Unofficial Translation

LEGISLATIVE DECREE 12 January 2016, no. 6: Implementation of Directive 2014/40/EU on streamlining the legislative, regulatory and administrative provisions of the member states regarding the processing, presentation and sale of tobacco products and related products, which replaces directive 2001/37/EC. (16G00009)

(Official Gazette no. 13 of January 18, 2016)

THE PRESIDENT OF THE REPUBLIC

Whereas Articles 76 and 87 of the Constitution;

Whereas the Law of July 9, 2015, no. 114, including the delegation of the Government to implement the European directives and other acts of the European Union - Laws of the European Delegation 2014 and, in particular, Article 6;

Whereas the Law of November 24, 1981, no. 689, including modifications to the criminal system, as amended;

Whereas the Law no. 400 of August 23, 1988 including the regulation on the Government's activity and the order of the Office of the Prime Minister, as amended, and, in particular, Art. 14;

Whereas Directive 2007/74/CE of the Council of December 20, 2007, on the waiver of the value added tax and the excise tax on merchandise imported by travelers from third party countries;

Whereas Directive 2011/64/EU of the Council of June 21, 2011, regarding the structure and excise tax rates applied to processed tobacco;

Whereas directive 2014/40/EU of the European Parliament and Council of April 3, 2014 on the implementation of Directive 2014/40/EU on streamlining the legislative, regulatory and administrative provisions of the member states regarding the processing, presentation and sale of tobacco products and related products, which replaces directive 2001/37/EC.

Whereas the Delegate Directive 2014/109/EU of the Commission of October 10, 2014, which modifies Annex II of Directive 2014/40/EU of the European Parliament and Council establishing the catalog of warnings illustrated to be used on tobacco products;

Whereas the Legislative Decree no. 184 of June 24, 2003 including the implementation of Directive 2001/37/EC on the processing, presentation and sale of tobacco products;

Whereas the preliminary resolution of the Office of the Prime Minister, adopted at the meeting on October 12, 2015;

Having obtained the opinion of the Permanent Conference for Relations between the State, Regions and Autonomous Provinces of Trento and Bolzano, handed down at the hearing on October 20, 2015;

Having obtained the opinions of the competent Commissions of the Lower House and Senate of the Italian Republic;

Whereas the resolution of the Office of the Prime Minister, adopted at the meeting on December 23, 2015;

At the proposal of the Office of the Prime Minister and the Minister of Economics and Finance, Economic Development, Agricultural, Food, Forest and Health Policies, in concert with the Ministry of Justice and Foreign Affairs and International Cooperation;

Enacts

the following Legislative Decree:

Title I
GOALS AND DEFINITIONS

Art. 1
Goals and Field of Application

1. The provisions of this Legislative Decree are aimed at:

a) guaranteeing a high level of protection for human health, particularly the youth, and fulfilling the obligations deriving from law no. 75 of March 18, 2008, ratifying and executing the WHO's framework agreement to fight against smoking (FCTC) as well as hindering excess products on the marketing and distributing tobacco to minors;

b) to facilitate the proper operation of the internal market for tobacco and related products.

2. This decree governs:

a) the ingredients and issuance of tobacco products and the relative reporting obligations, including the maximum tar, nicotine and carbon monoxide levels in cigarettes;

b) some aspects of the label and the package for tobacco products, including the relative health warnings that must be included on the tobacco product's individual packages and any external packaging for tracking and security elements applied to the tobacco products;

c) the transnational sale of tobacco products and related products;

d) the obligation to report next generation tobacco products;

e) the release on the market and labeling of some products related to tobacco products, or the electronic cigarettes and rechargeable liquid containers and herb-based products;

f) the ban on the sale of tobacco for oral use.

Art. 2 Definitions

For the purpose of and by effect of the provisions set forth in this decree, the following definitions apply:

b) tobacco: leaves and other natural parts, processed or not processed of the tobacco plant, including the expanded and reconstituted tobacco;

c) pipe tobacco: tobacco that can be consumed through a combustion process, to be used exclusively in a pipe;

d) rolling tobacco: the tobacco that can be used by consumers or retailers to wrap cigarettes;

e) tobacco products: products that can be consumed and including, even partially. tobacco, genetically modified or otherwise;

f) non-smoking tobacco product: a tobacco product that does not involve a combustion product, such as chewing tobacco, snuff and tobacco for oral use;

g) chewing tobacco: a tobacco non-smoking tobacco product used exclusively for chewing;

h) snuff: a non-smoking tobacco product that can be consumed through the nose;

i) tobacco products for oral use: all tobacco products for oral use, except for those that can be inhaled or checked, made in whole or in part from tobacco, in the form of powder, fine participles or any other

combination of these forms, specifically those provided in portion-size pouches or porous pouches;

j) smoking tobacco: tobacco products different from non-smoking tobacco products;

l) cigarette: a tobacco roll that can be consumed through a combustion process that is also defined in Article 3, paragraph 1 of Directive 2011/64/EU;

m) cigar: a tobacco roll that can be consumed through a combustion process as defined in Article 4 paragraph 1 of Directive 2011/64/EU;

n) cigarette: a type of small cigar, also as defined under Article 8, paragraph 1, of Directive 2007/74/CE of the Council;

o) water-pipe tobacco: a tobacco product that can be consumed with a water pipe. For the purposes of this decree, the water pipe tobacco is considered to be a type of smoking tobacco. If a product can be used with a water pipe or as rolled tobacco, it is considered rolling tobacco;

p) next generation tobacco product: a tobacco product that meets both of the following conditions:

1) does not fall under the following categories: cigarettes, rolling tobacco, pipe tobacco, water pipe tobacco, cigars, cigarettes, chewing tobacco, snuff or tobacco for oral use;

2) is issued on the market after May 19, 2014:

q) herb-based smoking product: a plant, herb or fruit-based product that does not contain tobacco and can be consumed by a combustion process;

r) electronic cigarettes: a product that can be used for the consumption of smoke containing nicotine through the mouth or any component of this product, including a cartridge, tank or private cartridge or tank device. The electronic cigarette can be disposable or rechargeable through a reloading container or tank or can be recharged with a disposable cartridge;

s) liquid rechargeable container: vial that contains a liquid with nicotine that can be used to recharge the electronic cigarette;

t) ingredient: the tobacco, an additive and any substance or element present in a finished tobacco product or related products, including papers, filters, ink, capsules and adhesive agents;

u) nicotine: the nicotine alkaloids;

v) tar: the raw smoke anhydrite condensate and without any nicotine;

z) emissions: the substances released by tobacco or a related product when used as intended, for example, in the substances present in smoke or substances issued during the use of non-smoking tobacco products;

aa) maximum level or maximum level of emissions: the quantity or maximum emission, equal to zero, of a substance, measured in milligrams for a tobacco product;

bb) additive: a substance other than tobacco that is added to a tobacco product in a single package or any external packaging;

cc) aroma: an additive that has an odor or flavor or odor and flavor;

dd)characterizing aroma: an odor or flavor that is clearly distinguishable other than from tobacco due to an additive or combination of additives, including, but not only, fruit, spices, herbs, alcohol, candies, menthol or vanilla, which is perceptible

