PARLIAMENT OF ROMANIA

CHAMBER OF REPRESENTATIVES **SENATE**

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on the establishment of conditions concerning the manufacture, presentation and marketing of tobacco and related products and amendments to Law No. 349/2002 on preventing the consumption of tobacco products and combating its effects

The Parliament of Romania adopts this Law.

CHAPTER I
General provisions

Art. 1. – Subject matter

(1) This Law sets the measures applicable to:

a) the manufacture, presentation and marketing of tobacco and related products by regulating the use of ingredients, emissions of tobacco products and related reporting obligations that apply to maximum emission levels for tar, nicotine and carbon monoxide for cigarettes;

b) labeling and packaging, including health warnings to appear on unit packets of tobacco products and on any outside packaging, traceability and security features that are applied to tobacco products;

c) the prohibition of placing on the market tobacco products for oral use;

d) cross-border distance sales of tobacco products;

e) the notification of novel tobacco products;

f) placing on the market and labeling of certain products that are similar to tobacco products, such as electronic cigarettes and refill containers and herbal products for smoking.

(2) The purpose of this Law is to ensure a high level of protection of public health, especially of young people, from the harmful effects of consumption of tobacco and related products, while ensuring free circulation of tobacco and related products in accordance with the provisions of the WHO Framework Convention for Tobacco Control, adopted at Geneva, Switzerland, on 21 May 2003, ratified by Law No. 332/2005, published in the Official Gazette of Romania, Part I, No. 1.088 of 2 December, 2005.

Art. 2. – Definitions

For the purposes of this Law, the terms and phrases below shall have the following meaning:

a) *tobacco* – means leaves and other processed or unprocessed natural parts of the tobacco plants, including expanded and reconstituted tobacco;

b) *pipe tobacco* – means tobacco that can be consumed via a combustion process intended exclusively for use in a pipe;

c) *roll-your-own tobacco* – means tobacco that can be used for making cigarettes by consumers;

d) *tobacco product* – means products that can be consumed and consist, even partly, from tobacco whether genetically modified or not;

e) *smokeless tobacco product* – means a tobacco product not involving a combustion process including, chewing tobacco, nasal tobacco and tobacco for oral use;

f) *chewing tobacco* – means a tobacco product exclusively intended for chewing;

g) *nasal tobacco* – means a smokeless tobacco product that can be used via the nose;

h) *tobacco for oral use*– means all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination thereof, particularly those presented in sachet portions or porous sachets;

i) *tobacco products for smoking* - means tobacco products other than a smokeless tobacco product;

j) *cigarette* – means a roll of tobacco wrapped in paper that can be used via a combustion process as defined in Art. 354 para. (2) of Law No. 227/2015 on the Tax Code, with subsequent amendments and completions;

k) *cigar ("trabuc")* – means a roll of tobacco that can be used via a combustion process as defined in Art. 354 para. (3) of Law No. 227/2015, with subsequent amendments and completions;

l) *cigarillo* – means a small size cigar with a maximum weight of 3 g each;

m) *waterpipe tobacco* – means a tobacco product that can be consumed via a waterpipe. For the purpose of this law, waterpipe tobacco is considered to be a tobacco product for smoking. If a tobacco product can be used via waterpipe and as roll-your-own [tobacco], it is considered to be roll-your-own tobacco;

n) *novel tobacco product* – means a tobacco product placed on the EU market after 19 May 2014 and which does not fall under any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigar, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use;

o) *herbal product for smoking* – means a product based on plants, herbs or fruits which contains no tobacco and can be consumed via a combustion process;

p) *refill container for electronic cigarette* – means a receptacle that contains a nicotine-containing liquid and which can be used to refill an electronic cigarette;

q) *ingredient* – means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products including paper, filter, ink, capsules and adhesives;

r) *nicotine* – means nicotinic alkaloids;

s) *tar* – means the raw anhydrous, nicotine-free condensate of smoke;

ş) *emissions* – means substances that are released when a tobacco product or a related product is used as intended, such as substances found in smoke or substances released during the process of using smokeless tobacco products;

t) *maximum level or maximum emission level* – means the content or maximum emission, including zero, for a substance in a tobacco product measured in milligrams;

ţ) *additive* – means a substance other than tobacco that is added to a tobacco product, a unit packet or any outside packaging;

u) *flavorings* – means an additive that imparts smell and/or taste;

v) *characterizing flavor* – means a clearly noticeable smell or taste other than one of tobacco resulting from an additive or a combination of additives, including but not limited to, fruit, condiments, herbs, alcohol, sweeteners, menthol or vanilla, and that is noticeable before or during the consumption of the tobacco product;

w) *addictiveness* – means pharmacological potential of a substance to cause addiction, a state which affects the ability of an individual to control his/her behavior, usually by instilling a reward mechanism or easing of withdrawal symptoms, or both;

x) *toxicity* – means the degree to which a substance can cause harmful effects on the human organism, including effects that occur over time, usually through repeated or continuous consumption or exposure;

y) *substantial change of circumstances* – means an increase in sales volumes by product categories of at least 10% in at least five Member States, based on sales data transmitted in accordance with Art. 5 para. (1) let. i), or an increase in the level of prevalence of use in the under 25 years of age consumer group with at least 5% in at least five Member States for the respective product category based on the Special Eurobarometer 385 Report „Attitudes of Europeans towards Tobacco" of May 2012 or equivalent prevalence studies. A substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2.5% of the total sales volume of tobacco products at EU level;

z) *outside packaging* – means any packaging used to place tobacco or related products on the market and which includes a unit packet or an aggregate of unit packets; the transparent wrapper is not considered outside packaging;

aa) *unit packet* – means the smallest individual packaging of a tobacco or related product that is placed on the market;

bb) *pouch* – means a unit packet of roll-your-own tobacco either in the form of a rectangular pocket with the flap that covers the opening, or in the form of a standing pouch;

cc) *health warning* – means a health warning regarding the adverse effects on human health of the product or other unwanted consequences of its consumption, including text warnings, combined health warnings, general warnings and information messages, in accordance with this Law;

dd) *combined health warning* – means a health warning that combines a text warning with a photograph or illustration in accordance with this Law;

ee) *cross-border distance sales* – means distance sales where, at the time the consumer orders the product from a retail outlet, the consumer is in a Member State other than the Member State or third country where that retail outlet is established. A retail outlet is deemed to be established in a Member State:

- *in the case of a natural person* – if such person has his/hers place of business in that state;

- *in other cases* – if the retail outlet has its headquarters, central administration or place of business, including branch, agency or any other economic establishment in that Member State;

ff) *consumer of tobacco and related products* – means a natural person who is acting for purposes other than commercial, business, craft or professional;

gg) *age verification system* – means a computing system that unequivocally confirms the age of the consumer electronically, in accordance with the requirements of the Member State of the consumer;

hh) *manufacturer of tobacco and related products* – means any natural or legal person who manufactures tobacco or related products, or, has such product designed or manufactured and markets that product under their name or trademark;

ii) *import of tobacco and related products* – means the entry into the EU territory of such products, with the exception of products that are subject to a suspensive customs arrangement or procedure upon their entry into the EU, as well all as their release from a customs suspensive arrangement or procedure;

jj) *importer of tobacco and related products* – means the legal person, owner or administrator who has the right to dispose of tobacco and related products that were brought into the territory of the EU;

kk) *placing on the market* – means to make products, regardless of their place of manufacture, available to consumers in Romania or in other Member States of the EU, with or without payment, including by means of distance sales. In the case of cross-border distance sales, the product is deemed to be placed on the market in the Member State where the consumer is located;

ll) *retail outlet* – means any sale outlet through which the tobacco products are placed on the market including by a natural person;

mm) *advertisement for electronic cigarettes and/or refill containers* – means any form of commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes and/or refill containers;

nn) *sponsorship for the promotion of electronic cigarettes and/or refill containers* – means any form of public or private contribution to events or activities, or in favor of a person, if this contribution has either the aim or the direct or indirect effect of promoting electronic cigarettes and/or refill containers;

oo) *information society services* – means any services of this type as defined under Art. 4 para. (1) pt. 2 of the Government Resolution No. 1.016/2004 concerning the measures for the organization and exchange of information in the field of standards and technical regulations, as well as the rules concerning the information society services between Romania and EU Member States, and the European Commission, published in the Official Gazette of Romania, Part I, No. 664 of July 23, 2004, with subsequent amendments and completions;

pp) *professionals in the trade of electronic cigarettes and/or refill containers* – means any natural or legal person involved in the manufacture or marketing of electronic cigarettes and/or refill containers, or professional counseling relative to electronic cigarettes and/or refill containers;

rr) *CMR properties* – means carcinogenic, mutagenic or reprotoxic properties of additives in tobacco products, including in combusted form;

ss) *member state* – means Member States of the European Union and of the European Economic Area.

