

[logo]

Executive Branch
Ministry of Public Health and Social Welfare
S.G. Resolution No. 630 -

WHICH ESTABLISHES HEALTH PROTECTION MEASURES RELATING TO ELECTRONIC CIGARETTES, VAPE PENS, VAPORIZERS AND OTHER SIMILAR NICOTINE DELIVERY SYSTEMS (ENDS) AND SIMILAR NON-NICOTINE SYSTEMS (ENNDS), AND SUBSTANCES USED THEREIN.

Asunción, December 12, 2019

PURSUANT TO:

DGVS [General Directorate of Health Surveillance] Note No. 878/2019, submitted by the General Directorate of Health Surveillance, to which the draft regulation establishing health protection measures relating to electronic cigarettes, vape pens, vaporizers and other similar nicotine delivery systems and similar non-nicotine systems, and substances used therein is attached; and

WHEREAS:

Article 68 of the National Constitution guarantees that the Paraguayan State shall protect and promote health as a fundamental right of the individual and in the interest of the community.

Article 3 of Law No. 836/80 - Health Code, states that: *"The Ministry of Public Health and Social Welfare, hereinafter referred to as the Ministry, is the highest State agency competent in matters of health and fundamental aspects of social welfare."*

Law No. 2969/2006 approved and ratified the World Health Organization Framework Convention on Tobacco Control (WHO-FCTC).

Recommendation No. CNFv - 001-17 of October 19, 2017 of the National Commission on Pharmacovigilance, consisting of S.G. Resolution No. 045/16, recommends the regulation of consumables used by the electronic cigarette.

Electronic cigarettes, vape pens, vaporizers and any ENDS/ENDDS can serve as a gateway to smoking and it is a public health concern to prevent this outcome. It is intended to make starting and continuing to smoke as difficult as possible, to minimize the potential risks and to protect non-users from exposure to their emissions, if any.

Currently, the use of electronic cigarettes, vape pens, vaporizers and any ENDS/ENNDS is a risk to public health, one the State must react to by enacting measures to prevent future harm and keep non-smokers and young people from starting to use these products, with a particular emphasis on vulnerable groups.

WHO Report FCTC/COP/7/11 of August 2016 presented during the Conference of the Parties to the WHO Framework Convention on Tobacco Control held in New Delhi, India in November 2016 states that: *"The typical use of unadulterated ENDS/ENNDS produces aerosol that ordinarily includes glycols, aldehydes, volatile organic compounds (VOCs), polycyclic aromatic hydrocarbon (PAHs), tobacco-specific nitrosamines (TSNAs), metals, silicate particles and other elements. Dicarbonyls (glyoxal, methylglyoxal, diacetyl) and hydroxycarbonyls (acetol) also are thought to be important compounds in the aerosol."*

[Signature]

[stamp]

[logo]

Executive Branch

Ministry of Public Health and Social Welfare

S.G. Resolution No. 630 -

WHICH ESTABLISHES HEALTH PROTECTION MEASURES RELATING TO ELECTRONIC CIGARETTES, VAPE PENS, VAPORIZERS AND OTHER SIMILAR NICOTINE DELIVERY SYSTEMS (ENDS) AND SIMILAR NICOTINE-FREE SYSTEMS (ENNDS), AND SUBSTANCES USED THEREIN.

December 12, 2019

Page 2/10

Many of these substances are toxicants that have known health effects resulting in a range of significant pathological changes."

The same report points out: "The number and level of known toxicants generated by the typical use of unadulterated ENDS/ENNDS is on average lower or much lower than in cigarette smoke, with a few new toxicants specific to ENDS such as glyoxal. However, the levels of toxicants can vary enormously across and within brands and sometimes reach higher levels than in tobacco smoke."

The above WHO document states that: "ENDS aerosol contains nicotine, the addictive component of tobacco products. In addition to dependence, nicotine can have adverse effects on the development of the fetus during pregnancy and may contribute to cardiovascular disease. Although nicotine itself is not a carcinogen, it may function as a "tumor promoter" and seems to be involved in the biology of malignant diseases, as well as of neurodegeneration. Fetal and adolescent nicotine exposure may have long-term consequences for brain development, potentially leading to learning and anxiety disorders. The evidence is sufficient to warn children and adolescents, pregnant women, and women of reproductive age against ENDS use and nicotine."