before or during consumption of the tobacco product;

ee) ability to be addictive: the pharmacological potential of a substance to create addiction, a condition which affects the capacity of the individual to control his behavior, usually through a reward mechanism or reduction in withdrawal symptoms, or both;

ff) toxicity: the degree of harmfulness of a substance in the human body, understanding the effects that occur over time, usually by consumption or repeated or continuous exposure;

gg) substantial change in the situation: a minimum increase of 10 percent of the volume of sales for a certain category of products in at least five Member States, registered on the basis of sales data provided pursuant to Article 6, paragraph 7, or a minimum increase of five percentage points of the widespread use the under 25 consumer group in at least five Member States for the relevant product category, registered on the special Eurobarometer survey base 385 of May 2012 or similar distribution studies; in any case, it is considered that there is no substantial change in the situation when the volume of sales of the category of retail products does not exceed 2.5 percent of total tobacco products sales on the EU level;

hh) outer packaging: any packaging in which tobacco products or related products are marketed and that includes a single package or a set of individual packages; the transparent wrappers are not considered as outer packaging;

ii) packaging for each unit: the smallest single tobacco product or related product package placed on the market;

ll) envelope: unit pouch of tobacco to roll in the form of a rectangular bag with a flap that closes or of a self-supporting envelope;

mm) health notice: a warning about the harmful effects on human health of the product or other unwanted consequences of its consumption, including text warnings, the combined warnings related to health, general warnings and information messages, based on that set forth in this decree;

nn) combined warning about heath: a warning on health consists of a combined warning along with a photograph or corresponding illustration according to the provisions of this decree;

oo) transnational sales: distance sales to consumers where, when ordering the product for retail, the consumer in a Member State other than the Member State or third party facility country of retail. Retail is deemed to be established in a Member State:

1) if, in the case of a natural person, this has its place of activity in that Member State;

2) if, in other cases, the retail has its registered offices, central administration or place of activity, including branches, agencies or other establishments, in that Member State;

pp) consumer: means a natural person acting for purposes unrelated to its commercial activity, business, craft or profession;

qq) age verification system: a computer system that unequivocally confirms the age of the consumer by electronic means, in accordance with national rules;

rr) manufacturer: any natural or legal person who manufactures a product or a product designed or manufactured and marketed under its name or trademark;

ss) import of tobacco products or related products: the entry of such products in the European Union, unless they are placed under a suspensive customs procedure or a suspensive customs regime at the time of entry in the European Union as well as the release of these products from a customs suspensive procedure or a suspensive customs regime;

tt) importer of tobacco products or related products: the owner or holder of a right to sell tobacco products or related products introduced into the European Union;

uu) release of the market: the face of placing products, regardless of their place of manufacture, available to EU consumers, for payment or free of charge, including through remote selling; in the case of transnational sales of the product, it is considered to have been placed on the market in the Member State where the consumer is located;

vv) resale: any point of sale where tobacco products are placed on the market, even by a natural person.

Title II
TOBACCO PRODUCTS

Section I
Ingredients and Emissions

Art. 3
Maximum levels of tar emissions, nicotine and carbon monoxide and other substances

1. The levels of cigarette emissions placed on the market in Italy, the following maximum emission levels cannot be exceed respectively:

a) 10 mg of tar per cigarette;

b) 1 mg of nicotine per cigarette;

c) 10 mg of carbon monoxide per cigarette.

Art. 4
Measuring Methods

1. The maximum levels of emissions of tar, nicotine and carbon monoxide in cigarettes are measured, respectively, on the basis of ISO 4387 for tar, ISO 10315 for nicotine and ISO 8454 for carbon monoxide. The accuracy of the emission level measurements for tar, nicotine and carbon monoxide are determined according to ISO 8243.

2. The measurement referred to in paragraph 1 is verified by the laboratory referred to in the decree of the Minister of Finance of August 31, 1994, published in the Official Gazette no. 232 of October 4, 1994, and by laboratories approved in accordance with Article 5. These laboratories must not be owned or controlled directly or indirectly by the tobacco industry.

3. Decree of the Minister of Health, in concert with the Minister of Economy and Finance, identifying the structural, technological and functional laboratories authorized for the analyzes referred to in paragraph 2.

4. The Ministry of Health shall share the list of approved laboratories with the European Commission, specifying the authorization criteria and monitoring procedures applied and updates this list for any subsequent amendment. The Ministry of Health and the Ministry of Economy and Finance

publish the list of laboratories used on their corporate websites.

5. The Ministry of Health, with the Ministry of the Economy and Finance notifies the Commission about any additional measurement methods used for the emissions of different cigarettes other than the emissions referred to in paragraph 1 and the emissions of tobacco products other than cigarettes.

6. For the verification set forth in section 2 the applicable rates, pursuant to Article 30, are identified:

Art. 5

Authorization procedure for testing laboratories

1. The Higher Institute of Health is the body responsible, after a technical assessment, for the issuance of permits and the subsequent laboratory supervision referred to in Article 4, which carries out emission level audits of tar, nicotine and carbon monoxide in cigarettes and any additional measurements to determine the level of emissions of other harmful substances, excluding laboratories performing the power of control for the control activity performed by the competent authorities.

2. It does not affect the competence of the laboratory referred to in the decree of the Minister of Finance of August 31, 1994 to definitively verify the accuracy of the information concerning the level of emission of substances referred to in Article 4 either for issuance on the market or during the sale of the product.

3. For the purpose of the authorizations referred to in paragraph 1, the laboratory heads involved are the Higher Institute of Health’s specific request, accompanied by a declaration of compliance with the structural, technological and functional requirements set forth in the decree referred to in Article 4, paragraph 3.

4. The Higher Institute of Health , experienced in the technical assessment on the prescribed fitness requirements, authorizes the laboratories referred to in paragraph 1 to conduct the emission level audits set out in that paragraph and can proceed to the next audit as it deems appropriate.

Art. 6

Reporting ingredients and emissions

1. Manufacturers and importers of tobacco products shall present the following information, broken down by brand and type to the Ministry of Health and the Customs and Monopoly Agency:

a) the list, with all the relative quantities, of all the ingredients used to manufacture tobacco products, in descending order by the weight of each ingredient included in the tobacco products;

b) the emission levels set out in Article 3, paragraph 1;

c) information on other emissions and relative levels where available.

2. For products already on the market, the information set forth in section 1 is provided by November 20, 2016. Manufacturers and importers also inform the Ministry of Health and the Customs and Monopoly Agency about the composition of a product that would affect the information provided under this article. For a new tobacco product or changed product, the information required under this Article shall be presented before the placing that product on the market.

3. The list of ingredients referred to in paragraph 1, letter a), is accompanied by a statement specifying the reasons for inclusion

of such ingredients in tobacco products in question; this list also indicates the status of the ingredients, whether they are registered pursuant to (EC) Regulation No. 1907/2006 of the European Parliament and Council and their classification in accordance with (EC) Regulation No. 1272/2008 of the European Parliament and Council.

