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### **CONTENTS**

4-14

Pág.

#### LEGISLATIVE BRANCH

Decreto No. 498.- Reformas a la Ley de la Caja Mutual de

#### MINISTERIO DE HACIENDA

#### RAMO DE HACIENDA

los Empleados del Ministerio de Educación.....

Acuerdo No. 1753.- Se aprueba la Resolución No. 1-CDF-1172/16, de fecha 3 de noviembre de 2016, emitida por el Consejo Directivo del Fondo Salvadoreño para Estudios de

Preinversión.

#### **EXECUTIVE BRANCH**

#### MINISTERIO DE GOBERNACIÓN Y DESARROLLO TERRITORIAL

Escrituras públicas, estatutos de la Fundación Ayudando Familias y Decreto Ejecutivo No. 46 declarándola legalmente establecida, aprobándole sus estatutos y confiriéndoles el carácter de persona jurídica.

MINISTERIO DE ECONOMÍA

RAMO DE ECONOMÍA

Acuerdo No. 1328.- Se otorgan los beneficios de la Ley General de Asociaciones Cooperativas a la Asociación Cooperativa de Ahorro, Crédito y Servicios Técnicos de Oriente, de Responsabilidad Limitada.....

#### RAMO DE GOBERNACIÓN Y DESARROLLO TERRITORIAL

Escrituras públicas, estatutos de la Asociación Comunitaria para la Protección Ambiental Marino Costera de Ahuachapán Sur y Acuerdo Ejecutivo No. 210, aprobándoles sus estatutos y confiriéndole el carácter de persona jurídica. .....

Acuerdo No. 1580.- Se autoriza a la sociedad Saram, Sociedad Anónima de Capital Variable la construcción de seis tanques para consumo privado, ubicados en el municipio de Armenia.....

## MINISTERIO DE EDUCACIÓN

#### RAMO DE EDUCACIÓN

AcuerdosNos.15-1217,15-1442y15-1585.-Reconocimiento de estudios académicos.....

Acuerdo No. 15-1470.- se autoriza la ampliación de servicios del centro educativo privado denominado Queens School Of 

#### MINISTERIOS DE JUSTICIA Y SEGURIDAD PÚBLICA Y DE LA DEFENSA NACIONAL

Decreto No. 64.- Se declara prohibida la portación de armas de fuego por un período de sesenta días, en todo el municipio de San Miguel, departamento del mismo nombre, incluyendo sus cantones y caseríos.....

DIARIO OFICIAL Volume N° 413			
	Pág.		Pág.
MINISTRY OF HEALTH		DE SEGUNDA PUBLICACION	
DIVISION OF HEALTH		Aceptación de Herencia	79
Order No. 1732Technical Standard for Implementation of Health Warnings for Tobacco Control	49-63	Título Supletorio	79
		Título Municipal	79-80
JUDICIAL BRANCH  CORTE SUPREMA DE JUSTICIA		DE TERCERA PUBLICACION	
Acuerdos Nos. 987-D, 1006-D, 1013-D, 1054-D, 1058-D, 1067-D y 1076-D Autorizaciones para ejercer la profesión de		Herencia Yacente	80
abogado en todas sus ramas	64-65	SECCION CARTELES PAGADOS	
INSTITUCIONES AUTÓNOMAS  ALCALDÍAS MUNICIPALES		DE PRIMERA PUBLICACION	
Decreto No. 3 Prórroga de la Ordenanza Transitoria		Declaratoria de Herencia	81-90
para el Pago de Tasas e Impuestos, con Dispensa de Multas e Intereses Moratorios, del municipio de Sonzacate, departamento de Sonsonate.	65-66	Aceptación de Herencia	90-97
Estatutos de las Asociaciones "Comunal para el Desarrollo		Herencia Yacente	97-98
Ambientaldel municipio de Perquín" ydela "Comunidad Girasoles de Guadalupe" y Acuerdos Nos. 1 y 3, emitidos por las Alcaldías Municipales de Perquín y San Luis La Herradura, aprobándolos y confiriéndoles el carácter de persona jurídica		Título de Propiedad	98-99
	67-76	Título Supletorio10	)0-102
SECCION CARTELES OFICIALES		Título de Dominio10	)2-103
DE PRIMERA PUBLICACION		Sentencia de Nacionalidad	)3-105
Aceptación de Herencia	77-78	Juicio de Ausencia10	)5-106
Aviso de Inscripción	78	Cancelación de Marca 10	)6-107