It then states: "Based mostly on the levels and number of toxicants produced during the typical use of unadulterated ENDS/ENNDS made with pharmaceutical-grade ingredients, it is very likely that ENDS/ENNDS are less toxic than cigarette smoke. However, ENDS/ENNDS are unlikely to be harmless, and long-term use is expected to increase the risk of chronic obstructive pulmonary disease, lung cancer, and possibly cardiovascular disease as well as some other diseases also associated with smoking.

It goes on to state: "A recent systematic review of the health risks from passive exposure to exhaled aerosol from ENDS/ENNDS users - or second-hand aerosol (SHA) - concluded that 'the absolute impact from passive exposure to electronic cigarette vapor has the potential to lead to adverse health effects.' A WHO-commissioned review found that while there are a limited number of studies in this area, it can be concluded that SHA is a new air contamination source for particulate matter, which includes fine and ultrafine particles, as well as 1,2-propanediol, some VOCs, some heavy metals, and nicotine."

The WHO report further states: "While some argue that exposure to SHA is unlikely to cause significant health risks, they concede that SHA can be deleterious to bystanders with some respiratory pre-conditions. It is nevertheless reasonable to assume that the increased concentration of toxicants from SHA over background levels poses an increased risk for the health of all bystanders."

[Signature]

[stamp]

[logo]
Executive Branch
Ministry of Public Health and Social Welfare
S.G. Resolution No. 630 -

WHICH ESTABLISHES HEALTH PROTECTION MEASURES RELATING TO ELECTRONIC CIGARETTES, VAPE PENS, VAPORIZERS AND OTHER SIMILAR NICOTINE DELIVERY SYSTEMS (ENDS) AND SIMILAR NICOTINE-FREE SYSTEMS (ENNDS), AND SUBSTANCES USED THEREIN.

December 12, 2019
Page 3/10

In view of the foregoing, it is in the interest of the State, via the Ministry of Public Health and Social Welfare, to adopt measures for the benefit of the health of the population and, in this regard, to have control regulations for the aforementioned products, as well as for the raw materials, substances used in electronic cigarettes, vape pens, vaporizers and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS), that govern the operation of the establishments that manufacture, import, export, distribute and sell them.

The General Directorate of Legal Affairs of the Ministry of Public Health and Social Welfare has issued a favorable opinion on the signing of this Resolution, pursuant to Opinion A. J. No. 2255/2019.

THEREFORE, in exercise of its legal powers,

**THE MINISTRY OF PUBLIC HEALTH AND SOCIAL WELFARE
HEREBY RESOLVES:**

Article 1. To establish health protection measures relating to the use of electronic cigarettes, vape pens, vaporizers and substances used for vaping and vaporizing and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) and to establish the rules for the authorization of establishments that import, export, manufacture, distribute and sell those products, in accordance with the provisions of this resolution.

SECTION I

Definitions

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

ENDS/ENNDS: acronyms for Electronic Nicotine Delivery System/acronym for Electronic Non-Nicotine Delivery Systems recognized as categories of tobacco or similar products, and including any electronic nicotine or non-nicotine delivery system, whether electrically rechargeable or not, that contain replaceable or reusable cartridges in which substances of natural or synthetic origin are contained, which are used to inhale the vapors generated by the heating of that system.

Health warning: warnings intended for the consumer and the public about the risks and harm to health caused by the use of electronic cigarettes, vape pens, vaporizers and substances used for vaping and vaporizing and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) and exposure to smoke or vapor, which may consist of pictograms, images, wording and the like.

[Signature]

[stamp]

[logo]
Executive Branch
Ministry of Public Health and Social Welfare
S.G. Resolution No. 630 -

WHICH ESTABLISHES HEALTH PROTECTION MEASURES RELATING TO ELECTRONIC CIGARETTES, VAPE PENS, VAPORIZERS AND OTHER SIMILAR NICOTINE DELIVERY SYSTEMS (ENDS) AND SIMILAR NICOTINE-FREE SYSTEMS (ENNDS), AND SUBSTANCES USED THEREIN.

December 12, 2019
Page 4/10

Essences: substances used in electronic cigarettes, electronic cigarettes, vape pens, vaporizers and substances used for vaping and vaporizing and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) to impart flavor and aroma.

