

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA
COLLEGIATE DIRECTORATE

RESOLUTION - RDC Nº 14, OF MARCH 15, 2012

Establishes maximum levels of tar, nicotine and carbon monoxide in cigarettes and restrictions on the use of additives in all tobacco products, and gives other provisions.

The Collegiate Directorate of the *Agência Nacional de Vigilância Sanitária* [ANVISA – National Health Surveillance Agency], in the exercise of the authority conferred upon it by sub-paragraph IV of Art. 11 of the Regulation approved by Decree n. 3.029, of April 16, 1999, and taking into consideration the established in sub-paragraph II and in §§ 1 and 3 of Art. 54 of the Internal Regimen approved pursuant to the terms of Annex I of Administrative Ruling n. 354 of Anvisa, dated August 11, 2006, republished in the DOU of August 21, 2006, at a meeting held on March 13, 2012,

adopts the following Resolution of the Collegiate Directorate and I, Director-President, order its publication:

Art. 1 The maximum levels for tar, nicotine and carbon monoxide in the primary stream of cigarette smoke are established, as well as restrictions on the use of additives in all tobacco products sold in Brazil, pursuant to the terms of this Resolution.

CHAPTER I
INITIAL PROVISIONS

Section I

Scope

Art. 2 This Resolution applies to all tobacco products sold in Brazil, whether made in Brazil or imported.

Section II

Definitions

Art. 3 For the purposes of this Resolution, the following definitions shall apply:

I - additive: any substance or compound that is not tobacco or water, used in the processing of tobacco leaf and reconstituted tobacco, in the manufacture and packaging of a tobacco product, including sugars, sweeteners, flavoring agents and (ameliorants);

II - sugars: monosaccharides and disaccharides, including the sucrose obtained from raw sugarcane juice (garapa; *Saccharum officinarum L.*) or from beets (*Beta alba L.*), and may present itself in different granulometries and appearances;

III - sweetener: product comprised of artificial sweetener(s), that may contain other ingredient (s), that give a sweet taste to a tobacco derivative smoking product;

IV – ameliorants: a substance that reduces irritating aspects of the smoke of tobacco products;

V – flavoring agents: a natural or synthetic substance or mixture of substances that imparts, modifies, enhances or intensifies the flavor of tobacco products;

VI - primary stream: smoke that comes out of the tip of a smoking product that goes into the mouthpiece and is breathed in by the smoker during the process of smoking, also referred to as the firsthand smoke;

VII – sweetener: a substance other than sugars that imparts a sweet taste to a tobacco product;

VIII - packaging: wrapping, container or any kind of packaging intended to contain tobacco products;

IX - flavor: a natural or synthetic substance or mixture of substances that imparts, modifies, improves or intensifies the taste and aroma of tobacco derivative smoking products;

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

XI – tobacco product: any product that is manufactured or derived from tobacco, containing in its composition tobacco leaf, even if it is only partially composed of tobacco.

CHAPTER II

MAXIMUM LEVELS OF TAR, NICOTINE AND CARBON MONOXIDE IN CIGARETTES

Art. 4 In cigarettes sold in in Brazil, the maximum levels for tar, nicotine and carbon monoxide permitted in the primary stream of the smoke are as follows:

I - tar: 10 mg/cigarette (ten milligrams per cigarette);

II - nicotine: 1 mg/cigarette (one milligram per cigarette); and

III - carbon monoxide: 10 mg/cigarette (ten milligrams per cigarette).

§ 1 The maximum levels established in the *caput* refer to the average content determined by quantitative laboratory analysis, with the addition of the respective analytic standard deviation.

§ 2 In the quantification of content, any analytical methodology that is internationally accepted is to be used, or else those adopted by law, agreement or international convention ratified and internalized by Brazil.

CHAPTER III

CLAIMS ON PACKAGES

Art. 5 It is prohibited to use any descriptor on any package of tobacco products that might induce consumers to make a mistaken interpretation regarding the content levels contained in these products, such as: class(es), ultra-low content, low content levels, smooth, light, soft, mild, moderate content levels or high content levels, among others.

