ANNEX II

(referred to in Article 8.)

Republication of Law N.º 37/2007, of August 14

CHAPTER I

General provisions

Article 1.

Purpose

1 — This Law establishes standards conducive to the prevention of tobacco use, in particular with regard to protection from exposure to second-hand tobacco smoke, to ingredients and emissions of tobacco products, the information that is to be provided about these products, the labeling and packaging of tobacco products, the prohibition of the sale of tobacco for oral use, remote cross-border sales of tobacco products, the requirement to provide notification of new tobacco products, the sale and labeling of certain products related to tobacco products, raising awareness and education for health, the prohibition of advertising, promotion and sponsorship for tobacco, measures for reducing demand relating to addiction and quitting consumption, sale to minors and through mechanical devices, so as to contribute towards reducing the risks or negative effects that the use of tobacco entails for the health of individuals.

2 — This Law also renders enforceable what is set forth in the Framework Convention for Tobacco Control of the World Health Organization, approved by Decree N.º 25- A/2005, of November 8, transposing into the internal legal system Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014, Delegated Directive 2014/109/UE, of the Commission, of October 10, 2014, and Directive 2003/33/CE, of the European Parliament and Council, of May 26, 2003.

Article 2.

Definitions

For the purposes of what is set forth in this Law, the following definitions shall apply:

a) "Additive ingredient," a substance, with the exception of tobacco, which is added to a tobacco product, to an individual package or any external packaging;

b) " Combined health warning," a health warning indicated in this Law and that consists of a combination of a written warning and corresponding photograph or illustration;

c) "Health warning," a warning on the adverse effects of a product on human health or other undesirable consequences of its consumption, including written warnings, combined health warnings, general warnings and informational message;

d) "Tar," condensate of raw anhydrous smoke and without nicotine;

e) "Distinctive aroma," a clearly perceptible odor or flavor that is not of tobacco, resulting from an additive or combination of additives including, without limitation, fruit, spices, aromatic herbs, alcohol, sweets, menthol or vanilla, and which can be discerned before or during the consumption of the tobacco product;

f) "Aromatic agent," an additive that conveys an odor and/or a flavor;

g) "Pouch," a package of rolling tobacco, whether in the form of a rectangular pouch with a flap that covers the opening, or in the form of a flat-backed pouch;

h) "Cigar," a roll of tobacco that can be consumed through a process of combustion, defined in greater detail in the Code of Special Taxes on Consumption, approved by Decree-Law N.º 73/2010, of June 21;

i) "Cigarillo," a cigar with a maximum weight of 3 g per unit;

j) "Cigarette," a roll of tobacco that can be consumed through a process of combustion and defined in greater detail in the Code of Special Taxes on Consumption, approved by Decree-Law N.º 73/2010, of June 21;

k) "Electronic cigarette," a product that can be used to consume vapor that contains nicotine, through a mouthpiece, or any component of such product, including a cartridge, a reservoir and a device without a cartridge or reservoir, and electronic cigarettes can be disposable or refillable through a refill and a reservoir, or refilled by a non-reusable cartridge;

l) "Commercialization," making available products, regardless of whether it is from their place of manufacture, to consumers located in the national territory, with or without payment, including through remote sales, noting that in the case of remote cross-border sales, the product is considered to be commercialized in the country where the consumer is located;

m) "Consumer," an individual who acts with aims that do not fall within the scope of his commercial, industrial, artisanal or professional activity;

n) "Outer packaging," any packaging in which tobacco products or related products are placed on the market, and which include an individual package or a set of individual packages, noting that transparent wrappings are not considered to be outer packaging;

o) "Individual package," a smaller individual package for a tobacco product or related product that is not placed on the market;

p) "Emissions," substances that are released when a tobacco product or related product is consumed in accordance with its intended aims, such as substances contained in smoke, or substances released during the process of using tobacco products without combustion;

q) "Retail establishment," any establishment where tobacco products are commercialized, including by a natural person;

r) "Manufacturer," a natural or juridical person that manufactures a product or causes it to be designed or manufactured, and commercializes it in his name or under a commercial brand;

s) "Smoking," the consumption of tobacco products, with the exception of tobacco products without combustion, the consumption of plant-based products for smoking or the use of electronic cigarettes;

t) "Second-hand smoke," smoke released into the atmosphere coming from the combustion of tobacco products;

u) "Importer of tobacco products or related products," the owner or person who has the right to dispose of tobacco products and related products that are introduced into the national territory, coming from another member State, or a third country or territory, defined as such in the Code of Special Taxes on Consumption, approved by Decree-Law N.º 73/2010, of June 21;

v) "Ingredient," tobacco, an additive, or any substance or element present in a finished tobacco product or related product, including papers, filters, dyes, capsules and adhesives;

w) "Work place" any place where workers are located, and where they are directly or indirectly subject to the control of their employer;

x) "Place of sale of tobacco" any place where tobacco products are on sale;

y) "Nicotine" nicotinic alkaloids;

z) “Maximum level " or "maximum emissions level," the maximum content or emission, including a value equal to zero, of a substance in a tobacco product, measured in milligrams;

aa) "New tobacco product," a tobacco product that: i) Does not belong to any of the following categories: cigarettes, rolling tobacco, pipe tobacco, tobacco for water pipes, cigars, cigarillos, chewing tobacco, snuff or tobacco for oral use; and ii) Is commercialized after May 19, 2014.

bb) "Potential to cause addiction," the pharmacological potential of a substance to cause addiction, a state that affects the capacity of an individual to control his behavior, usually by having a pleasing effect or relief of symptoms of discomfort, or both;

cc) "Plant-based product for smoking," a product derived from plants, aromatic herbs or fruits that does not contain tobacco and can be consumed through a process of combustion;

dd) "Tobacco product without combustion," a tobacco product that does not involve a process of combustion, including chewing tobacco, snuff and tobacco for oral use;

ee) "Tobacco products," products that can be consumed and that are not composed of tobacco, even partially, whether genetically modified or otherwise;

ff) "Tobacco products for smoking," a tobacco product, except for tobacco products without combustion;

gg) "Tobacco advertising," any kind of communication performed by entities of a public or private character, in the context of a commercial, industrial, artisanal or liberal activity, with the direct or indirect purpose of promoting a tobacco product or its consumption;

hh) "Snuff," a tobacco product without combustion which can be consumed through the nose;

ii) "Refill," a receptacle with liquid that contains nicotine, which can be used to refill an electronic cigarette;

jj) "Enclosed space," any space totally enclosed by partitions, walls or other surfaces and endowed with a roof;

kk) "Online service," any service provided remotely, by digital means, through individual request of a recipient of services, and in exchange for payment of a price, pursuant to the terms of Decree-Law N.º 7/2004, of January 7, as amended by Decree-Law N.º 69/2009, of March 10, and Law N.º 46/2012, of August 29;

ll) "Advertising vehicle" the vehicle used for transmission of an advertising message;

mm) "Tobacco," the leaves and other natural parts, whether processed or unprocessed, of the tobacco plant, including expanded and reconstituted tobacco;

nn) "Rolling tobacco," tobacco that can be used to make cigarettes by consumers or by retail establishments;

oo) "Chewing tobacco," a tobacco product without combustion intended exclusively for chewing;

pp) "Pipe tobacco," tobacco that can be consumed through a process of combustion and intended exclusively for use in a pipe;

qq) "Water pipe tobacco," a tobacco product that can be consumed in a Water pipe (hookah), and for purposes of what is set forth in this Law, Water pipe tobacco is a tobacco product for smoking, unless the product is usable in both water pipes and also as rolling tobacco, in which case it is considered to be rolling tobacco;

rr) "Tobacco for oral use," all tobacco products for oral use, with the exception of those intended to be inhaled or chewed, composed totally or partially of tobacco, in the form of powder or fine particles, or any combination of these forms, notably those provided in individual doses or porous packets;

ss) "Telesale," the dissemination of offers directly to the public, made by television channels, with the aim of providing cigarettes or other tobacco derivative products, plant-based products for smoking or electronic cigarettes, in exchange for payment;

tt) "Toxicity," the degree to which a substance can cause harmful effects to the human organism, including effects that occur over the long term, usually because of repeated or continuous consumption or exposure;

uu) "Remote cross-border sales," remote sales to consumers in which, when a product is sent to a a retail establishment, the consumer is located in a country other than the one in which the retail establishment is based, with a retail establishment considered to be based in a country:

i) In the case of a natural person, if the latter has his place of commercial activity in that country;

ii) In other cases, if the retail establishment has its company headquarters, its main office, or its place of commercial activity, including a branch, agency or any other establishment, in that country.

CHAPTER II

Restrictions on tobacco consumption

Article 3.

General principle

What is set forth in this chapter seeks to establish restrictions on tobacco consumption in enclosed spaces intended for collective use so as to ensure protection from exposure to second-hand tobacco smoke.

Article 4.

