

**OFFICIAL GAZETTE OF THE FEDERATION**

Decree prohibiting the circulation and commercialization anywhere in the Republic, regardless of their origin, of Electronic Nicotine Delivery Systems, Electronic Non-Nicotine Delivery Systems, Alternative Nicotine Delivery Systems, electronic cigarettes, and vaporizing devices with similar uses, as well as the solutions and mixtures used in such systems.

Executive Branch / SECRETARIAT OF HEALTH

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**There is a stamp bearing the National Coat of Arms in the margin, which reads: United Mexican States. - Presidency of the Republic.**

**ANDRÉS MANUEL LÓPEZ OBRADOR**, President of the United Mexican States, in exercise of the authority conferred on me by article 89, section I of the Political Constitution of the United Mexican States, based on articles 1, 4, 5 and 131 of the Constitution; 34 and 39 of the Organic Law of the Federal Public Administration, and 17 bis, sections X, XII and XIII of the General Health Law, and

**TAKING INTO CONSIDERATION**

On October 22, 2021, a Decree was published in the Official Gazette of the Federation amending the tariff of the Law of General Import and Export Taxes, which prohibits the import and export of Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), Alternative Nicotine Delivery Systems (ANDS), electronic cigarettes and vaporizing devices with similar uses, as well as the solutions and mixtures used in such systems, among others;

That the purpose of that decree was to implement fundamental human rights. This is due to the fact that, in accordance with Article 1 of the Constitution, all persons shall enjoy the human rights recognized in the Constitution itself and in the international treaties to which the Mexican State is a party, and that all authorities are obligated, within the scope of their competencies, to promote, respect, protect and guarantee human rights in accordance with the principles of universality, interdependence, indivisibility, and progressiveness;

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That, in this vein, the current federal administration is permanently obliged to ensure the fundamental right of every inhabitant of this country, established in Article 4 of the Constitution, which recognizes the right of every person to the protection of health and to a healthy environment for his or her development and wellbeing. It must be understood that the right to health must be conceived as a right to the enjoyment of a full range of benefits, goods, services and conditions necessary to achieve the highest attainable standard of health (1). Likewise, according to the provisions of the ninth paragraph of the aforementioned article, all decisions and actions of the State shall ensure and comply with the principle of the best interests of children, which fully guarantees their rights, including the right to health, a principle that should guide the design, implementation, monitoring and evaluation of public policies aimed at children;

That, on the other hand, the Mexican State is a party to the International Covenant on Economic, Social and Cultural Rights, ratified by the Senate of the Republic in 1981, which establishes in Article 12 that the States Parties "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", for which purpose they must adopt measures for the prevention and treatment of illnesses of any kind;

That, for this reason, "General Comment 14" of the Committee on Economic, Social and Cultural Rights of the Economic and Social Council of the United Nations, dated August 11, 2000, is applicable, which in paragraph 1 defines health as "a fundamental human right indispensable for the exercise of other human rights. Every human being has the right to the enjoyment of the highest attainable standard of health conducive to life with dignity", and paragraph 51 states that "violations of the obligations to protect arise from the failure of a State to take all necessary measures to protect individuals within its jurisdiction against violations of the right to health by third parties. This category includes such omissions as the failure to regulate the activities of individuals, groups or enterprises so as to prevent those individuals, groups or enterprises from violating the right to health of others; the failure to protect consumers and workers against practices harmful to health, as in the case of some employers and manufacturers of medicines or food";

That the Supreme Court of Justice of the Nation (SCJN), in the legal opinion 1a./J.8/2019 entitled "Right to Health Protection, Individual and Social Dimensions", established that the right to health has an individual or personal dimension and a public or social dimension and that in the latter the State must address the health problems that affect society in general and take the necessary actions to achieve that end, such as the development of public policies (2);

That, in consistency with its obligations, the Federal Public Administration, in the National Development Plan 2019-2024, established in its General Pillar 2. "Social Policy" that health is for the entire population so that the right to health is not denied either totally or partially to the Mexican population;

