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REPUBLIC OF VENEZUELA
MINISTRY OF POPULAR POWER FOR HEALTH
OFFICE OF THE MINISTER

CARACAS, MAY 31, 2023
213º, 164º and 24º
RESOLUTION Nº 362

In exercise of the powers conferred by Articles 65 and 78 numbers 2 and 19 of the Decree with rank, value, and force of the Organic Law of the Public Administration, and in accordance with Articles 2, 5, and 25 of the Organic Law of Health, this Ministerial Office

WHEREAS

In accordance with the provisions of Article 139 of Decree No. 1,424 with rank, value, and force of Organic Law of Public Administration, published in the Official Gazette of the Bolivarian Republic of Venezuela No. 6,147 Extraordinary dated November 17, 2014, the organs and entities of the public administration shall promote citizen participation in public management,

WHEREAS

Health is a fundamental and constitutional social right. It is an obligation of the State to guarantee it as part of the right to life through the promotion and development of policies aimed at raising the quality of life, collective welfare, and access to services by the Executive Branch through the Single National Public Health System. That system is intersectoral, intergovernmental, and participatory, and it is integrated into the Social Security System and governed by the principles of gratuity, universality, integrality, equity, social integration, and solidarity;

WHEREAS

The Plan of the Homeland, Third Socialist Plan for the Economic and Social Development of the Nation 2019-2025, published in the Official Gazette of the Bolivarian Republic of Venezuela No. 6. 446 Extraordinary dated April 08, 2019, establishes that it is the duty of the State to ensure the health of the population, through the continuous strengthening of the welfare of the population and the consolidation of all levels of care and services of the National Public Health System, prioritizing Primary Health Care for the promotion of healthy lifestyles and living conditions in the entire population residing in the national territory,

WHEREAS

The World Health Organization (WHO), in its Global Tobacco Epidemic Report 2019, recommends regulating Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS) and other accessories, as well as rejects that Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS) can be considered a smoking cessation aid because "there is insufficient evidence to support such claim. For tobacco users who wish to quit, there are other proven products, such as nicotine replacement therapies (not patches), and specialized treatments for tobacco dependence."

WHEREAS

Various International Health Organizations have warned about "Lung injuries associated with the use of electronic cigarette products". They also recommend that electronic cigarette products should never be used by young people or pregnant women,

WHEREAS

The Bolivarian Republic of Venezuela approved the "World Health Organization Framework Convention on Tobacco Control" published in Official Gazette No. 38,304 dated November 1, 2005,

WHEREAS

The Secretariat of the Framework Convention on Tobacco Control issued a verbal note CS/NV/19/14 FCTC-WHO, with the purpose of augmenting vigilance with respect to novel and emerging nicotine and tobacco products,

WHEREAS

It is the duty of the Venezuelan State to watch over the rights of the people, in the face of the risks caused by products, which could be considered harmful or dangerous, in the development of the guarantee and protection of health,

DECIDES

To issue the following:

RESOLUTION REGULATING THE MANUFACTURE, IMPORTATION, EXPORTATION, DISTRIBUTION, COMMERCIALIZATION, USE AND CONSUMPTION, ADVERTISING, AND PROMOTION OF ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS), ELECTRONIC NON-NICOTINE DELIVERY SYSTEMS (ENNDS), CONSUMABLES, AND OTHER ACCESSORIES.

OBJECT

Article 1. The purpose of this Resolution is to establish the regulatory guidelines that establishments dedicated to the manufacture, importation, exportation, distribution, and/or commercialization of Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), consumables, deposits, or cartridges, refill consumable containers and other accessories must comply with; in the same way, to establish mechanisms for the protection of people's health through the regulation of the use and consumption, promotion and advertising of the same throughout the national territory.

DEFINITIONS

Article 2°. For the purposes set forth in this Resolution, the following definitions are established:

Areas intended for the use of Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), consumables, and other accessories: It is any space or point that has a current control number for that activity, issued by the competent health authority, with exclusive entrance for adults of legal age and for commercial activity.

