Unofficial Translation

MINISTRY OF PUBLIC HEALTH AND SOCIAL WELFARE

GOVERNMENT AGREEMENT NO. 299-2014

Guatemala, September 2, 2014

THE PRESIDENT OF THE REPUBLIC

WHEREAS:

Decree No. 90-97 of the Congress of the Republic, the Health Code, and its amendments contained in Decree No. 50-2000 of the Congress of the Republic regarding regulation of tobacco-product advertising in Article 49, develops the prohibitions, limitations and requirements for advertising with which private entities that sell tobacco products must comply. Its purpose is to make the population aware of their harmful effects on consumer health.

WHEREAS:

In order to achieve effective implementation of the provisions of Article 49 of the Health Code, dated August 23, 2013, Government Agreement No. 338-2013 was published. It develops new regulatory provisions to establish the authority and responsibilities of each of those involved in authorizing advertising conducted by the mass media, which must have authorization from the Ministry of Public Health and Social Welfare prior to its dissemination in written, graphic, radio, television, electrical or electronic and mobile unit media, as well the strengthening the monitoring provisions for strict compliance.

WHEREAS:

In order to achieve the health goals through procedures for the authorization of tobacco-product advertising material, strengthen the procedure, clearly identify the prohibitions and limitations established in the Health Code, and monitor compliance with each and every one of the obligations incumbent upon the companies that market this product, it is necessary to modify Government Agreement No. 338-2013, thereby consolidating the modernization and updating of those procedures and making clear the importance of limiting the use of advertising in strict adherence to what was intended in the Constitution of the Republic and the provisions of Article 49 of the Health Code.

THEREFORE:

In exercise of the functions conferred on it by Article 183, paragraph e) of the Constitution of the Republic of Guatemala, and based on Articles 38, 47, 49, 68 and 244 of Decree No. 90-97 of the Congress of the Republic, the Health Code, and its amendments contained in Decree No. 50-2000 of the Congress of the Republic.

AGREES:

To issue the following:

Amendments to Government Agreement No. 338-2013, which contains the "Regulation of Health Standards for the Authorization and Monitoring of Tobacco-Product Advertising."

Article 1. Article 5 of Government Agreement No. 338-2013 is amended to read as follows:

ARTICLE 5 – ADMINISTRATIVE PROCEDURE. Once received for processing, the file generated by the request for authorization to disseminate tobacco-product advertising will be transferred by the leadership of the Department for the Regulation of Health and Environmental Programs to the Health Authorizations Unit. In addition, it will convene the Technical Commission on Tobacco to perform its assessment in accordance with the health standards established in this regulation and the general requirements provided with respect to paragraphs b), d), e) and f) of Article 49 of Decree No. 90-97 of the Congress of the Republic, the Health Code, and

the amendments contained in Decree No. 50-2000 of the Congress of the Republic. When the assessment is complete, a technical opinion will be issued and it will return the file to the leadership of the Department for it to assign a unique registration number and issue the appropriate technical opinion. The complete file will be transferred to the General Directorate of Health Regulation, Monitoring and Control, the department that is in charge of granting the authorization for the dissemination of advertising or not. A copy of the decision shall be forwarded to the Department for the Regulation of Health and Environmental Programs for the corresponding registry.

The General Directorate of Health Regulation, Monitoring and Control, will reject advertising materials that communicate consumer promotions when they involve free distribution of cigarettes or other tobacco products.

Furthermore, in order to comply with the limitations established in paragraph f) of Article 49 of the Health Code, tobacco-product advertising materials must refer to the product itself in their presentation. The use of human models, cartoons, sports athletes, and public figures for the purpose of demonstrating or directly suggesting the consumption of the product is prohibited. For implementation of the concepts noted above, they are understood as:

1) **Demonstrate directly:** to display or show lit or unlit tobacco products in hands, in the direction or in the mouth of human models, cartoons, sports athletes and public figures for this purpose.
2) **Suggest directly:** to evoke in any way the direct consumption of the product.

