Ministry of Health - MS
National Agency of Health Oversight – ANVISA

RESOLUTION OF THE COLLEGIATE DIRECTORATE – RDC Nº 226, OF APRIL 30, 2018

(Published in the DOU nº 83, May 2, 2018)

Addresses the registration of smoking products derived from tobacco.

The Collegiate Directorate of the National Agency of Health Oversight, in the exercise of the attributions conferred upon it by Art. 15, III and IV together with Art. 7, III, and IV, of Law nº 9.782, of January 26, 1999, Art. 53, V, §§ 1 and 3 of the Internal Regimen approved pursuant to the terms of Annex I of the Resolution of Collegiate Directorate - RDC nº 61, of February 3, 2016, hereby resolves to adopt the following Resolution of Collegiate Directorate, as decided in a meeting held on March 20, 2018, and I, Executive Director, order its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Purpose

Art. 1 This Resolution sets forth the technical requirements and procedures to be observed in the enrollment of processed tobaccos and in procedures for the enrollment and registration of smoking products derived from tobacco.

Sole paragraph. A totally electronic procedure is hereby instituted for application and filing the applications addressed in this Resolution with ANVISA.

Section II

Definitions

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

I - additive: any substance or compound, other than tobacco or water, used in the processing of leaf tobacco, homogenized tobacco and reconstituted tobacco, in the manufacture and packaging of a smoking product derived from tobacco;

II - enrollment of a smoking product derived from tobacco exclusively for purposes of export: an administrative act to regularize a smoking product derived from tobacco with ANVISA via enrollment exclusively for purposes of export;

III - enrollment of processed tobacco: an electronic application submitted by the national processing company to enroll the quantity and origin of the types of tobacco that were processed during the year immediately prior to the year of application, and intended for use as a raw material to obtain smoking products derived from tobacco;

IV - primary or principal stream: smoke that is emitted by the tip of the smoking product, that goes into the mouth and is exhaled by the smoker during the process of smoking;

V - secondary or lateral stream: any smoke emitted during the burning of a smoking product, except the primary stream;

VI - declaration of qualitative and quantitative composition: declaration by the registering company that its smoking product derived from tobacco has the same qualitative and quantitative composition as another smoking product derived from tobacco already registered with ANVISA;

VII - package: wrapping, receptacle or any kind of packaging intended to contain smoking products derived from tobacco, having the following classification:

a) primary packaging: packaging that contains a smoking product derived from tobacco, intended for the end consumer;

b) secondary packaging: external packaging of the product, that contains more than one primary package, and may or may not be intended for the end consumer; and

c) tertiary packaging: external packaging of the product, which contains more than one package, not intended for the end consumer;

VIII – processing company: a company that engages in activities having to do with any stage of the processing of leaf tobacco, homogenized tobacco or reconstituted tobacco, used in smoking products;

IX - distributor: company charged with commercial distribution of the product, that may act as an intermediary between the manufacturer or importer and commercial establishments;

X - manufacturer: a company that produces any smoking product derived from tobacco;

XI - importer: a company engaged in the commercial and fiscal process of importing any smoking product derived from tobacco;

XII - filter wrapping: paper directly wrapping the filter of the smoking product derived from tobacco;

XIII - product wrapping: material that wraps the column of tobacco to form the cylinder of the smoking product derived from tobacco;

XIV - filter: component attached to the end of the cylinder of the smoking product derived from tobacco to retain part of the particulate matter and nicotine contained in the smoke;

XV - electronic application form: document made available in the Electronic Application System to be filled out online with the information required under this rule;

XVI - visual identity: set of graphic elements that visually and systematically represent the product, such as images, texts, typefaces, chromatic patterns and the arrangement of elements;

XVII - analytical report: a technical report, issued by a laboratory, with the specifications and results from physical and chemical analyses of smoking products derived from tobacco;

XVIII - name of the smoking product: name, which may or may not be accompanied by any descriptor, such as a word, number or color of packaging, applied to the product package, which will be recognized as a way of distinguishing the product from others of the same character;

XIX - end paper: paper wrapped around the filter and extending to the cylinder of the smoking product derived from tobacco;

XX - electronic application: a procedure performed by the interested party to fill out online the required by this rule, and issuance of the Federal Tax Schedule (GRU - *Guia de Recolhimento da União*) for payment of the Sanitary Oversight Enforcement Tax (TFVS - *Taxa de Fiscalizaçao de Vigilância Sanitária*), using the Electronic Application System available at ANVISA's online portal;

XXI - manual application: procedure performed by the interested party to print the cover sheet and GRU, using the Electronic Application System available at ANVISA's online portal;

XXII - smoking product: a manufactured product, whether or not it is a tobacco derivative, containing leaves or extracts of leaves or other parts of plants in its composition;

XXIII - smoking product derived from tobacco: any manufactured smoking product containing tobacco as one of its components;

XXIV - automatic filing: a totally electronic procedure for filing applications with ANVISA, using the Electronic Application System, without the need for physical filing of documents;

XXV - processed tobacco: any type of tobacco subject to processing by a processing company, intended for use as raw material to obtain smoking products derived from tobacco; and

XXVI - total tobacco: a blend of different kinds of tobacco comprising smoking products derived from tobacco.

Section III

Scope

Art. 3 This Resolution applies to smoking products derived from tobacco and to tobacco processed in this country.

