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SUMMARY:

It covers the concept of smoking new tobacco products without combustion to produce aerosols, vapors, gases or inhalable particles and strengthens measures to be applied to these new products in the area of exposure to environmental tobacco smoke, advertising and promotion, proceeding to the second amendment to <u>Law No 37/2007</u> of 14 August

TEXT

Law No. 63/2017

of August 3

It covers the concept of smoking of new smokeless tobacco products which produce inhalable aerosols, vapors, gases or particulates and reinforces the measures to be applied to these new products in relation to exposure to environmental tobacco smoke, advertising and promotion, No. 37/2007 of 14 August.

The Assembly of the Republic decrees, in terms of letter c) of article 161 of the Constitution, the following:

Article 1

Object

This Act amends Law No. 37/2007 of 14 August, which approves rules for the protection of citizens of involuntary exposure to tobacco smoke and measures to reduce demand related to dependence and cessation of tobacco use. its consumption, amended and republished by Law no. 109/2015 of 26 August,

168/2018 the concept of smoking new smokeless to back products which produce aerosols, vapors, gases or inhalable particles and reinforcing the measures to be applied to them exposure to environmental tobacco smoke, advertising and promotion.

Article 2

Amendment to Law no. 37/2007, of August 14

Articles 2, 4, 5, 10, 10a, 11, 11a, 11c, 14b, 14a, D, 15, 16, 20, 21, 25, 26 and 28 of Law 37/2007, of August 14, amended and republished by Law no. 109/2015, of 26 August, shall be replaced by the following:
'Article 2
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smoking, the consumption of tobacco products for smoking, the consumption of herbal products for smoking, the use of electronic cigarettes with nicotine, or the consumption of new smokeless tobacco products which produce aerosols, vapors, gases or inhalable particles;		
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Article 4
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(f) in places intended for persons under the age of 18 years, including nursery schools, crèches and other child care establishments, homes for children and youth, leisure centers, camps and holiday camps, playgrounds and similar establishments;
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11/2 <u>8</u> /2018	Law 63/2017, 2017-08-03 - DRE
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12 - Discrimination against smokers in employ regards selection and admission, termination of en	ment relationships shall be prohibited, in particular as mployment, wages or other rights and benefits.
Article 10	
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preceding paragraphs which shall include a summ literature on that additive and a summary of the months after the additive concerned has been include	report on the results of the studies referred to in the nary and a detailed compilation of the available scientific internal data on the effects of the additive, within 18 luded in the priority list referred to in paragraph 1, to the ctorate-General for Health, which may require further
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Article 10a

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10 - Tobacco products other than cigarettes and rolling tobacco shall not be subject to the prohibitions set out in paragraphs 1 and 5.
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Article 11
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6. The dimensions of the health warnings provided for in Articles 11a, 11b, 11c and 11d shall be calculated in relation to the area in question when the package is closed.
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11(28(2))18 	Law 63/2017, 2017-08-03 - DRE
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c) Cover 50% of the surfaces on which	ch they are printed.
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Article 11c	
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7. The general warning referred to individual packaging and of any oute	in this Article shall cover 30% of the most visible surface of the packaging.
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Article 14b	
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1328 Where references are made that a new tobacco product 15-potentially less harmful than others, or

presents a reduced risk to the health of the consumer, manufacturers or importers, in addition to the

studies referred to in the preceding paragraph, shall submit scientific basis that proves that:

(a) the product concerned reduces the risk of tobacco-related diseases in current consumers and does not

increase attractiveness, toxicity and potential for dependence, as well as carcinogenic, mutagenic or toxic

to reproduction properties compared to tobacco products already on the market;

(b) there is a health benefit for the population as a whole, including consumers and non-consumers, with

particular attention given to the young.

4. Manufacturers and importers of new tobacco products shall communicate to the Directorate-General

for Health any new or updated information on the studies, analyzes and other information referred to in

the preceding paragraphs.

5 - (Previous No. 4.)

6 - The introduction of new tobacco products under the terms of the previous numbers shall be subject to

authorization from the General Directorate of Economic Activities, after obtaining the opinion of the

Directorate General of Health, in terms to be defined by an order of the members of the Government

responsible for the areas of finance, economy and health.

7 - (Previous paragraph 6.)

8 - (Previous paragraph 7.)

Article 14d

[...]

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3 - ...

4. Individual packagings and outer packagings of electronic cigarettes and refills shall, in accordance with

Article 11d (2) and (3), present the following health warning:

'This product contains nicotine, a substance that creates strong dependence. It is not recommended for use

by non-smokers. '

5 - ...

6 - ...

Article 15

11/28/2018 sale of tobacco products, herbal tobacco products and refills with nicotine containing liquid shall be prohibited:
The)
B)
W)
(d) by means of teleshopping, telephone or postal services;
e) Through the Internet.
2. The provisions of points a), b), c) and d) of the previous paragraph apply to electronic cigarettes and their components, electronic heating devices for tobacco and other devices or recharges, including the paper of curling cigarettes and hookahs the use of tobacco products.
3 - The sale of tobacco products, herbal products for smoking and electronic cigarettes through the use of databases, electronic customer registration, loyalty card issuance, premiums, or the use of other customer loyalty techniques.
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5 - (Anterior paragraph 2.)
6 - (Previous paragraph 3.)
Article 16
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12 - The provisions of this Article shall also apply to devices or recharges, including rolling paper, electronic heating devices for tobacco and other devices or accessories necessary for the use of tobacco products, electronic cigarettes and herbal products for smoking.

Article 20

[...]

1 - ...

2. Health services, regardless of their legal nature, such as health centers, hospitals, clinics, doctors' offices and pharmacies, should promote and support information and education for the health of citizens with regard to the harm caused by smoking and the importance of prevention and smoking cessation through campaigns, programs and initiatives aimed at the general population or specific groups, such as children and young people, pregnant women, parents, women of childbearing age, sick people, teachers and other workers, or even for those smokers for whom conventional methods of cessation prove to be ineffective, the existence of alternatives, as evidenced by the Directorate-General for Health, which entail risk reduction and harm.

3 - ...

4 - ...

Article 21

[...]

- 1. A network of intensive tobacco cessation support consultations should be established in all clusters of health centers to ensure the proximity and accessibility of all users to their functional units and consultations should also be established in hospitals of the National Service (SNS) to meet the needs of patients, especially in cardiology, pulmonology, anesthesia, surgery, psychiatry and obstetrics, in oncology institutes and services, psychiatric hospitals and alcohol and drug treatment centers.
- 2. Where the size of the services and population served does not justify the establishment of an intensive care consultation for smoking cessation, protocols should be established with other intensive care consultations for smoking cessation available in NHS health center clusters or hospitals in order to ensure adequate access for smokers who need this type of support to stop smoking.

Article 25

[...]

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The) ...

W) ...

d) ...

(e) from EUR 30 000 to EUR 250 000 for infringements of Article 8 (1), Article 9 (1), (2), (3) and (6), Article 11 (1), (4) and (5), Article 11 (1) to (8), Articles 11a, 11b, 11c, 13 (1) to (6), (8), (10) and (14), Article 13b (1) and (4), Articles 14 and 14a Article 14c (1) and (2), Article 14d, Article 14e, Article 14g, paragraphs 1, 2, 3 (5) and (6), and Articles 16, 17, 18 and 19, the value being reduced to (euro) 2000 and (euro) 3750, respectively, if the offender is individual.

2 - ...

3 - ...

4 - ...

5 - ...

Article 26

[...]

1 - ...

2. Non-compliance with the provisions of Article 15 (1), (3) and (6) shall determine the application of the accessory prohibition sanction for the sale of any tobacco product, herbal tobacco products and electronic cigarettes.

Article 28

[...]

- 1 Without prejudice to the powers conferred by Article 7 on administrative and police authorities, the provisions of this law shall be the responsibility of the Food and Economic Security Authority, except for the inspection of publicity matters provided for in Article 14- Article 16 (1), Article 18 (1) and Article 19, which is the responsibility of the Directorate-General for Consumer Affairs and the Media Regulatory Entity within the framework of the respective areas of competence.
- 2 The investigation of the processes of back-office is the responsibility of the Food and Economic Security Authority, the Consumer Directorate-General or the Regulatory Entity for Social Communication, within the scope of their attributions, and to whom should be sent the files raised by other entities.
- 3 The Inspector General of the Food and Economic Security Authority, the Director General of the Consumer and the Regulatory Council of the Regulatory Body for Social Communication shall be responsible for the application of the respective fines and ancillary sanctions, which give them to the

¹1/28/2018 rate-General for Health.

4 - ... »

Article 3

Amendment to Law no. 37/2007, of August 14

Are added to Law no. 37/2007, dated August 14, amended and republished by Law no. 109/2015, of August 26, Articles 20-A and 21-A, with the following essay:

'Article 20a

Protection of workers

1 - Occupational health services should promote tobacco prevention and control actions and programs, providing concrete information on the consequences of tobacco use and exposure to tobacco smoke, and support or refer workers intend to start the smoking cessation treatment for the family doctor or for cessation visits.

2 - Occupational health services should monitor the health of workplaces, in particular with regard to air quality, avoiding their contamination with tobacco smoke, thus ensuring adequate health, hygiene and safety conditions.

Article 21a

Reimbursement of medicines

Access to nicotine replacement drugs and prescription-only anti-tobacco medicines should be promoted in an innovative way and for anti-tobacco prescription drugs progressively reimbursed under existing legislation on reimbursement in connection with consultations intensive support for the cessation of smoking in clusters of health centers and NHS hospitals."

Article 4

Transitional rule

1 - Until 20 May 2019, the positioning obligation provided for in paragraph 4 of article 11-B of Law no. 37/2007, of August 14, as amended by Law no. 109 / 2015, of August 26, becomes:

(a) in the case of an individual carton pack, the combined health warning on the rear face shall be positioned directly below the special stamp;

(b) where the individual packaging is made of soft material, a rectangular surface not exceeding 13 mm between the upper edge of the package and the upper edge of the combined health warning shall be reserved for the special stamp.

