

MINISTRY OF PUBLIC HEALTH AND SOCIAL WELFARE

Be it agreed to issue the following "Health Standard Regulations for the Authorization and Monitoring of Tobacco-Product Advertising."

GOVERNMENT AGREEMENT NO. 338-2013

Guatemala, August 16, 2013

THE PRESIDENT OF THE REPUBLIC

WHEREAS:

Through Government Agreement No. 426-2001, dated October 16, 2001, the Regulations for the Regulation, Approval and Control of Advertising and Places for Use for Tobacco-Related Products, were issued. Standards and provisions were established directed at involving manufacturers, importers, marketers and advertisers in promoting programs to provide information about the risks of consuming substances harmful to health, and in particular, tobacco use and the harm it causes to health.

WHEREAS:

In order to correctly apply the provisions contained in 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, relating to regulation of tobacco-product advertising, it is necessary to update the regulations to establish the authority and responsibilities of everyone involved in the authorization of advertising, whether realized in written, graphic, radio, television, electric or electronic, or mobile unit media. This advertising must be authorized by the Ministry of Public Health and Social Welfare before being disseminated by those media. For this reason, it is necessary to promote the modernization of the authorization and monitoring processes, respectively.

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.

AGREES:

To issue the following:

"Health Standard Regulations for the Authorization and Monitoring of Tobacco-Product Advertising."

CHAPTER I GENERAL PROVISIONS

Article 1 – Object. This regulation aims to establish specific health standards to authorize the dissemination of tobacco-product advertising, as well as to provide the standards and procedures necessary for monitoring them.

Article 2 – Authority. The application of these regulations is the responsibility of the Ministry of Public Health and Social Welfare.

Article 3 – Scope and Subjects of Compliance. The health standards contained in these regulations are applicable to all tobacco-product advertising intended for dissemination in the territory of Guatemala through written, graphic, radio, television, electrical, electronic, or mobile unit media. The manufacturers, importers or advertisers responsible for the material, as well as the media that would disseminate it, are subject to compliance.

CHAPTER II

HEALTH AUTHORIZATION

Article 4 – Application for Authorization. All requests for authorization for the dissemination of tobacco-product advertising must be submitted in writing to the Department for the Regulation of Health and Environmental Programs. The applicant must specify his full name, address, and telephone contact information for notifications. He must also indicate the capacity in which he acts. This should have been duly verified previously in writing to the Department for the Regulation of Health and Environmental Programs. The application must be accompanied by two copies of the advertising materials intended for dissemination, in accordance with the following:

- a) If the application concerns the dissemination of advertising by written, graphic or mobile unit media, or static electric or electronic media without the use of video, the advertising materials must be submitted in the form of printed sketches with a minimum print quality of 600 dots per inch and occupying a minimum area of 400 square centimeters.
- b) If the request concerns the dissemination of advertising by television, or electrical or electronic media that make use of video, it must be submitted in the form of electronic files of high-definition digital video capable of supporting a minimum image resolution of 1280 x 720 pixels.
- c) If the application concerns the dissemination of advertising by radio, the advertising materials must be submitted in the form of electronic files of uncompressed audio, suitable for playback at a minimum speed of 192 kilobits per second. The written transcript of the corresponding radio script must be submitted as an attachment.

Article 5 – Administrative Procedure. Once received for processing, the file generated from the application for authorization for the dissemination of tobacco-product advertising will be transferred by the leadership of the Department for the Regulation of Health and Environmental Programs to the appropriate unit, which shall evaluate it in accordance with the health standards established in this regulation and the general requirements provided for in this regard by 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. When the assessment is completed, a technical opinion will be issued and it will return the file to the leadership of the Department to assign a unique registration number and issue the relevant technical opinion. The completed file will be transferred to the General Directorate of Health Regulation, Monitoring and Control, the entity in charge of deciding whether or not to authorize the dissemination of the advertising. A copy of the decision shall be forwarded to the Department for the Regulation of Health and Environmental Programs for the appropriate registry.

Article 6 – Term. For the administrative process described in Article 5 of the Regulations, the Ministry of Public Health and Social Welfare will have a period of 15 business days from the date of receipt of the file by the Department of Regulation of Health and Environmental Programs.

Article 7 – Authorization Effective Period. Any authorization for the dissemination of tobacco-product advertising will be valid for a period of one year. In the case of those advertising materials that have been authorized prior to the date this regulation takes effect, the authorization will remain in effect for a period of one year from that date.