The Technical Committee on Tobacco has the authority to issue the technical opinion indicated in the first paragraph of this article and shall be composed of three experts appointed by the head of the Department of Health and Environmental Programs and, additionally, by two delegates, one from the Guatemalan Chamber of Commerce and the other from the Guatemalan Chamber of Industry. The Technical Committee on Tobacco shall meet at least twice a week, and the Head of the Department must schedule and inform them of the date and time of the sessions, no later than January 15 of each calendar year. The decisions of the Technical Commission on Tobacco shall be determined by a majority vote of its members. The positions of the delegates from the business chambers will be ad honorem. Each of the chambers shall submit the name and personal identification data of the persons designated as delegates and alternates in a letter addressed to the Director of Health Regulation, Monitoring and Control of the Ministry of Public Health and Social Welfare. As regards the procedure for meeting announcements, the sessions and other operational provisions to achieve the objective of the Technical Commission on Tobacco, it will be determined by ministerial agreement.

In addition, publication of price lists that contain only the brand name, package image, and suggested retail price, will not be considered advertising material, and therefore will not be subject to the standards contained in Article 49 of the Health Code.

The information and documents that the Ministry of Public Health and Social Welfare and any of its departments receives in compliance with the standards in this regulation are confidential, so that they may not be disclosed, made available or delivered to an individual or legal entity other than the party directly concerned and entitled to receive or know of them, except when a court issues an order for such disclosure or delivery.

Article 2. Article 6 of Government Agreement No. 338-2013 is amended to read as follows:

ARTICLE 6 – Term. For the administrative procedure described in Article 5 of this Regulation, the Ministry of Public Health and Social Welfare, through the appropriate departments, shall have a peremptory and non-extendable deadline of 10 business days from the date the application is submitted to the Department for the Regulation of Health and Environmental Programs. The official or public employee

that does not meet that deadline will be responsible, in accordance with the applicable cases regulated under Article 226 of the Health Code.

In accordance with the provisions of Article 241 of the Health Code, in cases where the Ministry of Public Health and Social Welfare or its departments do not rule within the time limits established in this regulation, the application shall be decided in favor of the applicant.

Without prejudice to the time limit established in the first paragraph of this article, the Ministry of Public Health and Social Welfare, through the departments involved in the approval process for the advertising material, in accordance with the provisions of this regulation and in order to facilitate the approval process for the material submitted, may at any point in the process prior to a definitive ruling, require the applicant in writing to make changes to the material submitted if they, at their discretion, contain errors or omissions that can be corrected. The deadline for submitting the material, having met the requirements, will be of two business days from the day following the notification of the request. After this period, the process will continue. The time limit established in this paragraph shall have the effect of a suspension, so that after the two business days have passed, the time to rule definitively will continue in accordance with the provisions of this article.

Article 3. Article 7 of Government Agreement No. 338-2013 is amended to read as follows:

ARTICLE 7 – EFFECTIVE PERIOD FOR AUTHORIZATIONS. Any authorization for the dissemination of tobacco-product advertising, granted in accordance with this regulation shall be in effect for a period of five years. In the case of those advertising materials that were authorized prior to the date this regulation enters into effect, the authorization will remain in effect for a period of one year from the date this regulation takes effect.

Article 4. Article 9 of Government Agreement No. 338-2013 is amended to read as follows:

ARTICLE 9. – REGISTRY. The Department for the Regulation of Health and Environmental Programs shall create a registry of current authorizations for tobacco-product advertising and keep it updated.

The Directorate of Health Regulation, Monitoring and Control must send an updated registry to the General Directorate of the Comprehensive Health Care System every two months, for the appropriate control and monitoring established in Article 13 of this regulation.

The General Directorate of the Comprehensive [Health] Care System, through its environmental health inspectors and supervisors, as well as the rural health care technicians of the Regional Health Directorates for the whole country, in accordance with the powers established in this regulation, shall verify that the advertising materials encountered in the marketplace are duly authorized, in accordance with the reports submitted.