- **Indoor Areas:** Any enclosed space, whether roofed or not, regardless of the material used and whether the structure is permanent or temporary.
- **Puff:** The action of inhaling smoke from a cigarette, cigar, ENDS, ENNDS, and others.
- **Commercialization:** Set of actions and procedures carried out to introduce the products or merchandise into the distribution system, according to the existing legal mechanisms.
- **Retailer:** Space where the retail sale of ENDS and ENNDS, consumables, and other accessories takes place.
- **Consumables:** These are liquid solutions composed of solvents, flavorings, and may or may not contain nicotine, among other components accepted under Venezuelan legislation applicable to the matter.
- **Distributor:** Legal entity in charge of distributing and/or wholesaling ENDS and ENNDS, consumables and other accessories.
- **Consumable container for a refill:** Container with liquid of consumable with nicotine or not, which can be used to refill a tank or cartridge of an ENDS or ENNDS.
- **Establishment:** Space where the activities regulated in this Resolution are carried out, such as the manufacture or packaging, importation, exportation, distribution and wholesale or retail commercialization of ENDS and ENNDS, consumables and other accessories.
- **Manufacturer:** Legal entity that designs and/or manufactures electronic systems or devices, liquids, disposable cartridges or tanks, equipment, and accessories, in its own name or through third parties, intended for the administration or not of nicotine, and marketed through a commercial brand, in compliance with the regulations in force on the matter.
- **Pharmaceutical Grade Vegetable Glycerin (VG) or USP:** Vegetable glycerin, also known as glycerol, is a colorless, odorless liquid with a sweet taste, soluble in water and alcohol,

extracted from some vegetable oils, such as coconut or palm oil, commonly used in the cosmetic, pharmaceutical and food industry.

- **Workplace:** Any place used by people during their employment or work, whether paid or unpaid, including related places such as: corridors, elevators, stairways, lobbies, cafeterias, bathrooms, halls, dining rooms and annexes, among others.
- **Public Place:** Any space of public property, public domain and public use. It is the place where any person has the right to circulate in peace and harmony, where the passage cannot be restricted by criteria of private property and intentionally by governmental reserve.
- **Nicotine:** It is an organic compound, alkaloid type that is mainly found in the leaves of the tobacco plant (Nicotiana tabacum), it can also be produced synthetically. It is the substance responsible for dependence and addiction, as it acts at the level of the central nervous system.
- **Consumable Control Number:** It is the correlative number granted to the ENDS and ENNDS, consumables and other accessories, registered before the Autonomous Service of Health Control (SACS for its acronym in Spanish).
- **Establishment Registration Number:** It is the correlative number granted to every establishment registered before the Autonomous Service of Health Control (SACS), for the import, export, manufacture, commercialization and distribution of ENDS and ENNDS.
- **Product:** It includes Electronic Nicotine Administration Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), consumables, tanks or cartridges, refill consumable containers and other accessories.
- **Propylene Glycol (PG) of Pharmaceutical Grade or USP:** Propylene glycol, also known as propylene glycol, food additive E-1520, is tasteless, odorless, colorless and capable of absorbing moisture from its environment, whose appearance is a transparent oily liquid and completely soluble in water; commonly used in the cosmetic industry and pharmaceuticals.
- **Legal responsible:** Legal representative of the company before the SACS, for the technical and legal information provided by the manufacturer, importer, exporter, distributor and marketer and for the technical and quality specifications of the products.
- Flavorings: Substances of natural (vegetable) or artificial origin, capable of acting on the senses of taste and smell, either to reinforce their own inherent flavor, or to confer a new flavor and/or specific aroma, in order to make it more appetizing or pleasant.
- Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS): Electronic nicotine or non-nicotine delivery devices consisting of four (4) elements: a cartridge or reservoir, containing a liquid solution (consumable) with or without nicotine; a heating element (vaporizer), a power source (rechargeable battery or not); and a mouthpiece, through which nicotine or non-nicotine vapor doses are released. ENDS and ENNDS can be disposable or refillable, with a refill container and reservoir, or with single-use cartridges.
- **Solvents:** They are substances, generally liquid, used to dissolve another substance, and that can be incorporated in a determined medium.