Prohibition of smoking in particular places

1 — Smoking is prohibited:

a) In places where bodies of government, services and agencies of Public Administration, and where public juridical persons are established;

b) In work places;

c) In places where direct service is provided for the public;

d) In establishments where health care is provided, notably hospitals, clinics, centers and houses of health care, medical consulting offices, emergency care units and other similar units, laboratories, pharmacies and places where non-prescription medications are dispensed ;

e) At homes and other institutions that care for the elderly, or persons with handicaps or disabilities;

f) In places intended for minors under the age of 18, notably nursery schools, daycare centers and other childcare establishments, homes for children and youth, recreation centers, summer camps and other similar establishments;

g) At educational institutions, regardless of the age of the students and level of instruction, including, in particular, classrooms, study rooms, rooms of teachers and meetings rooms, libraries, gymnasia, lobbies and hallways, bars, restaurants, canteens, eating places and leisure spaces;

h) At vocational training centers;

i) At museums, collections subject to visitation, and places where classified cultural wealth is kept, at cultural centers, in archives and libraries, conference rooms, reading rooms, and exhibit spaces;

j) In rooms and venues for spectacles, as well as other places intended for the dissemination of arts and spectacles, including antechambers, entrance halls and adjoining areas;

l) In facilities for entertainment, casinos, bingo halls, gaming rooms and other kinds of facilities intended for spectacles of a non-artistic variety;

m) In enclosed areas at athletic facilities;

n) In market spaces and exhibit halls;

o) In complexes and large commercial areas, and in commercial establishments for sale to the public;

p) In hotel establishments and other tourist facilities where lodging services are provided;

q) In eating and drinking establishments, including those that have rooms or spaces intended for dancing;

r) In canteens, dining halls and bars at public and private institutions intended exclusively for the respective personnel;

s) In service areas and gasoline stations;

t) At airports, in train stations, bus stations and maritime and river shipping terminals;

u) In subway facilities intended for the public, particularly terminal or intermediate stations, in all their entrances and establishments or contiguous installations;

v) In covered parking areas;

x) On escalators, in elevators and the like;

z) In closed phone booths;

aa) In enclosed spaces for automatic bank teller machines (ATMs);

bb) In any other place where smoking is prohibited, by determination of management, the government or other applicable legislation, particularly with regard to the prevention of occupational risks.

2 — Smoking is also prohibited in vehicles intended for urban, suburban and inter-urban passenger transportation, as well as bus, railway, aerial, maritime and river transportation, on express and tourist services and services for hire, in taxis, ambulances, vehicles for transportation of invalids and funiculars.

3 — What is set forth in the foregoing paragraphs is applicable to the use of electronic cigarettes with nicotine, that is, products that can be used to consume vapor through a mouthpiece, and that contain nicotine or any component of this product.

Article 5.

Exceptions

1 — Without impairment to what is set forth in sub-paragraph d) of N.º 1 of the foregoing Article, rooms can be created that are exclusively intended for patients who are smokers in hospitals and psychiatric facilities, treatment and rehabilitation centers, rehabilitation units for drug addicts and alcoholics, homes for the elderly and assisted living, as long as:

a) Due notification is provided, with the posting of signs in visible locations, pursuant to the terms of what is set forth in the following Article;

b) At the entrance there is a prominent statement of the maximum occupancy allowed, to be regulated by an edict to be approved by the members of the Government responsible for the areas of the economy, the environment and health;

c) They are physically separated from the rest of the facilities or, in cases where they are located inside buildings, to be totally compartmentalized in accordance with rules to be regulated by an edict to be approved by the members of the Government responsible for the areas of the economy, the environment and health;

d) They have a ventilation system to the outside with extraction of air that allows for the maintenance of a negative pressure of at least 5 Pa (Pascal), measured by differential pressure switch, to be defined on the basis of occupancy, size and location of the room and separate from the building's overall climate control system, to be regulated by an edict to be approved by the members of the Government responsible for the areas of the economy, the environment and health.

2 — Without impairment to what is set forth in the foregoing Article, smoking areas can be created at correctional institutions in housing units, cells or dormitory quarters, for inmates who are smokers, as long as they comply with the requirements set forth in sub-paragraphs c) and d) of the foregoing paragraph, while it is also allowed to smoke in outdoor areas.

3 — In the places mentioned in sub-paragraphs a), b), c), d), e), h), i), j), l), n), o), p), q), r) and t) of N.º 1 of the foregoing Article, as well as in the places mentioned in sub-paragraph g) of N.º 1 of the same Article that comprise part of the system of higher education, it is allowed to smoke in outdoor areas .

4 — In the places mentioned in sub-paragraph s) of N.º 1 of the foregoing Article, it is allowed to smoke in outdoor areas, with the exception of zones for refueling of vehicles.

5 — In the places mentioned in sub-paragraphs j), l), n), o), p), q) and t) of N.º 1 of the foregoing Article, spaces can be reserved for smokers, as long as they comply with the requirements mentioned in sub-paragraphs a) to d) of N.º 1, and do not have any service, particularly bar and restaurant service.

6 — Access to the places mentioned in the foregoing paragraph is reserved to adults over the age of 18.

7 — In the places mentioned in sub-paragraph q) of N.º 1 of the foregoing Article, the spaces indicated in N.º 5 can only be set up in areas intended for customers, if they are of a size greater than a limit to be regulated by an edict to be approved by the members of the Government responsible for the areas of the economy, the environment and health;

8 — In the places mentioned in sub-paragraph l) of N.º 1 of the foregoing Article, where games of chance are played, the spaces indicated in N.º 5, can only be set up in an area no greater than 40% of the size of the gaming rooms.

9 — In the places mentioned in sub-paragraph p) of N.º 1 of the foregoing Article, floors, lodging units or rooms can be reserved for smokers, up to a maximum of 40% of the respective total, occupying contiguous areas or a total of one or more floors, as long as they comply with the requirements mentioned in sub-paragraphs a) a c) of N.º 1 and have a system for ventilation or the extraction of air to the outside that prevents the smoke from spreading to contiguous areas.

10 — Without impairment to what is set forth in N.º 2 of the foregoing Article, and the limitations stated in regulations issued by transportation companies or by the port authorities, it is allowed to smoke in uncovered areas on vessels intended for maritime or river traffic.

11 — The definition of areas for smokers is the responsibility of the entities in charge of the establishments under consideration, and the respective departments of safety, hygiene and occupational health must be consulted, as well as the commissions of safety, hygiene and occupational health, or, in the absence thereof, the representatives of workers for safety, hygiene and occupational health.

Article 6.

Signage

1 — The banning of smoking, or setting of conditions for smoking inside the places noted in Articles 4. and 5. must be posted with signs by the respective competent entities, by putting up placards with a red background, pursuant to Template A in Annex I of this Law, and which makes up an integral part thereof , being an illustration that includes the caption and the cross, in white, with minimum dimensions of 160 mm x 55 mm.

2 — The areas where smoking is permitted are identified by the putting up of placards with a blue background, also exhibiting the other characteristics noted in the foregoing paragraph, pursuant to Template B in Annex I.

3 — The placards mentioned in the foregoing paragraphs must have added to them in the lower portion of the Template, a caption identifying this Law.

4 — The placard noted in N.º 1 must also contain the amount of the maximum fine applicable to smokers who violate the prohibition on smoking.

5 — The placards must be posted or glued in such a way that they are not easy to remove, and must be visible from outside the establishments.

Article 7.

Responsibility

1 — Compliance with what is set forth in Articles 4. a 6. must be ensured by the public or private entities that are responsible for the places referred to in this Law.

2 — Whenever infractions are ascertained of what is set forth in Articles 4. to 6., the entities noted in the foregoing paragraph must notify the smokers that they are to abstain from smoking and, in the event that they do not comply, to summon the administrative or police authorities, who are to draw up the respective notification of violation.

3 — All of the users of the places noted in N.º 1 have the right to demand compliance with what is set forth in Articles 4. to 6., and are authorized to file a detailed, written complaint, availing themselves in particular for such purpose of the book of complaints available at the establishment in question.

CHAPTER III

Ingredients and emissions

Article 8.

Maximum levels for emissions of tar, nicotine, carbon monoxide and other substances

1 — Levels for emissions from cigarettes sold or manufactured in the national territory cannot be greater than:

a) 10 mg of tar per cigarette;

b) 1 mg of nicotine per cigarette;

c) 10 mg of carbon monoxide per cigarette.

2 — The Government can set, through an edict by a member of the Government responsible for the area of health, maximum emission levels for other emissions besides that indicated in the foregoing paragraph, as well as for emissions of tobacco products that are not cigarettes, which must be reported to the European Commission.

Article 9.

Methods of measurement

1 — Emissions of tar, nicotine and carbon monoxide from cigarettes are to be measured, respectively, by the standards ISO 4387, ISO 10315 and ISO 8454.

2 — The accuracy of measurements concerning tar, nicotine and carbon monoxide is to be determined in accordance with ISO standard 8243.