Authorization: The approval that allows an establishment to begin the proposed activities, with prior verification of compliance with specific technical, legal and administrative requirements.

Cartridge: container for substances used in electronic cigarettes, vape pens, vaporizers and substances used for vaping and vaporizing and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS)

Certificate of registration: sequentially numbered document authorizing the sale of electronic cigarettes, vape pens, vaporizers and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) and substances used therein.

Retailer: place or point of retail sale of electronic cigarettes, vape pens, vaporizers and any other and any other [sic] Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) covered by this Resolution.

Distributor: any natural or legal person who is regularly engaged in the wholesale or retail distribution or sale of electronic cigarettes, vape pens, vaporizers and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) and the substances necessary for their use.

DNVS: *Dirección Nacional de Vigilancia Sanitaria* [National Health Surveillance Directorate], part of the Ministry of Public Health and Social Welfare.

Manufacture: all operations necessary to obtain the products covered by this resolution.

Open space: any space not enclosed or not covered by a roof or enclosed by two or more walls, regardless of the material covering the roof or the sides, regardless of whether these elements are temporary or permanent.

Manufacturer: any natural or legal person who manufactures the products covered by this Resolution.

Company: natural person or legal entity that, in accordance with the current laws, performs the economic activity or manufactures a product covered by this Resolution.

[Signature]

[stamp]

[logo]

Executive Branch
Ministry of Public Health and Social Welfare
S.G. Resolution No. 630 -

WHICH ESTABLISHES HEALTH PROTECTION MEASURES RELATING TO ELECTRONIC CIGARETTES, VAPE PENS, VAPORIZERS AND OTHER SIMILAR NICOTINE DELIVERY SYSTEMS (ENDS) AND SIMILAR NICOTINE-FREE SYSTEMS (ENNDS), AND SUBSTANCES USED THEREIN.

December 12, 2019

Page 5/10

Establishment: company where the activities regulated by this Resolution are carried out and where electronic cigarettes, vape pens, vaporizers and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) and their parts, as well as the substance to be used, are manufactured, processed, imported, exported, packaged, stored, distributed or sold.

Exporter: National or foreign natural or legal person who engages in the activity of sending the products covered by this Resolution outside the national territory.

Importer: national or foreign natural or legal person who engages in the activity of bringing the products covered by this Resolution into the country.

Ingredients: chemical substances that are part of a compound, intended for use in ENDS and ENNDS.

Product registration: administrative process by which the manufacture, import, export, distribution and sale of the products covered by this Resolution is registered and authorized once the product has complied with the established requirements.

MSPBS: Ministry of Public Health and Social Welfare.

Sponsorship: any form of contributing to any act, activity or individual for the purpose, effect or possible effect of directly or indirectly promoting the products referred to in this regulation.

Product: electronic cigarettes, vape pen, vaporizer and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) and the substances used with them.

Technical Officer: pharmaceutical professional or pharmaceutical chemist authorized by the MSPBS responsible for the technical information submitted by the manufacturer, importer, exporter, distributor and seller and for the product's technical specifications.

Section II
Authorization of establishments

Article 3. The establishments that intend to carry out the activities included in this resolution must be authorized to operate by the DNVS and comply with the requirements that shall be established for that purpose.

[Signature]

[stamp]

[logo]
Executive Branch
Ministry of Public Health and Social Welfare
S.G. Resolution No. 630 -

WHICH ESTABLISHES HEALTH PROTECTION MEASURES RELATING TO ELECTRONIC CIGARETTES, VAPE PENS, VAPORIZERS AND OTHER SIMILAR NICOTINE DELIVERY SYSTEMS (ENDS) AND SIMILAR NICOTINE-FREE SYSTEMS (ENNDS), AND SUBSTANCES USED THEREIN.

December 12, 2019
Page 6/10

Article 4. To establish that the DNVS will conduct a pre-inspection in order to verify:

- The conditions for its operation.
- Manufacturing, storage, distribution and sales conditions, as appropriate.

Section III
Product registration

Article 5. To establish that the products covered by this Resolution must be registered with the DNVS in compliance with the requirements to be established by it.

Article 6. Electronic cigarettes and refill containers, cartridges and similar shall have a safety mechanism to prevent their handling and use by minors and shall be protected against breakage and fluid leaks.

