

[emblem:] REPUBLIC OF PARAGUAY

OFFICIAL GAZETTE

OF THE REPUBLIC OF PARAGUAY

“SESQUICENTENNIAL OF THE NATIONAL EPIC: 1864–1870”

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PRESIDENT’S OFFICE OF THE REPUBLIC OF PARAGUAY
MINISTRY OF PUBLIC HEALTH AND SOCIAL WELFAREDECREE No. 7605

WHICH REGULATES ARTICLES 4, 9, 10, 11, 12, 13, 14, 15, 16, 18, 25, 26, 27, 28, 29, 30, and 31 OF LAW No. 5538, DATED DECEMBER 23, 2015, “WHICH AMENDS LAW No. 4045/2010, ‘WHICH AMENDS LAW No. 125/1991, AMENDED BY LAW No. 2421/2004,’ ON ITS TAX SYSTEM, WHICH REGULATES ACTIVITIES RELATED TO TOBACCO AND ESTABLISHES HEALTH MEASURES TO PROTECT THE POPULATION.”

Asunción, August 14, 2017

HAVING REGARD TO: Law No. 5538/2015, “Which amends Law No. 4045/2010, ‘Which amends Law No. 125/1991, amended by Law No. 2421/2014, on its tax system, which regulates activities related to tobacco and establishes health measures to protect the population,’” promulgated on December 23, 2015;

Which, in accordance thereof, is governed by the World Health Organization (WHO) Framework Convention on Tobacco Control, approved by Paraguay through Law No. 2969/2006; and

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WHEREAS: Article 238, Section 3) of the Constitution grants the President of the Republic the power to participate in the creation of laws, pursuant to the Constitution, promulgate and publish them, regulate them, and monitor compliance thereof; while Section 5) of the aforementioned Article grants the President the power to issue decrees that, for their validity, require endorsement of the relevant Minister.

Through Note VMRE1/DGPE/DOEM/No. 37/17 dated March 7, 2017, the Ministry of Foreign Affairs, through the Office of Multilateral Economic Organizations, informed the Ministry of Public Health and Social Welfare that the Peruvian Ministry of Health authorized the use of the “smoking causing lung cancer” and “smoking causes heart attack” images.

The WHO Framework Convention on Tobacco Control, mentioned in the “With Regard To” section of this Decree, aims to protect current and future generations from the devastating health, social, environmental, and economic consequences of

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tobacco use and exposure to tobacco smoke, providing a framework for tobacco control measures that must be applied by the Parties on a national, regional, and international level, in order to continuously and substantially reduce the prevalence of tobacco use and exposure to tobacco smoke.

Law No. 5538/2015, “Which amends Law No. 4045/2010, ‘Which amends Law No. 125/1991, amended by Law No. 2421/2004, on its tax system, which regulates activities related to tobacco and establishes health measures to protect the population,’” states in 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 34 of the aforementioned law establishes that the Executive Branch will regulate this law through the Ministry of Public Health and Social Welfare within no more than sixty (60) days.

The regulating of the aforementioned law involves a regulatory document necessary to clarify the scope of the provisions contained therein and establish the procedures to comply with the law’s objectives.

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The Ministry of Public Health and Social Welfare sent the regulatory proposal, under the terms of Note S.G. No. 989, dated June 21, 2016.

THEREFORE, in exercise of his constitutional powers,

THE PRESIDENT OF THE REPUBLIC OF PARAGUAY

DECREES:

**Chapter I
Regarding the Objective**

Art. 1. *Articles 4, 9, 10, 11, 12, 13, 14, 15, 16, 18, 25, 26, 27, 28, 29, 30, 31 of Law No. 5538, promulgated on December 23, 2015, “Which amends Law No. 4045/2010, ‘Which amends Law No. 125/1991, amended by Law No. 2421/2014, on its tax system, which regulates activities related to tobacco and establishes health measures to protect the population,’” are hereby regulated.*

**Chapter II
Health Messages and Warnings**

Art. 2. *It is hereby established that when this Regulation uses the expression “the Law,” it will be understood to refer to Law No. 5538/2015, “Which amends Law No. 4045/2010, ‘Which amends Law No. 125/1991, amended by Law No. 2421/2004, on its tax system, which regulates activities related to tobacco and establishes health measures to protect the population.’” When the term “Ministry” is used, it will be understood to refer to the Ministry of Public Health and Social Welfare.*

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Art. 3. *For the purposes of the exception set forth in Article 9 of Law No. 5538/2015, authorized spaces for smoking, vaping, or e-smoking, or for keeping tobacco products lit, will be considered open spaces and those closed spaces especially authorized for such purpose.*

Closed spaces for smoking, vaping, e-smoking, or keeping tobacco products lit may be made available in pubs, restaurants, night clubs, bars, casinos, gambling halls, etc.

