COLLEGIATE BOARD RESOLUTION – RDC NO. 559 OF 30 AUGUST 2021

(Published in the Federal Official Gazette no. 165 of 31 August 2021)

Provides for the marketing authorization for tobacco products.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, and Article 7, items III and IV, of Law no. 9,782 of 26 January 1999, and considering the provisions in Article 53, item VI, and paragraphs 1 and 3 of Anvisa Regulation approved pursuant to Collegiate Board Resolution – RDC no. 255 of 10 December 2018, adopts the following Resolution, as decided upon in a meeting held on 30 August 2021, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Article 1. This Resolution provides for the technical requirements and the procedures to be complied with in the register of processed tobaccos and in processes of register of and marketing authorization for tobacco products.

Sole paragraph. A totally electronic procedure is hereby established for petition and submission to Anvisa of the applications provided for in this Resolution.

Section II

Definitions

Article 2. For the purposes of this Resolution, the following definitions are adopted:

I – additive: any substance or compound, other than tobacco or water, used in the processing of tobacco leaves, homogenized tobacco, and reconstituted tobacco, in the manufacture and packaging of a tobacco product;

II – tobacco product register exclusively for the purpose of export: administrative act of regularization at Anvisa through registering the tobacco product exclusively for the purpose of export;

III – processed tobacco register: electronic petition submitted by the Brazilian processing company to register the quantity and the origin of the types of tobacco processed in the year immediately prior to the submission, and intended for use as raw material to obtain tobacco products;

IV – mainstream smoke: aerosol coming from the end of the tobacco product, through the mouth, and aspirated by the smoker during puff-drawing;

V – sidestream smoke: all aerosol emitted during the burning of a tobacco product, except for mainstream smoke;

VI – package: wrap, recipient, or any other form of packaging intended to contain tobacco products, with the following classification:

a) primary package: package that accommodates the tobacco product, intended for the final consumer;

b) secondary package: external package of the product, which accommodates more than one primary package, intended or not for the final consumer; and

c) tertiary package: external package of the product, which accommodates more than one package, not intended for the final consumer.

VII – processing company: company that performs activities related to any stage of processing of tobacco leaves, homogenized tobacco, or reconstituted tobacco, used in tobacco products;

VIII – distributing company: company responsible for the commercial distribution of the product, which may play an intermediary role between the manufacturing or importing company and the commercial establishments;

IX – manufacturing company: company that produces any tobacco product;

X – importing company: company that carries out the import commercial and fiscal process of any tobacco product;

XI – plug wrap: paper that directly wraps the tobacco product filter plug;

XII – product wrapper: material that wraps the tobacco column to form the tobacco product cylinder;

XIII – filter plug (or rod): component placed at the end of a tobacco product cylinder to retain part of the particulate material and the nicotine contained in the smoke;

XIV – petition electronic form: document available in the Electronic Petition System for electronic filling of the information required by this Resolution;

XV – visual identity: set of graphic elements that represent the product in a visual and systematized way, such as images, texts, typographs, chromatic patterns, and arrangement of elements;

XVI – analytical report: technical report, issued by a laboratory, with the specifications and the results of physical and chemical analyses of tobacco products;

XVII – tobacco product name: name, accompanied or not of any description, such as word, number, or package color, attached to the product package, which will be recognized as a way to distinguish the product from others of the same nature;

XVIII – paper wrap: paper that covers the filter plug, extending to the tobacco product cylinder;

XIX – electronic petition: procedure carried out by the interested party to electronically fill the data required by this Resolution and issue the Federal Collection Slip (GRU, in Portuguese) to

pay the Health Surveillance Inspection Fee (TFVS, in Portuguese), using the Electronic Petition System available on Anvisa's website;

XX – manual petition: procedure carried out by the interested party to print the front page and the Federal Collection Slip (GRU, in Portuguese), using the Electronic Petition System available on Anvisa's website;

XXI – smoke product: manufactured product, derived or not from tobacco, that contains leaves or leaf extracts, or other parts of plants in its composition;

XXII – tobacco product: any manufactured smoke product containing tobacco in its composition;

XXIII – automatic submission: fully electronic procedure to submit applications to Anvisa, through the Electronic Petition System, without the need for physical submission of documents;

XXIV – processed tobacco: any type of tobacco submitted to processing in a processing company, intended for use as raw material to obtain tobacco products; and

XXV – total tobacco: mixture of different types of tobacco that compose tobacco products.