CHAPTER IV

ADDITIVES

Art. 6 It is prohibited to import or sell in Brazil tobacco products that contain any of the following additives:

I – synthetic and natural substances in any form (pure substances, extracts, oils, distillates, balms, among others), with flavoring properties that can impart, intensify, modify or enhance the flavor of the product, including additives identified as flavoring agents:

a) by the Joint FAO/WHO Expert Committee on Food Additives - JECFA; or

b) by the Flavor and Extract Manufacturers Association - FEMA.

II – processing aids for flavorings;

III – additives with nutritional properties, including:

a) amino acids;

b) vitamins;

c) essential fatty acids; and

d) minerals, except for those that are demonstrably essential to the manufacture of the tobacco products.

IV - additives associated with alleged stimulating or invigorating properties, including taurine, guaraná, caffeine and glucuronolactone;

V - pigments (or coloring agents);

VI - fruits, vegetables or any product originating from the processing of fruits and vegetables, except activated charcoal and amides;

VII – sweeteners, honey, molasses or any other substance that can impart a sweet flavor, apart from sugars;

VIII – seasonings, herbs and spices or any substance that can impart a flavor of seasonings, herbs and spices;

IX - ameliorants; and

X – ammonia or any of its compounds and derivatives.

Art. 7 The use of the following additives is permitted in tobacco products:

I – sugars, exclusively for the restitution of the sugar originally present in tobacco leaf prior to the curing process;

II – adhesives;

III – binders;

IV – combustion agents;

V – processing aids that are not for flavorings;

VI - pigments (or coloring agents) used to whiten the paper or the filter, to imitate a cork pattern in the wrapping of the filter tip and those used to print logos or brand names;

VII - glycerol and propylene glycol; and

VIII – potassium sorbate.

§ 1 The addition of sugars indicated in sub-paragraph I is subject to the declaration of losses and the need for restitution, to be submitted by the companies when applying for Registration or Renewal of Registration of the Tobacco Product - Registration Data or Alteration of Data.

§ 2 The Collegiate Directorate may, through issuance of its own regulatory provisions, approve the use of other additives, considering the justifications submitted by companies concerning their necessity for the manufacture of the tobacco product, as long as they do not alter its flavor.

CHAPTER V

FINAL AND TRANSITORY PROVISIONS

Art. 8 A period of 18 (eighteen) months is granted, counting from the date of publication of this Resolution, to allow manufacturers and importers of tobacco products that are already registered in compliance with Article 5.

§ 1 At the end of the period indicated in the *caput*, products that are not in compliance with Article 5 can be sold on a retail basis for a period of 6 (six) months.

§ 2 At the end of the period established in § 1, the products must be taken off the market by manufacturers, importers, distributors and retailers.

§ 3 The periods set forth in this Article do not apply to cigarettes.

Art. 9 A period of 18 (eighteen) months is granted, counting from the date of publication of this Resolution, to allow manufacturers and importers of tobacco products that are already registered in compliance with Article 6.

§ 1 At the end of the period indicated in the *caput*, products that are not in compliance with Article 6 can be sold on a retail basis for a period of 6 (six) months.

§ 2 At the end of the period established in § 1, the products must be taken off by manufacturers, importers, distributors and retailers.

Art. 10. Any alteration in the composition, packaging or brand name of the product for purposes of compliance with Articles 5 and 6 of this Resolution, must be implemented through the application form entitled “Alter Data” or the application form entitled “Renewal of Registration of a Tobacco Product – Registration Data”.

Art. 11. Failure to comply with the provisions contained in this Resolution constitutes a health violation pursuant to the terms of Law n. 6.437, of August 20, 1977, without impairment to such civil, administrative and criminal liabilities as may be applicable.

Art. 12. RDC Resolution n. 46, of March 28, 2001, is hereby revoked.

Art. 13. This Resolution of the Collegiate Directorate enters into force on the date of its publication.

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