4. The list set forth in section 1, letter a), is accompanied by the relevant toxicological data for the burned or unburnt ingredients as appropriate, with particular attention to their impact on consumer health and taking into account, among other things, any addictive effects. In addition, for cigarettes and rolling tobacco, the manufacturer or importer shall present a technical paper that provides a general description of the additives used and their properties. Except for tar, nicotine and carbon monoxide and the emissions referred to in Article 4, paragraph 5, the manufacturers and importers indicate the emission measurement methods used.

5. The Ministry of Health, in cooperation with the Ministry of Economy and Finance, may require manufacturers or importers performing studies to evaluate the health effects of some ingredients, taking into account, among other things, their capacity to create addiction and their toxicity.

6. The Ministry of Health and the Customs and Monopoly Agency make publicly available on their corporate websites the information submitted pursuant to paragraph 1 and Article 7, taking into account the need to protect commercial secrets. Manufacturers and importers are required to specify in the submission document referred to in paragraph 1 and Article 7 the information they consider commercial secrets pursuant to Legislative Decree no. 30 of February 10, 2005, as amended.

7. Manufacturers and importers are required to submit every three years internal and external studies on market research and different consumer groups' preferences, including young people and current smokers, about the ingredients and emissions as well as summaries of any market surveys carried out by those offering new products to the Ministry of Health and the Customs and Monopolies Agency. Manufacturers and importers also report their annual sales volumes by brand and type, expressed in the number of cigarettes, cigars, cigarillos or kg, to the Ministry of Customs and Monopolies on an annual basis starting on January 1, 2015.

8. All information and data provided pursuant to this Article and Article 7 shall be prepared in electronic form and stored electronically. The Ministry of Health and the Ministry of Economy and Finance ensure for the European Commission and other EU Member States access to such data and ensure the confidential processing of commercial secrets and other confidential information pursuant to Legislative Decree no. 30 of February 10, 2005, as amended, and Law no. 241 of August 7, 1990, as amended.

9. To manage all information and all data provided under this Article and Article 7, a manufacturer and importer rate for tobacco products is identified in accordance with Article 30.

Art. 7

Priority list of additives and additional reporting requirements

1. For the additives contained in cigarettes and rolling tobacco on the priority list provided for in Article 6

of Directive 2014/40/EU, in addition to the reporting requirements set forth in Article 6, there are additional reporting requirements. With the decree enacted in accordance with Article 26, paragraph 2the priority list is adopted that includes additives:

a) for which there are early indications, research or regulations in other jurisdictions that suggest that they have one of the properties set forth in section 2, letters a-d);

b) that are among the most commonly used additives by weight and unit according to ingredient reports in accordance with Article 6, paragraphs 1 and 4.

2. Manufacturers and importers of cigarettes and rolled tobacco containing an additive included on the priority list referred to in paragraph 1 conduct in-depth studies that examine, for each additive, or combination of several additives if it:

a) contributes to toxicity or addiction due to the products in question and if this has the effect of significantly or quantifiably increasing the toxicity or ability to be addictive of the products in question;

b) produces a characteristic aroma;

c) facilitates the inhalation or absorption of nicotine;

d) determines the formation of substances that have carcinogenic, mutagenic or toxic properties for reproduction, hereinafter CMR, and the relative quantities and if that significantly or quantifiably increases the CMR properties of any of the products in question.

3. The studies referred to in paragraph 2 shall take account of the products in question and examine, in particular, the emissions resulting from the combustion process which involves the additive in question. The studies also examine the interaction of the additive with other ingredients contained in the products in question. Manufacturers or importers who use the same additive in their tobacco products can perform a joint study when using the additive in the composition of a comparable product.

4. Manufacturers and importers must prepare a report on the results of the studies referred to in paragraph 2. The report includes a summary and a complete picture of the available scientific literature on the additive in question with an internal data synthesis on the effects of that additive. Manufacturers or importers, in the case where a product containing the additive concerned has been placed on the market within eighteen months of the inclusion of the additive in the priority list referred to in paragraph 1, submit the report to the European Commission, the Ministry of Health and the Ministry of Economy and Finance. The Ministry of Health and the Ministry of Economy and Finance may require producers or importers to provide additional information on the additive in question. This additional information will be part of the report. The Ministry of Health and the Ministry of Economy and Finance may require that such reports be subject to a peer review by an independent scientific body referred to in Article 6, paragraph 4 of Directive 2014/40/EU with particular regard to thoroughness, the method and the conclusions. The information received is used by the Ministry of Health and the Ministry of Economy and Finance to make decisions in accordance with Article 8.

5. The small and mid-sized companies as defined in the recommendation 2003/361/EC of the Commission are exempt from their obligations under this Article if a report on the additive in question is prepared by another manufacturer or importer.

Art. 8 Regulation of Ingredients

1. Placing tobacco products on the market with a unique aroma identified by decree in accordance with Article 26, paragraph 2 is prohibited.

2. The use of essential additives is allowed to manufacture tobacco products, such as sugar to replace that lost during the handling process, unless these additives result in a product with a unique aroma and significantly and quantifiably increase the addiction, toxicity of the tobacco product or its CMR as identified by decree in accordance with Article 26, paragraph 2.

3. Issuing the tobacco products on the market is prohibited if it contains the following additives:

a) the vitamins or other additives that create the impression that a tobacco product produces health benefits or involves fewer health risks;

b) caffeine or taurine or other additives and stimulant compounds that refer to energy and vitality;

c) additives with emissions with dye properties;

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

e) additives have CMR properties in their unburned form.

4. Tobacco products cannot be placed on the market that contain aromas in any of its components, such as filters, papers, packages, capsules or specifications that change the smell or taste of the tobacco products in question or the intensity of the smoke. The filters, papers and capsules must not contain tobacco or nicotine.

5. The provisions and conditions set forth in the regulation (EC) no. 1907/2006 shall apply, where compatible, to tobacco products.

6. Based on scientific data, placing tobacco products on the market containing additives in the quantities concerned by decree enacted in accordance with Article 26, paragraph 2, such as to enhance the toxic effect or addictive effect of a tobacco product or its CMR when consumed in a significant or quantifiable amount.

7. The provisions set forth in sections 1 and 4 do not apply to tobacco products other than cigarettes and rolling tobacco, except, by decree in accordance with Article 26, paragraph 1, in the case of bans on a particular product category if there has been a substantial change in the situation.

8. To assess whether a tobacco product has a distinctive aroma, if banned additives or aromas are used and if a tobacco product contains additives in such volumes as to significantly and quantifiably increase the toxic or addictive effect of the tobacco product in question or its CMR, a rate is established by decree referred to in Article 30 for manufacturers and importers of tobacco products.

9. The provisions of this Article shall apply from May 20, 2020 in the case of tobacco products with a unique aroma with sales volume throughout the EU greater than or equal to 3 percent in a particular product category.

10.The Ministry of Health and the Ministry of Economy and Finance shall notify the European Commission of measures adopted pursuant to sections 1 and 6.

Section II

Labeling and Packaging

Art. 9 General provisions

1. Each individual pack of tobacco products and any outside packaging include the health warnings referred to in this decree.

2. The health warnings cover the entire surface of the individual pack or external packaging reserved to them and are not subject to any comment, paraphrase or reference in any form.