SECTION IV
Packaging and labeling

Article 7. To provide that the labels, containers or cases of electronic cigarettes, vape pens, vaporizers and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) and the substances used therein, manufactured domestically or imported, shall contain health warnings in accordance with the text that shall be established by the Ministry of Public Health and Social Welfare.

Article 8. The health warnings shall be printed directly on the product so as to be visible at all times, including during display at points of sale.

Article 9. To establish that the labeling, package or case of the products covered by this resolution must contain easily legible and visible indelible characters and must contain the following information:

- a. The name of the product
- b. The qualitative composition with the generic name of the active ingredients/additives
- c. Content
- d. Date of manufacture
- e. Expiration date
- f. Wording to ensure proper use of the product
- g. How to store
- h. Instructions for use

[Signature]

[stamp]

[logo]

***Executive Branch
Ministry of Public Health and Social Welfare
S.G. Resolution No. 630 -***

WHICH ESTABLISHES HEALTH PROTECTION MEASURES RELATING TO ELECTRONIC CIGARETTES, VAPE PENS, VAPORIZERS AND OTHER SIMILAR NICOTINE DELIVERY SYSTEMS (ENDS) AND SIMILAR NICOTINE-FREE SYSTEMS (ENNDS), AND SUBSTANCES USED THEREIN.

December 12, 2019

Page 7/10

Article 10. To establish that when the size of the package does not allow information on how to store and instructions for use to be included, it shall be included in an attached leaflet and the phrase "See attached leaflet" shall be written on the package.

Article 11. To prohibit the use on the primary and secondary packaging of the products covered by this Resolution of descriptive terms or elements, trademarks, device marks or other marks that have the direct or indirect effect of creating the false impression that the products are less harmful than others with respect to their content, risks or emissions.

Article 12. To specifically prohibit the use of the following expressions on primary and secondary packaging: "light," "ultra light," "mild," or other similar expressions in Spanish or in any language.

**SECTION V
Places and points of sale**

Article 13. The sale of electronic cigarettes, vape pens, vaporizers and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) and the substances used with them to the public shall be carried out exclusively at the places and points of sale of the establishments authorized by the DNVS.

Article 14. To establish that the retail sale and supply of the products covered by this Resolution may only be done in person and directly, and prohibiting remote sale and supply or similar procedures such as telephone, digital, electronic and other similar means.

Article 15. To prohibit the sale and distribution of ENDS/ENDDS electronic system devices and substances to minors under eighteen (18) years of age.

Article 16. To prohibit the free delivery, supply or distribution of the products covered by this Resolution.

[Signature]

[stamp]

[logo]

***Executive Branch
Ministry of Public Health and Social Welfare
S.G. Resolution No. 630 -***

WHICH ESTABLISHES HEALTH PROTECTION MEASURES RELATING TO ELECTRONIC CIGARETTES, VAPE PENS, VAPORIZERS AND OTHER SIMILAR NICOTINE DELIVERY SYSTEMS (ENDS) AND SIMILAR NICOTINE-FREE SYSTEMS (ENNDS), AND SUBSTANCES USED THEREIN.

December 12, 2019

Page 8/10

**SECTION VI
Advertising and promotion**

Article 17. To establish that the sellers of electronic cigarettes, vape pens, vaporizers and any other Electronic Nicotine Delivery System (ENDS) and Similar Non-Nicotine System (ENNDS) and substances used with them shall be required to place visible, clear and prominent signs inside the places and points of sale authorized by the DNVS indicating the cost of the product, the prohibition of their sale to minors and the health warnings to be established by this Ministry.

Article 18. To provide that it shall be required to place notices indicating that the use of the products covered by this Resolution is prohibited and that they "are harmful to health" and specific wording stating "The Ministry of Public Health and Social Welfare warns" in all enclosed public and private spaces, in all enclosed public and private workplaces, public and private educational institutions and healthcare facilities, as well as in public transportation services.

