

COLLEGIATE BOARD RESOLUTION – RDC NO. 855 OF 23 APRIL 2024

Prohibits the manufacture, importation, commercialization, distribution, storage, transportation, and advertising of electronic smoking devices (ESDs).

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, item III, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and item VI, paragraphs 1 and 3 of Article 187 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 19 April 2024, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Article 1. This Resolution provides for the prohibition of manufacture, importation, commercialization, distribution, storage, transportation, and advertising of electronic smoking devices (ESDs).

Sole Paragraph. This Resolution applies to all electronic smoking devices, as well as accessories, pieces, parts, and refills intended for use with/ in electronic smoking devices.

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

I – smoke product: manufactured product, derived or not from tobacco, that contains leaves or leaf extracts, other vegetal components, synthetic or natural substances, or substances that mimic tobacco products;

II – electronic smoking device: smoke product that generates emissions with the aid of a system fed by electricity, battery, or other non-combustible source, that mimics the act of smoking, including:

a) disposable or reusable products;

b) products that use solid and/ or liquid matrix, or others, depending on its building and design;

c) products composed of a unit that heats one or more matrices: liquid (with or without nicotine); solid (usually composed of tobacco extract or leaves – ground, minced, milled, cut, or whole, or other plants); composed of synthetic substances that reproduce components of tobacco or extracts from other plants; essential oils; vitamin complexes, or other substances; and

d) products known as electronic cigarettes, e-cigs, electronic nicotine delivery systems (ENDS), electronic non-nicotine delivery systems (ENNDS), e-pod, "pen-drive", pod, vapes, heated tobacco product (HTP), heat not burn, vaporizers, among others;

III – other electronic smoking devices: electronic smoking devices with different operation and/or matrices from the ones provided for in item II of Article 2 of this Resolution;

IV – matrix: material that will generate, or from which there will be extraction, or that will serve as a source for the emission of substances of interest for consumption in electronic smoking devices;

V – enclosed collective space: public or private space accessible to the public or of collective use, totally or partially closed in any of its sides by a wall, partition, ceiling, awning, or roof, in a permanent or provisional manner, as described in Law no. 9,294 of 15 July 1996 and Decree no. 2,018 of 1 October 1996, as well as their updates; and

VI – advertising of electronic smoking devices: exposure and any form of promotion, by printed, electronic, or digital means, including the internet, or any other form of communication to the public, being consumers of the products or not, with the purpose of promoting, propagating, disseminating, persuading, selling, or encouraging the use of electronic smoking devices, either directly or indirectly, made by the company responsible for the product or a company contracted by it, also including:

a) promotion of catalogs or displays of electronic smoking devices in printed, electronic, or digital form;

b) promotion of brand name and brand elements of electronic smoking devices or of their manufacturing company on products different from tobacco products;

c) association of brand name and brand elements of electronic smoking devices, or of their manufacturing company, to brand names of products different from tobacco products, to the names of other companies, or commercial establishments;

d) disclosure of information or allegations about the product without scientific evidence;

e) any other form of communication or action that promotes electronic smoking devices, including sponsored articles in media vehicles, attracting people's attention and interest, either being consumers of the products or not, and may stimulate consumption or initiation of use; and

f) any accessory, part, piece, or refill intended for the use of electronic smoking devices.

Paragraph 1. The matrix defined in item IV may usually be solid or liquid. In devices with two tanks operating simultaneously, the main matrix will be the one from which flavor and/ or other substances of interest are extracted.

Paragraph 2. The definition referred to in item VI does not reach the exclusively technical-scientific debate on electronic smoking devices.

CHAPTER II

REGULATION

Article 3. This Resolution prohibits the manufacture, importation, commercialization, distribution, storage, transportation, and advertising of all electronic smoking devices.

Paragraph 1. The prohibitions referred to in the caption of this article include the following:

I – any accessories, parts, pieces, or refills intended for use with/ in electronic smoking devices;

II – other electronic smoking devices with operation and/ or matrices different from the ones provided for in this Resolution;

III – products and packages intended for children and young people, as well as food or food packaging that simulate, imitate, or reproduce the form of electronic smoking devices, in accordance with Law no. 12,921, of 26 December 2013, and Collegiate Board Resolution – RDC no. 635, of 24 March 2022; and

IV – the entry into Brazil of products brought by travelers through any form of importation, including the category of accompanied luggage.

Paragraph 2. The prohibition referred to in the caption of this article excludes imports for exclusively scientific or technological research purposes, provided the following requirements are met:

I – imports by Scientific, Technological and Innovative Institutions duly accredited by CNPq, provided they comply with the requirements established by Collegiate Board Resolution – RDC no. 172 of 8 September 2017; and

II – in Siscomex importation category.

Article 4. This Resolution prohibits the use of any electronic smoking device in enclosed collective spaces, in accordance with Law no. 9,294, of 15 July 1996, and Decree no. 2,018, of 1 October 1996, as well as their updates.

CHAPTER III

FINAL PROVISIONS

Article 5. Anvisa shall do periodic systematic reviews of the literature on the theme, whenever there is a technical-scientific justification.

Paragraph 1. The systematic reviews referred to in the caption of this article must be independent and free of conflicts of interest.

Paragraph 2. Anvisa shall publish a Public Notice for the presentation of scientific studies to support the systematic reviews referred to in the caption of this article.

Paragraph 3. The interested parties, at their discretion, may protocol toxicological studies, specific scientific tests, and peer-reviewed scientific articles, published in indexed journals, that confirm the alleged purposes of any electronic smoking devices, which shall be submitted to technical analysis by Anvisa.

Paragraph 4. The protocolled documents shall be analyzed by the General Office for Marketing Authorization and Inspection of Smoke Products Derived or Not from Tobacco (GGTAB, in Portuguese) for the compliance with the criteria provided for in Paragraph 3 of this article, which shall give cause to:

I – return to the interested party, in case of non-compliance with the criteria; or

II – referral for specific technical analysis of the evidence presented.

Article 6. Failure to comply with the provisions contained in this Resolution shall constitute a health infraction, and violators shall be subject to the penalties provided for in Law no. 9,294, of 2 July 1996 and Law no. 6,437, of 20 August 1977, and other applicable sanctions, without prejudice to the applicable administrative, civil, and criminal liabilities.

Article 7. In case a health infraction is identified, resulting from incompliance with this Resolution, the organism integrating the Brazilian Health Surveillance System (SNVS, in Portuguese) shall immediately notify the Public Prosecutor's Office of the respective location for the purposes of eventual initiation of the applicable procedure of civil and criminal verification of the fact notified.

Article 8. Collegiate Board Resolution – RDC no. 46 of 28 August 2009, published in the Federal Official Gazette no. 166 of 31 August 2009, Section 1, page 45, is hereby revoked.

Article 9. This Resolution shall enter into force on 2 May 2024.

ANTONIO BARRA TORRES

Director-President