

RESOLUTION RDC No. 90, OF 27 DECEMBER 2007(*)

Establishes regulations for the registration of cadastral data
pertaining to smoking products obtained from tobacco.

With the authority invested by Article 11, section IV, of the Regulation approved by Decree No. 3.029 of 16 April 1999, and bearing in mind the provisions of paragraph II and §§ 1 and 3 of Article 54 of the Internal Regulation (*Regimento Interno*) approved under the terms of Annex I of ANVISA Ruling No. 354 of 11 August 2006, republished in the DOU of 21 August 2006;

considering the terms of Law No. 9.782, of 26 January 1999, as amended by Provisional Measure No. 2190-34 of 23 August 2001, which provides regulations for the control and inspection of products and services involving public health hazards;

considering the terms of Article 8 paragraph X of Law No. 9.782 of 1999, as amended by MP No. 2190-34 of 2001;

considering the provisions of paragraph 4 of Article 8 of Law 9.782 of 1999, as amended by MP No. 2190-34 of 2001;

considering the terms of Law No. 9.782 of 1999, as amended by MP No. 2190-34, of 2001, with regard to the classification entitled "registration, revalidation or renewal of the registration of smoking products" referred to in Item 9.1 of Annex II;

considering the need to establish criteria for the cadastral registration of smoking products;

considering the health risks inherent in tobacco-derivative products and their specific characteristics, distinguishing them from other products that are subject to the health surveillance regime;

at a meeting held on 20 December 2007, the Collegiate Board of the National Health Surveillance Agency adopted the following regulation governing the established procedures, applicable to tobacco leaves and smoking products that are processed, manufactured, marketed and/or stored in national territory, or imported or exported; and I, the Chairman, hereby order its publication:

CHAPTER I

Initial Provisions

Article 1. This Resolution concerns the regulations and procedures to be observed when applying for the registration and renewal of registration of cadastral data pertaining to smoking products.

CHAPTER II

Definitions

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

I - Smoking product: Manufactured product, whether or not obtained from tobacco, which uses leaves or extracts thereof, or other parts of plants, in its composition, for the purpose of smoking, chewing, or inhaling;

II – Tobacco-derivative product: Any product manufactured for consumption purposes, to be smoked, inhaled or chewed, the composition of which includes tobacco leaves, even if only partly consisting of tobacco;

III - Product: Outcome of the processing of raw material into material of marketable economic value-added.

IV - Brand: Name given to a product, whether or not accompanied by other descriptive elements, which will be recognized by the consumer as a way of distinguishing the product from others of the same kind. Sub-brands will be considered as brands;

V - Registration of smoking products - Cadastral data: As provided for in Law 9.782/99 Annex II, this means approval of the application for registration of a smoking product brand, following an analysis of the documentation and cadastral data which must necessarily be sent to ANVISA;

VI - Renewal of the registration of smoking products - Cadastral data: As provided for in Law 9.782/99, the term renewal of registration shall mean the act of renewing the cadastral data of the smoking product brand, before its validity has expired, complying with the deadline specified in this Resolution;

VII - Processed tobacco: Raw material consisting of tobacco leaves that have undergone an enhancement process for the purpose of obtaining other tobacco-derivative products;

VIII - Processed tobacco cadastre: Electronic application submitted by the processing firm to register the types and quantity of tobacco processed in the immediately preceding year, for use as raw material to obtain tobacco-derivative products;

IX - Additive: Any substance or compound, other than tobacco or water, used in the processing, manufacturing and packaging of a smoking product;

X- Wrapper for tobacco-derivative products: Material that surrounds the tobacco rod to form the product cylinder;

XI - Filter wrapper: Paper that directly surrounds the filter;

XII - Tipping paper: Paper that surrounds the filter and extends to the cigarette cylinder; material that attaches the filter to the cigarette cylinder;

XIII- Filter: Placed at the end of the cigarette cylinder to retain some of the particulate material and nicotine that accompanies the smoke;

XIV - Primary smoke current: Also known as the main smoke current; the smoke that issues from the end of the cigarette and enters the mouth for inhalation by the smoker during the smoking process;