Article 19. To prohibit any form of advertising, promotion or sponsorship of the products covered by this Resolution with the exception of that carried out in places and points of sale, in which case it must contain the health warnings provided by this Ministry and may not include the following:

- a. Images of minors, figures or characters representing children and adolescents;
- b. Images and expressions related to family environments;
- c. Images and expressions related to sports or athletic activities.
- d. Images and expressions directly or indirectly linked to sexual intercourse;
- e. Images and expressions that lead one to believe that the products covered by this Resolution are beneficial to health, promote family or personal wellbeing, or the consumer's social, economic, political or cultural advancement.

Article 20. To prohibit the use of descriptive terms or elements, trademarks, device marks or other marks that have the direct or indirect effect of creating the false impression that these products are less harmful than others with respect to their content, risks or emissions in the advertising, promotion or sponsorship of the products covered by this Resolution in places and points of sale.

[Signature]

[stamp]

[logo]
Executive Branch
Ministry of Public Health and Social Welfare
S.G. Resolution No. 630 -

WHICH ESTABLISHES HEALTH PROTECTION MEASURES RELATING TO ELECTRONIC CIGARETTES, VAPE PENS, VAPORIZERS AND OTHER SIMILAR NICOTINE DELIVERY SYSTEMS (ENDS) AND SIMILAR NICOTINE-FREE SYSTEMS (ENNDS), AND SUBSTANCES USED THEREIN.

December 12, 2019
Page 9/10

- Article 21.** To specifically prohibit in the advertising, promotion or sponsorship of the products covered by this Resolution in places and points of sale the use of the following expressions: "light," "ultra light," "mild," or other similar expressions in Spanish or in any language.
- Article 22.** To prohibit implicit or explicit statements about virtues, or the efficacy of the products as an aid to stop smoking, as well as about their harmlessness or non-addictive nature; and about their safety or addictiveness compared with other tobacco products and similar products in the advertising, promotion or sponsorship of the products subject to this Resolution in places and points of sale.
- Article 23.** To establish that this Ministry shall prepare the necessary health warnings to disclose the harmful effects of the use of the products covered by this Resolution and it shall be mandatory to place them in all State, regional and municipal agencies and entities, public and private workplaces, public and private educational institutions and healthcare facilities, as well as in public transportation services.

Section VII
Restrictions and prohibitions

- Article 24.** To establish that electronic smoking, vaping, vaporizing or using any other ENDS and ENNDS shall only be allowed in open spaces.
- Article 25.** To expressly prohibit the use of electronic cigarettes, vape pens, vaporizers or any other ENDS and ENNDS in:
- a. The headquarters or centers of State, regional and municipal agencies and entities,
 - b. Public and private educational institutions and healthcare facilities.
 - c. Parks, town squares, sports facilities and all recreational areas in general.
 - d. Public transportation in all its forms.
 - e. Any other place where smoking is prohibited.

SECTION VIII
Final provisions

- Article 26.** To provide that the establishments affected by this Resolution shall be subject to periodic inspections ordered by this Ministry.

[Signature]

[stamp]

[logo]

***Executive Branch
Ministry of Public Health and Social Welfare
S.G. Resolution No. 630 -***

WHICH ESTABLISHES HEALTH PROTECTION MEASURES RELATING TO ELECTRONIC CIGARETTES, VAPE PENS, VAPORIZERS AND OTHER SIMILAR NICOTINE DELIVERY SYSTEMS (ENDS) AND SIMILAR NICOTINE-FREE SYSTEMS (ENNDS), AND SUBSTANCES USED THEREIN.

December 12, 2019

Page 10/10

Article 27. To establish that the holder of the registration for the products covered by this Resolution shall be responsible for the consequences of the adverse effects caused by the use of those products.

Article 28. The National Customs Directorate shall not allow the import or export of the products covered by this Resolution without the prior authorization of the DNVS.

Article 29. The DNVS shall take samples of the products covered by this Resolution at the points of sale when it deems it necessary for monitoring purposes.

Article 30. To provide that in the event of any non-compliance or violation of the provisions of this Resolution, the provisions of the Health Code shall apply.

Article 31. Establishments that are currently carrying out some of the activities regulated by this Resolution shall comply within a period of no more than sixty (60) days from this administrative act's entry into force.

Article 32. This Resolution shall become effective thirty (30) days after it has been signed.

Article 33. To notify those concerned and once this is done, to file it.



[Signature]

**DR. JULIO DANIEL MAZZOLENI INSFRÁN
MINISTER**

[text cut off]