3 — What is set forth in the foregoing paragraphs must be checked by test laboratories accredited by the Portuguese Institute of Accreditation (*Instituto Português de Acreditação*), I. P., pursuant to the terms of Article 3. of Decree-Law N.º 81/2012, of March 27, or by the competent authorities of other member States, and such laboratories cannot be owned or controlled, directly or indirectly, by the tobacco industry.

4 — The list of laboratories accredited by the Portuguese Institute of Accreditation, I. P., is to be announced on the website of this Institute, and reported by it to the General Administration of Health,

by January 31 of each year, and whenever alterations occur, with the list stating the criteria used for the accreditation of each one, and the means for monitoring implemented.

5 — The General Administration of Health shall submit to the European Commission a list of the laboratories noted in the foregoing paragraph, specifying the criteria used for approval and the means for monitoring implemented, as well as any alterations that may occur.

6 — Cigarettes are to be submitted for measurement at the laboratories indicated in N.º 3, by the manufacturer or importer of tobacco products, who is responsible for the respective costs.

7 — What is set forth in this Article is applicable, with the necessary adaptations, to the emissions levels noted in N.º 2 of the foregoing Article.

8 — (Rescinded.)

9 — (Rescinded.)

10 — (Rescinded.)

Article 9. - A

Reporting of ingredients and emissions

1 — Manufacturers and importers of tobacco products shall submit to the General Administration of Health, prior to their commercialization, the following information, by brand and by type:

a) A list of all ingredients, and their respective quantities, used in the manufacture of tobacco products, in decreasing order of weight for each ingredient included in the tobacco products;

b) The emissions levels noted in Article 8.;

c) Information on other emissions and their levels, if any, in which case the methods for the measurement of emissions used must be stated.

2 — Manufacturers and importers of tobacco products must also notify the General Administration of Health of any alteration in the composition of a product that may affect the information provided under the terms of this Article.

3 — The list of ingredients noted in sub-paragraph a) of N.º 1:

a) Shall indicate the status of the ingredients, including whether these have been registered under the terms of Regulation (CE) N.º 1907/2006, of the European Parliament and Council, of December 18, 2006, as well as the respective classification under the terms of Regulation (CE) N.º 1272/2008, of the European Parliament and Council, of December 16, 2008;

b) Is to be accompanied by the pertinent toxicological data on the ingredients, with or without combustion, as appropriate, mentioning, in particular, their effects on the health of consumers, notably the risk of creation of addiction;

c) Is to be accompanied by a declaration that sets forth the reasons for the inclusion of these ingredients in the tobacco products in question;

d) Must also be accompanied by a technical document with a general description of the additives used and their properties, in the case of cigarettes and rolling tobacco.

4 — Whenever the General Administration of Health may so determine, manufacturers or importers of tobacco products must conduct studies in order to assess the effects of the ingredients on health, bearing in mind, in particular, the potential for causing addiction and their toxicity, and the respective costs are to be borne by the latter.

5 — Manufacturers and importers of tobacco products must submit to the General Administration of Health any internal and external studies at their disposal on the market and preferences of various groups of consumers, including young people and current smokers, with respect to ingredients and emissions, as well as summaries of any market research that they may conduct when they release new products.

6 — Manufacturers and importers of tobacco products must also notify the General Administration of Health, annually, by September 30 of each year, of the volumes of sales, broken down by brand and by type, stated in the number of cigarettes, cigarillos or cigars, or in kilograms, and by country of the European Union.

7 — All of the data and information to be submitted under the terms of this Article and of the following Article are to be reported in digital format, to be defined by statute of a member of the Government responsible for the area of Health, and such information must be stored electronically and kept accessible to the European Commission and the member States, with respect for commercial confidentiality and other confidential information.

8 — The format for submission and making available to the public the information indicated in this Article and in the following Article is to defined and, if necessary, updated, in accordance with procedures defined pursuant to the terms of N.º 5 of Article 5. and of Article 25. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014.

9 — The General Administration of Health shall see to the disclosure on its website of the data submitted pursuant to the terms of N.º 1 and of the following Article, bearing in mind, whenever appropriate, information that falls within the scope of commercial confidentiality and that has been specified as such by the manufacturer or importer of tobacco products.

10 — For tobacco products that are already being commercialized on the date of entry into force of this Law, the notification referred to in N.º 1 must be done by November 20, 2016.

11 — Fees, which are to be set by statute issued by members of the Government responsible for the areas of finance and health for the receipt, storage, processing, analysis and publication of the information indicated in this Article, are to be borne by manufacturers and importers of tobacco products.

Article 10.

Priority list of additives and enhanced reporting requirements

1 — Over and above the reporting requirements indicated in the foregoing Article, additives contained in cigarettes and rolling tobacco that appear on a priority list established in accordance with the procedures defined pursuant to the terms of N.º 1 of Article 6. and of Article 25. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014, are subject to enhanced reporting requirements.

2 — Manufacturers and importers of cigarettes and rolling tobacco containing an additive that appears on the priority list indicated in the foregoing paragraph must conduct detailed studies to ascertain whether each one of the additives:

a) Contributes to the toxicity or potential for addiction of the products in question, and whether it has the effect of increasing the toxicity or potential for addiction of any of the products in question, to a significant or measurable degree;

b) Gives off a characteristic aroma;

c) Facilitates the inhalation or absorption of nicotine; or

d) Gives rise to the formation of substances with carcinogenic, mutagenic or toxic properties with respect to reproduction, the quantities of these substances, and whether this element has the effect of increasing the carcinogenic, mutagenic or toxic properties with respect to reproduction of any of the products in question, to a significant or measurable degree.

3 — The studies referred to in the foregoing paragraph are to take into account the intended purpose of the products in question, and to ascertain, in particular, the emissions resulting from the process of combustion in which the additive in question is involved, as well as the interaction of this additive with other ingredients contained in the products in question, with the possibility of joint studies being conducted by manufacturers or importers who are using the same additive in their tobacco products, as long as such additive is used in a comparable composition of the product.

4 — Manufacturers or importers are to draw up a report on the results of the studies indicated in the foregoing paragraphs, which should include a summary and detailed compilation of the scientific literature available on this additive, and a summary of the internal data on the effects of the additive, and submit it within a period of 18 months after the additive in question has been included on the priority list noted in N.º 1, to the General Administration of Health and to the European Commission, with the possibility that the latter may require supplementary information to be included in the report.

5 — The European Commission and the General Administration of Health may require that the report referred to in the foregoing paragraph must be subject to review by an independent scientific agency, in particular with respect to its comprehensiveness, methodology and conclusions.

6 — For the review of the report noted in N.º 4, fees will be payable by manufacturers and importers of tobacco products, to be set by an edict of the members of the Government responsible for the areas of finance and health.

7 — Small and medium-sized companies, as defined by Decree-Law N.º 372/2007, of November 6, as amended by Decree-Law N.º 143/2009, of June 16, shall be exempt from the requirements established in this Article, if the report on the additive in question is drawn up by another manufacturer or importer.

Article 10. - A

Regulation of ingredients

1 — The sale of tobacco products with a distinctive aroma is hereby prohibited, with the use of additives essential to the manufacture of tobacco products not to be construed as such, as long as these additives do not result in a product with a distinctive aroma and do not increase, to a significant or measurable

degree, the toxicity, potential for causing addiction or the carcinogenic, mutagenic or toxic properties with respect to reproduction, for the tobacco products in question.

2 — The General Administration of Health may call upon the European Commission to determine whether a tobacco product falls within the scope of N.º 1, or consult the independent consultative panel established at the level of the European Union prior to taking measures for the implementation of N.º 1.

3 — Rules concerning the procedures for determining whether a tobacco product falls within the scope of N.º 1 are to be defined in accordance with the procedures defined pursuant to the terms of N.º 3 of Article 7. and of Article 25. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014.

4 — The sale of tobacco products containing the following additives is hereby prohibited:

a) Vitamins or other additives that give the impression that a tobacco product has benefits for health, or poses a reduced risk to health;

b) Caffeine or taurine, or other stimulant additives and compounds associated with energy and vitality;

c) Additives that confer a color on emissions;

d) For tobacco products for smoking, additives that facilitate the inhalation or absorption of nicotine; or

e) Additives that, in the form without combustion, have carcinogenic, mutagenic or toxic properties with respect to reproduction.

5 — The sale of tobacco products containing aromatic agents in their components, such as filters, papers, packages, capsules or any technical characteristics that make it possible to modify the odor or flavor of the tobacco products in question, or the intensity of their smoke, is hereby prohibited, while filters, papers and capsules must not contain tobacco or nicotine.

6 — The provisions and conditions established under the terms of Regulation (CE) N.º 1907/2006, of the European Parliament and Council, of December 18, 2006, as appropriate, are applicable to tobacco products.