Article 8 – Media. It is forbidden to disseminate tobacco-product advertising without authorization from the Ministry of Public Health and Social Welfare. Consequently, it is the media's obligation to require evidence of that authorization from manufacturers, importers or advertisers prior to disseminating any advertising materials. In addition, they must keep a written record of documentation supporting this action for any related health monitoring, which may be requested at any time by the relevant health authority.

Article 9 – Registry. The Department for the Regulation Health and Environmental Programs shall create and maintain an updated registry of current authorizations for tobacco-product advertising.

CHAPTER III HEALTH STANDARDS

Article 10 – Static Materials. All tobacco-product advertising material intended for dissemination by written, graphic or mobile unit media, or 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 shall be not greater than 75% of the total surface area of the material. The first term is understood as the space exclusively allocated for displaying the advertising concept. Consequently, a minimum of 25% of the total surface area of the material must be allocated for the appropriate health warnings and identification of the advertising material, in accordance with the following:
 - 1) Each of the health warnings must be displayed on a band with a yellow background, which must extend across the entire width of the advertising material and occupy an area equivalent to at least 10% of the total surface area of the material. One of the bands will be located at the upper end, the other at the lower end of the advertising material.
 - 2) The identification of the advertising material must be displayed on a band with a white background, which must extend across the entire width of the advertising material and occupy an area equivalent to at least 5% of the total surface of the material. This band will be located immediately above the band allocated for the lower health warning.

Advertising materials that are not rectangular parallelograms are considered as irregular shapes. The Department for the Regulation of Health and Environmental Programs is empowered to require modifications to the geometric presented, if it considers that it is not the most appropriate format for comprehension of the health warnings. The foregoing is without prejudice to the ratio of the advertising material to the total area established as the effective area of that 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 on the upper part of the material, one of the alternative health warnings must appear. On the background band located on the lower part of the material, it must include the general warning, "CONSUMPTION OF THIS PRODUCT CAUSES SERIOUS HARM TO HEALTH." Both health warnings must be written in capital letters, in black, using the Arial Black font.
 - 2) Each of the health warnings must occupy the equivalent of at least 7.5% of the total surface area of the advertising material. Thus, they must cover at least 75% of the minimum area established for their respective background bands.
- c) The identification of the advertising material must include the registration number assigned by the Department for the Regulation of the Health and Environmental Programs, in accordance with the following:

- 1) On the corresponding background band, the text, "AUTHORIZED ADVERTISING MATERIAL, UNDER REGISTRATION NUMBER," must be inserted, followed by the corresponding registration number. This identification must be written in capital letters, in black, using the Arial Black font.
- 2) The identification of the advertising material must occupy at least the equivalent to 2% of the total surface area of advertising material. Therefore, it must cover at least 40% of the minimum area established for its respective background band.
- d) In accordance with the provisions of paragraph f) of Article 49 of the Health Code, tobacco-product advertising shall refer to the form of the product's presentation or packaging. Thus, when it is included in advertising materials, it must be done in such a way that the health warnings corresponding to the front and lateral sides are fully visible.

Figure 1 illustrates what is required by this health standard in the general case of advertising material whose geometry corresponds to a rectangular parallelogram:

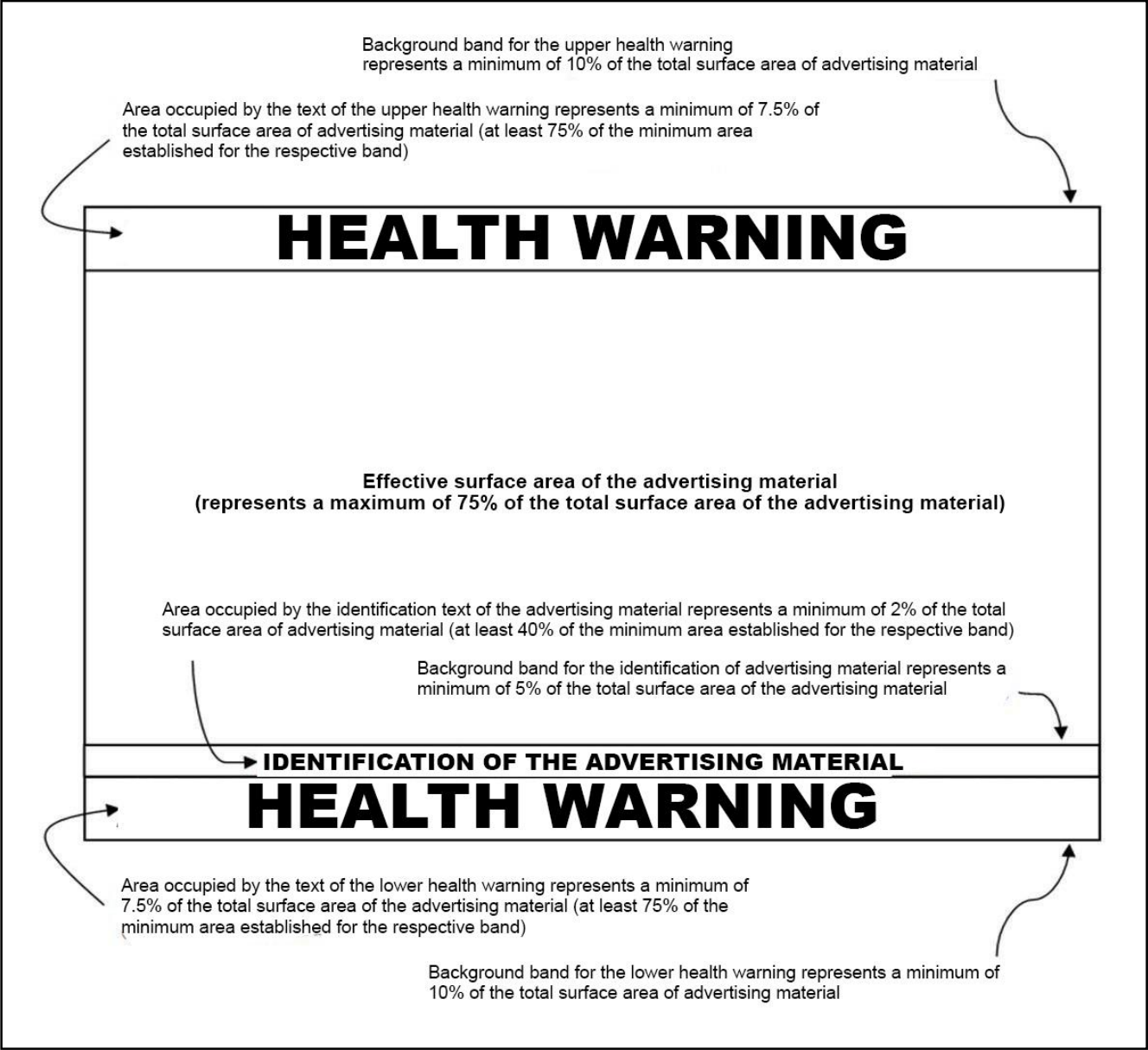


Figure 1. Health Standards for Static Materials

Article – 11 Dynamic Materials. Any tobacco-product advertising material intended for dissemination by television, or by either 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 75% of the total display area of the material. The first term is understood as the space exclusively allocated for displaying the advertising concept. Consequently, 25% of the total display area of the advertising material must be allocated for the appropriate health warnings and the identification of the material, in accordance with the following:
- 1) Each of the health warnings must be displayed on a band with a yellow background, which must extend across the entire width of the total display area of the material and occupy an area equivalent to 10% of this area. One shall be located at the upper end, the other at the lower end of the display area of the advertising material.
 - 2) The identification of the advertising material must be displayed on a band with a white background, which must extend across the entire width of the total display area of the material and occupy an area equivalent to 5% of that area. It shall be located immediately above the band allocated for the lower health warning.

Advertising materials whose display area does not correspond to a rectangular parallelogram shall be considered as irregular shapes. For this case, the Department for the Regulation of Health and Environmental Programs is empowered to require modifications to the geometric layout submitted, if it considers that it is not the most appropriate format for comprehension of the health warnings. The foregoing is without prejudice to the ratio of the advertising material to the total area established as the effective area of that 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 on the upper part of the material, one of the alternative health warnings must appear. On the background band located on the lower part of the material, the general warning, "CONSUMPTION OF THIS PRODUCT CAUSES SERIOUS HARM TO HEALTH," must be included. Both health warnings must be written in capital letters, in black, using the Arial Black font.
 - 2) Each of the health warnings must occupy an area equivalent to at least 7.5% of the total display area of the advertising material. Thus, they must cover at least 75% of the minimum area established for their respective background band.
 - 3) The health warnings and their respective background bands must be visible during the entire duration of the advertising material.
- c) Identification of the advertising material must include the registration number assigned by the Department for the Regulation of the Health and Environmental Programs, in accordance with the following:
- 1) On the corresponding background band, the text, "AUTHORIZED ADVERTISING MATERIAL, ACCORDING TO REGISTRATION NUMBER," must be inserted, followed by the corresponding registration number. This identification must be written in capital letters, in black, using the Arial Black font.
 - 2) The identification of the advertising material must occupy an area equivalent to at least 2% of the total display area of the advertising material. Therefore, it must cover at least 40% of the minimum area established for the respective background band.
 - 3) The identification of the advertising material must be visible during its entire duration.