§1 The following classification is adopted for the products covered by these regulations:

I - bidi: a product without a filter, containing chopped tobacco wrapped in leaves of tendu or temburi, intended to be smoked;

II - blunt: a product containing tobacco as one of its components, for use as a wrapping of a smoking product, intended to be smoked;

III - cigar: a product without a filter, weighing more than 1.360g/1000 units, intended to be smoked, made up of whole, chopped, shredded or ripped tobacco leaf or by reconstituted tobacco, rolled in the shape of a cylinder, wrapped in a subcover and cover made of tobacco leaf or reconstituted tobacco;

IV - cigarillo: a product weighing less than or equal to 1.360g/1000 units, intended to be smoked, made up of leaves of chopped, shredded, powdered or ripped tobacco, or reconstituted tobacco, forming a cylinder, and whose wrapping is made up of tobacco leaf or reconstituted tobacco;

V - cigarette: a product intended to be smoked, and which, regardless of the manner in which it is produced, is made up of tobacco, wholly or in part, wrapped in paper or homogenized tobacco or reconstituted tobacco or a blend of cellulose and tobacco, or by any other wrapping that is not exclusively tobacco leaf;

VI - straw cigarette: a product without a filter, intended to be smoked, containing chopped tobacco wrapped exclusively in straw;

VII - twist tobacco: a product also called "rope tobacco," intended to be smoked, containing leaves of semi-stripped tobacco, interwoven and rolled up, and cured in the sun;

VIII - shredded tobacco: a product made up of leaves of shredded tobacco, intended to be smoked;

IX - pipe tobacco: a product containing tobacco, intended to be smoked in a conventional pipe;

X - narghile tobacco: a product containing tobacco, intended to be smoked in a device known as a narghile, water pipe, Shisha or Hookah;

XI - snuff: a product containing tobacco, intended to be sniffed; and

XII - chewing tobacco: a product containing tobacco, intended to be chewed, sucked or ingested.

§ 2 Smoking products derived from tobacco not included in this Resolution will be subject to analysis and deliberation regarding their classification.

CHAPTER II

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FORMULATION OF APPLICATION AND PROCESS ILLUSTRATION

Section I

Application for Registration of Smoking Product Derived from Tobacco

Art. 4 It is mandatory to register with ANVISA all smoking products derived from tobacco intended for:

I - manufacture and commercialization in the national territory; and

II - importing and commercialization within the national territory.

§1 Approval of the application to register a smoking product derived from tobacco does not generate a registration number.

§2 Any disclosure, publicity or promotion associated with the process of registering with ANVISA is prohibited.

§3 Different importers can obtain through ANVISA registration of a single smoking product derived from tobacco manufactured outside the country, when this does not have the brand protected by intellectual property rights granted by the National Institute of Intellectual Property INPI – *Instituto Nacional da Propriedade Intelectual*).

§4 Importers must apply for registration of smoking products that are to be imported, regardless of whether a product has already been registered by another importer.

§5 A smoking product derived from tobacco manufactured in the country or imported with a brand protected by intellectual property rights granted by the INPI, can only be registered by the company that holds the brand registration or by the company licensed to use the brand.

Art. 5° Prior to industrialization and commercialization, national manufacturers, exporters and importers of smoking products derived from tobacco must:

I - Be in possession of an Executive Declaratory Act (ADE - *ato declaratório executivo*) granted by the Special Registry of Manufacturers or Importers, issued by the Secretariat of Federal Revenue of Brazil (SRF/MF – *Secretaria da Receita Federal do Brasil*); and

II - Enroll or register the products with ANVISA.

Sole paragraph. What is set forth in sub-paragraph I applies only to cigarillos and cigarettes, pursuant to the legislation in force.

Art. 6 Prior to filing an electronic application to register a smoking product, national manufacturers and importers of smoking products derived from tobacco must satisfy the following conditions:

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I – Have the Executive Declaratory Act (ADE) granted by the Special Registry of Manufacturers or Importers, issued by the Secretariat of Federal Revenue of Brazil (SRF/MF), pursuant to the terms of the legislation in force, as pertaining to cigarillos and cigarettes;

II – Have been granted the registration or have the receipt for the application to register the brand issued through official channels as indicated by INPI in cases involving a product that has a brand under industrial protection; and

III – documentation of the licensing of the brand to third parties issued through official channels as indicated by INPI, when a product is involved that has a brand under industrial protection licensed to third parties.

Sole paragraph. If at any time the conditions indicated in sub-paragraphs I, II, and III of this article are not in effect, applications for registration will be rejected or cancelled.

Art. 7 Electronic applications for registration of smoking products must be filed by national manufacturers and importers of smoking products derived from tobacco, using ANVISA's electronic application system, on an individual basis, for each smoking product derived from tobacco.

§ 1 Applications for the registration of smoking products are required to include the following documentation:

I - An electronic application form with all of the data required in Annex I and Annex II of this Resolution;

II - A digital file of the primary packages of the product, and of secondary packages, if any, that are intended for commercialization;

III - A digital file of the analytical report containing all statements of quantity required in Annex I of this Resolution, regarding the composition of the primary and secondary streams and of total tobacco, obtained for one single sample;

IV - A digital file with a complete description of the methodologies used, from reception of the sample until the final result, for the statements of quantity required in this rule, accompanied by a certificate proving that the respective analyses fall within the scope of the laboratory's accreditation;

V - A digital file of the declaration of the loss of total reducing sugars, and the need for replacement, exclusively in cases where there is the addition of any kind of sugar in the composition of the product, observing what is set forth in the regulations themselves;

VI - A digital file of the analytical report that corroborates the declared data of the loss of total reducing sugars and their replacement, observing what is set forth in the regulations themselves, accompanied by a certificate proving that the respective analysis falls within the scope of the laboratory's accreditation;

VII - A digital file with a declaration by the applicant company to the effect that the product in question meets the requirements set forth in sub-paragraphs I, II and III of Art. 6° of this Resolution;

VIII - A digital file with a declaration of the qualitative and quantitative composition, as per Annex III, when applicable.