7 — On the basis of scientific data, the sale of tobacco products containing additives in quantities that increase to a significant or measurable degree the toxic or addictive effect of a tobacco product or the carcinogenic, mutagenic or toxic properties with respect to reproduction during the phase of consumption, can be prohibited, pursuant to terms to be defined by an edict of a member of the Government responsible for the area of health.

8 — The General Administration of Health shall notify the European Commission of any measures that it may take in application of the foregoing paragraph.

9 — The General Administration of Health may call upon the European Commission to determine whether a tobacco product falls within the scope of N.º 7.

10 — The prohibitions indicated in Nos. 1 and 7 do not apply to tobacco products that are not cigarettes and rolling tobacco.

11 — Manufacturers and importers of tobacco products shall bear the necessary costs for the evaluation as to whether a tobacco product has a distinctive aroma, whether prohibited additives or aromas are being used, and whether a tobacco product contains additives in quantities that increase to a significant

and measurable degree the toxic or addictive effect of the tobacco product in question, or its carcinogenic, mutagenic or toxic properties with respect to reproduction.

CHAPTER IV

Labeling and packaging

Article 11.

General provisions

1 — Each individual package of tobacco products and each outer package must exhibit the health warnings indicated in this chapter, in Portuguese, and must cover the entire surface of the individual package or outer packaging that is assigned to it, which cannot be paraphrased, commented on or have references included.

2 — Health warnings on individual packages and on any external packaging must be printed in such a way that they are unremovable, indelible and perfectly visible.

3 — Health warnings on individual packages and on any external packaging cannot be partially or wholly concealed or separated by special labels, price marks, security elements, wrappings, pouches, purses, cases or other elements when the tobacco products are commercialized, nor can they conceal or separate, in any way, special labels, price marks, location and tracking marks and/or security elements on individual packages.

4 — Health warnings can be affixed using self-adhesives on individual packages of tobacco products that are not cigarettes or rolling tobacco in pouches, as long as they are unremovable.

5 — Health warnings must remain intact when the individual package is opened, with the exception of packs with a soft folding lid, in which case the health warning can be divided when the packaging is opened, but only in a way that ensures the graphic completeness and visibility of the text, photographs and information for help quitting smoking.

6 — The dimensions of health warnings indicated in Articles 11. -A, 11. -B and 11. -C are calculated in relation to the surface in question when the package is closed.

7 — Health warnings are to be surrounded with a black frame 1 mm wide within the surface reserved for these warnings.

8 — The rules in this chapter are applicable to the images for advertising purposes on individual packages and on any external packaging.

9 — (Rescinded.)

10 — (Rescinded.)

11 — (Rescinded.)

Article 11. -A

General warnings and informational messages on tobacco products for smoking

1 — Each individual package and each outer package of tobacco products for smoking must display the following general warning: "Smoking kills — quit now."

2 — Each individual package and each outer package of tobacco products for smoking must display the following informational message: "Tobacco smoke contains more than 70 substances that cause cancer."

3 — The general warning and the informational message mentioned in the foregoing paragraphs must be:

a) Printed in bold black Helvética typeface on a white background in lower case letters, with the exception of the initial letter and as per grammatical requirements, and with a font size that ensures that the text occupies the largest possible amount of space on the surface reserved for the general warning and the informational message;

b) Placed in the center of the surface reserved for them and, on polyhedron-shaped packages and on any external packaging, parallel to the lateral edge of the individual package or the outer packaging.

4 — On cigarette packs, as well as on packages of rolling tobacco that are polyhedron-shaped, the general warning must appear in the lower part of one of the lateral surfaces of individual packages, with the informational message on the lower part of the other lateral surface, and these health warnings must have a width not less than 20 mm.

5 — On box-shaped packs with a folding cover, on which the lateral surfaces are divided into two parts when the pack is opened, the general warning and informational message must appear in their entirety on the larger one of the these surfaces that is divided, and the general warning must also appear on the side inside the upper flap that becomes visible when the pack is open, while the lateral surfaces of this type of pack must not have a height less than 16 mm.

6 — In the case of rolling tobacco, the general warning and informational message must cover 50% of the surfaces on which they are printed, and they must appear:

a) On surfaces that ensure the complete visibility of such health warnings, pursuant to terms to be established in accordance with the procedures defined in N.º 6 of Article 9. and in Article 25. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014, if the rolling tobacco is commercialized in pouches;

b) On the outer surface of the cover of the package, for the general warning, and on the inner surface of the cover of the package, for the informational message, if the rolling tobacco is commercialized in cylindrical packages.

Article 11. -B

Combined health warnings for tobacco products for smoking, including cigarettes,

rolling tobacco and tobacco for water pipes

1 — Each individual package and each outer package of tobacco products for smoking, including cigarettes, rolling tobacco and tobacco for water pipes, must display combined health warnings that

include one of the written warnings and the corresponding color photographs indicated in Annex II to this Law, of which it comprises an integral part.

2 — The combined health warnings must include information for quitting smoking, such as phone numbers, e-mail addresses and/or websites intended to inform consumers on support programs available to people who intend to quit smoking, to be regulated by an edict to be approved by members of the Government responsible for the area of health.

3 — The combined health warnings are grouped in three series, with each series to be used in a given year and in annual rotation, while each combined health warning available for use in a given year must be displayed an equal amount on each brand of tobacco products.

4 — The combined health warnings must exhibit the same written warning and corresponding color photograph on both sides of the individual package, and any external packaging, appearing next to the upper edge of an individual package and any external packaging, and being oriented in the same direction as any other information that appears on this surface of the package.

5 — The combined health warnings must cover 65% of both the front and back surfaces of the individual package, and of any external packaging , while cylindrical packages must display two combined health warnings, equidistant from one another and with each health warning covering 65% of the respective half of the curved surface.

6 — In the case of cigarette packs, the combined health warnings may not have a height less than 44 mm, or a width less than 52 mm.

7 — The technical specifications for the configuration, design and format of the combined health warnings, bearing in mind the different kinds of packages, are to be established in accordance with the procedures defined pursuant to the terms of N.º 4 of Article 10. and of Article 25. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014.

Article 11. -C

Labeling of tobacco products for smoking, with the exception of cigarettes, rolling tobacco and tobacco for water pipes

1 — Tobacco products for smoking, with the exception of cigarettes, rolling tobacco and tobacco for water pipes, are exempt from the requirement to display the informational message indicated in N.º 2 of Article 11.-A and the combined health warnings indicated in Article 11.-B.

2 — In the cases indicated in the foregoing paragraph, and in addition to the general warning indicated in N.º 1 of Article 11.-A, each individual package and each outer package of these products must display one of the written warnings specified in Annex II to this Law.

3 — The general warning indicated in N.º 1 of Article 11.- A, must include a reference to support services for quitting smoking, such as phone numbers, e-mail addresses and/or websites intended to inform consumers about available support programs for people who intend to quit smoking, and must appear on the most visible surface of individual packages and any external packaging .

4 — Each written warning must appear, whenever possible, an equal amount on each brand of products.

5 — Written warnings are to appear on the most visible surface of individual packages and any external packaging .

6 — On individual packages with a folding lid, the other most visible surface is the one that is visible when the packaging is open.

7 — The general warning noted in this Article must cover 30% of the surfaces of the individual package and any external packaging, and appear on the two largest surfaces of the individual package and any external packaging .

8 — The written warning mentioned in this Article must cover 40% of the relevant surface of the individual package and any external packaging.

9 — If the health warnings mentioned in this Article appear on a surface greater than 150 cm2, the warnings must cover an area of 45 cm2.

10 — The health warnings mentioned in this Article are in compliance with the requirements indicated in N.º 3 of Article11 -A.

11 — The text of the health warnings must be parallel to the main text on the surface reserved for these warnings.

12 — Health warnings must be surrounded by a black border with a width not less than 3 mm and not greater than 4 mm, and this border must appear outside the surface reserved for health warnings.

Article 11. -D

Labeling of tobacco products without combustion

11.1 — Each individual package and each outer package of tobacco products without combustion must display the following health warning: "This tobacco product is harmful to your health and causes addiction."

2 — The health warning indicated in the foregoing paragraph must be parallel to the main text on the surface reserved for these warnings, and must respect the requirements indicated in N.º 3 of Article 11. -A.

3 — The health warning must cover 30% of the surfaces of the individual package and any external packaging, and appear on the two largest surfaces of the individual package and any external packaging.

Article 12.

Appearance and content of individual packages

1 — Individual packages of cigarettes must be polyhedron-shaped.

2 — Individual packages of rolling tobacco must be polyhedron-shaped, cylindrical or pouches.

3 — Individual packages of cigarettes must contain at least 20 cigarettes.

4 — Individual packages of rolling tobacco must contain at least 30 g of tobacco.

5 — Individual packages of cigarettes can be of cardboard or soft material, as long as the opening cannot be closed again or sealed after being opened for the first time, with the exception of the soft folding flap and the box with a folding lid, while for the latter two, the flap and the lid are only to be folded on the rear side of the individual package.

Article 13.