XV - Secondary smoke current: Also known as lateral smoke; any smoke emitted during the burning of a smokable product, apart from that which issues from the end of the cigarette and enters the mouth for inhalation by the smoker;

XVI - Analytical ruling: Technical report issued by the laboratory containing the results of physical and chemical analyses performed on smoking products;

XVII - Processing firm: The firm that undertakes an activity relating to any type of enhancement of the tobacco leaf used in smoking products;

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XVIII - Manufacturer: Firm that produces any tobacco-derivative product;

XIX - Tobacco blend: Mixture of tobacco types contained in the final composition of smoking products;

XX - Electronic application: Procedure completed by the interested party to file the cadastral data required by this regulation, submission of electronic documentation and printing of the Single Guideline for Collecting the Health Surveillance Inspection Duty, using the Electronic Application and Collection System, available on the ANVISA website;

XXI - Primary application: Request containing all documentation relating to the case, which will result in the opening of a process;

XXII - Secondary application: Request containing all documentation relating to the case, associated with the pre-existing primary process;

XXIII - Smoking Product Application Form: Standardized document made available through the Electronic Application System, containing spaces to electronically enter the cadastral data required by this regulation;

XXIV - Postal protocol: Administrative voucher verifying postal receipt of the documents required by this regulation;

XXV - Online protocol: Administrative voucher verifying electronic receipt of cadastral data completed and submitted to ANVISA via the Electronic Application and Collection System;

XXVI - Electronic address: The address of ANVISA on the Internet, which offers application and collection services, and publication of the Situation Listing of the Smoking Product Brands, established in this Resolution, identified as <http://www.anvisa.gov.br>;

CHAPTER III

Formulation of the application, implementation of the process and announcement of the Registration of the Tobacco-Derivative Smoking Product - Cadastral data

Article 3. Registration of cadastral data is obligatory for all smoking product brands obtained from tobacco made in national territory, or imported or exported.

Sole paragraph. The cadastral data and information contained in the applications do not generate a registration number, and any disclosure, publicity or promotion related to the ANVISA registration process is forbidden.

Article 4. National manufacturers and importers of smoking products obtained from tobacco must send the primary application for the registration of cadastral data to ANVISA for each brand to be marketed, imported or exported.

§ 1 The primary application for the registration of cadastral data must be made individually for each product brand, accompanied by the following documentation:

I - Original voucher verifying payment of the Health Surveillance Inspection Duty, generated via the Electronic Collection and Attendance System, available on the ANVISA website;

II - CD-ROM containing an electronic file of the packaging, presenting all faces available to the public, or a voucher verifying the submission of the packaging through the Electronic Application System;

III - An example of the packaging as for sale;

IV - Copy of the Executive Declarative Act (ADE) granting Special Registration for the manufacturer or importer, in the case of a cigarette-type product, issued by the Federal Revenue Secretariat of Brazil - SRF/MF under the terms of current regulations;

V - Copy of the Executive Declarative Act (ADE) for Tax Classification of the cigarette brand with the Federal Revenue Secretariat of Brazil - SRF/MF under the terms of current regulations;

VI - Original Analytical Ruling of the quantifications required in §2 of this article regarding the composition of the smoke and the tobacco blend;

VII - Original voucher verifying the transmission of data notified via the Electronic Application System.

§ 2 Data to be notified via the Electronic Application System for registration of the brand's cadastral data relate to:

I - Brand characteristics: brand name, product type, origin, destination and types of packaging;

II - List of tobacco types used;

III - List of additives used;

IV - Physical specifications of the filter and wrapping papers;

V - Parameters and compounds present in the primary smoke current, as per Annex I;

VI - Parameters and compounds present in the secondary smoke current, as per Annex I;

VII - Parameters and compounds present in the tobacco blend, as per Annex I;

§ 3 The analytical data referred to in paragraphs V, VI and VII must be obtained through laboratory analysis, for the specific brand to be registered.

§ 4 The laboratory analyses used to quantify the compounds must comply with internationally accepted methodologies, or those adopted under an international agreement or convention ratified and internalized by Brazil, pursuant to Annex I of this Resolution.

