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DECREE No. 63.

THE PRESIDENT OF THE REPUBLIC OF EL SALVADOR,

WHEREAS:

- I. Pursuant to Legislative Decree No. 662, dated April 24, 2014, published in Diario Oficial No. 76, Volume No. 403, on the 29th of that same month and year, the Framework Convention on Tobacco Control of the WHO was ratified by our country;
- II. Pursuant to Legislative Decree No. 771, dated June 23, 2011, published in Diario Oficial No. 143, Volume No. 392, on the 29th of July of that same year, the Law for Tobacco Control was issued;
- III. As established by the aforesaid Law, there is an obligation to protect the health of the human person, in order to reduce the incidence of diseases caused by the consumption of tobacco, its products and derivatives; and
- IV. In accordance with the foregoing clauses, the implementation of permanent health actions is required to make it possible to promote and foster the prevention of tobacco consumption in the context of health care and such other matters as may prove to be related thereto, with the necessity of issuing provisions to such end.

THEREFORE,

in the exercise of his constitutional faculties, he

DECREES the following:

**REGULATIONS OF THE LAW FOR TOBACCO CONTROL
TITLE I**

**FUNDAMENTAL PROVISIONS
SOLE CHAPTER**

Purpose

Art. 1.- The purpose of these Regulations is to develop the provisions and procedures of the Law for Tobacco Control, hereinafter, "the Law," as well as its proper implementation, consistent with what is established in the Framework Convention on Tobacco Control of the WHO; for the purpose of protecting the health of the individual, the family and the community from the sanitary, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke; which shall develop the procedures and define the mechanisms necessary to regulate matters having to do with the importation, promotion, advertising, sponsorship, commercialization, and consumption of tobacco, its products and derivatives, as well as protection against exposure to tobacco smoke.

Scope of application

Art. 2.- Any natural or juridical person who exports, imports, promotes, advertises, sponsors, commercializes or consumes tobacco, its products and derivatives, is required to comply with these Regulations.

Unofficial Translation

Concepts

Art. 3.- Without impairment to what is established in Article 5 of the Law, for a better understanding of the technical part, the following concepts are established:

- a) **Enclosed or indoor areas or spaces with public access:** this refers to any public or private space, that is covered by a roof or has at least two partitions or walls, regardless of the material used for their construction, or whether it is a permanent or temporary structure. For the purposes of this definition, the concept of a roof includes sunshades, awnings, collapsible roofs or roofs that can be dismantled, and tarps.
- b) **Open areas or spaces:** this refers to a space that does not have a roof, nor is it confined within more than one partition or wall, regardless of the material used for their construction, or whether it is a permanent or temporary structure. For the purposes of this definition, the concept of a roof includes sunshades, awnings, collapsible roofs or roofs that can be dismantled, and tarps.
- c) **Work place:** public or private premises or facilities where work is performed that uses one or more workers, whether employed or on a voluntary basis, during working hours. Included are all adjacent or attached places as well as vehicles that workers use for the performance of their work. Also considered under this heading are areas where the public is served.
- d) **Pack:** this refers to primary packaging used for the sale of tobacco and its products.
- e) **Cigars and Cigarettes:** tobacco products to be smoked. For the purposes of the Law and these Regulations, they are considered synonymous.
- f) **Electronic cigarette:** this refers to electronic systems for administering nicotine, which constitute a category of products for consumption designed to release nicotine, after placing in one's mouth the tip of a plastic or metal cylinder, and inhaling with the aim of extracting a mixture of air and vapors from the device, and releasing it into the respiratory system. Devices whose design is similar or otherwise, which have the purpose of administering nicotine to someone, are included.
- g) **Tobacco derivatives:** these are products made totally or in part from tobacco leaf as their raw material, as well as its by-products, waste and substitutes, and which are intended to be smoked, sucked, chewed, sniffed or inhaled. They contain nicotine as a psychoactive and addictive ingredient.
- h) **Wholesale Distributors:** natural or juridical persons who engage in the distribution of products made from tobacco, to be sold at diverse authorized points of sale, from tertiary packages.
- i) **Smoke-free space:** this refers to the area where for reasons of public order, consuming or holding lit tobacco products and tobacco derivatives, as well as exposure to tobacco smoke, are prohibited.
- j) **Label:** the combination of statements, captions, marks and provisions that are printed on primary, secondary or tertiary packages containing cigarettes or some derivative of tobacco products, for their identification.
- k) **Smoking:** this refers to the act of inhaling and exhaling smoke from a tobacco product, and includes the act of being in possession or control of a burning tobacco product that is generating emissions.
- l) **Sponsorship of tobacco:** this refers to any kind of contribution to any act, activity or individual with the purpose, effect or possible effect of directly or indirectly promoting a tobacco product, or the use of tobacco and tobacco derivatives.
- m) **Tobacco products:** these are products made totally or in part from tobacco leaf as their raw material, and which are intended to be smoked, sucked, chewed, sniffed or inhaled
- n) **Point of sale:** this refers to the fixed physical location where authorization is held to sell tobacco products and derivatives.
- o) **Promotion of tobacco:** this refers to any stimulation of the demand for tobacco products, which may include advertising and any act intended to attract the attention and provoke the interest of consumers and non-consumers of tobacco products or derivatives.
- p) **Direct sale:** this refers to the transfer of a good from one person to another.

