

REGULATION to the General Law on Tobacco Control.

In the margin, there is a stamp with the National Shield, that says: United Mexican States – President of the Republic.

I, FELIPE DE JESÚS CALDERÓN HINOJOSA, President of the United Mexican States, with the authority conferred upon me by Article 89, Section I, of the Political Constitution of the United Mexican States, and pursuant to Articles 1, 2, 3, 4, 5, 24, 45, 46 and 48 of the General Law on Tobacco Control and 39 of the Organic Law of Federal Public Administration, do hereby issue the following

REGULATION TO THE GENERAL LAW ON TOBACCO CONTROL

TITLE ONE

General Provisions

Single Chapter

Article 1. The purpose of this regulation is to regulate the General Law on Tobacco Control. It must be applied throughout the land, and its provisions are by public order and of social interest.

Article 2.- In addition to the definitions established in Article 6 of the Law, for purposes of this Regulation, the following shall be understood:

ADDITIVES. Any substance included in the preparation of tobacco products whose purpose is to perform a technological function as a preservative or modifier of organoleptic characteristics, such as substances that modify their absorption or the physiological behavior of any component of such products;

ENCLOSED PHYSICAL AREA WITH PUBLIC ACCESS. Any space covered by a roof or that has at least two walls, regardless of the material used for its construction and whether the structure is permanent or temporary;

COFEPRIS. Federal Commission for Health Risk Protection;

OUTDOOR SPACE. One that has no roof nor that is limited between more than one wall, regardless of the material used for its construction and whether the structure is permanent or temporary. For the purposes of this definition the concept of roof includes no patio umbrellas, palm shades, open structures with tin roofs, hinges or removable roofs and canvasses;

ISOLATED INTERIOR SPACE. Any interior space designed for the use of tobacco products and identified as such that has the technical specifications established in this Regulation.

ESTABLISHMENT. Considered to be the premises and their facilities, their buildings and covered or uncovered annexes, in which the production, manufacture, storage or importing of tobacco products or the provision of a service is carried out.

V. SMOKE. The act of inhaling and exhaling smoke from a tobacco product, and includes the fact of being in possession or control of a lit tobacco product which creates emissions;

VIII. INGREDIENTS. The list of substances and raw materials used in the process of making tobacco products;

IX. LAW. General Law on Tobacco Control;

X. HEALTH LICENSE. The administrative act by which the Secretariat through COFEPRIS authorizes tobacco products producers, manufacturers or importers to perform activities related to the production, manufacture or import of tobacco products under the conditions and with the requirements and methods determined by this Regulation and other applicable legal provisions.

XI. LOT. The quantity of a tobacco product prepared in the same place during a single cycle, made up of homogenous units of the same product.

XII. INTERIOR WORK PLACE. Any fixed or movable zone that has at least a roof and two walls, used by people during their employment or permanent or eventual, paid or voluntary job. Includes not only the site where the work is done, but also all connected and annexed places that workers are accustomed to using in the performance of their duties, including those hired for the performance of events;

XIII. HEALTH MESSAGES. Refers to any text or representation that prevents or warns about the presence of a component, emission, specific ingredient or about the health dangers that can come from the use or consumption of tobacco products, along with the exposure to tobacco smoke, which may include warning legends, graphics, figures, and statements related to: illnesses, symptoms, syndromes, anatomical data, physiological phenomena or statistical data;

XIV. SUBLIMINAL MESSAGES. Those incorporated into advertising that influence the recipient without his having a conscious perception of such messages;

XV. JOB-RELATED EXPOSED PERSONNEL. One who, in the performance of and for the purpose of his occupation, is exposed to tobacco smoke;

XVI. PROCESS. The set of activities related to the acquisition, production, manufacture, preparation, preservation, mixing and adaptation of tobacco products under this Regulation;

XVII. ADVERTISING. The message aimed at the public or a segment of same with the direct or indirect purpose of informing about the existence or characteristics of a tobacco product, its manufacturer or its activities.

Article 3.- Application of this Regulation is the responsibility of the Secretariat, as well as the Federal entity governments in their

Unofficial Translation

respective spheres of jurisdiction, pursuant to the cooperative agreements signed to that effect.

Article 4.- Public offices and entities, as well as owners, administrators or those responsible for a 100% tobacco smoke free space, will aid in applying obedience to the Law, the Regulation and other health provisions, and when they find irregularities which in their judgment constitute violations of same, they will bring it to the attention of competent health authorities so that they might apply the corresponding penalties in the areas of their competency.

Article 5.- Notwithstanding the powers granted to other competent authorities determined in the Law and this Regulation, for the correct application of the Law and this Regulation, this Secretariat will exercise the following powers:

Accept and attend to reports or complaints filed in that regard due to the failure to comply with the Law and this Regulation.