Display of the product

1 — The labeling of an individual package and any external packaging, as well as the tobacco product itself, cannot include any element or characteristic consisting of texts, symbols, indications, commercial brands, figurative or other signs that:

a) Promote the tobacco product or encourage its consumption, by giving a false impression with respect to its characteristics, effects on health, risks or emissions, while the labels cannot include any information on the content of nicotine, tar or carbon monoxide in the tobacco product;

b) Suggest that a particular tobacco product is less harmful than another, or seek to reduce the effect of certain harmful components in smoke, or suggests that they have invigorating, energizing, curative, rejuvenating, natural or ecological properties, or other benefits to health or lifestyle;

c) Refers to the flavor, odor, any aromatic agent or other additives, or to their absence;

d) Bears a resemblance to a food or cosmetic product; or

e) Suggests that a particular tobacco product has better biodegradability, or presents other environmental advantages.

2 — Individual packages and any external packaging cannot, through texts, symbols, indications, commercial brands, figurative or other signs, suggest economic advantages in the form of printed coupons, discount offers, free distribution, two for the price of one, or other similar offers.

Article 13. -A

Traceability

1 — All individual packages of tobacco products commercialized in the national territory must be marked with a unique identifier, which must be printed or affixed in such a way that it is unremovable and indelible, and not to be in any way concealed or separated, including by special labels, or price marks, or by the opening of the individual package, that make it possible to determine:

a) The date and place of manufacture;

b) The manufacturing facility;

c) The machine used to manufacture the tobacco products;

d) The production shift or time of manufacture;

e) The description of the product;

f) The intended retail market;

g) The expected shipping route;

h) The importer, when applicable;

i) The shipping route actually taken, from the factory to the first retail establishment, including all warehouses used, as well as the shipping date, the shipping destination, the point of departure and arrival;

j) The identity of all purchasers, from the factory to the first retail establishment; and

k) The invoice, delivery number and records of payment by all purchasers, from the factory to the first retail establishment.

2 — The information referred to in sub-paragraphs a) to g) of the foregoing paragraph and, when applicable, that referred to in sub-paragraph h) of the same paragraph, must be a part of the unique identifier, and the information referred to in sub-paragraphs i), j) and k) of the foregoing paragraph must be electronically accessible through a link to the unique identifier.

3 — All economic operators involved in the commerce of tobacco products, from the manufacturer to the last economic operator prior to the first retail establishment, must record the entry of all individual packages in his possession, as well as all intermediate movements, and the definitive exit of the individual packages in his possession, and such record can be made by tallying and recording the total package, as long as it continues to be possible to locate and track all individual packages.

4 — All individual and juridical persons involved in the supply chain of tobacco products must maintain complete and accurate records of all transactions referred to in this Article.

5 — Manufacturers of tobacco products must provide all economic operators involved in the commerce of tobacco products, from the manufacturer to the last economic operator prior to the first retail establishment, including importers, warehouse agents and shipping companies, with the equipment necessary for recording of tobacco products acquired, sold, stored, transported or handled in any other way, and such equipment must be capable of reading and transmitting the data recorded electronically to an information storage facility.

6 — For the purposes of what is set forth in the last part of the foregoing paragraph, manufacturers and importers of tobacco products must execute data storage contracts with an independent third party, with a view to having the facility be a host for data storage, and the data storage facility must be physically located in the territory of the European Union and be fully available for access by the European Commission, the competent authorities of the member States and the external auditor.

7 — The suitability of the independent third party referred to in the foregoing paragraph, notably his independence and technical capacities, as well as the data storage contract, are to be approved by the European Commission.

8 — The activities of the independent third party must be monitored by an external auditor, to be appointed and paid by the tobacco manufacturer and approved by the European Commission, who must submit an annual report to the Tax and Customs Authority and to the European Commission, evaluating in particular any irregularities with regard to access.

9 — In duly justified cases, access to stored data can be granted by manufacturers or importers, either by the Tax and Customs Authority or by the European Commission, as long as commercially sensitive information remains suitably protected, in accordance with the applicable legislation.

10 — Recorded data cannot be modified or deleted by any economic operator involved in the commerce of tobacco products, with legislation concerning the protection of personal data being respected.

11 — Technical standards for the creation and operation of the location and tracking system noted in this Article, including marking with a unique identifier, the recording, transmission, processing and storage of data and access to stored data are to be approved in accordance with procedures to be

defined pursuant to the terms of N.º 11 of Article 15. and Article 25. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014.

12 — The numbering of the special label defined by the Tax and Customs Authority and provided by the National Press - Mint (*Imprensa Nacional -Casa da Moeda, S. A.*), can be used as a unique identifier, including any alterations that may prove necessary to ensure compliance with the technical standards and functions required pursuant to the terms of Article 15. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014.

13 — The key elements in the data storage contracts referred to in N.º 6, such as their duration, renewal, the necessary technical knowledge and confidentiality, including regular oversight and evaluation of these contracts, are to be defined in accordance with procedures defined pursuant to the terms of N.º 12 of Article 15. and of Article 27. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014.

14 — What is set forth in Nos. 1 to 10 is applicable to cigarettes and rolling tobacco as of May 20, 2019, and to tobacco products other than cigarettes and rolling tobacco as of May 20, 2024.

Article 13. -B

Security element

1 — In addition to the unique identifier referred to in the foregoing Article, all individual packages of tobacco products commercialized must display an inviolable security element, made up of visible and invisible elements, which must be printed or affixed in a way that is unremovable and indelible, and that cannot be concealed or separated, including by special labels and price marks.

2 — The technical standards for the security element and its eventual rotation are to be approved in accordance with procedures defined pursuant to the terms of N.º 2 of Article 16. and of Article 25. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014.

3 — The special label defined by the Tax and Customs Authority and provided by the *Imprensa Nacional-Casa da Moeda, S. A.,* is used as a security element, and for this purpose, it must be adapted in such a way that it complies with the technical standards and functions required by Article 16. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014.

4 — What is set forth in N.º 1 is applicable to cigarettes and rolling tobacco as of May 20, 2019, and to tobacco products other than cigarettes and rolling tobacco as of May 20, 2024.

CHAPTER V

Tobacco for oral use, remote cross-border sales and new tobacco products

Article 14.

Tobacco for oral use

The sale of tobaccos for oral use is prohibited.

Article 14. - A

Remote cross-border commerce

Remote cross-border purchases by consumers established in the national territory, of tobacco products, plant-based products for smoking and electronic cigarettes and refills, transacted by a retailer established in another member State, or in a third country or territory, defined as such in the Code of Special Taxes on Consumption, approved by Decree-Law N.º 73/2010, of June 21, are prohibited.

Article 14. -B

Notification of new tobacco products

1 — Manufacturers and importers of new tobacco products must provide digital notification to the General Administration of Health, and with advance notice of at least six months, of any new tobacco product that they intend to commercialize in the national territory.

2 — The notification referred to in the foregoing paragraph is to be accompanied by a detailed description of the new tobacco product in question, as well as by instructions on use and information concerning ingredients and emissions, pursuant to the terms of Article 9. -A, and the following things must also be made available:

a) Any scientific studies they may have at their disposal on toxicity, the potential for causing addiction and the attractiveness of the new tobacco product, notably with respect to its ingredients and emissions;

b) Any studies and respective summaries and market analyses they may have at their disposal on the preferences of various groups of consumers, including young people and current smokers;

c) Other available and pertinent information, including an analysis of the risks and benefits of the product, its expected effects in terms of quitting tobacco consumption and starting tobacco consumption, and predictions on consumer perceptions.

3 — Manufacturers and importers of new tobacco products must notify the General Administration of Health of any new or updated information on studies, analyses and other information referred to in the foregoing paragraph.

4 — The General Administration of Health may request the conduct of additional tests or the submission of supplementary information.

5 — The introduction of new tobacco products is subject to authorization by the General Administration of Economic Activities, following an opinion by the General Administration of Health, in terms to be defined by an edict of the members of the Government responsible for the areas of the economy and health.

6 — Fees are to be charged for the process of authorization referred to in the foregoing paragraph, to be defined by an edict of the members of the Government responsible for the areas of finance, the economy and health.

7 — The new tobacco products being commercialized must respect the requirements indicated in this Law, based on their classification as tobacco products without combustion, or tobacco products for smoking.

CHAPTER VI

Unofficial Translation

Electronic cigarettes and plant-based products for smoking

Article 14. -C

Electronic cigarettes and refills

1 — Only electronic cigarettes and refills that comply with the requirements indicated in this Law can be commercialized, with the exception of the electronic cigarettes and refills that are subject to what is set forth in Decree-Laws No. 176/2006, of August 30, 36/2007, February 16, and 145/2009, of June 17, as amended by Laws No. 21/2014, of April 16, and 51/2014, of August 25.

2 — Electronic cigarettes and refills must be safe for children, as well as inviolable, unbreakable and spill-proof, and must have a mechanism to ensure filling without spills.

