

Law on Amending and Supplementing the Law on Tobacco and Tobacco Products

**DECREE No 89**

Pursuant to art. 98, item 4 of the Constitution of the Republic of Bulgaria

I HEREBY DECREE:

To promulgate in the "Official Gazette" the Law on Amending and Supplementing the Law on Tobacco and Tobacco Products, adopted by the XLIII National Assembly on March 24, 2016.

Published in Sofia on April 6, 2016.

President of the Republic: **Rosen Plevneliev**

Stamped with the State Seal.

Minister of Justice: **Ekaterina Zaharieva**

**LAW**

**on Amending and Supplementing the Law on Tobacco and Tobacco Products** (prom. SG, issue 101 of 1993; amend., issue 19 of 1994, issue 110 of 1996, issue 153 of 1998, issue 113 of 1999, issue 33 and 102 of 2000, issue 110 of 2001, issue 20 of 2003, issue 57 and 70 of 2004, issue 91, 95, 99 and 105 of 2005, issue 18, 30, 34, 70, 80 and 108 of 2006, issue 53 and 109 of 2007, issue 36, 67 and 110 of 2008, issue 12, 82 and 95 of 2009, issue 19 of 2011, issue 50 of 2012, issue 12 and 14 of 2015, and issue 19 of 2016.)

§ 1. In the law's name the words "and tobacco" are hereby replaced with "tobacco and related".

§ 2. In art. 1, the words "and trade in tobacco" are hereby replaced by "the presentation and sale of tobacco and related".

§ 3. Article 2 shall be amended and supplemented as follows:

1. In par. 1 the words "and tobacco" are hereby replaced by "tobacco and related".

2. In par. 3 the phrase "and the related thereto" is hereby added after the word "tobacco".

§ 4. In art. 23 the conjunction "and" is hereby replaced by a coma and the phrase "tobacco for water pipes and a new tobacco product" is hereby added.

§ 5. A new Chapter 9 "a" with art. 26a—26c is hereby created:

"Chapter 9 "a"

**NEW TOBACCO PRODUCTS**

Art. 26a. (1) Manufacturers, importers and other persons, introducing new tobacco products to Bulgaria from another EU Member State, shall notify the Ministry of Economy of each tobacco product they plan to sell in Bulgaria.

(2) The notification under par. 1 shall be given in digital form six months before the planned start of the sale of that product in Bulgaria.

(3) The notification under par. 1 shall include:

1. The Unified Identification Code [Bulgarian: EIK] of the trader, and for those, registered in another EU Member State, or in another country which has ratified the EEA Agreement—the pertinent identification code or number;

2. The address and telephone number of the manufacturer, the responsible natural or legal person on the territory of the European Union, and of the importer, when import has taken place.

(4) The notification under par. 1 shall be accompanied by:

1. A detailed description of the new tobacco product;

2. A user guide;

3. Information on the ingredients and emissions in compliance with art. 35b, par. 1-3;

4. Available scientific studies on the toxicity, addictiveness and attractiveness of the new tobacco product, particularly in respect of its ingredients and emissions;

5. The available studies, the summarised assessments of the new tobacco product and market research about the preferences of different user groups including young people and smokers;

6. Other available and relevant information, including analysis of the risks and benefits of the new tobacco product, the expected consequences of the commencement and cessation of tobacco use, and projections relating to consumer attitudes.

(5) The notification under par. 1 and its annexes shall be reviewed by officials authorised by the Minister of Economy within the 14-day period, following the date on which the notification and its annexes were submitted.

(6) In the event that the information in the notification under par. 1 and its annexes is incomplete or inaccurate, the Ministry of Economy requires that within 14 days the manufacturer, importer or the person, introducing new tobacco products to Bulgaria from another EU Member State, completes the information or removes any inaccuracies.

(7) The Ministry of Economy requires that the Ministry of Health and the Tobacco and Tobacco Products Institute submit a reasoned opinion on the new tobacco product's compliance with the legal prescriptions. Opinions must be submitted to the Ministry of Economy within the two-month period, following the date on which the request was received by the corresponding administration.

(8) If necessary, or based on the opinions under par. 7, the Ministry of Economy may require that manufacturers, importers or persons, introducing new tobacco products to Bulgaria from another EU Member State, carry out additional tests or provide additional information.

(9) Manufacturers, importers and persons, introducing new tobacco products to Bulgaria from another EU Member State, shall submit to the Ministry of Economy any new or updated information on studies, surveys and other information under par. 4, that has become known to them after the submission of the notification under par. 1.

(10) The Ministry of Economy shall provide to the European Commission all the information under par. 1-9.

