

“Bicentennial of National Independence: 1811 – 2011”

[EMBLEM: REPUBLIC OF PARAGUAY]

*Presidency of the Republic
Ministry of Public Health and Social Welfare*

Decree No. 4.106. –

	WHEREBY COMPLIANCE WITH ARTICLE 11 OF LAW NO. 2969/06 IS REGULATED, WHICH APPROVES THE FRAMEWORK CONVENTION ON TOBACCO CONTROL OF THE WORLD HEALTH ORGANIZATION (WHO) <i>Asunción, March 25, 2010</i>	
<i>Nº. <u>729</u></i>	IN LIGHT OF: WHEREAS:	<i>The presentation of the Ministry of Health and Social Welfare, whereby it conveys the proposal for the regulation of compliance with Article 11 of Law No. 2969, dated August 10, 2006, which approves the Framework Convention on Tobacco Control of the World Health Organization (WHO); and</i> <i>Article 11, concerning the packaging and labeling of tobacco products, of Law No. 2969/06, which approves the Framework Convention on Tobacco Control of the World Health Organization (WHO), establishes as follows:</i> <i>1. “Each Party, within a period of three years starting with the entry into force of the Convention for this Party, shall adopt and implement, in accordance with its national legislation, effective measures to accomplish the following:</i> <i>a) That on packs and labels of tobacco products a tobacco product is not to be promoted in a false, equivocal or deceptive manner, or one that misleads with respect to its characteristics, health effects, risks or emissions, and does not use terms, descriptive elements, manufacturing or trademarks, figurative signs, or of another kind that have the direct or indirect effect of creating the false impression that one particular tobacco product is less harmful than others, for example, expressions such as “low in tar content,” “light,” “ultralight” or mild; and</i>

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- b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:*
- i. shall be approved by the competent national authority;*
 - ii. shall be rotating;*
 - iii. shall be large, clear, visible and legible;*
 - iv. They should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas surfaces;*
 - v. may be in the form of or include pictures or pictograms...”*

Scientific evidence and the Framework Convention for Tobacco Control reveal that exposure to tobacco smoke is the cause of death, illness and disability;

The consumption of cigarettes and other tobacco products in any of their forms poses a risk to people’s health, due to the presence of carcinogens, contaminants and other toxic substances.

It falls within the competency of the State to initiate public policies for the promotion of health and the prevention of disease, ensuring an informative climate that allows people to grow adopting healthy forms of conduct.

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It has been scientifically demonstrated that the use of tobacco in any of its forms is addictive and its presentation can constitute a means that instigates the purchase and consumption of the product.

That no level of toxic compounds contained in cigarettes and other tobacco products is safe for the exposed population, and that on the contrary, all have been demonstrated to pose a risk to health;

The National Constitution states, in its Article 4 – The Right to Life, that “All persons shall be protected by the State in their physical and psychic wholeness;” in Article 28 – The Right to Be Informed: “The right of people to receive true, responsible and balanced information is recognized;” and in Article 68 – The Right to Health, that “The State shall protect and promote health as a fundamental right of the person and in the interest of the community.”

Article 203 of Law No. 836/80 of the Health Code states: “The Ministry, when it considers it necessary, shall be able to determine that the packages in which products made from tobacco are sold must clearly and prominently display a warning that they can be harmful to health.”

Furthermore, Article 325 of the same legal source establishes: “The Executive Branch shall regulate the provisions contained in this Code.”

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Law No. 2969/06 – Whereby the Framework Convention for Tobacco Control of the World Health Organization (WHO) is approved, states in its Article 2, 1: “In order to better protect human health, Parties are encouraged to implement measures beyond those required by this Convention and its protocols, and nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are in accordance with international law.

And moreover, Article 4 of the law in question determines that: “Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke and effective legislative, executive, administrative or other measures should be contemplated at the appropriate governmental level to protect all persons from exposure to tobacco smoke...” And in its Article 5, the same law states that

“In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.”

In the document: Guidelines for the implementation of Article 11 of the Convention approved by the Conference of the Parties in the Framework Convention for Tobacco Control of the World Health Organization (WHO), it says: “Well-designed health warnings and messages are part of a range of effective measures to communicate health risks and to reduce tobacco use. Evidence demonstrates that

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the effectiveness of health warnings and messages increases with their prominence. In comparison with small, text only health warnings, larger warnings with pictures are more likely to be noticed, better communicate health risks, provoke a greater emotional response and increase the motivation of tobacco users to quit and to decrease their tobacco consumption.

