COLLEGIATE BOARD RESOLUTION – RDC NO. 14 OF 15 MARCH 2012

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Provides for the maximum limits of tar, nicotine, and carbon monoxide in cigarettes, as well as restrictions on the use of additives in tobacco products and gives other provisions.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under item IV of Article 11 of the Regulation approved by Decree no. 3,029 of 16 April 1999, and considering the provisions in Article 54, item II, and paragraphs 1 and 3 of Anvisa Regulation approved pursuant to Annex I of Anvisa Administrative Rule no. 354 of 11 August 2006, republished in the Federal Official Gazette of 21 August 2006, as decided upon in a meeting held on 13 March 2012, adopts the following Collegiate Board Resolution and I, Director-President, determine its publication:

Article 1. This Resolution establishes the maximum limits of tar, nicotine, and carbon monoxide in the mainstream smoke of cigarettes, as well as restrictions on the use of additives in all tobacco products commercialized in Brazil, in the terms hereof.

CHAPTER I

INITIAL PROVISIONS

Section I

Scope

Article 2. This Resolution applies to tobacco products commercialized in Brazil, either imported or manufactured nationally.

Section II

Definitions

Article 3. 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 and reconstituted tobacco, in the manufacture and packaging of a tobacco product, including sugars, sweeteners, coloring matters, flavorings, artificial flavors, and ameliorants;

II – sugars: monosaccharides and disaccharides, including the sucrose obtained from sugarcane juice (*Saccharum officinarum* L.) or beetroot juice (*Beta alba* L.), and it may be in a wide grain size range and several presentation forms;

III – sweetener: product consisting in one or more artificial sweeteners, and it may contain other ingredient(s), which gives a sweet taste to the tobacco product;

IV – ameliorant: substance that reduces the irritating aspects of the smoke from tobacco products;

V – flavorings: natural or synthetic substance, or mixture of substances, which gives, alters, improves, or intensifies aromas in tobacco products;

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

VII – artificial flavor: substance other than sugars, which gives a sweet taste to the tobacco product;

VIII – package: wrap, recipient, or any other form of packaging intended to contain tobacco products;

IX – artificial flavor: natural or synthetic substance, or mixture of substances, which gives, alters, improves, or intensifies flavors and aromas in tobacco products;

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

XI – tobacco product: any manufactured product derived from tobacco, which contains tobacco leaves in its composition, even if it is partially constituted of tobacco.

CHAPTER II

MAXIMUM LIMITS OF TAR, NICOTINE, AND CARBON MONOXIDE IN CIGARETTES

Article 4. In the cigarettes commercialized in Brazil, the maximum permitted limits of tar, nicotine, and carbon monoxide in the mainstream smoke are:

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).

Paragraph 1. The maximum limits established in the caption of this article refer to the mean content determined through a quantitative laboratory analysis, added with the respective analytical standard deviations.

Paragraph 2. In content quantifications, the company must use any analytical methodologies accepted internationally or those adopted by legislation or international agreement ratified and internalized by Brazil.

CHAPTER III

EXPRESSIONS ON PACKAGES

Article 5. This Resolution forbids the use of any expression on the packages of all tobacco products that might induce consumers to a wrong interpretation about the contents contained in such products, namely: class(es), ultralow content(s), low content(s), smooth, light, soft, moderate content(s), high content(s), among others.

CHAPTER IV

ADDITIVES

Article 6. This Resolution forbids imports into and the commercialization in Brazil of tobacco products containing any of the following additives:

I – synthetic and natural substances, in any form of presentation (pure substances, extracts, oils, absolutes, balms, among others), with flavoring or scenting properties that might give, intensify, alter, or highlight flavor or scent of the product, including the additives identified as scenting or flavoring agents by the following organizations:

a) Joint FAO/WHO Expert Committee on Food Additives; or

b) Flavor and Extract Manufacturers Association – FEMA.

II – technology co-builders (or processing aids) for flavorings and artificial flavors;

III – additives with nutritional properties, including:

a) amino acids;

b) vitamins;

c) essential fatty acids; and

d) minerals, except those provenly essential for the manufacture of tobacco products.

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

V – pigments (or coloring agents);

VI – fruits, vegetables, or any product originated from the processing of fruits and vegetables, except activated coal and starch;

VII – sweeteners, honey, molasses, or any other substance that might give sweet scent or flavor, other than sugars;

VIII – seasonings, herbs, and spices, or any substance that might give scent or flavor of seasonings, herbs, and spices;

IX – ameliorants; and

X – ammonia and all its compounds and derivatives.

Article 7. This Resolution allows the use of the following additives in tobacco products:

I – sugars, exclusively to recompose the sugar content originally present in the tobacco leaf before the drying process;

II – adhesive stickers;

III – bonding agents;

IV – combustion agents;

V – technology co-builders (or processing aids) not intended for flavorings and artificial flavors;

VI – pigments (or dyes) used to whiten papers or filters, in order to imitate the cork pattern on tip wrappers, and those used to print logos or brands;

VII – glycerol and propylene glycol; and

VIII – potassium sorbate.

Paragraph 1. The addition of sugars provided for in item I is hereby conditioned to the declaration of losses and of the need of recomposition, to be presented by the companies at the moment of submitting the application for Marketing Authorization or Renewal of Marketing Authorization for Tobacco Products – Registration Data or Data Alteration.

Paragraph 2. Through its own normative act, the Collegiate Board may approve the use of other additives, considering the justifications presented by the companies about their necessity for the tobacco product, as long as they do not alter their flavor or scent.

CHAPTER V

FINAL AND TRANSITIONAL PROVISIONS

Article 8. This Resolution grants the period of 18 (eighteen) months, counting from the date of its publication, for tobacco product manufacturing and importing companies that already hold Tobacco Product Marketing Authorization – Registration Data to comply with the provisions of Article 5.

Paragraph 1. When the period referred to in the caption of this article is expired, the products that do not comply with Article 5 may be commercialized by retailers for the period of 6 (six) months.

Paragraph 2. When the period established in Paragraph 1 is expired, the products must be recalled from the market by manufacturers, importers, distributors, and traders.

Paragraph 3. The periods provided for in this article do not apply to cigarettes.

Article 9. This Resolution grants the period of 18 (eighteen) months, counting from the date of its publication, for tobacco product manufacturing and importing companies that already hold Tobacco Product Marketing Authorization – Registration Data to comply with the provisions of Article 6.

Paragraph 1. When the period referred to in the caption of this article is expired, the products that do not comply with Article 6 may be commercialized by retailers for the period of 6 (six) months.

Paragraph 2. When the period established in Paragraph 1 is expired, the products must be recalled from the market by manufacturers, importers, distributors, and traders.

Article 10. Any alteration in composition, packaging, or brand name of the product, for the purposes of compliance with articles 5 and 6 of this Resolution, must be carried out through an application for Data Alteration or an application for Renewal of Marketing Authorization for Tobacco Products – Registration Data.

Article 11. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, pursuant to Law no. 6,437 of 20 August 1977, without prejudice to the applicable civil, administrative, and criminal liabilities.

Article 12. Collegiate Board Resolution no. 46 of 28 March 2001 is hereby revoked.

Article 13. This Collegiate Board Resolution enters into force on the date of its publication.

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