Areas authorized for smoking must have duly posted signs, be physically separate from the rest of the rooms, not be areas that non-smokers are required to pass through, and have adequate ventilation that allows for air purification and prevents air contamination of the areas where smoking is prohibited. These places may only be authorized in establishments that are larger than 80 square meters, and the surface area intended for the specific closed smoking area may not exceed 30% of the covered surface area. Additionally, individuals younger than eighteen (18) years of age will not be permitted to enter these spaces, and a sign warning of the existence of such an area must be visibly posted at the entrance.

Art. 4. *Warnings to be placed in the areas established in Articles 9 and 10 of the Law will include the international no smoking symbol and the text: “No smoking. 100% smoke-free environment” and [Guaraní:] “Ndaikatúi ojepita. Ko’ápe nda’ijái tataĩ.” These signs will be placed in a visible location and will be at least 40 centimeters long and 20 centimeters wide, with a neon yellow background and black text.*

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Art. 5 *It is hereby ordered that the authorities in charge of public establishments, owners, managers, or people in charge of private establishments, and the owners, managers, people in charge, or drivers of public transportation will be responsible for complying with or enforcing the provisions in the Law and in this regulation 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, establishment, or public transportation order the violator to cease their behavior, in the event the law in those smoke-free locations is not being followed.

No. _____

Art. 6. *It is hereby established pursuant to the provisions in Article 12, Subsection a) of the Law, all advertisements in stores and points of sale must bear the following text: “Smoking causes cancer and respiratory diseases. Warning by the Ministry of Public Health and Social Welfare,” taking up 10% of the advertisement, in clearly visible text contrasting with the background color of the advertisement.*

Art. 7. *Advertisements with the following characteristics are prohibited:*

- a) Those using images of minors, as well as those using figures or characters representing children or adolescents*
- b) Those relating to family environments, unless the people appearing in the advertisements are of legal age and in adult-specific settings*
- c) Those that are linked to sporting or athletic activities that require good physical condition or are associated in any way with playing sports.*

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- d) *Those containing images directly or indirectly related to sex or that suggest, encourage, or facilitate sex*
- e) *Those provoking abuse or excessive and irresponsible use of the product*
- f) *Those expressing or intending to persuade the public that said products are beneficial to health, that they promote family or personal welfare, or social, economic, political, or cultural advancement of the user.*

Chapter III

Product Packaging and Labelling

No. _____

Art. 8. *It is hereby established that the designs of the health messages and warnings describing the harmful effects of tobacco will consist of four (4) formats or combinations of images and texts, which will be permanently printed on the outside faces or main display surfaces, every box, pack, carton, or package of tobacco products as well as all the outer packaging and labelling of these products, whether produced domestically or abroad, intended for domestic use, pursuant to the Law and this regulation, and in accordance with the following indications:*

- a) *The formats or combinations of images and texts must cover forty percent (40%) of the bottom portion of both main display faces of the tobacco pack or bag.*
- b) *The health warnings will be printed directly on the outer packaging and labelling of the tobacco products intended for retail sale and must remain visible at all times, including the display period at the points of sale. The exceptions are cigars and cigarillos, the warnings for which must be adhered*

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locally, following the minimum sizes and forms established in the Law and in these regulations. 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.