TITLE II**TRADE, PROMOTION****AND PACKAGING OF TOBACCO PRODUCTS****CHAPTER I****MANUFACTURE, IMPORTATION, EXPORTATION, COMMERCIALIZATION AND DISTRIBUTION****Registering for a Permit**

Art. 4.- Any natural or juridical person who engages in the manufacture, importation, exportation, commercialization or wholesale distribution of tobacco products and derivatives, prior to or parallel to its authorization, must apply for registration of the activity they are engaging in or will engage in, at the respective Regional Health Bureaus of the Ministry of Health, hereinafter, 'MINSAL'; the aforementioned Bureaus shall fill out the general register of natural or juridical persons engaging in such activities, delivering to MINSAL a single register thereof.

Unofficial Translation

To undertake the processing of registration and subsequently receive the respective permit, the following procedure must be implemented:

- a) Submission of a written application for the registration of the manufacture, importation, exportation, commercialization or wholesale distribution of tobacco products and derivatives, as per the template established in the respective technical legal instrument. The documents indicated in Article 5, paragraphs 3 and 4 of these Regulations must be attached to the application.
- b) A certification issued by the competent authority in the country of origin responsible for regulating the processing and quality of tobacco products and derivatives to be imported, in which it states that the product in question was manufactured in the country of origin and that it is subject to regular oversight by the competent authority, and states its physical and chemical composition and the place of geographic provenance thereof, with validity by lot, or as a certified good freely obtainable, issued by a competent authority who is the party in charge of ensuring that tobacco products and derivatives comply with legal provisions, and that they are freely used or consumed without any restriction in the country of origin or provenance, as the case may be, with validity for one year.

Art. 5.- Permits.**A. Authorization to Manufacture, Import and Export.**

Any natural or juridical person who engages in the manufacture, importation and exportation of tobacco products and derivatives, shall have the following obligations:

1. To submit a written application for a permit to MINSAL, through the competent Regional Bureau of Health, as per the template established in the legal technical instrument.
2. To submit attestations that he has registered with MINSAL, pursuant to article 4 of these Regulations.
3. For juridical persons, a Notary Certified photocopy must be submitted of:
 - a) The Company's Tax Identification Card.
 - b) The Taxpayer Registration Number (NRC – *Número de Registro de Contribuyente*), demonstrating that the company is registered in the special register of producers, manufacturers and importers of tobacco products and derivatives of the Ministry of the Treasury.
 - c) Unique Identity Document (DUI – *Documento Único de Identidad*), for Salvadoran natural persons, or those with a residency card or passport in the case of foreigners, of the Company's Legal Representative.
 - d) Tax Identification Card of the Company's Legal Representative.
 - e) A record of the Registered Public Instrument of the Company's establishment, as well as amendments thereto, if any.
 - f) A document proving the legal status of the legal representative, that is up to date.
 - g) Valid registration of the company or establishment.
 - h) Sanitary permit for installation and operation of the establishment and, if necessary, for operation of warehouses, issued by MINSAL, through the respective Community Family Health Unit.
 - i) In cases of warehouse rental, a certified copy of the lease should be presented, as well as a valid permit for installation and operation thereof issued by MINSAL, through the Community Family Health Unit.
 - j) Submit a copy of the authorization of health warnings, images and pictograms together with a sample of the primary and secondary package, in color and to scale, for the authorized tobacco products and derivatives, which must be provided in their different brands and presentations.
4. For natural persons, a Notary Certified photocopy must be submitted of:
 - a) The Company's Tax Identification Card.
 - b) The Taxpayer Registration Number (NRC – *Número de Registro de Contribuyente*), demonstrating that he is registered in the special register of producers, manufacturers and importers of tobacco products and derivatives of the Ministry of the Treasury.
 - c) Unique Identity Document (DUI – *Documento Único de Identidad*), for Salvadoran natural persons, or those with a residency card or passport in the case of foreigners.
 - d) Registration of the company or establishment.
 - e) Sanitary permit for installation and operation of the establishment issued by MINSAL, through the respective Community Family Health Unit.
 - f) In cases of warehouse rental, a certified copy of the lease should be presented, as well as a valid permit for installation and operation thereof issued by MINSAL, through the Community Family Health Unit.