1228/16118 the situations mentioned in the previous nulfill 613/26113 final 1888 and 1890 should not be placed above the health warnings.
Article 5
Revocatory standard
Article 6 (6) of Law no. 109/2015 of 26 August is hereby repealed.
Article 6
Republishing
The law no. 37/2007, of August 14, with the current wording and other material corrections, is republished in the annex to the present law, of which it is an integral part.
Article 7
Implementation
This law shall enter into force on January 1, 2018.
Approved June 1, 2017.
The President of the Assembly of the Republic, Eduardo Ferro Rodrigues.
Enacted on July 14, 2017.
Post it.
The President of the Republic, Marcelo Rebelo de Sousa.
Countersigned on July 24, 2017.
The Prime Minister, António Luís Santos da Costa.
ATTACHMENT
(referred to in Article 6)
Republishing of Law no. 37/2007, of August 14
CHAPTER I
General provisions
Article 1
Object

11/28/Fhis Act lays down rules for the prevention of wshill his hard particular as regards the protection of exposure to environmental tobacco smoke, the ingredients and emissions of tobacco products, the information to be provided on tobacco products, the labeling and packaging ban on the marketing of tobacco for oral use, cross-border sales of tobacco products, the obligation to notify new tobacco products, the marketing and labeling of certain products related to tobacco products, and health education, the prohibition of tobacco advertising, promotion and sponsorship, demand reduction measures relating to dependence and cessation of consumption, sale to minors and via automatic means, in order to contribute to the reduction of the risks or negative effects that the use of tobacco causes for the health of individuals.

2 - This law also implements the provisions of the World Health Organization Framework Convention on Tobacco Control, approved by Decree No. 25-A / 2005, of November 8, and transposes into the domestic legal order <u>Directive 2014/40 / EU</u> of the European Parliament and of the Council of 3 April 2014, the Commission <u>Directive 2014/109 / EU</u> of 10 October 2014 and <u>Directive 2003/33 / EC</u> of the European Parliament and of the European Parliament and of the Council of 26 May 2003.

Article 2

Definitions

For the purposes of this law, the following definitions shall apply:

- (a) 'additive' means a substance, other than tobacco, which is added to a tobacco product, to an individual packaging or to any outer packaging;
- (b) 'combined health warning' means a health warning provided for in this law and consisting of a combination of a warning in text and the corresponding photograph or illustration;
- (c) 'health warning' means a warning on the adverse effects of a product on human health or other undesirable consequences of its use, including text warnings, combined health warnings, general warnings and informational messages;
- (d) 'Tar' means the anhydrous and nicotine-free crude smoke condensate;
- (e) 'distinctive flavoring' means a clearly visible odor or taste other than tobacco, resulting from an additive or a combination of additives, including but not limited to fruit, spices, herbs, alcohol, and which is established before or during consumption of the tobacco product;
- (f) 'flavoring' means an additive which imparts an odor and / or flavor;
- (g) 'bag' means a carton of rolling tobacco either in the form of a rectangular pocket with a flap covering the opening or in the form of a flat bottomed bag;
- (h) 'cigar' means a roll of tobacco which may be consumed by means of a combustion process and defined in more detail in the Code of Special Taxes on Consumption, approved by Decree-Law no. 73/2010, of 21 June;

- 1/(f)*/2018/arette' means a roll of tobacco which may be 266137 means of a combustion process and defined in more detail in the Code of Special Taxes on Consumption, approved by Decree-Law No 73/2010 of 21 June;
- (k) 'electronic cigarette' means a product which may be used to consume nicotine-containing vapor, by means of a mouthpiece, or any component thereof, including a cartridge, a reservoir and the device without a cartridge or reservoir, and electronic cigarettes may be disposable or rechargeable through a recharge and a reservoir, or recharged by a non-reusable cartridge;
- (l) 'placing on the market' means the supply of products, regardless of their place of manufacture, to consumers located in the national territory, with or without payment, including through distance sales, and in the case of cross-border distance selling, the product is marketed in the country where the consumer is located;
- (m) 'consumer' means a natural person acting for purposes which do not fall within the scope of his commercial, industrial, craft or professional activity;
- (n) 'outer packaging' means any packaging in which tobacco products or related products are placed on the market and which includes individual packaging or individual packaging, the transparent packaging being not considered as outer packaging;
- (o) 'individual packaging' means the smallest individual packaging of a tobacco product or related product which is placed on the market;
- (p) 'emissions' means substances that are released when a tobacco product or related product is consumed for the intended purpose, such as substances contained in smoke or substances released during the process of using smokeless tobacco products;
- (q) 'retail establishment' means any establishment where tobacco products are marketed, including by a natural person;
- (r) 'manufacturer' means a natural or legal person who manufactures a product or makes it designed or manufactured and markets it on its behalf or under its trade mark;
- (s) 'smoking' means the consumption of tobacco products for smoking, the consumption of herbal products for smoking, the use of electronic cigarettes with nicotine, or the consumption of new smokeless tobacco products which produce aerosols, vapors, gases or inhalable particles;
- (t) 'environmental smoke' means smoke released into the atmosphere from the combustion of tobacco products;
- (u) 'importer of tobacco products or related products' means the owner or person enjoying the right to dispose of tobacco products and related products which have been introduced into the national territory from another Member State or from a country or territory third, as defined in the Code of Special Taxes on Consumption, approved by Decree-Law no. 73/2010, of June 21;

- 11(28/2018 redient' means tobacco, an additive, as well 63/2017y 2017 508 63 consistence of element present in a finished tobacco product or a related product, including paper, filter, paints, capsules and adhesives;
- (w) 'place of work' means any place where the employee is and where he is, directly or indirectly, under the control of the employer;
- (x) 'place of sale of tobacco' means any place where tobacco products are offered for sale;
- (y) 'nicotine' means nicotinic alkaloids;
- (z) 'maximum level' or 'maximum emission level' means 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' means a tobacco product which:
- (i) does not belong to any of the following categories: cigarettes, rolling tobacco, pipe tobacco, pipe tobacco, cigars, cigarillos, chewing tobacco, snuff or tobacco for oral use; and
- ii) It is marketed after May 19, 2014;
- (bb) 'Potential to create dependency' means the pharmacological potential of a substance to create dependency, a state that affects an individual's ability to control his or her behavior, usually by offering a reward effect or relief from the withdrawal symptoms, or both;
- (cc) 'herbal product for smoking' means a herbal product, herbs or fruit which does not contain tobacco and may be consumed by a combustion process;
- (dd) 'smokeless tobacco product' means a tobacco product which does not involve a combustion process, including chewing tobacco, snuff and tobacco for oral use;
- (e) 'tobacco products' means products which may be consumed and which are produced, even partially, by tobacco, genetically modified or not;
- (ff) 'tobacco products for smoking' means a tobacco product, other than smokeless tobacco products;
- (gg) 'tobacco advertising' means any form of communication made by public or private entities in the course of a commercial, industrial, artisanal or liberal activity, with the direct or indirect objective of promoting a tobacco product or its consumption;
- (hh) 'snuff' means a smokeless tobacco product which may be consumed nasally;
- (ii) 'recharging' a container of liquid containing nicotine, which may be used to recharge an electronic cigarette;
- (jj) 'enclosure' means any space completely enclosed by walls, walls or other surfaces and provided with a cover;

- (II) 'advertising medium' means the vehicle used for the transmission of the advertising message;
- (mm) 'tobacco' means the leaves and other natural parts, whether processed or unprocessed, of the tobacco plant, including expanded and reconstituted tobacco;
- (nn) 'Rolling tobacco' means tobacco which may be used to make cigarettes by consumers or retail establishments;
- (oo) 'chewing tobacco' means a smokeless tobacco product intended exclusively for chewing;
- (pp) 'pipe tobacco' means tobacco which may be consumed by means of a combustion process and intended exclusively for use in a pipe;
- (qq) 'pipe tobacco' means a tobacco product which may be consumed by means of a water pipe (hookah), it being understood, for the purposes of this Law, that pipe tobacco is a tobacco product for smoking, unless the product is usable in both pipes and roll-on tobacco, in which case it is considered to be rolled tobacco;
- (rr) 'tobacco for oral use' means all oral tobacco products, other than those intended to be inhaled or chewed, wholly or partly made up of tobacco, in the form of powder or fine particulates or any combination thereof, in particular those in individual doses or porous packs;
- (ss) 'telemarketing' means the distribution of direct offers to the public by television channels for the supply of cigarettes or other tobacco products, herbal products for smoking or electronic cigarettes, for payment;
- (tt) 'Toxicity' means the extent to which a substance may cause harmful effects to the human body, including long-term effects, usually by repeated or continuous consumption or exposure;
- (uu) 'cross-border distance sales' means distance sales to consumers in which the consumer is in a country other than the one in which the retail establishment is established when it orders the product to a retail establishment, the retail establishment is established in a country:
- (i) in the case of a natural person, if he has his place of commercial activity in that country;
- (ii) in all other cases, where the retail establishment has its registered office, central administration or place of business, including a branch, agency or other establishment in that country.

CHAPTER II

Limitations on smoking

The provisions of this chapter are intended to establish limitations on the use of indoor tobacco for collective use in order to ensure the protection of exposure to environmental tobacco smoke.