II. Implement oversight and health control procedures;

Impose within the area of their competency the safety measures and penalties determined for that purpose due to the failure to comply with the Law, this Regulation and other applicable provisions;

Issue and revoke the corresponding authorizations to which the Law, this Regulation and other applicable provisions refer;

Publish the agreements on the characteristics and contents that health messages and pictograms referenced in the Law will have and which will be used on the packaging and labeling of tobacco products;

Establish the characteristics which 100% tobacco smoke free spaces and smoking-only areas must have;

Others that other applicable regulations may give it.

Article 6.- The periods or terms for decision shown in this Regulation will begin to be counted starting the day after the one on which the notification or filing of the respective petition takes place.

TITLE TWO

Tobacco Products

Chapter One

Manufacturing and Importation

Article 7.- When requesting the health license, tobacco product producers, manufacturers or importers must attach information on the components, additives, residues and other substances used in their manufacture or which their components contain, as well as technical support, the limits allowed and known or potential risks.

The Secretariat may require supplementary or additional information on the manufacturing and importing processes for health oversight purposes when irregularities are found.

Article 8.- Information that tobacco product producers, manufacturers or importers disclose to the general public must comply with the provisions of this Regulation and other application provisions and will be published in major circulation newspapers or magazines in the country, as well as on official electronic web pages of the tobacco industry.

Chapter Two

Establishment Health License

Article 9.- COFEPRIS will grant health licenses to tobacco product producers, manufacturers and importers only when their principal place of address is in the country and they show that the processes and handling during tobacco product manufacture and storage are done by controlling and reducing, where applicable, the presence of factors which involve additional or associate risks to their tobacco products after a verification visit.

Article 10.- The health license to which Article 14 of the Law refers will be in force for three years, and its renewal must be requested at least 30 working days in advance of its expiration date. COFEPRIS will have 30 working days from receipt of the request for renewal to issue the corresponding decision, and in the event it does not do so, the license will be considered as extended.

Article 11.- To obtain the health license, the request will be filed in official format, which will specify the information on the establishment for which the license is requested. The Secretariat will have sixty working days to decide on the license request.

Article 12.- To grant the health license the Secretariat will make a verification visit within 20 working days after the request is filed to confirm that the establishments meet the requirements shown by Law and this Regulation and as stated on the request.

If as a result of the verification visit irregularities are warned of or additional information is requested, the Secretariat will grant the interested party a period of time equivalent to one-third of the response period in which to correct the irregularities or supply the requested information. In this case the time period in which the Secretariat answers the paperwork will be suspended and will be reengaged on the working day immediately following the one on which the interested party responds.

In case the requirement is not satisfied or the irregularity corrected in the period shown in the above paragraph, the request will be deemed as not filed.

Article 13.- The health license involves no acceptance by the Secretariat of the use and consumption of tobacco products.

Tobacco sales must not use the number or legend "health license" on packages or wrappers or any other phrase which indicates that tobacco is a product endorsed by the Secretariat.

Unofficial Translation

Article 14.- Requirements to obtain a health license as a tobacco products producer, manufacturer or importer will be of two types
Administrative: Duly set up request, an original or certified copy of the document, as applicable

Articles of incorporation, verification of the legal entity, letter of representation or legally validated distributor, as applicable, Federal tax payers' record, proof of payment of rights in a form authorized by the Ministry of Finance and Public Credit, and

Technical: Establishments are required to have proper facilities that ensure health, order, safety in the performance of activities, the process of manufacture or storage of tobacco products, process control according to their activities and the respective documentation under the terms established by the corresponding statutes.

Chapter Three

Pre-Import Health Permit

Article 15.- Pre-import health permits for tobacco products will be issued only to those holding health licenses.

Article 16.- Pre-import health permits for tobacco products, set forth in Article 31 of the Law, will be granted by COFEPRIS according to the provisions of the Law and this Regulation.

Article 17.- Tobacco products importers must present the original of the pre-import health permit at the time of the Customs shipment together with the Customs license.

Article 18.- Importers must keep pre-import health permits for at least three years and will be required to show them to the health authority whenever the latter may so require.

Article 19.- COFEPRIS will issue the pre-import health permit after the petitioner has satisfied the requirements shown by Law, this Regulation and other applicable legal provisions and the rights established by legislation which may ensue are paid.

Article 20.- In order to obtain the pre-import health permit for tobacco products, the importer will file his request in the duly set up official format, signed by the interested party or his legal representative, and attach the following documents:

Proof issued by the competent authority in the country of origin who is responsible for regulating the process and quality of the product for import, which shows that the tobacco product in question was manufactured in the country of origin and that it is subject to regular oversight by the competent authority and that shows its physiochemical composition and the geographic place from whence it comes, with validity by lot or else certificate of free sale issued by the competent authority responsible for guaranteeing that tobacco products meet the legal provisions and are used or consumed freely and without any restriction in the country of origin or source, as the case may be, valid for one year;

Copy of the establishment's health license;

Original of the label of origin;

Original of the label with which it will be marketed in Mexico that meets the applicable provisions of current health legislation, and

Proof of rights payment in the form authorized by the Ministry of Finance and Public Credit.