CHAPTER II
Ingredients and emissions

Art. 3. – Maximum emission levels for tar, nicotine, carbon monoxide and other substances

(1) Maximum emission levels for cigarettes placed on the market or manufactured in Romania shall not be greater then:

a) 10 mg tar/cigarette;

b) 1 mg nicotine/ cigarette;

c) 10 mg carbon monoxide/ cigarette.

(2) The decrease of the maximum emission levels for cigarettes set forth in para.(1), adopted by means of delegated acts of the European Commission, is implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days from their publication in the Official Journal of the European Union.

(3) The Ministry of Health shall notify to the European Commission of any maximum emission levels it sets for emissions for cigarettes other than the maximum emission levels set forth in para. (1), and for emission levels from tobacco products other than cigarettes.

(4) Standards relating to maximum emission levels for emission levels from cigarettes other than the emissions under para. (1), and for emission from tobacco products other than cigarettes, adopted by means of delegated acts of the European Commission, are implemented by order of the minister of health,

published in the Official Gazette of Romania, Part I, within 60 days from their publication in the Official Journal of the European Union.

Art. 4. – Measurement methods

(1) The tar, nicotine and carbon monoxide emission levels for cigarettes shall be measured on the basis of ISO Standard 4387 for tar, ISO 10315 Standard for nicotine and ISO Standard 8454 for carbon monoxide.

(2) The accuracy of tar, nicotine and carbon monoxide measurements shall be determined in accordance with ISO Standard 8243.

(3) The measurements set forth in paras. (1) and (2) shall be verified by laboratories in Romania which are approved and monitored by the Ministry of Health, or by laboratories in other Member States which are approved and monitored by competent authorities of those states, included in the list of authorized and monitored laboratories in the Member States published by the European Commission.

(4) Laboratories referred to in para. (3) shall not be owned or directly or indirectly controlled by the manufacturers and importers of tobacco products.

(5) The Ministry of Health shall establish and update, whenever changes occur, a list of approved and monitored laboratories in Romania and shall communicate the list to the European Commission together with the criteria used for approval and the monitoring methods applied.

(6) The criteria used for the approval of laboratories in Romania and the monitoring methods set forth in para. (3) shall be drawn up and approved by order of the minister of health, published in the Official Gazette of Romania, Part I, within 45 days of the entry into force of this law.

(7) The measurement methods of tar, nicotine and carbon monoxide emissions adapted to scientific and technical developments or to internationally agreed standards adopted by means of delegated acts of the European Commission shall be implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the publishing in Official Journal of the European Union.

(8) The Ministry of Health shall notify to the European Commission of any measurement methods they use for any emissions from cigarettes other than those set forth in para. (7), and for emissions from tobacco products other than cigarettes.

(9) The standards agreed by the parties to the WHO Framework Convention for Tobacco Control regarding the measurements methods adopted by means of delegated acts of the European Commission shall be implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

(10) The Ministry of Health shall charge manufacturers and importers of tobacco products proportionate fees for the verification of the measurements set forth in paras. (1) and (2).

(11) The amount and the procedure of collecting fees set forth in para. (10) shall be approved by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the entry into force of this law.

Art. 5. – Reporting of ingredients and emissions

(1) The manufacturers and importers of tobacco products shall establish, a product file for each brand name and for each type containing the following:

a) a list of all ingredients and quantities thereof used in the manufacture of tobacco products, in descending order of the weight of each ingredient included in the tobacco products;

b) the status of the ingredients listed in the list mentioned in let. a), including whether they have been registered under Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94, as well as Council Directive 76/769/ EEC and Commission Directives 91/155/ EEC, 93/67/ EEC, 93/105/ EC and 2000/21/ EC, published in the Official Journal of the European Union series L No. 396 of 29 May 2007, as well as their classification under Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 concerning classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/ EEC and 1999/45/ EC, and amending Regulation (EC) No. 1907/2006, published in the Official Journal of the European Union series L No. 353 of 31 December 2008;

c) a statement describing the reasons for the inclusion of such ingredients in the tobacco products concerned;

d) relevant toxicological data for the ingredients listed in the list mentioned in let. a), in burnt or unburnt form, as appropriate, referring in particular to their effects on the health of the consumers and taking into account, inter alia, any form of addictive effects;

e) a technical document setting out general description of the additives used and their properties, for cigarettes and roll-you-own tobacco;

f) emission levels for cigarettes and tobacco products other than the cigarettes mentioned in Art. 3 paras. (1) and (4);

g) information on emissions and their levels, other than the ones mentioned in let. f), where available;

h) methods used for emission measurement, other than those for tar, nicotine and carbon monoxide set forth in Art. 4 para. (8);

i) annual sales volume in Romania, by brand name and type, for the year preceding the year of reporting, reported in number of cigarettes or kilograms, starting from 1 January 2015;

j) internal and external studies available to manufacturers and importers of tobacco products on market research and preferences of various consumer groups, including young people and current smokers, on ingredients and emissions;

k) summaries of any market surveys manufactures and importers of tobacco products carry out when launching new products.

(2) The Ministry of Health may require manufacturers and importers to conduct and submit electronically, within 18 months of the request, studies to assess the effects of the ingredients on health, taking into account, among others, their addictiveness and toxicity.

(3) The information set forth in para. (1) shall be provided to the Ministry of Health electronically by the manufacturers and importers of tobacco products:

a) for products already placed on the EU market by 20 November 2016;

b) prior to the placing on the market of a new or modified tobacco product;

c) whenever the composition or other information regarding a tobacco product is changed in a way that affects the information provided under this Article.

(4) When submitting information under para. (1),manufacturers and importers of tobacco products shall specify what data they consider to constitute:

a) trade secrets, for information submitted pursuant to para. (1) lets. a), f) and g);

b) confidential information for all other information.

(5) The Ministry of Health shall apply necessary legal measures to ensure the confidentiality of the information specified to constitute trade secrets and of those deemed confidential information according to legal provisions.

(6) Information submitted pursuant to provisions in para. (1) lets. a), f) and g) that are not specified as constituting trade secrets by the manufacturers and importers of tobacco products when submitting the product files shall be made publicly available by the Ministry of Health on its official website.

(7) Public institutions that have data on the sales volume of tobacco products in Romania shall provide them to the Ministry of Health in the first trimester of the current year, for the preceding year starting on 1 January 2016, reported in number of cigarettes or kilograms.

(8) The Ministry of Health shall store the information received pursuant to this article and shall make it available electronically to the European Commission and to other competent authorities in the Member States for the purpose of implementing this law.

(9) The procedures for the implementation of the provisions in paras. (1) – (8) shall be approved by order of the minister of health published in the Official Gazette of Romania, Part I, in accordance with the provisions of implementing acts of the European Commission establishing the format for the submission and the making available of the information regarding tobacco products within 45 days of the entry into force of this law.

(10) The Ministry of Health shall charge manufacturers and importers of tobacco products proportionate fees for receiving, storing processing and analyzing information submitted pursuant to this article.

(11) The amount and procedure for levying the fees pursuant to para. (10) shall be approved by order of the Minister of Health, published in the Official Gazette of Romania, Part I, within 60 days of the entry into force of this law.

(12) All data and information, to and by the Ministry of Health shall be submitted in electronic form pursuant to this article.

Art. 6. – Priority list of additives and enhanced reporting obligations

(1) In addition to the reporting obligations under Art. 5, manufacturers and importers of tobacco products placed on the market in Romania shall have enhanced reporting obligations for certain additives contained in cigarettes and roll-your-own tobacco that are included in the priority list.

(2) The priority list shall contain additives:

a) for which initial indications, research or regulation in other jurisdiction exist suggesting that they have one of the properties set forth in para. (4);

and

b) which are among the most commonly used additives by weight or number according to the reporting of ingredients pursuant to Art. 5 para. (1) lets. a) and c) – h).

(3) The priority list of additives shall be drawn up and subsequently updated by the European Commission, by means of implementing acts, and shall comprise at least 15 additives.

(4) Manufacturers and importers of roll-you-own tobacco placed on the market in Romania and containing an additive that is included in the priority list set forth in para. (3) shall carry out comprehensive studies which shall examine for each additive whether it:

a) contributes to toxicity or addictiveness of the products concerned and whether this has the effect of increasing toxicity and addictiveness in any of the products concerned to a significant or measurable level;

b) results in a characterizing flavor;

c) facilitates the inhalation or uptake of nicotine; or

d) leads to the formation of substances that have CMR properties, the quantities thereof and whether this has the effect of intensifying CMR properties of any of the products concerned to a significant or measurable degree.

(5) The studies mentioned in para. (4) shall take into account the intended use of the products concerned and analyze in particular, emissions that result from the combustion process that involve the additive concerned. The studies shall analyze the interaction of the additive concerned with other ingredients contained in those products.