3 — Manufacturers and importers of electronic cigarettes and refills must provide digital notification to the General Administration of Health, with advance notice of at least six months, of any products of this type that they intend to commercialize.

4 — The notification referred to in the foregoing paragraph must include, depending on whether the product is an electronic cigarette or a refill, the following information:

a) The name and contact information for the manufacturer, the natural or juridical person responsible and, if appropriate, the importer into the European Union;

b) A list of all ingredients contained in the product and the emissions resulting from its use, by brand and by type, including the respective quantities;

c) The toxicological data on ingredients and emissions of the product, including when they are heated up, having to do particularly with their effects on the health of consumers when inhaled, and bearing in mind especially its effects in causing addiction;

d) Information on doses and absorption of nicotine, when consumed under normal or reasonably predictable conditions;

e) A description of the components of the product, including, when applicable, the mechanism for opening and filling electronic cigarettes and refills;

f) A description of the production process, particularly if this involves production in series, and a declaration that the production process guarantees compliance with this Article;

g) A declaration that the manufacturer and importer shall assume full responsibility for the quality and safety of the product, when commercialized and used in normal or reasonably predictable conditions.

5 — The General Administration of Health may require that the information referred to in the foregoing paragraph be completed, if it finds that it is incomplete.

6 — Manufacturers and importers of electronic cigarettes and refills must undertake a new notification for each substantial alteration of their products.

7 — The General Administration of Health shall see to the disclosure on its website of the data submitted pursuant to the terms of this Article, bearing in mind, when appropriate, information that is subject to commercial confidentiality and that has been so specified by the manufacturer or importer of electronic cigarette and refill products.

8 — For electronic cigarettes and refills that are already being commercialized on May 20, 2016, the notification referred to in this Article must be done within a period of six months, counting from that date.

9 — The format for notification indicated in this Article, as well as the technical standards for the filling mechanism referred to in N.º 2, are to be set in accordance with procedures to be defined pursuant to the terms of N.º 13 of Article 20. and of Article 25. of Directive 2014/40/UE, of the European Parliament and Council, of April 3, 2014.

10 — Fees are to be paid by manufacturers and importers of electronic cigarettes and refills for the receipt, storage, processing and analysis of the information indicated in this Article, to be set by an edict of the members of the Government responsible for the areas of finance and health.

Article 14. -D

Ingredients and labeling of electronic cigarettes and refills

1 — For electronic cigarettes and refills, the liquid containing nicotine must be manufactured exclusively with ingredients of great purity and:

a) Can only be commercialized in their own refills that do not exceed a volume of 10 ml, in disposable electronic cigarettes or in non-reusable cartridges, and the cartridges or reservoirs may not exceed a volume of 2 ml;

b) It cannot contain more than 20 mg/ml of nicotine;

c) It cannot contain the additives indicated in N.º 4 of Article 10. -A;

d) It can only include other substances, besides the ingredients stated on the list referred to in sub-paragraph b) of N.º 4 of the foregoing Article, in trace amounts, if they are technically unavoidable in the manufacturing process;

e) It can only include, in addition to nicotine, ingredients that do not pose a risk to human health whether heated or unheated.

2 — Electronic cigarettes must release doses of nicotine in consistent amounts, under normal conditions of use.

3 — Individual packages of electronic cigarettes and refills must include a leaflet with information including:

a) Instructions for use and storage of the product, including a statement that the product is not recommended for young people and non-smokers;

b) Contraindications;

c) Warnings to specific risk groups;

d) Possible adverse effects;

e) Potential for causing addiction and toxicity; and

f) Contact information for the manufacturer or importer and the natural or juridical person to get in touch with.

4 — Individual packages and outer packages for electronic cigarettes and refills must display, pursuant to the terms indicated in Nos. 2 and 3 of Article 11.-C, the following health warning: "This product contains nicotine, a substance that is highly addictive. Its use for non-smokers is not recommended."

5 — Individual packages and outer packages of electronic cigarettes and refills must also contain a list of all product ingredients, by decreasing order of weight, a statement of the product's nicotine content and release per dose, the lot number and a recommendation to the effect that the product should be kept out of the reach of children.

6 — Individual packages and outer packages of electronic cigarettes and refills cannot include the elements or characteristics indicated in Article 13., with the exception of those indicated in sub-paragraphs a) and c) of N.º 1 of the same Article, with regard to information on nicotine content and aromatic agents.

Article 14. -E

Advertising and sponsorship of electronic cigarettes and refills

1 — Commercial communication is prohibited in online services, the press and other printed publications, that seeks or has as its direct or indirect effect the promotion of electronic cigarettes and refills, with the exception of publications intended exclusively for professionals engaged in the commerce of electronic cigarettes and refills, and publications that are printed and published in third countries, if these publications are not chiefly intended for the market of the European Union.

2 — Commercial communication on the radio is prohibited that seeks or has as its direct or indirect effect the promotion of electronic cigarettes and refills.

3 — Any kind of public or private contribution to radio programs that seeks or has the direct or indirect effect of promoting electronic cigarettes and refills is prohibited.

4 — Any kind of public or private contribution to any event, activity or individual that seeks or has the direct or indirect effect of promoting electronic cigarettes and refills, and that involves or occurs in several member States or has any other trans-border effect, is prohibited.

5 — What is set forth in N.º 10 of Article 16. and Articles 17. and 19 is applicable to electronic cigarettes and refills .

Article 14. -F

Communications regarding electronic cigarettes and refills

1 — Manufacturers and importers of electronic cigarettes and refills must submit annually to the General Administration of Health:

a) Detailed data on sales volumes, by brand and by product type;

b) Information on the preferences of various groups of consumers, including young people, non-smokers and the main types of users at that time;

c) The way that products are sold; and

d) Syntheses of all market analyses conducted on the domains indicated in the foregoing sub-paragraphs, including their translation into English.

2 — The General Administration of Health shall oversee the evolution of the market for electronic cigarettes and refills, including any elements that demonstrate that its use is a means of access to nicotine addiction and, ultimately, to traditional tobacco consumption by young people and non-smokers.

3 — Manufacturers, importers and distributors of electronic cigarettes or refills must establish and maintain a system for collecting information on all presumed adverse effects of these products on human health.

4 — Whenever manufacturers, importers and distributors of electronic cigarettes or refills consider or have reason to believe that the electronic cigarettes or refills that are in their possession and are commercialized, or are intended for such purpose, are not safe, are not of good quality or are not in compliance with this Law, they must immediately take all necessary corrective measures to bring the product in question into compliance with what is set forth in this Law, or to remove or withdraw it from the market, depending on the circumstances.

5 — In the cases indicated in the foregoing paragraph, manufacturers, importers and distributors of electronic cigarettes or refills are to inform the Bureau of Food and Economic Security, and the General Administration of Health immediately, indicating in particular the risk to human health and safety, and any corrective measures taken, as well as the results of such measures.

6 — The Bureau of Food and Economic Security, as well as the General Administration of Health, may require manufacturers, importers and distributors of electronic cigarettes or refills to provide additional information, particularly on aspects of safety and quality, or on the adverse effects of electronic cigarettes or refills.

7 — In the case of electronic cigarettes and refills that are in compliance with what is set forth in this Law, and without impairment to the competencies attributed to the entities exercising authority over health, if the Bureau of Food and Economic Security should ascertain, or have reasonable grounds to believe, that a specific electronic cigarette or refill, or a type of electronic cigarette or refill, could pose a serious risk to human health, it can take the appropriate provisional measures, and the General Administration of Health may be asked to provide an opinion in the matter.

8 — Measures adopted under the terms of the foregoing paragraph must be immediately reported to the European Commission and the competent authorities of the member States, and any data on which such measures are based should also be reported.

Article 14. -G

Plant-based products for smoking

1 — Each individual package and each outer package of plant-based products for smoking must display the following health warning: "Smoking this product is harmful to your health"

2 — The health warning indicated in the foregoing paragraph must be printed on the front and back outer surface of the individual package and any external packaging, and must respect the requirements indicated in N.º 3 of Article 11. -A.

3 — The health warning must cover 30% of the respective surface area of the individual package and any external packaging.

4 — Individual packages and any external packaging of plant-based products for smoking cannot include the elements or characteristics referred to in sub-paragraphs a), b) and d) of N.º 1 of Article 13., nor can they state that the product is free of additives or aromatic agents.

Article 14. -H

Communication of ingredients of plant-based products for smoking

1 — Manufacturers and importers of plant-based products for smoking must submit to the General Administration of Health a list of all ingredients, and the respective quantities, used in the manufacture of such products, by brand and by type.

2 — Manufacturers and importers of plant-based products for smoking must also communicate to the General Administration of Health, and prior to its commercialization, any alteration in the composition of a product that would affect the information provided under the terms of this Article.

3 — The General Administration of Health shall see to the disclosure on its website of the data submitted pursuant to the terms of this Article, bearing in mind, whenever applicable, information subject to commercial confidentiality and that has been specified as such by the manufacturer or importer of plant-based products for smoking.