Unofficial Translation

- g) Submit a copy of the authorization of health warnings, images and pictograms together with a sample of the primary and secondary package, in color and to scale, for the authorized tobacco products and derivatives, which must be provided in their different brands and presentations.
- 5. If applying for permit renewal, the same requirements must be fulfilled.
- 6. If the application, together with the respective documentation, is not submitted by the proprietor or legal representative, an administrative power of attorney must be presented, with a special clause to such effect.
- 7. The permit in question must be granted for each one of the establishments. If the juridical person is the proprietor or legal representative of several similar establishments, it may submit one single application, attaching a sworn statement of the list of establishments to be authorized for each health region.
- 8. For importation intended for personal consumption, MINSAL must issue technical guidelines, which should address the needs of the interested party.

B. Permit for Commercialization and Wholesale Distribution.

Any natural or juridical person who engages in the commercialization and wholesale distribution of tobacco products shall have the following obligations:

- a) To submit a written application for their respective registration in the Register.
- b) To establish the fixed location where the commercial activity is to be performed, and the storage warehouse for distribution. If this should change, a new permit must be applied for.
- c) Unique Identity Document (DUI – *Documento Único de Identidad*), for Salvadoran natural persons, or those with a residency card or passport in the case of foreigners; if a juridical person, the respective documentation of the Legal Representative.
- d) The Tax Identification Card of the Company and the Legal Representative.
- e) The Registered Public Instrument of the Company's establishment, as well as amendments thereto, if any.
- f) A document proving the legal status of the legal representative, that is up to date.
- g) Valid registration of the company or establishment.

The permit in question must be granted for establishments where there is commercialization and wholesale distribution of tobacco products.

With respect to what is established in this article, merchants whose monthly sales do not exceed the contents of a tertiary package must only comply with what is established in items a, b and c of this article.

On the Register of permits and transgressions.

Art. 6.- MINSAL shall maintain a National Register of permits and sanctions, which shall contain a record of natural and juridical persons who process permit applications, those to whom permits are granted, and those who are subject to sanctions for violations of the Law for Tobacco Control and these Regulations, as well as whether fines have been imposed, and the status thereof.

When a permit for installation and operation is at issue, or its renewal, the Community Family Health Unit shall ask the competent Regional Bureau of Health for verification in the National Register as to whether the party in question is up to date in the payment of fines, for which a certification must be included in the respective administrative case file.

CHAPTER II

PLACES OR POINTS OF SALE

Art. 7.- Each place or point of sale must comply with the following requirements:

- a) Have the respective MINSAL authorization for commercialization or sale of tobacco products and derivatives. Said authorization may not be assigned to a mobile point of sale.
- b) Keep a sign posted inside the establishment with captions on the prohibition of sale, distribution or giving away for free to minors, pursuant to what is established in the respective sanitary technical standard.
- c) Demand that persons appearing to purchase tobacco products and derivatives prove that they are of age with an official photo identification.