3. For tobacco products, at the time of release on the market, the health warnings on the unit and the possible outer packaging are printed in permanent and indelible ink and are fully visible, not partially or fully concealed or truncated by fiscal stamps, price tags, security features, wrappers, enclosures, boxes or other items.

4. On the individual pack of tobacco products other than cigarettes and rolling tobacco in pouches, health warnings may be placed with adhesives, provided that they are irremovable. The health warnings remain intact when opening the packaging for each unit, except for the “flip-top” packs where the warnings may be separated upon opening the box, but only to ensure the integrity of the graphics and visibility of the text, photographs and information about smoking cessation.

5. The health warnings do not conceal or truncate the excise stamps, the price labels, tracking labels or the security features on the individual packages in any way.

6. The size of the health warnings set out in Articles 10, 11, 12 and 13 are calculated in relation to the affected area when the package is closed.

7. The health warnings are surrounded by a 1 mm black border inside the surface area reserved for the warning text with the exception of the health warnings referred to in Article 12.

8. The illustrations on the unit packages and on any outer packaging intended for consumers in the EU comply with the provisions of this Section.

Art. 10
General warnings and informational messages for smoking tobacco products

1. Each individual pack and any outside packaging for smoking tobacco products carry the following general warning: "Smoking Kills - Stop Immediately."

2. Each individual pack and any outside packaging for smoking tobacco carry the following informational message: "Tobacco smoke contains over 70 carcinogens."

3. For cigarette packages and rolling tobacco in parallelepiped packages, the general warning is on the lower part of one of the side surfaces of the individual pack and the information message is on the lower part of the other side surface. The health warnings are no less than 20 mm in length. For the packages

in box form with hinged closure with a side surface divided into two when the package is open, the general warning and the informational message are entirely on the larger parts of these two surfaces. The general warning also appears within the top surface visible at the time of opening the package. The lateral surfaces of this type of package have a height of no less than 16 mm. For rolling tobacco sold in pouches, the general warning and informational message appear on the surfaces that provide full visibility for such health warnings. For rolling tobacco in cylindrical-shape packs, the general warning appears on the outer surface of the closure and the informational message on its internal surface. Both the general warning and the informational message covers 50 percent of the surface on which they are printed.

4. The general warning and the informational message referred to in paragraphs 1 1 and 2 are:

a) printed in black bold Helvetica type on a white background, the size of the font determined so that the text takes up most of the surface allocated to these health warnings;

b) the center of the area reserved for them, and on the parallelepiped packaging and any outer packaging, are parallel to the lateral edge of the unit packaging or outer packaging.

Art. 11
Combined health warnings
for smoking tobacco products

1. Each individual pack and any outside packaging for smoking tobacco products carry the following general combined health warnings.

2. Combined health warnings:

a) include one of the warnings listed in Annex 1 and a corresponding color photograph, included in the catalog in Annex 2;

b) include, as information on smoking cessation, the following reference: "Toll-Free Number 800-554-088 to quit smoking," to support people who want to quit smoking;

c) occupy 65% of the outer front and back of the individual pack and any outer packaging. The cylindrical packages have two combined health warnings equidistant from each other and each relative health warning takes up 65 percent of the respective half of the curved surface;

d) show the same text warning and the corresponding color photograph both on the front and back of the individual pack and any outside packaging;

e) appear on the upper edge of an individual pack and any outside packaging and have the same orientation as any other information appearing on the surface of the pack;

f) the layout, graphics and proportions, identified with the decree set forth in Article 26, section 2 are reproduced;

g) respect, in the case of individual packs of cigarettes, the following sizes:

1) height: not less than 44 mm;

2) width: not less than 52 mm.

3. When the following legitimizing marks are used, up to

May 20, 2019:

a) for had unit packs, the combined health warning that is on the back should be placed directly below the tax stamp;

b) for unit packs made from soft materials, the tax stamp goes in the rectangular area that is no more than 13 mm between the upper edge of the package and the upper edge of the combined health warnings.

4. In the cases referred to in letters a) and b) of section 3, the trademarks or the logos are not placed above the health notes.

5. The combined health warnings are grouped in three groups as indicated in Annex 2, each of which is used in a given year and alternates with the next harvest the following year, starting with series 1 and respecting the numerical order of the planned series therein, as amended by Directive 2014/109/EU. Series 1 is affixed to tobacco products manufactured from May 20, 2016 to December 31, 2017. The Customs and Monopolies Agency verifies that each combined health warning that can be used in a given year is shown, as far as possible, on the same number of each brand of tobacco products.

6. By decree issued pursuant to Article 26, paragraph 1:

a) the text warnings listed in Annex 1 are adequate;

b) the catalog of images is established and adequate as referred to in section 1, letter a).

7. By decree issued pursuant to Article 26, paragraph 2, the technical specifications for layout, graphics and the shape of the combined health warnings are defined depending on the different forms of packaging.

Art. 12
Labeling several types of smoking tobacco other than cigarettes, rolling tobacco and water pipe tobacco

1. The smoking tobacco products other than cigarettes, rolling tobacco and water pipe tobacco are required to bear the general warning provided for in Article 10, paragraph 1. This general warning includes the reference to quitting smoking referred to in Article 11, paragraph 2, letter b). Each individual pack and any outside packaging for these products also carry one of the text warnings listed in Annex 1.

2. The tobacco products set forth in section 1 are exempt from the required informational message set forth in Article 10, paragraph 2 and the combined health warnings set forth in Article 11.

3. The general warning referred to in paragraph 1 are on the most visible surface and covers 30% of the unit pack's surface area and any external packaging. The text warning referred to in paragraph 1 is included on the next most visible surface area and covers 40% of the relevant surface of the individual pack and any outside packaging. For unit packages with hinged closes, the most visible surface is the one that appears when the package is open.

4. If the health warnings referred to in paragraph 1 are placed on a surface that exceeds 150 cm^2, the warning shall cover an area of 45 cm^2.

5. The health warnings referred to in section 1 respect

the provisions set forth in Article 10, section 4. The health warnings text is parallel to the main text on the surface allocated to these warnings. The health warnings are surrounded by a black border with a minimum width of 3 mm and 4 mm. This border is outside the area reserved for the health warning.

Art. 13

Labeling of smokeless tobacco products

1. Each individual pack and any outside packaging for smoking tobacco products carry the following general health warning: "Tobacco is harmful to your health and is addictive."

2. The health warnings referred to in section 1 respect the provisions set forth in Article 10, section 4. The text of the health warnings is parallel to the main text on the surface allocated for these warnings. Moreover, the warning:

a) is on the two major surfaces of the individual pack and any outside packaging;

b) covers 30% of the packaging for the individual pack's surfaces and any external packaging.

Art. 14 Product Presentation

1. The labeling of the individual pack and any outside packaging and the tobacco product itself does not involve any element or feature that:

a) promotes a product or encourages its consumption providing an incorrect impression about the features, health effects, risks or emissions; the labels do not contain any information on the nicotine, tar or carbon monoxide content of the tobacco product;

b) conveys, notwithstanding that set forth in Article 20, that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful elements of smoking or having revitalizing, energizing, healing, rejuvenating, natural or organic properties or produces other benefits to your health or lifestyle;

c) recalls a taste, smell, flavoring or other additives or their absence;

d) look like food or a cosmetic product;

e) suggests that a particular tobacco product has a higher biodegradability or other environmental benefits.

