

RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

WHEREAS:

Article 227 of the Constitution of the Republic of Ecuador stipulates that public administration constitutes a service to the community that is ruled by the principles of efficacy, efficiency, quality, hierarchy, deconcentration, decentralization, coordination, participation, planning, transparency and assessment;

Article 364 of the Constitution of the Republic establishes that addictions are a public health problem and that the State is responsible for developing coordination information, prevention and alcohol, tobacco and mood-altering and psychotropic drug programs, as well as for offering treatment and rehabilitation to occasional, habitual and problem users, in addition to control and regulation of alcohol and tobacco advertising;

The World Health Organization's Framework Convention on Tobacco Control contributes to the protection of present and future generations against the devastating health, social, environmental and economic consequences of tobacco use and the exposure to tobacco smoke;

It is estimated that between 9 and 11 tobacco-associated deaths per day take place in Ecuador, especially from malignant tumors, cardiac and cerebrovascular diseases and chronic obstructive pulmonary disease (COPD);

The objective of the Tobacco Regulation and Control Act is to promote the right to health of the inhabitants of the Republic of Ecuador by protecting them from the consequences of the use of tobacco products and their harmful effects;

It becomes necessary to issue the regulatory statute which allows proper application of Constitutional principles, international instruments and national laws on tobacco control, and;

Pursuant to the power set forth in Article 147 (13) of the Constitution of the Republic,

HE HEREBY DECREES:

Issuance of the following **REGULATION TO THE TOBACCO REGULATION AND CONTROL ACT**

**TITLE I
PURPOSE AND SCOPE**

Article 1. – For the purposes of this Regulation tobacco products shall be understood as cigarettes, cigars, tobacco, chopped tobacco, hookah or water pipes, tobacco leaf extracts and other products of similar use, prepared entirely or in part by using tobacco leaves as raw

RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

material and which are designed to be smoked, inhaled, sucked, chewed or used as snuff. It also includes electronic nicotine delivery systems.

Article 2. – For the purposes of applying the Tobacco Regulation and Control Act and this Regulation, the following shall be understood:

Additives: Refers to ingredients used to increase palatability (sugars and sweeteners, such as glucose, molasses, honey and sorbitol); aromatic substances, such as benzaldehyde, maltol, menthol and vanillin or spices and herbs, such as cinnamon, ginger and mint); ingredients used to give the impression that the products offer benefits to health or that they represent reduced risks to health (vitamins, such as C and E, fruit and vegetable juices, amino acids, such as cysteine and tryptophan, and essential fatty acids, such as omega-3's and omega-6's); or ingredients associated with energy and vitality (such stimulant compounds as caffeine, guarana, taurine, glucuronolactone) which are added to tobacco products in order to make them more attractive, achieve greater adherence to its initial use or the continuation of its use.

Emissions: All substances released when the product is put to the use for which it is designed. For example, in the case of cigarettes and other tobacco products consumed by burning, "emissions" is understood as the substances that form part of the smoke. In the case of tobacco products for oral use without smoke, "emissions" is understood as the substances released during the process of chewing or sucking, and in nasal use refers to the substances released by the particulates during the inhalation process.

Space: Enclosed: Any space that is covered by a roof, regardless of its height, enclosed at its perimeter by 30% or more of partition or exterior walls, regardless of the type of material used, whether these constructions are temporary or permanent and regardless of the number, type or size of windows or other openings it may possess.

Ventilation systems, whatever their type, ventilation ability, location and/or quality, do not affect the definition of enclosed space.

Places of public access: All places belonging to public entities or private property that is accessible to the general public, or places of community use, aimed at any activity, regardless of who owns it or of the right to its access.

Tobacco sponsorship: Any type of contribution to any action, activity or individual, with the goal, effect or possible effect of directly or indirectly promoting a tobacco product or the use of tobacco.

Tobacco accessory products: Pipes, mouthpieces [tips], lighters, cigarette cases, ashtrays and others related to the different forms of tobacco use.

RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

Electronic Nicotine Delivery Systems: Are conceived for delivery of nicotine directly to the breathing apparatus. The term encompasses products containing tobacco derived substances but in which this is not necessary for them to work. They are battery devices that administer inhalable doses of nicotine by releasing a vaporized mixture of this substance and propylene glycol. The most popular is the one denominated "electronic cigarette".