- c) *There will be a total of four (4) images, with the use of two (2) per year, alternating even and odd years. They will be identified as Images A and B for Group 1, and Images C and D for Group 2. The images for this year will be Group 1 images, and they will be effective until December 31, 2018. Starting on January 1, 2019, and in the subsequent odd years, the two (2) images from Group 2 will be used; and in the subsequent even years, the two (2) images from Group 1 will be used. The Group 1 images are included in the Appendix of this Decree, and the Group 2 images will be approved when the respective designs are available.*
- d) *Each Image will be printed with text in Spanish on the front of the package and Guaraní on the back. There must be equal quantities printed of each combination or format, according to the attached document. The text will contrast with the color or colors of the image established in the previous subsection. There must be four (4) texts, in Spanish and Guaraní, which will go with its corresponding image, with two (2) being used per year. The texts corresponding to the Group 1 images described in the subsection above must be as follows:*
- i) *In Spanish “Smoking causes lung cancer” and in Guaraní [Guaraní:] “Jepita nemomba’asyvaíta”*
 - ii) *In Spanish “Smoking causes heart attack” and in Guaraní [Guaraní:] “Jepita nemoñe’ãsoróta”*

The texts corresponding to the Group 2 images must be published in a timely manner along with the corresponding images.

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- e) *One of the two sides of the cigarette packs and tobacco product packages described in this article must be fully covered by the following qualifying text: “Burning this product releases tar, along with carcinogenic substances.” The text must be printed in a color contrasting with the background color or colors of tobacco products described in this article.*
- f) *In a space not specifically designated for the health warnings or information by the Ministry of Public Health and Social Welfare, the following texts will be applied: “For sale only in Paraguay” and “Sale prohibited to minors.”*
- g) *Information on tobacco product content and emissions that are harmful to health, i.e., nicotine, tar, and carbon monoxide, should be inserted in a square, in compliance with Article 14 of the Law.*
- h) *For the correct printing of the combinations or formats mentioned in Subsection a) of this article, the Ministry will provide a digital file of the high-resolution images to manufacturers and importers of tobacco products registered in the National Office of Health Monitoring; six (6) months after these warnings have been notified and delivered, the importers may not submit tobacco products without the new health warnings to customs clearance, and the national tobacco product industries may not manufacture tobacco products that do not bear these new warnings, unless otherwise established in Subsection a) of this article, with regard to cigars and cigarillos.*

No. _____

Art. 9. *The manufacturer or importer of tobacco products must report annually or every time a new product is introduced, through a sworn statement, to the National Office of Health Monitoring, an office of the Ministry of Public Health and Wellbeing, on*

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the quality and quantity of the products’ components and additives, which must be expressed as percentages, as well as the substances used to process the tobacco. Tobacco products containing additives not previously reported to this office may not be sold.

The Ministry will be authorized to prohibit the use of additives and substances that are included in the tobacco in the manufacturing process of the products mentioned in the law and are intended for sale 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.

Tobacco product importers and manufacturers, whether individuals or legal entities, must submit to the National Office of Health Monitoring, annually and each time a new product is introduced, under sworn statement, the ingredients and average emissions of nicotine, tar, and carbon monoxide of the products sold in Paraguay. Products that do not comply with the previous order may be confiscated and destroyed by the health authorities.

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Art. 10. *Misleading marketing about tobacco products to be used in the Paraguayan market will not be allowed, and:*

- 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.*

No. _____

Art. 11. *It is hereby established that for the purposes of controlling tobacco product packaging, content, and labelling, the composition and measurement of the content and emissions, and the functioning of the tobacco industry, the importers and manufacturers must register with the National Office of Health Monitoring, an office of the Ministry of Public Health and Social Welfare, pursuant to the provisions in Resolution No. 237/2010.*

Chapter IV
Prevention and Anti-Tobacco Programs

Art. 12. *The General Office of Health Monitoring, and office of the Ministry of Public Health and Social Welfare, will be responsible for the design, implementation, and evaluation of tobacco-dependence prevention, counseling, diagnostic, and treatment programs, as part of the comprehensive care of people in health establishments.*

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In addition, this office will be responsible for implementing tobacco-dependence diagnosis and treatment in public and private health department programs, plans, and national health strategies, promoting rehabilitation and dependence treatments. 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.

A toll-free phone line will be established to provide information and counseling to quit using tobacco products, and the necessary resources to implement these actions will be ensured by annually including them in the relevant budget lines.