Larger picture warnings are also more likely to retain their effectiveness over time and are particularly effective in communicating health effects to low-literacy populations, children and young people. Other elements that enhance effectiveness include locating health warnings and messages on principal display areas, and at the top of these principal display areas; the use of colour rather than just black and white; requiring that multiple health warnings and messages appear concurrently; and periodic revision of health warnings and messages.”

NOW THEREFORE, in the exercise of his constitutional duties,

THE PRESIDENT OF THE REPUBLIC OF PARAGUAY HEREBY

DECREES:

Art. 1. - *Compliance with Article 11 of Law No. 2969/06, “Approving the Framework Convention for Tobacco Control of the World Health Organization (WHO),” is to be regulated in the following terms:*

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It is to be established that packs and any other kind of packaging for cigarettes or tobacco products, whether of national or international production, intended for national consumption, shall contain health warnings as indicated in this Decree.

Art. 2. - *It is ordered that such warnings must comply with the following conditions:*

- a) *Be approved by the Ministry of Public Health and Social Welfare.*
- b) *Appear simultaneously on the external surface of each package of tobacco products. There shall be one warning, with a full color image, and corresponding text for said image per pack or package, and it shall include the series of four warnings in each lot of packages of tobacco products.*
- c) *Be available to manufacturers or importers of tobacco products, in the National Program for Control of the Tobacco Habit, of the Ministry of Public Health and Social Welfare.*
- d) *Use the following texts, accompanied by the respective images, that shall be determined by the Ministry of Public Health and Social Welfare:*
 - **SMOKING CAUSES LUNG CANCER, EMPHYSEMA and ASTHMA ATTACKS.**
 - **SMOKING CAUSES STROKES.**
 - **SMOKING CAUSES SEXUAL IMPOTENCE.**
 - **SMOKING CAUSES HEART ATTACKS AND HIGH BLOOD PRESSURE.**

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- e) The texts indicated in item 4 of this Article must be preceded by the statement: “The Ministry of Public Health and Social Welfare warns:” in a typeface smaller than that of the warnings, and be subject to annual revision and modification by the aforesaid Ministry.*
- f) The warnings are to be printed directly on the pack of tobacco products, so that the image shall remain visible at all times, including during the period of display at points of sale.*

Art. 3. -

It is ordered that starting on July 6, 2010, on which date the “National Day Free from Tobacco Smoke” is observed, the size of each warning shall occupy 50% of the lower portion of the main frontal surface, and 40% of the lower portion of the main rear surface of the cigarette pack or container for tobacco products; without spaces between the warning and the frame containing it.

That the images are to be distinct, and the texts clear and legible, and they are to be written in black characters on a white background for the years 2010 and 2011.

That starting on July 6, 2011, the size of the warning on the principal rear surface shall occupy 50% of the lower portion of said surface.

That starting on July 6, 2012, the warning shall occupy 60% of the lower portion of both principal surfaces.

That the background on which the warnings are written, starting on July 6, 2012, shall be yellow.

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- Art. 4. -** *It is established that on packs and labels of tobacco products, there shall be no promotion of tobacco products of a false, equivocal or deceptive nature, or that can mislead people with respect to their characteristics, health effects, risks or emissions; and that there shall be no use of terms, descriptive elements, manufacturing or trademarks, figurative signs or of another kind that have the direct or indirect effect of creating the false impression that one particular tobacco product is less harmful than others, for example, expressions such as “low in tar content,” “light,” “ultralight,” “mild” or the like.*
- Art. 5. -** *It is ordered that the packaging of tobacco products must indicate on one of the lateral sides thereof the classification of the substances composing it, stating: “This product contains more than 4,000 toxic and carcinogenic substances. There are no safe levels of exposure to tobacco smoke.”*
- Art. 6. -** *It is established that failure to comply with what is stipulated in this provision constitutes a serious offense, and shall render those responsible susceptible to the sanctions set forth in the Health Code.*
- Art. 7. -** *It is ordered that the National Bureau of Health Oversight shall oversee enforcement and compliance with these provisions.*
- Art. 8. -** *Final Provisions. Definitions:*
- a) *The phrase “external packaging and labeling” used in relation to tobacco products applies to all packaging and labeling used for wholesale sale of the product.*
 - b) *“Health warning,” refers to all messages through which the harmful effects on health of the use, consumption and exposure to tobacco and tobacco smoke are expressly stated, and that may consist of captions, pictograms or images of warning.*

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c) *“Tobacco product” encompasses products prepared totally or partially using tobacco leaf as a raw material, and intended to be [“]smoked, sucked, chewed or used as snuff.”*

Art. 9. - *This Decree shall be endorsed by the Ministry of Public Health and Social Welfare.*

Art. 10. - *Let notification be given hereof, and let it be published and conveyed to the Official Register.*

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