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EXECUTIVE BRANCH

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OFFICE OF THE PRESIDENT OF THE REPUBLIC

Official Letter No. T. 5994-SNJ-11-964

Quito, July 14, 2011.

HUGO E. DEL POZO BARREZUETA
Director of the Official Gazette
Hand Delivered

Dear Sir:

By way of official letter No. PAN-FC-0674 dated June 17 of the current year, Architect Fernando
Cordero Cueva, President of the National Assembly, put forth for consideration by the President
of the Republic the draft bill "ORGANIC LAW FOR THE REGULATION AND CONTROL OF
TOBACCO".

This draft bill was endorsed by the President on July 13, 2011, so that pursuant to the provisions
of Articles 137 of the Constitution of the Republic and 63 of the Organic Law of the Legislative
Branch, I hereby submit to you the aforesaid law in an original and certified copy, together
with the certificate in question, for its corresponding enactment in the Official Gazette.

Furthermore, I shall appreciate your sending the original copy to the National Assembly for
suitable purposes once the respective publication is made.

Sincerely,

Signed) Dr. Alexis Mera Giler, National Legal Secretary.
REPUBLIC OF ECUADOR
NATIONAL ASSEMBLY
CERTIFICATION

In my capacity as Secretary General of the National Assembly, I hereby certify that the bill ORGANIC LAW FOR THE REGULATION AND CONTROL OF TOBACCO was discussed and approved on the following dates:

FIRST DEBATE: April 6 and 7, 2011
SECOND DEBATE: June 7 and 14, 2011

QUITO, June 16, 2011

Signed) Dr. Andrés Segovia S., Secretary General

REPUBLIC OF ECUADOR
NATIONAL ASSEMBLY
PLENUM

WHEREAS:

Article 14 of the Constitution of the Republic recognizes the right of the people to live in a healthy and ecologically balanced environment that guarantees good living, and it states the preservation of the environment to be of public interest;

Article 19 of the Constitution of the Republic establishes that "the law shall regulate the prevalence of content with information, educational and cultural goals in the programming by the media";

Article 39, Subsection two, of the Constitution of the Republic stipulates that the State shall recognize and guarantee people the right to live in a healthy, ecologically balanced environment that is free of pollution and in harmony with nature;

Article 32 of the Constitution of the Republic stipulates that "health is a right guaranteed by the State whose realization is linked to the exercise of other rights, among them the right to water, food, education, physical culture, work, social welfare, healthy environments and others that support good living;

Article 83 (6) of the Constitution of the Republic enshrines that Ecuadorians have the duty and responsibility to respect the rights of nature and to preserve a healthy environment;

Article 84 (6) of the Constitution of the Republic enshrines as a Constitutional guarantee the obligation of the National Assembly to formally and materially make the laws and other legal
statutes conform to the rights set forth in the Constitution and international treaties and those which may be necessary to guarantee human dignity;

Article 133 (2) of the Constitution of the Republic establishes that it shall be organic laws which regulate the exercise of rights and Constitutional guarantees;

Article 364 of the Constitution of the Republic establishes that addictions are a public health problem and that it is the responsibility of the State to develop coordinated information on tobacco information, prevention and control and to offer treatment and rehabilitation to occasional, habitual and problem users. The State must also control and regulate alcohol and tobacco advertising;

The Republic of Ecuador in 2004 signed its adherence to the World Health Organization’s Framework Convention on Tobacco Control, thereby assuming the responsibility of adopting the directives meant to defend and protect present and future generations from possible environmental, health, social and economic devastations caused by the use of tobacco, its derivatives and the exposure to tobacco smoke;

Through Legislative Resolution No. R-26-123 dated May 25, 2006, published in the Official Gazette No. 287 on June 8, 2006, the then National Congress ratified the World Health Organization’s Framework Convention on Tobacco Control, which was placed for safekeeping at the Headquarters of the United Nations on July 25, 2006;

On September 5, 2006, the then National Congress approved the Amendatory Organic Law to the Organic Law of Consumer Defense, published in the Official Gazette No. 356 dated September 14, 2006, which regulated the use and consumption of tobacco and its derivatives without the objective of safeguarding from the harmful effects of tobacco consumption having taken effect or having been carried out.