Art. 26b. (1) A public register of new tobacco products shall be set up and maintained at the Ministry of Economy.

(2) All persons, who have submitted a notification about a new tobacco product, as well as information pertinent to the type and number of the submitted documents, shall be entered in a new section of said public register. Entries shall be made following the order of submission of the notifications, also noting the movement of the registration file.

Art. 26c. All new tobacco products, entering Bulgarian market, must comply with the law. Depending on the category to which the new tobacco products belong, the requirements for smokeless tobacco or tobacco products for smoking shall be complied with."

§ 6. In the title of Chapter 10 the words "and tobacco" are hereby replaced by "tobacco and related".

§ 7. Art. 30 shall be amended as follows:

1. Par. 2 shall be amended as follows:

"(2) No supply and sale of:

1. Tobacco and related products on the premises of nurseries and kindergartens, schools, student dormitories, hospitals, health centres and their surrounding areas;
2. Tobacco and related products at sports events and social events, intended for children and students;
3. Tobacco and related products to and by persons under 18 years of age;
4. Tobacco and related products whose unit packet has been tempered with, except for the sale of hand-rolled cigars;
5. Tobacco and related products without purchase invoice (delivery invoice) for selling tobacco or related products;
6. Tobacco and related products with damages and defects detrimental to their consumer properties;
7. Tobacco and related products without specified on the packaging mandatory elements to inform consumers in Bulgarian and encoding of the corresponding manufacturer product;
8. Tobacco and related products without announcing their prices where customers can clearly see them, and in a manner, suitable for proper comprehension;
9. Tobacco products in bulk or in individual units and pieces out of open packages, except for the sale of hand-rolled cigars;
10. Tobacco and related products from vending machines for tobacco and tobacco-related products and at self-service stands, except for duty-free shops;
11. Cigarettes not complying with the requirements of art. 35 a, par. 1;
12. Liquids, containing nicotine, and not compliant with the requirements of art. 43e;
13. Tobacco and related products in unit packets, not complying with the labelling and packaging requirements;
14. Tobacco products on the packages of which there are texts, names, trademarks and figurative or other signs that mislead that a product is less harmful;
15. Unit packets, containing fewer than 20 cigarettes;
16. Unit packets of roll-your-own tobacco, containing less than 30 grams of tobacco;
17. Tobacco products, containing:
  - a) vitamins or other additives, misleading that the tobacco product is beneficial to the health or that it is less harmful;
  - b) caffeine, taurine, or other additives and stimulant compounds that are associated with energy and vitality;
  - c) additives, colouring the emissions;
  - d) additives, facilitating inhalation or absorption of nicotine;
  - e) additives, characterised by properties that are carcinogenic, mutagenic and toxic to reproduction (CMTR properties) in unburned form;
18. Cigarettes and roll-your-own tobacco:
  - a) With characteristic flavours;
  - b) Containing flavourings in any of their components such as filters, paper, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or of their smoke intensity; filters, papers and capsules shall not contain tobacco or nicotine;
19. Tobacco and related products containing plants and substances prohibited by the Narcotic Substances and Precursors Control Act."

2. Paragraph 3 is hereby repealed.

§ 8. New art. 31 and art. 31 a are hereby created:

"Art. 31. It is prohibited to sell in Bulgaria tobacco for oral use.

Art. 31 a. Cross-border distance selling, as well as the supply and sale of tobacco and related products through the services of the information society is prohibited."

§ 9. Article 32 shall be amended as follows:

"Art. 32. (1) The legal compliance of the import of tobacco and related products shall be supervised by the relevant authorities designated in the corresponding Regulation for the implementation of the law.

(2) Tobacco and related products that are offered and sold in duty-free shops under the Duty-Free Trade Act must meet the requirements of this law."

§ 10. Article 35 shall be amended and supplemented as follows:

1. In par. 1:

- a) in the text preceding item 1, the words "and tobacco" are hereby replaced by "tobacco and related";
- b) in item 1 the words "or tobacco" are hereby replaced by "tobacco or related" and the words "and tobacco" are hereby replaced by "tobacco and related";
- c) the text "by other external characteristics of the advertising image with specific or special distinctiveness, recognisable mainly or solely by persons under 18 years of age" is hereby added at the end of item 2.

2. In par. 2 the words "and tobacco" are hereby replaced by "tobacco and related".

3. In par. 3:

- a) In the text preceding item 1, the words "and tobacco" are hereby replaced by "tobacco and related";
- b) In item 1 all occurrences of the words "and tobacco" are hereby replaced by "tobacco products, electronic cigarettes and refillable containers".

