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OFFICIAL GAZETTE

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LAW No. 5,538

WHICH AMENDS LAW No. 4,045/10, “WHICH AMENDS LAW No. 125/91, AMENDED BY LAW No. 2,421/04, ON ITS TAX SYSTEM, WHICH REGULATES ACTIVITIES RELATED TO TOBACCO AND ESTABLISHES HEALTH MEASURES TO PROTECT THE POPULATION.”

THE CONGRESS OF PARAGUAY HEREBY ENACTS AS LAW

CHAPTER I
GENERAL PROVISIONS

Article 1: Objective of the Law.

This is a public policy law that aims to establish the necessary measures to protect the health of individuals from the health, social, environmental, and economic consequences of tobacco use and exposure to tobacco product smoke.

This law regulates the measures that the Government will implement to apply the WHO Framework Convention on Tobacco Control (WHO-FCTC), approved and ratified by Law No. 2969/2006.

Article 2: Enforcement Authority and Jurisdiction.

Municipalities of the Republic, in cooperation with the National Police, are hereby established as Enforcement Authorities of this law, for which they must implement the mechanisms of information and reporting on the scope of this law, without detriment to the respective intervention of the following institutions in the sphere of their jurisdiction:

- a)** Regarding Public Health and Health Monitoring, the Ministry of Public Health and Social Welfare
- b)** Regarding tax matters, the Ministry of Finance
- c)** Regarding agricultural production of tobacco, the Ministry of Agriculture and Farming
- d)** Regarding distribution, marketing, and consumer protection, the Ministry of Industry and Trade, in this case in coordination with the municipalities, as established by Law No. 1,334/98 “REGARDING CONSUMER AND USER PROTECTION.”

These Government Organizations and Entities (OEE, by its Spanish acronym) are authorized to establish mechanisms of interinstitutional coordination to best fulfill the objectives of this law; the respective Municipality must be in charge of coordinating actions and measures.

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Article 3. Objectives.

The following are objectives of this law:

- a) To reduce the use of tobacco products
- b) To regulate the content of tobacco products
- c) To regulate dissemination of information about tobacco products
- d) To regulate the packaging and labelling of tobacco products
- e) To reduce exposure of people to harmful effects of tobacco smoke
- f) To reduce health, social, and environmental damage caused by tobacco use
- g) To prevent the start of tobacco use, especially in children and teenagers
- h) To encourage promotion, health education, and knowledge dissemination to current and future generations regarding the risks of using tobacco products and of exposure to tobacco smoke
- i) To regulate the advertisement, promotion, and financial support of tobacco and tobacco products
- j) To regulate the illegal sale of tobacco products
- k) To establish the system of sanctions and the organizations authorized to apply them

Article 4. Definition of Terms Used in the Law

For the purposes of this law, the terms indicated below will be understood as follows:

- a) **Tobacco:** Plant in the species *Nicotiana tabacum* that creates addiction if its leaves are consumed in their natural form or if they are industrially modified.
- b) **Tobacco products:** Products prepared fully or partially by using tobacco leaves as a raw material, and intended to be smoked, spat, chewed, or used as snuff, vaped, smoked, or inhaled in e-cigarettes, vape pens, etc.
- c) **Smoking:** Being in possession or control of a lit tobacco product, regardless of whether the smoke is being actively inhaled or exhaled.
- d) **Tobacco smoke:** Emission given off from the burning end of a cigarette, cigar, pipe, or other similar element, with tobacco products, generally in combination with exhaled smoke.

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e) Advertising and promotion of tobacco: Any form of advertisement, recommendation or sales action with the purpose, effect, or possible effect of directly or indirectly promoting a tobacco product or tobacco use.

f) Tobacco financial support: Any form of contribution to any action, activity, or individual with the purpose, effect, or possible effect of directly or indirectly promoting a tobacco product or tobacco use.

g) Promotion of tobacco: Any stimulation of the demand for tobacco products, which may include advertising and any action intended to attract attention and draw the interest of users or non-users of tobacco or tobacco-derivative products.

h) Public space or public places: Any place accessible to the general public and/or for collective use, regardless of who is the owner and regardless of who has the right to enter said places.

i) Closed public spaces or inside or closed area: Any space covered by a roof or enclosed with two or more inside walls or outside walls, regardless of the material used for the roof, inside walls, or outside walls, and regardless of whether the structure is permanent or temporary.