Article 4

No smoking in certain locations

- 1 Smoking is not allowed:
- a) In places where sovereign bodies, public administration services and bodies and public corporations are installed;
- (b) in the workplace;
- c) In the places of direct attendance to the public;
- (d) in establishments where health care is provided, in particular hospitals, clinics, health centers and homes, medical offices, emergency rooms and similar facilities, laboratories, pharmacies and places where non-prescription medicinal products are dispensed;
- (e) in homes and other institutions accommodating elderly or disabled persons or persons with disabilities;
- (f) in places intended for persons under the age of 18 years, including nursery schools, crèches and other child care establishments, homes for children and youth, leisure centers, camps and holiday camps, playgrounds and similar establishments;
- (g) in educational establishments, irrespective of the age of the pupils and the educational level, including, in particular, classrooms, study rooms, teachers and meetings, libraries, gyms, atriums and corridors, bars, restaurants, canteens, playgrounds;
- (h) in vocational training centers;
- i) In museums, visitable collections and places where classified cultural objects are stored, in cultural centers, archives and libraries, in conference, reading and exhibition rooms;
- (j) in the rooms and venues of shows and other places intended for the dissemination of the arts and the spectacle, including antechambers, entrances and contiguous areas;
- l) In the amusement enclosures, in the casinos, bingos, game rooms and other type of enclosures destined to spectacles of non-artistic nature;
- m) In enclosed areas of sports facilities;
- n) In the enclosures of the fairs and exhibitions;

¹½8120180tel establishments and other tourist develophye63/2017 48603 mDRE dation services are provided;

- (q) in catering or beverage establishments, including those with dance halls or spaces;
- (r) in canteens, cafeterias and pubs of public and private entities intended exclusively for their staff;
- s) In service areas and fuel stations;
- (t) at airports, at railway stations, at bus stations and at sea and inland waterways;
- u) In the metropolitan installations affected by the public, namely in the terminal or intermediate stations, in all their accesses and establishments or contiguous installations;
- (v) in covered car parks;
- (x) in lifts, lifts and the like;
- (z) in closed telephone booths;
- (aa) in the enclosures of automatic cash withdrawal systems;
- (bb) In any other place where, by determination of management, administration or other applicable legislation, in particular with regard to the prevention of occupational risks, smoking is prohibited.
- 2 Smoke-free vehicles for urban, suburban and interurban passenger transport, as well as road, rail, air, sea and river transportation, express, tourist and rental services, taxis, ambulances, transport of patients and cable cars.
- 3. The provisions of the preceding paragraphs shall apply to the use of new smokeless tobacco products which produce inhalable aerosols, vapors, gases or particulates and nicotine electronic cigarettes, ie products which may be used to consume steam by means of nicotine or any component of that product.
- 4. In establishments referred to in sub-paragraphs d) and g) of paragraph 1, whenever possible, outdoor smoking areas should be defined to ensure adequate protection of climatic elements and the image of the professionals who use them.

Article 5

Exceptions

- 1 Notwithstanding the provisions of paragraph d) of paragraph 1 of the preceding article, rooms may be created exclusively for patients who are smokers in hospitals and psychiatric services, treatment and rehabilitation centers, inpatient units for drug addicts and alcoholics, nursing homes of elderly and assisted residences, provided that:
- a) They are duly flagged, with display of signs in visible places, in accordance with the provisions of the following article;

- 1b)8/ffalse, at the entrance, a visible indication of the file of the Government responsible for the areas of economy, environment and health;
- (c) are physically separated from other premises or, if located inside buildings, are fully subdivided in accordance with rules to be regulated by an ordinance to be approved by Government members responsible for the areas of economy, environment and health;
- d) Have an outside ventilation system with extraction of air that allows the maintenance of a negative pressure, defined according to the capacity, size and location of the room and autonomous of the general system of air conditioning of the building, to be regulated by ordinance to approve the members of the Government responsible for the areas of economy, environment and health.
- 2 Notwithstanding the provisions of the previous article, accommodation units in cells or quarters for smoking inmates may be created in prisons, provided they meet the requirements set forth in subparagraphs c) and d) of the preceding paragraph, and smoking outdoor areas.
- 3. In the places mentioned in points a), b), c), d), e), h), i), j), l), n), o), p), q), r) of paragraph 1 of the previous article, as well as in the places mentioned in paragraph g) of paragraph 1 of the same article that are part of the higher education system, smoking is allowed in the outdoor areas.
- 4 In the places mentioned in sub-paragraph s) of no. 1 of the previous article smoking is allowed in the outdoor areas, except for the areas where the supply of vehicles is carried out.
- 5 Smoking rooms may be reserved at the places mentioned in points j), l), n), o), p), q) et) of paragraph 1 of the previous article, provided they meet the requirements mentioned in) ad) and do not have any service, namely bar and restaurant.
- 6 Access to the places mentioned in the previous number is reserved for persons over 18 years of age.
- 7 In the places mentioned in point q) of paragraph 1 of the previous article, the spaces provided for in paragraph 5 may only be constituted in the areas destined to clients, if these have a size greater than a limit to be regulated by ordinance to be approved Government members responsible for the economy, environment and health.
- 8 In the places referred to in paragraph l) of no. 1 of the previous article, where gambling is practiced, the spaces provided for in paragraph 5 may only be made up of an area of not more than 40% of the rooms game.
- 9 In the places mentioned in paragraph p) of no. 1 of the previous article, floors, accommodation units or rooms for smokers may be reserved, up to a maximum of 40% of the respective total, occupying contiguous areas or all of one or more floors as long as they comply with the requirements referred to in paragraph 1 (a) to (c) and have a ventilation or exhaust ventilation system that prevents smoke from spreading to contiguous areas.

¹¹[16⁸/2⁰¹Without prejudice to the provisions of paragraph ¹²/2 ²⁰f ⁷ the ⁰³previous article and the limitations contained in the regulations issued by the transport companies or by the captaincies of ports, smoking is permitted in the areas discovered in the boats assigned to maritime or fluvial routes.

- 11 The definition of smoking areas shall be the responsibility of the entities responsible for the establishments concerned and shall be consulted for their occupational safety and health and health services and for occupational safety and health and hygiene committees or, failing that, representatives of workers for safety, hygiene and health at work.
- 12 Discrimination against smokers in employment relationships shall be prohibited, in particular as regards selection and admission, termination of employment, wages or other rights and benefits.

Article 6

Signaling

- 1. The prohibition or conditioning of smoking within the places referred to in Articles 4 and 5 shall be marked by their competent authorities, by affixing red-colored signs to model A in Annex I to this Directive. and which forms an integral part thereof, the stroke, including the caption and cross, in white and with the minimum dimensions of 160 mm x 55 mm.
- 2 Areas where smoking is permitted are identified by displaying blue colored signs and the other characteristics indicated in the previous paragraph, conforming to model B in Annex i.
- 3 The signs referred to in the previous numbers must be marked, at the bottom of the model, a caption identifying the present law.
- 4. The label referred to in paragraph 1 shall also contain the maximum fine applicable to smokers who violate the smoking ban.
- 5. The signs shall be affixed or glued so as to be difficult to remove and shall be visible from outside the establishments.

Article 7

Responsibility

- 1 Compliance with the provisions of Articles 4 to 6 shall be ensured by the public or private entities that are in charge of the places referred to in this law.
- 2 Whenever there are violations of the provisions of articles 4 to 6, the entities referred to in the previous number must determine to the smokers that they abstain from smoking and, if they do not comply, call the administrative or police authorities, which must draw up their news report.
- 3 All users of the places referred to in paragraph 1 shall have the right to demand compliance with the provisions of articles 4 to 6, and may submit a written complaint, in a detailed manner, using for this purpose, in particular, the available at the establishment concerned.

Ingredients and emissions

Article 8

Maximum emission levels of tar, nicotine, carbon monoxide and other substances

- 1. The emission levels of cigarettes marketed or manufactured in national territory may not exceed:
- (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 may establish, through an order of the member of the Government responsible for health, maximum emission levels for emissions other than those provided for in the preceding paragraph, as well as for emissions of tobacco products other than cigarettes, of which must be notified to the European Commission.

Article 9

Measurement methods

- 1 The emissions of tar, nicotine and carbon monoxide from cigarettes are measured, respectively, by ISO standards 4387, ISO 10315 and ISO 8454.
- 2 The accuracy of the measurements for tar, nicotine and carbon monoxide is determined according to ISO 8243.
- 3 The provisions of the previous numbers shall be verified by testing laboratories accredited by the Portuguese Institute of Accreditation, under the terms of article 3 of Decree-Law no. 81/2012, of March 27, or by the competent authorities of the other Member States, and such laboratories may not be directly or indirectly owned or controlled by the tobacco industry.
- 4 The list of laboratories accredited by the Portuguese Institute of Accreditation, IP, is published on the Institute's website and communicated by the Institute to the Directorate-General for Health, by January 31 of each year and whenever changes occur, used for the accreditation of each and the means of monitoring put into practice.
- 5 The Directorate-General for Health shall communicate to the European Commission the list of laboratories referred to in the preceding paragraph, specifying the criteria used for approval and the means of monitoring put in place, as well as any changes that may occur.
- 6 Cigarettes shall be subjected to measurements in the laboratories referred to in paragraph 3 by the manufacturer or importer of tobacco products, who shall be responsible for their charges.

11/28/2018 provisions of this article shall apply, mutaff3/2017t201df38, to the emission levels referred to in paragraph 2 of the preceding article.

- 8 (Repealed.)
- 9 (Repealed.)
- 10 (Repealed.)

Article 9a

Communication of ingredients and emissions

- 1. Manufacturers and importers of tobacco products shall submit to the Directorate-General for Health, before being placed on the market, the following information, by brand and type:
- (a) a list of all the ingredients and their quantities used in the manufacture of the tobacco products in descending order of the weight of each ingredient included in the tobacco products;
- (b) the emission levels referred to in Article 8;
- (c) information on other emissions and their levels, if any, in which case the emission measurement methods used shall be indicated.
- 2. Manufacturers and importers of tobacco products shall also communicate to the Directorate-General for Health any change to the composition of a product that affects the information provided under this Article.
- 3. The list of ingredients referred to in paragraph 1 (a):
- (a) indicate the status of the ingredients, including whether they have been registered under <u>Regulation</u> (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 and their classification under <u>Regulation</u> (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008;
- (b) it shall be accompanied by the relevant toxicological data on the ingredients, with or without combustion, as appropriate, with particular reference to their effects on the health of consumers, in particular the risk of creating dependency;
- (c) it shall be accompanied by a statement setting out the reasons for the inclusion of those ingredients in the tobacco products concerned;
- (d) it 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. Where the Directorate-General for Health so decides, manufacturers or importers of tobacco products shall conduct studies to assess the effects of the ingredients on health, taking into account in particular the potential for addiction and toxicity, and the latter shall bear their own costs.

1528 Mahufacturers and importers of tobacco products \$16010 \$1600 the Directorate-General for Health internal and external studies available to them on the market and preferences of various consumer groups, including young people and current smokers, regarding ingredients and as well as summaries of any market studies they carry out when launching new products.