4. In par. 4 and 5 the words "and tobacco" are hereby replaced by "tobacco and related".

5. A new par. 7 is hereby added:

"(7) Audiovisual commercial messages about electronic cigarettes and refillable containers are prohibited. Such messages shall be treated according to the Law on Radio and Television."

§ 11. The name of Chapter 10 "a" is hereby amended as follows: "Ingredients and emissions".

§ 12. Article 35a is hereby amended as follows:

"Art. 35a. (1) The maximum level of emissions from cigarettes manufactured and/or sold in Bulgaria must not exceed:

1. 10 mg of tar per cigarette;
2. 1 mg of nicotine per cigarette;
3. 10 mg of carbon monoxide per cigarette.

(2) The content of tar, nicotine and carbon monoxide in cigarette emissions shall be measured on the basis of standard ISO 4387—for tar, standard ISO 10315—for nicotine, and standard ISO 8454—for carbon monoxide. The accuracy of the measurements of tar, nicotine and carbon monoxide shall be determined in accordance with standard ISO 8243.

(3) The measurements under par. 2 shall be verified by a laboratory accredited by the Executive Agency "Bulgarian Accreditation Service" under the direction of the Minister of Economy or by laboratories accredited by the competent authority of another EU Member State.

(4) The laboratories under par. 3 shall not be owned or controlled directly or indirectly by manufacturers of tobacco products.

(5) Executive Agency "Bulgarian Accreditation Service" shall submit to the European Commission the list of its accredited laboratories under par. 3, specifying the approval criteria and monitoring methods. The list shall be updated with each new change."

§ 13. Article 35b is hereby amended as follows:

"Art. 35b. (1) 9) Manufacturers, importers and persons, introducing tobacco products to Bulgaria from another EU Member State, shall submit to the Tobacco and Tobacco Products Institute:

1. A list of all ingredients used in the manufacture of tobacco products and their quantity (listed in descending weight order for each ingredient included in the product)—for every brand and type of tobacco product; The list shall be accompanied by:

a) a statement about the reasons for the inclusion of these ingredients in the manufactured tobacco products;

b) the status of the ingredients, including whether the ingredients 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, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Regulation (EEC) No 793/93 of the Council and Regulation (EC) No 1488/94 of the Commission, as well as Directive 76/769/EEC of the Council and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission;

c) classification of the ingredients under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OB, L 353/1 of 31 December 2008);

d) toxicological data on ingredients in burnt or unburnt form, including their impact on consumer health, taking into account all addictive properties;

2. The level of emissions under art. 35 a par. 1;

3. Information on other emissions and their content in the case when they have such information;

4. Information on all methods used to measure emissions of tobacco products.

(2) Manufacturers, importers and persons, introducing cigarettes and roll-your-own tobacco to Bulgaria from another EU Member State, in addition to the information under par. 1, shall submit to the Tobacco and Tobacco Products Institute:

1. A technical description of the additives used and their properties;

2. Information about additives included in the Priority Additives List; the latter shall be specified in the Regulation for the implementation of the law.

(3) Manufacturers, importers and persons, introducing tobacco products to Bulgaria from another EU Member State, shall notify the Tobacco and Tobacco Products Institute if the content of a certain product has been altered with respect to the data and information under par. 1 and 2:

(4) Before the introduction of new and/or modified tobacco products, the manufacturers, importers and persons, introducing tobacco products to Bulgaria from another EU Member State, shall provide the data and the information under par. 1 and 2 for the corresponding products.

(5) The data and information under par. 1 and 2 are provided in digital form under the terms and conditions set out in the Regulation for the implementation of the law.

(6) Upon submission of the data and information under par. 1 and 2, the manufacturers, importers and persons, introducing tobacco products to Bulgaria from another EU Member State, indicate which part of those products they consider the subject of a trade secret.

(7) The Tobacco and Tobacco Products Institute:

1. Shall store the data and information under par. 1 and 2 in digital form and provides access to the information for the European Commission and the other EU Member States for the purposes of law enforcement and 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 sale of tobacco and related products and repealing Directive 2001/37/EC (OJ, L 127/1 of 29 April 2014);

2. Shall publish on its website the data and information under par. 1 and 2, with the exception of the data and information that constitute a trade secret;

3. Shall take appropriate technical and organisational measures to protect the processing of data and information representing trade or other secrets protected by law;

4. Shall notify the European Commission of any maximum level of emissions, determined for emissions from cigarettes other than the emissions under art. 35 a, par. 1 and the emissions from tobacco products other than cigarettes;

5. Shall notify the European Commission of any measurement methods used for emissions from cigarettes other than the emissions under art. 35 a, par. 1, as well as of any emissions from tobacco products other than cigarettes;

6. Shall propose to the Ministry of Economy (based on scientific evidence) to introduce a ban on the marketing of tobacco products that contain additives in quantities that at the time of consumption increase significantly or to a measurable degree the toxic effect, the addictive properties or the CMTR properties of the tobacco product;

7. May require that manufacturers, importers and persons, introducing new tobacco products to Bulgaria from another EU Member State, conduct additional studies to evaluate the effects of the ingredients on the health of consumers, taking into account the addictiveness and toxicity of said products.