j) Workplace: Any place used by people during their employment or job. This definition includes paid and volunteer work. In addition, workplaces include not only places where the work is performed, but also all connected, attached places that workers usually use in the course of their job, such as hallways, elevators, stairwell skylights, vestibules, grouped facilities, cafeterias, restrooms, meeting rooms, eating areas, and attached structures such as sheds, etc. Vehicles used in the course of a job such as: taxis, public transportation, ambulances, school transportation, or other types of transportation.

k) Public transportation service: Any transportation service that is used or may be used to transport individuals from one place to another, either for profit or not.

l) Tobacco control: The group of strategies to reduce supply and demand of tobacco products, in order to improve the health of the population by reducing tobacco product use and eliminating second-hand tobacco smoke exposure.

m) Packaging: Comprises the following:

1. Primary packaging or pack: Any container that has direct contact with the tobacco product in order to protect it from deterioration, contamination, or adulteration, and to facilitate handling.

2. Secondary packaging or carton: Any container that contains two or more primary packages in order to protect them and facilitate their sale until reaching the end user. The secondary packaging is used to group several primary packages into a single retail unit.

n) Outer packaging and labelling: Any packaging or labelling used in the retail sale of tobacco products.

o) Health warning or message: Warnings directed to users and to the public about the risks and damages to health caused by use of tobacco products and

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exposure to tobacco product smoke. These may consist of pictograms, images, texts, etc.

p) Pictogram: Part of the health warning that may include photographs or images representing the negative effects of tobacco products.

q) Labelling: Labelling is understood as the set of inscriptions, texts, brands, and layouts that are printed on any primary or secondary package containing cigarettes or any tobacco product derivative.

r) Brand extension: A brand extension occurs when a brand name, emblem, registered trademark, logo, or trademark or any other distinctive feature (including distinctive color combinations) of tobacco is linked to a non-tobacco product or service, such that the tobacco product is usually associated with the non-tobacco product or service.

s) Generic trademark: A brand extension occurs when a brand name, emblem, registered trademark, logo, or trademark or any other distinctive feature (including distinctive color combinations) of a tobacco product [*sic*] or non-tobacco service is linked to a tobacco product or tobacco company such that the tobacco product or tobacco company is usually associated with the non-tobacco product or service.

t) Products related to use: Items that are directly linked to the action or rituals of the smoker, such as: lighters, matches, ashtrays, cigarette cases, etc.

u) Tobacco product sellers: Individuals or legal entities who perform any sales activity in order to sell, wholesale or retail, tobacco products, tobacco derivatives, and products related to use.

v) Point of sale: Point of sale is understood for the purposes of this law as the cash register or similar in a sales establishment.

w) Distributor: Any individual or legal entity, domestic or foreign, de facto or de jure entity, private or public, using their own name or that of a third party, acting on their own behalf or that of a third party, that habitually distributes or sells, wholesale or retail, a tobacco product.

x) Manufacturer: Any individual or legal entity that manufactures tobacco products.

y) Tobacco industry: The industry that encompasses manufacturers, distributors, wholesalers, and importers of tobacco products.

CHAPTER II

REGULATION OF SALE, SUPPLY, AND TRADE OF TOBACCO PRODUCTS.

Article 5. Sale and Supply of Tobacco Products.

a) Retail sale and/or supply of tobacco products may only be performed in person and directly;

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b) The sale and/or supply of any tobacco product indirectly or not in-person, via distance selling or similar procedures, for which the buyer's identification cannot be clearly or appropriately verified, is prohibited.

c) Sales to the user by telephonic, digital, electronic, postal means, etc. is prohibited; free delivery, supply, or distribution of any tobacco product, including free samples, is prohibited.

d) Sale of tobacco products to the public must be performed at checkouts or at points of sale in establishments, such that they are not directly accessible to the end user.

e) Sale of loose or retail cigarettes and packs that contain fewer than ten cigarettes is prohibited, and use of vending or dispensing machines for tobacco products or tobacco-derivative products is prohibited.

f) The sale, supply, or delivery of tobacco products within a one hundred-meter radius of public or private educational, sporting, and health establishments. The distance will be measured between the entrance doors of the respective establishments, through sidewalks, streets, and public spaces.