- d) Any advertising form or item exhibited at a place or point of sale must comply with the requirements established in the Law, in the Framework Convention on Tobacco Control of the WHO (Article 13, paragraph 4, item b) and these Regulations, regarding images, pictograms and health warnings. That is to say, they must contain warnings of harm and the respective pictograms and images occupying fifty percent of the item containing the advertising; nor may they make use of figurative signs, misleading terms such as "light, low in tar, mild," among others, or direct or indirect incitation to consume tobacco products and derivatives evoking settings, characters and situations, such as "you're free, so make your decision, it's your right," among others.
- e) Tobacco products and derivatives can only be publicly exhibited in display windows inside establishments where sale is authorized, as long as their packages and packs show the images or pictograms authorized by MINSAL directly to the public, showing the harm that tobacco causes to people's health. Under no circumstances will it be permitted to obstruct the visibility of the health warnings.
- f) In places or points of sale, advertising references can only be made to the brand of tobacco products and derivatives.
- g) If there is an ample availability of supply for sale of a single tobacco product or derivative, each pack is to be positioned one in front of the other.
- h) Stands, display racks and other arrangements for self-service or impersonal sale in supermarkets and convenience stores are prohibited, to prevent inducing girls, boys and adolescents to begin consumption. All that will be permitted is a written list of the tobacco products for sale, with their respective prices, and the information that provides a warning about the harm caused by tobacco smoke must be exhibited, in order to avoid compulsive consumption on the part of those people who wish to quit smoking.

Sales by electronic means

Art. 8.- Sales to consumers via telephonic, digital, electronic, internet, postal service or other comparable means, through which the identification of the buyer and the fact that he is of age cannot be proven in a clear, timely and decisive manner, are absolutely prohibited.

CHAPTER III

HEALTH WARNINGS

Authorization

Characteristics

Art. 9.- Any primary or secondary packaging intended for the commercialization and distribution of tobacco products and derivatives must exhibit a clear and precise warning of the harmful effects for people's health involved in their consumption, or exposure to tobacco smoke and the pertinent components thereof.

Health warnings expressing the harmful effects for people's health shall have the following characteristics:

- a) They must occupy 50% or more of the surface area on both of the main exposed surfaces of each primary and secondary package.
- b) They must be composed of messages with text in Spanish, and images and pictograms that are clear, prominent and legible.
- c) No less than ten health warnings, images and pictograms are to be used, combined in different pairs for each primary and secondary package. Similar warnings on both sides will not be permitted.
- d) The rotation of warnings will be for two years, after which MINSAL shall authorize replacing them for an additional two years; in the event of renewal, the interested party must technically justify its request.
If, upon entry into validity of a new lot of health warnings, surpluses of the previous warning should remain in warehouses, a written application must be submitted to MINSAL for their commercialization and distribution, and this may not be greater than three months.
- e) The use of false, mistaken or misleading messages that could prompt consumption or misunderstanding with respect to their characteristics, harmful health effects, risks, emissions, symbols, figurative signs and terms or other kinds that could have the direct or indirect effect of creating the false impression that a particular tobacco product is less harmful than others, such as the phrases "low in tar content," "light," "ultra-light" or "mild," among others, are prohibited.

MINSAL shall require that health warnings appearing on all primary and secondary packages of tobacco products and derivatives may not be removable under any circumstances.

Unofficial Translation

Any caption, information, characteristics or any other kind of text printed on packages of tobacco products and tobacco derivatives, must at all times be visible and in Spanish.

Informative Captions

Art. 10.- In addition to health warnings, primary packages of tobacco products and derivatives must exhibit informative captions on the lateral surfaces that should show texts in Spanish on one side, in black letters on a white background, where the following messages can be read from the lower to the upper part of the pack:

- a) This product KILLS.
- b) Contains nicotine, tar and carbon monoxide.
- c) Get help by phoning MINSAL and FOSALUD.
- d) Sale to minors prohibited.

It is prohibited to use messages, symbols, figures, images, figurative signs and logos inside the pack that are associated with product manufacture, instructions for use, or the promotion of tobacco products.

Information on changes of warnings.

Art. 11.- MINSAL shall inform manufacturers, importers and wholesale distributors of new health warnings nine months prior to the end of the rotation noted in Article 9, item "d" of these Regulations, in such a way that the latter can process the new authorizations, and print them and the respective packaging during this period.

Manufacturers or importers shall submit a written application to the head of MINSAL for authorization of the health warnings, images and pictograms on their different brands and presentations, attaching two sample copies of the primary and secondary package for tobacco products and derivatives, in color and to scale, that match the templates for assembled packs that are to be sold in El Salvador.