(8) The employees, processing and storing the data and information under par. 7, item 1, are obliged not to disclose the information and facts that become known to them in the execution of their duties, except where provided for by law or by written request of a state body.

(9) In the event of a ban under par. 7, item 6, the Ministry of Economy shall notify the European Commission."

§ 14. Article 35c is hereby amended as follows:

"Art. 35c. (1) Manufacturers, importers and persons, introducing cigarettes and roll-your-own tobacco to Bulgaria from another EU Member State, shall carry out in-depth studies of their proposed products containing an additive included in the Priority List under art. 35b, par. 2, item 2. These studies shall aim to determine whether said additive:

1. Contributes to the toxicity of the corresponding products, enhances their addictiveness or leads to a significant or measurable increase in toxicity, or the danger of addiction to any of the products;

2. Adds characteristic flavours;

3. Facilitates inhalation or absorption of nicotine or

4. Leads to the formation of substances with CMTR properties, [increases] their amount or leads to a significant or measurable increase of the CMTR properties of any of the corresponding products.

(2) Studies under par. 1 must take into account the intended use of the products and in particular must assess the emissions resulting from the combustion process, including the additive under par. 1. The studies must also evaluate the interaction of the additive under par. 1 with other ingredients of the corresponding products. Manufacturers, importers and persons, introducing cigarettes and roll-your-own tobacco (containing the same additive) to Bulgaria from another EU Member State, may carry out a joint study when using the same additive in the composition of comparable tobacco products.

(3) Manufacturers, importers and persons, introducing cigarettes and roll-your-own tobacco to Bulgaria from another EU Member State, shall prepare a report on the results of the studies under par. 1. The report shall include a summary evaluation and comprehensive review of the studies and indicate the available scientific literature on the additive under par. 1 and summarise the data on its impact.

(4) Manufacturers, importers and persons, introducing cigarettes and roll-your-own tobacco to Bulgaria from another EU Member State, shall send the report under par. 3 to the European Commission, and provide a copy to the Tobacco and Tobacco Products Institute not later than 18 months after the inclusion of the additive under par. 1 in the Priority List under art. 35b, par. 2, item 2.

(5) Where the European Commission and/or the Tobacco and Tobacco Products Institute have requested additional information on the additive under par. 1, this information shall be included in the report under par. 3.

(6) The Tobacco and Tobacco Products Institute shall review the reports under par. 3 on their completeness, methodology and conclusions."

§ 15. Article 35d is hereby amended as follows:

"Art. 35d, art. 35b, par. 2, item 2 and art. 35c shall not apply to small and medium enterprises under the Law for SMEs when another manufacturer, importer or person, introducing tobacco products to Bulgaria from another EU Member State, has submitted a report under art. 35c, par. 3."

§ 16. A new art. 35e is hereby added to Chapter 10 "a":

"Art. 35e. (1) 9) Manufacturers, importers and persons, introducing tobacco products to Bulgaria from another EU Member State, shall submit in digital form to the Tobacco and Tobacco Products Institute:

1. Their own and other available studies, related to market research and to the preferences of different consumer groups (including young people and smokers) on ingredients and emissions;

2. Summary evaluations of market studies carried out – relating to the sale in Bulgaria of new tobacco products;

3. Information about the sales volume of tobacco products by brand name and type, in pieces or in kilograms, and by EU Member State, on an annual basis since January 1, 2015.

(6) Upon submission of the data and information under par. 1, the manufacturers, importers and persons, introducing tobacco products to Bulgaria from another EU Member State, shall indicate which part of the data and information they consider the subject of a trade secret.

(3) The National Revenue Agency and/or the National Customs Agency shall provide to the Tobacco and Tobacco Products Institute the data on the sales volume that it has.

(4) The Tobacco and Tobacco Products Institute shall store the data and information under par. 1 and 3 in digital form and shall provide access to it for the European Commission and other EU Member States, subject to the requirements of data protection."