Article 6. Places Expressly Prohibited from Selling Tobacco Products

Notwithstanding the provisions in the previous article, the sale and supply of tobacco and tobacco-derivative products is prohibited in the following places and spaces:

a) Health centers or establishments and hospitals

b) Government agency and public law entity centers and offices

c) Public, private, subsidized, and training educational centers

d) Sporting facilities

e) Cultural centers, lecture halls, exhibition halls, libraries, conference halls, auditoriums, and museums

f) Recreational or entertainment centers for minors

Article 7. Prohibition of Sale by and to Minors

a) The marketing, sale, supply, and/or delivery of tobacco products, brand extensions or generic trademarks of tobacco products to individuals under 18 years of age is prohibited.

b) Wholesale and retail sellers of tobacco products must place visible, clear, and prominent signs inside places of sale indicating the cost of the product and the specific information that sale of tobacco products to individuals under 18 years of age is prohibited. Permanent or

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occasional vendors who sell tobacco products must require the presentation of an identification card or other identity document at the time of sale.

c) Individuals under 18 years of age may not be employed by other individuals for the promotion, sale, or marketing of tobacco products.

d) The import, manufacture, marketing, sale, supply, or delivery of sweets, snacks, toys, and other objects in the shape and design of tobacco products that may be attractive to minors is prohibited.

Article 8. Prohibited Objects

Promoting, displaying, producing, marketing, selling, or distributing any object that is not a tobacco product but contains any of the brand elements or any type of design or sound signal that identifies it with tobacco products is prohibited.

**CHAPTER III
REGULATION OF TOBACCO PRODUCT USE**

Article 9. Tobacco Smoke-Free Spaces

a) Smoking, vaping, or e-smoking or keeping tobacco products lit is prohibited in the following places and spaces listed below, except in sites especially authorized for such purpose:

b) Nursery, primary, and intermediate school establishments, regardless of whether they are open or closed spaces

c) Public passenger transportation units, including land, air, rail, sea, and river, including elevators, in addition to closed spaces of the public transportation stations, whether for land, river, rail, or air

d) Stadiums, movie theaters, theaters, libraries, auditoriums, museums, and any other enclosed area intended for public activities

e) Closed spaces of teaching centers, institutes, and universities, such as classrooms and conference rooms

f) Health centers and establishments, such as clinic, hospital, health centers, first aid posts, etc., whether open or closed

g) Customer service or service centers open to the general public and spaces intended for meetings in government offices

h) Inside of closed facilities that serve as retail food sellers, corner stores, supermarkets, etc.

i) Closed work areas, such as mines, factories, and workshops

j) Enclosed areas where fuel, gas services, etc. are sold

k) Places where explosives, flammable materials, drugs, or food are manufactured, processed, stored or handled

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- l) Supermarkets, malls, and similar establishments open to the public and drawing a large number of people
- m) Pubs, restaurants, night clubs, bars, casinos, etc.
- n) In elevators and lifts
- o) Phone booths, ATM kiosks, and other small, closed public-use spaces. A small public-use space is understood as one that is no larger than five square meters
- p) Children's playground enclosures and children's play areas or zones, understood as outdoor spaces that contain equipment or outfitting intended specifically for play and recreation for children and teenagers

Article 10. Obligation to Post Notices

All closed public spaces and all closed workspaces, public and private, and public and private educational institutions, in addition to public transportation services and health services, are required to post notices with the international “No Smoking” symbol and the text: “No smoking. 100% smoke-free environment” and [Guaraní:] “*Ndaikatúi ojepita. Ko’ápe nda’ijái tatati,*” and all ashtrays must be removed from inside these places.

Article 11. Compliance with Provisions of Article 10

The relevant authorities of the public establishments; owners, managers, or people in charge of private establishments; owners, managers, or drivers of public transportation will be responsible for complying with or enforcing the provisions in the previous article and, if necessary, may enlist the help of the National Police.

Non-smokers will have the right to demand that the owner, legal representative, manager, administrator, person in charge of the respective site or establishment order the violator to cease their behavior.

