

Ministério da Saúde Destaques do governo

National Health Surveillance Agency

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 **Tobacco Products**

Resolution - RDC nº 335, dated 21 November 2003
Federal Official Gazette D.O.U. dated of 11/24/2003

Revokes RDC nº 104 date 31 May 2001 and RDC nº 14 dated 17 January 2003.

The Collegiate Board of Directors of the National Sanitary Surveillance Agency, in the use of the attributions vested in it under Article 11, item IV, of the ANVISA Regulation approved by Decree nº 3.029 dated 16 April 1999 c/w Article 111, item I, letter "b", § 1 of the Internal Regulation approved by Presidential Decree nº 593, dated 25 August 2000, republished on 22 December 2000, in meeting held on 19 November 2003,

WHEREAS

Law nº 9782 dated 26 January 1999, that determines the regulation, monitoring and inspection of products and services that involve a risk to public health;

Law nº 9294 dated 15 July 1996;

Federal Law nº 10167 dated 27 December 2000;

Resolution - RDC nº 46 dated 28 March 2001;

Provisional Measure nº 2134-30 dated 24 May 2001;

Law nº 10702 dated 14 July 2003;

the significant increase of tobacco smoking that caused the loss of at least 3.5 million lives throughout the world in 1998, with an estimated loss of 10 million lives per year by 2030, 70% of which in developing countries,

the images that illustrate the warning messages need to be periodically updated,

has adopted the following Resolution, applicable to all smoking tobacco-derived products and marketed in the Brazilian territory, whether produced locally or imported, and to their publicity materials, and I, the Substitute Chairman, determine its publication:

Article 1. All smoking tobacco-derived products, shall display on their packaging and in all the associated publicity, a warning to consumers about the harmful effects that can result from the use of these products.

Paragraph 1 - Packaging shall be understood to mean packs, whether soft or cardboard, packets, tins, boxes and any other packing device used to present the products to the final consumer.

Paragraph 2 - Publicity shall be understood to mean, posters, advertising panels and signs posted inside sales areas.

Article 2. For smoking tobacco-derived products, the warnings below shall be displayed simultaneously or sequentially, and in the last case they shall be changed every five months at most. The warnings shall be legible, prominently displayed and include images, always preceded by the words "O Ministério da Saúde Adverte" [The Ministry of Health Warns]:

1. Esta necrose foi causada pelo consume do tabaco [This necrosis was caused by tobacco consumption];
2. Fumar causa impotência sexual [Smoking causes sexual impotence];
3. Crianças que convivem com fumantes têm mais asma, pneumonia, sinusite e alergia [Children in live in close contact with smokers have more asthma, pneumonia, sinusitis and allergy];
4. Ele é uma vítima do tabaco. Fumar causa doença vascular e pode levar a amputação [He is a victim of tobacco. Smoking causes vascular disease that may lead to amputation]
5. Fumar causa aborto espontâneo [Smoking causes spontaneous abortion];
6. Ao fumar você inala arsênico e naftalina, também usados contra ratos e baratas [When smoking, you inhale arsenic and naphthalene, also used against rats and cockroaches];
7. Fumar causa câncer de laringe [Smoking causes cancer in the larynge];
8. Fumar causa câncer de boca e perda dos dentes [Smoking causes mouth cancer and loss of teeth];
9. Fumar causa câncer de pulmão [Smoking causes lung cancer];
10. Em gestantes, fumar provoca partos prematuros e o nascimento de crianças com peso abaixo do normal [Smoking during pregnancy causes premature births and the birth of babies with low birth weight];

The packaging

Article 3. Concerning the packaging of cigarettes, in what are normally called "packs" or "box" in their different sizes, the new standard images provided in the ANVISA website, including warnings, images, logo and Stop Smoking Dial Number, must be printed on the part of the packaging most easily visible to the consumer, without changing the proportion among the elements nor the graphics parameters.

Paragraph 1 - Concerning any type of packaging of tobacco-derived smoking products that is the same size as those referred to in the caput of this Article, the standard images, shall be printed on the side most easily visible to the consumer, without changing the proportion among the elements nor the graphics parameters.