§ 17. Chapter 10 "b" with art. 35f—35s is hereby created:

#### "Chapter 10 "b"

#### LABELLING AND PACKAGING

Art. 35f. (1) Each unit packet and each outside packaging of tobacco products must contain health warnings.

(2) The health warnings under par. 1:

1. Shall occupy the entire surface of the unit packet or the outside packaging that is intended for them; the surface of the bevelled or rounded edges, if any, shall also be calculated as part of the unit packet;

2. Shall not be retold, reformulated or referred to in any form;

3. Shall be printed in a way that does not allow for their removal;

4. Shall be indelible and completely visible, neither hidden or interrupted in full or in part by excise stamps, price labels, protection elements, wrappers, covers, boxes or other elements;

5. Stickers may be positioned on unit packets of tobacco products other than cigarettes and roll-your-own tobacco in a pouch, provided that such stickers can not be removed;

6. Shall remain intact when opening the unit packet, other than packets with a flip-top lid, where the health warnings may be split when opening the packet, only in a manner that ensures the graphical integrity and visibility of the text, photographs and information on the cessation of tobacco use.

(3) The health warnings under par. 1 must not obscure or interrupt excise stamps, price labels, markings for tracking and tracing, and security features of unit packets.

(4) The size of health warnings under art. 35h, par. 1, art. 35k, par. 1, art. 35 l, par. 1 and art. 35 m, par. 1 shall be calculated based on the surface area of the closed unit packet.

(5) The health warnings under art. 35h para. 1, art. 35k, par. 1 and art. 35 l, par. 1 must be surrounded by a black line with a width of 1 mm within the borders of the surface intended for them.

(6) The health warnings under art. 35h, par. 1, art. 35k, para. 2, item 1, art. 35 l, par. 1 and art. 35 m, par. 1 on tobacco products, intended for duty-free shops, may be printed in English and must meet the requirements of the law. Information about the cessation of tobacco use, which is positioned on the packaging of tobacco products, intended for sale in duty-free shops, shall be determined by the Regulation for the implementation of the law, and may be printed in English.

Art. 35g. (1) On the unit packet and on the outer packaging of tobacco products and on the tobacco product itself no elements or distinctive markings shall be placed that:

1. Promote a tobacco product or encourage its consumption by misleading about its characteristics, health effects, risks or emissions;

2. Include any information about the nicotine, tar or carbon monoxide content of the tobacco product;

3. Mislead that a particular tobacco product is less harmful or aims to reduce the effect of some harmful components of smoke or has vitalising, energising, healing, rejuvenating, natural or organic properties, or has other health or lifestyle benefits;

4. Refer to taste, smell or other additives or the absence thereof;

5. Resemble a food or a cosmetic product;

6. Mislead that a tobacco product has improved biodegradability or other environmental advantages.

(2) The unit packet and outer packaging of a tobacco product shall not imply economic benefit by incorporating printed vouchers, offering discounts, free distribution, offering a "two for one" or other additions, as specified by law.

(3) The prohibited elements and distinctive markings under par. 1 and 2 may include texts, symbols, names, trademarks and figurative or other signs, but are not limited to them.

Art. 35h. (1) On each unit packet and on any outside packaging of cigarettes, roll-your-own tobacco and tobacco for water pipes the following shall be placed:

1. A general warning: "Smoking kills—quit now";
2. An information message: "Tobacco smoke contains over 70 substances known to cause cancer".

(2) For cigarette packets and parallelepiped-shaped packets of roll-your-own tobacco:

1. The general warning under par. 1, item 1 shall be positioned at the bottom of one of the sides of the unit packet, while the information message under par. 1, item 2 shall be positioned at the bottom of the opposite side of the packaging;

2. The width of the general warning under par. 1, item 1 and the information message under par. 1, item 2 shall not be narrower than 20 mm;

3. The width of the general warning under par. 1, item 1 and the information message under par. 1, item 2 must be parallel to the longest side edge of the package and correspond to the warning's reading direction.

(3) For the packets of cigarettes and roll-your-own tobacco in a solid box with a flip-top lid in which the sides are split into two parts when opening the packet, the general warning under par. 1, item 1 and the information message under par. 1, item 2 shall be positioned entirely on the larger of the two parts of the surface. The general warning under par. 1, item 1 shall be positioned on the inner side of the upper surface that is visible on opening the packet. The lateral surfaces of this type of packet shall have a height of not less than 16 mm.

(4) For roll-your-own tobacco in:

1. Pouch-shaped packets—the general warning under par. 1, item 1 and the information message under par. 1, item 2 shall be positioned on those surfaces that provide full visibility of these health warnings;

2. Cylindrical packets—the general warning under par. 1, item 1 shall be positioned on the outer side of the lid and the information message under par. 1, item 2—on the inner side of the lid.