ORDER No. 1732

# MINISTRY OF HEALTH

DIVISION OF HEALTH

San Salvador, November 21, 2016

EXECUTIVE BRANCH IN THE HEALTH DIVISION,

#### WHEREAS:

- I. The Law for Tobacco Control, in its Articles 2, 10, 11, 12, 16, 17 and 52, regulates the competency of the Ministry of Health on the issuance of health warnings and other characteristics that must be met by packages containing tobacco and derivative products;
- II. Based on what is prescribed in the Framework Convention on Tobacco Control of the WHO in Article 11, which prescribes the terms relating to the packaging and labeling of tobacco products;
- III. The Regulation of the Law for Tobacco Control in its Articles 7, items b, d, and h; and 9, 10, 12 and 20, regulates matters concerning the ways to establish and include the various health warnings on tobacco products, signs and advertising;
- IV. Pursuant to the Code of Health, Article 40, disposing that the Ministry of Health is the body charged with determining, planning, executing and setting pertinent standards, as well as organizing, coordinating and evaluating the execution of health-related activities; on the other hand, the Internal Regimen of the Executive Branch establishes in Article 42, item 2, that it is incumbent upon the Ministry of Health, "To set standards and techniques with regard to Health, and to order such measures and provisions as may be necessary to safeguard the health of the population;" and,
- V. In accordance with the foregoing clauses, and in order to achieve the fundamental purpose of the State, of ensuring the collective health, the present Technical Standard is hereby established.

THEREFORE: in the exercise of its legal faculties, it ORDERS the issuance of the following:

TECHNICAL STANDARD FOR THE IMPLEMENTATION OF HEALTH WARNINGS FOR TOBACCO CONTROL

49

#### DIARIO OFICIAL Volume Nº 413

50

# CHAPTER I FUNDAMENTAL PROVISIONS

#### **Purpose**

Art. 1.- The purpose of the present document is to establish the technical standard that regulates health warnings, pictograms and advertising, for activities involving tobacco and its products.

#### Scope of application

Art. 2.- Any natural or juridical person who imports, exports, produces, commercializes or distributes tobacco products and tobacco derivatives is required to comply with the present technical standard.

#### Competent authority

Art. 3.- It is incumbent upon the Ministry of Health (hereinafter, 'MINSAL'), to verify the implementation, oversight, monitoring and compliance with the present technical standard, through the Regional Bureau of Health and Office of the Community Agency for Family Health (hereinafter, 'UCSF'), as well as any others it or the head of MINSAL may legally appoint.

# CHAPTER II IMAGES AND PICTOGRAMS

#### **Health Warnings**

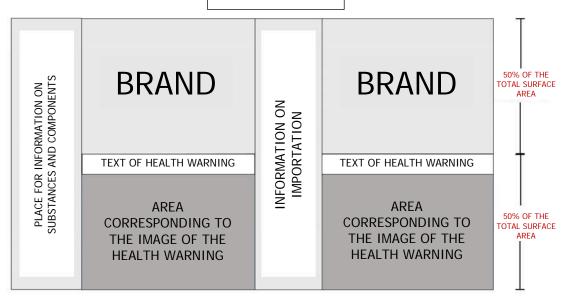
Art. 4.- Any primary or secondary packaging intended for the commercialization and distribution of tobacco products and derivatives, must contain clearly and precisely health warnings, consisting of an image and a text, on the harmful effects resulting from tobacco consumption or exposure to tobacco smoke and the components thereof, on the main outer surfaces, which must always be visible to the public.