Having ratified the World Health Organization’s Framework Convention on Tobacco Control and its protocols, the Republic of Ecuador has taken on the commitment to promote legislative measures to established proper policies designed to prevent and reduce tobacco consumption, the addiction to nicotine and the exposure to tobacco smoke;

It is necessary to issue a Law to prevent and control smoking as a measure for the prevention of sickness, disability and premature deaths and which is beneficial and has a positive impact on the environment the State economy and on business and families; and,

With the Constitutional and legal powers conferred upon him, he hereby issues the following:
ORGANIC LAW FOR THE REGULATION AND CONTROL OF TOBACCO

INTRODUCTORY TITLE

Purpose and Scope

Art. 1. – Purpose. – The purpose of this Law is to promote the right to health of the inhabitants of the Republic of Ecuador by protecting them from the consequences of consuming tobacco products and their harmful effects.

Art. 2. – Scope. – The provisions of this Law are of a public order, application and obligatory observance throughout the land.

The use of tobacco in ancient manifestations is not subject to the contents of this Law.

TITLE I

Institutional Framework

CHAPTER ONE

Responsibilities of the State

Art. 3. – Responsibility of the National Health Authority. – The national Health Authority is responsible within the scope of its competency for the formulation and execution of policies and strategies for the entire fulfillment of this Law.

Art. 4. – Responsibility in Educational Matters. – Through the Ministries of Education and Public Health sectors, and in coordination with other public and private institutions, the State shall develop sporting, health promotion, educational and prevention, detection and intervention activities on the consumption of tobacco products and their harmful effects.

Art. 5. – Responsibility in Environmental Matters. – It is the responsibility of the State through the Ministries of Environment, Industry and Agriculture sectors, within the scope of their respective competencies and in coordination with other public and private institutions, to design and follow up on policies related to the cultivation, industrial processing, commerce and consumption of tobacco.

Art. 6. – Tax and Customs Responsibility. – It shall be the responsibility of the Internal Revenue Service to promote and adopt measures for the tax control of tobacco products and of the National Customs Service to fight all forms of illegal trade and smuggling of such products, according to Law.

Art. 7. – Competencies on Control and Oversight. – The National Health Authority, in coordination with the Ministry charged with domestic security, the National Police and the
decentralized, autonomous governments shall be responsible for the control and oversight of compliance with the provisions of this Law and its regulations.

CHAPTER TWO

The National Health Authority

Art. 8. – Execution. - The National Health Authority shall carry out the activities necessary for compliance with this Law, notwithstanding those pertaining to other institutions.

Art. 9. – Coordination. – For the fulfillment of this Law, the National Health Authority shall coordinate with other public and private institutions and civil society organizations on actions to control and regulate tobacco and its harmful effects.

Art. 10. – Competencies. – The National Health Authority shall have the follow competencies:

a. Establish the public policies for the control of tobacco and other accessory and related products, bearing in mind the health risk, as well as the taking of steps to prevent consumption by children and teenagers;

b. Offer treatment and rehabilitation to smokers who may need it and create specialized centers for the purpose;

c. Monitor the components of tobacco products and other accessories and related products within the scope of its competency;

d. Establish methods of analysis to verify that the manufacture of tobacco products and their accessories is made according to the applicable technical and legal provisions;

e. Determine the information that manufacturers are required to provide to the pertinent authorities and the general public with respect to tobacco products and their harmful effects;

f. Issue the regulatory provisions regarding the characteristics, specifications and procedures regarding the packaging and labeling of tobacco products in all their presentations in which they are marketed, pursuant to the provisions of this Law;

g. Issue the regulatory provisions for the placement and content of non-advertising information in places where tobacco products are sold;

h. Issue the regulatory provisions for one hundred percent (100%) tobacco smoke free spaces according to this Law;

i. Promote educational bills to boost smoking control policies;

j. Promote actions of research and other steps that will allow the advances in tobacco control and compliance with this Law to be assessed;
k. Promote citizen participation in the execution of anti-smoking programs; and,

l. Others that may be established in this Law and its regulations.

The National Health Authority, through public servants appointed for the control and oversight of the traffic in tobacco products, their accessories and related products, are empowered in coordination with the corresponding authorities to intervene at seaports and airports, borders and, in general, anywhere in the land for the purpose of applying the health regulatory provisions.