Section III

Scope

Article 3. This Resolution applies to tobacco products and processed tobacco in Brazil.

Article 4. The following classification is adopted for the products covered in this Resolution:

I – bidi: product without filter, which contains cut tobacco wrapped in tendu or temburni leaves, intended to be smoked;

II – blunt wrap: product containing tobacco in its composition, to be used as a tobacco product wrapper, intended to be smoked;

III – cigar: product without filter, with weight above 1,360g/1,000 units, intended to be smoked, composed of whole, cut, ragged, or broken tobacco leaves, or of reconstituted tobacco, rolled up forming a cylinder, bound with a binder tobacco leaf, and sheathed with a wrapper tobacco leaf, or reconstituted tobacco;

IV – cigarillo: product with weight equal to or below 1,360g/1,000 units, intended to be smoked, composed of cut, ragged, powder, or broken tobacco leaves, or of reconstituted tobacco, forming a cylinder, the wrapper of which is composed of tobacco leaf or reconstituted tobacco;

V – cigarette: product intended to be smoked and, regardless of its production form, is totally or partially composed of tobacco, wrapped in paper or homogenized tobacco, or reconstituted tobacco, or a mixture of cellulose and tobacco, or in any other wrap other than exclusively tobacco leaf;

VI – straw cigarette: product without filter, intended to be smoked, which contains cut tobacco wrapped exclusively in corn husks;

VII – rope tobacco: product intended to be smoked that contains semi-stripped, intertwined twisted rolled up leaves, submitted to sun-curing;

VIII – shredded tobacco: product composed of shredded tobacco leaves, intended to be smoked;

IX – pipe tobacco: product that contains tobacco, intended to be smoked using a conventional pipe;

X – narghile (or hookah) tobacco: product that contains tobacco, intended to be smoked using a device known as narghile, water pipe, Shisha, or Hookah;

XI – snuff tobacco: product that contains tobacco, intended to be inhaled; and

XII – chewing tobacco: product that contains tobacco, intended to be chewed, sucked, or ingested.

Sole paragraph. The tobacco products not included in this Resolution shall be object of analysis and deliberation regarding their classification.

CHAPTER II

ELABORATION OF APPLICATION AND PROCESS SUBMISSION

Section I

Application for Marketing Authorization for a Tobacco Product

Article 4. The marketing authorization granted by Anvisa for all tobacco products is mandatory for the purposes of:

I – manufacturing and commercialization in Brazilian territory; and

II – import and commercialization in Brazilian territory.

Paragraph 1. The acceptance of the application for marketing authorization for a tobacco product does not generate a marketing authorization number.

Paragraph 2. Different import companies may be granted by Anvisa a marketing authorization for the same tobacco product manufactured abroad, when such product does not have a brand protected by intellectual property rights granted by the Brazilian Institute for Industrial Property (INPI, in Portuguese).

Paragraph 3. The import company must apply for the marketing authorization for the tobacco product to be imported, even if the product has already been granted marketing authorization requested by another import company.

Paragraph 4. The imported tobacco product, or the tobacco product manufactured in Brazil, which has a brand protected by intellectual property rights granted by the Brazilian Institute for Industrial Property (INPI, in Portuguese), may only be granted marketing

authorization through a petition by the company holding the marketing authorization for the brand or the company licensed to use the brand.

Article 5. Any disclosure, publicity, or promotion linked to the marketing authorization process at Anvisa is hereby forbidden.

Article 6. Before industrialization and commercialization, the Brazilian manufacturing companies, exporters and importers of tobacco products must:

I – have the executive declaration act (ADE, in Portuguese) of granting of the Special Manufacturer or Importer Registration, issued by the Brazilian Federal Revenue Secretariat (SRF/MF, in Portuguese); and

II – register the products at Anvisa.

Sole paragraph. The provisions in item I of this article apply to cigarillos and cigarettes only, in accordance with the Brazilian Federal Revenue Normative Instruction (IN RFB, in Portuguese) no. 770 of 21 August 2007.

Article 7. Before submitting the electronic petition for the marketing authorization for tobacco products, the Brazilian manufacturing and import companies of tobacco products must have the following conditions:

I – the executive declaration act (ADE, in Portuguese) of granting of the Special Manufacturer or Importer Registration, issued by the Brazilian Federal Revenue Secretariat (SRF/MF, in Portuguese), in accordance with the legislation in force, in case of cigarillos and cigarettes;

II – grant of registration or submission of application for brand registration issued through official means provided for by the Brazilian Institute for Industrial Property (INPI, in Portuguese), in case of a product that has a brand protected by industrial property rights; and

III – confirmation of brand licensing to third parties, issued through official means provided for by the Brazilian Institute for Industrial Property (INPI, in Portuguese), in case of a product that has a brand protected by industrial property rights, licensed to third parties.