(5) For packets of cigarettes, roll-your-own tobacco and tobacco for water pipes the general warning under par. 1, item 1, and the information message under par. 1, item 2 shall cover 50% of the corresponding surface.

Art. 35i. The general warning and the information message under art. 35h, par. 1:

1. Shall be printed in Bulgarian with the thick black font "Helvetica" on a white background;

2. Shall be located at the centre of the surface intended for them; for parallelepiped-shaped packets and for all outside packaging they must be parallel to the side edge of the unit packet or the outside packaging.

Art. 35k. (1) On each unit packet and on any outside packaging of cigarettes, roll-your-own tobacco and tobacco for water pipes the following combined health warnings shall be placed.

(2) The combined health warnings under par. 1:

1. Shall contain a text warning from the list in Annex 3a and the corresponding colour photograph from the picture library in Annex 3b;

2. Shall consist of the same text warning from the list in Annex 3a and the corresponding colour photograph from the picture library in Annex 3b on both sides of the unit packet and on any outside packaging;

3. Shall include the following information for cessation of tobacco use: "Help to quit smoking: 0700 10 323";

4. Shall cover 65% of the external front and back surface of the unit packet and any outside packaging; cylindrical packets shall display two combined health warnings, equidistant from each other, each covering 65% of their respective half of the curved surface;

5. Shall be positioned at the upper edge of the unit packet and any outside packaging in the same direction as any other information placed on the same side of the packaging;

6. Shall take the form, layout, design and proportions laid down in Commission Implementing Decision (EU) 2015/1842 of the Commission of 9 October 2015 on the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking (OJ, L 267/5 of 14 October 2015);

7. In unit packets of cigarettes they shall have:

a) height of not less than 44 mm;

b) width of not less than 52 mm.

(3) No trademarks or logos shall be placed over the combined health warnings under par. 1.

(4) The combined health warnings under par. 1 are divided into three groups as specified in Annex 3b. The groups shall be used in sequence for a period of one year, starting with Group 1.

(5) Any combined health warning under par. 1 (from the group in Annex 3b used in the relevant year) shall be printed, if at all possible, on an equal number of unit packets and outer packages in the same year for each brand of tobacco product.

(6) The Ministry of Economy shall provide to the manufacturers and/or importers of tobacco products technical specifications for the layout, design and format of the combined health warnings on tobacco products for smoking.

(7) Upon the provision of the technical specifications under par. 6, the manufacturers and importers of tobacco products shall sign the statement under Annex 3c.

Art. 35 l. (1) The following health warning shall be placed on each unit packet and on any outside packaging of smokeless tobacco products: "This tobacco product is addictive and harmful to your health".

(2) The health warning under par. 1:

1. Shall meet the requirements of art. 35i;

2. Shall be printed alongside the main text on the surface intended for it;

3. Shall be placed on the two biggest surfaces of the unit packet and on each outside packaging;

4. Shall cover 30 % of the surface of the unit packet and each outside packaging.

Art. 35m. (1) The following shall be placed on each unit packet and each outside packaging of tobacco products for smoking, other than cigarettes, roll-your-own tobacco and tobacco for water pipes:

1. The general warning under art. 35h, par. 1, item 1;

2. One of the text warnings from the list in Annex 3a.

(2) The general warning under par. 1 shall also include the following information for cessation of tobacco use: "Help to quit smoking: 0700 10 323".

(3) The general warning under art. 35h, par. 1, item 1:

1. Shall be placed on the most visible surface of the unit packet and each outside packaging;

2. Shall cover 30 % of the corresponding surface of the unit packet and each outside packaging.

(4) The text warning under par. 1, item 2:

1. Shall cover 40 % of the corresponding surface of the unit packet and each outside packaging;

2. Shall appear, as far as possible, with the same frequency for each brand of these products;

3. Shall be placed on the unit packet's second best surface in terms of visibility and on each outside packaging; in unit packets with a flip-top lid the second best surface in terms of visibility is one that becomes visible when opening the packet.

(5) Where the health warnings under par. 1 must be placed on a surface larger than 150 sq. cm, the warning must cover an area of 45 sq. cm.

(6) The health warnings under par. 1:

1. Meet the requirements under art. 35i; the text of the health warnings shall be parallel to the main body of text on the surface, designated for these warnings;

2. Shall be enclosed within a black line not less than 3 mm wide and not more than 4 mm wide; this line shall be located outside the surface designated for the health warning.

(7) Article 35h, par. 1, item 2 and art. 35k, par. 3 shall not be applicable to tobacco products for smoking, other than cigarettes, roll-your-own tobacco and tobacco for water pipes.