§ 5 Apart from quantifications, the laboratory analysis ruling should contain the name and address of the laboratory, name and signature of the person responsible for the analyses, indication of the methodologies used, the name of the brand analysed, and the date on which the analysis was completed.

§ 6 The laboratory analysis ruling will only be accepted for registration of cadastral data, if issued within six months before the date of application.

§ 7 The registration process will consider the brand name contained in the initial application; any alteration of the brand name applied for must be made through an application for Cancellation of Brand Registration, followed by an application to register the new brand.

Article 5. Any alteration to be made by the firm to the packaging presented in the registration of cadastral data must be submitted for analysis by ANVISA as an addendum.

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§ 1 The addendum to the application must be accompanied by an example of the packaging in which the product will be marketed;

§ 2 For the purpose of altering the packaging, the application referred to at the top of this article may be submitted by the firm at any time, but the packaging containing the alteration may only be marketed after the firm has been notified that the addendum has been approved.

Article 6. Upon completion of the analysis, and provided there is no requirement to be fulfilled, the application for Registration of Cadastral Data will be approved, and this will be announced in the Official Gazette (DOU) by publishing the specific brand, name of the firm and CNPJ; and the specific brand will be included in the Situation Listing of Smoking Product Brands, published on the ANVISA website.

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

Article 7. National manufacturers and importers of products obtained from tobacco should submit to ANVISA their request for Renewal of the Registration of Cadastral Data of Tobacco-Derivative Smoking Products annually, observing the deadlines indicated in this Resolution.

§ 1 An application for renewal of the registration of the brand's cadastral data must contain the following documentation:

I - Original voucher indicating payment of the Health Surveillance Inspection Charge, generated through the Electronic Attendance and Collection System which is available on the ANVISA website;

II - A CD-ROM containing an electronic file of the packaging, showing all faces available to the public, or a voucher verifying the submission of the packaging via the Electronic Application System;

III - An example of the packaging as for sale;

IV - A copy of the Executive Declarative Act (ADE) for Special Registration of the national manufacturer or importer, issued by the Federal Revenue Secretariat of Brazil - SRF/MF, in the case of cigarette-type products, under the terms of current regulations;

V - A copy of the Executive Declarative Act (ADE) for the Tax Classification of the cigarette brand, issued by the Federal Revenue Secretariat of Brazil - SRF/MF, under the terms of current regulations;

VI - Updated original Analytical Ruling of the quantifications required in Annex I of this regulation with regard to the composition of the smoke and tobacco blend.

VII - Original voucher verifying the transmission of data notified via the Electronic Application System.

§ 2 The data to be notified via the Electronic Application System to renew registration of the brand's cadastral data relate to:

I - Brand characteristics: brand name, product type, origin, destination and types of packaging;

II - List of the types of tobacco used and their origins;

III - List of additives used;

IV - Physical specifications of the filter and wrapping paper;

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V - Parameters and compounds present in the primary smoke current, as per Annex I;

VI - Parameters and compounds present in the secondary smoke current, as per Annex I;

VII - Parameters and compounds present in the tobacco blend, as per Annex I;

§ 3 The instructions contained in paragraphs 3, 4, 5 and 6 of Article 4 with regard to the analytical ruling must be observed.

§ 4 In the case of applications for the Renewal of Registration of Tobacco-Derivative Smoking Products - Cadastral data, the firm in question must have fulfilled all requirements in previous years for the specific brand.

Article 8. Upon conclusion of the analyses, and in the absence of any requirement that remains to be fulfilled, the application for Renewal of the Registration of Cadastral Data will be approved, and notification thereof will be made in the Official Gazette of the Union by publishing the specific brand, name of the firm and CNJP; and the specific brand will be maintained on the situation listing of smoking product brands, posted on the ANVISA website.

CHAPTER IV

Cadastre of Processed Tobacco

Article 9. Tobacco processing firms must register with ANVISA all tobacco processed in the previous year, and the information entered in the Electronic Application System must be renewed annually.

Article 10. A new entirely electronic application procedure has been instituted for the Cadastral Registration of Processed Tobacco and renewal thereof.

§ 1 Applications must be made through the Electronic Application System, and, on completion of the required data on the tobaccos processed, they should be officially submitted to ANVISA using the online Protocol available in the Electronic Collection and Attendance System, exclusively for the cadastral registration of processed tobacco and renewals thereof.