The text of the health warning must be within a frame with a black border, on a white background, and in black letters. The text on the primary packaging is to be placed on the upper part of the image.

Regardless of the dimensions of the surface of the advertising, the health warnings must cover fifty percent of the total size, and MINSAL shall determine whether one, two or more warnings are to be used, and they shall have the following characteristics:

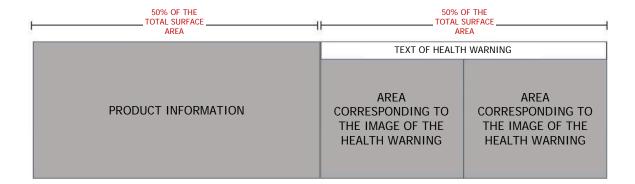
a) Primary Package of Tobacco Products of cigarettes in presentations of ten and twenty units, in short and long sizes.

#### PACK OF 20 UNITS



#### PACK OF 10 UNITS PLACE FOR INFORMATION ON SUBSTANCES AND INFORMATION ON IMPORTATION 50% OF THE TOTAL SURFACE **BRAND BRAND** AREA COMPONENTS TEXT OF HEALTH WARNING TEXT OF HEALTH WARNING **AREA AREA CORRESPONDING TO CORRESPONDING TO** 50% OF THE TOTAL SURFACE THE IMAGE OF THE THE IMAGE OF THE ARFA **HEALTH WARNING HEALTH WARNING**

b) Secondary package of tobacco products, in presentations of ten packs of twenty cigarettes each, and a presentation of twenty packs of ten cigarettes each.



In the case of secondary wrappings or packages having health warnings printed on them with their respective image and text, it shall not be authorized for this kind of package to be replaced by transparent wrappings that show the primary package of the internal products, such cases shall be regarded as non-compliance with what is established by the Law for Tobacco Control, its Regulation and the present technical standard, with the responsible party being liable for the respective sanction.

#### **Changes of Health Warnings**

Art. 5.- MINSAL shall inform manufacturers, importers and wholesale distributors, of new health warnings nine months before the end of the previous rotation, in such a way that the latter can process the new authorizations, and carry out their printing and respective packaging during this period.

The manufacturer or importer shall submit a written request to the head of MINSAL for authorization of health warnings, images and text in their various brands and presentations, attaching two copies of the primary and secondary package, in color and to scale, of the tobacco products and derivatives, that match the templates of assembled packs that are sold in El Salvador.

#### **Informative Captions**

Art. 6.- In addition to health warnings, primary packages of tobacco products and derivatives should exhibit informative captions on lateral surfaces, which should express on one of them texts in Spanish with in black letters on a white background, with the following information:

DIARIO OFICIAL.- San Salvador, November 25, 2016.

BOX OF 20 UNITS

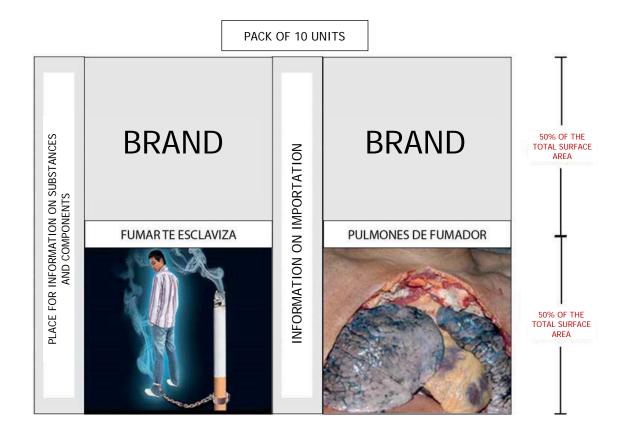
#### THIS PRODUCT KILLS

CONTAINS NICOTINE, TAR AND CARBON MONOXIDE GET HELP AT 2528-9727 (FOSALUD) OR 2205-1655 (MINSAL) SALE PROHIBITED TO MINORS