Sole paragraph. In case of failure to comply with the conditions provided for in items I, II, and III of this article, at any time, the application for marketing authorization shall be rejected or cancelled.

Article 8. The electronic petition for the marketing authorization for a tobacco product must be carried out by the Brazilian manufacturing and import companies of tobacco products, through Anvisa's Electronic Petition System, individually per tobacco product.

Article 9. The petition for the marketing authorization for a tobacco product must contain the following documentation, mandatorily:

I – electronic petition form filled with all data required in Annex I and Annex II of this Resolution;

II – electronic file of the product's primary packages and secondary packages, as appropriate, intended for commercialization;

III – electronic file of the analytical report including all quantifications required in Annex I of this Resolution, regarding the composition of mainstream smoke, sidestream smoke, and total tobacco, obtained from the same sample;

IV – electronic file with a full description of the methodologies used, from sample receipt to the final result, for the quantifications required in this Resolution, accompanied by a certificate confirming the corresponding analyses are part of the laboratory accreditation scope;

V – electronic file of the declaration of total reducing sugar loss and the need for replacement, exclusively in the cases where there is addition of any type of sugar in the product's composition, in compliance with the provisions of Collegiate Board Resolution no. 14 of 15 March 2012;

VI – electronic file of the analytical report confirming the declared data on total reducing sugar loss and replacement, in compliance with the provisions of Collegiate Board Resolution no. 14 of 15 March 2012, accompanied by a certificate confirming the analysis is part of the laboratory accreditation scope; and

VII – electronic file with a declaration by the petitioning company, stating that the product at issue complies with the requirements provided for in items I, II, and III of Article 7 of this Resolution.

Sole paragraph. In order to access the electronic petition form available in the Electronic Petition System, the Brazilian manufacturing or import company must be previously registered at Anvisa's system, and the company is responsible for keeping the declared information updated.

Article 10. In the Electronic Petition Form, the following data referring to the tobacco product at issue must be included:

I – name of the tobacco product 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 – specifications and physical characteristics of the filter and wrappers, in accordance with Annex II of this Resolution, in the case of cigarettes and cigarillos with filters;

V – parameter of and compounds present in the mainstream smoke, in accordance with Annex I of this Resolution, in the case of cigarettes, cigars, and cigarillos;

VI – parameter of and compounds present in the sidestream smoke, in accordance with Annex I of this Resolution, in the case of cigarettes; and

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

Paragraph 1. In the list of additives referred to in item III of this article, the company must declare all additives used at all manufacturing stages of the tobacco product at issue.

Paragraph 2. In order to meet the provisions in item III of this article, the company must comply with the requirements established by the health legislation in force on the use of additives in tobacco products and, in the cases where sugars are used in the composition, the company is required to present the original analytical reports confirming the content of total reducing sugars originally present in the tobacco leaf before the drying process, as well as the need for replacement of the content lost.

Paragraph 3. When deemed necessary, Anvisa may request physical samples of the product object of the application.

Article 11. The electronic files of primary and secondary packages of the tobacco product must present all sides available to the public and, when applicable, indicate folds and cuts.

Paragraph 1. The name of the tobacco product declared in the Electronic Petition Form and analytical reports must be represented on the product's package, mandatorily.

Paragraph 2. The packages intended for commercialization in the Brazilian market must comply with the requirements established in the legislation in force on the packages of tobacco products.

Paragraph 3. The characteristics of the tobacco product must be the same in all units contained in the package.

Paragraph 4. When deemed necessary, Anvisa may request physical samples of the product's packages.

Article 12. The Analytical Reports must include:

I – name and address of the laboratory;

II – name, title, and signature of the person responsible for analyses;

III – name of the tobacco product declared in the Electronic Petition Form;

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

V – date when the laboratory received the samples;

VI – date of analysis completion;

VII – quantity of sample analyzed;

VIII – sample packaging conditions;

IX – puff-drawing parameters, when applicable;

X – identification of the methodologies used;

XI – detection and quantification limits;

XII – statistical analysis of measurements and results;

XIII – unique identification of the report attached to all pages composing it; and

XIV – results of laboratory measurements.