Article 3. – Companies that prepare, import and market wholesale tobacco products listed in this regulation must be registered with the Ministry of Public Health and attach:

- a) Notarized copies of the corporation's or company's documents of incorporation, duly registered at the courts related to the production, importation and/or marketing; and,
- b) Documents on which there appear identifying data and physical addresses, telephone numbers, emails, websites, the addresses of social networks, etc., belonging to the institution. Data that must be updated each time there is a change in them.

Article 4. - Companies that prepare, import and market wholesale tobacco products must declare at the time of signup through a complete and clear technical report what type of tobacco product, brands and number of units per individual package for sale to the public they prepare, import or market, together with information on ingredients, components, additives and other substances used in their manufacture, design characteristics, residues and emissions, to which they shall add copies of study reports or tests done and laboratory data on where they were made.

This information shall not include data related to commercial secrets.

The information shall be updated annually up to June 30 of each year and will be made public in the manner stipulated by the National Health Authority.

Article 5. – The Ministry of Public Health shall regulate the content and emissions of tobacco products through Ministerial Agreement.

The corresponding information given to the National Health Authority by the tobacco industry in this regulatory process shall be updated annually up to June 30 of each year.

The National Health Authority shall define the information that must be distributed to the public in order to protect its health.

RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

TITLE II

CONSTITUTIONAL FRAMEWORK

Article 6. – For the purposes of the provisions for the First Transitional Provision of the Law, the National Coordinating Body for Tobacco Control, affiliated with the Ministry of Public Health, shall be the Inter-Institutional Committee for Anti Tobacco Struggle (CILA), created through Ministerial Agreement No. 955, published in the Official Gazette No. 146 dated March 10, 1989.

TITLE III

MARKETING AND PROMOTION

Article 7. – Any individual or legal entity may report those civil, commercial or industrial institutions or organizations to the competent authority which market tobacco products defined in this Regulation and which offer gifts in cash money or in kind in exchange for the consumption of such products.

Article 8. – Each year up to March 15, registered production or importation companies shall pick up the health warnings from the Ministry of Public Health in print and electronic versions with which they will market the product.

Article 9. – Advertising for cigarettes and other tobacco products shall be allowed exclusively in the interior of establishments whose access is for adults only. In no case shall the advertising be visible from the establishment's exterior, nor may it be displayed outside it.

Advertising in such places must occupy a maximum of one square meter on any of the premises' interior surfaces and may make no reference to sports, artistic, cultural, sexual or social success, wellbeing or health messages or images, nor may it be aimed at, make mention of or include in any way images of children and teenagers or who simulate being so.

Advertising and promotion on the exterior or on the doors of such places shall be sanctioned according to the Law.

Direct communications through email or the postal service for tobacco product advertising and promotion must be made with the inclusion of a record and supporting documents that ensure the recipients have requested them in writing, with a citizen identity card number, in order to receive such information.

RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

It shall be the responsibility of the producers, importers and marketers to prove that the recipient of the advertising and promotion is of majority age.

For the promotion of this type of personal advertising through email or the postal service among the adult population, its records and supporting documents shall be subject to control by the Health Authority.

Article 10. – It shall be understood that tobacco products are falsely, erroneously or deceptively promoted when they contain such terms and expressions as “filter plus”, “low in tar”, “light”, “ultra light”, “smooth” or other similar ones having the same intention and which insinuate the idea that some of these products are less harmful than others.

**TITLE IV
RESTRICTIONS ON USE**

Article 11. – The definition of enclosed spaces contemplated in the Law shall be considered to be buildings that meet the characteristics established in the Law and this Regulation, regardless of whether they are temporary or permanent.

Neither the amount, type or size of windows or other openings possessed by the enclosed space in question shall influence the above definition of an enclosed space.

The interior or exterior walls corresponding to 30% of the perimeter shown in the same article may not have windows that can be opened, nor shall they be at a distance of less than 3 meters from access doors, so that the flow of smoke is effectively prevented and tobacco smoke free areas are respected.

Ventilation systems of whatever type, ventilation capacity, location and/or quality do not affect the definition of an enclosed space shown in the Law and in this article.

Included in the definition of enclosed spaces are stairways, corridors and other physical areas located towards the interior of the buildings, even though these designated spaces may have natural ventilation.