§ 2 To access the electronic application form available on the Electronic Application System, national manufacturers or importers must be previously enrolled in the ANVISA system, and it is the responsibility of the company to keep the declared information up to date.

Art. 8 The following data regarding the smoking product derived from tobacco for which the application is being submitted must be stated on the Electronic Application Form:

I - The name of the smoking product derived from tobacco and its characteristics, in accordance with Annex II of this Resolution;

II - All types of tobacco used, in accordance with Annex II of this Resolution;

III - All additives used, including sugars, in accordance with Annex II of this Resolution;

IV - Physical specifications and characteristics of the filter and wrappings, in accordance with Annex II of this Resolution, in the case of filter cigarettes and cigarillos;

V - Parameters and compounds present in the primary stream, in accordance with Annex I of this Resolution, in the case of cigarettes, cigars and cigarillos;

VI - Parameters and compounds present in the secondary stream, in accordance with Annex I of this Resolution, in the case of cigarettes; and

VII - Parameters and compounds present in total tobacco, in accordance with Annex I of this Resolution, for all smoking products derived from tobacco.

§ 1 In the list of additives referred to in sub-paragraph III of this article, all additives used in all stages of manufacture of the smoking product derived from tobacco for which the application is being submitted must be stated.

§ 2 In order to comply with what is set forth in sub-paragraph III of this article, the requirements set forth in the health legislation in force that addresses the use of additives in smoking products derived from tobacco must be observed, and in cases where sugars have been used in the composition, it shall be required to submit the original analytical reports that demonstrate the content of total reducing sugars originally present in the tobacco leaf before the drying process and the need for replacement of the lost content.

§ 3 Whenever it may deem it necessary, ANVISA can request physical samples of the product for which the application is being submitted.

Art. 9 The digital files for the primary and secondary packages of the smoking product derived from tobacco must exhibit all available surfaces to the public and, when applicable, indicate folds and cuts.

§ 1 The name of the smoking product stated in the Electronic Application Form and the analytical reports must be represented on packages of the product.

§ 2 Packages intended for commercialization on the national market must comply with the requirements of the legislation in force that addresses packaging for smoking products derived from tobacco.

§ 3 Characteristics of smoking products must be uniform in all units contained in the package.

§ 4 Whenever it may deem it necessary, ANVISA can request physical samples of the packaging of the product.

Art. 10. Analytical Reports must contain:

I - name and address of the laboratory;

II - The name, title and signature of the party responsible for the analyses;

III - The name of the smoking product derived from tobacco stated on the Electronic Application Form;

IV - A description of the sample, including the length and circumference of the product, when applicable;

V - Date of reception of samples by the laboratory;

VI - Date of conclusion of analysis;

VII - Number of samples analyzed;

VIII - Conditions for packaging of samples;

IX - Parameters of smoke, when applicable;

X - Identification of methodologies used;

XI - Limits of detection and quantification;

XII - Statistical analysis of measurements and results;

XIII - Unambiguous identification placed on all pages comprising the report;

XIV - Results of laboratory measurements.

§ 1 Only analytical reports that have been completed within a period not greater than 6 (six) months prior to the date of the application filing will be accepted.

§ 2 Analytical reports will be subject to verification by ANVISA with the laboratory responsible for the analyses.

§ 3 The laboratory analyses required by this Resolution must be performed in laboratories accredited by a national or international accreditation body, and must adhere to analytical methodologies that are internationally accepted, or to those adopted by law, treaty or international agreement ratified and internalized by Brazil.

§ 4 National manufacturers and importers shall have a period of 18 (eighteen) months, counting from the date of publication of this Resolution, to submit the accreditation of the laboratories, tests and methods used in the conduct of the analyses.

§ 5 Laboratory analyses for quantification of total content of reducing sugars in the tobacco, before and after the drying process, must adhere to ISO (International Organization for Standardization) methodology.

§ 6 National manufacturers or importers shall be required to store samples from the same lot, or by other criterion for representation of control of the product used for the performance of the laboratory analyses, for a period of 2 (two) years counting from the date of the issuance of the report, and in sufficient quantity for the performance of 2 (two) complete laboratory analyses.

Section II

Application for Renewal of Registration of Smoking Products Derived from Tobacco

Art. 11. Electronic applications for renewal of registration of a smoking product must be filed annually through ANVISA's electronic application system, by national manufacturers and importers of smoking products derived from tobacco.

§ 1 In applying for renewal of the registration of a smoking product, the information required in Art. 7 must be submitted, and the provisions of Arts. 8 to 10 of this Resolution must be observed.

§ 2 In applying for renewal of the registration of a smoking product, the inclusion of new types of packages will be permitted, as long as the visual identity of the packages approved in the registration of the smoking product is maintained.

§ 3 In applying for renewal of the registration of a smoking product, alteration of the information contained on packages approved in the registration of the smoking product will be permitted, solely for purposes of updating the data on the manufacturer or importer and on the ingredients.

§ 4 In applying for renewal of the registration of a smoking product, alteration in the composition of the smoking product approved in the registration will be permitted, as long as it has to do specifically with adjustments resulting from variations in the tobacco harvest or a change of suppliers.

§ 5 Under the conditions set forth in the foregoing paragraph, the company must submit technical justifications that prove the need for the alteration.

§ 6 In applying for renewal of the registration, alterations related to the following things will not be permitted:

I - technologies for wrappings and filters; and

II - the name of the smoking product.