Paragraph 2 - Concerning any type of packaging of tobacco-derived smoking products that is smaller than those referred to in the caput of this Article, the standard images, shall be printed on the side most easily visible to the consumer and it is the responsibility of the manufacturing company or importer of the product to proportionally reduce the standard image, without changing its graphic characteristics so that it fits in the front of the packaging.

Paragraph 3 - Concerning other packaging of tobacco-derived smoking products that are larger than those referred to in the caput of this Article, the standard images, shall

be printed on the lower right of the part most easily visible to the consumer, without changing the proportion among the elements and keeping its size.

Paragraph 4 - The warning included in the standard image made available by the National Sanitary Surveillance Agency, shall be printed in white letters in on a 100% black rectangular background. Companies that do not have access to the traditional polychrome technique may use dark gray instead of 100% black, according to the Pantone™ Scale 419 CV or any other composition which reproduces the black color, in order to preserve the visual warning characteristics.

Article 4. The use of any other type of wrapping or device that makes the visualization of the standard image impossible or difficult or of resources such as cards or stickers that may be used by the consumer to cover the image on the packs of the products mentioned in this Resolution is hereby forbidden.

Sole paragraph. The control stamp of the Federal Revenue Agency shall not be placed over the standard image, nor may there be a reduction or change of the graphics parameters of the standard images to adapt the stamp to the largest side.

Article 5. The printing of the standard image on the pack may be replaced by a sticker whenever the pack is made of a material which does not allow or hinders its printing.

Paragraph 1 - The sticker shall comply with the standard image made available by the National Sanitary Surveillance Agency maintaining the graphic characteristics and shall not be applied to the external part of the packaging.

Paragraph 2 - The provisions in this Article apply to imported cigarettes and to all other smoking tobacco-derived products.

Paragraph 3 - The provisions in this Article do not apply to cigarettes manufactured or packaged in Brazil.

Article 6. Article 3 of Resolution RDC nº 46 dated 28 March 2001 of the Collegiate Board of Directors shall enter into force with the following changes:

“Article 3. The printing of the levels of tar, nicotine and carbon monoxide on the mainstream on cigarette packs shall be optional.

Paragraph 1 - The text referred to in the caput of this Article shall indicate in full length and legible type the levels, expressed in milligrams per cigarette, up to one decimal place for nicotine, and in whole numbers for tar and carbon monoxide anywhere on the pack save for the area reserved for the warning information on the side or for the standard image

Paragraph 2 - Packaging shall be understood to mean packs, whether soft or cardboard, packets and any other packing device for products destined for the final consumer market.

Paragraph 3 - (Revoked).

Paragraph 4 - (Revoked).

Article 7. The printing on the packs of the levels of tar, nicotine and carbon monoxide present in the mainstream smoke is optional, as long as it is displayed in an area other than that reserved for the additional phrase mentioned in the caput of Article 5 or for the standard image, and complies with the following requirements:

I – They shall be expressed in milligrams per cigarette, up to one decimal place for nicotine and in whole numbers for tar and carbon monoxide;

II – They shall be printed in standard Arial font, body 7, in a color that contrasts with the background;

III – None of the levels may be printed on the pack in isolation, i.e., without the levels of the other substances;

IV – They shall not be used in association to the brand name of the product, or as a way to identify the brand, thus creating a false impression that one brand is less harmful to health than another.

V – They shall not be used for the promotion of the product, leading to erroneous conclusions as to their characteristics, composition and risk to health.

Article 8. The following phrase shall be printed along $\frac{3}{4}$ of the length of cigarette packs, and occupying the width of the whole of one of the sides of the pack, using white letters on a 100% black rectangular background:

" Este produto contem mais de 4.700 substâncias tóxicas, e nicotina causa dependência física ou psíquica. Não existem níveis seguros para consumo destas substâncias." [This product contains more than 4,700 toxic substances and nicotine which causes physical or psychic dependence. No safe levels exist for the consumption of these substances].