Pre-import health permits will be granted for 90 days and may be extended for an equal period. The corresponding request must be filed with the health authorities before the authorization expires.

The extension will proceed only when the requirements shown in the Law, this Regulation and other applicable legal provisions are being met and after payment of the corresponding rights, attaching the original pre-import health permit to the request.

The unused pre-import health permit must be returned to the Health Authority that issued it for cancellation within a maximum period of 30 days after its expiration.

Article 21.- In dealing with pre-import health permits, the Secretariat will have fifteen working days to decide on the requests and five working days when dealing with their changes, corrections and/or extensions. In the case of pre-import health permit extensions, the paperwork must be started at least 5 working days before its expiration date.

The Secretariat may require additional or missing information from the interested party related to the technical and administrative requirements to obtain the pre-import health permit within a period that will be equal to one-third of the granted time period to decide on the request when it is of an administrative nature and two-thirds when it is of a technical nature. Once the above period has passed, the pre-import health permit cannot be denied due to lack of information.

In case the requirement is not satisfied in the period shown in the above paragraph, the request will be deemed as not filed.

Article 22.- When tobacco products are imported, the Secretariat may take samples of them in order to verify that they meet the requirements established by the Law, this Regulation and other applicable legal provisions.

Article 23.- Tobacco products requiring a pre-import health permit and which are brought into the country without this permit will be deemed to have been brought in illegally. The Secretariat will apply the corresponding safety measures and penalties to the illegal trade of tobacco products and make the competent authority aware of this fact.

Article 24.- The import of tobacco products whose use or consumption has been banned for health reasons in its country of origin or source or by the recommendation of specialized international bodies will not be authorized.

Article 25.- In the event of a national or international health alert, the Secretariat will take the necessary measures to prevent the importation of tobacco products that can cause harm due to the associated risks.

Article 26.- When the intention is to return the tobacco that has not been accepted by the destination country, the exporter and, where

Unofficial Translation

applicable, the manufacturer must ask for a pre-import health permit to return the merchandise, covering the requirements established by this Regulation and other applicable legal provisions for the purpose and showing the reasons for which these tobacco products were rejected in the country to which they were destined.

COFEPRIS will determine the final destination of the above tobacco products after evaluating their health condition.

The Secretariat will have five working days from when the notification is made by the importer that the products arrived at their destination to take samples or apply security measures, and ten working days from receipt of the analysis results or documentation proving the correction in order to issue the corresponding response.

Storage expenses and losses created during the time needed for the ruling and, where applicable, for destruction will be borne by the exporter or manufacturer who has requested the re-entry of products to the country.

The request for pre-entry health permit to return merchandise must meet the following requirements:

Copy of the original export license;

Export invoice protecting the exported product, where the quantity, name and complete business address of the recipient are specified;

Where applicable, letter of rejection issued by the competent authority from the country to which it was exported and which shows the reason for rejection and, if not rejected, by the competent authority, a

letter on letterhead paper from the company where the reason for return is shown;

Letter from the importer showing the quantity, destination, product use and lot, on company letterhead;

Labels with which the product will be marketed in Mexico, as applicable and

Proof of rights payment.

Article 27.- When tobacco products that are subject to any of the following circumstances are imported or when their entry is requested due to return of merchandise, COFEPRIS may decide on the pre-import health permit:

Sampling and seizure. The importer brings the merchandise into the country, takes it to its final destination and notifies COFEPRIS so that will do the sampling and seizure and cannot make use of it until the health authority has results from the laboratory and issued the corresponding decision, or

Destination seizure. Where applicable, with sampling and analysis the importer notifies COFEPRIS of the merchandise's entry to ensure it to its final destination and, if such is the case, to do the sampling. It will also notify the local health authority to withdraw the security measures at the final destination, and if the sampling has been done, the importer will have the merchandise until the authority issue, the corresponding decision based on results of the laboratory analysis.

In the event of circumstances referenced by Sections I and II above, COFEPRIS will have five working days from the importer's notification that the products reached their destination to take samples or apply safety measures and ten working days from receipt of the analysis results to issue the appropriate decision. The importer may sell the products once the sampling is done, so long as no safety measures have been applied, in which case it must proceed according to the provisions of Article 414 of the General Health Law.

Article 28.- Pre-import health licenses and health permits to which the Law and this Regulation refer may be reviewed by the competent health authority under the terms of the applicable general provisions.