- 6. Manufacturers and importers of tobacco products shall also report annually to the Directorate-General for Health, by September 30 of each year, the sales volumes, broken down by brand and by type, expressed in number of cigarettes, cigarillos or cigars or in kilograms, and per country of the European Union.
- 7. All data and information to be submitted under this article and the following article shall be communicated in electronic format, to be defined by the Government's official responsible for health, and such information shall be kept electronically and kept accessible to the European Commission and to the member states, with respect for confidentiality and other confidential information.
- 8. The format for presenting and making available to the public the information referred to in this Article and the following Article shall be defined and, if necessary, updated in accordance with the procedures defined in accordance with Article 5 (5) and Article 25 of <u>Directive 2014/40 / EU</u> of the European Parliament and of the Council of 3 April 2014.
- 9 The Directorate-General for Health shall ensure the dissemination, on its website, of the data submitted in accordance with paragraph 1 and the following article, taking into account, where appropriate, information that constitutes a business secret and that have been specified by the manufacturer or importer of tobacco products.
- 10 For tobacco products already on the market at the date of entry into force of this law, the communication referred to in paragraph 1 shall be made by November 20, 2016.
- 11 For the receipt, conservation, treatment, analysis and publication of the information provided for in this article, fees are payable by manufacturers and importers of tobacco products, to be set by order of the members of the Government responsible for the areas of finance and health.

Article 10

Priority list of additives and enhanced reporting obligations

- 1. In addition to the communication obligations provided for in the previous article, the additives contained in cigarettes and rolled tobacco shall be subject to enhanced reporting obligations and shall be included in a priority list drawn up in accordance with the procedures defined in accordance with paragraph 1 of this Article. Article 6 and Article 25 of <u>Directive 2014/40 / EU</u> of the European Parliament and of the Council of 3 April 2014.
- 2. Manufacturers and importers of cigarettes and rolling tobacco containing an additive on the priority list referred to in the preceding paragraph shall carry out detailed studies to examine whether each of the additives:

11/28/2018 tribute to the toxicity or potential dependence 1/2017 the products concerned and has the effect of increasing the toxicity or potential dependence of any of the products concerned to a significant or measurable extent:

- b) results in a characteristic aroma:
- c) Facilitates the inhalation or absorption of nicotine; or
- (d) results in the formation of substances with carcinogenic, mutagenic or toxic properties for reproduction, the quantities of such substances, and if this has the effect of increasing the carcinogenic, mutagenic or toxic properties for reproduction of any of the products concerned, in significant or measurable degree.
- 3. The studies referred to in the preceding paragraph take into account the purpose for which the products in question are intended and examine, in particular, the emissions resulting from the combustion process in which the additive in question is involved, as well as the interaction of that additive with other ingredients contained in the products concerned, and joint studies may be carried out by manufacturers or importers using the same additive in their tobacco products, provided that such an additive is used in a comparable composition of the product.
- 4. Manufacturers or importers shall draw up a report on the results of the studies referred to in the preceding paragraphs which shall include a summary and a detailed compilation of the available scientific literature on that additive and a summary of the internal data on the effects of the additive, within 18 months after the additive concerned has been included in the priority list referred to in paragraph 1, to the European Commission and a copy to the Directorate-General for Health, which may require further information to be included in the report.
- 5. The European Commission and the Directorate-General for Health may request that the report referred to in the preceding paragraph be reviewed by an independent scientific body, in particular as regards its completeness, methodology and conclusions.
- 6 For the review of the report referred to in paragraph 4, fees are charged by manufacturers and importers of tobacco products, to be set by decree of the members of the Government responsible for the areas of finance and health.
- 7. Small and medium-sized enterprises, within the meaning of Decree-Law no. 372/2007, of November 6, modified by Decree-Law no. 143/2009, of June 16, shall be exempt from the obligations established in this Article, if the report on the additive in question is drawn up by another manufacturer or importer.

Article 10a

Regulation of ingredients

1. The marketing of tobacco products with a distinctive flavor shall be prohibited and the use of additives essential for the manufacture of tobacco products shall not be understood as such provided that such additives do not result in a product having a distinctive flavor and do not increase for the products of https://dre.pt/home/-/dre/107805893/details/maximized

11/28/2018, to a significant or measurable extent, av 63/2017, 2017 08 03 a PRF or creation of dependence or carcinogenic, mutagenic or toxic to reproduction properties.

- 2. The Directorate-General for Health may request the European Commission to determine whether a tobacco product falls within the scope of paragraph 1 or to consult the independent advisory panel established at EU level before taking action under (1).
- 3. The rules relating to the procedures for determining whether a tobacco product falls within the scope of paragraph 1 shall be defined in accordance with the procedures defined in accordance with Articles 7 (3) and 25. Of Directive 2014/40 / EU of the European Parliament and of the Council of 3 April 2014.
- 4. The marketing of tobacco products containing the following additives shall be prohibited:
- (a) vitamins or other additives which give the impression that a tobacco product has health benefits or low health risks;
- (b) Caffeine or taurine or other additives and stimulant compounds associated with energy and vitality;
- (c) additives which color the emissions;
- (d) for tobacco products for smoking purposes, additives which facilitate the inhalation or absorption of nicotine; or
- (e) additives which in their non-combustion form have carcinogenic, mutagenic or toxic properties for reproduction.
- 5. The marketing of tobacco products containing flavorings in their constituents, such as filters, paper, packaging, capsules or any technical characteristics which modify the odor or taste of the tobacco products in question or the intensity of their smoke, shall be prohibited., and filters, papers and capsules should not contain tobacco or nicotine.
- 6 The provisions and conditions established under <u>Regulation (EC) No 1907/2006</u> of the European Parliament and of the Council of 18 December 2006, as appropriate, shall apply to tobacco products.
- 7. On the basis of scientific evidence, the marketing of tobacco products containing additives in quantities which significantly or measurably increase the toxic or addictive effect of a tobacco product or the carcinogenic, mutagenic or toxicological properties of the product may be prohibited. reproduction in the phase of consumption, in terms to be defined by ordinance of the member of Government responsible for health.
- 8 The Directorate-General for Health shall notify the European Commission of the measures it adopts pursuant to the preceding paragraph.
- 9 The Directorate-General for Health may request the European Commission to determine whether a tobacco product falls within the scope of paragraph 7.

11/18/2018 bacco products other than cigarettes and rolffly \$3/2007 shafts not be subject to the prohibitions set out in paragraphs 1 and 5.

11. Manufacturers and importers of tobacco products bear the burden of assessing whether a tobacco product has a distinctive aroma, whether prohibited additives or flavorings are used, and whether a tobacco product contains additives in quantities which increase to a significant degree and the toxic effect or dependence of the tobacco product concerned or its carcinogenic, mutagenic or toxic properties for reproduction.

CHAPTER IV

Labeling and packaging

Article 11

General provisions

- 1. Each individual packaging of tobacco products and each outer packaging shall bear the health warnings provided for in this Chapter in Portuguese which shall cover the entire surface of the individual packaging or outer packaging which is reserved for it and may not be commented upon, paraphrased or referred to.
- 2 Health warnings on an individual packaging and on any outer packaging shall be printed in an irremovable, indelible and clearly visible form.
- 3. Health warnings in an individual packaging and in any outer packaging may not be partially or fully concealed or separated by special stamps, price tags, security features, wrappers, pouches, wallets, boxes or other items where tobacco products are not marketed, nor can they conceal or separate, in any way, special stamps, price marks, location and tracking marks or security features on the individual packaging.
- 4. In individual packagings of tobacco products other than cigarettes and bag-wrapping tobacco, health warnings may be affixed by means of stickers, provided that they are not removable.
- 5 Health warnings shall remain intact when the individual packaging is opened, except for packs with soft hinged flaps, in which case the health warning may be divided when the package is opened, but only in a way that ensures the integrity graphic and visibility of text, photos and information to help quit smoking.
- 6. The dimensions of the health warnings provided for in Articles 11a, 11b, 11c and 11d shall be calculated in relation to the area in question when the package is closed.
- 7 Health warnings shall be surrounded by a black frame 1 mm wide within the area reserved for such warnings, with the exception of the health warnings provided for in Article 11c.
- 8 The rules of this chapter shall apply to individual packagings and any external packaging for advertising purposes.

11 - (Repealed.)

10 - (Repealed.)

Article 11a

General warnings and informational messages on smoking tobacco products

1 - Each individual package and each outer carton of tobacco products for smoking purposes shall present the following general warning:

«Smoking kills - leave now.»

2 - Each individual package and each outer carton of tobacco products for smoking purposes shall present the following information message:

'Tobacco smoke contains more than 70 cancer-causing substances.'

- 3 The general warning and informative message referred to in the previous numbers should:
- a) It shall be printed in Helvetica black body on a white background, in lower case letters, except for the first letter and the grammatical requirements, and with the font size to ensure that the text occupies as much space as possible for the general warning surface and the message informative;
- (b) be placed in the center of the area reserved for them and, in the parallelepipedic packages and in any outer packaging, parallel to the side edge of the individual packaging or the outer packaging;
- c) Cover 50% of the surfaces on which they are printed.
- 4 On cigarette packets as well as in parallelepiped-shaped rolling tobacco packagings, the general warning shall appear on the underside of one of the side surfaces of the individual packagings and the informational message on the underside of the other side surface. health warnings have a width of not less than 20 mm.
- 5 In carton packs with a hinged lid, where the side surfaces are divided into two parts when the pack is opened, the general warning and the information message shall appear in their entirety on the largest of those divided surfaces, the general warning also appears on the inside of the upper flap which is visible when the pack is opened and the side surfaces of this pack type can not be less than 16 mm in height.
- 6. In the case of rolled tobacco, the general warning and the informational message shall cover 50% of the areas on which it is printed and shall include:
- (a) on surfaces which ensure the full visibility of these health warnings in terms to be established in accordance with the procedures laid down in Article 9 (6) and Article 25 of <u>Directive 2014/40 / EU</u> of the European Parliament and European Parliament and of the Council of 3 April 2014, if rolled tobacco is

1/(68)/2018 the outer surface of the packaging cover, for the 'general' Warning, and on the inside surface of the packaging lid, for the information message, if the rolling tobacco is sold in cylindrical packages.