CHAPTER IV PROHIBITION OF ADVERTISING, PROMOTION AND FINANCIAL SUPPORT OF TOBACCO PRODUCTS

Article 12. Prohibition of Advertising, Promotion, and Financial Support of Tobacco Products

- a) Any form of advertisement, promotion, or financial support of tobacco products, with the exception of advertising performed in stores and points of sale, is prohibited. The prohibition includes radio, television, written media, billboards, mobile advertisements, internet, text messages, mail, and any other medium that is or may be used for the purposes of advertising.
- b) Brand extensions and generic trademarks are prohibited for tobacco products.

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LAW No. 5,538**CHAPTER V
PACKAGING, CONTENT, AND LABELLING OF TOBACCO PRODUCTS****Article 13. Health Warnings**

Every box, pack, carton, or package of tobacco products and all the outer packaging and labelling of these products, whether produced domestically or abroad, intended for domestic use, must be permanently printed with the health messages or health warnings describing the harmful effects of tobacco on their outside faces or main display surfaces, pursuant to the provisions in this law and its regulation.

a) The Ministry of Public Health and Social Welfare will define and approve the health messages and warnings that must be clear, visible, varied, legible, in full color, and have equal parts Spanish and Guaraní, and cover following spaces and percentages on the tobacco product pack or bag: 40% (forty per cent) of the bottom of both main display faces for the health message. Both faces must bear the image or pictogram, and 100% (one hundred percent) of one of the sides must have qualifying information about the content. In addition, the following texts must be placed in a space not specifically designated for the health warnings or information by the Ministry of Public Health and Social Welfare: “For sale only in Paraguay” and “Sale prohibited to minors.”

b) The health warnings will be printed directly on the packaging and outer labelling of the tobacco product.

c) The health warnings must remain visible at all times, including the display period at the points of sale.

d) The messages will be rotated according to guidance by the Ministry of Public Health and Social Welfare, and the tobacco industry will have a period of six months, from the time of notification and delivery of the respective designs, to implement the new health messages and warnings.

e) The manufacturers and sellers of tobacco products may not change the information assigned to the packs and cartons or place labels or other materials to hide it.

f) The warning images and texts will be renewed annually.

Article 14. Information on the Tobacco Product Components and Emissions that are Harmful to Health

All packs and packages of tobacco products and all outer packaging and labelling of these products, whether produced domestically or abroad, intended for domestic use, must contain information about the tobacco product content and emissions that are harmful to health. This information must be inserted in a box on the side of the pack, occupying the entire side.

Article 15. The headquarters of the manufacturer or importer of tobacco products must annually report to the Ministry of Public Health and Social Welfare, as determined by this Ministry, on the quality and quantity of the products' components and additives, as well as the substances used to process the tobacco. Tobacco products that contain additives that have not been previously reported to the Ministry of Public Health and Social Welfare may not be sold.

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The Ministry of Public Health and Social Welfare may prohibit the use of additives and substances in tobacco in the manufacturing process of the products mentioned by this law, intended to be marketed in Paraguay, when it is scientifically proven that such additives and substances increase addiction levels, harm, or risk to the users of these products. In addition, in the cases mentioned above, the Ministry may also establish the maximum allowable limits of the substances contained in tobacco products. Likewise, it will establish the standards regarding dissemination of the information regarding additives and substances included in tobacco and its effects on the health of users.

In addition, the Ministry of Public Health and Social Welfare, in the exercise of its health-related powers, will require tobacco product importers and manufacturers, whether individuals or legal entities, to annually present with a sworn statement the ingredients and emissions of nicotine, tar, and carbon monoxide of the products marketed in the country.

The products that do not comply with the foregoing may be confiscated and destroyed by the health authorities.

Article 16. Prohibition of Misleading Information on Tobacco Products

a) It is prohibited for packs, packages, outer packaging and labelling of tobacco products to be promoted falsely, incorrectly, or deceitfully, or in any way that may be misleading regarding their characteristics, effects or health risks.

b) It is prohibited to use terms, descriptive elements, trademarks or registered trademarks, and figurative symbols or symbols of another type that directly or indirectly create the false impression that a certain tobacco product is less harmful than others with respect to its content, risks, or emissions, e.g., using expressions such as: “low tar content,” “light,” “ultra light,” “smooth,” etc.

CHAPTER VI

MEASURES TO PREVENT TOBACCO USE, PROMOTE HEALTH, AND QUIT TOBACCO USE

Article 17. Inclusion of Educational Programs

The Ministry of Education and Culture must incorporate objectives and content to educate students on the bodily harm caused by tobacco product use and exposure to tobacco smoke, in addition to tobacco's addictive nature, into its academic curriculum and programs.