§ 2 The guidelines needed for the electronic procedure can be obtained on the ANVISA website.

CHAPTER V

Exceptions

Article 11. For the registration and renewal of cadastral data relating to brands of tobacco-derivative smoking products, other than cigarettes, the information indicated in the following paragraphs will not be required:

I - Specifications and physical characteristics of the filter and wrapping papers;

II - Parameter and compounds present in the primary smoke current;

III - Parameter and compounds present in the secondary smoke current;

Sole paragraph. For the products mentioned at the top of this article, the completion of fields relating to the Parameters and Compounds present in the Tobacco Blend is maintained, as per the list set out in Annex I of this Resolution.

Article 12. Tobacco-derivative products, whether or not smoking products, including cigarettes, produced in national territory exclusively for export, shall be exempted from providing the information indicated in Annex I of this Resolution.

CHAPTER VI

Deadlines

Article 13. Applications for the registration of cadastral data of tobacco-derivative smoking products maybe officially submitted to ANVISA at any time of the year.

§ 1 Applications for the aforementioned registration will be analysed within 90 days following official submission to ANVISA and, in the absence of any requirement remaining to be fulfilled by the firm, the analysis will be concluded and the application for registration approved.

§ 2 Commercialization of the brand may only begin after approval of the application for registration and publication in the DOU of the specific brand, name of the firm and CNJP, and its inclusion in the Situation Listing of Smoking Product Brands, posted on the ANVISA website.

Article 14. The Registration of Cadastral Data is valid for 12 months from the date of publication in the DOU of the resolution approving the initial registration request, and must be renewed annually.

§ 1 The application for Renewal of Registration of Cadastral Data must be filed annually by the firm within 90 days before the date of expiry of the registration.

§ 2 Should the application for the Renewal of Registration of Cadastral Data not be officially filed within the stipulated period, registration will be cancelled as expired, the corresponding resolution will be published in the DOU, and the brand will be removed from the Situation Listing of Smoking Product Brands, posted on the ANVISA website.

§ 3 Once registration has been cancelled, the firm must submit an application for a new Registration of Cadastral Data, pursuant to this Resolution for regularization purposes, even if no new brand is involved.

§ 4 The firm may cancel registration at any time, through a secondary application for Cancellation of Registration, which is available in the Electronic Application System.

CHAPTER VII

General provisions of the Protocol

Article 15. To gain access to the ANVISA Collection and Attendance System for application and official filing purposes, the electronic registration of the firm is mandatory under the terms of current Official Filing and Application Resolutions.

Sole paragraph. The guidelines for completing the electronic forms in the Electronic Application System are available on the ANVISA website.

Article 16. After the date of publication of this Resolution, documentation exclusively concerning processes or applications relating to smoking products must be filed with the Tobacco-Derivative

TE 080978i-TRA-OE

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Products Division (Gerência de Produtos Derivados do Tabaco - GPDTA) or with the Protocol Sector (UNIAP) at ANVISA headquarters in Brasília.

§ 1 Official filing with the GPDTA can only be done by post, at the following address:

Agência Nacional de Vigilância Sanitária Gerência de Produtos Derivados do Tabaco – GPDTA Caixa Postal: 21015 - Rio de Janeiro – RJ.

§ 2 Any document intended to fulfil a technical and/or administrative requirement to be attached to the process or application, will only be analysed after its official filing in GPDTARJ or in the Protocol Sector (UNIAP) at ANVISA headquarters in Brasília.

§ 3 Documentation may not be sent directly to the ANVISA server.

§ 4 To speed up the analysis, the application should contain the required documents, ordered by paragraphs, with separators of different colour or weight and sequentially numbered pages.

Article 17. An application filed without the voucher proving payment of the Health Surveillance Inspection Duty, relating to the subject of the application, or with a transaction number that has already been used in another application, will be immediately rejected by the sector that filed the application.

Article 18. Applications that have been submitted without the documentation required by this Resolution will be sent to the technical area on a provisional basis, provided they have presented proof of payment of the Health Inspection Duty, pursuant to the current resolution governing the documentary analysis of filed applications.