Art. 11. – Anti-Smoking Program. – Within the public health policy framework, the National Health Authority shall define and implement the tobacco control program and the discouragement of its consumption by making children and teenagers its priority.

CHAPTER THREE

Education for Prevention

Art. 12. – Educational Curriculum. – In coordination with the National Health Authority, the National Educational Authority shall consider cross-disciplinary strategies for the prevention, detection and early intervention of smoking in the educational curriculum and shall propose effective methodologies for their application.

Art. 13. – Communications and Education Campaigns. – In coordination with other public and private institutions and civil society, the National Health Authority and the National Educational Authority shall schedule and carry out information, communication and education activities and campaigns and make use of all technological resources and tools to prevent tobacco use by the public and, in particularly by workers, children and youth.

TITLE II

Commercialization

CHAPTER ONE

Bans and Restrictions on Sales

Art. 14. – Bans with Regard to Minors. - The sale and dispensing of tobacco products to minors and by minors under the age of 18 is prohibited.

Art. 15. – Ban on Sales. – The sale of tobacco products in childcare centers, public and private educational institutions at all levels, public and private health establishments, pharmacies, institutions and settings designed for the practice of sports and sporting , artistic and cultural performances, public institutions and offices and public and private recreational spaces for children and teenagers is banned.
Art. 16. – Restrictions on Sales. – The sale of tobacco products is obligatorily subject to the following restrictions, as a result of which the following is banned:

a. Placing cigarettes in places that let the consumer take them directly;

b. Marketing, selling, distributing or displaying any tobacco product through automatic vending machines;

c. Marketing, selling, distributing, displaying, promoting or producing any object that is not a tobacco product which contains elements from a tobacco product brand; and,

d. Manufacturing, importing, selling and distributing candies, snacks, toys and other objects having the shape and design of tobacco products and that may become attractive to children and teenagers.

Art. 17. – Ban on Free Distribution. – It is forbidden to freely distribute tobacco products to the general public for promotional purposes, as well as to use incentives that may encourage the purchase of such products.

CHAPTER TWO

Packaging, Labeling, Warnings and Presentation

Art. 18. – Packaging and Labeling. – Outside packages and labeling of tobacco products expended within the country must display captions and graphic illustrations or warning images that show the harmful effects of their consumption and be subject to the following provisions:

a. The warnings will be prepared and approved by the National Health Authority;

b. They shall be printed in a rotating manner and rotated yearly directly on the packages;

c. They shall be of a high preventive impact and be clear, visible, legible and must not be obstructed by any means;

d. They shall include graphic illustrations and messages related to the harmful effects of tobacco, must occupy sixty percent (60%) of the principal faces and be located on the lower portion of each face;

e. The health information must be directly printed on the package and fill seventy (70%) [percent] of one of the side faces;

f. Information on the tobacco components and emissions shall be qualitative only;

g. Packaging in presentations of fewer than ten units is prohibited. For other tobacco products, the package must contain no fewer than ten grams; and,
h. Both the warning captions and the text information must appear in the Spanish language.

CHAPTER THREE

Advertising, Promotion and Sponsorship

Art. 19. – Ban on Advertising, Promotion and Sponsorship. - Any type of advertising, promotion and/or sponsorship of tobacco products is banned in all mass media, as well as in any other form of interpersonal communication that may be identified. This ban includes the sponsorship by tobacco products at sporting, cultural and artistic activities, along with the promotion of programs of social responsibility by the tobacco industry.

Cigarette advertising and promotion shall be allowed only inside places where the product is marketed and accessed exclusive by those of majority age and through direct communication by email or the postal services, so long as the adult consumer asks to receive information in writing, and his being of majority age is verified.

Art. 20. – Ban on Deceptive Advertising. – It is prohibited for tobacco product packages and labels to promote themselves falsely, erroneously or deceptively so to lead to error with respect to their characteristics, health effects, risks or emissions.

It is also prohibited to use terms, descriptive elements, figurative symbols or those of another kind that have the direct or indirect effect of creating the false impression that a particular tobacco product is less harmful than another.