Article 18. Cessation Programs

The Ministry of [Public] Health and Social Welfare will:

a) Design, implement, and evaluate tobacco-dependence prevention, counseling, diagnosis, and treatment programs as part of the comprehensive care of people in health establishments.

b) Implement tobacco-dependence diagnosis and treatment in public and private health department programs, plans, and national health strategies, promoting rehabilitation and dependence treatments. In addition, public and private health departments must adequately publish the basic available services for tobacco-dependence treatment, including available pharmaceutical products, whether medications, products used to administer medications, and diagnostic means, as applicable.

c) Establish a toll-free phone line to provide information and counseling to quit using tobacco products.

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d) Ensure the necessary resources to implement these actions by annually including them in the relevant budget lines.

CHAPTER VII
USE TAX ON CIGARETTES AND OTHER TOBACCO PRODUCTS

Article 19. Sections I and II of Law No. 4,045/10, “WHICH AMENDS LAW No. 125/91, AMENDED BY LAW No. 2,421/04, ON SELECTIVE USE TAX AND ALLOCATION OF A PERCENTAGE THEREOF TO THE NATIONAL FUND FOR THE DEVELOPMENT OF SPORTS,” are hereby amended and written as follows:

Section I	Maximum Rate
1) Aromatic cigarettes or cigarettes made with Egyptian or Turkish blonde leaf tobacco, Virginia tobacco, etc.	20%
2) General cigarettes not included in item 1) above	20%
3) Cigarettes of any type	20%
4) Blond or dark tobacco, chopped or prepared in another form, except leaf tobacco	20%
5) Prepared, chopped, loose, powder (snuff), or any other form of tobacco	20%
6) Essences or other tobacco products to be vaped, inhaled, or breathed in through e-cigarettes, vaporizers, etc.	20%
Section II	Maximum Rate
1) Nonalcoholic carbonated beverages, sweet or not, and in general unspecified beverages without alcohol or with a maximum of 2% alcohol	5%
2) Fruit juice with a maximum of 2% alcohol	5%
3) Beer in general	9%
4) Artificial and distilled cognac, unspecified gin, rum cocktail, sugar cane rum, and aguardiente.	11%
5) Liquor store product, anise, bitters, fernet, etc.: vermouth, punch, liquor in general	11%
6) Ciders and fruit wines in general, sparkling or not: sparkling wines, fortified wines or grape must or concentrates and vins de liqueur.	11%
7) Natural grape juice wine (red, rosé, or white, except sweetened wines).	11%
8) Sweet wine (including natural sweetened wine), dessert wines, non-sparkling fruit wines and other artificial wines in general.	11%
9) Champagne and similar beverages	13%
10) Whiskey	11%

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Article 20. The use tax on cigarettes and other products produced from tobacco does not replace the VAT, which continues to be fully valid and is applied in addition to this tax.

Article 21. It is established that the total collected by applying the percentages established in numbers 1), 2), 3), 4), 5), and 6) of Law No. 125/91, Article 106, SECTION I, amended in turn by Article 19 of this law will be allocated as follows:

- a) 18% (eighteen percent) to the “National Fund for Development of Sports,” created by Law No. 2,874/06.
- b) 40% (forty percent) to the Ministry of Public Health and Social Welfare to develop programs for the prevention and treatment of non-communicable diseases.
- c) 10% (ten percent) to the “National Emergency Fund,” created by Law No. 2,615/05.
- d) 25% (twenty-five percent) to the Ministry of Agriculture and Farming for Family Farms and Agroecology Programs.
- e) Up to 5% (five percent) to the Enforcement Authorities for compliance with this law.
- f) 2% (two percent) to the Secretariat of Development for Refugees and Repatriates.

The Ministry of Finance must deposit these funds monthly into the special accounts authorized exclusively for these purposes, opened in the National Development Bank.

Participation in the tax income set forth in items a), b), c), d), e), and f) of this article will be applied instead of the percentages established in Law No. 2,874/06 “SPORTS” and Law No. 4,045/10 “WHICH AMENDS LAW No. 125/91, AMENDED BY LAW No. 2,421/04, ON SELECTIVE USE TAX AND ALLOCATION OF A PERCENTAGE THEREOF TO THE NATIONAL FUND FOR THE DEVELOPMENT OF SPORTS.”