Art. 35n. Unit packets of cigarettes:

1. Shall have the shape of a parallelepiped, including those with rounded or bevelled edges;

2. Shall be made of cardboard or another soft material;

3. Shall not have an opening that could be closed or re-sealed after the first opening other than the closing lid and the flip-top lid of the solid box; for packets with a flip-top lid and closing lid, the lid shall be hinged only at the back of the unit packet.

Art. 35o. Unit packets for roll-your-own tobacco shall have a parallelepiped, cylindrical or pouch-like shape.

Art. 35p. (1) Unit packets for tobacco products intended for marketing, shall be marked with a unique identifier.

(2) The unique identifier under par. 1:

1. Shall be printed or affixed in such a way that it can not be removed and its entirety cannot be broken;

2. Shall be indelible and not hidden or interrupted, including by excise stamps or price labels, nor when opening the packet;

3. Shall specify:

a) The production date and place;

b) The manufacturing facility;

c) The machine used to manufacture the tobacco products;

d) The production shift or time of production;

e) The description of the product;

f) The retail market, for which the tobacco products are intended;

g) The intended route of transportation;

h) The importer (when import has taken place);

i) The actual route of transportation from the production site to the first outlet for retail sale, including all the warehouses used, the date of departure, the destination, the departure point and the consignee;

k) The identity of all buyers—from the production site to the first outlet for retail sale;

l) The invoice, the order number and payment records of all purchasers from the production site to the first outlet retail.

(3) The information under par. 2, item 3, letters "a" to "g", as well as letter "h" (when import has taken place) is part of the unique identifier under par. 1.

(4) The information under par. 2, item 3, letters "i", "k" and "l" is available electronically through a link with the unique identifier under par. 1.

Art. 35q. (1) All economic operators involved in the marketing of tobacco products—from the manufacturer to the last economic operator before the first commercial outlet for retail sale (economic operators in the supply chain), shall record the arrival at their site of all unit packets, as well as any intermediate movement and their final delivery.

(2) The obligation under par. 1 can be realised by marking and recording of large packages, such as stacks, cartons or pallets, provided that the monitoring and tracking of the unit packets is still possible.

Art. 35t. All economic operators in the supply chain of tobacco products before the first outlet for retail sale shall maintain complete and accurate records of all relevant transactions.

Art. 35s. (1) The producers of tobacco products shall provide the necessary equipment, allowing for the recording of data about the purchased, sold, stored, transported (or subject to other types of transactions) tobacco products to all economic operators in the supply chain of tobacco products before the first outlet for retail sale, including importers, warehouses and transportation companies.

(2) The equipment under par. 1 must be capable of reading and transmitting recorded data electronically to the facility for storing data in accordance with par. 3.

(3) The manufacturers and importers of tobacco products conclude a contract for storing the data under par. 1 with an independent third party, at whose premises the facility for storing data can be located.

(4) The facility under par. 3 must be located on the territory of the European Union.

(5) The independence and technical capability of independent third party, as well as the contract under par. 3 shall be approved by the European Commission.

(6) The activities of the independent third party shall be monitored by an external auditor, which shall be proposed and remunerated by the manufacturer of the tobacco products and shall be approved by the European Commission.

(7) The European Commission, the National Customs Agency and the external auditor shall have full access to the facility for storing data under par. 1.

(8) In duly justified cases, the European Commission or National Customs Agency in compliance with art. 17, par. 1, item 6 of the Customs Act can provide to manufacturers or importers access to the data stored under par. 1, provided that commercial information is protected under the law of the European Union and Bulgarian legislation.

(9) The data under par. 1 must not be altered or deleted by economic operators in the supply chain of tobacco products before the first outlet for retail sale.

(10) Personal data shall be processed in accordance with the requirements of the Law on the Protection of Personal Data.

(11) The essential elements such as duration, possibility for renewal, required experience or confidentiality, including regular monitoring and evaluation of the execution of the contracts under par. 3 shall be determined by the Regulation for the implementation of the law.

Art. 35t. (1) A protective element shall be placed on the unit packets of all marketed tobacco products.

(2) The protective element under par. 1:

1. Shall be protected against counterfeiting;

2. Shall be composed of visible and invisible parts;

3. Shall be printed or applied so that it can not be removed;

4. Shall be indelible and not hidden or interrupted, including by excise stamps and price labels or by other items."

§ 18. A new Chapter Twelve with art. 43 a to 43h is hereby added:

"Chapter Twelve

ELECTRONIC CIGARETTES

Art. 43a. (1) Manufacturers, importers and persons, introducing electronic cigarettes and/or refillable containers to Bulgaria from another EU Member State, shall notify the Ministry of Economy of each product they want to market.