Article 5. Article 10 of Government Agreement No. 338-2013 is amended to read as follows:

ARTICLE 10 – STATIC MATERIALS. All tobacco-product advertising material intended for dissemination by written, graphic or mobile unit media, either by static electric or electronic media without use of video, must comply with the following health standards for approval:

a) The effective surface area of the material will not be greater than 80% of the total surface area. The first term is understood as the space exclusively allocated for displaying the advertising concept. Consequently, a minimum of 20% of the total surface area of the material must be allocated to include the respective health warnings, in accordance with the following:

1) Each of the health warnings must be displayed on a band with a white background which must extend across the entire width of the material. One of the bands shall be located at the upper end, the other at the lower end of the advertising material.

b) The health warnings established in paragraph b) of Article 49 of the Health Code must be included in the advertising material, in accordance with the following:

1) On the background band located in the upper part of the material, one of the alternative health warnings must appear. On the background band located in the lower part of the material, the general warning, "CONSUMPTION OF THIS PRODUCT CAUSES SERIOUS HARM TO HEALTH," must be included. Both warnings must be written in capital letters, in black, using the Arial Black font and must be printed legibly.

2) The text for each of the health warnings must occupy at least 80% of the minimum area established for their respective background bands.

c) In accordance with the provisions established in paragraph f) of Article 49 of the Health Code, tobacco-product advertising shall refer to the product itself in its presentation. Therefore, when it is included in advertising materials, must be done in such a way that it does not directly demonstrate or suggest the consumption of tobacco products.

Figure 1 illustrates what is required by this health standard:

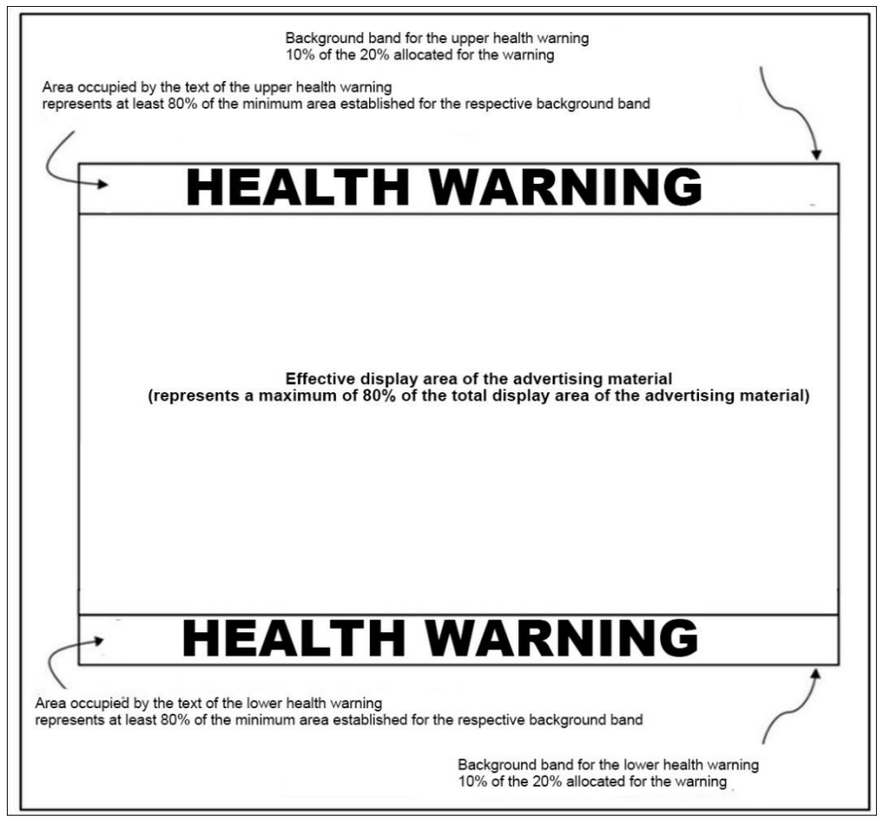

Figure 1 Health Standards for Static Materials

Article 6. Article 11 of Government Agreement No. 338-2013 is amended to read as follows:

ARTICLE 11 – DYNAMIC MATERIALS. All tobacco-product advertising material intended for televised broadcast, or by electrical or electronic media that make use of video, must comply with the following health standards for approval:

a) The effective display area shall be not greater than 80% of the total display area of the material. The first term is understood as the space exclusively intended for displaying the advertising concept. Consequently, 20% of the total display area of the advertising material must be allocated to include the respective health warnings, in accordance with the following:

1) Each of the health warnings must be displayed on a white background band, which must extend across the entire width of the total display area of the material. One of the bands is located at the upper end, the other at the lower end of the display area of the advertising material.

b) The health warnings established in paragraph b) of Article 49 of the Health Code must be included in the advertising material, in accordance with the following:

1) On the background band located in the upper part of the material, one of the alternative health warnings must appear. On the background band located in the lower part of the material, the general warning, "CONSUMPTION OF THIS PRODUCT CAUSES SERIOUS HARM TO HEALTH," must be included. Both warnings must be written in capital letters, in black, using the Arial Black font, and be legible.

2) The text for each of the health warnings must occupy at least 80% of the minimum area established for their respective background bands.

3) The health warnings and their respective background bands must be visible during the entire duration of the advertising material.

c) In accordance with the provisions established in paragraph f) of Article 49 of the Health Code, tobacco-product advertising shall refer to the product itself in its presentation or packaging. Therefore, when it is included in advertising materials, it must be done in such a way that it does not directly demonstrate or suggest the consumption of the tobacco products.

Figure 2 illustrates what is required of advertising materials by this health standard in the general case:

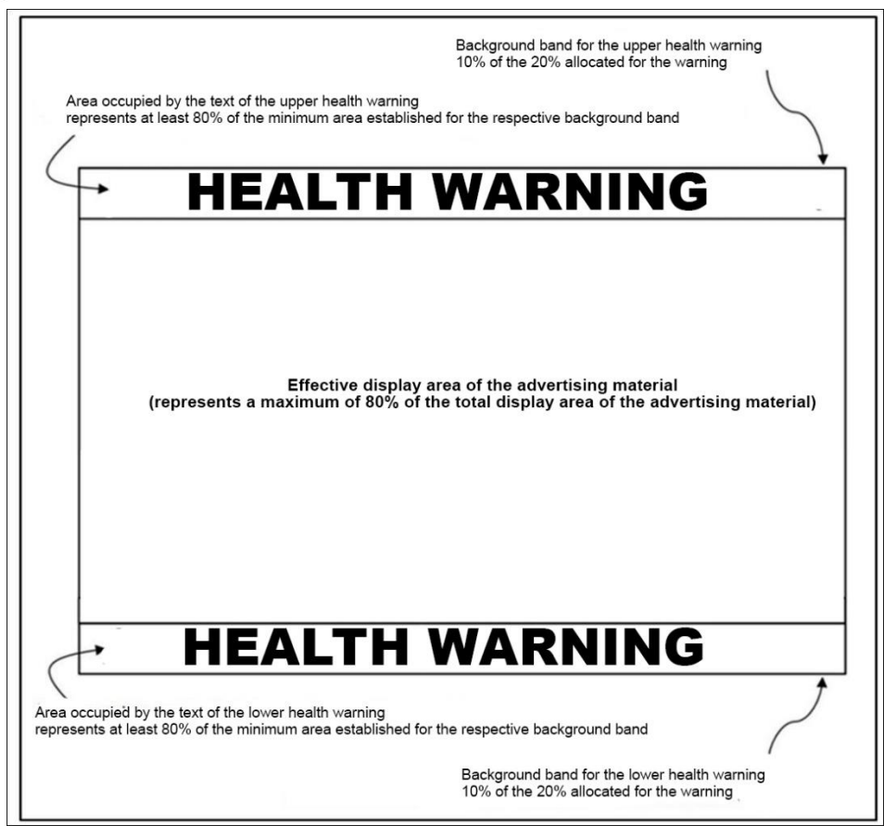

Figure 2 Health Standards for Dynamic Materials

Article 7. Article 12 of Government Agreement No. 338-2013 is amended to read as follows:

ARTICLE 12 – RADIO MATERIALS. All tobacco-product advertising material intended for dissemination by radio must comply for authorization with the following health standards for approval:

The health warnings established in paragraph b) of Article 49 of the Health Code must be included in the radio script, in accordance with the following:

a) At the beginning of the radio script, one of the alternative health warnings must be included. At the end of the script, the general warning, "CONSUMPTION OF THIS PRODUCT CAUSES SERIOUS HARM TO HEALTH," must be included.

b) A minimum pause of one second must be inserted between the health warning and the rest of the contents of the advertising material.

c) The health warnings must be audibly articulated during the dissemination and at a maximum rate of 200 words per minute.

Article 8. Article 13 of Government Agreement No. 338-2013 is amended to read as follows:

ARTICLE 13 – MONITORING. The General Directorate of the Comprehensive Health Care System has the authority to conduct the health monitoring for compliance with the health standards established for dissemination of tobacco-product advertising by virtue of its role in executing policy within the Ministry of Public Health and Social Welfare. The monitoring will be carried out by the environmental health inspectors and supervisors, as well as rural health technicians from all the country's Regional Health Directorates, who will have under their responsibility compliance with the following specific functions:

a) Verify that tobacco-product advertising which is disseminated through written, graphic, radio, television, electrical, electronic, or mobile unit media, has the appropriate authorization, and that it is obtained by the means and measures that have been authorized.

b) Verify that, as established in paragraph g) of Article 49 of the Health Code, tobacco-product advertising will not be placed within five hundred meters of the entrances and exits of educational institutions, sports facilities or complexes, hospitals, and recreation centers.

c) Verify that the media request the appropriate health authorization from advertisers, before proceeding to disseminate tobacco-product advertising.

d) Verify that, as established in the paragraph e) of Article 49 of the Health Code, tobacco-product advertising will not be disseminated during the time scheduled for children's programming.

e) Verify that, as established in paragraph b) of article 49 of the Health Code, that the containers, wrapping, and packs of the products have the appropriate health warnings.

Article 9. Article 19 of Government Agreement No. 338-2013 is amended to read as follows:

Article 19 – Transition. Once this agreement takes effect, the files that the Commission currently knows about which were created under Government Agreement No. 426-2001 dated October 16, 2001, shall be transferred to the Department for the Regulation of Health and Environmental Programs for continued processing.

The Technical Committee on Tobacco established in Article 5 of this agreement must be formed to start operations within a period of not more than 15 business days from the date this regulation takes effect. The internal provisions for the functioning of the Technical Commission on Tobacco shall be issued by ministerial agreement within a period of not more than 30 business days from the date this regulation takes effect.

Members of the Technical Commission on Tobacco shall meet within a period of not more than five days from the day following its formation. The head of the Department of Health and Environmental Programs must participate in order to establish the provisional operating standards applicable during the period established for the issuance of the corresponding ministerial agreement.

Article 10 – Final Provisions. Once this government agreement takes effect, the files that are currently in process or have been approved under Government Agreement No. 338-2013 dated August 16, 2013, may be adjusted to the new provisions established in this regulation. To that end, in the case of files in process, the interested party may submit the request for modification at any time during the procedure before the Directorate makes a decision. The applicant must attach the respective advertising materials, duly-modified, within five working days from the date this Government Agreement takes effect. In the case of advertising materials approved under the provisions in this article, the interested party may request the modification within the same period of five working days from the date this agreement takes effect.

Materials approved under the auspices of Government Agreement No. 338-2013 dated August 16, 2013, shall be valid for five years from the date this Government Agreement takes effect.

Article 11 – Effective Date. This Government Agreement takes effect the day after its publication in the Diario de Centro America.

Let it be known.

OTTO FERNANDO PEREZ MOLINA