(6) Manufacturers and importers using the same additive in their tobacco products may carry out a joint study when using the same additive concerned in a comparable product composition.

(7) Manufacturers and importers shall establish a report on the study results mentioned in para. (4), that contains a summary and a comprehensive presentation compiling available scientific literature on the additive concerned and summarizing internal data on the effects of that additive.

(8) Manufacturers and importers shall transmit the report set forth in para. (7) to the European Commission and a copy thereof to the Ministry of Health, no later than 18 months after the date the additive concerned has been included in the priority list pursuant to para. (3).

(9) Where the European Commission or the Ministry of Health request supplementary information from manufacturers and importers regarding an additive included in the priority list of additives pursuant to para. (3), manufacturers and importers of tobacco products, shall include such information, no later than six months, in the report set forth in para. (7).

(10) The procedure for the submission and the making available for the public of information regarding tobacco products that must be reported according to the provisions in this Article, shall be approved by order of the minister of health published in the Official Gazette of Romania, Part I, in accordance with the provisions of the implementing acts of the European Commission laying down the format for the submission and the making available of information on tobacco products, within 45 days of the entry into force of this Law.

(11) The Ministry of Health may request that the report set forth in para. (7) be evaluated by an independent scientific body, in particular as regards their comprehensiveness, methodology and conclusions, so that the information received is used in the decision making process pursuant to Art. 7.

(12) The Ministry of Health may charge manufacturers and importers of tobacco products, proportionate fees for the evaluations pursuant to para. (11).

(13) The amount and procedure for levying the fees pursuant to para. (12) shall be approved by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the entry into force of this law.

(14) When submitting the information set forth in this Article, manufacturers and importers of tobacco products shall specify the data they consider to constitute trade secrets.

(15) The Ministry of Health shall apply necessary legal measures to ensure the confidentiality of the information specified to constitute trade secrets and of those deemed confidential information according to legal provisions.

(16) Information that is not specified by manufacturers and importers of tobacco products to constitute trade secrets when submitting information pursuant to this Article, including the reports set forth in para. (7), shall be made publically available by the Ministry of Health, on the official website.

(17) All data and information submitted to and by the Ministry of Health pursuant to this Article shall be provided in electronic form.

(18) The Ministry of Health shall store all information received pursuant to this Article and shall make it available to the European Commission and other competent authorities in Member States, in electronic form.

(19) Small and medium-sized enterprises, as defined by Law No. 346/2004 on stimulating the establishment and development of small and medium-sized enterprises, published in the Official Gazette of Romania, Part I, No. 681 of 29 July 2004, with subsequent amendments and completions, shall be exempted from the obligations set forth in paras. (1) – (9), if a report is prepared by another manufacturer or importer of tobacco products.

Art. 7. – Regulation of ingredients

(1) The placing on the market of tobacco products with characterizing flavor shall be prohibited.

(2) The use of additives essential for the manufacture of tobacco products, for example sugar that is used to replace the sugar lost during the curing process, is allowed only if those additives do not impart a characterizing flavor to the product and do not significantly and measurably increase the degree of addictiveness, toxicity or CMR properties of the tobacco product.

(3) Where the European Commission, at the request of a Member State or on its own initiative, determines by means of implementing acts, whether a tobacco product falls within the scope of paras. (1) and (2), and this product is placed on the market in Romania, the Ministry of Health shall approve that act by order of the minister of health, published in the Official Gazette of Romania, Part I, within 45 days of the publication in the Official Journal of the European Union.

(4) Where the Ministry of Health suspects that a tobacco product placed on the market in Romania has a characterizing flavor, it may initiate the procedure for determining whether a tobacco product has a characterizing flavor.

(5) The procedure mentioned in para. (4):

a) is in accordance with the provisions of the implementing acts of the European Commission which set forth uniform regulation for determining whether a tobacco product falls within the scope of paras. (1) and (2);

b) includes also the possibility of consulting, before adopting measures pursuant to para. (1), with the independent advisory panel, established at EU level pursuant to Art. 7 para. (4) of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and marketing of tobacco and related products and repealing Directive 2001/37/CE, published in the Official Journal of the European Union series L No. 127 of 29 April 2014.

(6) Ministry of Health shall notify to the European Commission the measures they have taken pursuant to paras. (1) and (2).

(7) Maximum level for additives or combination of additives that led to prohibitions pursuant to para. (1) and (2), adopted by means of delegated acts by the European Commission, shall be implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

(8) It is prohibited to place on the market tobacco products that contain the following additives:

a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents a reduced health risk;

b) caffeine or taurine or other additives and stimulating compounds that are associated with energy and vitality;

c) additives having coloring properties for emissions;

d) for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and

e) additives that have CMR properties in unburnt form.

(9) The list of additives mentioned in para. (8) let. e) classified or proposed for classification as having CMR properties shall be approved by order of the minister of health, published in the Official Gazette of Romania, Part I, within 45 days of the entry into force of this Law, and shall be updated depending on the priority list of additives mentioned in Art. 6 para. (2).

(10) It is prohibited to place on the market tobacco products that contain:

a) flavors in any of the tobacco products components, such as filters, papers, packages, capsules or any technical feature allowing the modification of the smell or taste of those tobacco products or their smoke intensity;

b) tobacco or nicotine in filters, papers or capsules.

(11) The provisions and conditions provided for in the normative acts mentioned in Art. 5 para. (1) let. b) are applied to tobacco products as appropriate.

(12) On the basis of scientific evidence, the Ministry of Health may prohibit the placing on the market of tobacco products that contain additives in amounts that increase the toxic or addictive effect, or the CMR properties of a tobacco product at the time of consumption to a significant or measurable degree.

(13) The Ministry of Health shall notify to the European Commission the measures it has taken pursuant to para. (12).

(14) Where the European Commission determines by means of implementing acts, whether a tobacco product falls within the scope of para. (12), and this is placed on the market in Romania, the Ministry of Health shall approve that act by order of the minister of health, published in the Official Gazette of Romania, Part I, within 45 days of the publication in the Official Journal of the European Union.

(15) The maximum levels for additives that amplify the toxic or addictive effects of a tobacco product, adopted by the European Commission by means of delegated acts, shall be implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

(16) Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the prohibitions set forth in paras. (1) and (10).

(17) The withdrawal of the exemption set forth in para. (16) for a particular product category adopted by the European Commission by means of delegated acts shall be implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

(18) The Ministry of Health shall charge manufacturers and importers of tobacco products proportionate fees for assessing whether a tobacco product has a characterizing flavor, whether prohibited additives or flavorings have been used, and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic and addictive effect or the CMR properties of that product.

(19) The amount and procedure for levying the fees pursuant to para. (18) shall be approved by order of the Minister of Health, published in the Official Gazette of Romania, Part I, within 60 days of the entry into force of this Law.

(20) In the case of tobacco products with a characterizing flavor whose Union-wide sales volumes represent 3% or more in a particular product category, on the date of entry into force of the present Law, the provisions of this Article shall apply from 20 May 2020.

(21) This article shall not apply to tobacco for oral use.

CHAPTER III
Labeling and packaging

Art. 8. – General provisions for warnings

(1) Each unit packet and any outside packaging of a tobacco product placed on the market in Romania shall carry the health warnings set forth in this chapter, in Romanian.

(2) Health warnings shall cover the entire surface of the unit packet or outside packaging that is reserved for them and they shall not be commented on, paraphrased or referred to in any form.

(3) When tobacco products are placed on the market, health warnings on a unit packet and on any outside packaging are irremovably printed, indelible and fully visible, including not being partially or totally hidden or interrupted by the stamp for marking processed tobacco products set forth in Law No. 227/2015, with subsequent amendments and completions, price labels, security features, wrappers, jackets, boxes or other items.

(4) On unit packets of tobacco products other than cigarettes and roll-your-own tobacco in pouches, the health warnings may be affixed by means of self-stickers provided that such stickers are irremovable.

(5) The health warnings shall remain intact when opening the unit packet, other than packets with a flip-top lid, where the health warning may be split when opening the packet, but only in a manner that ensures the graphic integrity and the visibility of the text, photographs and smoking cessation information.

(6) The health warnings shall not hide or interrupt in any manner the stamp for marking processed tobacco products forth in Law No. 227/2015, with subsequent amendments and completions, price labels, tracking and tracing marks, or security features on unit packets.

(7) The dimensions of the health warnings set forth in Art. 9 – 12 shall be calculated in relation to the surface concerned when the packet is closed.

(8) The health warnings shall be framed by a black border of the width of 1 mm that is inside the surface reserved for warnings except for health warnings under Art. 11.

(9) Images of unit packets and any outside packaging of tobacco products targeting consumers in the European Union shall comply with the provisions in this chapter.