Article 3. The sale, distribution, or commercialization of Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS) and other accessories shall only be allowed in those points of sale that have a valid License of Economic Activities issued by the competent authority.

Article 4. Every point of sale where the SEAN, SSSN, consumables and other accessories are commercialized, must permanently display a PUBLIC ADVERTISEMENT whose dimensions are equal to or greater than 80 centimeters (width) X 50 centimeters (length). It must have the following text:

IT IS FORBIDDEN TO SELL OR PROVIDE IN ANY WAY TO CHILDREN AND ADOLESCENTS ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS), ELECTRONIC NON-NICOTINE DELIVERY SYSTEMS (ENNDS), CONSUMABLES AND OTHER ACCESSORIES. WHOEVER SELLS, SUPPLIES OR DELIVERS TO CHILDREN OR ADOLESCENTS PRODUCTS THAT MAY CAUSE PHYSICAL OR CHEMICAL DEPENDENCE, SHALL BE PUNISHED ACCORDING TO THE PROVISIONS OF THE PENAL CODE IN FORCE AND THE SPECIAL LAW THAT REGULATES THE PROTECTION OF CHILDREN AND ADOLESCENTS.

Article 5. If deemed necessary, the retailer may request the identification of the purchaser of the ENDS, ENNDS, consumables, and other accessories to confirm or verify his or her age of majority, otherwise the retailer may refuse to sell the product.

Article 6. The packaging units, as well as all external packaging of electronic devices containing vape liquids, refill mechanisms, and containers, shall include:
1) A list of all ingredients and excipients, contained in the electronic device, vape liquids and containers, in descending order and an indication of the nicotine content (if applicable), of origin (provenance), and its administration per dose, the manufacturing lot number, name of the manufacturer, country of origin, importer and distributor, in addition to the quantity of the amount of nicotine administered per puff, lot number, consumable control number, date of manufacture, expiration date.
2) A recommendation to keep it out of the reach of children and adolescents, and the warning: "**PRODUCT EXCLUSIVELY FOR USE BY ADULTS OF AGE.**"
3) The warning "**FORBIDDEN FOR USE ON MINORS**" and "**KEEP AWAY FROM CHILDREN, TEENAGERS AND PREGNANT WOMEN.**"
4) Additionally, when the product contains nicotine, the following health warning: "**THIS PRODUCT IS HARMFUL TO HEALTH AND ADDICTIVE.**"

Article 7. The warnings mentioned in the previous article shall comply with the following requirements:
1) They shall be located on the two largest surfaces of the packaging unit, as well as on all external packaging on white background with black letters (no smaller than size 8), Printed directly and in Spanish language.

2) They shall cover 20% of the external face of the corresponding surface on the packaging unit and on all external packaging.
Single paragraph: It is forbidden to use texts, symbols, names, trademarks, figurative signs, drawings, photographs, or similar elements that have a direct or indirect effect of creating the impression that the ENDS and ENNDS are less harmful than other products, that they have energetic, curative, rejuvenating, natural, ecological or other positive effects on health; that they resemble a food product or cosmetics.

Article 8. The use of ENDS, ENNDS, consumables and other accessories in indoor or enclosed areas of workplaces and indoor areas of public spaces, including public transportation, is prohibited.
Single Paragraph: The owners, employers and managers of indoor or enclosed areas of workplaces and/or public places, regardless of their use, including public transportation, have the obligation to ensure compliance with this article.