That the Congress of the Union issued the Law of General Import and Export Taxes, soon to be published, which prohibits the import and export of electronic cigarettes and similar personal electric vaporization devices, including the novel and emerging ones that use heated tobacco,

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such as Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), and Alternative Nicotine Delivery Systems (ANDS) and similar ones, and the solutions and mixtures for their use;

That the actions implemented by the government have been insufficient because, in spite of the prohibition established in the above-mentioned decree, these goods (3) currently circulate freely in Mexican territory, which prevents the inhabitants of the country from exercising the right to health that the authorities of the Mexican State are bound to guarantee;

That this is due to the fact that the World Health Organization (WHO), in a statement dated March 25, 2020 (4), pointed out that more and more children and adolescents are falling victim to the advertising tactics of a new portfolio of products that are dangerous for their health, and that among the marketing maneuvers used for this purpose, there are elegant and pocket-sized designs that are widely promoted as attractive, harmless, modern, high-tech and luxury products that are easily hidden in the hand of a young person;

That the WHO, in its statement of July 27, 2020, in agreement with the US Food and Drug Administration's decision on IQOS-branded products (5), has reported that IQOS products are neither harmless nor result in less risk to human health compared to the combustible tobacco products they are intended to replace; on the contrary, WHO has noted that some toxins are present at higher levels in the aerosols of Heated Tobacco Products (HTPs) than in combustible cigarette smoke;

That also the WHO FCTC Conference of the Parties, in the "Harmful and Potentially Harmful Components" section of the "Comprehensive Report on Novel and Emerging Tobacco Products", documents that the aerosols generated by HTPs contain other toxic substances that are sometimes found at higher levels than in burning tobacco smoke, such as glycidol, pyridine, dimethyl trisulfide, acetoin and methylglyoxal, and that some toxic substances found in these aerosols are not present in combustible cigarette smoke (6);

That the use of ANDS generates inflammation of the respiratory tract due to the temperature ranges in which toxic irritant elements included in the aerosol are produced, and it has been reported that it originates diffuse infiltrates and nodular infiltrates of white blood cells that produce pulmonary opacities visible in chest computed tomography, as a consequence of lipoid pneumonia, low oxygenation of the blood and even respiratory failure (7). Furthermore, it has been identified that the toxic effects of HTPs are associated with impaired immune function because they disrupt the proliferation of a family of white blood cells, called T lymphocytes, which affects protection against the development of cancer (8);

That, from a systematic review of the scientific literature conducted by researchers from the National Institute of Respiratory Diseases and the National Autonomous University of Mexico, it is inferred that the use of ENDS and ANDS causes acute lung disease by mechanisms that are shared with combustible cigarettes and by mechanisms specific to such novel and emerging

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tobacco and nicotine products, which shows that there is significant evidence that these devices are an emerging public health problem and that they should be avoided (9);

That, according to WHO, HTPs, a type of ANDS, are devices in which physically and chemically processed tobacco is heated, rather than combusted, by battery-powered electrical systems. HTPs are designed to produce aerosols containing nicotine, a highly addictive substance from tobacco, and other chemicals from added additives and flavorings that are toxic to human life (10);

That ANDS, including HTPs, release high concentrations of nicotine to the user, and the consumption of this substance has adverse effects on the long-term brain function of children and adolescents and on the formation of developing fetuses (11);

That, according to the WHO, it is concluded with certainty that the aerosol generated by ANDS and consumed by users of these devices is a new source of air pollution affecting exposed persons (12);

That, on the other hand, there is growing scientific evidence that young people who start using ENDS, ENNDS and ANDS, increase two to four times their probability of smoking combustible cigarettes, which in turn fuels the tobacco epidemic. (13) According to the available evidence, using ENDS, ENNDS and ANDS increases the probability of starting to smoke combustible tobacco, since these products generate curiosity among adolescents, young people and adults, which is a gateway to perpetuating nicotine addiction (14);