Art. 9. – General warning and information messages for tobacco products for smoking

(1) Each unit packet and any outside packaging for tobacco products for smoking shall carry the following general warning: *Smoking kills*.

(2) Each unit packet and any outside packaging for tobacco products for smoking shall carry the following information message: *Tobacco smoke contains over 70 substances that cause cancer*.

(3) For cigarette packets and roll-your-own tobacco in cuboid packets:

a) The general warning shall appear on the bottom part of a lateral surface of a unit packet, and the information message shall appear on the bottom part of the other side;

b) The general warning and the information message shall have a minimum width of 20 mm.

(4) For cuboid packets with a flip-top lid the lateral surface of which is split into two when opening the packet:

a) the general warning and the information message shall appear in their entirety on the largest part of the two split surfaces;

b) and the general warning shall appear also on the inner surface of the top surface that is visible when the packet is open;

c) the lateral surface of this type of packet shall have a height of no less than 16 mm.

(5) For roll-your-own tobacco marketed in pouches, the general warning and the information message shall appear on the surfaces that ensure full visibility of those health warnings.

(6) For roll-your-own tobacco in cylindrical packets, the general warning shall appear on the outside surface of the lid, and the information message on the inside of the lid.

(7) The general warning and the information message set forth in paras. (1) and (2) shall cover 50 % of the surfaces on which they are printed.

(8) The general warning and the information message set forth in paras. (1) and (2) shall be printed in accordance with the following technical features:

a) in black Helvetica bold type, on a white background;

b) font size is determined by the manufacturer such that the text occupies the greatest possible surface of the surface reserved for these health warnings;

c) is centered on the surface reserved for them, and on cuboid packets and on any outside packaging they shall be parallel to the lateral edge of the unit packet or the outside packaging.

(9) Changes to the information message under para. (2) shall be approved in compliance with the provision of the delegated acts of the European Commission, and shall be implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

(10) The precise position of the general warning and the information message set forth in paras. (1) and (2) for the roll-your-own tobacco marketed in pouches, depending on the various forms of these pouches, shall be determined by means of implementing acts of the European Commission, and shall apply to tobacco products placed on the market in Romania.

Art. 10. – Combined health warnings for tobacco products for smoking

(1) Each unit packet and any outside packaging of tobacco products for smoking shall carry combined health warnings.

(2) Combined health warnings shall comply with the following features:

a) contain one of the text warnings set forth in Annex I and a corresponding color photograph specified in the picture library in Annex II;

b) include smoking cessation information, such as the telephone number intended to inform consumers about the programs that are available to help persons who wish to quit smoking: *Toll Free STOP SMOKING: 08008 78673*;

c) cover 65% of both the external front and back surface of the unit packet and of any outside packaging. Cylindrical packages shall display two combined health warnings equally spaced from each other, each covering 65% of their respective half of the curved surface;

d) show the same text warning and the same corresponding color photograph on both sides of the unit packets and on any outside packaging;

e) appear at the top edge of a unit packet and any outside packaging and be positioned in the same direction as any information appearing on that surface of the packaging;

f) be reproduced in accordance with the format, layout, design and proportions specified by the European Commission by means of implementing acts;

g) in the case of unit packets of cigarettes, respect the following dimensions: height – no less than 44 mm; width – no less than 52 mm.

(3) The combined health warnings are grouped into three sets as set forth in Annex III, and shall be used starting with set 1, upon the entry into force of this Law, and in compliance with the following rules as further defined by implementing regulations, approved by order of the minister of health, and published in the Official Gazette of Romania, Part I:

a) Each set shall be used for a period of 12 consecutive months, starting from 1 January, except for set 1 which shall be used from the date this Law enters into force, to December 31, 2017;

b) Each combined health warning available for use in a given year is displayed to the extent possible in equal numbers on each brand of tobacco products.

(4) Until 20 May 2019, transitional exemptions from the obligation on the position of the combined health warning shall apply as follows:

a) in the case of unit packets made of carton which have the stamp for marking processed tobacco products set forth in Law No. 227/2015, with subsequent amendments and completions, affixed at the top edge, the combined health warning which appears on the back surface may be positioned directly below the stamp for marking processed tobacco products set forth in Law No. 227/2015, with subsequent amendments and completions;

b) where a unit packet is made of soft material, a rectangular surface may be reserved for the stamp for marking processed tobacco products set forth in Law No. 227/2015, with subsequent amendments and completions, the height of which does not exceed 13 mm between the top edge of the packet and the top part of the combined health warning.

(5) Brand names or logos shall not be positioned above health warnings.

(6) The rules concerning the technical specifications for the layout, design and shape of the packets, established by means of implementing acts of the European Commission, shall apply to tobacco products placed on the market in Romania.

(7) Information on smoking cessation included in the combined health warnings under para. (2) let. b) may be modified by order of the minister health, published in the Official Gazette of Romania, Part I, at least six months before the set of combined health warnings set forth in para. (3), is changed so as into enter into force on the same day with the new set of combined warnings.

(8) The rules concerning the implementation of the provisions in para. (3) shall be approved by order of the minister health published in the Official Gazette of Romania, Part I, within 45 days, and shall enter into force starting from 1 January 2017.

(9) Adaptation of text warnings listed in Annex I, as well as establishing and adapting the picture library in Annex II, mentioned in para. (2) let. a), adopted by means of delegated acts by the European Commission, shall be implemented by order of the minister health, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

Art. 11. – Labeling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and water pipe tobacco

(1) Notwithstanding the provisions under Art. 9 and 10, cigars and cigarillos that are placed on the market in Romania in unit packets containing a single product unit shall carry on each unit packet and any outside packaging the general warning specified in Art. 9 para. (1) and one of the text warnings listed in Annex I.

(2) The general warning specified in Art. 9 para. (1) that will be printed on the products set forth in para. (1) shall comply with the following features:

a) include smoking cessation information set forth in Art. 10 para. (2) let. b);

b) appear on the most visible surface of the unit packet and any outside packaging;

c) cover 30% of the relevant surface of the unit packet or any outside packaging;

d) comply with the technical features set forth in Art. 9 para (8);

e) the text is parallel with the main text on the surface reserved for this warning;

f) shall be framed by a black border of a width of no less than 3 mm and not more than 4 mm. This border shall appear on the outside of the surface reserved for the health warning.

(3) Text warnings listed in Annex I that will be printed on the products referred to in para. (1) shall comply with the following features:

a) each text warnings is displayed to the extent possible in equal numbers on each brand of tobacco products;

b) shall appear on the next most visible surface of the unit packet and any outside packaging. For unit packets with a hinged lid, the next most visible surface is the one that becomes visible when the packet is open;

c) shall cover 40% of the relevant surface of the unit packet or any outside packaging;

d) shall comply with the technical features set forth in Art. 9 para. (8);

e) the text is parallel with the main text on the surface reserved for this warnings;

f) shall be framed by a black border of a width of no less than 3 mm and not more than 4 mm. This border shall appear on the outside of the surface reserved for the health warning.

(4) Where the general warning and the text warnings referred to in para. (1) are to be displayed on a surface exceeding 150 cm^2, the warnings shall cover an area of 45 cm2.

(5) Tobacco products for smoking, others than cigarettes, roll-you-own tobacco and waterpipe tobacco, which do not fall into the categories of products set forth in para. (1), as well as cigarillos and pipe tobacco, shall carry on each unit packet and any outside packaging, the health warnings referred to in Art. 9 and 10.

(6) The rule for the implementation of this Article shall be approved by order the Minister of Health, published in the Official Gazette of Romania, Part I, with the approval of the minister of public finance, within 45 days of the entry into force of this Law.

(7) Changes to the text health warning referred to in para. (1), adopted by means of delegated acts of the European Commission, shall be implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

Art. 12. – Labeling of smokeless tobacco products

(1) Each unit packet and any outside packaging for smokeless tobacco products shall carry the following health warning: *This tobacco product damages your health and is addictive.*

(2) The health warning set forth in para. (1) shall be reproduced in compliance with the technical features mentioned in Art. 9 para. (8).

(3) The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings.

(4) The warning shall appear on the two largest surfaces of the unit packet and any outside packaging and shall cover 30% of the surfaces of the unit packet and any outside packaging.

(5) Changes to the text health warning mentioned in para. (1), adopted by means of delegated acts of the European Commission, shall be implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

Art. 13. – Presentation of tobacco products

(1) The labeling of unit packets and any outside packaging and the tobacco product itself shall not include any feature or element that:

a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions. Labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product;

b) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke, or has vitalizing, energizing, healing, rejuvenating, natural, organic or other health or lifestyle benefits;

c) refers to taste, smell, flavorings, or other additives in the absence thereof;

d) resembles a food or a cosmetic product;

e) suggests that a particular tobacco product has improved biodegradability or other environmental advantages.