Article 11b

Combined health warnings for smoking tobacco products, including cigarettes, rolling tobacco and pipe tobacco

- 1. Each individual packaging and each outer carton of tobacco smoking products, including cigarettes, rolling tobacco and pipe tobacco, shall present combined health warnings, including one of the text warnings and a corresponding color photograph, included in annex ii of this law, of which it forms an integral part.
- 2. Combined health warnings shall include smoking cessation information such as telephone numbers, email addresses and / or websites designed to inform consumers about the support programs available to persons intending to quit smoking, by the ordinance to be approved by the members of the Government responsible for health.
- 3. The combined health warnings shall be grouped into three series, each series being used in a given year and in annual rotation, and each combined health warning shall be available for use in a given year to be displayed in equal numbers on each brand of tobacco products.
- 4. The combined health warnings shall show the same text warning and the corresponding color photograph on both sides of the individual packaging and any outer packaging appearing near the top edge of an individual packaging and any outer packaging and being positioned in the same direction as any other information on that surface of the package.
- 5. The combined health warnings shall cover 65% of both front and back outer faces of the individual packaging and of any outer packaging, and the cylindrical packaging shall show two health warnings combined, equidistant from each other and covering each health warning 65% of the respective half of the curved surface.
- 6. In the case of packs of cigarettes, the combined health warnings shall not be less than 44 mm in height and less than 52 mm in width.
- 7. The technical specifications for the configuration, design and format of the combined health warnings taking into account the different forms of packaging shall be established in accordance with the procedures defined in accordance with Article 10 (4) and Article 25 of <u>Directive 2014/40 / EU</u> of the European Parliament and of the Council of 3 April 2014.

Article 11c

Labeling of tobacco products for smoking purposes, with the exception of cigarettes, rolling tobacco and hookah tobacco

11/28/2818 oking tobacco products, with the exception of 22917 exters, 08 flat 10 be exempt from the obligation to bear the information message provided for in Article 11a (2) and the combined health warnings provided for in Article 11b, rolling tobacco and pipe tobacco.

- 2. In the cases referred to in the preceding paragraph, and in addition to the general warning provided for in Article 11a (1), each individual packaging and each outer packaging of such products shall bear one of the text warnings listed in Annex present law.
- 3. The general warning provided for in Article 11a (1) shall include a reference to cessation support services such as telephone numbers, e-mail addresses and / or websites consumers on the support programs available to persons wishing to quit smoking and should appear on the most visible surface of individual packagings and any outer packaging.
- 4 Each text warning shall, where possible, appear in equal numbers on each brand of products.
- 5. The text warnings shall appear on the next most visible surface of the individual packagings and any outer packaging.
- 6 In individual packages with hinged lid, the next most visible surface is the one that is visible when the package is opened.
- 7. The general warning referred to in this Article shall cover 30% of the most visible surface of the individual packaging and of any outer packaging.
- 8. The text advisory referred to in this Article shall cover 40% of the relevant surface area of the individual packaging and any outer packaging.
- 9 If the health warnings referred to in this Article are on an area of more than 150 cm2, the warnings shall cover an area of 45 cm2.
- 10 The health warnings referred to in this Article shall comply with the requirements of Article 11a (3).
- 11 The text of the health warnings must be parallel to the main text of the area reserved for such warnings.
- 12 Health warnings shall be surrounded by a black frame not less than 3 mm in width and not more than 4 mm in width and shall be located outside the area reserved for health warnings.

Article 11d

Labeling of smokeless tobacco products

- 1. Each individual packaging and each outer carton of smokeless tobacco products shall bear the following health warning: 'This tobacco product harms your health and creates dependency.'
- 2. The health warning provided for in the preceding paragraph shall be parallel to the main text on the area reserved for such warnings and shall comply with the requirements of Article 11a (3).

132.876018 health warning shall cover 30% of the share 30

Article 12

Appearance and contents of individual packagings

- 1. Individual packagings of cigarettes shall have a parallelepipedic shape.
- 2. Individual packagings of rolling tobacco shall be of a parallelepipedic, cylindrical or bag shape.
- 3 Individual cigarette packs must contain at least 20 cigarettes.
- 4. Individual packagings of rolling tobacco must contain at least 30 g of tobacco.
- 5. The individual cartons of cigarettes may be of cardboard or soft material, without the opening being closed or sealed again after opening for the first time, except for the hinged soft flap and the box with hinged lid; the latter, the flap and lid are hinged only to the rear of the individual package.

Article 13

Product presentation

- 1. The labeling of an individual packaging and of any outer packaging and the tobacco product itself may not include any element or characteristic contained in texts, symbols, designations, trade marks, figurative or other signs which:
- (a) promote a tobacco product or encourage its consumption by creating an erroneous impression as to its characteristics, health effects, risks or emissions, and the labels may not contain any information on the nicotine, tar or carbon monoxide content of the product of tobacco;
- (b) suggests that a particular tobacco product is less harmful than others or is intended to reduce the effect of certain harmful components of tobacco or has revitalizing, energetic, curative, rejuvenating, natural, biological or other health or lifestyle benefits. life;
- (c) it refers to the taste, odor, any flavoring or other additives or their absence;
- (d) it resembles a food product or a cosmetic product; or
- (e) suggest that a particular tobacco product has better biodegradability or other environmental benefits.
- 2 Individual packages and any outer packaging may not, through texts, symbols, designations, trade marks, figurative or other signs, suggest economic advantages by means of printed coupons, discount offers, free distribution, two for the price of one, or other similar offers.

Article 13a

Traceability

¹¹I²⁸/²A¹I individual packages of tobacco products marked in an irremovable, indelible manner, not in any way concealed or separated, including by special stamps or price, or by opening the individual packaging, to determine:

- (a) the date and place of manufacture;
- (b) the manufacturing plant;
- (c) the machinery used to manufacture tobacco products;
- (d) the production shift or the time of manufacture;
- (e) the description of the product;
- (f) the targeted retail market;
- g) The planned shipping route;
- h) The importer, when applicable;
- (i) the actual route of dispatch, from the manufacture to the first retail establishment, including all the warehouses used, as well as the date of dispatch, the destination of the dispatch, the starting point and the consignee;
- (i) the identity of all purchasers, from the manufacture to the first retail establishment; and
- (k) the invoice, order number and payment records of all purchasers, from the manufacture to the first retail establishment.
- 2. The information referred to in points (a) to (g) of the preceding paragraph and, where applicable, that referred to in point (h) of that paragraph, shall form part of the unique identifier and the information referred to in i), j) and number are electronically accessible through a connection to the unique identifier.
- 3. All economic operators engaged in trade in tobacco products, from the manufacturer to the last economic operator before the first retail establishment, shall record the entry of all individual packages in their possession, as well as all intermediate movements and exit of the individual packaging of their possession, such a registration being made by marking and recording the aggregate packaging, provided that it is still possible to locate and follow all individual packages.
- 4. All natural and legal persons involved in the supply chain of tobacco products shall keep complete and accurate records of all transactions referred to in this Article.
- 5. Manufacturers of tobacco products shall provide all economic operators involved in trade in tobacco products, from the manufacturer to the last economic operator before the first retail establishment, including importers, stockists and carriers, the equipment necessary for the registration of tobacco products purchased, sold, stored, transported or otherwise handled, such equipment being capable of reading and transmitting electronically recorded data to a data retention facility.

1628/2018 the purposes of the final part of the previous paragraph, handle turers and importers of tobacco products must enter into data storage contracts with an independent third party, in order to house the data retention facility, and the conservation facility 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 preceding paragraph, namely its independence and technical capacities, as well as the data retention contract are approved by the European Commission.
- 8. The activities of the independent third party shall be monitored by an external auditor, proposed and paid by the tobacco manufacturer and approved by the European Commission, who shall submit an annual report to the Tax and Customs Authority and the European Commission, assessing in particular all irregularities access.
- 9 In duly justified cases, access by manufacturers or importers to data held either by the Tax and Customs Authority or by the European Commission may be granted, provided that the commercially sensitive information remains adequately protected in accordance with the applicable legislation.
- 10 The registered data can not be modified or deleted by any economic operator involved in the trade of tobacco products, with respect to the legislation on the protection of personal data.
- 11. The technical standards for the establishment and operation of the tracking and tracing system provided for in this Article, including marking with a unique identifier, registration, transmission, processing and storage of data and access to the data retained are approved in accordance with the procedures defined in accordance with Article 15 (11) and Article 25 of <u>Directive 2014/40 / EU</u> of the European Parliament and of the Council of 3 April 2014.
- 12 The numbering of the special stamp defined by the Tax and Customs Authority and provided by Imprensa Nacional-Casa da Moeda, SA may be used as a unique identifier, including such changes as are necessary to ensure compliance with the standards and technical functions required in the accordance with Article 15 of <u>Directive 2014/40 / EU</u> of the European Parliament and of the Council of 3 April 2014.
- 13 The main elements of data retention agreements referred to in paragraph 6, such as their duration, renewal, required expertise or confidentiality, including regular monitoring and evaluation of such contracts, shall be defined in accordance with the procedures laid down in accordance with Article 15 (12) and Article 27 of <u>Directive 2014/40 / EU</u> of the European Parliament and of the Council of 3 April 2014.
- 14 The provisions of paragraphs 1 to 10 shall apply to cigarettes and rolling tobacco from 20 May 2019 and to tobacco products other than cigarettes and rolling tobacco from 20 May 2024.

Article 13b

Security element

11/28/2018 addition to the unique identifier referred to 11/28/2018 article, all individual packagings of marketed tobacco products must bear a tamper-evident security element, consisting of visible and invisible elements, which must be printed or affixed in an irremovable and indelible can be concealed or separated, including by special stamps and price tags.

2. The technical standards for the safety element and its possible rotation shall be adopted in accordance with the procedures defined in accordance with Article 16 (2) and Article 25 of <u>Directive 2014/40 / EU</u>, Parliament and of the Council of 3 April 2014.