§ 7 Alterations of technologies for wrappings, filters and the name of the smoking product derived from tobacco constitute a new product, requiring application for a new registration.

Section III

Application for Enrollment of a Smoking Product Derived from Tobacco exclusively for export purposes

Art. 12. Smoking products derived from tobacco manufactured in the national territory exclusively for export purposes must be enrolled with ANVISA.

§ 1 Electronic applications for enrollment of a smoking product derived from tobacco for export purposes must contain the following information:

I - Data on Manufacturer (name, full CNPJ address, State, City);

II - Product name;

III - Product type;

IV - Tax Schedule (GRU - *Guia de Recolhimento da União*) concerning the Health Oversight Enforcement Tax (TFVS – *Taxa de Fiscalização de Vigilância Sanitária*); and

V - A declaration that the product is intended exclusively for export purposes.

§ 2 Prior to commencing manufacture, the company must apply to ANVISA for enrollment of the smoking products derived from tobacco exclusively for export purposes.

§ 3 Commercialization in the Brazilian market of smoking products registered exclusively for export is prohibited.

§ 4 If non-compliance of this article is ascertained at any time, the enrollment will be cancelled, and the applicable sanctions will be imposed.

Section IV

Application for Cancellation at the Request of the Company

Art. 13. Electronic applications for cancellation of registration of a Smoking Product at the Request of the Company, national manufacturer or importer, must be filed in ANVISA's Electronic Application System, on an individual basis, for each smoking product derived from tobacco.

Section V

Application for Amendment

Art. 14. An application for Amendment is intended exclusively for the submission of information that has to do with improvement of the knowledge concerning the object in the process, and does not result in a statement by ANVISA on matters other than the item requested.

Sole paragraph. An application for Amendment must contain the file with the additional process information and must be filed with an electronic application available on ANVISA's Electronic Application System, on an individual basis, for each smoking product derived from tobacco.

Section VI

Technical Requirement

Art. 15. A technical requirement is a duly founded inquiry sent to the interested party or his legal representative, in order to obtain information and clarification regarding the documentation accompanying an application.

§1 Companies must observe the deadline for complying with requirements established in the health legislation in force that govern the procedure for applications subject to analysis by ANVISA's technical departments.

§ 2 An application to show compliance with a technical requirement must be filed using the electronic application available on ANVISA's Electronic Application System, and must contain a digital file with the required information.

§ 3 An application to show compliance with a technical requirement can be filed physically only in those cases where such is expressly stated in the technical requirement issued.

Section VII

Enrollment of Processed Tobacco

Art. 16. Electronic applications for enrollment of processed tobacco must be filed using ANVISA's electronic application system, and forwarded annually by national tobacco processing companies.

§ 1 Applications of the kind addressed in the heading of this article must contain the data indicated in Annex II of this Resolution.

§ 2 Companies must keep on file for a period of 5 (five) years, documentation that makes it possible to corroborate the information declared.

Section VIII

Filing of Applications

Art. 17. Filing with ANVISA the applications addressed in this rule is to be performed automatically by the electronic application and fee collection system, there being no need for physical filing of documents.

§ 1 The filing addressed in the heading is subject to payment of the Sanitary Oversight Enforcement Tax (TFVS - *Taxa de Fiscalizaçao de Vigilância Sanitária*), in cases where it is applicable.

§ 2 Filing of the application shall occur automatically within 2 (two) business days, counting from the date of collection, in cases where the TFVS applies.

§ 3 For applications exempt from payment of the TFVS, filing with ANVISA shall occur automatically as soon as the application is completed in the electronic application and fee collection system.

§ 4 After automatic filing of the electronic application, it is no longer possible to correct it.

CHAPTER III

DEADLINES

Section I

Registration of Smoking Products Derived from Tobacco

Art. 18. Applications to register a smoking product can be filed with ANVISA at any time of year.

§ 1 The applications for registration indicated in the heading will receive their first response within 60 (sixty) days counting from the date of filing with ANVISA.

§ 2 Publicity and commercialization for the smoking product for which the application is being submitted may begin after the approval of the respective application for registration and its publication in the *Diário Oficial da União*.

Art. 19. The registration of the product is valid for 01 (one) year, counting from the date of publication in the *Diário Oficial da União* of the resolution of approval of the primary application for registration of a smoking product, and its validity must be renewed annually.

Section II

Renewal of Registration of Smoking Products Derived from Tobacco

Art. 20. Applications for renewal of registration of a smoking product derived from tobacco must be filed by the company annually, within 90 (ninety) days and up to 30 (thirty) days prior to the expiration date of the registration.

§ 1 The applications for renewal of registration indicated in the heading will receive their first response within 120 (one hundred and twenty) days counting from the date of filing with ANVISA.

§ 2 If an application for renewal of registration of a smoking product is not filed within the deadline stipulated in the heading of this article, the registration will be declared to have elapsed after its expiration, with publication to such effect in the *Diário Oficial da União*.

Section III

Enrollment of Smoking Products Derived from Tobacco exclusively for export purposes

Art. 21. Applications to register smoking products derived from tobacco exclusively for export purposes can be filed with ANVISA at any time of year.

Sole paragraph. The product registration is valid for 01 (one) year counting from the date of filing the primary application for registration of a smoking product derived from tobacco exclusively for export purposes.

Art. 22. Applications to renew the registration of smoking products derived from tobacco exclusively for export purposes must be submitted annually by the company holding the enrollment, up to 30 (thirty) days prior to the expiration date of the enrollment.

Sole paragraph. Failure to submit the application for renewal within the deadline established in the foregoing paragraph shall result in cancellation of the enrollment.