Paragraph 1. Anvisa shall accept only analytical reports concluded within a maximum period of 6 (six) months before the date the application is submitted.

Paragraph 2. The analytical reports shall be subject to verification by Anvisa with the laboratory responsible for the analyses.

Paragraph 3. The laboratory analyses required in this Resolution must be carried out in laboratories accredited by a Brazilian or international accrediting organism and must follow analytical methodologies internationally accepted or those adopted in compliance with legislation or international agreement ratified and internalized by Brazil.

Paragraph 4. The Brazilian manufacturing and import companies must present the accreditation of laboratories, trials, and methodologies used in the analyses by 1 January 2022.

Paragraph 5. The laboratory analyses to quantify the content of total reducing sugars in tobacco, both before and after the drying process, must follow an ISO (International Organization for Standardization) methodology.

Paragraph 6. The Brazilian manufacturing or import companies must store the samples from the same batch, or another criterion of product control representation, used to carry out laboratory analyses, for the period of 2 (two) years counting from the date the report was issued, and in a quantity large enough to carry out 2 (two) full laboratory analyses.

Section II

Application for Renewal of Marketing Authorization for a Tobacco Product

Article 13. The electronic application for renewal of marketing authorization for a tobacco product must be carried out through Anvisa's electronic petition system, on a yearly basis, by the Brazilian tobacco product manufacturing and import companies.

Paragraph 1. In the application for renewal of marketing authorization for a tobacco product, the information required in Article 9 must be presented and the provisions in articles 10 to 12 of this Resolution must be complied with.

Paragraph 2. In the application for renewal of marketing authorization for a tobacco product, the following items shall be allowed:

I – the inclusion of new types of packages, as long as the visual identity of the packages approved in the tobacco product marketing authorization is maintained;

II – the alteration in the information included in the packages, approved in the tobacco product marketing authorization, solely for the purposes of updating the data on manufacturer or importer and ingredients; and

III – the alteration in the tobacco product composition approved in the marketing authorization, as long as it aims specifically at adjustments due to variations in tobacco harvest or change of suppliers, and the company must present technical justifications confirming the need for such alteration.

Paragraph 3. In the application for renewal of marketing authorization, alterations related to the following items shall not be allowed:

I – technologies of wrappers and filters; and

II – the name of the tobacco product.

Article 14. The alterations in technologies of wrappers and filters, and in the name of the tobacco product constitute a new product, and a new marketing authorization must be applied for.

Section III

Application for the Register of a Tobacco Product Exclusively for Export Purposes

Article 15. The tobacco products manufactured in Brazilian territory exclusively for export purposes must be registered at Anvisa.

Article 16. The electronic application for the register of a tobacco product for export purposes must include the following information, mandatorily:

I – data on the manufacturing company (name, Brazilian Registry of Legal Entities – CNPJ, full address, City, State);

II – name of product;

III – type of product;

IV – Federal Collection Slip (GRU, in Portuguese) related to the Health Surveillance Inspection Fee (TFVS, in Portuguese); and

V – statement that the product is intended exclusively for export purposes.

Article 17. Before the start of manufacturing, the company must submit to Anvisa an application for the register of tobacco products exclusively for export purposes.

Article 18. The commercialization in the Brazilian market of tobacco products registered exclusively for export purposes is hereby forbidden.

Article 19. In case of failure to comply with the provisions in articles 15 to 18, at any time, the register shall be cancelled, and the applicable sanctions shall be applied.

Section IV

Application for Cancellation at the Company's Request

Article 20. The electronic application for the cancellation of a register of a tobacco product at the company's request, either a Brazilian manufacturer or importer, must be carried out through Anvisa's Electronic Petition System, individually per each tobacco product.

Section V

Application for Addendum

Article 21. The application for Addendum is exclusively intended to the presentation of information with a view to improving the knowledge on the process object, which shall not result in a manifestation by Anvisa different from the original application.

Sole paragraph. The application for Addendum must contain an electronic file with the additional information to the process and must be carried out through an electronic application available in Anvisa's Electronic Petition System, individually per each tobacco product.

Section VI

Technical Requirement

Article 22. The technical requirement is a consolidated inquiry sent to the interested party or its legal representative, with a view to obtaining information and clarifications on the documents composing an application.