That, in order to prevent non-smokers, young people and the most vulnerable age groups from starting to use these novel and emerging systems, the WHO has endorsed the prohibition of their importation and the sale and distribution of goods identified as ENDS, ENNDS and ANDS, which highlights the need to implement complementary measures to protect the health of children and adolescents to comprehensively prevent the use of these devices (15);

That, for these reasons, the Ministry of Health, through the Federal Commission for Protection against Health Risks (Cofepris, for its acronym in Spanish) and the National Commission against Addictions (Conadic, for its acronym in Spanish), issued Health Alert No. 12/2021, regarding vapers and emerging tobacco products, because they cause serious damage to health, resulting from carcinogenic compounds, toxic substances and aerosol emissions, in addition to having a harmful impact on pulmonary health, which is alarming. Likewise, there is no evidence that proves its efficacy as an alternative to quitting smoking (16).

Similarly, and with the same purpose, on May 19, 2022, the Government-Cofepris Joint Statement No. 178/2022 was published, which "declares a maximum health alert due to the health risks posed by the products commonly known as vapers in all their forms and, in collaboration with the Ministry of the Interior (Segob, for its acronym in Spanish), designs a strategy to prevent risks and strengthen health control actions for these products, which are a priority for the federal health authority";

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That in the mentioned risk statement "it is informed how the inhalation of an excipient frequently found in vaping devices called vitamin E acetate constitutes a high risk to health as it is a toxic substance that can cause acute respiratory diseases and even death" (17);

That, in this sense, it is urgent to adopt the prohibition of the circulation and commercialization in the national territory of the merchandise, regardless of its origin, identified as ENDS, ENNDS, ANDS, electronic cigarettes and vaporizing devices with similar uses, as well as the solutions and mixtures used in such systems, among others, in order to preserve health in the terms determined by the SCJN and international treaties;

That said measure is valid and legitimate because it is based on articles 4, 5 and 131 of the Constitution. Certainly, Article 5 recognizes the freedom of business, as long as it is lawful; however, it establishes the authority's power so that, in use of its capacities, it may restrict such freedom through a governmental resolution when the rights of society are affected, as in this case in which the right to health in its social dimension is affected by the commercialization of the referred merchandise. Therefore, the measure is valid, since it seeks to protect society in general, especially the most vulnerable persons, by avoiding their exposure to novel and emerging products that induce serious health risks and damages;

That, likewise, the prohibition of the circulation and commercialization of such merchandise, regardless of its origin, is appropriate, in accordance with article 131 of the Political Constitution of the United Mexican States, since it is the exclusive power of the Federation to regulate at all times and even prohibit, for safety reasons, its circulation within the territory of the Republic;

That the State has as one of its primary functions the protection of the human rights to life, health and safety of its population, therefore, before the emergence of circumstances that endanger these fundamental rights, it is necessary to adopt and implement all necessary measures to prevent their infringement and, as the case may be, to effectively combat the causes that may lead to it.

That the free commercialization of any type of "vapers" affects society in general and, therefore, everything related to them is of utmost relevance since we are facing an evident risk that compromises the health protection of a great part of the Mexican population;

That the prohibition of the commercialization of the referred merchandise constitutes one of the fundamental pillars of control to the current situation of sanitary alert, a matter of public order, since it avoids an infringement on the health of all the members of the Mexican society, and of security, because it prevents a threat to the health of the population existing in the national territory;

That, therefore, in compliance with the ninth paragraph of article 4 of the Constitution, and in strict compliance with the principle of the best interest of the child, it is appropriate to prohibit the commercialization of the aforementioned merchandise, since it is intended, among other

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effects, to avoid the risk that children and young people acquire from a very early age a habit that damages their health in the long term and that therefore will affect their quality of life;

That the prohibition is appropriate, since the studies mentioned in the previous recitals refer that HTPs contain toxic substances similar to those of combustible cigarettes and, in addition, toxic substances of their own, different from the former, therefore it is clear that the consumption of such products affects health by different and complementary mechanisms to combustible tobacco products, which compromises health, a protected legal right;