Section IV

Enrollment of Processed Tobacco

Art. 23. The information stated on the Registration for Enrollment of Processed Tobacco must be updated annually by the processing company, by January 31st.

CHAPTER IV

PUBLICITY CONCERNING THE ACT AND ITS EFFECTS

Section I

Approval or Disapproval

Art. 24. Applications for registration and renewal of registration of smoking products derived from tobacco shall be approved as long as they satisfy the requirements of this Resolution and other health regulations in force.

Sole paragraph. The act of approval shall take effect through a Resolution published in the *Diário Oficial da União*.

Art. 25. Applications for registration or renewal of registration of a smoking product derived from tobacco will be disapproved when they do not completely meet the technical requirements set forth in this Resolution and in health regulations in force.

Art. 26. It is prohibited to use any number generated in the application for registration of a smoking product for other purposes besides the strict accompaniment of the process with ANVISA.

Sole paragraph. It is prohibited to use any information having to do with the registration process, that aims to enhance or attribute quality to the product, setting it apart from other smoking products.

Section II

Cancellation

Art. 27. Registrations of smoking products derived from tobacco will be cancelled in the following situations:

I – After the lapse of the registration has been declared, as per the deadline stipulated by this Resolution;

II - After a definitive decision of disapproval of renewal of registration;

III - At the request of the company, based on an electronic application for cancellation of the registration sought; and

IV – In the event of any breach of compliance with the health rules in force.

§ 1 The act of cancellation shall take effect through a Resolution published in the *Diário Oficial da União*.

§ 2 Cancellation of the registration of a smoking product entails withdrawal of the product throughout the national territory by the company that holds the registration, within a period stipulated in the act determining cancellation of the registration.

Art. 28. Companies that are holders of registrations must keep on file for a period of 5 (five) years, complete data that make it possible to prove the withdrawal of the product, in the event of a sanitary audit.

CHAPTER V

FINAL AND TRANSITORY PROVISIONS

Art. 29. It is prohibited to import, export or commercialize in the national territory any smoking product that is not duly regularized pursuant to this Resolution.

Art. 30. ANVISA may conduct inspections of manufacturers, exporters, importers, processors or third parties involved in

any of the phases of production of the product, for purposes of verifying the accuracy of the information stated in applications of registration and renewal of smoking products and enrollment of processed tobacco.

Art. 31. During inspections of registration for verification of accuracy, or enforcement actions, the company must provide complete documentation concerning the technical file required in the health regulations in force during the period of application having to do with the registration of smoking products and enrollment of processed tobacco.

§ 1 Companies must keep on file raw data concerning the results of tests backing up the analytical report.

§ 2 The raw data concerning the results of tests backing up the analytical report must be traceable.

§ 3 During inspections of registration for verification of accuracy, or enforcement actions, ANVISA can order an analysis of reference samples retained, to be performed in the presence of the inspectors and in the company's own laboratory, for any tests performed by the company itself and presented in the analytical report submitted in the registration file.

Art. 32. National manufacturers or importers must keep on file for a period of 10 (ten) years, complete data making it possible to identify the entire distribution chain of products in the event of a sanitary audit.

Art. 33. Applications filed physically prior to the date of publication of this Resolution will be analyzed in accordance with Resolution of Collegiate Directorate RDC nº 90, of December 27, 2007, in force at the time of the filing.

Art. 34. In the first year that this Resolution is in effect, companies must submit, in the form of an amendment to the application for registration or renewal filed electronically, a hard copy of the data declared electronically, and of the documents attached in the electronic application system, for purposes of validation of the totally electronic procedure.

Art. 35. ANVISA can establish other ways of applying and filing, including in non-electronic formats, at the discretion of the administration, including manual application and physical filing of applications.

Art. 36. Failure to comply with the provisions contained in this Resolution constitutes a sanitary violation, pursuant to the terms of Law nº 6.437, of August 20, 1977, subjecting the offender to the penalties set forth in this legal text and other applicable provisions, without impairment to relevant sanctions of a civil, administrative and penal nature.

Art. 37. The Resolutions of the Collegiate Directorate - RDC nº 90, of December 27, 2007, RDC nº 32, of May 29, 2008, and RDC nº 44, of June 18, 2008, are hereby rescinded.

Art. 38. This Resolution shall enter into force on August 6, 2018.

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JARBAS BARBOSA DA SILVA JR.

Executive Director

ANNEX I

PARAMETERS AND COMPOUNDS PRESENT IN PRIMARY AND SECONDARY STREAMS AND IN TOTAL TOBACCO

I - Parameters and Compounds Present in the Primary Stream[1]

Compound	Unit
1. Tar[2, 3]	mg/unit
2. Nicotine[2, 3]	mg/unit
3. Carbon monoxide[2, 3]	mg/unit
4. Benzo-a -pyrene	ng/unit
5. Formaldehyde	ug/unit
6. Acetaldehyde	ug/unit
7. Acetone	ug/unit
8. Acrolein	ug/unit
9. Propionaldehyde	ug/unit
10. Crotonaldehyde	ug/unit
11. Methylethylketone	ug/unit
12. Butanaldehyde	ug/unit
13. Hidroquinone	ug/unit
14. Resorcinol	ug/unit
15. Catechol	ug/unit
16. Phenol	ug/unit
17. Metacresol	ug/unit
18. Para-cresol	ug/unit