Composition of Technical Commission.

Art. 12. The head of MINSAL shall appoint a multidisciplinary Technical Commission that will analyze the sample copies of primary and secondary packaging to ascertain whether they are in compliance with everything what is established in the Law for Tobacco Control and these Regulations, as well as with the technical standards on health warnings, images and pictograms issued by MINSAL.

**CHAPTER IV
ADVERTISING****Prohibition**

Art. 13.- Any form of advertising, promotion or sponsorship of tobacco products and derivatives is prohibited, except for the exceptions expressly indicated in the Law and set forth in these Regulations.

At points of sale

Art. 14.- All managers or proprietors of points of sale of tobacco products and derivatives must submit a written application annually to the competent Regional Health Office for authorization of the advertising in the said place, following the requirements set forth in Art. 7 of these Regulations.

The promotion of tobacco products and derivatives must take place inside places where events are held for such purpose, with access restricted to adults only.

Brand logos

Art. 15. Visible use of the name, logo or emblem of brands of tobacco products and derivatives or of tobacco companies, as well as any kind of advertising, promotion or sponsorship at social responsibility, sports, recreational, religious, cultural, scientific or commercial activities, among others, are prohibited.

Unofficial Translation

Prohibited objects

Alt. 16.- The manufacture, importation, distribution for free or sale of foods, toys or other objects that have the shape, brand or design of tobacco products and derivatives, is prohibited.

Kind of advertising

Art. 17.- Advertising at points of sale must be stationary, and meet the requirements established in the Law and these Regulations, with regard to health warnings, images and pictograms.

Advertising may not be undertaken using fliers, or through the giving out of free samples, or by any means outside the point of sale.

The written or printed advertising exhibited at points of sale must have printed on fifty percent of its outer surface area the health warnings and messages authorized by the Ministry of Health.

Responsibility of the Health Region.

Art. 18.- The Health Region will be in charge of addressing matters relating to advertising at points of sale and authorizations for the promotion of tobacco products and derivatives.

Once authorization for advertising at points of sale has been obtained, the manager thereof must place said authorization in a location visible to all of the public, which can be ascertained upon inspection, and failure to do so will be subject to sanction.

TITLE III**PROTECTION AGAINST EXPOSURE TO TOBACCO SMOKE****CHAPTER I****SMOKE-FREE SPACES****Protection of non-smokers**

Art. 19.- Proprietors and managers of the public and private smoke-free spaces established in Article 6 of the Law for Tobacco Control must seek the protection of non-smokers as a matter of priority, prominently posting signs, notices or symbols that express the prohibition of smoking or holding lit tobacco.

Outside of spaces reserved for smokers, there should not be ashtrays of any kind.

Signs prohibiting smoking and their characteristics.

Art. 20.- Places where smoking or holding lit tobacco is restricted must have signs with the following characteristics:

- a) Be of rectangular shape, with minimum dimensions of forty-five centimeters long by thirty centimeters wide; the signs must be visible; they are to be positioned in accordance with the space or dimensions existing in the particular establishment, in such a way that the message is clear.
- b) Font: black VEGUR NORMAL.
- c) The background of the sign must be white, to allow for its visibility and set it apart from the place where it is posted.
- d) It must expressly state: SMOKING IS PROHIBITED IN THIS PLACE, adding the symbol for prohibiting smoking. This text and its respective symbol must cover at least forty percent of the total area of the sign. In the rest of the space, it must make reference to the text established by Articles 6 and 7 of the Law for Tobacco Control.
- e) Include the phone number or any other electronic means for reporting non-compliance with the Law and these Regulations.

MINSAL shall provide the electronic template of the sign in question to anyone who may request it.

Unofficial Translation

Rights of non-smokers.

Art. 21.- All users or clients of public and private smoke-free spaces or places shall have the following rights:

- a) – The manager, proprietor or representative of the place or workers shall challenge violators to desist from their conduct, because it is harmful to health and in violation of the legal provisions of the Law for Tobacco Control and these Regulations.
- b) If a user or client observes people smoking or consuming tobacco products, he may demand that the proprietor, manager, administrator, legal representative or other persons with decision power call upon the offender to desist from his conduct.
- c) In the event that the offender or offenders should refuse to desist from his or their conduct, the responsible persons mentioned above must request their eviction from the premises, and if necessary, they may request assistance from the National Civil Police, who shall take action, in accordance with their competency.