(2) The unit packet and any outside packaging shall not suggest economic advantages by including coupons, discount offers, free distribution, “two-for-one” offers or other similar offers.

(3) The elements and features that are prohibited pursuant to paras. (1) and (2) may include, but are not limited to texts, symbols, names, trademarks, figurative signs or other signs.

Art. 14. – Appearance and content of tobacco unit packets

(1) A unit packet of cigarettes shall have a cuboid shape and include at no less than 20 cigarettes.

(2) A unit packet of roll-your-own tobacco shall have a cuboid or cylindrical shape or the form of a pouch and shall contain no less than 30 g of tobacco.

(3) A unit packet of cigarettes may consist of carton or soft material and does not have an opening that can be reclosed or resealed after its first opening, other than the flip-top lid and boxes with lateral hinged lid. For packets with a flip-top or hinged lid, the lid shall be hinged only at the back of the unit packet.

Art. 15. – Traceability

(1) Unit packets of tobacco products placed on the market shall be marked with a unique identifier. In order to ensure the integrity of the unique identifier, it shall be printed or irremovably affixed, indelible and not hidden or interrupted in any form, including through tax stamps for marking processed tobacco products set forth in Law No. 227/2015, with subsequent amendments and completions, or price labels or by the opening of the unit packet.

(2) In the case of tobacco products that are manufactured outside of the European Union, obligations set forth in this Article shall apply only to those destined for, or placed on the market in Romania.

(3) The unique identifier shall allow the following to be determined:

a) the date and place of manufacture;

b) the manufacturing facility;

c) the machinery used to manufacture the tobacco products;

d) the production shift or time of manufacture;

e) the product description;

f) the intended market of retail sale;

g) the intended shipping route;

h) where applicable, the importer into the European Union;

i) the actual shipping route from the manufacturing facility to the first retail outlet including all warehouses used, as well as shipping dates, and destination, point of departure and consignee;

j) the identity of all purchasers from manufacturing to the first retail outlet; and

k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

(4) The information under para. (3) lets. a) – g) and, where applicable, let. h), shall form part of the unique identifier.

(5) The information under para. (3) lets. i) – k) shall be electronically accessible by means of a link to the unique identifier.

(6) The procedure for the implementation of the provisions in para. (5) shall be established by order of the president of the National Agency for Fiscal Administration [Agenţia Naţională de Administrare Fiscală (ANAF)], published in the Official Gazette of Romania, Part I, within six months from when the European Commission, identifies a solution for the implementation of the provisions on the traceability of tobacco product and security features.

(7) All economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator, before the first retail outlet, shall have an obligation to record the entry of all unit packets in their possession, as well as the intermediate movements and the final exit of the unit packets from their possession. This obligation may be complied with by marking and recording of aggregated packaging such as cartons, master cases or palettes provided that the tracking and tracing of all unit packets remains possible.

(8) All natural or legal persons involved in the supply chain of tobacco products shall have an obligation to maintain complete and accurate records of all relevant transactions.

(9) The manufacturers of tobacco products, shall have an obligation to provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies, with equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. That equipment shall be able to read and transmit the recorded data electronically to a data storage facility pursuant to para. (10).

(10) The manufacturers and importers of tobacco products shall have the obligation to conclude data storage contracts with independent third parties for the purpose of hosting the data storage facility for all relevant data.

(11) The data storage facility mentioned in para. (10) shall be physically located on the territory of the European Union. The suitability of the third party, in particular its independence and technical capacities, as well as the data storage contract shall be approved by the European Commission. The third party's activities shall be monitored by an external auditor who is proposed and paid by the tobacco product manufacturer and authorized by the European Commission. The external auditor shall present a yearly report to the National Agency for Tax Administration and the European Commission, assessing in particular any irregularities concerning access. The European Commission, the National Agency for Tax Administration and the external auditor shall have full access to the data storage facility. In duly justified cases, and in cases recommended by the European Commission, the National Agency for Tax Administration may grant manufacturers or importers access to the stored data, provided that commercially sensitive data remain adequately protected in conformity with EU and national law.

(12) Recorded data shall not be modified or deleted by any economic operator involved in the trade of tobacco products.

(13) Personal data shall be processed in accordance with the provisions of Law No. 677/2001 on the protection of individuals with regard to the processing of personal data and free movement of such data, published in the Official Gazette of Romania, Part I, No. 790 of 12 December 2001, with subsequent amendments and completions, as well as subsequent normative acts.

(14) The implementing acts adopted by the European Commission, approved by joint order of the minister of Economy, Trade, Industry and the Business Environment and of the president of the National Agency for Tax Administration, published in the Official Gazette of Romania, Part I, within 60 days of their publication in the Official Journal of the European Union, shall determine:

a) the technical standards for the establishment and the operation of the tracking and tracing system as set forth in this Article, including the marking with a unique identifier, recording, transmitting, processing and storing of data and access to stored data;

b) the technical standards that ensure that the systems used for the unique identifier and the related functions are fully compatible with each other throughout the EU territory.

(15) Defining the key elements of the data storage contracts set forth in para. (10), such as duration, renewability, expertise required, or confidentiality, including regular monitoring and assessing of those contracts, adopted by means of delegated acts by the European Commission, shall be implemented by order of the president of the National Agency for Tax Administration, published in the Official Gazette of Romania, Part I, within 60 days of their publication in the Official Journal of the European Union.

(16) The provisions in paras. (1) – (13) shall apply to cigarettes and roll-you-own tobacco from 20 May 2019, and to tobacco products other than cigarettes and roll-you-own tobacco, from 20 May 2024.

Art. 16. – Security feature

(1) In addition to the unique identifier set forth in Art. 15, all unit packets of tobacco products, which are placed on the market, shall carry a tamper proof security feature, composed of visible and invisible elements.

(2) The security feature is contained within the stamp for processed tobacco products, set forth in Law No. 227/2015, with subsequent amendments and completions, and produced by Compania Naţională „Imprimeria Naţională” – S.A. [Autonomous Public Service Undertaking “National Printing House”], in accordance with Art. 6 let. A.b) of the Annex to the Government Emergency Ordinance No. 199/2000 on the establishment of the Compania Naţională

„Imprimeria Naţională” – S.A. [Autonomous Public Service Undertaking “National Printing House”], published in the Official Gazette of Romania, Part I, No. 581 of 20 November 2000, approved with amendments by Law No. 402/2001, with subsequent amendments and completions, which shall be irremovably affixed, indelible and not hidden or interrupted in any form, including price labels or by any other elements imposed by law.

(3) The stamps for the marking of processed tobacco products provided for in Law No. 227/2015, with subsequent amendments and completions, and produced by Compania Naţională „Imprimeria Naţională” – S.A. shall fulfill all the functions and technical standards set forth in this Article for the security element.

(4) The technical standards for the security feature, their possible rotation and adaptation to scientific, technical and market developments, adopted be means of implementing acts by the European Commission, shall be approved by order of the minister of Public Finance, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

(5) The provisions in para. (1) shall apply to cigarettes and roll-you-own tobacco from 20 May 2019, and to tobacco products other than cigarettes and roll-you-own tobacco, from 20 May 2024.

CHAPTER IV
Tobacco for oral use, cross-border distance sales of tobacco products and novel tobacco products

Art. 17. – Tobacco for oral use

The placing on the market of tobacco for oral use is prohibited.

Art. 18. – Cross-border distance sales of tobacco products, electronic cigarettes and refill containers

(1) Cross-border distance sales of tobacco products, electronic cigarettes and refill containers to consumers in Romania are prohibited.

(2) The National Agency for Tax Administration cooperates with competent authorities in Member States and third States in order to prevent cross-border distance sales of tobacco products, electronic cigarettes and refill containers.

(3) Retail outlets in Romania that engage in cross-border distance sales of tobacco products, electronic cigarettes and refill containers may not supply such products to consumers in Member States where such sales have been prohibited.

(4) Retail outlets in Romania that intend to engage in cross-border distance sales to consumers located in Member States which do not prohibit such sales, shall register with the National Agency for Tax Administration and the competent authorities in the Member States where the actual or potential consumers are located.

(5) When registering pursuant to para. (4), retail outlets shall submit to the competent authorities at least the following information:

a) name or corporate name and permanent address of the place of activity from where the tobacco products, electronic cigarettes and refill containers will be supplied;

b) the starting date of the activity of offering tobacco products, electronic cigarettes and refill containers for cross-border sales by means of information society services;

c) the address of the website used for that purpose and any relevant information necessary to identify the respective page or pages.

(6) The National Agency for Tax Administration shall make available to consumers, on the official website, a list of all retail outlets registered in Romania that engage in cross-border distance sales of tobacco products, electronic cigarettes and refill containers to Member States which do not prohibit such sales, in accordance with the provisions and safeguards laid down in Law No. 677/2001, with subsequent amendments and completions.