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19. Ortho-cresol	ug/unit
20. Ammonia	ug/unit
21. Hydrocyanic acid	ug/unit
22. Pyridine	ug/unit
23. Quinoline	ug/unit
24. Butadiene	ug/unit
25. Isoprene	ug/unit
26. Acrylonitrile	ug/unit
27. Benzene	ug/unit
28. Toluene	ug/unit
29. Styrene	ug/unit
30. NNN: N-nitrosonornicotine	ng/unit
31. NAT: N-nitrosoanatabine	ng/unit
32. NAB: N-nitrosoanabasine	ng/unit
33. NNK : 4-(methylnitrosoamine) 1- (3-pyridyl)-1-butanone	ng/unit
34. 3-aminobiphenyl	ng/unit
35. 4-aminobiphenyl	ng/unit
36. 1-aminonaphthalene	ng/unit
37. 2-aminophthalene	ng/unit
38. Nitrogen Oxide	ug/unit
39. Eugenol	mg/unit
40. pH	unit
41. Efficiency of filter for nicotine	%
42. Mercury[4]	ng/unit
43. Nickel[4]	ng/unit
44. Lead[4]	ng/unit

45. Selenium[4]	ng/unit
46. Cadmium 4	ng/unit
47. Chrome 4	ng/unit
48. Arsenic 4	ng/unit
49. Menthol	ng/unit

[1] Required field for cigarettes.

[2] Required field for cigars and cigarillos, 1 (one) year after the date of entry into force of this Resolution.

[3] Laboratory analyses used for quantification of compounds in cigarettes must follow ISO methodologies. For cigars and cigarillos, other internationally recognized methodologies can be used.

4 For analyses of metals, this must be filled in for cigarettes, 1 (one) year after the date of entry into force of this Resolution.

II - Compounds Present in Secondary Stream[1]

Compound	**Unit**
1. Tar [2]	mg/unit
2. Nicotine [2]	mg/unit
3. Carbon monoxide [2]	mg/unit
4. Benzo-a -pyrene	ng/unit
5. Formaldehyde	ug/unit
6. Acetaldehyde	ug/unit
7. Acetone	ug/unit
8. Acrolein	ug/unit
9. Propionaldehyde	ug/unit
10. Crotonaldehyde	ug/unit
11. Methylethylketone	ug/unit
12. Butanaldehyde	ug/unit

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13. Hidroquinone	ug/unit
14. Resorcinol	ug/unit
15. Catechol	ug/unit
16. Phenol	ug/unit
17. Metacresol	ug/unit
18. Para-cresol	ug/unit
19. Ortho-cresol	ug/unit
20. Ammonia	ug/unit
21. Hydrocyanic acid	ug/unit
22. Pyridine	ug/unit
23. Quinoline	ug/unit
24. Butadiene	ug/unit
25. Isoprene	ug/unit
26. Acrylonitrile	ug/unit
27. Benzene	ug/unit
28. Toluene	ug/unit
29. Styrene	ug/unit
30. NNN: N-nitrosonornicotine	ng/unit
31. NAT: N-nitrosoanatabine	ng/unit
32. NAB: N-nitrosoanabasine	ng/unit
33. NNK : 4-(methylnitrosoamine) 1- (3-pyridyl)-1-butanone	ng/unit
34. 3-aminobiphenyl	ng/unit
35. 4-aminobiphenyl	ng/unit
36. 1-aminonaphthalene	ng/unit
37. 2-aminophthalene	ng/unit

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38. Nitrogen Oxide	ug/unit
39. Eugenol	mg/unit
40. Mercury[3]	ng/unit
41. Nickel[3]	ng/unit
42. Lead[3]	ng/unit
43. Selenium[3]	ng/unit
44. Cadmium [3]	ng/unit
45. Chrome [3]	ng/unit
46. Arsenic [3]	ng/unit
47. Menthol	ng/unit

[1] Required field for cigarettes.

[2] Laboratory analyses used for quantification of compounds must follow ISO methodologies.

[3] For analyses of metals, this must be filled in for cigarettes, 1 (one) year after the date of entry into force of this Resolution.

III - Parameters and Compounds Present in Total Tobacco[1]

Compound	**Unit**
1. Ammonia	ug/g of tobacco
2. Nicotine	ug/g of tobacco
3. Nornicotine	ug/g of tobacco
4. Myosmine	ug/g of tobacco
5. Anabasine	ug/g of tobacco
6. Anatabine	ug/g of tobacco
7. NNN: N-nitrosonornicotine	ng/g of tobacco
8. NAT: N-nitrosoanatabine	ng/g of tobacco
9. NAB: N-nitrosoanabasine	ng/g of tobacco

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10. NNK: 4-(methylnitrosoamine) 1- (3-pyridyl)-1-butanone	ng/g of tobacco
11. Lead	ng/g of tobacco
12. Cadmium	ng/g of tobacco
13. Mercury	ng/g of tobacco
14. Nickel	ng/g of tobacco
15. Selenium	ng/g of tobacco
16. Chrome	ng/g of tobacco
17. Arsenic	ng/g of tobacco
18. Eugenol	mg/g of tobacco
19. pH	unit
20. Benzo-a -pyrene	ng/g of tobacco
21. Glycerol	mg/g of tobacco
22. Propylene Glycol	mg/g of tobacco
23. Triethylene Glycol	mg/g of tobacco
24. Nitrate	ug/g of tobacco
25. Triacetine	ug/g of tobacco
26. Sodium Propionate	ug/g of tobacco
27. Sorbic Acid	ug/g of tobacco
28. Menthol	mg/g of tobacco
29. 2-ethyl-3(5 or 6)-dimethyl pyrazine[2]	ug/g of tobacco
30. 2-ethyl-3-methyl pyrazine[2]	ug/g of tobacco
31. 2-heptanone[2]	ug/g of tobacco
32. 2-methoxy-4-methyl phenol[2]	ug/g of tobacco
33. 2,3,5-trimethyl pyrazine[2]	ug/g of tobacco
34. 2,3,5,6-tetramethyl pyrazine[2]	ug/g of tobacco