Article 9. The advertising and promotion of Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS) and other accessories is prohibited throughout the national territory. This prohibition especially includes, but is not limited to:
a) External and internal areas of establishments or points of sale.
b) Outdoor advertising media, billboards, posters, murals, stops or transportation stations.
c) Printed media.
d) Public service of open signal television, internal cable, radio, or any other advertising media with cross-border effects.
e) Commercial establishments for public and private events.
f) Cinemas, auditoriums, theaters, electronic media rental spaces, museums and libraries.
g) Parks and zoos.
h) Sports facilities and gymnasiums.
j) Means of transportation providing public service.
k) Sports activities, competitions, exhibitions or events.
l) Educational centers of any level, public or private, as well as places destined for the care of children.
m) Public and private health establishments.
n) Any public entity of the National, State and Municipal Public Powers.

Article 10. The spaces destined for the use of the Electronic Nicotine Delivery Systems (ENDS), and Electronic Non-Nicotine Delivery Systems (ENNDS), shall be of two (2) types, open and closed, which shall be delimited and identified one from the other with their respective notice.
1) Open spaces: They shall be areas open to the environment, in which there shall be a physical separation between the area intended for the use of the product, with respect the one that is not, in case there is one.
2) Closed spaces: They shall be closed and physically separated areas, between the area destined for the use of the product, with respect to the one that is not, in case there is one. This area must have gas extraction mechanisms, as well as an air conditioning system independent from the other spaces. Likewise, the area destined for the use of the Electronic Nicotine

Delivery Systems (ENDS), and Electronic Non-Nicotine Delivery Systems (ENNDS), shall not be less than two (2) square meters per person.

Article 11. The establishments that wish to carry out the activities subject to regulation in the present Resolution, shall possess the Establishment Control Number, issued by the competent sanitary authority. In order to obtain the Establishment Control Number, the Autonomous Service of Health Control (SACS) shall carry out an inspection at the request of the interested party, in order to verify the conditions for its operation, according to the activity it performs: manufacture, importation, distribution, commercialization, storage, and areas of use.

Article 12. Health establishments, educational and training centers (basic education, secondary and technical education), higher education (technical and university), means of urban public transportation, cultural and sports spaces, and the enclosures of playgrounds are exempted with respect to possession, sale, distribution and/or commercialization.

OPERATION OF THE ESTABLISHMENT

Article 13. Establishments that wish to manufacture, import, export, commercialize and/or distribute the Electronic Nicotine Delivery Systems (ENDS), and Electronic Non-Nicotine Delivery System (ENNDS), consumables and other accessories, as well as areas destined for the use of the product, must be registered before the Autonomous Service of Health Control (SACS), which will grant an Establishment Control Number, with a validity of two (2) years as of the date of its notification, which must be renewed upon its expiration, with the warning that the non-compliance of this provision will entail the applicable administrative sanctions by the Autonomous Service of Health Control (SACS).

Article 14. For the application for the Establishment Control Number, the applicant shall submit the following documents:

TO MANUFACTURE:

a) Communication addressed to the Autonomous Service of Health Control (SACS).
b) Commercial Registry corresponding to the corporate purpose.
c) Registration of Fiscal Information.
d) List of the products to be manufactured or conditioned in primary and/or secondary packaging.
e) Authenticated power of attorney granted to the legal representative to represent the company before the Ministry of Popular Power for Health (MPPS, for its acronym in Spanish) through the Autonomous Service of Health Control (SACS).
f) Descriptive report of the premises, indicating: the physical characteristics of the premises (floors, walls, ceiling, lighting), including water, ventilation and extraction systems, and plans.
g) Plans corresponding to the areas where the different operations inherent to the manufacture will be carried out indicating the flow of personnel and supplies.

h) Any other information that the applicant deems convenient to add or legible document required by the sanitary authority.