Article 22. The provisions of this chapter will enter into force ninety days from the publication of this law or from the date ordered by the Executive Branch within the aforementioned timeframe.

CHAPTER VIII MINISTRY OF HEALTH CONTROLS

Article 23. The Ministry of Public Health and Social Welfare, in accordance with this law, will be authorized to establish:

- a) Testing methods for tobacco products
- b) Measurement of the tobacco product content
- c) Emissions of tobacco products
- d) Requirements to regulate the content and emissions
- e) Methods to check compliance with international standards

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f) Information that the manufacturers must provide to the health authority and the public regarding the ingredients used in tobacco products

Laboratories that are accredited by the relevant health authority may perform these tests and measurements, in compliance with the provisions issued by the Ministry of Health.

Article 24. The Executive Branch must reinforce control procedures for tobacco product production and marketing and will implement control procedures regarding tobacco product manufacturing for the purposes of proper sale and taxation, applying inviolable and inalterable physical control instruments as well as technological tools that facilitate the application and identification thereof.

The Executive Branch will determine the characteristics of the distinctive system and how it will be applied.

For the purposes of the effectiveness of systems and/or tools to control production and marketing of the products taxed under Article 106 of Law No. 125/91 “WHAT ESTABLISHES THE NEW TAX SYSTEM,” amended by this law, the fixed or specific Selective Use Tax established will be used to pay for the cost of the indicated system.

Article 25. Sanctions System. The following criteria are established to implement the Sanctions System:

a) The enforcement authorities, defined in Article 2, in the exercise of their powers, will monitor compliance with this law and will be authorized to apply sanctions when violations of the law are confirmed.

b) The enforcement authorities may establish jurisdiction delegation agreements amongst themselves.

c) Any individual who commits the infractions described in this law will be sanctioned according to the provisions herein.

d) Notwithstanding the sanctions imposed on the legal entity, sanctions may be applied additionally to directors and salespeople.

**CHAPTER IX
INFRACTIONS AND SANCTIONS SYSTEM**

Article 26. Infractions

a) For the purposes of this law, infractions are any contrary action or failure to comply.

b) Likewise, those who allow, promote, or tolerate any of these prohibited behaviors, whether they be private parties or public authorities, will be considered violators in this system.

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Article 27. Infractions, as applicable, will be subject to the following sanctions:

a) Violation of the provisions in Article 5 will be sanctioned with confiscation of the tobacco products and a fine equivalent to five times the value of the confiscated products, to be applied to the individuals or legal entities that sell or supply tobacco products in violation of this law. If there is a repeat violation in a store not duly authorized, the store will be notified of a thirty-day suspension, without prejudice to starting procedures to shut down the store.

b) Violation of the provisions in Article 6 will be sanctioned with confiscation of the tobacco products and a fine equivalent to ten times the value of the confiscated products, without prejudice to the suspension or shutdown of the establishment or store in the event of a repeat violation.

c) Violation of the provisions in Article 7, items a) and c) will be sanctioned with a fine equivalent to twenty-five minimum daily wages. In the event of violation of item d), the sanction will be confiscation of the products and a fine equivalent to five times the value of the confiscated products. In the event of a repeat violation, the store will be notified of a thirty-day suspension, without prejudice to starting procedures to shut down the establishment or store.

d) Violation of the provisions in Article 8 will be sanctioned with confiscation of the tobacco products and a fine equivalent to five times the value of the confiscated products, without prejudice to a thirty-day suspension or shutdown of the establishment or store in the event of a repeat violation.

e) Violation of the provisions in Article 9 will be sanctioned with a fine equivalent to two daily minimum wages.

f) Violators of Article 9 may be compelled to leave the enclosures or spaces and if they persist with their actions, they may be removed from the place with the help of law enforcement.

g) Violation of the provisions in Article 10 will be sanctioned with a fine equivalent to ten daily minimum wages to be applied to the owners or people in charge of them.

h) Violation of the provisions in Article 12 will be sanctioned with the removal of the advertisement and a fine equivalent to ten times the value of the issued advertising campaign.

i) Violation of the provisions in Articles 13 and 14 will be sanctioned with confiscation of the tobacco products and a fine equivalent to double the value of the confiscated products.