3 - The special stamp defined by the Tax and Customs Authority and provided by Imprensa Nacional-Casa da Moeda, SA, is used as a security element and, for this purpose, must be adapted to comply with the standards and technical functions required by article 16 of <u>Directive 2014/40 / EU</u> of the European Parliament and of the Council of 3 April 2014.

4. The provisions of paragraph 1 shall apply to cigarettes and rolling tobacco from 20 May 2019 and to tobacco products other than cigarettes and rolling tobacco from 20 May 2024.

CHAPTER V

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

Article 14

Tobacco for oral use

The marketing of tobaccos for oral use is prohibited.

Article 14a

Cross-border distance trade

Cross-border purchases by a consumer established in the national territory of tobacco products, herbal products for smoking and electronic cigarettes and refills, made to a retailer established in another Member State or in a country or third territory, as defined in the Code of Special Taxes on Consumption, approved by Decree-Law no. 73/2010, of June 21.

Article 14b

Notification of new tobacco products

- 1. Manufacturers and importers of new tobacco products shall notify the Directorate-General for Health, in electronic form and at least six months in advance, of any new tobacco product they wish to market on national territory.
- 2. The notification referred to in the preceding paragraph shall be accompanied by a detailed description of the new tobacco product in question as well as the instructions for use and the information on ingredients and emissions in accordance with Article 9a, and shall also be made available:

11(28)/3018 entific studies available on the toxicity, potentials / 1817 creating dependency and attractiveness of the new tobacco product, in particular as regards ingredients and emissions;

(b) studies and their summaries and market analyzes at their disposal on the preferences of various

consumer groups, including young and current smokers;

(c) other available and relevant information, including an analysis of the risks and benefits of the product,

its expected effects in terms of cessation of smoking and initiation of tobacco consumption, and forecasts

of consumer perceptions.

3. Where references are made that a new tobacco product is potentially less harmful than others, or

presents a reduced risk to the health of the consumer, manufacturers or importers, in addition to the

studies referred to in the preceding paragraph, shall submit scientific basis that proves that:

(a) the product concerned reduces the risk of tobacco-related diseases in current consumers and does not

increase attractiveness, toxicity and potential for dependence, as well as carcinogenic, mutagenic or toxic

to reproduction properties compared to tobacco products already on the market;

(b) there is a health benefit for the population as a whole, including consumers and non-consumers, with

particular attention given to the young.

4. Manufacturers and importers of new tobacco products shall communicate to the Directorate-General

for Health any new or updated information on the studies, analyzes and other information referred to in

the preceding paragraphs.

5 - The Directorate-General for Health may request additional tests or the presentation of supplementary

information.

6 - The introduction of new tobacco products under the terms of the previous numbers shall be subject to

authorization from the General Directorate of Economic Activities, after obtaining the opinion of the

Directorate General of Health, in terms to be defined by an order of the members of the Government

responsible for the areas of finance, economy and health.

7 - For the authorization process referred to in the previous number, fees are charged, to be defined by

order of the members of the Government responsible for the areas of finance, economy and health.

8 - The new tobacco products marketed must comply with the requirements of this law, depending on

their classification in the products of smokeless tobacco or smoking tobacco products.

CHAPTER VI

Electronic cigarettes and herbal products for smoking

Article 14c

Electronic Cigarettes and Refills

- 2. Electronic cigarettes and refills shall be child-resistant and shall be tamper-proof, unbreakable and shall be leak-proof.
- 3. Manufacturers and importers of electronic cigarettes and refills shall notify the Directorate-General for Health in electronic form at least six months in advance of any such products they wish to place on the market.
- 4 The notification referred to in the previous number shall include, depending on the product being an electronic cigarette or a recharge, the following information:
- (a) the name and contact details of the manufacturer, the legal or responsible natural person and, where appropriate, the importer in the European Union;
- (b) a list of all the ingredients contained in the product and the emissions resulting from their use, by brand and by type, including their quantities;
- (c) the toxicological data relating to the ingredients and the emissions of the product, including when heated, with particular reference to their effects on the health of consumers when inhaled, taking into account in particular the effect of creating dependency;
- (d) information on the doses and absorption of nicotine when consumed under normal or reasonably foreseeable conditions;
- (e) a description of the components of the product, including, where applicable, the electronic cigarette opening and refilling mechanism and refills;
- (f) a description of the production process, in particular if it involves mass production, and a statement that the production process ensures compliance with this Article;
- (g) a statement that the manufacturer and the importer assume full responsibility for the quality and safety of the product when marketed and used under normal or reasonably foreseeable conditions.
- 5 The Directorate General for Health may require that the information referred to in the preceding number be completed if it considers that the information is not complete.
- 6. Manufacturers and importers of electronic cigarettes and refills shall re-notify for each substantial change in the products.
- 7 The Directorate-General for Health shall ensure the dissemination, on its website, of the data submitted pursuant to this Article, taking into account, where appropriate, information that constitutes a commercial secret and for that purpose has been specified by the manufacturer or importer of electronic cigarette products and refills.

- 8 For electronic cigarettes and recharges that are already being marketed on May 20, 2016, the communication referred to in this article must be made within six months, as of that date.
- 9. The format for the notification provided for in this Article as well as the technical standards for the filling mechanism referred to in paragraph 2 shall be established in accordance with the procedures defined in accordance with Article 20 (13). and Article 25 of <u>Directive 2014/40 / EU</u> of the European Parliament and of the Council of 3 April 2014.
- 10 For the reception, conservation, treatment and analysis of the information provided for in this article, fees are charged by manufacturers and importers of electronic cigarettes and refills, to be set by order of the Government members responsible for the areas of finance and health.

Article 14d

Ingredients and labeling of electronic cigarettes and refills

- 1 For electronic cigarettes and refills, the liquid containing nicotine shall be manufactured exclusively with high purity ingredients and:
- (a) may be marketed only in its own refills not exceeding a volume of 10 ml, in disposable electronic cigarettes or in non-reusable cartridges, the cartridges or reservoirs not exceeding 2 ml;
- (b) it may not contain more than 20 mg/ml of nicotine;
- (c) it may not contain the additives provided for in Article 10a (4);
- (d) may only include substances other than ingredients listed in point (b) of paragraph 4 of the preceding Article, in the form of traces and if these are technically unavoidable during manufacture;
- (e) may include, in addition to nicotine, ingredients which do not constitute a risk to human health in the form of heating or non-heating.
- 2 Electronic cigarettes should release nicotine doses at consistent levels under normal conditions of use.
- 3 Individual packagings of electronic cigarettes and refills shall include a leaflet with information on:
- a) Instructions for use and conservation of the product, including the reference that the product is not recommended for young and non-smokers;
- b) Contraindications;
- c) Warnings for specific risk groups;
- d) Possible adverse effects;
- e) Potential to create dependency and toxicity; and
- (f) the contact details of the manufacturer or importer and the legal or natural person to be contacted.

4. Individual packagings and outer packagings of electronic cigarettes and refills shall, in accordance with Article 11d (2) and (3), present the following health warning:

«This product contains nicotine, a substance that creates strong dependence. It is not recommended for use by non-smokers. »

- 5. The individual packagings and outer packagings of electronic cigarettes and refills shall also contain the list of all ingredients of the product in descending order of weight, indication of the nicotine content of the product and release per dose, batch number and a recommendation to keep the product out of the reach of children.
- 6. Individual packagings and outer packagings of electronic cigarettes and refills may not include the elements or characteristics provided for in Article 13, with the exception of those referred to in paragraph 1 (a) and (c) of that Article, in information on nicotine content and flavorings.

Article 14e

Advertising and sponsorship of electronic cigarettes and refills

- 1 Commercial communication in information society services, in the press and other printed publications, aimed at or has the direct or indirect effect of promoting electronic cigarettes and refills, except for publications intended exclusively for professionals of the cigar trade and publications which are printed and published in third countries if such publications are not intended primarily for the European Union market.
- 2 Commercial communication on radio is prohibited that has or directly or indirectly the promotion of electronic cigarettes and recharges.
- 3 Any form of public or private contribution to radio programs aimed at or having a direct or indirect effect on the promotion of electronic cigarettes and recharges is prohibited.
- 4 Any form of public or private contribution to any event, activity or individual that has or has the direct or indirect effect of the promotion of electronic cigarettes and recharges is prohibited and which implies or occurs in several Member States or has any other cross-border effect.
- 5 Article 16 (10) and Articles 17 and 19 shall apply to electronic cigarettes and refills.

Article 14f

Communications concerning electronic cigarettes and refills

- 1. Manufacturers and importers of electronic cigarettes and refills shall submit annually to the Directorate-General for Health:
- (a) details of sales volumes by brand and type of product;
- (b) information on the preferences of the various consumer groups, including young people, non-smokers and the main types of users at the moment;

- c) Way of selling the products; and
- d) Summaries of all market analyzes carried out in the areas mentioned in the previous paragraphs, including their translation into English.
- 2. The Directorate-General for Health monitors market developments in relation to electronic cigarettes and refills, including any evidence that their use is an access route to nicotine dependence and, ultimately, to tobacco consumption traditional for young and non-smokers.
- 3. Manufacturers, importers and distributors of electronic cigarettes or refills shall establish and maintain a system for collecting information on all presumed adverse effects on human health of such products.
- 4 Whenever manufacturers, importers and distributors of electronic cigarettes or refills consider or have reason to believe that electronic cigarettes or refills in their possession and are on the market or are intended for that purpose are unsafe, are not good they shall immediately take all corrective measures necessary to adapt the product concerned to the provisions of this law or withdraw or recall it from the market, as the case may be.
- 5. In the cases referred to in the preceding paragraph, manufacturers, importers and distributors of electronic cigarettes or refills shall immediately inform the Food and Economic Safety Authority and the Directorate-General for Health, indicating, in particular, the risk to health and safety, and any corrective measures taken, as well as the results of such measures.
- 6. The Food and Economic Safety Authority and the Directorate-General for Health may request from manufacturers, importers and distributors of electronic cigarettes or refills additional information, in particular on the safety and quality aspects or adverse effects of electronic cigarettes or refills.
- 7 In the case of electronic cigarettes and recharges complying with the provisions of this law, and without prejudice to the powers attributed to the entities exercising the power of health authorities, if the Food and Economic Safety Authority finds or has reasonable grounds to believe that a specific electronic cigarette or refill, or a type of electronic cigarette or refill, may constitute a serious risk to human health, may take appropriate provisional measures and an opinion may be requested from the Directorate-General for Health.
- 8. The measures adopted under the preceding paragraph shall be immediately communicated to the European Commission and to the competent authorities of the other Member States, and any information on which it is based shall be communicated.