TO IMPORT AND/OR DISTRIBUTE:

a) Communication addressed to the Autonomous Service of Health Control (SACS).
b) Commercial registry corresponding to the corporate purpose.
c) Tax Information Registry (RIF for its initials in Spanish).
d) List of the products to import and/or distribute indicating: Brand, Flavor, Presentation, Net Content, lot, date of elaboration and expiration date. In the case of importation must include quantities to be imported.
e) Description of the packaging material in direct contact with the Consumable issued by the manufacturer, signed and sealed.
f) Quali-quantitative formula of each Product.
g) Analytical Certificate issued by the manufacturer of the Product, where the specifications of the Product and its quali-quantitative content are described and where the innocuousness of the Product is shown.
h) Power of Attorney granted by the Owner of the Product to the Importer and/or Distributor in Venezuela with Consular or Apostilled Seal.
i) Power of Attorney granted to the Legal Representative to represent the company before the Ministry of Popular Power for Health (MPPS) through the Autonomous Service of Health Control (SACS).
j) Certificate of free sale of the product corresponding to the country of origin of importation that grants it.
k) Any other information that the applicant deems convenient to add or legible document required by the sanitary authority.

TO COMMERCIALIZE:

a) Communication addressed to the Autonomous Service of Health Control (SACS).
b) Commercial Registry.
c) Tax Information Registry (RIF).
d) List of the products to be commercialized: Brand, Flavor, Presentation, Net Content.
e) Copy of the Consumable Control Number Certificate.
f) Any other information that the applicant deems convenient to add or legible document required by the sanitary authority.

FOR USE IN THE ESTABLISHMENTS:

a) Communication addressed to the Autonomous Service of Health Control (SACS) with its corresponding reasoned Act.
b) Mercantile Registry.
c) Registry of Fiscal Information (RIF).

d) Plans of the building, where the area destined for the use of the ENDS and ENNDS is indicated, with emphasis on the ventilation systems.
e) Any other information that the applicant deems convenient to add or legible document required by the health authority.

Single Paragraph: It is established as the maximum legal limit of nicotine concentration in the ENDS consumables as follows: Free Base Nicotine from 0 mg to 3 mg, Nicotine Salts from 0 mg to 35 mg, and in ENDS with cartridges or Disposable deposits from 0 mg to 50 mg or its equivalent at 5%. All raw materials used must meet the standards suitable for human consumption, must be of high quality and must be duly standardized.

CONTROL NUMBER OF THE CONSUMABLE PRODUCT

Article 15. Consumables with or without nicotine contained in refillable or disposable cartridges or tanks, consumable containers for recharge and similar products are subject to control number by the Autonomous Service of Health Control (SACS).

Article 16. The Consumable Product Control Number referred to in this provision shall be valid for two (2) years as of its notification, therefore, it shall be renewed at its expiration date, before the corresponding address:
a) The consumable with nicotine or not shall be marketed only in consumable containers for a refill in a volume not exceeding 10 ml, and the disposable or refillable tanks or cartridges shall be marketed only in a volume not exceeding 2 ml.
b) If there is any modification in the qualitative and quantitative formula, it must be reported to the Autonomous Service of Health Control (SACS) as soon as possible.

Single Paragraph: In case of infractions to the sanitary regulations in force, the competent Sanitary Authority will proceed to the suspension or cancellation of that Control Number. Likewise, companies, legal representatives, as well as manufacturers, those involved in the manufacturing process and other participants in the supply chain of the product shall be responsible for compliance with the provisions set forth in this Resolution.

Article 17. For the granting of the Consumable Control Number before the Autonomous Service of Health Control (SACS), the applicant shall submit the following documents:
1. Communication addressed to the Autonomous Service of Health Control (SACS).
2. Copy of the Registry of Operation of the Establishment.
3. Description of the product, indicating: Denomination, Brand, Variety (color, smell, flavor), Presentation, Net Content.
4. Certificate of phytochemical and microbiological analysis of each product issued by the manufacturer, signed and sealed.
5. Qualitative and quantitative formula issued by the manufacturer, signed and sealed.
6. Description of the packaging material in direct contact with the consumable, signed and sealed by the manufacturer.