§ 1 An application that has been filed on a provisional basis must be complemented with the missing documentation, through the Electronic Application Service available on the ANVISA website, before the technical analysis is concluded.

§ 2 The technical area will formulate Technical Requirements when necessary, to request information or clarifications on the documentation accompanying filed applications.

§ 3 Insufficiency of the documentation required at the time of official filing, and unsatisfactory conclusion of the technical analysis shall result in the application being rejected.

Approval

Article 19. The request for Registration of Cadastral Data, or renewal thereof, will be approved for smoking product brands that satisfy the requirements of this Resolution; and this will be notified in the DOU by publishing the specific brands, name of the firm and CNJP, as well as the inclusion of these specific brands on the Situation Listing of Smoking Product Brands posted on the ANVISA website.

Article 20. The specific brand may only be marketed after publication of approval of the application for the Registration of Cadastral Data in the Official Gazette of the Union.

§ 1 The importation, exportation and commercialization in national territory of any smoking product brand that is not duly regularized, pursuant to this Resolution, is prohibited, even if the brand is intended for research.

§ 2 Commercialization in the Brazilian domestic market of smoking product brands registered exclusively for export is prohibited.

Article 21. The use of any number generated in the Application for Registration of Cadastral Data, other than in strict pursuit of the process with ANVISA, is prohibited.

Provisional suspension

Article 22. An application for the registration of cadastral data or renewal of the cigarette brand will only be approved by ANVISA, if the brand is up-to-date with its obligations to the Federal Revenue Secretariat of Brazil - SRF/MF.

§ 1 Cancellation of Special Registration for the national manufacturer or importer of cigarettes, provided through the Executive Declaratory Act issued by the Federal Revenue Secretariat of Brazil - SRF/MF, shall result in the provisional suspension of all of the firm's brands, through notification in the Official Gazette of the Union, its removal from the ANVISA website and a ban on commercialization of the specific brands.

§ 2 The situation of brands subject to provisional suspension will be regularized on the ANVISA website following presentation of a copy of the Executive Declaratory Act (ADE), issued by the Federal Revenue Secretariat of Brazil - SRF/MF, re-establishing the Special Registration for the national cigarette manufacturer or importer.

§ 3 The name of the cigarette brand shown on the application for registration or renewal must be the same as shown on the Executive Declaratory Act (ADE) for Tax Classification of the cigarette brand at the Federal Revenue Secretariat of Brazil - SRF/MF.

§ 4 Cancellation of the Tax Classification of the cigarette brand by the Federal Revenue Secretariat shall result in provisional suspension of the brand through publication in the Official Gazette of the Union, its removal from the ANVISA website, and a ban on its sale.

Rejection

Article 23. An application for Registration of Cadastral Data or renewal thereof shall be rejected when:

I – The application does not comply with the requirements set out in this Resolution;

II - It does not satisfy technical requirements.

§ 1 Notification of the rejection of the application will be made by publishing the corresponding resolution in the Official Gazette of the Union.

§ 2 Rejection of an application for Registration of Cadastral Data or renewal thereof, can be appealed before the authority that made the decision, in which the regulated agent must observe the procedures adopted by ANVISA in current legislation.

Cancellation

Article 24. The registration of cadastral data will be cancelled when:

I - Renewal was not applied for within the deadline established by this regulation;

II - The application for Renewal of Registration has been rejected;

III - At the request of the firm, through the electronic application for Cancellation of Registration;

Sole paragraph. The brand for which cadastral data registration is cancelled must be withdrawn by the manufacturer or importer from all commercial outlets and sales points within 30 days following the date of cancellation.

Chapter VIII

Final and Transitory Provisions

Article 25. Within 12 months following the date of publication of this Resolution, the analyses contained in Annex I and indicated as optional will not be required for cigarettes.

Sole paragraph. On expiry of the deadline stipulated at the top of this article, all analyses contained in Annex I of this Resolution will be required.

Article 26. Within 12 months following the date of publication of this Resolution, for smoking products other than cigarettes, the analyses contained in Annex I and indicated as optional, in relation to the listing of Parameter and Compounds present in the Tobacco Blend, will not be required.