In case of failure to meet the provisions of the Law, this Regulation and other applicable legal provisions issued by the Secretariat, the pre-import health licenses and health permits will be revoked under the terms established in the General Health Law.

Article 29.- Paperwork to which this Title refers must be started by using the authorized formats and published in the Official Gazette of the Federation. These formats will specify the data, requirements and documents that the petitioner must provide, fulfill and attach in each case.

Chapter Four

Packaging and Labeling

Article 30.- All tobacco products outside packaging and labeling must display at least the following information:

Tobacco products for sale in the country must show the statement "For exclusive sale in Mexico";

The statement on contents, emissions and risks, according to the applicable provisions issued by the Secretariat for that purpose;

Identification and business address of the manufacturer, importer, packager, assembler or national or foreign distributor, as the case may be;

Identification of the lot to which it pertains, and

Health messages and pictograms which the Secretariat may establish.

The information shown above must be specified in the Spanish language, and when dealing with imported tobacco products in original packaging, the information on their outside packaging and labeling must also appear in the Spanish language and meet the requirements contained in the applicable provision which the Secretariat issues to that effect.

Article 31.- Health messages and pictograms must be directly printed on the tobacco product packages and on all their outside packaging and labeling so that they are permanently available and visible at all times, including the time of display at points of sale and

Unofficial Translation

until their use or consumption under normal conditions.

During the display and marketing of tobacco products it is forbidden to cover, distort or obstruct in any way the visibility of health messages and pictograms on their outside packaging and labeling through the use of decals, bags, boxes, covers or any other artifact.

Article 32.- The information that must appear on every outside tobacco product package and label pursuant to provisions of the Law, this Regulation and other applicable legal provisions must be shown with clear, visible, indelible characters in contrasting colors that are easy to read by the consumer under normal circumstances of purchase and use.

Article 33.- Establishments selling “puro” cigars by the unit must meet the following requirements:

Keep the product in its original box until the time of its sale;

The outside packaging and labeling used in its sale must have the health messages and pictograms referenced above and be equally visible and available at all times, and

For packages that ordinarily remain open for the display of “puro” cigars, the health messages and pictograms must appear on the packages containing them, both on the external and internal portion of the top cover to ensure that the health messages and pictograms will be seen where they are located.

The requirement to include health messages and pictograms on the outside packaging and labeling applies to any tobacco product whose use is or is not done through burning.

Article 34.- Health warnings and pictograms displayed on the tobacco products packages and on all their outside packaging and labeling must be adapted to provisions established in the Law, this Regulation and other applicable legal provisions.

Article 35.- All tobacco products packages and all their outside packaging and labeling must obligatorily bear at least one image or pictogram and two different warning legends pursuant to the provisions issued by the Secretariat to that effect, according to provisions of the Law and this Regulation.

Health messages and pictograms included on the tobacco products packages and on all their outside packaging and labeling and other requirements must be adapted to the measurements and proportions required by Law, regardless of their type, shape, size and presentation.

Article 36.- Tobacco products packages and all their outside packaging and labeling must not contain detachable inserts or documents with any warning legend or any other information alluding to the characteristics, uses or similar.

Article 37.- All tobacco products packages and all their outside packaging and labeling must contain, in addition to the specified warning legends, information that the Secretariat will decide about the contents of tobacco products, their emissions and risks, which will be determined in the agreement which the Secretariat will issue to that end.

Article 38.- In cases where the tobacco product packages and/or their outside packaging and labeling are manufactured or prepared so that during their display, use or consumption the interior face or any one other than the ones mentioned earlier are open as a basis for exhibiting the product, it must be considered as the front face and therefore must comply with the above shown provisions.

Article 39.- All forms of promotion are banned on all tobacco products packages and their outside packaging and labeling which may lead to error regarding their features, health effects, risks or emissions. It is also forbidden to use descriptive terms, manufacturer's or business trademarks, figurative symbols or phrases such as "low in tar", "light", "ultra-light", "smooth", "extra", "lights", "mild", "soft" or any other which in this or any other language may have the direct or indirect effect of creating the false impression that a particular tobacco product is less harmful than another.

Chapter Five

Advertising and Promotion

Article 40.- Tobacco products may be advertised only in magazines for adults, personal communications by correspondence, pursuant to the provisions of the Mexican Postal Service Law, and inside of places for adult access only.

Article 41.- Advertising exposed inside establishments for adult access only will be done in the print media.

Article 42.- Advertising broadcast in the country, regardless of its source, will be adapted to the provisions of the Law, this Regulation and other applicable legal provisions.

Article 43.- Advertising and promotion will be congruent with tobacco product characteristics or specifications, so that it must not:

Lead to behavior, practices or habits related to the use of tobacco products.