TEXT ON PACK OF 20 UNITS

THIS PRODUCT KILLS	Características tipográficas: impac regular, 24 puntos.
CONTAINS NICOTINE, TAR AND CARBON MONOXIDE	Myriad Pro, regular 7.5 puntos, interlineado de 9 puntos
GET HELP AT 2528-9727 (FOSALUD) OR 2205-1655 (MINSAL)	Myriad Pro, light 7.5 puntos, interlineado de 9 puntos
SALE PROHIBITED TO MINORS	Myriad Pro, regular 6 puntos, interlineado de 7.2 puntos

# PHOTOGRAPHS AND EXAMPLE OF WARNING APPLIED TO 20 10 UNIT SIZES, PRICE LISTS AND ADVERTISING



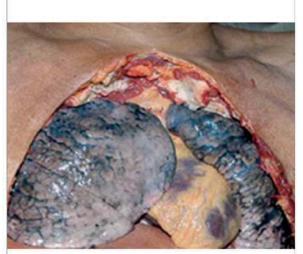


#### DIARIO OFICIAL.- San Salvador, November 25, 2016.

50% OF THE TOTAL 50% OF THE TOTAL SURFACE AREA SURFACE AREA

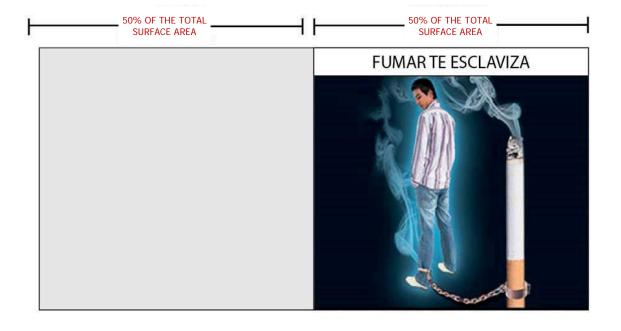
#### **LISTA DE PRECIOS** 20 unidades 10 unidades MARCA \$ 0.00 \$ 0.00 \$ 0.00 MARCA \$ 0.00 MARCA \$ 0.00 \$ 0.00

Listado informativo de precios para el consumidor



SALE PROHIBITED TO MINORS

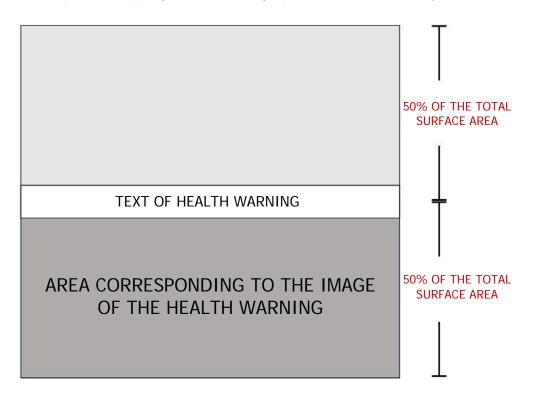
**PULMONES DE FUMADOR** 



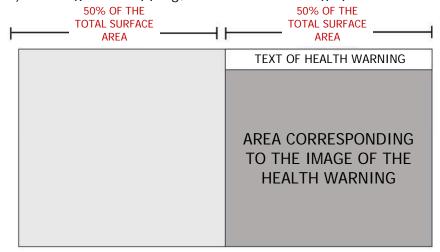
#### Packaging of other products

Art. 7.- In addition to the Health Warnings established for the kinds of packages stated in Article 4 of the present technical standard, the form, surface or material of the wrapping should, as appropriate, have printed, stamped or attached to it the health warnings on all packages of products containing tobacco, or be drawn up on this basis, as follows:

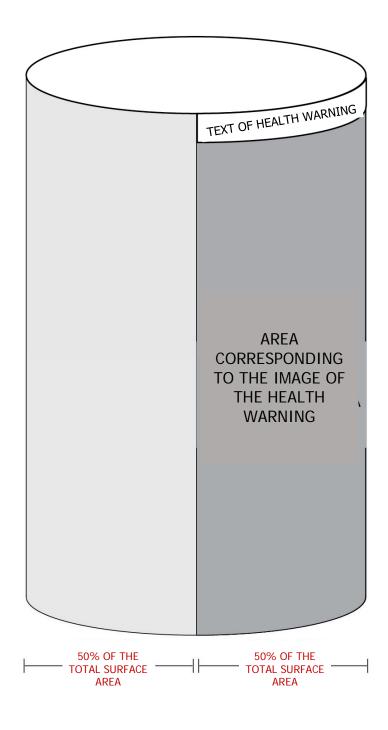
a) Square wrapping, with warnings positioned horizontally.



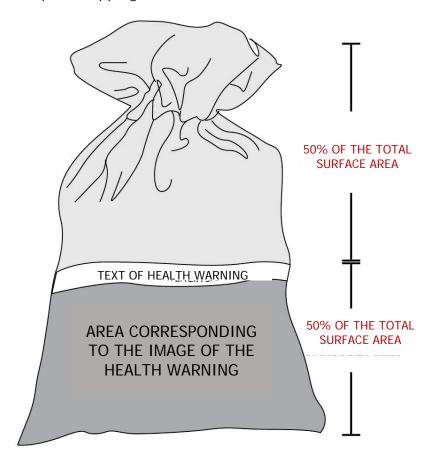
b) Rectangular wrapping, with health warnings positioned vertically.



### c) Cylindrical Wrapping



d) Irregular shaped wrapping.



The foregoing descriptions of the placement and size of health warnings are to be applied to packages of tobacco products and tobacco derivatives which have square, rectangular, cylindrical and irregular shapes; regardless of whether their presentation includes one or several units and the material of which the package is made, whether in a bag, carton or box.

In cases where a package exhibits an irregular shape, the type of material that it is made of must be taken into account for the inclusion of the health warning, as per the following rules:

1) If the material of the package or wrapping is metal or plastic, the health warning with its respective image and text must be printed on an adhesive decal and firmly affixed to the surface of the wrapping on the two main surfaces, and in the sizes and sequence stated herein.

2) If the material of the package or wrapping is wood, cardboard or paper, the health warning with its respective image and text should be printed on bond or ledger paper with the use of a glue that enables the affixing of the warning to the package in the aforementioned terms, and in no case may the paper containing them be detached or ripped away.

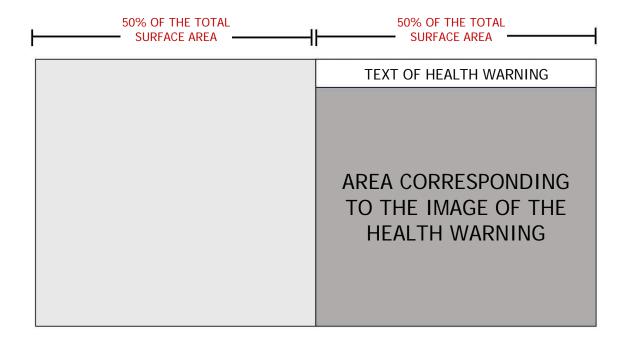
Art. 8. In cases where, due to the shape or size of the primary and secondary package, the image becomes distorted, preventing it from clearly and precisely fulfilling the purpose of the health warning, then one, two or more images are to be included sequentially, each one with its respective health warning text.

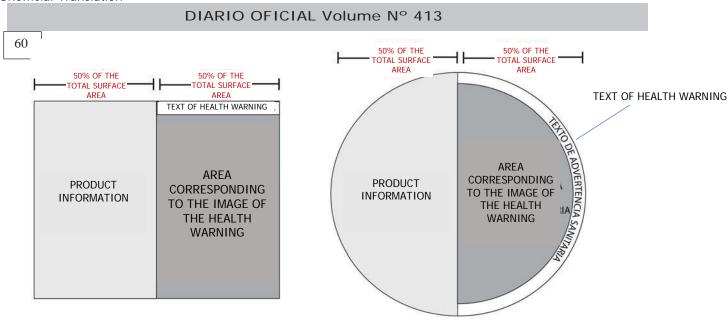
# CHAPTER III POINTS OF SALE

#### Advertising

Art. 9.- Any kind of sign, poster, printed or stamped advertising at points of sale, regardless of its size, must have health warnings that cover fifty percent of the total size.