Sole paragraph. On expiry of the deadline stipulated at the top of this article, all analyses contained in the listing of Parameters and Compounds present in the tobacco blend as published in Annex I of this Resolution, will be required.

Article 27. For registrations of cadastral data obtained during the period of validity of RDC 346 of 2 December 2003, which were published on the ANVISA website in the first half of 2007, and for registrations renewed in 2007, the deadline for renewal is 31 March 2008, and the same date will be used as a deadline for successive renewals.

Article 28. For registrations of cadastral data obtained during the period of validity of RDC 346, of 2 December 2003, which were published on the ANVISA website in the second half of 2007, the deadline for renewal is 31 March 2009, and the same date will be used as a deadline for successive renewals.

Article 29. Failure to comply with the terms this Resolution constitutes a violation of health regulations, for which the offender will be liable to the penalties set out in Law No. 6.437 of 20 August 1977, and other applicable provisions.

Article 30. In the case of doubts or events that lead to complementary assessments, ANVISA may, at its discretion, require additional information relating to the documents and data reported on the application for the Registration or Renewal of Registration of Cadastral Data.

Article 31. The National Health Surveillance Agency (ANVISA) may publish regulatory instructions governing situations that are not foreseen in this Resolution.

Article 32. Resolution RDC No. 346 of 2 December 2003 is hereby repealed.

Article 32. (sic) This Resolution shall enter into force on the date of its publication.

DIRCEU RAPOSO DE MELLO

ANNEX I

I - Parameter and Compounds present in the Primary Smoke Current

Compounds - Unit

1. Tar¹ mg/cig
2. Nicotine¹ mg/cig
3. Carbon monoxide¹ mg/cig
4. Benzo [a] pyrene ng/cig
5. Formaldehyde µg/cig
6. Acetaldehyde µg/cig
7. Acetone µg/cig
8. Acrolein µg/cig
9. Propionaldehyde µg/cig
10. Crotonaldehyde µg/cig
11. Ethyl methyl acetone µg/cig
12. Butanaldehyde µg/cig
13. Hydroquinone µg/cig
14. Resorcinol µg/cig
15. Cathecol µg/cig
16. Phenol µg/cig
17. *meta*-Cresol µg/cig
18. *para*-Cresol µg/cig
19. *ortho*-Cresol µg/cig
20. Ammonia µg/cig
21. Hydro cyanic acid µg/cig
22. Pyridine µg/cig
23. Quinoline µg/cig

TE 080978i-TRA-OE
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- 24. 1, 3-butadiene µg/cig
- 25. Isoprene µg/cig
- 26. Acrylonitril µg/cig
- 27. Benzene µg/cig
- 28. Toluene µg/cig
- 29. Styrene µg/cig
- 30. NNN: *N'*-nitrosonornicotine ng/cig
- 31. NAT: *N'*-nitrosoanatabine ng/cig
- 32. NAB: *N'*-nitrosoanabasine ng/cig
- 33. NNK : 4-(methylnitrosoamino) 1- (3-pyridyl)-1-butanone ng/cig
- 34. 3-aminobiphenyl ng/cig
- 35. 4-aminobiphenyl ng/cig
- 36. 1-aminonaphthalene ng/cig
- 37. 2-aminophthalene ng/cig
- 38. NO_x µg/cig
- 39. Eugenol² mg/cig
- 40. pH -
- 41. Efficiency of the nicotine filter %
- 42. Mercury³ ng/cig
- 43. Nickel³ ng/cig
- 16
- 44. Lead³ ng/cig
- 45. Selenium³ ng/cig
- 46. Cadmium³ ng/cig
- 47. Chromium³ ng/cig
- 48. Arsenic³ ng/cig

49. Menthol^{2 3} mg/cig

¹ The laboratory analyses used to quantify the compounds should adhere to ISO methodologies.

² Mandatory notification if applicable.

³ These compounds are of optional notification in the first year of application of this Resolution only.