Indicate or lead to the explicit or implicit belief that the product has ingredients or properties it does not have;

Indicate that a product is less harmful than another because of its emissions, ingredients or properties which it lacks, and

Be false, mistaken or deceitful, or create the erroneous impression regarding its characteristics, health effects, risks and emissions.

Article 44.- Tobacco products advertising which is broadcast in the country will be presented only in the Spanish language and refer exclusively to the tobacco product with which it is dealing.

Article 45.- Advertising and promotion must not distort or infringe the provisions on preventive and educational matters.

Article 46.- Advertising leads to a false opinion regarding tobacco products when, including, but not limited to:

Unofficial Translation

It leads to error or confusion;

It exaggerates the characteristics or properties of the products;

It indicates or suggests that use of the product is a factor to change individuals' behavior or physical, intellectual, economic or sexual characteristics in general or of the real persons included in the message, and

It sets up comparisons between products.

Article 47.- In any advertising if a package of any tobacco product appears figuratively, it must comply with health messages and pictograms and also be adapted to the health requirements established in the Law, this Regulation and other applicable legal provisions.

Article 48.- Tobacco products advertising will be understood as encouraging its use when:

Tobacco products are presented as promoters of success, wellbeing or health;

Tobacco products are directly or indirectly ascribed soothing, stimulating or uninhibiting properties or those that lead to risky behavior;

They are directly or indirectly associated with food and beverages or other goods or services;

Use is made of absolute, categorical or superlative terms;

It is aimed at minors;

Animated drawings or virtual, fictitious or caricatures of persons are used;

Persons under age 18 participate in the message or are associated with activities, behaviors or personal qualities typical of young people who are minors;

Moods are transmitted that directly or indirectly lead to use;

Tobacco products are directly or indirectly used;

It is associated with athletics, sports or popularity ideas or images, and

They are promoted through lotteries, raffles, contests or collectibles, refund programs, discounts and other event where chance is involved.

Chapter Six

Sale of Tobacco Products

Article 49.- Information on the tobacco products presented within the points of sale must be equal for all equivalent products and consist solely of their name and price, written in black print on a white background and must not include written or visual information that might make it possible or lead the consumer to think that one of the products or brands represents less risk to consumers.

Article 50.- Those who display tobacco products found in establishments that market, sell, distribute, supply or dispense tobacco products only must include the following information:

The telephone number provided by the Secretariat to offer advice and guidance regarding treatment and help centers on tobacco use cessation and which must be in public view;

The legend "Sale of cigarettes by the unit prohibited";

The legend "Trade, sale, distribution or supply to minors prohibited";

The text "Report to" followed by the telephone number to file a citizen's report for non-compliance, and

Others issued by the Secretariat for the purpose in applicable legal regulations.

TITLE THREE

Protection Against Tobacco Smoke Exposure

Chapter One

Article 51.- On the matter of protection against the exposure to tobacco smoke, this Regulation has the following goals:

Protect the general public against exposure to tobacco smoke in any publicly accessible physical area, interior work place and public transportation vehicle;

Protect personnel who are exposed at work to tobacco smoke in interior work places;

Reduce the likelihood that the at-risk population will take up smoking;

Promote the development of actions intended to reduce tobacco use and the exposure to its smoke in the population, as well as its resulting morbidity and mortality, and

Establish coordinating mechanisms for citizen participation and reporting for strict oversight of the Law and this Regulation.

Article 52.- On the matter of guidance, education and prevention, the actions coming from this Regulation will include the

Unofficial Translation

following:

Education and information of the public on the serious health consequences that accompany smoking, the exposure to tobacco smoke, guidance and advice to prevent the onset of tobacco use and information to abstain from smoking in public places;

Broadcast of the information to the public about the benefits of smoking cessation and the promotion of quitting, and

Support for smokers when they request it in order to quit smoking through different existing therapeutic options and the telephone number the Secretariat implements for that purpose.

Article 53.- In order to ensure people's right to health protection, the proprietor, administrator or person responsible for a 100% tobacco smoke free space will be obliged, when a person is smoking in such a place, the first time to ask them to stop smoking and put out their cigar or any other tobacco product he may have lit. If the instruction is ignored, require him to leave the 100% tobacco smoke free space and move to a smoking-only area. If he puts up resistance, refuse him service and, where applicable, seek the help of the corresponding authority.

The responsibility of proprietors, owners or administrators, to which this article refers, will end when they warn the corresponding authority, for which they must have the report key which the authority is required to issue for the purpose.

Article 54.- Owners and administrators of Public Administration offices, bodies and entities and those of Legislative, Legal and Autonomous Federation Bodies will be those responsible for implementing, fulfilling and enforcing this Regulation in their respective areas.