(7) Retail outlets in Romania may start placing on the market tobacco products, electronic cigarettes and refill containers in Member States by means of cross-border distance sales when they have received confirmation of their registration with the competent national authorities in those Member States.

(8) The supplying retail outlet, in Romania, shall designate a natural person to be responsible for verifying that the tobacco products, electronic cigarettes and refill containers sold via cross-border distance sales comply with national provisions adopted pursuant to Directive 2014/40/EU in the Member State of destination, before they reach the consumer.

(9) Paragraph (8) is applicable when such verification is necessary in order to ensure compliance and adequate implementation of the provisions of Directive 2014/40/EU, and the measure is requested by the Member State of destination.

(10) Retail outlets in Romania engaged in cross-border distance sales have the obligation to use an age verification system, which verifies at the time of sale, that the purchasing consumer complies with the minimum age requirement laid down under the national law of the Member State of destination.

(11) The retail outlet in Romania or the natural person designated under para. (8) has the obligation to submit to the competent authorities of the Member State of destination a description of the details and functioning of the age verification system.

(12) The retail outlets in Romania engaged in cross-border distance sales, shall process personal data of the consumer in accordance with Law No. 677/2001, with subsequent amendments and completions.

(13) Personal data laid down in para. (12) shall not be disclosed to the manufacturer of tobacco products, electronic cigarettes and refill containers or companies forming part of the same group of companies or any other third parties and shall not be used or transferred for purposes other than the actual purchase.

(14) The provisions under para. (13) shall apply also when the retail outlet is part of a manufacturer of tobacco products, electronic cigarettes and refill containers.

(15) The legal persons which ensure the cross-border transport of the goods have the obligation to take measures to prevent the transport of tobacco products, electronic cigarettes and refill containers to consumers in Romania.

(16) The measures set forth in para. (15) shall be approved by Government Resolution, published in the Official Gazette of Romania, Part I, within 60 days of the entry into force of this law.

Art. 19. – Notification of novel tobacco products

(1) Manufacturers and importers of novel tobacco products shall notify the Ministry of Health of any such novel tobacco products which they intend to place on the market in Romania.

(2) The notification set forth in para. (1) shall be submitted electronically no later than six months before the intended placing on the market.

(3) The notification set forth in para. (1) shall contain the following types of information:

a) detailed description of the novel tobacco product;

b) instructions concerning the use of the novel tobacco product;

c) information regarding ingredients and emissions in accordance with Art 5;

d) available scientific studies on toxicity, addictiveness and attractiveness of the novel tobacco product, in particular with regard to its ingredients and emissions;

e) studies, summaries thereof and available market research on preferences of various consumer groups, including young people and current smokers;

f) other relevant and available information including a risk/benefit analysis for the product, its expected effects on cessation of tobacco consumption, its expected effects on initiation of tobacco consumption and anticipated consumer perception.

(4) The manufacturers and importers of novel tobacco products shall transmit to the Ministry of Health any new or updated information on the studies, research and other information set forth in para. (3) lets. d) – f).

(5) The Ministry of Health may require that manufacturers and importers of novel tobacco products carry out additional tests or submit additional information.

(6) The Ministry of Health shall transmit to the European Commission all information received pursuant to this article.

(7) The placing on the market of novel tobacco products which do not comply with the requirements under the present Law is prohibited.

(8) Determining which of the provisions of this Law, apply to novel tobacco products, depends on whether those products fall under the definition of smokeless tobacco product or of a tobacco product for smoking.

CHAPTER V
Electronic cigarettes and herbal products for smoking

Art. 20. – Electronic cigarettes

(1) The placing on the market of electronic cigarettes and refill containers which do not comply with the provisions of this Law and other relevant dispositions in EU legislation, is prohibited.

(2) The provisions referred to in para. (1) shall not apply to electronic cigarettes and refill containers to the extent they fulfill the conditions for authorization as medication/medical devices under Title XVIII of Law No. 95/2006 on the health system reform, re-published in the Official Gazette of Romania, Part I, No. 652 of 28 August 2015, with subsequent amendments and completions, or the Government Resolution No. 54/2009 on the placing on the market of medical devices, published in the Official Gazette of Romania, Part I, No. 94 of 17 February 2009, with subsequent amendments

(3) Manufacturers and importers of electronic cigarettes and refill containers shall notify to the Ministry of Health of any such product which they intend to place on the market.

(4) The notification under para. (3) shall be transmitted electronically:

a) within six months of the date of the placing on the market;

b) until 20 November 2016, in the case of electronic cigarettes and refill containers already placed on the market at that date;

c) whenever there is a substantial modification of the product.

(5) Depending on the category of products, whether the product is an electronic cigarette or a refill container, the notification set forth in para. (3) shall contain the following information:

a) the name and contact information of the manufacturer, a responsible legal or natural person within the EU and, if applicable, the importer in the EU;

b) a list of all the ingredients contained in, and emissions resulting from the use of the product, by brand name and type, including quantities thereof;

c) toxicological data regarding the product's ingredients and emissions, including situations when the ingredients are heated, referring in particular to their effects on the health of the consumer when inhaled, and taking into account, inter alia, any possible addiction effect;

d) information on the nicotine doses and the nicotine uptake when consumed under normal or reasonably foreseeable conditions;

e) a description of the components of the product, including, where applicable, the opening and refill mechanism of the electronic cigarette and refill containers;

f) a description of the production process including whether it involves series production, and a declaration that the production process ensures conformity with the requirements set forth in this Article;

g) a declaration that the manufacturer and importer of the electronic cigarettes and refill containers bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

(6) Where the Ministry of Health considers that, the information submitted pursuant to para. (5) is incomplete, it shall request manufacturers and importers of electronic cigarettes and refill containers the completion of the information concerned within a timeframe established by order of the Minister of Health set forth in para. (25).

(7) Manufacturers and importers of electronic cigarettes and refill containers shall specify when submitting information set forth in la para. (5) and (6), which information they consider to constitute trade secrets.

(8) The Ministry of Health shall apply necessary legal measures to ensure the confidentiality of the information specified to constitute trade secrets, by the manufacturers and importers of electronic cigarettes and refill containers and of those deemed to be confidential information according to legal provisions.

(9)The Ministry of Health shall charge manufacturers and importers of electronic cigarettes and refill containers proportionate fees for receiving, storing processing and analyzing information submitted pursuant to this Article.

(10) The amount and procedure for levying the fees pursuant to para. (9) shall be approved by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the entry into force of this Law.

(11) Electronic cigarettes and refill containers must comply with the following requirements upon their placing on the market:

a) the nicotine containing liquids placed on the market only in dedicated refill containers, not exceeding a volume of 10 ml, in disposable electronic cigarettes or single-use cartridges, and the maximum volume of the cartridges and refill containers not exceeding 2 ml;

b) the nicotine containing liquid does not contain nicotine in excess of 20 mg/ml;

c) the nicotine containing liquid does not contain the additives mentioned in Art. 7 para. (8);

d) only high purity ingredients are used in the manufacture of nicotine containing liquids. Substances other than those set forth in para. (5) let. b) are present only at trace level, if such traces are technically unavoidable during the manufacturing process;

e) except for nicotine, only ingredients are used in nicotine containing liquids that do not pose a risk to human health, whether heated or unheated;

f) electronic cigarettes deliver uniform doses of nicotine under normal conditions of use;

g) are tamper- and child-proof;

h) are protected against breakage and leakage;

i) have a mechanism that ensures refilling without leakage;

j) unit packets of electronic cigarettes and refill containers include a leaflet containing the following information:

1. instructions for use and storage, that specify that the product is not recommended for use by young people and non-smokers;

2. contraindications;

3. warnings for specific risk groups;

4. possible adverse effects;

5. addictiveness and toxicity; and

6. contact information of the manufacturer or importer and a natural or legal contact person within the European Union;

k) unit packets and any outside packaging of electronic cigarettes and refill containers:

1. include a list of all ingredients contained in the products in descending order of the weight, and information on the nicotine content of the product and the delivery per dose, the batch number and the recommendation to keep the product out of the reach of children;

2. without prejudice to pt. 1 of this letter, do not include elements or features referred to in Art. 13, with the exception of para. (1) lets. a) and c) of Art. 13 concerning information on the nicotine content and flavorings;

3. carry the following health warning: *This product contains nicotine. Nicotine is a highly addictive substance*;

l) health warnings comply with the requirements specified in Art. 12 paras. (2) – (4).

(12) Advertising for electronic cigarettes and refill containers shall be prohibited:

a) in information society services, in the press or other printed publications, except for publications and materials intended exclusively for professionals in the trade of electronic cigarettes and refill containers and except for publications and materials which are printed and published in third countries, where those publications or materials are not principally intended for the EU market;

b) on radio channels;

c) advertising that falls under the scope of Law No. 504/2002, the Audio-visual Law, published in the Official Gazette of Romania, Part I, No. 534 of 22 July 2002, with subsequent amendments and completions;

d) in theaters, cinemas or other types of projection halls for visual materials intended for the public;

e) on billboards, awnings or any other display structure, regardless of their location or fees due.