4 — The submission of the list indicated in N.º 1 must be done prior to the sale of new plant-based products for smoking.

CHAPTER VII

Sale of tobacco products, plant-based products for smoking and electronic cigarettes

Article 15.

Prohibition of sale of tobacco products, plant-based products for smoking and electronic cigarettes

1 — The sale of tobacco products, plant-based products for smoking and electronic cigarettes is prohibited under the following circumstances:

a) In the places referred to in sub-paragraphs a), d), e), f), g), h), i), r), v), aa) and bb) of N.º 1 of Article 4., and in the facilities referred to in sub-paragraph m) of the same Article;

b) Through automatic vending machines, whenever these do not meet all of the following requirements:

i) They are equipped with an electronic device or other blocking system that prevents access to them by minors under the age of 18;

ii) They are located inside a commercial establishment in such a way that they can be seen by the person in charge of the establishment, and cannot be placed in the respective entrance area, stairways or similar areas, or in hallways of shopping centers and large commercial spaces;

c) To minors under the age of 18, which is to be proven by showing a an identification document with a photograph;

d) Through any techniques of remote sale, particularly through telesale or the Internet.

2 — The prohibition referred to in sub-paragraph c) of the foregoing paragraph must be stated in a notice printed in easily legible characters, on a contrasting background, and prominently posted at places where tobacco products, plant-based products for smoking and electronic cigarettes are sold.

3 — The sale of promotional packages or sale at a reduced price is prohibited.

4 — (Rescinded.)

CHAPTER VIII

Advertising, promotion and sponsorship of tobacco and of tobacco products

Article 16.

Advertising and promotion

1 — All forms of advertising and promotion for tobacco and tobacco products are prohibited, including secret, concealed or subliminal advertising, through national advertising media or those based in Portugal, including online services, except as provided in Nos. 3, 4 and 7.

2 — Advertising for tobacco, or its use, in automatic vending machines is prohibited.

3 — What is set forth in N.º 1 is not applicable to commercial information confined to statements of price, brand and origin displayed exclusively on the inside of establishments that sell tobacco products, as long as it is not visible from outside such establishments, particularly the respective samples.

4 — Advertising in the press and other print media is only permitted in publications intended exclusively for professionals in the tobacco trade, or in publications printed and published in third countries, as long as they are not chiefly intended for the community market.

5 — The free distribution or promotional sale of tobacco products or of any consumption goods, that seeks, or has the direct or indirect effect, of promoting such tobacco products or their consumption, is prohibited.

6 — The distribution of gifts, awarding of prizes or conduct of contests, even if they are exclusively intended for smokers, by companies directly or indirectly related to the manufacture, distribution or sale of tobacco products, is prohibited.

7 — The promotion of tobacco products is only permitted when it is exclusively addressed to professionals in the tobacco trade, and is conducted outside the domain of activity of sales to the public.

8 — The insertion of coupons or other extraneous elements into packages and on packages of tobacco products, or between the former and the latter, apart from the tobacco product itself and the respective labeling, is prohibited.

9 — The promotion of sales and offering for consumption miniature packages of brands already commercialized, or that are going to be commercialized, is prohibited.

10 — Audiovisual commercial communication for tobacco products, as indicated in Law N.º 27/2007, of July 30, as amended by Laws No. 8/2011, of April 11, and 40/2014, of July 9, is prohibited .

11 — What is set forth in this Article is applicable to plant-based products for smoking.

Article 17.

Advertising on objects of consumption

1 — In advertising activities, it is prohibited to place names, brands or emblems of a tobacco product on objects of consumption other than the tobacco products themselves.

2 — Excepted from the prohibition stated in the foregoing paragraph are goods and services that make use of names or brands identical to those of tobacco products, as long as they meet the following requirements:

a) Their sale or sponsorship is not related to the sale of tobacco products;

b) Such goods or services were introduced onto the Portuguese market prior to the date of publication of this Law;

c) The method for the use of such names and brands is clearly different from that of the names and brands of tobacco products.

3 — The manufacture and sale of games, toys, video games, foods or sweets with the shape of tobacco products, or with the logos of tobacco brands, is prohibited.

4 — What is set forth in this Article is applicable to plant-based products for smoking.

Article 18.

Sponsorship

1 — Any kind of public or private contribution, particularly by companies engaged in the manufacture, distribution or sale of tobacco products, for an event, an activity, an individual, an audiovisual work, a radio or television program, that seeks, or has the direct or indirect effect of promoting a tobacco product or its consumption, is prohibited.

2 — The sponsorship of events or activities by companies in the tobacco industry that involve, or are carried out in several member States, or that have any other trans-border effects, is prohibited.

3 — Distribution of tobacco products for free or at promotional prices in the context of the sponsorship referred to in the foregoing paragraph, that seeks or has the direct or indirect effect of promoting such products, is prohibited.

4 — What is set forth in this Article is applicable to plant-based products for smoking.

CHAPTER IX

Measures for the prevention and control of tobacco use

Article 19.

Campaigns of information, prevention or sales promotion

Campaigns or other initiatives promoted or sponsored by companies, their subsidiaries or the like, that produce or distribute tobacco products and plant-based products for smoking, that seek, directly or indirectly, to provide information and promote the prevention of tobacco use, are prohibited.

Article 20.

Information and education for health.

1 — The State, and in particular the sectors of health care, education, youth affairs, sports, consumer protection, the environment, labor, the economy and culture, as well as the autonomous regions and local authorities, must undertake to inform the citizenry, whenever possible using sign language and Braille, and foster the creation of conditions favorable to the prevention and control of tobacco use.

2 — Health care services, regardless of whether they are public or private, particularly health care centers, hospitals, clinics, medical consulting offices and pharmacies, must undertake and support efforts to inform and educate the citizenry about health with regard to the harmful effects resulting from tobacco consumption and the importance of quitting tobacco, through campaigns, programs and initiatives intended for the general population or specific groups, particularly children and young people, pregnant women, parents, women of child-bearing age, people who are ill, teachers and other workers.

3 — The theme of prevention and control of tobacco use must be taken up in the domain of education for the citizenry, at the primary and secondary levels and curricula for vocational training, as well as undergraduate and graduate education of teachers at these levels of instruction.

4 — The theme of prevention and treatment for use and addiction to tobacco must be part of the educational curricula for undergraduate and graduate health care professionals, in particular doctors, dentist physicians, pharmacists and nurses, as privileged agents in health education and promotion.

Article 21.

Consultations on quitting tobacco

1 — Consultations of intensive support for quitting tobacco are to be established in all clusters of health care centers and hospitals of the National Health Service, particularly in the departments of cardiology, pneumology, psychiatry and obstetrics, at institutes and departments of oncology, at psychiatric hospitals and centers for the treatment of alcoholics and drug addicts.

2 — Whenever the size of these departments and the population served do not justify the establishment of a consultation of intensive support for quitting tobacco, protocols must be established with other consultations of intensive support for quitting tobacco available in other clusters of health care centers or hospitals of the National Health Service, in such a way as to guarantee adequate access for smokers who need this kind of support to quit smoking.

Article 22.

The technical consulting group

1 — Within the direct authority of the Director General of Health, a technical consulting group is hereby created for the purpose of providing technical advice, as well as helping to define and implement programs and other initiatives in the domain of prevention and control of tobacco use.

2 — The technical consulting group, as appointed by the office of the Director General of Health, is to be composed, on an equal basis, by representatives of Government and civil society, and with regard to the latter, in particular professionals from the fields of health care, unions and employers associations, scientific societies, as well as by individuals of recognized merit in the field of prevention and control of tobacco use.

3 — The persons referred to in the foregoing paragraph must state the absence of any conflict of interest with the objectives of the technical consulting group, in the field of prevention and control of tobacco use.

Article 23.

Duty of compliance

The General Administration of Health shall foster compliance with what is set forth in this Law, with the collaboration of offices services and public agencies with responsibilities in this area.

Article 24.

Statistical studies

1 — The General Administration of Health, in coordination with the National Observatory of Health and the technical consulting group, shall see to the statistical and epidemiological oversight of tobacco consumption in Portugal, as well as the impact resulting from the application of this Law, particularly with regard to compliance, the evolution of conditions in work places and service to the public, in order to allow for proposals of appropriate alterations in the prevention and control of tobacco consumption.

2 — With the aim of evaluating the impact of this Law on public health and the health of workers, the Ministry of Health must provide the Assembly of the Republic with a report containing the elements referred to in the foregoing paragraph, every five years.

3 — The first report must be delivered to the Assembly of the Republic after the lapse of three years following the entry into force of this Law.

CHAPTER X

Sanctions regime

Article 25.