- d) In accordance with the provisions of paragraph f) of Article 49 of the Health Code, tobacco-product advertising shall refer to the form of the product in terms of its packaging or presentation. Therefore, when it is included in advertising materials, it must be done in such a way that the health warnings corresponding to the front and lateral sides are fully visible.

Figure 2 illustrates what is required by this health standard in the general case of advertising material whose display area corresponds geometrically to a rectangular parallelogram:

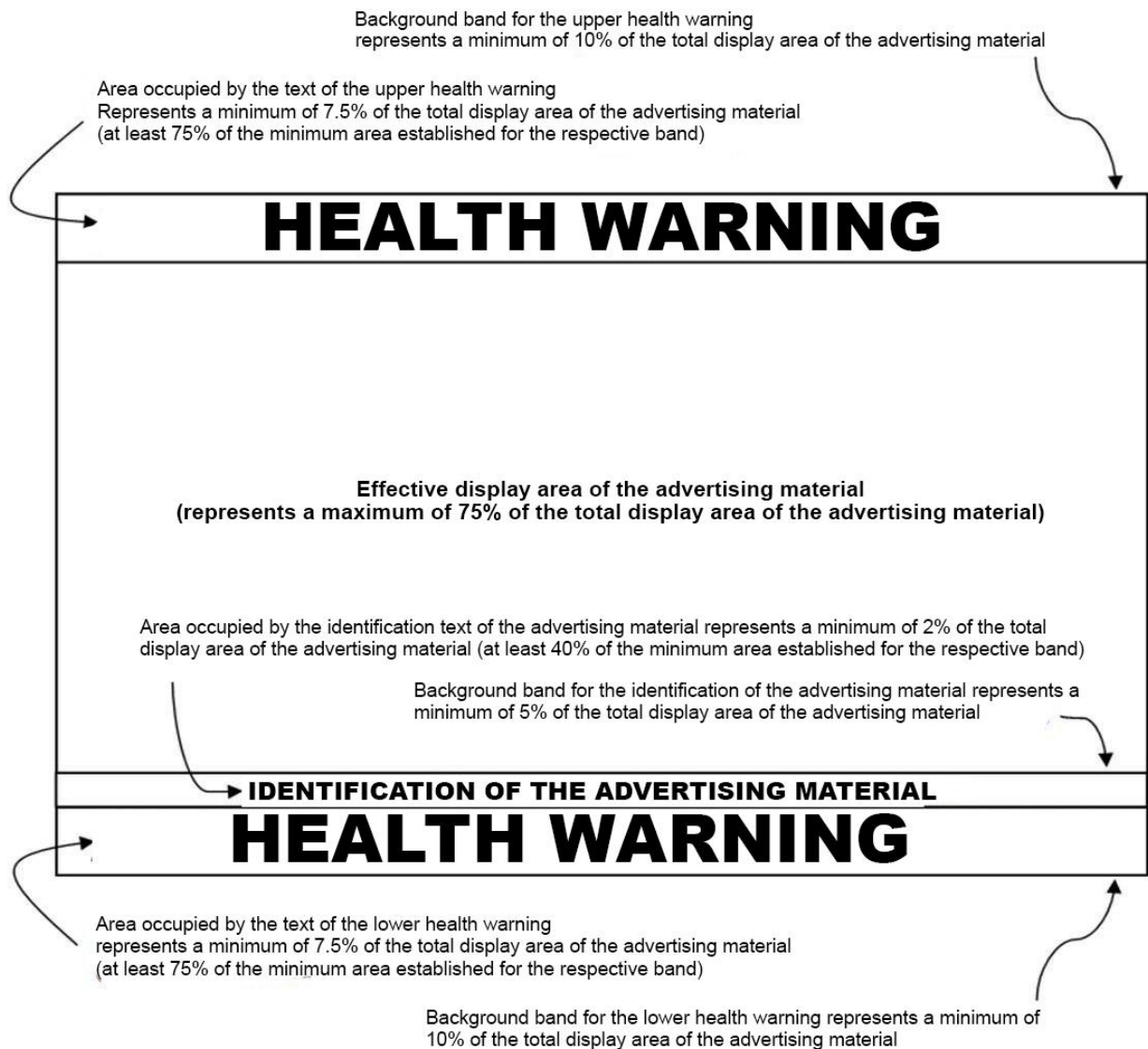


Figure 2 Health Standards for Dynamic Materials

Article 12 – Radio Materials. All tobacco-product advertising material intended for dissemination by radio must comply with the following health standards for approval:

- a) 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:
- 1) At the beginning of the radio script, one of the alternative health warnings must be included. The end of the same script must include the general warning, "CONSUMPTION OF THIS PRODUCT CAUSES SERIOUS HARM TO HEALTH."
 - 2) A minimum pause of one second must be inserted between the health warning and the rest of the contents of the advertising material.

- 3) The health warnings must be articulated during the dissemination at a maximum rate of 200 words per minute.
- b) Identification of the advertising material must include the registration number assigned by the Department for the Regulation of the Health and Environmental Programs, in accordance with the following:
 - 1) Identification of the advertising material shall be made by incorporating the following text into the radio script: "Authorized advertising material, per registration number," followed by the registration number assigned to the advertising material.
 - 2) The identification must be inserted in the radio script immediately before the general health warning, "CONSUMPTION OF THIS PRODUCT CAUSES SERIOUS HARM TO HEALTH."
 - 3) The text referring to the identification of the advertising material must be articulated during the dissemination at a maximum rate of 200 words per minute.

CHAPTER IV MONITORING

Article 13 – Monitoring. The General Directorate of the Comprehensive Health Care System has the authority to carry out health monitoring of compliance with the health standards in regard to 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 environmental health inspectors and supervisors, as well as by rural health technicians from all the country's Regional Health Directorates, who will have within their responsibilities 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, 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 may 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 required health authorizations from advertisers, before proceeding to disseminate tobacco-product advertising.
- d) Verify that, as established in paragraph e) of Article 49 of the Health Code, the 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, the containers, wrapping, and packs of the products have the appropriate health warnings.

Article 14 – Coordination of Monitoring. The Ministry of Public Health and Social Welfare shall facilitate the continuity of the institutional coordination required to develop appropriate health monitoring. To this end, the Department for the Regulation of Health and Environmental Programs must share the contents of the registry of current health authorizations for tobacco-product advertising with the General Directorate of the Comprehensive Health Care System. The latter will distribute it to all of the Regional Health

Directorates, so that they have the background information needed to conduct appropriate health monitoring at the local level. For their part, the Regional Health Directorates are obligated to inform the Department for the Regulation of Health and Environmental Programs on an ongoing basis regarding the monitoring activities carried out, as well as the results of those activities.

Article 15 – Systematization of the Information. The Department for the Regulation of the Health and Environmental Programs, with support from the Health Management Information System Unit, must standardize the technical instruments necessary for the systematization of information collected from health monitoring in the Health Management Information System (SIGSA).

Article 16 – Monitoring Program. In the two-year peremptory period from the date this regulation takes effect, the Department for the Regulation of Health and Environmental Programs must create a specific monitoring program for dissemination of advertising for tobacco products. This program will be responsible for: centrally coordinating the monitoring work to be executed at the implementation level of the Ministry of Public Health and Social Welfare; to standardize and implement procedures, manuals and technical instruments required for the implementation of the monitoring; to train personnel at the implementation level responsible for monitoring the application of the procedures, manuals, and instruments created for that purpose; and to supervise the implementation of the monitoring, appropriately updating and modifying the required procedures, manuals, and instruments based on the evaluation developed.

CHAPTER V VIOLATIONS, PENALTIES AND PROCEDURES

Article 17 – Violations and Penalties. Those subject to compliance under this regulation who contravene the prescriptive and prohibitive provisions established in the regulation, commit a health violation and are therefore subject to sanction pursuant to the provisions of Book III of Decree No. 90-97 of the Congress of the Republic, the Health Code.

Article 18 – Procedures. Any decision issued in accordance with this regulation may be appealed in accordance with the provisions of the Law on Administrative Disputes.

CHAPTER VI FINAL PROVISIONS

Article 19 – Transition. Once this agreement takes effect, the files that the Commission currently knows about that 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.

Article 20 – Repeal. Government Agreement No. 426-2001 dated October 16, 2001, "Regulations for the Regulation, Approval and Control of Advertising and Places for Use of Tobacco-Related Products," is repealed.

Article 21 – Effective Date. This Government Agreement shall come into effect 15 days after its publication in the Diario de Central America.

Let it be known.

OTTO FERNANDO PEREZ MOLINA