TITLE III

Restrictions on Use

CHAPTER ONE

Smoke Free Spaces

Art. 21. – Smoke Free Spaces. – The following are hereby declared to be one hundred percent (100%) tobacco smoke free spaces, and it is also hereby forbidden to smoke or to keep tobacco products lit in:

a. All enclosed spaces of public institutions;

b. All enclosed spaces that are workplaces, places for public service and of public access;

c. All enclosed or open, public or private spaces that pertain to health offices and education at any level, except for open spaces of higher education establishments that are duly signposted;
d. Means of public transportation for the general public; and,

e. Enclosed public and private environments designed for sports activities.

For the application of this article, enclosed space shall be understood to be any space covered by a roof, regardless of how high it is, enclosed on its perimeter by 30% or more of interior or exterior walls, regardless of the material used.

Notwithstanding the aforementioned in this article, any public or private institution may be declared one hundred percent (100%) tobacco smoke free if it is deemed as such.

Art. 22. - Adoption of Measures on Smoke Free Spaces. - The proprietor or whoever is the tenant of the spaces defined by this Law as one hundred percent (100%) smoke free, shall take all the steps necessary for its due implementation.

In the event that all the necessary steps for implementation have been taken and it is the smokers who are not obeying the restrictions, the fact shall be notified to the competent authority, showing that all necessary precautions were taken. Only in this case of exception shall there be no responsibility.

Art. 23. – Exceptions on Smoke Free Spaces. – It is prohibited to establish areas designed for smokers in places established as one hundred percent (100%) smoke free according to this Law.

Exempted from this ban, and through a willful decision by the proprietor, are rooms in places of lodging at a maximum of 10% of their capacity, exclusively dedicated to smokers, provided they comply with the regulations issued by the National Health Authority and this Law.

CHAPTER TWO

Signage

Art. 24. – Signage. – All places defined as one hundred percent (100%) smoke free in this Law must have signage that is graphic, written or any other type, in the Spanish language and, where necessary, in other official languages, that clearly indicates that they have been declared as such.

The signs must include a telephone number to report the failure to obey this Law and/or its regulations.

TITLE IV

Citizen Participation and Public Action

SOLE CHAPTER

Citizen Participation and Public Action
Art. 25. – Citizen Participation. – The National Health Authority and decentralized autonomous governments shall promote the participation of civil society in the prevention of smoking and control of tobacco products in the following actions:

   a. Promotion of 100% smoke free spaces;
   b. Education for the prevention and control of smoking in educational establishments, neighborhoods and urban and rural communities;
   c. Circulation of the legal provisions on the matter of tobacco products control; and,
   d. Actions to help with the application of this Law.

Art. 26. – Contact. – The National Health Authority shall put computer and free access telecommunications systems into operation so that citizens may contact the Authority and make reports, complaints and/or suggestions related to the one hundred percent (100%) tobacco smoke free spaces.

TITLE V

ADMINISTRATIVE AND PENALTY SYSTEM

CHAPTER ONE

Administrative and Regulatory Actions

Art. 27. – Legal Activity. – Administration actions, regulatory actions, the challenging of administrative actions, administrative competency, the exercise of competency and administrative procedure shall be subject to the provisions of this Law, its regulations and the Statute of Executive Branch Administrative Legal System.

Art. 28, - Responsibility of the Authorities. – The authorities who are responsible for applying this Law who do not meet their obligation shall be subject to administrative, civil and/or criminal actions, as applicable, pursuant to Law.

CHAPTER TWO

System of Administrative Penalties

Section One

Inspection and Control and Preventive Measures
Art. 29. – Inspection and Control. – Within the scope of this Law the National Health Authority shall perform the duties of inspection and control by its own account or at the party’s request.

Art. 30. - Preventive Steps. - In the event that actions or omissions take place that may cause harm or constitute a danger to people’s health as a result of the failure to observe this Law, the National Health Authority shall establish the preventive steps to be taken, according to the corresponding regulation.

Section Two

Violations and Administrative Sanctions

Art. 31. – Sanctions. – Administrative violations determined in this Law shall be sanctioned by the National Health Authority in the following manner:

a. Fine;

b. Temporary closure of the establishment for one to eight (8) days; and,

c. Temporary closure of the establishment for fifteen (15) day for subsequent repeat violation.

These sanctions shall be carried out notwithstanding any civil and criminal actions that those affected by tobacco products may carry out against the ones who caused the harm.