7. Text or model of label, package, case and leaflet, when applicable, which must comply with the specifications stated in this resolution.
8. Power of Attorney granted by the Owner of the Product to the Importer and/or distributor in Venezuela with a Consular or Apostilled Seal, when applicable.
9. Power of Attorney granted to the Legal Representative to represent the company before the MPPS through the SACS.
10. Marketing Permit of the product corresponding to the country of origin of importation that grants it, when applicable.
11. Affidavit in which the manufacturer and the importer are fully responsible for the quality and safety of the products, once marketed and under normal conditions of use.
12. Certificate of physical-chemical and microbiological analysis issued by the National Institute of Hygiene "Rafael Rangel" or other laboratory authorized by SACS.
13. All other necessary documents requested by SACS.

Article 18. The consumable control number shall be used as authorization for the mobilization of the products throughout the national territory, which shall be stamped on the packaging.

Article 19. A permanent table shall be held between the Autonomous Service of Sanitary Controllership (SACS), the Expert Associations in the matter, the Trade Associations and Natural Persons with interest in the matter, for the discussion of everything corresponding to the products governed by this regulation.

LABELING AND PACKAGING

Article 20. The packaging units, cases, labels, brochures, as well as all external packaging of the consumables, shall include: Name of the product, list of all the ingredients contained in the consumable in descending order, indication of the nicotine content in mg/ml (if applicable), country of origin, name of the manufacturer, importer and distributor, in addition to the quantity of the amount of nicotine administered per puff, lot number, consumable control number, date of manufacture, expiration date.

PROMOTION AND ADVERTISING

Article 21. All forms of advertising and promotion of the ENDS, ENNDS, consumables and other accessories are prohibited throughout the national territory, with the exception of the establishments destined for this activity such as points of sale, marketers, and distributors, which shall comply with the provisions stated in this resolution, and shall not use the following references:

- Representative or figurative images of minors, or characters associated with children and adolescents.
- Figurative or representative images of family environments or sports activities.
- Figurative or representative images directly or indirectly related to the sexual act.
- Figurative or representative images of social, economic, political or cultural promotion.

Single paragraph: It is forbidden to use texts, symbols, names, trademarks, figurative signs, drawings, photographs, or similar elements that have a direct or indirect effect of creating the impression that the ENDS and ENNDS, consumables and other accessories, are less harmful in relation to their content, innocuousness or non-addictive character, with respect to another product.

RESTRICTIONS AND PROHIBITIONS

Article 22. The remote sale and retail supply of the products covered by this Resolution, as well as the sale and retail supply through similar procedures, such as telephonic, digital, electronic and other similar means, is prohibited. Likewise, the free delivery, supply, or distribution of the products object of this Resolution is prohibited.

Article 23. It is prohibited the manufacture of the products covered by this regulation in an artisanal, domestic, rudimentary and similar manner, in contravention of the sanitary regulations in force.

MINISTRY OF THE POPULAR POWER FOR HEALTH

Article 24. The Ministry of the Popular Power for Health (MPPS) through the Autonomous Service of Health Control (SACS) will carry out the registration, control and regulation of the import, export, manufacture, distribution, commercialization, use, advertising and promotion of the ENDS, ENNDS, consumables and other accessories; likewise, it will be in charge of the inspection, surveillance and control of the present resolution in accordance with the legal framework in force. The National Institute of Hygiene will be the entity that will carry out the analytical quality control in the surveillance process of this type of products.

Article 25. In the event of non-compliance or violation of the provisions set forth in this regulation, the appropriate precautionary measures and/or administrative, civil and/or criminal sanctions shall be applied, according to the nature and seriousness of the offense, in accordance with the Laws, Regulations, Decrees and Resolutions provided for in the legal system in force.

Article 26. This Resolution shall become effective as of its publication in the Official Gazette of the Bolivarian Republic of Venezuela.

Be informed and published.

[Signature]
MAGALY GUTIÉRREZ VIÑA
MINISTER OF THE POPULAR POWER FOR HEALTH
Decree No. 4.639 dated February 9, 2022,
Official Gazette No. 42.315 of February 9, 2022.