No. _____

Chapter V
Sanctions

Art. 13. *It is hereby ordered that those responsible for any breach of the provisions in this regulation will be subject to the sanctions outlined in Law No. 5538/2015, “Which amends Law No. 4045/2010, ‘Which amends Law No. 125/1991, amended by Law No. 2421/2004, on its tax system, which regulates activities related to tobacco and establishes health measures to protect the population.’”*

Art. 14. *It is hereby determined that implementation of the Sanctions System will adhere to the following criteria established by Law No. 5538/2015:*

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- a) *By virtue of Article 2 of the Law, the Ministry of Public Health and Social Welfare is the enforcement authority regarding Public Health and Health Monitoring, which, in exercise of its powers, will monitor compliance with the Law and this regulation. The Ministry is authorized by the Law to apply sanctions when violations of the Law are confirmed.*
- b) *The Ministry may establish jurisdiction delegation agreements with other enforcement authorities of Law No. 5538/2015.*
- c) *Any individual who commits the infractions described in Law No. 5538/2015 and this regulation will be sanctioned according to the provisions herein.*
- d) *Notwithstanding the sanctions imposed on legal entities, directors and salespeople may also be sanctioned along with legal entities.*

No. _____

Art. 15. *For the purposes of this regulation, any contrary action or failure to comply will constitute an infraction. Likewise, violators accordingly are those who allow, promote, or tolerate any of these prohibited behaviors, whether they be private parties or public authorities.*

Art. 16. *The Ministry of Public Health and Social Welfare, in exercise of its powers granted by the Law, is the appropriate authority to apply the sanctions to the infractions indicated in Article 27, Subsections e), f), g), h), i), j), and k) of Law No. 5538/2015, following an Administrative Investigation that will be carried out following the procedure established in Book VII, Title IV of Law 836/1980, “Health Code.”*

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Art. 17. *In the event of alleged infractions or offenses subject to the penalty of confiscation, the Ministry may order the seizure of the tobacco products, for the purposes of ensuring compliance with the aforementioned sanction, with a list of the confiscated products put on record. The Ministry may agree to replace this measure with another equivalent measure, aimed at preventing sale or transfer of the products, with the presentation of securities or bonds deemed applicable, on a case-by-case basis.*

In the event of dismissal or judgement for the defendant of the case under investigation or in the event a sanction other than confiscation is applied, the confiscated products will be returned.

No. _____

Art. 18. *The Ministry, through the General Office of Health Monitoring, will create a “Violator Register,” in order to record, process, and document the identifying data of the violators and the applied sanctions. In compliance with the provisions in the Law, the Municipalities must report the applied sanctions in their area of jurisdiction to the Ministry.*

Art. 19. *It is ordered that regarding Public Health and Health Monitoring, the Ministry will monitor compliance with the provisions in the law and this regulation 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.*

Art. 20. *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*

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MINISTRY OF PUBLIC HEALTH AND SOCIAL WELFARE

DECREE No. 7605

WHICH REGULATES ARTICLES 4, 9, 10, 11, 12, 13, 14, 15, 16, 18, 25, 26, 27, 28, 29, 30, and 31 OF LAW No. 5538, DATED DECEMBER 23, 2015, “WHICH AMENDS LAW No. 4045/2010, ‘WHICH AMENDS LAW No. 125/1991, AMENDED BY LAW No. 2421/2004,’ ON ITS TAX SYSTEM, WHICH REGULATES ACTIVITIES RELATED TO TOBACCO AND ESTABLISHES HEALTH MEASURES TO PROTECT THE POPULATION.”

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- 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

Art. 21. Decree No. 4106/2010 “Which regulates compliance with Article 11 of Law No. 2969/2006, “Which approves the WHO Framework Convention on Tobacco Control” is hereby repealed.

Art. 22 This Decree will be endorsed by the Ministry of Public Health and Social Welfare.

No. _____

Art. 23. Be it hereby communicated, published, and entered into the Official Record.

[signature]

[emblem:] REPUBLIC OF PARAGUAY	PRESIDENT’S OFFICE OF THE REPUBLIC OF PARAGUAY OFFICE OF DECREES AND LAWS
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APPENDIX TO DECREE No. 7605

GROUP 1

IMAGE A



In Spanish: Smoking causes lung cancer

In Guaraní: [Guaraní:] *Jepita nemomba'asyvaíta*

IMAGE B

[signature]



In Spanish: Smoking causes heart attack

In Guaraní: [Guaraní:] *Jepita nemoñe'ãsoróta*