Article 14g

Herbal products for smoking

1 - Each individual package and each outer carton of herbal products for smoking purposes must present the following health warning:

Smoking this product is harmful to your health.

2. The health warning provided for in the preceding paragraph shall be printed on the front and rear outer surface of the individual packaging and any outer packaging and shall comply with the requirements of Article 11a (3).

3 - The health warning shall cover 30% of the corresponding surface area of the individual packaging and any outer packaging.

4. Individual packagings and any outer packaging of herbal products for smoking purposes may not include the elements or characteristics referred to in points (a), (b) and (d) of Article 13 (1). also indicate that the product is free of additives or flavorings.

Article 14h

Communication of ingredients of herbal products for smoking

1. Manufacturers and importers of herbal products for smoking must submit to the Directorate-General for Health the list of all ingredients and their quantities used in the manufacture of such products by brand and type.

2. Manufacturers and importers of herbal products for smoking must also communicate to the Directorate-General for Health, and prior to their marketing, any change to the composition of a product that affects the information provided under this Article.

3 - The Directorate-General for Health shall ensure the dissemination, on its website, of the data submitted pursuant to this Article, taking into account, where appropriate, information that constitutes a commercial secret and for that purpose has been specified by the manufacturer or importer of herbal products for smoking.

4. The list provided for in paragraph 1 shall be submitted before the marketing of new herbal products for smoking.

CHAPTER VII

Sale of tobacco products, herbal products for smoking and electronic cigarettes

Article 15

Prohibition on the sale of tobacco products, herbal products for smoking and electronic cigarettes

1. The sale of tobacco products, herbal tobacco products and electronic cigarettes which include a cartridge or reservoir and refills with nicotine containing liquid shall be prohibited:

(a) in the places referred to in Article 4 (1) (a), (f), (g), (h), (i), (r), (v), (aa) and (bb) And in the installations referred to in sub-paragraph m) of the same article;

(b) by vending machines where these do not meet the following requirements cumulatively:

- i) they are equipped with an electronic device or other blocking system that prevents their access to minors under 18;
- (ii) are located within the commercial establishment in such a way as to be visualized by the person in charge of the establishment and can not be placed in their access areas, stairs or similar areas and in the corridors of shopping centers and large commercial areas;
- c) To minors under the age of 18, to be proved by the display of an identification document with a photograph;
- (d) by means of teleshopping, telephone or postal services;
- e) Through the Internet.
- 2. The provisions of points a), b), c) and d) of the previous paragraph apply to electronic cigarettes and their components, electronic heating devices for tobacco and other devices or recharges, including the paper of curling cigarettes and hookahs the use of tobacco products.
- 3 The sale of tobacco products, herbal products for smoking and electronic cigarettes through the use of databases, electronic customer registration, loyalty card issuance, premiums, or the use of other customer loyalty techniques.
- 4 (Repealed.)
- 5. The prohibition referred to in paragraph 1 (c) shall include a notice printed in easily legible characters, on a contrasting background, and prominently displayed at the places of sale of tobacco products, herbal products for smoking and electronic cigarettes.
- 6 The marketing of promotional or reduced price packages is prohibited.

CHAPTER VIII

Advertising, promotion and sponsorship of tobacco and tobacco products

Article 16

Advertising and promotion

- 1. All forms of advertising and promotion of tobacco and tobacco products, including concealed, subliminal and hidden advertising, shall be prohibited through national or Portuguese-based advertising media, including information society services, except for in paragraphs 3, 4 and 7.
- 2. Tobacco advertising, or its use, shall be prohibited in vending machines.
- 3. Paragraph 1 shall not apply to commercial information limited to indications of price, trade mark and origin displayed exclusively within establishments selling tobacco products, provided that it is not visible outside the establishments, in particular in their respective establishments. shop windows

- 4. Publicity in the press and in other printed means of communication is permitted only in publications intended exclusively for professionals engaged in the tobacco trade or in printed and edited publications in third countries, provided that they are not intended primarily for the Community market.
- 5 The free distribution or promotional sale of tobacco products or of any consumer goods aimed at, or having a direct or indirect effect, the promotion of these tobacco products or their consumption shall be prohibited.
- 6 The distribution of gifts, the awarding of prizes or the holding of competitions, even if exclusively intended for smokers, by companies directly or indirectly related to the manufacture, distribution or sale of tobacco products shall be prohibited.
- 7 The promotion of tobacco products is permitted only when it is intended exclusively for professionals in the tobacco trade and is carried out outside the scope of the sale to the public.
- 8 The introduction of coupons or other foreign elements into packaging or on packagings of tobacco products, or between them and those in addition to the tobacco product itself and its labeling, shall be prohibited.
- 9 The promotion of sales and the release for consumption of miniature packagings of marks already on the market or marketed shall be prohibited.
- 10 Audiovisual commercial communication, provided for in Law no. 27/2007, of July 30, as amended by Laws 8/2011, of April 11, 40/2014, of July 9, and 78 / 2015, of July 29, to tobacco products.
- 11 The provisions of this Article shall apply to herbal products for smoking.
- 12 The provisions of this Article shall also apply to devices or recharges, including rolling paper, electronic heating devices for tobacco and other devices or accessories necessary for the use of tobacco products, electronic cigarettes and herbal products for smoking.

Article 17

Advertising on consumer objects

- 1 In advertising activities, it is prohibited to place names, trademarks or emblems of a tobacco product on consumer objects other than the tobacco products themselves.
- 2. Except for the prohibition set forth in the preceding paragraph, goods and services that use names or trademarks identical to those of tobacco products, provided that the following requirements are met:
- (a) its sale or sponsorship is not related to the sale of tobacco products;
- b) Such goods or services were introduced on the Portuguese market prior to the date of publication of this law;
- (c) the method of use of such names and trademarks is clearly distinct from that of the names and trade marks of tobacco products.

- 3. The manufacture and marketing of games, toys, video games, food or sweets in the form of tobacco products or with tobacco brand logos shall be prohibited.
- 4. The provisions of this Article shall apply to herbal products for smoking.

Article 18

Sponsorship

- 1. Any form of public or private contribution shall be prohibited, in particular by undertakings whose activity is the manufacture, distribution or sale of tobacco products, for an event, an activity, an individual, an audiovisual work, a program radio or television advertising, aimed at, or having a direct or indirect effect on, the promotion of a tobacco product or its consumption.
- 2. The sponsorship of events or activities by tobacco companies involving or taking place in several Member States or having any other cross-border effects is prohibited.
- 3 The free distribution or promotional prices of tobacco products, in the context of the sponsorship referred to in the preceding number, which prohibits or has the direct or indirect effect of promoting such products, shall be prohibited.
- 4. The provisions of this Article shall apply to herbal products for smoking.

CHAPTER IX

Measures to prevent and control smoking

Article 19

Information, prevention or sales promotion campaigns

Campaigns or other initiatives promoted or sponsored by producers, distributors, subsidiaries or similar companies of tobacco products and herbal products for smoking that directly or indirectly aim at information and prevention of smoking are prohibited.

Article 20

Health education and information

- 1. The State, in particular the health, education, youth, sport, consumer protection, environment, labor, economy and culture sectors, as well as the Autonomous Regions and local citizens, using sign language and Braille as much as possible, and contributing to the creation of conditions conducive to the prevention and control of smoking.
- 2. Health services, regardless of their legal nature, such as health centers, hospitals, clinics, doctors' offices and pharmacies, should promote and support information and education for the health of citizens with regard to the harm caused by smoking and the importance of prevention and smoking cessation through campaigns, programs and initiatives aimed at the general population or specific groups, such as

children and young people, pregnant women, parents, women of childbearing age, sick people, teachers and other workers, or even for those smokers for whom conventional methods of cessation prove to be ineffective, the existence of alternatives, as evidenced by the Directorate-General for Health, which entail risk reduction and harm.

- 3 The theme of prevention and control of smoking should be addressed in the field of citizenship education, in basic and secondary education and in vocational training curricula, as well as pre and postgraduate training of teachers at these levels, teaching.
- 4 The theme of prevention and treatment of tobacco use and dependence should be part of the curricula of pre- and post-graduate training of health professionals, in particular doctors, dentists, pharmacists and nurses, as agents education and health promotion.

Article 20a

Protection of workers

- 1 Occupational health services should promote tobacco prevention and control actions and programs, providing concrete information on the consequences of tobacco use and exposure to tobacco smoke, and support or refer workers intend to start the smoking cessation treatment for the family doctor or for cessation visits.
- 2 Occupational health services should monitor the health of workplaces, in particular with regard to air quality, avoiding their contamination with tobacco smoke, thus ensuring adequate health, hygiene and safety conditions.

Article 21

Smoking cessation consultations

- 1. A network of intensive tobacco cessation support consultations should be established in all clusters of health centers to ensure the proximity and accessibility of all users to their functional units and consultations should also be established in hospitals of the National Service (SNS), which respond to patients' needs, namely in the cardiology, pulmonology, anesthesia, surgery, psychiatry and obstetrics departments, at oncology institutes and services, in psychiatric hospitals and in alcohol and drug treatment centers.
- 2. Where the size of the services and population served does not justify the establishment of an intensive care consultation for smoking cessation, protocols should be established with other intensive care consultations for smoking cessation available in NHS health center clusters or hospitals in order to ensure adequate access for smokers who need this type of support to stop smoking.