Paragraph 1. The company must observe the deadline to comply with the requirement, as provided for in the health legislation in force on the procedures for applications submitted for analysis by Anvisa's technical areas.

Paragraph 2. The application for compliance with technical requirements must be carried out through an electronic application available in Anvisa's Electronic Petition System and must include an electronic file with the information required.

Paragraph 3. The application for compliance with technical requirements may be submitted physically, solely in the cases where the authorization for such is expressed in the technical requirement sent.

Section VII

Application for the Register of Processed Tobacco

Article 23. The electronic application for the register of processed tobacco must be carried out through Anvisa's Electronic Petition System, on a yearly basis, by the Brazilian tobacco product processing companies.

Paragraph 1. The application referred to in the caption of this article must include the data provided for in Annex II of this Resolution.

Paragraph 2. The companies must keep in file the documents confirming the information declared, for a period of 5 (five) years.

Section VIII

Submission of Applications

Article 24. The submission to Anvisa of the applications provided for in this Resolution shall be carried out automatically through the electronic petition and payment system, and the physical submission of documents is not required.

Paragraph 1. The submission referred to in the caption of this article is subject to payment of the Health Surveillance Inspection Fee (TFVS, in Portuguese), in the cases where such fee is collected.

Paragraph 2. The submission of the application shall occur automatically in up to 2 (two) working days, counting from the date of payment, in the cases where the TFVS is collected.

Paragraph 3. For the applications exempted from TFVS payment, the submission to Anvisa shall occur automatically at the moment when the application in the electronic petition and payment system is completed.

Paragraph 4. After the automatic submission of the electronic application, its rectification shall be no longer possible.

CHAPTER III

DEADLINES

Section I

Marketing Authorization for Tobacco Products

Article 25. The application for marketing authorization for tobacco products may be submitted to Anvisa at any time of the year.

Paragraph 1. The period for the first manifestation with regards to the application referred to in the caption of this article shall be up to 90 (ninety) days, counting from the date of submission to Anvisa.

Paragraph 2. Promotion and commercialization of the tobacco product object of the application may start only after the approval of the corresponding application for marketing authorization and its publication in the Federal Official Gazette.

Article 26. The marketing authorization for the product is valid for 01 (one) year, counting from the date of publication of the resolution approving the primary application for marketing authorization for the tobacco product in the Federal Official Gazette, and its validity must be renewed on a yearly basis.

Section II

Renewal of Marketing Authorization for Tobacco Products

Article 27. The application for renewal of marketing authorization for a tobacco product must be submitted by the company on a yearly basis, in the period from 90 (ninety) days to 30 (thirty) days before the expiration date of the marketing authorization.

Paragraph 1. The period for the first manifestation with regards to the application for renewal of marketing authorization referred to in the caption of this article shall be of 150 (one hundred and fifty) days, counting from the date of submission to Anvisa.

Paragraph 2. In case the application for renewal of marketing authorization for a tobacco product is not submitted in the period established in the caption of this article, the marketing authorization shall be declared expired after its expiration date, and such declaration shall be published in the Federal Official Gazette.

Section III

Register of Tobacco Products Exclusively for Export Purposes

Article 28. The application for the register of a tobacco product exclusively for export purposes may be submitted to Anvisa at any time of the year.

Sole paragraph. The product register is valid for 01 (one) year, counting from the date of submission of the primary application for the register of a tobacco product exclusively for export purposes.

Article 29. The application for renewal of the register of a tobacco product exclusively for export purposes must be submitted by the company holding the register, on a yearly basis, in up to 30 (thirty) days before the register expiration date.

Sole paragraph. Failure to submit the application for renewal within the period provided for in the caption of this article shall result in register cancellation.

Section IV

Processed Tobacco Register

Article 30. The information declared in the Processed Tobacco Register must be updated by the processing company on a yearly basis, up to 31 January.

CHAPTER IV

PUBLICATION OF THE ACT AND ITS EFFECTS

Section I

Approval or Rejection

Article 31. The applications for marketing authorization and renewal of marketing authorization for tobacco products shall be approved provided they comply with the requirements in this Resolution and other health regulations in force.

Sole paragraph. The act of approval shall occur through a Resolution published in the Federal Official Gazette.

Article 32. The application for marketing authorization or renewal of marketing authorization for tobacco products shall be rejected when it does not fully comply with the technical requirements provided for in this Resolution and health regulations in force.

Article 33. This Resolution forbids the use of any number generated in the application for marketing authorization for tobacco products for other purposes than the close follow-up of the process at Anvisa.