j) In the event of failure to comply with the provisions in Article 15, the establishments will be subject to suspension of their tobacco product importing or manufacturing activities until the situation is regulated, with the Ministry of Public Health and Social Welfare and the Ministry of Industry and Trade being in charge of these cases.

k) Violation of the provisions in Article 16 of that law will be sanctioned with the confiscation and removal from circulation of the tobacco products that violate this order, in addition to a fine equivalent to double the value of the confiscated products. In the event of a repeat violation, the store will be notified of a thirty-day suspension, without prejudice to starting procedures to shut down the store.

l) In the event of tax evasion or under reporting of the actual production, import, or export duly confirmed by the enforcement authority, the fine will be

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double the amount evaded, without prejudice to suspension or shutdown of the establishment in the event of a repeat violation.

If the same act or failure to comply is accompanied by two or more infractions, categorized in this or other laws, all the applicable sanctions will be applied.

Article 28. Administrative, Civil, and Criminal Liabilities

The administrative liabilities established in this law are without prejudice to the civil, criminal, or other liabilities that may simultaneously apply.

Article 29. Past History Record

The Ministry of Public Health and Social Welfare will create a “Violator Register,” in order to record, process, and document the identifying data of the violators and the applied sanctions.

Municipalities must report the applied sanctions in their area of jurisdiction to the other OEE.

**CHAPTER X
PROCEDURES**

Article 30. Controls

Regarding public health and health monitoring, the Ministry of Public Health and Social Welfare; regarding tax matters, the Ministry of Finance; and regarding distribution, marketing, and consumer protection, the Ministry of Industry and Trade will monitor compliance with the provisions in this law according to its own decision or because of a complaint by any individual or civil society organization who has evidence that an infraction was committed.

Article 31. Funding

The expenses required for compliance with the Law and this regulation will be paid for with resources coming from:

- a) The result of the established fines
- b) The amounts allocated for these purposes in the Paraguayan General Budget
- c) Gifts and legacies that are made with that specific intention
- d) Funds allocated for compliance with Law No. 5538/2015 indicated in Article 21 thereof

**CHAPTER XI
FINAL AND TRANSIENT ORDERS**

Article 32. The Executive Branch will regulate and institute the System for Tobacco Traceability in Paraguay (SITRATAP, by its Spanish acronym) to identify the legal origin of the tobacco as well as systems for control, registering, recording, and transmission in product manufacturing, for the purposes of proper sale and taxation, applying inviolable and inalterable physical control instruments as well as technological tools that facilitate the application and identification thereof, through the Ministry of Finance in coordination with the Ministry of Industry and Trade within no more than one hundred eighty days.

Article 33. This law will enter into force from the day following its publication with the exception of the provisions in articles contained in Chapters IV and V, which will go into effect

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three months later. Chapter VII will enter into force as stipulated in Article 22 of this law.

Article 34. The Executive Branch will regulate this law, through the Ministry of Finance, the Ministry of Public Health and Social Welfare, and the Ministry of Industry and Trade within no more than sixty days.

Article 35. All the provisions contrary to this law are hereby repealed.

Article 36. Be it hereby communicated by the Executive Branch.

The draft of the law is approved by the Honorable Chamber of Representatives, on August twenty-seventh of two thousand fifteen, and by the Honorable Chamber of Senators, on November nineteenth of two thousand fifteen. It is hereby approved, pursuant to the provisions in Article 207, Section 3 of the National Constitution.

[signature]
Hugo Adalberto Velázquez Moreno
Chairperson
Honorable Chamber of Representatives

[signature]
Mario Abdo Benítez
Chairperson
Honorable Chamber of Senators

[signature]
Del Pilar Eva Medina de Paredes
Parliamentary Secretary

[signature]
Esperanza Martínez
Parliamentary Secretary

Asunción, December 23, 2015

Let this be Law of the Republic, published and entered into the Official Record.

President of the Republic
[stamp:] [illegible]
General Secretary
Civil Office
www.presidencia.gov.py
Horadio Manuel Cartes Jara
[signature]

Antonio Carlos Barrios Fernández
Minister of Public Health and Social Welfare

[signature]
Santiago Peña Palacios
Minister of Finance

[signature]
[stamp:] **DR. MARÍA TERESA BARÁN WASILCHUK**
INTERIM MINISTER