Notice of violation.

Art. 22.- In cases where notice is received of non-compliance with the provisions established in the Law and these Regulations, the National Civil Police can take enforcement action anywhere in the country, calling for compliance with the law, and if the violation persists, they must draw up the respective document, giving notification thereof to the alleged offender with a notice; this must be forwarded to the competent Community Family Health Unit, which in turn must convey it to the Regional Bureau of Health for the competent jurisdiction, in order for the respective sanctions proceedings to be undertaken, in accordance with what is established in Article 31, sub-paragraph 3 of the Law for Tobacco Control.

Places where smoking is prohibited.

Art. 23.- Pursuant to what is established in the Law for Tobacco Control and its Articles 1, item f) and 5, paragraph 2, item b) of the Framework Convention on Tobacco Control of the WHO (FCTC) concerning smoke-free places, it is prohibited to smoke or hold lit tobacco products and tobacco derivatives that give off smoke, gases or vapors, in any of their forms, or in devices, including electronic cigarettes and pipes, in the following places:

- a) Work places include access areas, traffic zones, motor vehicles and parking lots, pursuant to Article 8, paragraph 2 of the FCTC.
- b) Venues where events, spectacles and activities bringing together large crowds of people take place, whether of a political, athletic, recreational, religious, cultural, scientific or commercial nature, among others.
- c) Land, sea and air transportation vehicles, with point of origin and destination within the national territory.
- d) Premises or establishments where food is produced, processed, prepared, tasted or sold.
- e) Bus terminals and bus stops, as well as any means of passenger transportation.
- f) Shopping centers, casinos, nightclubs, discotheques, bars, restaurants and cafeterias.
- g) Offices of government ministries and related facilities, autonomous agencies and non-governmental public service institutions.
- h) Public and private educational institutions at all levels.

Smoking areas

Art. 24.- MINSAL shall authorize areas for smokers, among those established in Article 6, item k) of the Law for Tobacco Control, as long as they comply with all of the following requirements:

- a) They are separated from all places where smoking is prohibited; accordingly, they can never be in enclosed or indoor places, areas or spaces with public access.
- b) They cannot be located in spaces where service is provided directly to customers.
- c) Have appropriate signage that prohibits the entry of minors and warns about the health risks to which one is exposed by entering such spaces, particularly pregnant women, the elderly and those suffering from cardiovascular, and respiratory diseases, cancer and asthma, among others.
- d) Be identified as spaces for smoking by clear and visible signage, that must be authorized by the competent MINSAL Regional Bureau of Health.
- e) Carry out quarterly measurements of contamination of the air by tobacco smoke with facilities authorized for such purpose by MINSAL, demonstrating that they fall within a parameter that is not damaging to the health of human beings.

CHAPTER II

PREVENTION AND QUITTING

The National Health System.

Art. 25.- The National Health System, under the direction of MINSAL, must coordinate actions with the Ministry of Education to incorporate into the Science curriculum and at all levels the subject of prevention of tobacco consumption and the creation of smoke-free spaces, in such a way that sufficient, continuing, up to date and truthful information on the harmful health effects, addictive nature, mortal threat from tobacco consumption and harm caused by exposure to second-hand tobacco smoke is imparted.

Publicizing and disseminating the harmful effects of tobacco.

Art. 26.- As the guiding authority on health, MINSAL must publicize and disseminate to the public the addictive characteristics of tobacco, the harm that it causes and the existence of specialized services to help with quitting and rehabilitation from tobacco consumption, via strategies of information, education and communication.

Prevention.

Art. 27.- Strategies for prevention, detection and short-term intervention to encourage quitting smoking should be implemented at health care institutions; furthermore, actions should be undertaken for: referral and resumption with specialized services, tracking the prevalence of tobacco addiction and interventions undertaken through a system of epidemiological monitoring.

Specialized services.

Art. 28.- MINSAL should provide free specialized health services for prevention, quitting and rehabilitation from tobacco addiction, through Centers for the Prevention and Treatment of Addiction, and furthermore, to increase on an ongoing basis access to and coverage by such services to protect, respect and guarantee the health of the population.

