tobacco Derivative Smoking Product exclusively for Export - Identification data

1. Characteristics of Brand:
   - Brand Name
   - Type of Product: Cigarette with filter, Cigarette without filter, Clove Cigarette, Cigar, Cigarillo, Bidis, Pipe or Hookah Tobacco, Rolling Tobacco, Chewing Tobacco, Corn Silk Cigarette, Inhalable Tobacco, Loose tobacco, tobacco for oral use and other manufactured tobacco derivative products intended for smoking, inhalation or chewing, even if only partially comprised of tobacco.
   - Length (mm)
   - Circumference (mm)
2. Origin:
   - National Manufacture.
3. Purpose:
   - Exclusively for export;
4. Packaging:
   - Types of Packaging: pack, carton, can, pouch, box, shoulder box;
   - Quantity of product per Package.
5. List of Types of Tobacco used in the product:
   - Types of Tobacco, Total Quantity of Tobacco used in the product.
6. List of Additives used in the product:
   - Names of Additives;
   - Categories of additives: Sugar, Adhesive, Binding Agent, Combustion Agent, Ameliorant, Process Assistant, Flavoring, Fungicide, Preservative, Dye and Moistener;
   - Places of application: in the blend of Tobacco, in the paper wrapping, in the filter, in the Filter Paper, in the Tip Paper, in the packaging;

- Maximum Quantity of use of Additives.

7. Specifications of Filter and Wrapping:
   - Type of Filter
   - Characteristics of Filter:
     Total Ventilation (0-100%),
     Drop of Pressure with open vents (mmH_2O),
     Drop of Pressure with closed vents (mmH_2O);
   - Composition of the Filtering Material: Substances, Quantities;
   - Physical Characteristics of Paper Wrapping Filter:
     Grams (g/m^2);
     Permeability ($cm^3 . min^{-1} . cm^{-2}$) a 1 kPa; e
     Weight (mg/cig).
   - Physical Characteristics of Tip Paper:
     Grams (g/m^2);
     Permeability ($cm^3 . min^{-1} . cm^{-2}$) a 1 kPa; e
     Weight (mg/cig);
   - Physical Characteristics of Paper Wrapping Product:
     Grams (g/m^2);
     Permeability ($cm^3 . min^{-1} . cm^{-2}$) a 1 kPa; e
     Weight (mg/cig).
8. Attach electronic file of Packagings reported (optional);

Note: Pa => Pascal (Unit of Pressure in the International System of Units = $N \cdot m^{-2} = m^{-1} \cdot kg \cdot s^{-2}$)