Art. 32. – Failure to Comply with the Restrictions on Use. - The proprietor or whoever is the tenant of the spaces defined by this Law as one hundred percent (100%) smoke free and who fails to comply with the provisions of Title II of this Law regarding the restrictions on use shall have imposed upon him a fine of from one (1) to five (5) unified basic remunerations of the general private worker.

In the event of a repeat violation, he shall have imposed upon him a fine of from six (6) to ten (10) unified basic remunerations of the general private worker. In the event of a second repeat violation, the sanction shall be temporary closure of the establishment from one (1) to eight (8) days, and for subsequent repeat violation cases, the establishment shall be sanctioned with closure for fifteen (15) days.

The sanction for closure shall not be applied to health or educational institutions, nor to bodies and offices of the public sector.

Art. 33. – Failure to Comply with the Restrictions on Sales. – Whosoever in his institutions or premises fails to comply with the bans shown in Chapter I of Title II of this Law regarding the restrictions on sales, shall have imposed upon him a fine of from one (1) to five (5) unified basic remunerations of the general private worker.

In the event of a second reoccurrence, he shall have imposed upon him a fine of from six (6) to ten (10) unified basic remunerations of the general private worker. In the event of a second reoccurrence, the sanction shall be temporary closure of the establishment from one (1) to eight
(8) days, and for subsequent cases of reoccurrence, the establishment shall be sanctioned with closure for fifteen (15) days.

The sanction for closure shall not be applied to health or educational institutions, nor to bodies and offices of the public sector.

Art. 34. – Failure to Comply with the Provisions on Advertising, Promotion and Sponsorship by the Media. - Media that fail to comply with the bans established in Chapter III of Title II of this Law regarding advertising shall be sanctioned with a fine of from ten (10) to one hundred (100) unified basic remunerations of the general private worker. In the event of reoccurrence, they shall be sanctioned with a fine of from twenty (20) to two hundred (200) unified basic remunerations of the general private worker. In the event of a second reoccurrence, they shall be sanctioned with a similar fine and temporary closure of from one (1) to eight (8) days, and in the event of a subsequent reoccurrence, they shall be sanctioned with a similar fine and temporary closure of fifteen (15) days.

Art. 35. – Failure to Comply with the Provisions on Advertising, Promotion and Sponsorship. – An Individual or legal entity that is not the media and who fails to comply with the bans established in Chapter II of Title II of this Law regarding advertising and sponsorship shall be sanctioned with a fine of from one hundred (100) to two hundred (200) unified basic remunerations of the general private worker. In the event of reoccurrence, he or it shall be sanctioned with a fine of from two hundred (200) to four hundred (400) unified basic remunerations of the general private worker and temporary closure of from one (1) to eight (8) days, and in the event of subsequent reoccurrence, he or it shall be sanctioned with a similar fine and temporary closure of fifteen (15) days.

Art. 36. – Failure to Comply with the Provisions on Labeling. – Producers and marketers who fail to comply with the provisions in Chapter II of Title II of this Law shall be sanctioned with a fine of from fifty (50) to one hundred (100) unified basic remunerations of the general private worker. In the event of reoccurrence, they shall be sanctioned with a fine of from one hundred (100) to two hundred (200) unified basic remunerations of the general private worker and temporary closure of up to eight (8) days, and in the event of subsequent reoccurrence, they shall be sanctioned with a similar fine and temporary closure of fifteen (15) days.

In addition to the sanctions set forth in the above section, the National Health Authority shall move to seize the articles that have not complied with the provisions of Chapter II of Title II of this Law.

Art. 37. – Failure to Comply by the Smoker. – Any person who makes use of tobacco products in spaces defined as one hundred percent (100%) smoke free, according to this Law, shall be sanctioned with a fine equivalent to twenty-five percent (25%) of the unified basic
remunerations of the general private worker, who shall be charged according to the procedure established for the purpose by the regulations to this Law.

**Art. 38. – Sanction on Public Servants.** – The sanction on public servants who fail to comply with this Law within the performance of their duties shall be applied pursuant to the provisions of this Law that regulates the performance of public service and its regulations.