CHAPTER III

MONITORING OF TOBACCO ADDICTION

Responsible agency

Art. 29.- MINSAL, acting through the Regional Bureaus of Health and the Community Family Health Unit (UCSF), shall have the responsibility of fulfilling all of the functions and conducting activities relating to the control of tobacco, its products and derivatives. Actions for execution must be in keeping with what is set forth in the Law and these Regulations, without impairment what is established by other applicable provisions.

At the local level, UCSFs must provide the conditions necessary to requisition support from Municipalities, local sectors and actors for protection against tobacco and the development of actions to promote health and prevent tobacco use.

Functions of Regional Bureaus.

Art. 30- It is incumbent upon MINSAL's Regional Bureaus of Health, supported by the Bureau of Environmental Health, to assume the following responsibilities:

- a) To participate in the development of national strategies for tobacco control.
- b) To process and resolve administrative proceedings for the implementation of the Law for Tobacco Control and these Regulations, such as the authorizations, inspections and sanctions indicated, in coordination with UCSFs.
- c) To maintain the register of natural and juridical persons authorized to manufacture, import, export, commercialize and distribute tobacco products and derivatives.
- d) To observe and ascertain whether tobacco products and tobacco derivatives that are sold and distributed in their geographical jurisdiction have approval for their packaging and labeling, above all for health warnings issued by the management of MINSAL.
- e) To verify implementation of the Law for Tobacco Control and its Regulations.

Unofficial Translation

- f) To facilitate the training of personnel serving the Regional Health Bureaus, the Basic Comprehensive Health System (SIBASI – *Sistema Básico de Salud Integral*), hospitals and UCSFs, on tobacco use and control measures, in coordination with Centers for Prevention and Treatment of Addiction (CPTA – *Centros de Prevención y Tratamiento de Adicciones*) and other agencies.
- g) To promote research and scientific activities involving various subject areas relating to the tobacco epidemic.
- h) To implement a strategy for information, education and communication on the health risks caused by tobacco consumption and exposure to tobacco, in coordination with Centers for Prevention and Treatment of Addiction (CPTA) and other agencies.

Community Family Health Units (UCSF – *Unidades Comunitarias de Salud Familiar*)

Art. 31.- The following things are incumbent upon UCSFs:

- a) To promote the active participation of Municipalities, local sectors and actors, through alliances, to protect against tobacco and to undertake actions for the promotion of health and the prevention of tobacco use.
- b) To implement strategies for information, education and communication on the health risks caused by tobacco consumption and exposure to tobacco, in coordination with the Centers for Prevention and Treatment of Addiction (CPTA) and other agencies.
- c) To implement sanitary control actions that make it possible to identify sectors resistant to compliance with the Law, periodic visits to places and establishments subject to control, identifying violators of the Law and coordinating with the legal advisor of the Regional Bureau of Health to substantiate the administrative process.

Inspections.

Art. 32.- The UCSF must verify compliance with the Law and these Regulations through the use of health inspectors. UCSFs must report to the competent Regional Bureau of Health any irregularities that in their judgment constitute violations of the aforesaid law.

Frequency of Inspections.

Art. 33.- The following inspections must be conducted:

- a) Scheduled Inspections, which are those that are included in the monthly plan, and are meant to ascertain compliance with the legal and regulatory provisions of the Law for Tobacco Control and these Regulations.
- b) Special, or unscheduled inspections, which are those that are conducted to ascertain expressly determined facts associated with the commission of some sort of misdeed, which require immediate and urgent proof.

When verification of compliance concerns provisions involving smoke-free spaces, where it is prohibited to smoke or hold lit tobacco products and tobacco derivatives, if necessary, the inspection authority shall have at its disposal the participation of specialized technical personnel to measure contamination of the air by tobacco smoke, as well as law enforcement personnel.

Evidence and reports

Art. 34.- Inspection visits are to be conducted with the participation of the manager or person in charge of the establishment subject to verification; if none of the aforementioned individuals are on the premises at the time of the inspection, intervention by personnel of higher rank will be required, and they must facilitate the conduct of the inspection visit. ' •

The inspector can avail himself of different evidence that records or captures the incidents noted in the investigation, and this can include photographs, videos, particle emissions captured by devices for measuring smoke contamination, reports by witnesses and/or victims and others. Subsequently, the inspector will meet with any persons who may have figured in the inquiries, in order to explain any offenses that have, in his opinion, been committed.