Sole paragraph. This Resolution forbids the use of any information related to the marketing authorization process, with a view to praise or attribute quality to the product, highlighting it from other tobacco products.

Section II

Cancellation

Article 34. The marketing authorization for a tobacco product shall be cancelled in the following scenarios:

I – after the marketing authorization is declared expired, in accordance with the period provided for in this Resolution;

II – after the final decision for rejection of marketing authorization renewal;

III – at the company's request, through the Electronic Application for Cancellation of Marketing Authorization at the Company's Request; and

IV – when the health regulations in force are not complied with.

Paragraph 1. The cancellation act shall occur through a Resolution published in the Federal Official Gazette.

Paragraph 2. The cancellation of marketing authorization for a tobacco product gives cause to recall of the product throughout the Brazilian territory, by the company holding the marketing authorization, by the deadline established in the marketing authorization cancellation act.

Article 35. The company holding the marketing authorization must keep in file, for a period of 5 (five) years, the full data confirming the product recall, in case of health audits.

CHAPTER V

FINAL AND TRANSITIONAL PROVISIONS

Article 36. This Resolution forbids the import, export, and commercialization, in the Brazilian territory, of any smoke product not duly regularized in the terms hereof.

Article 37. Anvisa may carry out inspections in the manufacturing, export, import, processing companies, or subcontracted companies involved in any manufacturing stage of the product, in order to verify compliance with the information declared in the applications for marketing

authorization and renewal of marketing authorization for smoke products and applications for the register of processed tobacco.

Article 38. During the marketing authorization inspections for compliance verification, or during fiscal inspection actions, the company must provide the full documentation related to the technical dossier, as required in the health regulations addressing the marketing authorization for smoke products and the register of processed tobacco, in force at the time the application was submitted.

Paragraph 1. The company must keep in file the raw data related to the results of tests supporting the analysis report.

Paragraph 2. The raw data related to the results of tests supporting the analysis report must be traceable.

Paragraph 3. During the marketing authorization inspections for compliance verification, or during fiscal inspection actions, Anvisa may request the analysis of reference samples retained for the conduction of any tests carried out by the company itself, in the presence of inspectors and at the company's own laboratory, and presented in the analytical report submitted in the marketing authorization dossier.

Article 39. The Brazilian manufacturing or import companies must keep in file, for a period of 10 (ten) years, the full data allowing to identify the whole distribution chain of the products, in case of health audits.

Article 40. The applications submitted in hard copies before 6 August 2018 shall be analyzed in accordance with Collegiate Board Resolution no. 90 of 27 December 2007, which was in force at the moment of submission.

Article 41. Anvisa may establish other forms of petitioning and submission, including in non-electronic format, according to administrative interests, including manual petitioning and physical submission of applications.

Article 42. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, pursuant to Law no. 6,437 of 20 August 1977, and the offender is subject to the penalties provided for therein and in other applicable regulations, without prejudice to the applicable civil, administrative, and criminal sanctions.

Article 43. The following are hereby revoked:

I – Collegiate Board Resolution no. 226 of 30 April 2018, published in the Federal Official Gazette no. 83 of 2 May 2018, Section 1, page 127; and

II – Collegiate Board Resolution no. 452 of 17 December 2020, published in the Federal Official Gazette no. 245 of 23 December 2020, Section 1, page 122.

Article 44. This Resolution enters into force on 1 October 2021.

ANTONIO BARRA TORRES
Director-President

ANNEX I

PARAMETERS AND COMPOUNDS PRESENT IN MAINSTREAM SMOKE, SIDESTREAM SMOKE, AND TOTAL TOBACCO

I – Parameters and Compounds Present in Mainstream Smoke[1]

Compounds	**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. Hydroquinone	ug/unit
14. Resorcinol	ug/unit
15. Catechol	ug/unit
16. Phenol	ug/unit
17. Metacresol	ug/unit
18. Paracresol	ug/unit
19. Orthocresol	ug/unit
20. Ammonia	ug/unit
21. Hydrocyanic acid	ug/unit
22. Pyridine	ug/unit
23. Quinoline	ug/unit
24. 1, 3-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-(methyl nitrosamine) 1- (3-pyrydil)-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. NOx	ug/unit
39. Eugenol	mg/unit
40. Ph	unit
41. Efficiency of the filter for	%

nicotine	
42. Mercury	ng/unit
43. Nickel	ng/unit
44. Lead	ng/unit
45. Selenium	ng/unit
46. Cadmium	ng/unit
47. Chromium	ng/unit
48. Arsenic	ng/unit
49. Menthol	ng/unit

[1] Compulsory filling for cigarettes.
[2] Compulsory filling for cigars and cigarillos from 1 July 2021.
[3] Laboratory analyses used to quantify compounds in cigarettes must follow ISO methodologies. For cigars and cigarillos, other internationally acknowledged methodologies may be used.