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35. 2,3-diethyl pyrazine[2]	ug/g of tobacco
36. 2,4-heptadienal[2]	ug/g of tobacco
37. 2,5-dimethyl pyrazine[2]	ug/g of tobacco
38. 3-hexen-1-ol[2]	ug/g of tobacco
39. 3-methylbutyraldehyde[2]	ug/g of tobacco
40. 4-methylacetophenone[2]	ug/g of tobacco
41. 4-vinyl-guaiacol[2]	ug/g of tobacco
42. 4-(para-hydroxyphenyl)-2- butanone[2]	ug/g of tobacco
43. 5-ethyl-3-hydroxy-4-methyl-2(5h)- furanone[2]	ug/g of tobacco
44. 6-methyl-3,5-heptadienone[2]	ug/g of tobacco
45. 6-methylcoumarin[2]	ug/g of tobacco
46. 6-methyl-3,5-heptadien-2-one[2]	ug/g of tobacco
47. 6,10-dimethyl-5,9-undecadien-2-one[2]	ug/g of tobacco
48. acetanisole[2]	ug/g of tobacco
49. benzyl acetate[2]	ug/g of tobacco
50. bornyl acetate [2]	ug/g of tobacco
51. ethyl acetate [2]	ug/g of tobacco
52. phenethyl acetate[2]	ug/g of tobacco
53. furfuryl acetate [2]	ug/g of tobacco
54. geranyl acetate [2]	ug/g of tobacco
55. hexyl acetate [2]	ug/g of tobacco
56. isoamyl acetate [2]	ug/g of tobacco
57. menthyl acetate[2]	ug/g of tobacco
58. neomenthyl acetate[2]	ug/g of tobacco

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59. p-tolyl acetate [2]	ug/g of tobacco
60. trans-3-hexenyl acetate [2]	ug/g of tobacco
61. acetyl pyrazine[2]	ug/g of tobacco
62. acetophenone[2]	ug/g of tobacco
63. acetoin[2]	ug/g of tobacco
64. 2-methylbutyric acid[2]	ug/g of tobacco
65. acetic acid [2]	ug/g of tobacco
66. butyric acid [2]	ug/g of tobacco
67. citric acid [2]	ug/g of tobacco
68. decanoic acid [2]	ug/g of tobacco
69. Phenylacetic acid [2]	ug/g of tobacco
70. glycyrrhizic acid [2]	ug/g of tobacco
71. hexanoic acid [2]	ug/g of tobacco
72. isobutyric acid [2]	ug/g of tobacco
73. isovaleric acid [2]	ug/g of tobacco
74. lactic acid [2]	ug/g of tobacco
75. lauric acid [2]	ug/g of tobacco
76. levulinic acid [2]	ug/g of tobacco
77. octanoic acid [2]	ug/g of tobacco
78. benzyl alcohol (phenyl carbinol)[2]	ug/g of tobacco
79. c-6 alcohol (n-hexanol) [2]	ug/g of tobacco
80. cinnamic alcolhol (styryl carbinol)[2]	ug/g of tobacco
81. phenethyl alcohol (benzyl carbinol)[2]	ug/g of tobacco
82. isobutyl alcohol (isopropyl carbinol)[2]	ug/g of tobacco

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83. anisyl alcohol [2]	ug/g of tobacco
84. alpha-ionone[2]	ug/g of tobacco
85. alpha-terpineol[2]	ug/g of tobacco
86. anisaldehyde[2]	ug/g of tobacco
87. methyl anthranilate[2]	ug/g of tobacco
88. benzaldehyde[2]	ug/g of tobacco
89. benzyl benzoate[2]	ug/g of tobacco
90. methyl benzoate[2]	ug/g of tobacco
91. beta-damascenone[2]	ug/g of tobacco
92. beta-damascone[2]	ug/g of tobacco
93. beta-ionone[2]	ug/g of tobacco
94. ethyl butyrate [2]	ug/g of tobacco
95. geranyl butyrate [2]	ug/g of tobacco
96. caffeine[2]	ug/g of tobacco
97. carvone[2]	ug/g of tobacco
98. cinamaldehyde[2]	ug/g of tobacco
99. methyl cinnamate[2]	ug/g of tobacco
100. triethyl citrate[2]	ug/g of tobacco
101. coumarin[2]	ug/g of tobacco
102. delta-octalactone[2]	ug/g of tobacco
103. delta-decalactone[2]	ug/g of tobacco
104. methyl dihydrojasmonate [2]	ug/g of tobacco
105. d,l-citronellol[2]	ug/g of tobacco
106. sclariolide[2]	ug/g of tobacco
107. trans- cinnamic acid methyl ester [2]	ug/g of tobacco