That, in addition to the foregoing, the prohibition of circulation and commercialization of such goods is objectively and logically related to the purposes to be achieved, such as protecting the health, both of the consumers themselves and of those who are close to them and receive their emissions, as well as safeguarding, to the extent possible, the health of new generations;

That, in the same sense, the aforementioned prohibition is necessary, since these new and emerging products have a negative influence on the control of the tobacco epidemic since their availability discourages the abandonment of tobacco consumption and increases the probability of relapsing into the consumption of combustible tobacco, and even favors dual consumption;

That the prohibition of circulation and commercialization of ENDS, ENNDS, ANDS, electronic cigarettes and vaporizing devices with similar uses, as well as the solutions and mixtures used in such systems, among others, is proportional in a strict sense, since it should not be lost sight of the fact that the measures contained in this decree highlight three constitutional rights that the State is obliged to protect: (a) the right to health, in its dual perspective, individual and social, (b) the right to a healthy environment and (c) the right to security because it protects the population from a threat to health existing in the national territory which fully guarantees its right to health needs, as well as the general principle that the State in all its decisions and actions should ensure and comply with protecting the best interests of children;

That, furthermore, although the right to the free development of the personal autonomy of the individual, which includes the right to acquire and consume these goods, must be respected, it is not absolute. This has been held by the First Chamber of the Supreme Court of Justice of the Nation (18), stating that the rights of third parties and public order constitute external limits to the right to the free development of the personal autonomy, so it must be taken into account that when a person, derived from the purchase and consumption of these products, falls into a situation of illness or permanent disability, a high economic and psychoemotional impact is generated to his family environment and also to the health system of the country, which translates into an individual and family damage, and to the society in general;

That, in the same sense, the right to freedom of trade is not absolute, so it is valid to limit it (19) when the rights of third parties might be infringed or when higher interests are protected (20), as in the case at hand, since it is clear that the consumption of ENDS, ENNDS, ANDS, electronic cigarettes and vaporizing devices with similar uses, as well as the solutions and mixtures used in such systems, among others, cause damages to the health of the consumer and have

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repercussions on the right to a healthy environment, as they are a source of additional contamination, and therefore, have effects on the health of the individuals who are in the same environment and of society in general, in addition to infringing on the best interest of children, by inducing them to the consumption of harmful substances;

That, in view of the foregoing, it is appropriate to prohibit the circulation and commercialization in the territory of the Republic, regardless of their origin, of ENDS, ENNDS, ANDS, electronic cigarettes and vaporizing devices with similar uses, as well as the solutions and mixtures used in those systems, among others, and consequently to impose sanctions, in the terms provided by the applicable legal provisions, to those who do not comply with this prohibition, hence I have had the pleasure to issue the following

### DECREE

**Article One.-** The circulation and commercialization of Electronic Nicotine Delivery Systems, Electronic Non-Nicotine Delivery Systems, Alternative Nicotine Delivery Systems, electronic cigarettes and vaporizing devices with similar uses, as well as the solutions and mixtures used in such systems, regardless of their origin, is prohibited in the territory of the Republic.

**Article Two.-** Whoever fails to comply with the provisions set forth in the first article shall be subject to the penalties set forth in the applicable legal provisions.

### TRANSITORY

**Unique.-** This Decree shall enter into force on the day of its publication in the Official Gazette of the Federation.

Given at the residence of the Federal Executive Power, in Mexico City, on May 31, 2022.- **Andrés Manuel López Obrador.-** Signature.- The Secretary of Economy, **Tatiana Clouthier Carrillo.-** Signature.- The Secretary of Health, **Jorge Carlos Alcocer Varela.-** Rubric.