In cases where, due to the shape or size of the sign, poster or printed advertising, the image has been distorted, preventing it from clearly and precisely fulfilling the purpose of the health warning, then one, two or more images are to be included sequentially, each one with its respective health warning text, as indicated below:





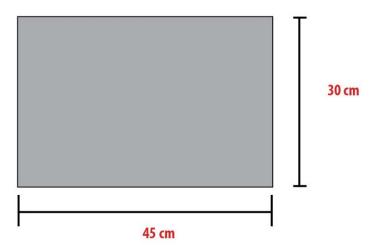
#### **Notices**

Art. 10.- Notices having to do with prohibiting sale to minors must exhibit the following characteristics:



#### Sign measurements

Art. 11.- The sign "Smoking Prohibited" should be produced as per the following measurements:



#### Content of sign

Art. 12.- The sign to prohibit smoking should be produced in accordance with the following characteristics:

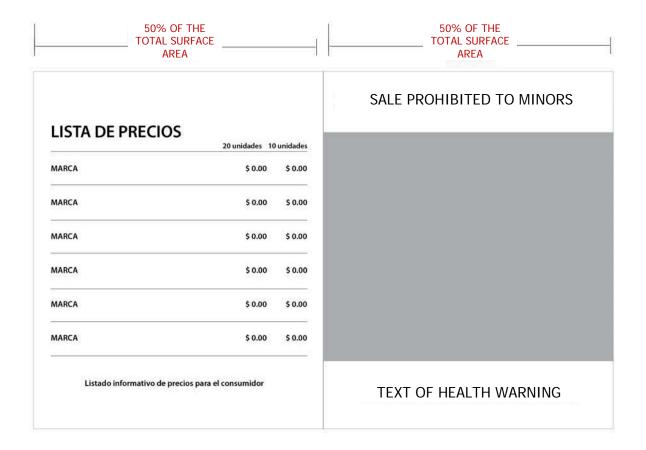


#### DIARIO OFICIAL Volume Nº 413

62

#### List of prices

The sign that provides a written list of products should be produced in accordance with the following characteristics:



#### IV. GENERAL PROVISIONS

#### **Electronic files**

Art. 13.-Any person selling tobacco and its derivative products in the national territory must submit a written application to the Executive Management of the Solidarity Health Fund (FOSALUD – *Dirección Ejecutiva del Fondo Solidario para la Salud*), for the electronic files of the health warnings and pictograms previously authorized by the Head of MINSAL that are to be used on products and in various commercial activities, pursuant to what is set forth in the Law for tobacco control and the Regulation thereof; as per the Framework Convention on Tobacco Control of the WHO.

On the other hand, one may request the digital template of the various kinds of signs and posters.

#### Failure to comply with this Standard

Art. 14.- Any failure to comply with this Technical Standard will be sanctioned pursuant to what is set forth in the Law for Tobacco Control and the Regulation thereof.

#### Regarding what has not been established

Art. 15.- Anything that has not been established in the present technical standard, should be taken up in writing in a request by the interested party, addressed to the head of this government Ministry, setting forth the rationale for the elements not established, technically and legally.

#### Rescission

Art. 16.- The Technical Guidelines for implementation of the health warnings in the Law for Tobacco Control, issued and authorized by the head of MINSAL, on February seventeenth, two thousand fourteen, are hereby rescinded.

#### **Entry into Force**

Art. 17.- The present technical standard shall enter into force as of the date of its publication in the *Diario Oficial*.

LET NOTICE HEREOF BE GIVEN,

Dra. Elvia Violeta Menjivar Escalante

Minister of Health