II. Parameter and Compounds present in the Secondary Smoke Current

Compounds - Unit

1. Tar¹ mg/cig
2. Nicotine¹ mg/cig
3. Carbon monoxide¹ mg/cig
4. Benzo[a]pyrene ng/cig
5. Formaldehyde µg/cig
6. Acetaldehyde µg/cig
7. Acetone µg/cig
8. Acrolein µg/cig
9. Propionaldehyde µg/cig
10. Crotonaldehyde µg/cig
11. Ethyl methyl acetone µg/cig
12. Butanaldehyde µg/cig
13. Hydroquinone µg/cig
14. Resorcinol µg/cig
15. Cathecol µg/cig
16. Phenol µg/cig
17. *meta*-Cresol µg/cig
18. *para*-Cresol µg/cig
19. *ortho*-Cresol µg/cig

TE 080978i-TRA-OE
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20. Ammonia $\mu\text{g/cig}$
21. Hydro cyanic acid $\mu\text{g/cig}$
22. Pyridine $\mu\text{g/cig}$
23. Quinoline $\mu\text{g/cig}$
24. 1, 3-butadiene $\mu\text{g/cig}$
25. Isoprene $\mu\text{g/cig}$
26. Acrylonitril $\mu\text{g/cig}$
27. Benzene $\mu\text{g/cig}$
28. Toluene $\mu\text{g/cig}$
29. Styrene $\mu\text{g/cig}$
30. NNN: *N'*-nitrosonornicotine ng/cig
31. NAT: *N'*-nitrosoanatabine ng/cig
32. NAB: *N'*-nitrosoanabasine ng/cig
33. NNK: 4-(methylnitrosoamino) 1- (3-pyridyl)-1-butanone ng/cig
34. 3-aminobiphenyl ng/cig
35. 4-aminobiphenyl ng/cig
36. 1-aminonaphthalene ng/cig
37. 2-aminophthalene ng/cig
38. NO_x $\mu\text{g/cig}$
39. Eugenol² mg/cig
40. pH -
41. Efficiency of the nicotine filter %
42. Mercury³ ng/cig
43. Nickel³ ng/cig
44. Lead³ ng/cig
45. Selenium³ ng/cig

TE 080978i-TRA-OE
Translated from Portuguese

46. Cadmium³ ng/cig

47. Chromium³ ng/cig

48. Arsenic³ ng/cig

¹The laboratory analyses used to quantify the compounds should adhere to ISO methodologies.

² Mandatory notification if applicable.

³ These compounds are of optional notification in the first year of application of this Resolution only.

III - Parameter and Compounds present in the Tobacco Blend

Compounds - Unit

1. Ammonia µg/g of tobacco

2. Nicotine¹ µg/g of tobacco

3. Nornicotine µg/g of tobacco

4. Myosmine µg/g of tobacco

5. Anabasine µg/g of tobacco

6. Anatabine³ µg/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-(metilnitrosoamino) 1- (3-piridil)-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

TE 080978i-TRA-OE
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- 18. Eugenol² mg/g of tobacco
- 19. pH -
- 20. Benzo[a]pyrene³ ng/g of tobacco
- 21. Glycerol³ mg/g of tobacco
- 22. Propylene Glycol³ mg/g of tobacco
- 23. Triethylene Glycol³ mg/g of tobacco
- 24. Nitrate³ µg/g of tobacco
- 25. Triacetine³ µg/g of tobacco
- 26. Sodium Propionate³ µg/g of tobacco
- 27. Sorbic Acid³ µg/g of tobacco
- 28. Menthol^{2 3} mg/g of tobacco

¹The laboratory analyses used to quantify the compounds should adhere to ISO methodologies.

² Mandatory notification if applicable.

³ These compounds are of optional notification only in the first year of application of this Resolution.