(13) sponsorship for the promotion of electronic cigarettes or refill containers shall be prohibited:

a) public or private radio and television broadcast;

b) at any events or activities, including those that involve or take place in at least two Member States, one of which is Romania, or which have cross-border effects in any other way.

(14) Manufacturers and importers of electronic cigarettes and refill containers shall submit, yearly to the Ministry of Health, by 20 November of the current year, the following information concerning the preceding year, in electronic format:

a) data on sales volumes, by brand name and type of products;

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

c) information on the mode of sales of the products; and

d) summaries of any market research conducted in regards to the above.

(15) The Ministry of Health shall monitor the market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and a link to traditional tobacco use for young people and non-smokers.

(16) Information set forth in para. (5) and (6) which are not specified to constitute trade secrets are made available to the public by the Ministry of Health, on the official website.

(17) The Ministry of Health shall, upon request, make all information received pursuant to this Article available to the European Commission and competent authorities in other Member States, ensuring that trade secrets and other confidential information is treated confidentially, according to law.

(18) Manufacturers and importers of electronic cigarettes and refill containers establish and maintain a system of collecting information about any suspected adverse effects on human health of these products.

(19) Where any of the economic operators referred to in para. (18) consider or have reasons to assume that the electronic cigarettes and refill containers in their possession, which are intended to be placed on the market or are on the market, are not safe or of good quality, or are otherwise not in compliance with the present Law, that economic operator shall immediately take the necessary corrective action to ensure the product is brought into conformity with this Law, or, to recall it or withdraw it, as appropriate. In such case, the economic operator shall inform, without delay, the Ministry of Health and the National Authority for Consumer Protection, particularly with regard to the risks to human health and safety, and all corrective action taken, as well as to the results of such corrective action.

(20) Where the Ministry of Health or the National Authority for Consumer Protection request additional information from the economic operators, for example on the safety and quality aspects or on possible adverse effects of the electronic cigarettes and refill containers, the manufacturers and importers shall respond to such request within six months after the request is made.

(21) In the case of electronic cigarettes and refill containers that comply with the requirements of this Article, where the Ministry of Health determines or has reasonable grounds to believe that specific electronic cigarettes and refill containers could present a serious risk to human health, it may take adequate provisional measures, such as prohibiting the placing on the market of a specific electronic cigarette or refill container, or of a type of electronic cigarette or refill container. Such measures shall be notified without delay to the European Commission and competent authorities of other Member States, accompanied by all substantiating data.

(22) The Ministry of Health shall approve appropriate subsequent measures based on recommendations of the European Commission resulting from the notification referred to in para. (21).

(23) The adoption of the prohibition of placing on the market of specific electronic cigarettes or refill containers, or of a type of electronic cigarette and refill container by means of delegated acts of the European Commission shall be implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

(24) Adaptation of the text of the health warning set forth in para. (11) let. k) pt. 3, adopted by means of delegated acts of the European Commission, shall be implemented by order of the minister of health, published in the Official Gazette of Romania, Part I, within 60 days of the publication in the Official Journal of the European Union.

(25) The common format for the notification set forth in para. (3), established by means of implementing acts by the European Commission, including the time frame during which information set forth in para. (6) may be submitted, shall be approved by order of the minister of health, published in the Official Gazette of Romania, Part I, within 45 days of the entry into force of this law.

(26) The technical standards for the refill container set forth in para. (11) let. i) established by the European Commission means of implementing acts, shall apply to products placed on the market in Romania.

Art. 21. – Herbal products for smoking

(1) Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning: *Smoking this product damages your health.*

(2) The health warning shall be printed on the front and back external surface of the unit packet and on any outside packaging.

(3) The health warning shall comply with the technical features set forth in Art. 9 para. (8). The warning shall cover 30% of the area of the corresponding surface of the unit packet and of any outside packaging.

(4) Unit packets and any outside packaging of herbal products for smoking shall not include any of the elements or features set forth in Art. 13 para. (1) lets. a), b) and d) and shall not mention that the product is free of additives or flavorings.

(5) Manufacturers and importers of herbal plants for smoking submit to the Ministry of Health a list of all ingredients and quantities thereof used in the manufacture of such products, for each brand name and for each type.

(6) Whenever the composition of a product is changed in a way that affects the information provided under this Article, manufacturers and importers shall inform the Ministry of Health accordingly.

(7) Information set forth in para. (5) and (6) shall be submitted at least six months prior to the placing on the market of a novel or modified herbal product for smoking.

(8) Manufacturers and importers of herbal products for smoking shall specify when submitting information set forth in paras. (5) and (6), which information they consider to constitute trade secrets.

(9) Information submitted in accordance with paras. (5) and (6) which are not specified to constitute trade secrets shall be made publicly available by the Ministry of Health on the official website.

CHAPTER VI
Responsibilities and Penalties

Art. 22. – Responsibilities

(1) Producers and importers of tobacco and related products shall provide to the European Commission and the Ministry of Health complete and correct information as requested pursuant to this Law, within the prescribed time limit.

(2) The obligation to provide the requested information under Art. 5 para. (1) and (2), Art. 6 paras. (1), (2), (7), (8) and (9), Art. 19 paras. (1), (3), (4) and (5), Art. 20 paras. (3), (5), (6), (14), (19) and (20) and Art. 21 paras. (5) and (6) shall rest primarily with the manufacturer, if the manufacturer is established inside the EU, and primarily with the importer, if the manufacturer is established outside the EU and the importer is established inside the EU.

(3) The obligation to provide the information pursuant to para. (1) shall rest jointly with the manufacturer and the importer, if both are established outside the EU.

(4) Tobacco and related products which do not comply with this Law, including the implementing acts adopted pursuant to this Law, may not be placed on the market in Romania.

(5) Tobacco and related products which do not comply with this Law, and for which the reporting obligations provided for in Art. 5 paras. (1) and (2), Art. 6 paras. (1), (2), (7), (8) and (9), Art. 19 paras. (1), (3), (4) and (5), Art. 20 paras. (3), (5), (6), (14), (19) and (20) and Art. 21 paras. (5) and (6) are not complied with, may not be placed on the market in Romania

Art. 23. – Penalties

(1) The acts [committed] set forth in para. (2) – (7) constitute contraventions, unless the acts have been committed under conditions such as to be considered criminal offenses according to the law.

(2) Failure to comply with the provisions in Art. 3 para. (1), Art. 4 paras. (1) – (3), Art. 5 paras. (1) and (3), Art. 6 paras. (1), (4), (7) and (8), Art. 7 paras. (1), (8) and (10), Art. 8, Art. 9 paras. (1) – (8) and (10), Art. 10 paras. (1) – (3) and (5), Art. 11 paras. (1) – (5), Art. 12 paras. (1) – (4), Art. 13 paras. (1) and (2), Art. 14, Art. 15 paras. (1), (3), (7) – (10) and (12), Art. 16 paras. (1) and (2), Art. 17, Art. 18 paras.(3) – (5), (7), (8), (10) and (11), Art. 19 paras. (1) – (4) and (7), Art. 20 paras. (1), (3) – (5), (11) – (14) and (19), Art. 21 paras. (1) – (7), Art. 22 para. (4) constitute a violation and shall be sanctioned with a fine from 75.000 lei to 100.000 lei.

(3) Failure to comply with the provisions in Art. 5 para. (2), Art. 6 para. (9), Art. 19 para. (5) and Art. 20 paras. (6), (18) and (20) constitute a violation and shall be sanctioned with a fine from 50.000 lei to 100.000 lei.

(4) Failure to comply with the provisions in Art. 3 para. (1) shall be sanctioned with the supplementary measures of the suspension of production activity and marketing of non-compliant products, until the situation that led to the suspension of production activity and the prohibition of the marketing of non-compliant products, is remedied

(5) Failure to comply with the provisions in Art. 7 paras. (1), (8) and (10), Art. 17, Art. 19 paras. (1) – (4) and (7) and Art. 20 paras. (1) – (5), (11) and (14) shall be sanctioned with the supplementary measures of the prohibition of the marketing of non-compliant products.

(6) Failure to comply with the provisions in Art. 4 paras. (1) – (3), Art. 5 paras. (1) – (3), Art. 6 paras. (1) and (8), Art. 8, Art. 9 paras. (1) – (8) and (10), Art. 10 paras. (1) – (3) and (5), Art. 11 paras. (1) – (5), Art. 12 paras. (1) – (4), Art. 13 paras. (1) and (2), Art. 14, Art. 15 paras. (1), (3), (7) – (9) and (12), Art. 16 paras. (1) and (2), Art. 18 paras. (3) – (5), (7) and (10) and Art. 21 paras. (1) – (7) shall be sanctioned with the supplementary measures of the suspension of marketing activity of non-compliant products, until the situation that led to the suspension of activity is remedied .