At the end of the visit, the inspector shall draw up the respective report, on the premises where the inspection took place, recording the facts ascertained and the allegations of the parties, as well as the deadline or deadlines by which the offenses observed are to be remedied, and he must take note, if appropriate, of any objections that may have been put forward.

Unofficial Translation

The inspector is authorized to set differentiated deadlines, based on the nature of the offenses. These deadlines and what is set forth in the foregoing sub-paragraph must not exceed fifteen business days. With the express consent of the party who must meet the said deadline, the period in question can be shortened.

The report is to be signed by any people who have figured in the investigation. Refusal on the part of any of them to sign the report does not invalidate it, and in such case, the inspector must register the fact, as well as any recommendations that may be appropriate.

Follow-up inspections.

Art. 35. Follow-up inspections are to be carried out at the end of the period set by the inspector in the inspection report. If, in the course of the follow-up inspection, it is ascertained that the violations have not been remedied, the inspector shall draw up a report, which he will forward to the competent Regional Bureau of Health, to impose whatever sanction may be called for.

Removal and suspension.

Art. 36.- In the event that advertising materials for tobacco products and derivatives are found that have not been authorized, their immediate removal shall occur; moreover, if activities that have not been authorized of a promotional nature or involving sponsorship of tobacco products and derivatives are discovered, the immediate suspension thereof will take place. For both offenses, the health inspector will initiate the respective administrative proceedings.

CHAPTER IV**MEASURES TO FIGHT ILLEGAL PRODUCTION AND THE ILLEGAL TRADE****Oversight**

Art. 37.- MINSAL will see to it that tobacco products and derivatives, as well as imported materials, comply with the Law and these Regulations, as well as with other applicable legal provisions.

Coordination between institutions

Art. 38.- For purposes of oversight and sanitary enforcement, MINSAL, acting through the Health Regions, in coordination with the respective Law Enforcement authorities and the Ministry of the Treasury, is authorized to take action in maritime ports and airports, on the border, and in general, at any point in the national territory.

Confiscation.

Art. 39.- Health inspectors, guided by the Legal Advisor of the Regional Bureau of Health, who in the exercise of his functions, and with the assistance of the National Civil Police of the locality, conduct total or partial preventive confiscation of tobacco products and derivatives, must draw up a report of such action, and shall make it available to the Regional Bureau of Health of the jurisdiction where the action took place, within no more than three business days.

Upon completion of the process of administrative settlement, the authority that presided over the proceedings shall order the destruction or the return of the tobacco products and derivatives, as the case may be.

If an administrative proceeding is resolved in favor of the alleged offender and he does not appear to remove the confiscated product, MINSAL shall order the destruction of the property, for which it must draw up the respective report. When the destruction of such property is undertaken, expenses are to be borne by the owner of the product, and appropriate measures must be taken to prevent risks to health and the environment.

TITLE IV

OFFENSES, SANCTIONS AND APPEALS

CHAPTER I

OFFENSES AND SANCTIONS

Violations

Art. 40.- Violations of these Regulations will be sanctioned in accordance with what is established in Articles 23, 24 and 25 of the Law for Tobacco Control.

Sanctions

Art. 41.- Failure to comply with the provisions established in these Regulations, will be sanctioned in accordance with what is set forth in Article 27 of the Law for Tobacco Control.

CHAPTER II

SANCTIONS PROCEEDINGS

Proceedings

Art. 42.- Administrative proceedings to sanction any contravention of this Law and what is established in these Regulations, are to be conducted in accordance with what is set forth in Articles 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 and 41 of the Law for Tobacco Control.

CHAPTER II

APPEALS

Acceptance

Art. 43.- Appeals due to non-acceptance of rulings issued in the administrative proceedings established in this Law shall adhere to the terms set forth in the Law for Tobacco Control, pursuant to Articles 46 and following.

Entry into force

Art. 44.- This Decree shall enter into force eight days after its publication in the *Diario Oficial*.

ISSUED AT THE PRESIDENTIAL RESIDENCE: San Salvador, on July twenty-night, two thousand and fifteen.

SALVADOR SÁNCHEZ CERÉN,
PRESIDENT OF THE REPUBLIC.

ELVIA VIOLETA MENJÍVAR ESCALANTE,
MINISTER OF HEALTH.