Any Federal public servant who holds an upper rank post must require any person found smoking to stop doing so in the office or facility assigned to his service and to immediately put out his cigar or any tobacco product he may have lit. If he continues smoking, he must ask him to move to an outdoor area, and if he refuses, he must ask him to leave, so long as this person is an individual. If he refuses to leave the building, he must request help from the corresponding authority.

If dealing with a public service under his direction, he must report him to the Comptroller's Office of the body, office or entity to which he is attached.

Persons who violate the provisions in this Chapter after being warned to change their behavior and do not do so may be placed at the disposal of the corresponding administrative authority, who will define the appropriate penalties.

Article 55.- At all accesses to 100% tobacco smoke free spaces it will be necessary for proprietors, owners, administrators or those responsible to place a standing ashtray with the sign: "Put out your cigar or any tobacco product before entering".

At and inside their entrances there must be signage and signs advising workers, users and visitors that this is a 100% tobacco smoke free space, and signs with legends warning of non-compliance and the telephone number where complaints and reports can be made.

Article 56.- Proprietors, owners or those responsible for public land transportation vehicles must put up in their interior and access signs, visible logotypes or emblems that show the ban on smoking. If a passenger refuses to comply with the ban, he must be urged to put out his cigar or any tobacco product he may be using. If he resists, he must be invited to leave the vehicle, and if the refusal persists, the corresponding authority must be warned.

Drivers of vehicles that do not observe the provisions of the above paragraph must be reported to the competent authorities so that corresponding administrative penalties can be implemented, where applicable.

With respect to public air transportation, this will be governed by the provisions of Civil Aviation Law Regulations in addition to the provisions of this Regulation.

Article 57.- Students, teachers, administrative personnel, parents and members of parent associations at schools and educational institutions up to upper middle level, whether public or private, may participate individually or collectively in the oversight so that the ban on using or having any tobacco product lit inside is followed, regardless of whether the spaces are enclosed or outdoors, and with the ability to notify the corresponding authority about the person or persons not obeying this Regulation.

Article 58.- Students, teachers, administrative personnel, parents and members of parent associations at schools and educational institutions, whether public or private, may participate individually or collectively in the oversight so that the ban on selling tobacco products to minors, as well as loose cigarettes or cigarettes by the unit or any other tobacco product, is obeyed and report the existence of fixed, semi-fixed or street vendors who do not obey this Regulation.

Article 59.- Proprietors, administrators, and event organizers in 100% tobacco smoke free spaces, with the support of the employees and workers who work there, will be responsible for implementing, obeying and enforcing the Law and this Regulation in the spaces it occupies, as well as asking whoever does not obey such provisions to leave the site, and are compelled to notify the corresponding administrative authority if it is not done.

Article 60.- Smoking-only areas must be located outdoors or in isolated interior spaces and have the following characteristics:

Those located outdoors must be physically separated and unconnected from the 100% smoke free spaces, not be a required walkway for people or be at building entrances or exits. No minors may be in these spaces, and pregnant women must be warned of the risks they run and about the product upon entering this area, and

When dealing with isolated interior spaces, these must comply with the technical requirements established in the Law, this Regulation and other applicable legal provisions.

Article 61.- Isolated interior spaces must comply with the following requirements:

Be totally separated from floor to ceiling and wall to wall from the 100% tobacco smoke free spaces on all sides;

Unofficial Translation

Have one automatically opening and closing door with a side movement, not collapsible, that will remain closed permanently and be opened only during entering or leaving such areas;

Have proper signage that bans the entry of minors and warns about the health risks to which one is exposed when entering these spaces, and especially pregnant women,

the elderly and those suffering cardiovascular, respiratory diseases, cancer, asthma and others, as specified in the respective Secretarial Agreement, and

Not be a required passageway for people.

Article 72.- The tobacco smoke free space must be at least twice the size of the isolated interior space. As applicable, the overall space measurement will exclusively consider the surface aimed at offering service and in no case may include the areas designed for cooking, preparing beverages, sound equipment and their operators, bathrooms, terraces or parking lots.

Article 63.- The isolated interior space must obligatorily have a ventilation and purification system that guarantees the following:

Clean, continuous and permanent air exchange that corresponds to the total interior volume every 20 minutes. Air recirculation equipment may not be used. This minimum air supply can transfer air from other non-smoking areas of the building or establishment and must be continuously maintained during the premises' working hours. Besides this minimum air supply the certificate of occupancy must be clearly specified;

Proper filtration of the contaminated air before it is expelled to outside the building where the establishment is found at a height that does not affect pedestrians who pass in front of this exit. The air coming from a designated smoking room must not have an exit within a perimeter of 6 meters around any building exit door, air intakes, tobacco smoke free patios or at street level. In cases where this 6-meter perimeter cannot be met, a minimum separation of 3 meters will be allowed, provided the expelled air is filtered for both particulates and gases. A record for maintenance and for filter changes must be kept, which will be presented in case it is required during verification;