II – Compounds Present in Sidestream Smoke[1]

Compounds	**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
13. Hydroquinone	ug/unit
14. Resorcinol	ug/unit
15. Catechol	ug/unit
16. Phenol	ug/unit
17. Metacresol	ug/unit
18. Paracresol	ug/unit
19. Orthocresol	ug/unit
20. Ammonia	ug/unit
21. Hydrocyanic acid	ug/unit
22. Pyridine	ug/unit
23. Quinoline	ug/unit
24. 1, 3-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-(methyl nitrosamine) 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. NOx	ug/unit
39. Eugenol	mg/unit
40. Mercury	ng/unit
41. Nickel	ng/unit
42. Lead	ng/unit
43. Selenium	ng/unit
44. Cadmium	ng/unit
45. Chromium	ng/unit
46. Arsenic	ng/unit
47. Menthol	ng/unit

[1] Compulsory filling for cigarettes.
[2] Laboratory analyses used to quantify compounds must follow ISO methodologies.

III – Parameter and Compounds Present in Total Tobacco [1]

Compounds	**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
10. NNK: 4-(methyl nitrosamine) 1-(3- pyrydil)-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. Chromium	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. Tri-ethylene glycol	mg/g of tobacco
24. Nitrate	ug/g of tobacco
25. Triacetin	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
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-methylcoumarine[2]	ug/g of tobacco
46. 6,10-dimethyl-5,9-undecadien-2-one[2]	ug/g of tobacco
47. acetanisole[2]	ug/g of tobacco
48. benzyl acetate[2]	ug/g of tobacco
49. bornyl acetate[2]	ug/g of tobacco
50. ethyl acetate[2]	ug/g of tobacco
51. phenethyl acetate[2]	ug/g of tobacco
52. furfuryl acetate[2]	ug/g of tobacco
53. geranyl acetate[2]	ug/g of tobacco
54. hexyl acetate[2]	ug/g of tobacco
55. isoamyl acetate[2]	ug/g of tobacco
56. menthyl acetate[2]	ug/g of tobacco
57. neomenthyl acetate[2]	ug/g of tobacco
58. para-tolyl acetate[2]	ug/g of tobacco
59. trans-3-hexenyl acetate[2]	ug/g of tobacco
60. acetyl pyrazine[2]	ug/g of tobacco
61. acetophenone[2]	ug/g of tobacco
62. acetoin[2]	ug/g of tobacco
63. 2-methylbutyric acid[2]	ug/g of tobacco

64. 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. phenyl acetic acid[2]	ug/g of tobacco
70. glycyrrhizinic 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. alcohol c-6 (n-hexanol) [2]	ug/g of tobacco
80. cinnamic alcohol (steryl 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
83. para-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 butirate[2]	ug/g of tobacco
95. geranyl butirate[2]	ug/g of tobacco
96. caffeine[2]	ug/g of tobacco
97. carvone[2]	ug/g of tobacco
98. cinnamaldehyde[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. sclareolide[2]	ug/g of tobacco
107. methyl ester of trans-cinnamic acid[2]	ug/g of tobacco
108. ethyl maltol[2]	ug/g of tobacco