Paragraph 1 - Companies that do not have access to the traditional polychrome technique may use dark gray instead of 100% black, according to the Pantone™ Scale 419 CV or any other composition which reproduces the black color, in order to preserve the visual warning characteristics.

Paragraph 2 - Besides the additional phrase that constitutes a sanitary warning, no other information may be printed in the area mentioned in the caput of this Article.

Article 9. The following phrase shall be printed along $\frac{1}{4}$ of the length of one of the sides of all tobacco-derived smoking products in a contrasting and easily legible type: "Venda proibida a menores de 18 anos – Lei 8069/1990 e Lei 10.702/2003" [Sale forbidden to minors under 18 – Law 8069/1990 and Law 10702/2003]; the use of phrases such as "somente para adultos" [for adults only], "produto para maiores de 18 anos"[product for people over 18 years of age] is forbidden.

Sole paragraph. Save for cigarettes, another side that is visible to the consumer may be used in tobacco-derived smoking products in order to better adapt the printing. The publicity

Article 10. The commercial publicity of tobacco-derived products that takes place through posters, panels and signs displayed in the interior of sales points shall contain the standard image made available at the ANVISA website. This shall be printed without any change to its graphic characteristics, and shall occupy an area of 10% of the total publicity material in order to ensure its visibility.

Paragraph 1 - The following additional phrase shall be included in the publicity mentioned in the caput of this Article: "This product contains more than 4,700 toxic substances and nicotine which causes physical or psychic dependence. No safe levels exist for the use of these substances." using white letters printed on a black rectangular background, with an internal white strip as a frame, using Arial Bold font, complying with the following minimum dimensions:

0 to 250cm², body 20
251 to 500 cm², body 24
501 to 1000 cm², body 26
1001 to 1500 cm², body 30
1501 to 2000 cm², body 36
2001 to 3000 cm², body 40
3001 to 4000 cm², body 48

4001 to 5000 cm², body 52

Paragraph 2 - The printing of the levels of tar, nicotine and carbon monoxide on the advertising materials of cigarettes is optional, but when used shall comply with the following requirements:

I - They shall be expressed in milligrams per cigarette, up to one decimal place for nicotine, and in whole numbers for tar and carbon monoxide;

II – None of the levels may be printed on the pack in isolation, i.e., without the levels of other substances;

III– They shall not be used in association to the brand name of the product, or as a way to identify a brand, thus creating a false impression that one brand is less harmful to health than another.

IV – They shall not be used for the promotion of the product, leading to erroneous conclusions as to their characteristics, composition and risk to health.

Deadlines for Compliance

Article 11. A period of 9 months counting from the publication date of this Resolution is hereby established for the manufacturing companies and importers to make available to the retail market packs of tobacco-derived products and publicity materials that comply with this Resolution. Once this deadline has expired, only the packs that comply with the present Resolution may be made available for retail.

Paragraph 1 - Products manufactured or imported prior to the period established in the caput of this Article and which do not comply with the provisions of this Resolution, i.e., that comply with Resolution RDC n^o 104 dated 31 May 2001, may be marketed up to 18 months after the publication of the present Resolution.

Paragraph 2 - The above-mentioned deadlines shall apply to every product derived from smoking tobacco, without exception, including cigars, mini cigars, Bali cigarettes, kretek cigarettes, and others.

Article 12. Resolution RDC n^o 104 dated 31 May 2001 and RDC n^o 14 dated 17 January 2003 and their republications by the Collegiate Board of Directors are hereby revoked.

Sole paragraph. Notwithstanding the revocation of Resolution RDC n^o 104 dated 31 May 2001, its determinations shall be complied with when manufacturing packaging and publicity materials manufactured or imported before the end of the deadline established in the caput of the previous Article, if the Company has not yet started to manufacture them according to the new rules of this resolution.

Article 13. . Failure to comply with the provisions set forth in this Resolution constitutes a sanitary infraction, rendering the offenders liable to the penalties established in Law n^o 6437 dated 20 August 1977 and other regulations.

Article 14. This Resolution of the Collegiate Board of Directors enters into force on the date of its publication.

CLAUDIO MAIEROVITCH PESSANHA HENRIQUES