Minimum supply ensuring 30 liters of air per second per person inside the space, based on an index value of 1 person per 1.5 square meters;

Keep a negative pressure with the rest of the establishment no less than 6 Pascals, which must be automatically recorded throughout the day that the establishment is open. These records must be kept by the person responsible for the establishment for two years so it can be shown in case of verification. If there are none, it will be concluded that they did not operate during such days and the corresponding penalties will be applied for each of the missing days;

The provision of a pressure difference monitor will be required whose reading can be made from outside the area, located near its entrance. The area designated for smoking must have an alarm that is audible both inside and outside of it. This alarm will be activated when the pressure differential between the smoking area and the adjacent area is less than 5 Pa. Likewise, there must be a sign outside that says that no one may enter the area while the alarm is activated and a sign inside that tells everyone inside the area to extinguish their cigarettes or any other tobacco products and to leave there immediately ;

The incoming air for this space is not recycled and is invariably expelled outside the building, and

Installation and maintenance according to prevailing regulations.

Article 64.- The Secretariat may hold meetings of coordination or agreement, as the case may be, with scientific and professional societies and with civil, business and union associations to develop research, prevent the onset of smoking, reduce tobacco use and the exposure to its smoke, to encourage and support the cessation of tobacco use, and for training and development of human resources regarding tobacco control.

Article 65.- In places designed for lodging people, it is strictly forbidden to smoke and is only permitted to do so in those rooms designed for persons who smoke, so long as:

They represent no more than twenty-five percent of the total rooms in the business establishment;

Minors are not allowed to enter, even when accompanied by an adult;

They are permanently identified inside and outside the room as rooms for people who smoke, with signage located in places visible to the visiting public;

They have permanent signage showing the ban on access by minors;

They have signage related to the risks and illnesses caused by tobacco use;

They are physically isolated from the rest of the rooms;

They have ventilation directly to the outdoors and have an air extraction system that does not permit recirculation and expels it to the outside of the building, that is not thrown towards patios or internal cubes nor mixed with other injection, purification, heating or air cooling systems;

They are located by floor, block or complete building, according to the distribution of people gathering there;

They not used as a leisure area, this being understood as the access to other guests or the adaptation of rooms to improvise a party or meeting hall, and

No one may smoke while any worker from the establishment is inside the room.

Chapter Two
Citizen Participation

Article 66. The Secretariat shall promote the participation of public and civil society organizations in the prevention of smoking and the control of tobacco products with the following actions:

Promotion of 100% tobacco smoke free spaces and reporting establishments where smoking is allowed;

Promotion of community health;

Education and information for health protection;

Researching health and creating scientific and operative evidence on tobacco control;

V. Publication of legal provisions regarding the control of tobacco products;

The encouragement of compliance with the provisions related to the ban on smoking in 100% smoke free spaces, the sale of tobacco products to minors or loose cigarettes by the unit, the packaging and labeling of tobacco products, advertising, promotion or sponsorship of tobacco products, smuggling and illegal trade of tobacco products and other irregularities identified and reported to the corresponding authority, and

Coordination with national and state anti-addiction councils and helpful actions applying to this Law, such as citizen reporting.

Article 67.- The Secretariat will promote the public's and civil society's active participation in applying the Law and this Regulation and, if possible, that they will collaborate with it in preparing continuous information campaigns to sensitize the public and opinion leaders on the risks implied by tobacco use and the exposure to its smoke, as well as the benefits of not starting its use and quitting the use of tobacco products as soon as possible.

Article 68.- Any citizen may file a report before the corresponding authority if he sees a failure to obey the Law or this Regulation, who will take note of the case and do the necessary follow up, acting according to established procedures.

Article 69.- The Secretariat will put a free telephone number into operation through which reports and complaints can be made about non-compliance with the Law, this Regulation and other applicable legal provisions. Guidance will also be given to citizens who ask for it about the risks involved with the use of tobacco products and the appropriateness of quitting smoking.

Article 70.- The Secretariat will guarantee confidentiality of the informant's personal information under the terms of the Federal Law on Transparency and Access to Government Public Information.

TITLE FOUR

Health Oversight, Safety Measures and Penalties

Chapter One

Health Oversight

Article 71.- The Secretariat and the governments of the Federal entities are responsible in their respective competencies for overseeing compliance with the Law, this Regulation and other applicable legal provisions.