1 Legal opinion [A]: 1a. LXV/2008, *DERECHO A LA SALUD. SU REGULACIÓN EN EL ARTÍCULO 4o. DE LA CONSTITUCIÓN POLÍTICA DE LOS ESTADOS UNIDOS MEXICANOS Y SU COMPLEMENTARIEDAD CON LOS TRATADOS INTERNACIONALES EN MATERIA DE DERECHOS HUMANOS* [RIGHT TO HEALTH. ITS REGULATION IN ARTICLE 4 OF THE CONSTITUTION OF THE UNITED MEXICAN STATES AND ITS COMPLEMENTARITY WITH THE INTERNATIONAL TREATIES ON THE RIGHT TO HEALTH. INTERNATIONAL TREATIES ON HUMAN RIGHTS], Ninth Epoch, Volume XXVIII, July 2008, page 457. Available at: <https://sif2.scjn.gob.mx/detalle/tesis/169316>.

2 Legal opinion [J]: 1a./J. 8/2019 (10a.), *DERECHO A LA PROTECCIÓN DE LA SALUD. DIMENSIONES INDIVIDUAL Y SOCIAL* [RIGHT TO PROTECTION OF HEALTH. INDIVIDUAL AND SOCIAL DIMENSIONS], Tenth Epoch, Book 63, February 2019, Volume I, page 486. Available at: <https://sif2.scjn.gob.mx/detalle/tesis/2019358> [accessed September 23, 2021].

3 A movable thing that is subject to purchase, sale, transport, deposit, brokerage, mandate, bailment, insurance or other mercantile operation; that is to say, of lucrative activities in the traffic, more or less direct, between producers, manufacturers, other traders or the public in general.

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<https://mexico.leyderecho.org/mercancias/#::text=Lucro%2C%20Marcas-Concepto%20de%20Mercanc%C3%ADas,o%20el%20p%C3%BAblico%20en%20general>.

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12 Seventh Conference of the Parties. WHO report on electronic nicotine delivery systems and electronic non-nicotine delivery systems. FCTC/COP7(11), New Delhi, India. 7-12 November 2016. Available at: <http://www.who.int/fctc/cop/cop7/FCTC COP 7 11 ES.pdf?ua=1> [accessed September 23, 2021].

13 National Institute of Public Health of Mexico. Updated scientific evidence on vaping. Available at [https://www.insp.mx/resources/images/stories/2021/docs/210415\\_reporte\\_ends\\_repository.pdf](https://www.insp.mx/resources/images/stories/2021/docs/210415_reporte_ends_repository.pdf) [accessed September 23, 2021]

14 Idem.

15 World Health Organization. Ninth Conference of the Parties to the FCTC WHO. Comprehensive report on the research and evidence on novel and emerging tobacco products, in particular heated tobacco products. FCTC/COP9/9, Geneva, Switzerland 8-13 November 2021. Available at <https://untobaccocontrol.org/downloads/cop9/main-documents/FCTC COP9 9 SP.pdf> (accessed September 23, 2021).

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19 Legal opinion [A]: P. LXXXVIII/2000 *LIBERTAD DE COMERCIO. ALCANCES DE LO DISPUESTO EN EL ARTÍCULO 5o. DE LA CONSTITUCIÓN FEDERAL* [RIGHT TO TRADE. SCOPE OF THE PROVISIONS OF ARTICLE 5 OF THE FEDERAL CONSTITUTION], Ninth Epoch, Volume XI, June 2000, page 28. Available at: <https://sjf2.scjn.gob.mx/detail/tesis/191691>

20 Legal opinion [J]: P./J. 25/2011 *PROTECCIÓN A LA SALUD DE LOS NO FUMADORES EN EL DISTRITO FEDERAL. LA LEY RELATIVA NO VIOLA LA GARANTÍA DE LIBERTAD DE COMERCIO* [PROTECTION TO THE HEALTH OF NON-SMOKERS IN THE FEDERAL DISTRICT. THE MENTIONED LAW DOES NOT VIOLATE THE GUARANTEE OF FREEDOM TO TRADE], Ninth Epoch, Volume XXXIV, August 2011, page 9. Available at: <https://sjf2.scjn.gob.mx/detalle/tesis/161230>