2. The individual packs and any external packaging do no suggest economic benefits by including printed material with coupons, free distribution offers, two-for-one deals or other similar offers.

3. The elements and characteristics prohibited under paragraphs 1 and 2 include, among other things, texts, symbols, names, trademarks, figurative signs or other.

Art. 15

Appearance and content of the individual pack and presentation of packaging for sale

1. The individual packs of cigarettes are parallelepiped in shape. The individual rolling tobacco packs are cylindrical or parallelepiped or are an envelope. An individual cigarette pack contains at least 20 cigarettes. A individual pack of rolling tobacco contains no less than 30

g of tobacco.

2. A individual pack of cigarettes can consist of hard or soft material and has a reclosable or resealable system after the pack is opened except for "flip-tops" and hinged box pack closures. For "flip-top" packs and hinged packs, the hinge may be on the back of the individual pack.

Art. 16 Tracking

1. All individual packs of tobacco products are marked with a unique identifier. Notwithstanding the provisions of article 1, paragraph 5 of Legislative Decree no. 188 of December 15, 2014 to ensure its integrity, the unique identifier is printed or permanently and indelibly affixed and is not covered up or truncated, for example, with tax stamps or price tags, after the opening of the individual pack.

2. The unique identifier allows the following to be determined:

a) the processing date and place;

b) the processing facility;

c) the machinery used for processing tobacco products;

d) the production shift or work schedule;

e) description of the product;

f) the intended retail market;

g) the planned transportation route;

h) where appropriate, the EU importer;

i) the actual transportation route from the manufacturer to the first sale, including deposits used as well as the date of transport, transportation destination, the starting point and the recipient;

l) the identity of all purchasers from the manufacturer until the first sale.

m) the invoice, order number and payment records of all purchasers from the manufacturer until the first sale.

3. The information set forth in letters a), b), c), d), e), f), g) and, if applicable, h) of section 2 are part of the sole identifier.

4. The information set forth in section 2, letters i), l) and m), are electronically accessible through a unique identifier link.

5. All economic operators involved in the trade of tobacco products by the manufacturer to the last economic operator following the first sale, recording all individual packs that they acquire, all intermediate transactions and final transfers of ownership of the individual packs. Labeling and recording aggregate packaging, such as cartons or pallets, may constitute fulfillment of this obligation so long as it remains possible to track and trace individual packages.

6. Any individual or legal entity involved in the procurement chain for tobacco products are fully registered accurately for all pertinent transactions.

7. The manufacturers of tobacco products provide to all economic operators involved in the trade of tobacco products by the manufacturer until the last economic operator following the first sale, including importers, transportation and storage companies, with the recording equipment needed

for purchases, sales, storage, transport or other tobacco products. This equipment must be able, as required by paragraph 8, to read and send the recorded data electronically to a data storage center.

8. The manufacturers and the importers of tobacco products sign data storage contracts with an independent third party to host the central storage for all data, established in the European Union. The fitness of the third party, in particular its independence and its technical ability as well as the data storage contracts are approved by the European Commission under Article 15, paragraph 8, of Directive 2014/40/EU. The third party activities are controlled by an external auditor, proposed and employed by the tobacco manufacturer and approved by the European Commission under the same article 15, paragraph 8. The external auditor shall report to the Ministry of Health and the Customs and Monopolies Agency and the European Commission, examining in particular any irregularities concerning access. The Ministry of Health, the Customs and Monopolies Agency and the external auditors have full access to the data storage centers. In duly justified cases, the Customs and Monopolies Agency may allow, having heard those manufacturers required to record and transmit data on the handling of products to the data storage center, manufacturers or importers who meet specific requirements to access the archived information as long as commercially sensitive information remains adequately protected in accordance with the relevant law.

9. The stored data cannot be modified or deleted by an economic operator involved in the trade of tobacco products.

10. Personal data shall be processed solely in accordance with the rules and safeguards set forth in Directive 95/46/EC.

11. Sections 1-10 apply to cigarettes and rolling tobacco starting on May 20, 2019 and various tobacco products other than cigarettes and rolling tobacco starting on May 20, 2014.

Art. 17 Security Features

1. In addition to the unique identifier referred to in Article 16, all individual packs of tobacco products placed on the market shall bear an security anti-tampering element, composed of visible and invisible parts. The safety element is printed or permanently and indelibly affixed and not covered up or truncated by tax stamps and price tags or other items required by law. The legal marks can be used as a safety feature.

2. The provisions set forth in paragraph 1 shall apply to cigarettes and rolling tobacco effective on May 20, 2019 and for tobacco products other than cigarettes and rolling tobacco effective on May 20, 2024. The provisions set forth in Article 1, section 5 of legislative decree no. 188 of December 15, 2014 remain in effect.

3. With the Decree of the Ministry of the Economy and Finance the technical features of the safety element set forth in section 1 are defined.

Section III
Tobacco for oral use, transnational sales of tobacco products and next generation tobacco products

Art. 18 Tobacco for Oral Use

1. The sale of tobacco for oral use is banned.

Art. 19
Transnational Sales of Tobacco Products

1. The transnational sale of tobacco products is prohibited for consumers in the State.

2. In the consolidated text of legislative provisions concerning taxes on production and consumption and related criminal and administrative penalties, pursuant to Legislative Decree no. 504 of October 26, 1995, Article 10-bis, first paragraph, the following is added to the end of the sentence: "The purchases of manufactured tobacco, carried out under this paragraph, occurs using methods other than the transnational sales as per the directive of the European Parliament and Council of April 3, 2014, n. 2014/40/EU."

Art. 20
Notice of Next Generation Tobacco Products

1. Without prejudice to that set forth in Article 39 terdecies of Legislative Decree no. 504 of October 26, 1995, as amended, manufacturers and importers of the next generation tobacco products shall notify the Ministry of Health and the Ministry of Economy and Finance about every product that it wishes to place on the market. The notice is filed electronically six months before the planned placement on the market and is accompanied by a detailed description of the next generation tobacco product and the instructions for use as well as information on the ingredients and emissions required under Article 6. For next generation tobacco products placed on the market prior to May 20, 2016, notification is submitted within six months from that date. For any substantial modification to the product, a new notification is presented.

2. Manufacturers and importers who send notice of a next generation tobacco product also provide:

a) the available scientific studies on toxicity, on addictiveness and on the attractiveness of the next generation tobacco products, especially with regard to the ingredients and emissions;

b) the available studies, the relative summaries and the market research on the presence of various consumer groups, including youth and current smokers.

c) other pertinent information available, regarding among other things, the risk analysis of the product’s benefits, its expected effects in terms of quitting smoking, its expected effects in terms of beginning tobacco use and anticipated perception of the consumer.

3. The manufacturers and the importers of next generation tobacco products send the Ministry of Health and the Ministry of Economy and Finance all new or updated information on studies, research and other information referred to in paragraph 2, letter a)-c), which can provide evidence to the public only after assessments by the Ministry of Health;

the disclosure activities for scientific and research purposes are always allowed. The Ministry of Health and the Ministry of Economy and Finance may require manufacturers or the next generation tobacco product importers to conduct further tests or submit additional information. The same Ministries shall provide the European Commission with all information received.