Offenses

1 — Infractions of what is set forth in Articles 4. a 6., in N.º 2 of Article 7. and in Articles 8. to 19. constitute offenses, which are punishable by the following fines:

a) From € 50 to € 750, for smokers who smoke in the places indicated in sub-paragraphs a) to bb) of N.º 1 and N.º 2 of Article 4. or outside of areas outdoors or areas for smokers indicated in Nos. 1 to 9 of Article 5.;

b) From € 50 to € 1000, for owners of private establishments, juridical persons, companies even if they are not regularly established, or associations without legal personality, as well as for administrative bodies or chief directors of agencies, establishments or services of Public Administration who violate what is set forth in N.º 2 of Article 7.;

c) From € 2,500 to € 10,000, for the entities referred to in the foregoing sub-paragraph that violate what is set forth in Nos. 1, 2, 4, 5, 6, 7, 8, 9 and 10 of Article 5. and Article 6.;

d) From € 10,000 to € 30,000, for infractions of Nos. 1 to 7 and 10 of Article 9.- A, Nos. 2 and 4 of Article 10., Nos. 1 to 3 of Article 14.- B, Nos. 3, 4, 6 and 8 of Article 14.- C, Article 14.- F and Nos. 1, 2

and 4 of Article 14.- H, with the amount being reduced to € 1,500 and € 3,000, respectively, if the offender is a natural person;

e) From € 30,000 to € 250,000, for infractions of N.º 1 of Article 8., Nos. 1, 2, 3 and 6 of Article 9., Nos. 1, 4 and 5 of Article 10.- A, Nos. 1 to 8 of Article 11., Articles 11.- A, 11.- B, 11.- C, 12. and 13., Nos. 1 to 6, 8, 10 and 14 of Article 13. -A, Nos. 1 and 4 of Article 13.- B, Articles 14. and 14. -A, Nos. 1 and 2 of Article 14. -C, Article 14. -D, Article 14. -E, Article 14. -G, Nos. 1 to 3 of Article 15., and Articles 16., 17., 18. and 19., with the amount being reduced to € 2,000 and € 3 750, respectively, if the offender is a natural person.

2 — Negligence is punishable, with the minimum and maximum limits on applicable fines being reduced by half.

3 — In the cases indicated in sub-paragraph e) of N.º 1, attempted offenses are punishable, with the minimum and maximum limits on applicable fines being reduced by half.

4 — When the infraction involves a form of secret or hidden advertising, the punishment indicated in general legislation regarding advertising activity is applicable.

5 — For the offenses indicated in this Law, and with regard to everything appertaining thereto that is not especially regulated, the general regime of offenses is applicable, as approved by Decree-Law N.º 433/82, of October 27.

Article 26.

Accessory sanctions

1 — In the case of the offenses indicated in sub-paragraphs c), d) and e) of N.º 1 of the foregoing Article, the accessory sanctions indicated in N.º 1 of Article 21. of the general regime of offenses, approved by Decree-Law N.º 433/82, of October 27, can also be imposed.

2 — Failure to comply with what is set forth in Nos. 1 to 3 of Article 15. shall incur the imposition of the accessory sanction of prohibition of the sale of any tobacco product.

Article 27.

Joint liability

1 — Manufacturers and importers of tobacco products are jointly liable for payment of fines imposed upon perpetrators of infractions of what is set forth in N.º 1 of Article 8., N.º 6 of Article 9., Nos. 1 to 7 and 10 of Article 9.- A, Nos. 2 and 4 of Article 10., Nos. 1, 4 and 5 of Article 10.- A, Nos. 1 to 8 of Article 11.,Articles 11. -A, 11. -B, 11. -C, 12. and 13., Nos. 1 to 6, 8, 10 and 14 of Article 13.- A, Nos. 1 and 4 of Article 13.- B, Article 14., Nos. 1 to 3 of Article 14.- B, Nos. 1 to 4, 6 and 8 of Article 14.- C, Articles 14.- D, 14.- E, 14.- F and 14.- G and Nos. 1, 2 and 4 of Article 14.- H.

2 — Owners of automatic tobacco vending machines, as well as the individual engaged in the actual management of the premises in which the equipment is installed, are jointly liable for payment of fines imposed upon perpetrators of infractions of what is set forth in sub-paragraph b) of N.º 1 of Article 15. and N.º 2 of Article 16.

3 — Manufacturers or importers and owners of premises or the managers of operations where these products are made available for payment or free of charge, are jointly liable for payment of fines imposed upon perpetrators of infractions of what is set forth in Article 17.

4 — Advertisers, advertising professionals or agencies, or any other entity engaging in advertising activities, the owner of advertising vehicles or the respective licensee, as well as any participant in the transmission of advertising messages, are jointly liable for payment of fines imposed upon perpetrators of infractions of what is set forth in sub-paragraph d) of N.º 1 of Article 15., Nos. 1, 5, 6, 8, 9, 10 and 11 of Article 16. and Article 19.

5 — Sponsoring entities and sponsored entities are jointly liable for payment of fines imposed upon perpetrators of infractions of what is set forth in Article 18.

6 — Entities that own the advertising vehicle used, or the respective licensee, shall be exempt of the liability referred to in N.º 4, if they are able to demonstrate that they did not have prior knowledge of the advertising message that was conveyed.

Article 28.

Enforcement and prosecution

1 — Without impairment to the competencies attributed by Article 7. to administrative and police authorities, the enforcement of what is set forth in this Law is incumbent upon the Bureau of Food and Economic Security, except for the enforcement indicated in sub-paragraph d) of N.º 1 of Article 15., N.º 1 of Article 16., N.º 1 of Article 18. and Article 19., which is incumbent upon the Bureau of Consumer Affairs.

2 — Prosecution of offenses is incumbent upon the Bureau of Food and Economic Security or the Bureau of Consumer Affairs, within the scope of their respective attributions, to which notifications of violation drawn up by other authorities must be forwarded.

3 — It is incumbent upon the Inspector-General of the Bureau of Food and Economic Security and the General Director of the Bureau of Consumer Affairs, as appropriate, to impose the respective fines and accessory sanctions, notification of which is to be forwarded to the General Administration of Health.

4 — Proceeds from fines are to be distributed as follows:

a) 60% for the State;

b) 40% for the entity that conducted the prosecution and imposed the fine;

c) (Rescinded.)

CHAPTER XI

Transitory and final provisions

Article 29.

Autonomous Regions

1 — The Autonomous Regions exercise the competencies indicated in this Law through the agencies defined by the government’s own bodies.

2 — Proceeds from fines imposed in the Autonomous Regions shall constitute the latter's own revenues.

Article 29. -A

Provision of information

For the purposes of what is set forth in Chapters III, V and VI, the requirement to provide the obligatory information is incumbent in the first place upon the manufacturer, if it is established in the European Union, on the importer, if the manufacturer is established outside the European Union and the importer is established in the European Union, and jointly upon the manufacturer and the importer, if both are established outside the European Union.

Article 30.

Clause revoking earlier provisions

The following are hereby rescinded: a) Law N.º 22/82, of August 17; b) Decree-Law N.º 226/83, of May 27; c) Decree-Law N.º 393/88, of November 8; d) Decree-Law N.º 287/89, of August 30; e) Decree-Law N.º 253/90, of August 4; f) Article 18. and N.º 2 of Article 24. of the Advertising Code, approved by Decree-Law N.º 330/90, of October 23; g) Decree-Law N.º 200/91, of May 29; h) Decree-Law N.º 276/92, of December 12; i) Decree-Law N.º 283/98, of September 17; j) Article 95. of the Code of Special Taxes on Consumption, approved by Decree-Law N.º 566/99, of December 22; l) Decree-Law N.º 25/2003, of February 4; m) Decree-Law N.º 138/2003, of June 28; n) Decree-Law N.º 76/2005, of April 4; o) Decree-Law N.º 14/2006, of January 20; p) N.os 2 to 5 of Resolution of the Council of Ministers N.º 35/84, of June 11; q) Edict N.º 165/84, of March 26; r) Edict N.º 432/91, of May 24; s) Edict N.º 735/93, of August 13; t) Order N.º 19/MS/88, of January 25, 1989; u) Order N.º 8/ME/88, of February 8, 1989.

Article 31.

Entry into force

This Law enters into force on January 1, 2008.

ANNEX I

Template A

Template B

ANNEX II

(referred to in N.º 1 of Article 11. -B and o N.º 2 of Article 11. -C)

1 — List of written warnings:

a) "Smoking causes 9 out of 10 cases of lung cancer";

b) "Smoking causes cancer of the mouth and throat";

c) "Smoking damages your lungs";

d) "Smoking causes heart attacks";

e) "Smoking causes strokes and disabilities";

f) "Smoking causes blocking of the arteries";

g) "Smoking exacerbates the risk of blindness";

h) "Smoking causes injuries to your teeth and gums";

i) "Smoking can kill your child before it is born";

j) "Your smoke is harmful to your children, family and friends";

k) "Children of smokers are more likely to take up smoking";

l) "Quit smoking now — think of your loved ones"

m) "Smoking reduces fertility";

n) "Smoking exacerbates the risk of impotence."