(7) Failure of the carrier to comply with the provisions in Art. 18 para. (15) constitutes contravention and shall be sanctioned with a fine equal to the excise duties due to the state budget.

(8) The imposition of sanctions under this Law shall not exempt offenders from disciplinary liability.

(9) The offender may pay on the spot, or no later than 48 hours from the date the order to pay a fine was drawn up, or where applicable, from the date of the communication of such order, half of the minimum fine provided for in this Article, a remark to that effect being made by the official in the report.

(10) The establishment and sanctioning of contraventions shall be made on the basis of individual qualifications by persons authorized to do so by:

a) the Ministry of Health, for failure to comply with the provisions in Art. 3 para. (1), Art. 4 paras. (1) – (3), Art. 5 paras. (1) – (3), Art. 6 paras. (1), (4) and (7) – (9), Art. 7 paras. (1), (8) and (10), Art. 19 paras. (1) – (5) and (7), Art. 20 paras. (1), (3) – (6), (11) lets. a) – f), (14) and (18) – (20) and Art. 21 paras. (5) – (7);

b) the National Authority for Consumer Protection, for failure to comply with the provisions in Art. 8, Art. 9 paras. (1) – (8) and (10), Art. 10 paras. (1) –(3) and (5), Art. 11 paras. (1) – (5), Art. 12 paras. (1) – (4), Art. 13 paras. (1) and (2), Art. 14, Art. 17, Art. 20 paras. (11) lit. g) – l), (12), (13), (19) and (20), Art. 21 paras. (1) – (4) and Art. 22 para. (4);

c) National Agency for Tax Administration, for failure to comply with the provisions Art. 15 paras. (1), (3), (7) – (10) and (12), Art. 16 paras. (1) and (2), Art. 18 paras. (3) – (5), (7), (8), (10), (11) and (15).

(11) The provisions concerning the establishment and sanctioning of contraventions in this Law as amended by the provisions of Government Ordinance No. 2/2001 on the legal regime of contraventions, approved with amendments and completions by Law No. 180/2002.

(12) The Ministry of Health, the National Agency for Consumer Protection and the National Agency for Fiscal Administration shall cooperate with each other and with the competent authorities in other Member States and with the European Commission to ensure the correct application and due enforcement of this Law and shall transmit to each other, to this end, all necessary information.

CHAPTER VII
Transitional and final provisions

Art. 24. – Free circulation

(1) With the exception of the provisions in para. (2), for considerations relating to aspects regulated by Directive No. 2014/40/EU of the European Parliament and of the Council of April 3, 2014, on the approximation, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, the placing on the market of tobacco or related products which comply with this Directive may not be prohibited or restricted.

(2) The regulations applicable to all tobacco and related products placed on the market in Romania, concerning the standardization of the packaging of tobacco products, where it is justified on grounds of public health, the prohibition of certain categories of tobacco or related products in Romania, provided that the prohibition is justified by the necessity to protect human health, taking into account the high level of human health achieved through this Law, shall be approved by Government resolution and shall be published in the Official Gazette of Romania, Part I. These regulations must be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction of trade between Member States.

(3) The regulations provided for in (2) shall be notified to the European Commission prior to their adoption, by the Minister of Economy, Trade, Industry and the Business Environment, together with the grounds for introducing them.

(4) The measures for prohibition set forth in la para. (2) shall be notified to the European Commission by the Ministry of Health, together with the grounds for introducing them.

(5) Depending on the decision by the European Commission, the Ministry of Health shall apply appropriate measures, by order of the minister of health, that shall enter into force within 12 months of the publishing in the Official Gazette of Romania, Part I.

(6) In the absence of a decision of the European Commission within six months of the date of receiving the notification by the European Commission, the measures for prohibition provided for in para. (2) shall deemed to be approved and shall enter into force no later than 12 months from the expiry of the above period.

Art. 25. – Competent authorities

(1) The Ministry of Health shall notify to the European Commission, by the date of the entry into force of the present Law, the competent authorities responsible for the implementation and enforcement of the provisions of this Law.

(2) The Ministry of Health and National Agency for Tax Administration shall submit to the European Commission all available information for preparing the report set forth in Art. 28 (1) in Directive 2014/40/EU.

Art. 26. – The structure of the excise duty applied to tobacco and related products is regulated by Law No. 227/2015, with subsequent amendments and completions.

Art. 27. – Entry into force

(1) This law shall enter into force within 30 days of its publication in the Official Gazette of Romania, Part I, with the exception of Art. 7 para. (20), Art. 10 para. (4), Art. 15 para. (16) and Art. 16 para. (5).

(2) The placing on the market of the following products which are not in compliance with this Law is allowed until 20 May 2017:

a) tobacco products manufactured or released for free circulation and labeled in accordance with Law No. 349/2002 on preventing the consumption of tobacco products and combating its effects, with subsequent amendments and completions, before the date of entry into force of this Law;

b) electronic cigarettes or refill containers manufactured or released for free circulation before 20 November 2016;

c) herbal products for smoking manufactured or released for free circulation before the entry into force of this Law.

(3) the provisions in Art. 23 para. (7) shall apply on the date of entry

into force of the Government Resolution provided for in Art. 18 para. (16).

Art. 28. – Annexes I-III constitute an integral part of this Law.

Art. I. – Law No. 349/2002 on preventing the consumption of tobacco products and combating its effects, published in the Official Gazette of Romania, Part I, No. 435 of 21 June 2002, with subsequent amendments and completions, shall be amended as follows:

Article 1 shall be amended to read as follows:

„Art. 1. – This Law sets forth some measures on preventing the consumption of tobacco products and combating its effects, by completely prohibiting smoking in all enclosed public spaces, enclosed spaces in the workplace and playgrounds for the children, through public information and education campaigns, with the aim of protecting the health of smokers and non-smokers from the harmful effects of smoking, preventing the spreading of smoking among minors and ensuring an adequate quality of life for the population in Romania."

2. In Article 2, letters a) – d) are repealed.
3. In Article 2, letters f) – l) are repealed.
4. In Article 2, letters o) – q) are repealed.
5. In Article 3, paragraphs (8) – (10) are repealed.
6. Articles 3^1 – 3^4 are repealed.
7. Article 6 is repealed.
8. Articles 7 and 7^1 are repealed.
9. In article 10, letters c) and d) are repealed.
10. Article 11 is repealed.

11. Article 12, paragraph (1) shall be amended to read:

„Art. 12. – (1) Failure to comply with provisions in Art. 3 paras. (5^2) and (6) and Art. 4 para. (2) shall be sanctioned with removal from the market of the respective product, for destruction by competent authorities in accordance with the law."

12. Article 14[1] shall be amended to read as follows:

„Art. 14[1]. – Violations are assessed and sanctions are imposed by authorized persons from the Ministry of Health and the National Authority for Consumer Protection, with the exception of the provisions in Art. 10 let. a) and b), where violations are assessed and sanctions are imposed by representatives of the Local Police or the Ministry of Internal Affairs.

13. Article 14[2] is repealed.

14. Article 15 is repealed.

15. The Annex is repealed.

Art. II. – Within 30 days of the entry into force of this Law, the Government shall bring all its implementing acts in line with this Law.

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This Law transposes Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and marketing of tobacco and related products and repealing Directive 2001/37/EC, published in the Official Journal of the European Union series L, No. 127 of April 29, 2014 and delegated Directive No. 2014/109/EU of the Commission of 10 October 2014, on amending Annex II of Directive 2014/40/EU of the European Parliament and of the Council on the establishment of the picture library to be used on tobacco products, published in the Official Journal of the European Union series L, No. 360 of 17 December 2014.

This Law was adopted by the Romanian Parliament, in accordance with Art. 75 and Art. 76 para. (2) of the Constitution of Romania, as republished.

PRESIDENT OF THE CHAMBER OF REPRESENTATIVES	**PRESIDENT OF THE SENATE**
FLORIN IORDACHE	**CĂLIN POPESCU-TĂRICEANU**

Bucharest,
No.

ANNEX I

LIST OF TEXT WARNINGS

Smoking causes 9 out of 10 lung cancers
Smoking causes mouth and throat cancer
Smoking damages your lungs
Smoking causes heart attacks
Smoking causes strokes and disability
Smoking clogs your arteries
Smoking increases the risk of blindness
Smoking damages your teeth and gums
Smoking can kill your unborn child
Your smoke harms your children, family and friends
Smokers' children are more likely to start smoking
Quit smoking – stay alive for those close to you
Smoking reduces fertility
Smoking increases the risk of impotence