4. With the decree of the Ministry of Health and Economic Development in concert with the Minister of Economy and Finance, within six months from May 20, 2016, the procedures and methods through which the Ministry of Health have established, after hearing the Higher Institute of Health, assessments of information and studies mentioned in paragraph 2 in order to recognize the reduction of toxic substances or reduced potential risk of next generation tobacco products compared to combustion products under the same conditions of use as well as their labeling method.

5. The next generation tobacco products released on the market respect the requirements of this decree concerning smokeless tobacco products or smoking tobacco products.

Title III
ELECTRONIC CIGARETTES AND HERBAL SMOKING PRODUCTS AND MEASURES TO PROTECT MINORS

Section I
Electronic cigarettes and herbal smoking products

Art. 21 Electronic Cigarettes

1. Electronic cigarettes and the rechargeable liquid containers are placed on the market only if they comply with the provisions of this Decree. This decree does not apply to electronic cigarettes and the rechargeable liquid containers subject to an authorization requirement pursuant to Legislative Decree no. 219 of April 24, 2006, as amended, or with the requirements of Legislative Decree no. 46 of February 24, 1997, as amended.

2. Based on the category set forth in Article 62-quater of Legislative Decree no. 504 of October 26, 1995, as amended, manufacturers and importers of electronic cigarettes and the rechargeable liquid containers must notify the Ministry of Health and the Ministry of Economy and Finance about any product of this type that they intend to place on the market. The notice is filed electronically six months before the planned release on the market. For electronic cigarettes and rechargeable liquid containers placed on the market before May 20, 2016, the notice is submitted within six months after that date. For any substantial modification to the product, a new notification is presented.

3. Depending on whether the product is an electronic cigarette or a rechargeable liquid container, the notification contains the following information:

a) name and address of the manufacturer, of the legal entity or responsible individual within the European Union and, if necessary, the importer in the European Union;

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

c) toxicological data regarding the burned or unburnt ingredients as appropriate, even when heated, with particular attention to their impact on consumer health when inhaled and taking into account, among other things, any addictive effects.

d) information on doses and the absorption of nicotine under normal consumption or reasonably foreseeable conditions;

e) a description of the components of the product, including, where appropriate, the opening mechanism and the charger of the electronic cigarette or the rechargeable liquid container;

f) description of the production process, including if it involves mass production and a statement certifying that the production process ensures compliance with the requirements of this article;

g) declaration of full responsibility of the manufacturer and importer on the quality and safety of the product, when it is placed on the market and used under normal or reasonably foreseeable conditions.

4. With the decree referred to in Article 30, a separate fee is established for manufacturers and importers of electronic cigarettes and the rechargeable liquid containers to receive, store, manage, analyze and publish data sent to them under this Article.

5. The applicants shall settle payment of the amount due by presenting the relevant certificate together with the submission of the application.

6. The liquid containing nicotine contained in the electronic cigarettes or rechargeable liquid containers respects the following requirements:

a) it is issued on the market only:

1) in the appropriate rechargeable liquid containers with a volume not exceeding 10 ml;

2) in disposable electronic cigarettes with tanks not exceeding 2 ml;

3) in disposable cartridges with a cartridge volume of no more than 2 ml;

b) presents a nicotine content of no more than 20 mg/ml;

c) must not contain the additives listed in Article 8, section 3;

d) must be produced only by using highly pure ingredients. The substances other than the ingredients referred to in paragraph 3, letter b), may be present in the liquid containing nicotine only at trace levels, if these traces are technically unavoidable during production;

e) except for nicotine, it must only contain ingredients that do not pose, even if heated, danger to human health.

7. Electronic cigarettes are release doses of nicotine at constant levels under normal conditions of use. The electronic cigarettes and rechargeable liquid containers must be child-proof and tamper-proof and must be protected against breaking and leaks and have a leak-proof rechargeable mechanism.

8. The individual electronic cigarette packages and the rechargeable liquid containers are accompanied by a sheet with:

a) instructions for use and storage of the product, including a reference to the fact that the use of the product is not recommended for young people and non-smokers;

b) counter indications;

c) warnings for specific at-risk groups;

d) information on harmful effects;

e) addictive nature and toxicity;

f) address of the manufacturer or a legal or individual within the European Union.

9. The individual pack and any outside packaging for electronic cigarettes and the rechargeable liquid containers:

a) include a list of all the ingredients contained in the product in descending order by weight, and an indication of the nicotine content in the product and the quantity released per dose, the batch number and a recommendation to keep the product out of the reach of children;

b) notwithstanding the provisions set forth under letter a), elements or features set forth in article 14 are not included except for article 14, section 1, letters a) and c) regarding information on nicotine contents and aromas;

c) shall bear the following health warnings: "This product contains nicotine, a substance that is highly addictive. Not recommended for non-smokers."

d) the health warnings are in accordance with the requirements set forth in Article 13, section 2.

10. The following shall be prohibited:

a) commercial notices for company services regarding information, the press and other printed publications, which have the purpose or the direct or indirect effect of promoting electronic cigarettes and rechargeable liquid containers, with the exception of publications intended exclusively for electronic cigarettes for trade professionals and rechargeable liquid containers and publications printed and edited in third party countries if those publications are not principally intended for the EU market;

b) commercial radio communications with the aim or direct or indirect effect of promoting electronic cigarettes and rechargeable liquid containers;

c) any form of public or private contribution to radio programs having the goal or direct or indirect effect of promoting electronic cigarettes and rechargeable liquid containers;

d) any form of public or private contribution to events, activities or individuals with the aim or direct or indirect effect of promoting electronic cigarettes and rechargeable liquid containers and who participate or operate in several Member States or have transnational implications;

e) for electronic cigarettes and the rechargeable liquid containers, audiovisual commercial communications that are subject to Directive 2010/13/EU of the European Parliament and Council.

11. The transnational sales of electronic cigarettes and the rechargeable liquid containers to consumers who buy in the State are prohibited.

12. The Customs and Monopoly Agency, notwithstanding the powers of authority and judicial police where the fact constitutes a crime, informs Internet connectivity suppliers or other electronic or telecommunications network suppliers or operators that for the electronic or telecommunication services provided, the websites to which to prohibit access through the aforementioned networks, offering non-combustible inhalation products with liquid substances containing nicotine in accordance with Article 62-quater, paragraph 1-bis of Legislative Decree no. 504 of October 26, 1995, lacking the authorization referred to in the Decree of the Ministry of Economy and Finance of December 29, 2014 in accordance with Article 62-quater, paragraph 4, of Legislative Decree no. 504 of 1995, or otherwise in violation of the laws, regulations, limits or requirements defined by the Agency.

13.The manufacturers and the importers of electronic cigarettes and rechargeable liquid containers submit annually to the Ministry of Health and the Ministry of Economy and Finance:

a) comprehensive data on the volume of sales, divided by product brand and type;

b) information on the various consumer preference groups, including young people, non-smokers and the main types of current users;

c) method of selling the products;

d) a summary of any market investigations conducted with respect to the above, with its English translation.