Article 21a

Reimbursement of medicines

Access to nicotine replacement drugs and prescription-only anti-tobacco medicines should be promoted in an innovative way and for anti-tobacco prescription drugs progressively reimbursed under existing legislation on reimbursement in connection with consultations intensive support to the smoking cessation of health centers and NHS hospitals.

Article 22

Technical Advisory Group

- 1 A technical advisory group is created under the direct supervision of the Director General for Health, to provide technical advice and to collaborate in the definition and implementation of programs and other initiatives in the field of tobacco prevention and control.
- 2 The technical advisory group, designated by the order of the director general of Health, is composed, by parity, of representatives of the Public Administration and of civil society, and in this one, especially of professional orders of the health area, of trade union associations and employers, of scientific societies, as well as personalities of recognized merit in the field of smoking prevention and control.
- 3. The persons referred to in the preceding paragraph shall declare the absence of any conflict of interest with the objectives of the technical advisory group in the field of prevention and control of smoking.

Article 23

Duty of collaboration

The Directorate-General for Health promotes compliance with the provisions of this law, with the collaboration of public services and bodies with responsibilities in this area.

Article 24

Statistical study

- 1. The Directorate-General for Health, in conjunction with the National Health Observatory and the technical advisory group, shall ensure the statistical and epidemiological monitoring of tobacco consumption in Portugal, as well as the impact resulting from the application of this law, namely compliance with developments in workplace conditions and public service in order to enable appropriate changes to the prevention and control of tobacco consumption to be proposed.
- 2 In order to evaluate the impact of this law on public health and workers' health, the Ministry of Health shall authorize the Assembly of the Republic with a report containing the elements referred to in the previous number, every five years.
- 3 The first report must be submitted to the Assembly of the Republic after three years on the entry into force of the law.

CHAPTER X

Sanctioning regime

Counter-orders

- 1 Infringements of Articles 4 to 6, Article 7 (2) and Articles 8 to 19 constitute infractions, which shall be punishable by the following fines:
- (a) from EUR 50 to EUR 750 for smokers who smoke in the places provided for in points (a) to (b) of paragraph 1 and in paragraph (2) of Article 4 or outside air areas or smoking areas provided for in Article 5 (1) to (9);
- (b) from \in 50 to \in 1000, for owners of private establishments, legal persons, companies, even if irregularly constituted, or associations without legal personality, as well as for the governing bodies or heads of the bodies, establishments or services of the Public Administration that violate the provisions of paragraph 2 of article 7;
- c) From \in 2500 to \in 10 000 for entities referred to in the previous paragraph that violate the provisions of paragraphs 1, 2, 4, 5, 6, 7, 8, 9 and 10 of article 5. and Article 6;
- (d) from EUR 10 000 to EUR 30 000 for infringements of Article 9a paragraphs 1 to 7 and 10, Article 10 (2) and (4), Article 14b (1) to (3), Article 14c (3), (4), (6) and (8), Article 14f and paragraphs 1, 2 and 4 of Article 14h, the value being reduced to (euro) 1500 and (euro) 3000, respectively, if the offender is a natural person;
- (e) from EUR 30 000 to EUR 250 000 for infringements of Article 8 (1), Article 9 (1), (2), (3) and (6), Article 11 (1), (4) and (5), Article 11 (1) to (8), Articles 11a, 11b, 11c, 13 (1) to (6), (8), (10) and (14), Article 13b (1) and (4), Articles 14 and 14a Article 14c (1) and (2), Article 14d, Article 14e, Article 14g, paragraphs 1, 2, 3 (5) and (6) and Articles 16, 17, 18 and 19, the value being reduced to (euro) 2000 and (euro) 3750, respectively, if the offender is a person singular.
- 2 Negligence shall be punishable, the minimum and maximum limits of the applicable fines being reduced by half.
- 3. In the cases provided for in paragraph 1 (e), the attempt shall be punishable, with the minimum and maximum limits of the applicable fines reduced by half.
- 4 When the infraction implies a form of hidden or concealed publicity, the punishment provided for in the general norms on the advertising activity applies.
- 5 The general regime of administrative misconduct, approved by Decree-Law no. 433/82, of October 27, shall apply to the misconduct contemplated in this law, and in everything that is not specially regulated in it.

Article 26

Related sanctions

1 - In the case of misdemeanors provided for in points c), d) and e) of paragraph 1 of the previous article, the additional sanctions provided for in article 21, paragraph 1, of the general regime of by Decree-Law no. 433/82 of October 27.

2. Non-compliance with the provisions of Article 15 (1), (3) and (6) shall determine the application of the accessory prohibition sanction for the sale of any tobacco product, herbal tobacco products and electronic cigarettes.

Article 27

Solidarity responsibility

1. For the payment of fines in which the offenders are convicted of the provisions of article 8, paragraph 1, article 9, paragraph 6, article 9, paragraphs 1 to 7 and 10 Article 10a (2) and (4), Article 10a (1), (4) and (5), Article 11 (1) to (8), Articles 11a, 11b, 11c, 12 and 13, paragraphs 1 to 6, 8, 10 and 14 of Article 13a, (1) and (4), Article 14, Article 14b (1) to (3), Article 14b (1) to (4), C in Articles 14d, 14e, 14f and 14g and in Article 14h (1), (2) and (4), the manufacturer shall be jointly and severally liable and the importer of tobacco products.

2 - For the payment of fines in which the offenders are convicted of the provisions of Article 15 (1) (b) and Article 16 (2), the owner of the automatic sales of tobacco and one that has the effective direction of the space in which the equipment is installed.

3 - For the payment of the fines in which the agents of the infringements are condemned to the provisions of article 17, the manufacturer or importer and the owner of the premises or the owners of the holding where these products are made available, in a costly or gratuitous manner.

4 - For the payment of fines in which the offenders are convicted of the provisions of article 15, paragraph 1, point d), in paragraphs 1, 5, 6, 8, 9, 10 and 11 of article 16 and 19, the advertiser, the professional, the advertising agency or any other entity that carries out the advertising activity, the holder of the advertising medium or its concessionaire, as well as any other intervening party in the issue of the advertising message.

5 - For the payment of fines in which the agents of infractions are sentenced to the provisions of article 18, the sponsoring entity and the sponsored entity shall be jointly and severally liable.

6 - The entities holding the publicity medium used or the respective concessionaire shall be exempt from the responsibility referred to in paragraph 4, if they demonstrate that they did not have prior knowledge of the broadcast advertising message.

Article 28

Inspection and procedure

1 - Without prejudice to the powers conferred by Article 7 on administrative and police authorities, the provisions of this law shall be the responsibility of the Food and Economic Security Authority, except for the inspection of publicity matters provided for in Article 14- Article 16 (1), Article 18 (1) and Article 19, which is the responsibility of the Directorate-General for Consumer Affairs and the Media Regulatory Entity within the framework of the respective areas of competence.

2 - The investigation of the processes of back-office is the responsibility of the Food and Economic Security Authority, the Consumer Directorate-General or the Regulatory Entity for Social Communication, within the scope of their attributions, and to whom should be sent the files raised by other entities.

3 - The Inspector General of the Food and Economic Security Authority, the Director General of the Consumer and the Regulatory Council of the Regulatory Body for Social Communication shall be responsible for the application of the respective fines and ancillary sanctions, which give them to the Directorate-General for Health.

4 - The proceeds of the fines are distributed as follows:

a) 60% for the State;

(b) 40% for the entity which instituted the proceedings and imposed the fine;

c) (Repealed.)

CHAPTER XI

Transitional and final provisions

Article 29

Autonomous regions

1 - The Autonomous Regions exercise the powers provided for in this law through the bodies defined by the self-governing bodies.

2 - The proceeds of the fines imposed in the Autonomous Regions constitute their own revenue.

Article 29a

Provision of information

For the purposes of Chapter III (vi), the obligation to provide the required information shall be the primary responsibility of the manufacturer, if he is established in the European Union, to the importer, if the manufacturer is established outside the European Union and the importer is established in the European Union, and jointly with the manufacturer and the importer, if both are established outside the European Union.

Article 30

Revocatory standard The following shall be repealed: a) Law no. 22/82 of 17 August; b) Decree-Law no. 226/83, of May 27; c) Decree-Law no. 393/88, of November 8; d) Decree-Law no. 287/89, of August 30; e) Decree-Law no. 253/90, of August 4; f) Article 18 and paragraph 2 of article 24 of the Advertising Code, approved by Decree-Law no. 330/90, of October 23; g) Decree-Law no. 200/91, of May 29; h) Decree-Law no. 276/92, of December 12; i) Decree-Law no. 283/98 of 17 September; j) Article 95 of the Code of Special Taxes on Consumption, approved by Decree-Law no. 566/99, of December 22; 1) Decree-Law no. 25/2003, of February 4; m) Decree-Law no. 138/2003, of June 28; n) Decree-Law no. 76/2005, of April 4; o) Decree-Law no. 14/2006, of January 20; p) Paragraphs 2 to 5 of Resolution of the Council of Ministers no. 35/84 of June 11; q) Ministerial Order no. 165/84, of March 26; r) Ordinance no. 432/91, of May 24; s) Ordinance no. 735/93, of August 13; t) Order No. 19 / MS / 88 of January 25, 1989; u) Order No. 8 / ME / 88 of February 8, 1989. Article 31 Implementation

This law shall enter into force on January 1, 2008.

Model A
(see original document)
Model B
(see original document)
ANNEX II
(referred to in Article 11b (1) and Article 11c (2))
1 - List of warnings in text:
(a) 'Smoking causes 9 out of 10 lung cancers';
(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 obstruction of the arteries';
(g) 'smoking exacerbates the risk of blindness';
(h) 'Smoking causes damage to your teeth and gums';
(i) 'Smoking may kill your child before he is born';
j) "Your smoking harms your children, family and friends";
(k) 'Children of smokers are more likely to smoke';
l) "Stop smoking already - think of who likes you";
(m) 'smoking reduces fertility';
(n) 'Smoking aggravates the risk of impotence'.
2 - Color photographs - library of images (of combined health warnings) referred to in Article 11b:
Series 1
(see original document)
Series 2

ANNEX I

(see original document)

Series 3

(see original document)