ANNEX II

Cadastral Data contained in the Electronic Application System

I - Electronic Application - Tobacco Processing Firm - Cadastral Data:

1. Origin of the Types of Tobacco Processed during the Previous year: Type of Tobacco, Quantity, Country, State, City;

II - Electronic Application System - Product Registration and Renewal thereof

Tobacco-derivative Smoking Product - Cadastral Data:

1. Brand Characteristics:

. Brand Name

. Product type: cigarette with filter, cigarette without filter, kretek cigarette, cigar, cheroot, bidis, smoking product for a pipe or narguilé, rolled cigarette, chewing tobacco, straw cigarette, snuff;

. Length (mm)

. Diameter (mm)

2. Origin:

. National manufacture

. Imported

3. Destination:

. For domestic sale only

. For sale on the domestic and foreign markets;

4. Packaging:

. Types of packaging: pack, carton, tin, case, box;

. Quantity of product/packaging

5. List of tobacco types used in the product:

. Types of tobacco, total amount of tobacco used in the product;

6. List of additives used in the product:

. Names of additives

. Additive categories: sugar, adhesive, glutinous agent, combustion agent, enhancement, process auxiliary, flavouring, fungicide, preservative agent, ink and humidifier;

. Application sites: in the tobacco mixture, in the wrapping paper, in the filter, in the filter paper, in the tipping paper, in the packaging;

. Maximum quantity of additive use;

7. Specifications of filter and wrapping papers:

. Type of filter:

. Filter characteristics: total ventilation (0-100%), pressure drop with open perforations (mmH₂O), pressure drop with closed perforations (mmH₂O);

. Composition of filter material: substances, quantities;

. Physical characteristics of the filter wrapping paper: density (g/m²), permeability (cm³.(min⁻¹. cm⁻²) to 1 kPa) and weight (mg/cig);

. Physical characteristics of the tipping paper: density (g/m²), permeability (cm³.(min⁻¹. cm⁻²) to 1 kPa) and weight (mg/cig);

. Physical characteristics of the product wrapping paper: density (g/m²), permeability (cm³.(min⁻¹. cm⁻²) to 1 kPa) and weight (mg/cig);

8. Parameter and Compounds present in the Primary Smoke Current:

Average content, standard deviation and methodologies used;

9. Parameter and Compounds present in the Secondary Smoke Current:

Average content, standard deviation and methodologies used;

10. Parameter and Compounds present in the Tobacco Blend:

Average content, standard deviation and methodologies used;

11. Attach electronic file of packaging notified;

III - Electronic Application System - Product Registration and Renewal thereof

Tobacco-Derivative Smoking Product exclusively for Export - Cadastral Data

1. Brand Characteristics:

. Brand Name

. Product Type: cigarette with filter, cigarette without filter, kretek cigarette, cigar, cheroot, bidis, smoking product for a pipe or narguilé, rolled cigarette, chewing tobacco, straw cigarette, snuff;

. Length (mm)

. Diameter (mm)

2. Origin:

. National manufacture

3. Destination:

. For export only;

4. Packaging:

. Types of packaging: Pack, carton, tin, bag, box;

. Quantity of product/packaging

5. List of tobacco types used in the product:

. Types of tobacco, total quantity of tobacco used in the product;

6. List of additives used in the product:

. Names of additives

. Additive categories: sugar, adhesive, glutinous agent, combustion agent, enhancement, process auxiliary, flavouring, fungicide, preservative agent, ink and humidifier;

. Sites of application: in the tobacco mixture, in the wrapping paper, in the filter, in the filter paper, in the tipping paper, in the packaging;

. Maximum quantity of additive use;

7. Specifications of Filter and Wrapping Papers:

. Type of filter:

. Filter characteristics: Total ventilation (0-100%),

Pressure drop with open perforations (mmH₂O), pressure drop with closed perforations (mmH₂O);

. Composition of filter material: substances, quantities;

. Physical characteristics of the filter wrapping paper: density (g/m²), permeability (cm³.(min-1. cm-2) to 1 kPa) and weight (mg/cig);

TE 080978i-TRA-OE

Translated from Portuguese

. Physical characteristics of the tipping paper: density (g/m^2), permeability ($\text{cm}^3 \cdot (\text{min}^{-1} \cdot \text{cm}^{-2})$ to 1 kPa) and weight (mg/cig);

. Physical characteristics of the product wrapping paper: density (g/m^2), permeability ($\text{cm}^3 \cdot (\text{min}^{-1} \cdot \text{cm}^{-2})$ to 1 kPa) and weight (mg/cig);

8. Attach electronic file of packaging notified;

(*) Republished having been published with errors in the Official Gazette of the Union No. 249 of 28 December 2007, Section 1, page 115.