Article 12. – The highest authority or highest board of directors or property owner who enjoys or who obtains a benefit in any way from the establishments defined as 100% tobacco smoke free shall, among the steps that they shall take for due implementation of the law, find the following:

- a) Regularly communicate through written and oral means that it is a tobacco smoke free space;

No. 1047

RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

- b) In the case of venues for sporting, artistic and cultural events, as well as bars, dance halls, casinos and the like, depending on the case, announce at the users' entrance, at the beginning of the event and while they are taking place in written and/or oral form over the speaker systems, if such is the case, that it is a 100% tobacco smoke free establishment and that smoking or keeping tobacco products lit are prohibited, including in the bathrooms and sanitary facilities, whose disobedience will entail the corresponding sanctions;
- c) Display signs written in the Spanish language and other languages, as needed, in places with the largest public gathering as well as the sanitary facilities, that express the following, as the case may be:

In upper case and in larger letters:

“BUILDING”/ “PREMISES” / “ESTABLISHMENT: / or the specific name of the place / “100% TOBACCO SMOKE FREE”

And in smaller letters and in lower case:

“Tobacco Regulation and Control Act”, Official Registry No. 497, July 22, 2011.

Reports for breaking the Law: to (telephone numbers and email addresses which the Ministry of Public Health and its deconcentrated bodies define).”

These signs shall include a commonly used graphic that will let the tobacco smoke free area distance to be adequately seen.

- d) Ashtrays and similar objects shall be removed from the interiors of spaces defined in the Law as 100% tobacco smoke free, and advertising and promotion bans, as defined in the Law, shall be respected.
- e) For compliance with and upholding of the legal provision not to establish areas designed for smokers, warning shall be given regarding the places where smoking is allowed pursuant to provisions of the Law or in open spaces, so long as these are not places accessed by the general public or workers.

In coordination with the health authority, autonomous decentralized governments shall demand the broadcast of messages in pre-event advertising, on tickets and while they are taking place, reporting that it is a 100% tobacco smoke free performance as one of the requirements for authorizing public performances in places defined as 100% tobacco smoke free spaces.

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RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

Article 13. – Establishments of higher education with open campuses not declared 100% tobacco smoke free shall establish areas separate from the enclosed spaces, duly identify them by written signs and other symbols, distributed them in different locations on the campus, see that they have none of the features of the enclosed spaces defined in the Law and this Regulation and ensure that in no case do they exceed 5% of the total surface of the open campus.

Article 14. – Hotels, hostels and other places of lodging that opt not to declare themselves 100% tobacco smoke free and want to dedicate up to 10% of their rooms for smokers must meet the prevailing safety norms, in addition to the following requirements:

- a) Rooms for smokers must preferably have balconies or terraces, plenty of windows that can be opened and air extraction systems to the outdoors in order to facilitate their ventilation;
- b) In the blocks aimed at smokers, no smoking is permitted in the hallways or in other common spaces, such as staircases. These spaces shall not be passed through by minors under the age of 18 years of age.
- c) Rooms for smokers and non-smokers shall be clearly identified at their entrance doors.;
- d) In no way shall children and teenagers under the age of 18 be housed in rooms for smokers, even when there is a scarcity of rooms; and,
- e) When new guests arrive, they must be clearly informed of the hotel's characteristic, the difference in the rooms and the norms defined in this Article.

These statutes shall also be displayed in visible locations in the place of lodging and in each of the rooms.

**TITLE V
CITIZEN PARTICIPATION**

Article 15. – Through its website and other mechanisms in the IT network, as well as through various communications media, the Ministry of Public Health and its National Tobacco Control Program, with support from the National Office of Communications and CILA, shall report to the citizenry on advances and problems in implementing the Law and the Regulation, plus other tobacco control-related information.

No. 1047

RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

In addition, all provinces shall facilitate the forms of free access via telephone, internet or physically so that citizens may make reports on non-compliance with the Law and the Regulation.

TITLE VI

SYSTEM OF ADMINISTRATION AND SANCTIONING

Article 16. – The National Health authority shall establish preventive measures with participation and social control so that the authorities and institutional boards of directors, public servants and the owners of establishments who disobey the Law through action or omission will be subject to its provisions.

Measures are related to the issuing of policies, the structuring of programs or plans, information and community education, institutions and individuals in particular.

Article 18. – Tobacco products which were seized shall be destroyed by the Health Authority by using methods that do not affect the environment as much as possible, stating this for the record in a document that will be signed by the Authority the Secretary and the products' owner, if there is one, whose original shall be sent to the corresponding authority for his information.

SOLE TRANSITORY PROVISION. – As of July 15, 2012, no tobacco products may be circulated in the country without the health warnings that were prepared and approved by the National Health Authority.

SOLE PROVISION OF REPEAL. – All statutes of equal or lesser rank which oppose this Regulation are hereby repealed.

Issued at the National Palace in Quito on February 10, 2012

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