109. ethyl vanillin[2]	ug/g of tobacco
110. eucalyptol[2]	ug/g of tobacco
111. farnesol[2]	ug/g of tobacco
112. phenylacetaldehyde[2]	ug/g of tobacco
113. ethyl phenylacetate[2]	ug/g of tobacco
114. phenethyl phenylacetate[2]	ug/g of tobacco
115. isoamyl phenylacetate[2]	ug/g of tobacco
116. methyl phenylacetate[2]	ug/g of tobacco
117. benzyl formate[2]	ug/g of tobacco
118. cis-3-hexenyl formate[2]	ug/g of tobacco
119. geranyl formate [2]	ug/g of tobacco
120. isoamyl formate[2]	ug/g of tobacco
121. furfural[2]	ug/g of tobacco
122. gama-decalactone[2]	ug/g of tobacco
123. gama-dodecalactone[2]	ug/g of tobacco
124. gama-heptalactone[2]	ug/g of tobacco
125. gama-hexalactone[2]	ug/g of tobacco
126. gama-nonalactone[2]	ug/g of tobacco
127. gama-octalactone[2]	ug/g of tobacco
128. gama-undecalactone[2]	ug/g of tobacco
129. gama-valerolactone[2]	ug/g of tobacco
130. geraniol[2]	ug/g of tobacco
131. guaiacol[2]	ug/g of tobacco
132. ethyl heptanoate[2]	ug/g of tobacco
133. ethyl hexanoate[2]	ug/g of tobacco
134. isoamyl hexanoate[2]	ug/g of tobacco
135. hexen-2-al[2]	ug/g of tobacco
136. isobutyraldehyde[2]	ug/g of tobacco
137. isophorone[2]	ug/g of tobacco
138. ethyl isovalerate[2]	ug/g of tobacco
139. isoamyl isovalerate[2]	ug/g of tobacco
140. ethyl lactate[2]	ug/g of tobacco
141. l-carvone[2]	ug/g of tobacco
142. limonene[2]	ug/g of tobacco
143. linalol[2]	ug/g of tobacco
144. methyl linoleate[2]	ug/g of tobacco
145. maltol[2]	ug/g of tobacco
146. menthone[2]	ug/g of tobacco
147. methyl cyclopentenolone[2]	ug/g of tobacco
148. methyl vanillin[2]	ug/g of tobacco
149. nonanal[2]	ug/g of tobacco
150. ethyl nonanoate[2]	ug/g of tobacco
151. piperonal[2]	ug/g of tobacco
152. propenyl guaethol[2]	ug/g of tobacco
153. citronellyl propionate[2]	ug/g of tobacco
154. ethyl propionate[2]	ug/g of tobacco
155. geranyl propionate[2]	ug/g of tobacco
156. sacylaldehyde[2]	ug/g of tobacco
157. ethyl salicylate[2]	ug/g of tobacco

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

[1] Compulsory filling for all products.
[2] Compulsory filling for all products, from 1 July 2021.

ANNEX II

ELECTRONIC PETITIONING

I – Processed Tobacco Electronic Petitioning:

1. Origin of the Types of Processed Tobacco in the previous year:

Type of Tobacco;

Quantity of each type of tobacco;

Country, State, City.

II – Electronic Petitioning for Marketing Authorization and Marketing Authorization Renewal of Tobacco Products:

1. Product Characteristics:

Name of Product;

Type of Product;

Length (mm);

Circumference (mm);

2. Origin:

Brazilian Manufacture:

Data on the Processing Company (Name and Brazilian Registry of Legal Entities – CNPJ);

Imported Product:

Data on the International Manufacturing Company (Name and Address);

3. Destination:

Exclusively for commercialization in the Brazilian market;

Commercialization in the Brazilian and external market;

Exclusively for export;

4. Packages:

Types of Packages;

Quantity of product/ Package;

5. List of types of tobacco used in the product:

Types of tobacco;

Quantity of each type of tobacco;

Total quantity of tobacco used in the product;

6. List of additives used in the product:

Official nomenclature or common name of additive;

Category of additive;

CAS (Chemical Abstracts Service) number, when applicable;

Specific location of addition;

Quantity added;

7. Specifications of Filter and Wrappers:

Type of Filter;

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

Composition of Filtering Material: Substances, Quantities;

Physical Characteristics of the Filter Paper Wrapper:

Grammage (g/m^2);

Permeability ($cm^3 . min^{-1} . cm^{-2}$) at 1 kPa;

Weight (mg/cig);

Physical Characteristics of the Product Paper Wrapper:

Grammage (g/m^2);

Permeability ($cm^3 . min^{-1} . cm^{-2}$) at 1 kPa;

Weight (mg/cig);

8. Parameters and Compounds Present in Mainstream Smoke, in accordance with Annex I of this Resolution:

Mean Content, Standard Deviation, and Methodologies Used;

9. Compounds Present in Sidestream Smoke, in accordance with Annex I of this Resolution:

Mean Content, Standard Deviation, and Methodologies Used;

10. Parameter and Compounds Present in Total Tobacco, in accordance with Annex I of this Resolution:

Mean Content, Standard Deviation, and Methodologies Used;

11. Electronic Files of Packages.