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108. ethyl maltol[2]	ug/g of tobacco
109. ethyl vanillin[2]	ug/g of tobacco
110. eucalyptol[2]	ug/g of tobacco
111. eugenol[2]	ug/g of tobacco
112. farnesol[2]	ug/g of tobacco
113. phenylacetaldehyde[2]	ug/g of tobacco
114. ethyl phenylacetate [2]	ug/g of tobacco
115. phenethyl phenylacetate [2]	ug/g of tobacco
116. isoamyl phenylacetate [2]	ug/g of tobacco
117. methyl phenylacetate [2]	ug/g of tobacco
118. benzyl formate [2]	ug/g of tobacco
119. cis-3-hexenyl formate [2]	ug/g of tobacco
120. geranyl formate [2]	ug/g of tobacco
121. isoamyl formate [2]	ug/g of tobacco
122. furfural[2]	ug/g of tobacco
123. gama-decalactone[2]	ug/g of tobacco
124. gama-dodecalactone[2]	ug/g of tobacco
125. gama-heptalactone[2]	ug/g of tobacco
126. gama-hexalactone[2]	ug/g of tobacco
127. gama-nonalactone[2]	ug/g of tobacco
128. gama-octalactone[2]	ug/g of tobacco
129. gama-undecalactone[2]	ug/g of tobacco
130. gama-valerolactone[2]	ug/g of tobacco
131. geraniol[2]	ug/g of tobacco
132. guaiacol[2]	ug/g of tobacco
133. ethyl heptanoate [2]	ug/g of tobacco

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134. ethyl hexanoate [2]	ug/g of tobacco
135. isoamyl hexanoate [2]	ug/g of tobacco
136. hexen-2-al[2]	ug/g of tobacco
137. isobutyraldehyde[2]	ug/g of tobacco
138. isophorone[2]	ug/g of tobacco
139. ethyl isovalerate [2]	ug/g of tobacco
140. isoamyl isovalerate [2]	ug/g of tobacco
141. ethyl lactate [2]	ug/g of tobacco
142. l-carvone[2]	ug/g of tobacco
143. limonene[2]	ug/g of tobacco
144. linalool[2]	ug/g of tobacco
145. methyl linoleate [2]	ug/g of tobacco
146. maltol[2]	ug/g of tobacco
147. mentone[2]	ug/g of tobacco
148. methyl cyclopentenolone[2]	ug/g of tobacco
149. methyl vanillin[2]	ug/g of tobacco
150. nonanal[2]	ug/g of tobacco
151. ethyl nonanoate [2]	ug/g of tobacco
152. para-methoxybenzaldehyde[2]	ug/g of tobacco
153. piperonal[2]	ug/g of tobacco
154. propenyl guaetol[2]	ug/g of tobacco
155. citronellyl propionate[2]	ug/g of tobacco
156. ethyl propionate[2]	ug/g of tobacco
157. geranyl propionate [2]	ug/g of tobacco
158. sacilaldehyde[2]	ug/g of tobacco
159. ethyl salicylate[2]	ug/g of tobacco

160. methyl salicylate [2]	ug/g of tobacco
161. theobromine[2]	ug/g of tobacco
162. terpineol[2]	ug/g of tobacco
163. trans-anethole[2]	ug/g of tobacco
164. thymol[2]	ug/g of tobacco
165. vanillin[2]	ug/g of tobacco

[1] Required field for all products.

[2] Required field for all products, 1 (one) year after the date of entry into force of this Resolution.

ANNEX II

ELECTRONIC APPLICATIONS

I - Electronic Application for Processed Tobacco:

1. Origin of Types of Processed Tobacco the year before:

Type of Tobacco;

Quantity of each type of tobacco;

Country, State, City.

II - Electronic Applications for Registration and Renewal of Registration of Smoking Product Derived from Tobacco:

1. Product characteristics:

Product name;

Product type;

Length (mm);

Circumference (mm);

2. Origin:

National Manufacture:

Data on processing company (Name and CNPJ);

Imported:

Data of International Manufacturer (Name and address);

3. Destination:

Exclusively for commercialization on the domestic market;

Commercialization on the domestic and foreign market;

Exclusively for export;

4. Packaging:

Types of Packaging;

Quantity of product per Package;

5. List of types of tobacco used in product:

Types of tobacco;

Quantity of each type of tobacco;

Total quantity of tobacco used in product;

6. List of additives used in product:

Official nomenclature or common name of additive;

Additive category;

CAS Number (Chemical Abstracts Service), when applicable;

Specific place of addition;

Quantity added;

7. Specifications for Filter and Wrappings:

Filter Type;

Characteristics of Filter: Total Ventilation (0-100%), Pressure Drop with vents open (mmH2O), Pressure Drop with vents closed (mmH2O);

Composition of Filtering Material: Substances, Quantities;

Physical characteristics of Paper Wrapping of Filter:

Grammage (g/m^2);

Permeability (cm3. min-1. cm-2) at 1 kPa;

Weight (mg/cig);

Physical Characteristics of Paper Tip:

Grammage (g/m²);

Permeability (cm3. min-1. cm-2) at 1 kPa;

Weight(mg/cig);

Physical Characteristics of Paper Wrapping of

Product: Grammage (g/m²);

Permeability (cm3. min-1. cm-2) at 1 kPa;

Weight (mg/cig);

8. Parameters and Compounds Present in Primary Stream, as per Annex I of this resolution:

Average Content, Standard Deviation and Methodologies Used;

9. Compound Present in Secondary Stream, as per Annex

I of this resolution:

Average Content, Standard Deviation and Methodologies Used;

10. Parameters and Compounds Present in Total Tobacco, as per Annex I of this resolution:

Average Content, Standard Deviation and Methodologies Used;

11. Digital files of Packaging.

ANNEX III

DECLARATION OF QUALITATIVE-QUANTITATIVE COMPOSITION

The undersigned Legal Manager of the Company_____ declares, for purposes of evaluation by ANVISA, pursuant to the terms of Resolution of Collegiate Directorate n°_____, of_____, that the smoking product derived from tobacco_____to be registered has the same qualitative and quantitative composition as the smoking product derived from tobacco_____, already registered by ANVISA, that is to say, both smoking products derived from tobacco have the same composition and the same parameters. *Legal Representative of the Company - (full name and digital signature) CPF nº