**Art. 39. – Compulsory Jurisdiction.** – For collection of the fines imposed by application of this Law the National Health Authority shall have compulsory jurisdiction, for which the procedure established in the Civil Code of Procedure shall be followed.

**Art. 40. – Disposition of the Fines.** – The total value of the fines applied by the National Health Authority for failure to comply with this Law shall be deposited into the Sole Account of the National Treasury and be designated exclusively for the Smoking Control Program.

**Art. 41. – Educational Procedures.** - The National Health Authority shall apply educational procedures to violators and carry out recovery and treatment programs on persons who require them.

**GENERAL PROVISIONS**

**ONE.** – In case of question about the scope when applying one of the articles of this Law, the interpretation that most favors the right to health shall prevail.

**TWO.** – The National Health Authority shall be responsible for coordinating compliance with the provisions of the World Health Organization’s Framework Convention on Tobacco Control (FCTC) and its additional protocols to which the Republic of Ecuador is signatory with whatever public and private institutions are necessary.

**THREE.** - The National Health Authority shall be responsible for carrying out this Law in conjunction with the national coordinating body for tobacco control.

**FOUR.** - Government and municipal authorities must adapt their regulations, ordinances and other statutory provisions according to their respective competencies so that they are in accordance with this Law, notwithstanding the direct application of this Law.

**FIVE.** - Through the National Health Authority and other competent institutions, the State shall promote socio-educational actions meant to reduce the supply, demand and consumption of tobacco products.

**SIX.** – The State shall assign the funds needed for the execution and oversight of the obedience with this Law through the health sector budget.

**SEVEN.** – In applying this Law, the rights of workers must be respected. Under no circumstances, nor through the pretext of applying the statutes established in this Law, shall sanctions or provisions be established that breach their job stability.
DEROGATORY PROVISIONS


TWO. – Articles 40, 41, 42 and 43 of the Organic Health Law (Law No. 67), published in the Supplement to the Official Gazette No. 432 dated December 22, 2006, are hereby repealed.

THREE. – All statutes of equal or lesser rank that oppose this Law are hereby repealed.

TRANSITIONAL PROVISIONS

ONE. – The President of the Republic shall, within the period of ninety (90) days from when this Law goes into effect, create the national coordinating body for tobacco control, attached to the National Health Authority. Until the date of its formation, the Inter-Institutional Committee on the Fight Against Smoking, CILA, created through Ministerial Agreement No. 955 dated March 10, 1989, shall continue fulfilling these duties.

TWO. – The President of the Republic shall issue the regulations for the execution of this Law within the period of ninety (90) days from its publication in the Official Gazette. These regulations shall be periodically updated in concert with the progress of the directives and protocols of the Framework Convention on Tobacco Control (FCTC) which are approved by the Conferences of the Parties of that Convention.

THREE. – Decentralized, autonomic canton sectional governments shall issue the corresponding ordinances for adaptation to this Law within three hundred (360) [sic] days after this Law goes into effect.

FOUR. – For implementation of the statutes related to cigarette packaging or other manufactured or imported tobacco products, a non-extendable period of three hundred sixty (360) days is granted from when this Law goes into effect.

FIVE. – The authority competent in the matter of importations shall, in coordination with the National Health Authority, oversee that tobacco products and their accessories comply with this Law and its regulations.

SIX. – Once this Law is enacted, and in coordination with the related entities, the National Health Authority shall carry out informational and educational activities regarding its content over the year following enactment of this Law.

SEVEN. – The National Health Authority shall create the Tobacco Control Program within a period of one year from when this Law takes effect.
FINAL PROVISION. – This Law shall take effect following the date of its publication in the Official Gazette.

Issued and signed at the headquarters of the National Assembly, located in the Metropolitan District of Quito, Pichincha Province, on the fourteenth day of the month of June in the year two thousand eleven.

Signed) Fernando Cordero Cueva, President.

Signed) Dr. Andrés Segovia S., Secretary General.

National Palace in San Francisco de Quito, Metropolitan District, July thirteenth, two thousand eleven.

Let it be approved and enacted

Signed) Rafael Correa Delgado, Constitutional President of the Republic.

This is a copy of the original. – I hereby certify:

Quito, July 13, 2011.

Signed) Atty. Oscar Pico Solórzano, National Deputy Secretary of Public Administration