14. The Ministry of Health monitors the relative performance of electronic cigarettes and the rechargeable liquid container market, including any evidence that their use constitutes a step toward nicotine addiction and, ultimately, traditional tobacco consumption among young people and non-smokers.

15. The Ministry of Health and the Ministry of the Economy provide the public with the information set forth in section 2 on the respective site considering the needs to protect the reserved commercial information.

16. All information received pursuant to this Article shall be made available by the Ministry of Health and the Ministry of Economy and Finance, upon request, from the European Commission and other EU Member States, ensuring confidential processing of commercial secrets and other confidential information.

17. Manufacturers, importers and distributors of the electronic cigarette and rechargeable liquid containers institute and maintain an information collection system for all presumed harmful effects of these products on human health. Should any of these economic operators consider or have reason to believe that electronic cigarettes or rechargeable liquid containers at its disposal that are intended to be placed on the market or are placed on the market are unsafe or are not of good quality or are otherwise not in accordance with this decree, they must immediately take the corrective measures necessary to bring that product into compliance with this decree by withdrawing it or recalling it at their own expense, as appropriate. In these cases, the operator shall immediately inform the Ministry of Health and the Ministry of Economy and Finance, as well as the authorities in the Member States where the product is made available or intended to be made available, specifying, in particular, the risk to human health and safety and any corrective actions taken, as well as the results of these corrective measures. The Ministry of Health and the Ministry of Economy and Finance may request additional information from economic operators, even about safety and quality aspects or the possible harmful effects of electronic cigarettes or rechargeable liquid containers.

Art. 22

Herbal-based Smoking Products

1. Each individual pack and any outside packaging for herbal-based smoking products carry the following general warning: "The smoke from this product is harmful to your health"

2. The warning about health is printed on the front and back of the external surface of the individual pack and any external packaging.

3. The health warning on the provisions set forth in Article 10, section 4 covers 30% of the area corresponding to the surface area of the unit packages and any external packaging.

4. The unit packages and any external packaging of the

herb-based products does not include any elements or characteristics set forth in Article 14, section 1, letters a), b) and d), and do not indicate that the products does not contain additives or perfumes.

Art. 23
Tobacco-based Product Ingredients List

1. The manufacturers and importers of herb-based products file a list with the Ministry of Health about the amounts of all ingredients used to process these products, divided by brand and type. The manufacturers or importers also report any changes to the composition of a product that impacts the information provided pursuant to this article. The information set forth in this article is submitted before a new or modified herb-based product is released on the market.

2. The Ministry of Health ensures that the information submitted pursuant to section 1 is provided to the public on its institutional site, considering the needs to protect confidential commercial information. The economic operators carefully specify which information is considered a commercial secret.

Chapter II
Measures to Protect Minors

Art. 24
Supply Reduction and Protection of Minors

1. Under Article 51 of the Law no. 3 of January 16, 2003, as amended, under paragraph 1-bis after the word "training," the following words were added: “as well as external appurtenances of teaching hospitals, hospitals and research centers and external gynecology and obstetrics, neonatology and pediatrics departments at teaching hospitals, hospitals and research centers."

2. Under Article 51 of Law no. 3 of January 16, 2003, as amended, after paragraph 1-bis, as amended by paragraph 1, the following is added: 1-c The ban referred to in paragraph 1 is extended to the driver of motor vehicles, whether parked or moving, and to passengers in those vehicles if there are children or pregnant women in the vehicle…"

3. Article 25 of the consolidated text of the laws on protection and assisting mother and child, as per the Royal Decree no. 2316 of December 24, 1934, as amended, is replaced by the following:

"Art. 25. Anyone who sells tobacco products or electronic cigarettes or rechargeable liquid containers with the presence of nicotine or next generation tobacco products is obliged to ask the buyer, upon purchase, for an ID card except in cases where it is clear the buyer is of age.

Anyone who sells or administers tobacco products to minors under the age of eighteen or electronic cigarettes or rechargeable liquid containers with the presence of nicotine or next generational products, the pecuniary administrative fine applies from €500.00 to €3,000.00 and the suspension of the license to operate for fifteen days. If the act is committed more than once, the pecuniary administrative sanction applies from €1,000.00 to €8,000.00 and the

revocation of the license to operate."

4. Under Article 20 of Law no 556 of August 8, 1977, as amended, the second paragraph is replaced by the following: "The vending machines for the public sale of tobacco products or electronic cigarettes or rechargeable liquid containers containing nicotine, equipped with an automatic detection system of for the buyer's age registry and considered appropriate for the automatic scanning of personal documents issued by the government, may be subject to various controls at the Customs and Monopolies Agency at the time of their installation and then periodically afterwards."

5. The provisions set forth in this Article apply starting on the date this decree goes into effect.

Title IV
PENALTY PROVISIONS

Art. 25 Sanctions

1. Unless the act constitutes a crime, manufacturers and importers of tobacco products or related products that produce, import or place on the cigarette market with maximum emission levels higher than those referred to in Article 3 shall be subject to pecuniary administrative sanctions for payment of a sum of €30,000.00 to €150,000.00. Unless the act constitutes a crime, manufacturers or retailers that sells cigarettes with maximum emission levels higher than those referred to in Article 3, shall be subject to a pecuniary administrative sanction of €500.00 to €5,000.00 if it is aware that these maximum levels were exceeded.

2. Unless the act constitutes a crime, manufacturers and importers of tobacco products or related products that produce, import or place on the tobacco market with unique aromas or containing additives or aromas in violation of the provisions set forth in Article 8, sections 1, 2, 3, 4, 6 and 7 shall be subject to pecuniary administrative sanctions for payment of a sum of €30,000.00 to €150,000.00. Unless the act constitutes a crime, manufacturers or retailers who places tobacco products with unique aromas or containing prohibited additives or aromas on the market as described in Article 8, paragraphs 1, 2, 3, 4, 6 and 7, shall be subject to a pecuniary administrative sanction of €500.00 to €5,000.00 if they are aware of the presence of a unique aroma as well as prohibited additives and aromas.

3. Unless the act constitutes a crime, manufacturers and importers of tobacco products or related products that produce, import or place on the market tobacco for oral use, in violation of the provision of Article 18, or the transnational sale of tobacco products to consumers in violation of the provisions of Article 19, paragraph 1, or the transnational sale of electronic cigarettes and rechargeable liquid containers to consumers in violation of the provisions of Article 21, paragraph 11, shall be subject to an pecuniary administrative fine of € 30,000.00 to €150,000.00. Unless the act constitutes a crime, the manufacturer or retailer who places on the tobacco for oral use on the market in violation of the provision of Article 18 or for transnational sale of tobacco products to consumers in violation of the provision in

Article 19, paragraph 1, or who sells transnationally electronic cigarettes and rechargeable liquid containers in violation of the provisions of Article 21, paragraph 11, shall be subject to a pecuniary administrative fine of € 500.00 to € 5,000.00.