Article 72.- The Secretariat will promote participation for the prevention of smoking by:

The proprietors, owners or persons responsible and employees of premises, enclosed establishments, offices, industries and businesses, as well as public passenger transportation vehicles;

The users of enclosed establishments, offices, industries and businesses and public transportation vehicles, who at any time may demand compliance with the provisions of this Law;

Internal control bodies or comptroller's offices of the various Government Body offices, and

Heads of the offices and entities of the Government and Autonomous Bodies, aided by the corresponding administrative area,

Article 73.- Health oversight of the provisions referenced by the Law, this Regulation and other applicable legal provisions will be carried out through the following actions:

Verification visits, under the responsibility of personnel expressly authorized by the competent health authority to carry out physical verification for compliance with the Law, this Regulation and other applicable legal provisions, and

Verification reports from the health authority dealing with the advertising allowed for tobacco products.

Article 74.- Verification visits will be done in accordance with the procedure established in Title Seventeen of the General Health Law.

Verification visits may be ordinary and extraordinary. The first will be carried during working days and during working hours, and the second, on any schedule.

Article 75.- The verification visit order must include the telephone number of the health authority that issues it so that the proprietor, person in charge, or person responsible for the establishment or place or whoever is making the visit can formulate questions, complaints and reports and, where applicable, confirm proceeding with the act of verification.

Article 76.- Whenever the health authority discovers any advertising that does not meet the requirements demanded by the Law, this

Unofficial Translation

Regulation and other general health provisions, it will prepare a detailed report containing:

The place, date and hour of detection;

Corporate name or name of the advertiser and the person responsible for the establishment where the advertising was discovered.

Where applicable, the name of the publication in which the advertising was discovered which does not meet the requirements established in the Law, this Regulation and other applicable provisions;

The text of the anomalous advertising if it is written material or else its description, in any case, and

Any other information suited for the best development of the conferred duties.

The verification report must invariably be included with a copy, or else if conditions do not allow securing the copy of same, with a photograph, video or description of the anomalous advertising where, besides the text or advertising message, the name of the medium or publication and its date appear.

Article 77.- When the verification process or creation of the advertising report is completed, the Secretariat and governments of the Federal entities will assess compliance with the applicable provisions of the tobacco products and establishments to which this Regulation refers, and it will report in writing through a notice directed to the individual with the results of the ruling.

Chapter Two

Safety Measures

Article 78.- Safety measures to which Article 404 of the General Health Law refers and which correspond will be applied to protect public health through activities related to the production, advertising and importing of tobacco products..

Measures referenced in the above paragraph will be immediately applicable and will last as long as is strictly necessary to correct the irregularities which put people's health at risk or until the cause giving rise to its application ceases.

Article 79.- Safety measures referenced in the previous article consist of:

Suspension of the advertising, jobs or services. This may be partial, total or permanent;

Seizure of advertising or tobacco products and the equipment used for their manufacture or distribution;

Destruction of advertising or tobacco products and the equipment used for their manufacture;

Withdrawal from the market, and

Others as determined by the Secretariat.

Chapter Three

Administrative Penalties

Article 80.- Breaches to the precepts of the Law, this Regulation and other provisions emanating from it will be penalized administratively by COFEPRIS under the terms established in Articles 46, 48, 49, 51 and 52 of the Law, notwithstanding sentences that correspond when they are established as crimes.

Chapter Four

Procedure for Applying the Safety Measures and Administrative Penalties

Article 81. Provisions of the General Health Law shall be applied to all aspects regarding procedures for the application of safety measures and penalties.

Chapter Five

Resources

Article 82.- For all administrative procedures related to the application of the provisions set forth in the Law, this Regulation and other applicable legal provisions, provisions of the General Health Law will be applied.

TRANSITORY PROVISIONS

ONE.- This Regulation will take effect 30 calendar days following its publication in the Official Gazette of the Federation.

TWO.- The Regulation on Tobacco Use, published in the Official Gazette of the Federation on July 27, 2000, is hereby rendered null and void once this Regulation takes effect.

THREE.- Chapter III of Title Four of the Regulation on the General Health Law concerning advertising, Title Twenty-One of the Regulation on Health Control for Products and Services and Roman numerals XIX, XIX.1 and XIX.2 of the Appendix to the Regulation on Health Control for Products and Services, published in the Official Gazette of the Federation on August 19, 1999, are hereby repealed.

FOUR.- Federal entities must adjust their local regulations on protection against the exposure to tobacco smoke, where they must contain the provisions of this Regulation at a minimum.

FIVE.- In the event that pursuant to this Regulation is copy of the establishment's health license is desired for provision in order to secure the pre-import health permit and it is pending a decision by the competent authority, paperwork may be done showing the request number of the health license, provided it has been entered within 60 calendar days prior to filing of the request for the pre-import health permit in question.

Unofficial Translation

Where for any reason the health license is denied by the competent authority, the pre-import health permit to which this Regulation refers will not be granted.

Issued at the Federal Executive Residence in Mexico City, Federal District, on May twenty-ninth, two thousand nine. - **Felipe de Jesús Calderón Hinojosa**.- Signature.- Secretary of Health, **José Ángel Córdova Villalobos**.- Signature.