4. Unless the act constitutes a crime, manufacturers and importers who produce, import and place on the market electronic cigarettes without respecting the provisions set forth in Article 21, sections 6, 7, 8 and 9 or that perform commercial notices or offer forms of public or private contributions in violation of the provisions set forth in Article 21, section 10, the pecuniary administrative fine applies for a sum of €30,000.00 to €150,000.00. Unless the act constitutes a crime, the manufacturer or retailer that sells electronic cigarettes in violation of the law: the provisions of Article 21, paragraph 6, if respect for the requirements set forth in letter a) is not verified; the provisions of Article 21, paragraph 6, letter b), if there is the presence of a known nicotine content over the prescribed limit; the provisions of Article 21, paragraph 6, letter c), d) and e), if there is the known presence of banned additives and ingredients or the necessary requirements are not fulfilled; is subject to a pecuniary administrative sanction of between € 500.00 to € 5,000.00.

5. Unless the act constitutes a crime, manufacturers and importers of tobacco products or related products that produce, import or place on the market tobacco products without the warnings and informational messages on the individual packs and on any outside packaging in accordance with the provisions of Articles 9, 10, 11, 12, 13, 14 and 22 or without respecting the requirements for the appearance and content of the packages provided for in Article 15, paragraphs 1 and 2 or labeled with a unique identification code on the individual pack of tobacco products referred to in Article 16 or the security elements on individual tobacco packs referred to in Article 17, may be subject to a pecuniary administrative fine of between € 20,000.00 to €120,000.00. Unless the act constitutes a crime, the manufacturer or retailer who sells tobacco products without warnings and informational messages referred to in Articles 10, paragraphs 1 and 2; 11, paragraphs 1 and 2, letters a), b), d) and e); 12, paragraph 1; 13, paragraph 1, is subject to a pecuniary administrative sanction of between € 500.00 to €5,000.00.

6. Unless the act constitutes a crime, manufacturers and importers of tobacco products or related products without the information, statements, reports, studies, reports, notifications, lists and data not provided according to the provisions of articles 6, paragraphs 1, 2, 3, 4, 7 and 8; 7, paragraphs 2, 3 and 4; 20; 21, paragraphs 2, 3 and 12; 23, paragraph 1, are subject to a pecuniary administrative sanction of between € 10,000.00 to €50,000.00.

7. Unless the act constitutes a crime, the person in charge of a laboratory as reported in Article 4, paragraph 2, which carries out the measurements referred to in Article 4, paragraph 1, without the required authorization is subject to a pecuniary administrative sanction of between €10,000.00 to €50,000.00.

8. The application of the administrative sanctions provided for in this decree is set forth based on the methods set forth in Law no. 689 of November 24, 1981, as amended. The report provided for in Article 17 of the Law is presented to the Police Station to determine the sum owed for the violation and the subsequent payment order.

Title V
TRANSITIONAL AND FINAL PROVISIONS

Art. 26
Implementation of European Commission Acts

1. Using the procedure set forth in Article 31, paragraph 6 of Law no. 234 of December 24, 2012, the delegated acts adopted by the European Commission under Article 27 of Directive 2014/40/EU are implemented for the implementation of Article 3, paragraphs 2 and 4, of Article 4, paragraphs 3 and 5, Article 7, paragraphs 5, 11 and 12, Article 9, paragraph 5, Article 10, paragraph 3, Article 11, paragraph 6 of Article 12, paragraph 3, Article 15, paragraph 12 and Article 20, paragraphs 11 and 12, of the same Directive.

2. With the Decree of the Minister of Health, in concert with the Ministries of Economy and Finance, Economic Development, Food and Forest Agricultural Policies to be acquired under the terms set forth by Article 17b of Law no. 241 of August 7, 1990, as amended, as introduced by Article 3 of the Law no. 124 of August 7, 2015, the executive acts adopted by the European Commission under Article 25, paragraph 2 of Directive 2014/40/EU for the execution of the provisions of Articles 5, 6, 7, 8, 9, 10, 15, 16 and 20 of Directive 2014/40/EU are implemented.

Art. 27 Competent Authorities

1. The competent authorities responsible for the implementation and enforcement of obligations under this Decree shall be the Ministry of Health and the Ministry of Economy and Finance.

Art. 28 Transitional and Final Provisions

1. The provisions of this Decree shall apply from May 20, 2016, unless otherwise provided herein.

2. Issuance on the market is authorized on May 20, 2017 for the following products that are non-compliant with this decree:

a) tobacco products manufactured and issued under free practice and labeled in accordance with directive 2001/37/EC before May 20, 2016, including products as per Article 12 based on the aging and production times;

b) electronic cigarettes or rechargeable liquid containers produced or issued under free practice on November 20, 2016;

c) herb-based smoking products produced or issued under free practice before May 20, 2016.

3. The non-compliant tobacco products eventually stored with the retailer after May 20, 2017 are the same as products with packaging defects and manufacturer defects:

a) in consideration of the joint distribution system for manufactured tobacco by the deadline of August 20, 2016, these products can be transferred by the manufacturer or importer to the authorized warehouse; by October 20, 2016, these products may be sold by the authorized depositary for retail;

b) for tobacco-only products from different smoking products other than cigarettes, rolling tobacco and water pipe tobacco in consideration of the aging time, the terms set forth under letter a) do not apply,

notwithstanding the term set forth in section 2, paragraph.

Art. 29 Repeals

1. On May 20, 2016, legislative decree no, 184 of June 24, 2003 has been appealed, implementing Directive 2001/37/EC, except for the application of the provisions of Article 28, sections 2 and 3.

Art. 30 Rate Provisions

1. The activities referred to in Articles 4, 6, 8 and 21 shall be covered by pre-set rates, based on the actual service costs, paid by the manufacturers and importers of tobacco products.
2. With a decree of the Minister of Health, in consultation with the Minister of Economy and Finance, to be adopted within sixty days from the date this decree goes into effect, the rates referred to in paragraph 1 shall be identified and their payment method.
3. The rates referred to in paragraph 1 shall be updated at least every two years.
4. The revenues from the rates set forth in section 1 are paid to the Treasurer to be reallocated, with one or more decrees of the Minister of Economy and Finance, to the Ministry of Health as per the appropriate sections on conducting these activities.

Art. 31 Invariance Clause

1. The implementation of this Decree shall not result in new or increased burdens on public finances.
2. The competent authorities shall ensure the implementation of the tasks entrusted to human resources, equipment and financial resources available under the current legislation.

This decree, bearing the seal of the State, will be included in the official collection of legislative acts of the Italian Republic. Everyone must observe it and ensure it is observed.

Done in Rome on January 12, 2016

Annex I
(as per Art. 11, section 2, letter a)
List of Text Warnings

1) Smoking causes 90% of cases of lung cancer.
2) Smoking causes mouth and throat cancer.
3) Smoking damages your lungs.
4) Smoking causes heart attacks.
5) Smoking increases your risk of stroke and disability.
6) Smoking clogs your arteries.
7) Smoking increases the risk of blindness.
8) Smoking is harmful for your teeth and gums.
9) Smoking can kill your unborn child.
10) Smoking can harm your children, your family and your friends.

11) Children of smokers are more likely to start smoking.
12) Quit smoking - Live for your loved ones.
13) Smoking reduces fertility.
14) Smoking increases the risk of impotence.

Annex II
Catalog of images (combined health warnings) (included under Art. 11)

(The annex is omitted, which is provided separately)