(2) The notification under par. 1 shall be given in digital form six months before the planned start of the sale of that product in Bulgaria.

(3) Depending on whether the device is an electronic cigarette or a refillable container, the notification under par. 1 shall include:

1. The Unified Identification Code [Bulgarian: ЕИК] of the trader, and for those, registered in another EU Member State, or in another country which has ratified the EEA Agreement—the pertinent identification code or number;

2. The address and telephone number of the manufacturer, the responsible natural or legal person on the territory of the European Union, and of the importer, when import has taken place;

3. The list of ingredients contained in the product and the emissions resulting from its use (including their quantities)—for each brand and each type;

4. The available toxicological data on ingredients and product emissions, including when heated, indicating in particular their impact on consumer health if inhaled and their potential addictiveness;

5. Information on the dose of nicotine and its absorption when consumed under normal or reasonably foreseeable conditions;

6. A description of the device's components; where applicable, a description of the mechanism for opening and charging the electronic cigarette or the refillable containers;

7. The description of the manufacturing process, including whether it involves mass production, and a statement that the manufacturing process ensures compliance with this Article;

8. A statement that the manufacturer, importer and the persons, introducing electronic cigarettes and/or refillable containers to Bulgaria from another EU Member State, shall bear full responsibility for the quality and safety of the product when marketed and used under normal or reasonably foreseeable conditions.

(4) If the information provided in the notification under par. 1 is incomplete, the Ministry of Economy may request the supplementing of the relevant information.

(5) The Ministry of Economy shall make an entry in the register under par. 8 after removal of the incompleteness under par. 4.

(6) Any material changes to the electronic cigarette and/or refillable container, the manufacturers, importers and persons, introducing electronic cigarettes and/or refillable containers to Bulgaria from another EU Member State, shall submit a notification under the terms and conditions of par. 1—4.

(7) The Ministry of Economy may require additional information from the persons under par. 1 related to the safety and quality, the presence of adverse effects, as well as other product information.

(8) The Ministry of Economy maintains a public register of the persons under par. 1 and the products offered by them.

(9) The Ministry of Economy shall publish on its website the information under par. 3 and part of the register under par. 8, except for the information that constitutes a trade secret.

Art. 43b. (1) Manufacturers, importers and persons, introducing electronic cigarettes and/or refillable containers to Bulgaria from another EU Member State, shall provide annually to the Ministry of the Economy:

1. The details of the sales volume for each brand and each type of product;

2. Information about the preferences of different user groups including young people, non-smokers and the main types of smokers;

3. Information on the methods of product sale;

4. A summary of the market studies carried out in relation to items 1—3, accompanied by an English translation.

(2) The Ministry of Economy shall publish on its website the information under par. 1 and part of the register under art. 43 a, par. 8, except for the information that constitutes a trade secret.

(3) Upon request by the European Commission or a EU Member State, the Ministry of Economy shall provide the information under par. 1, while observing the requirements for data protection.

Art. 43c. Manufacturers, importers and persons, introducing electronic cigarettes and/or refillable containers to Bulgaria from another EU Member State, shall establish and maintain a system for collecting information on all adverse effects of these products on human health.

Art. 43 d. Economic operators, when they believe or have reasons to believe that the electronic cigarettes or refillable containers they are selling are not safe, or not of good quality, or otherwise not compliant with the law:

1. Shall take immediate action either to make that product compliant with the requirements of the law or else—withdraw it from the market;

2. Shall immediately inform the Ministry of Economy of their actions under item 1.

Art. 43e. (1) Liquids containing nicotine:

1. Shall only be marketed in special refillable containers of not more than 10 ml, in disposable electronic cigarettes, or in disposable cartridges, with the volume of cartridges or tanks not exceeding 2 ml;

2. Shall not contain more than 20 mg/ml of nicotine;

3. Shall not contain:

a) vitamins or other additives, misleading that the product is beneficial to health or is less harmful;

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

c) additives, colouring the emissions;

d) additives, facilitating inhalation or absorption of nicotine;

e) additives with CMTR properties in unburnt form.

(2) Only ingredients with a high degree of purity shall be used for the production of liquids, containing nicotine. The presence of substances other than those listed in art. 43 a, par. 3, item 3 shall be allowed only in the form of residues which are technically impossible to avoid.

(3) In addition to nicotine, the liquids containing nicotine, shall only contain ingredients that do not pose a risk to human health in a heated or unheated form.

Art. 43f. Under normal conditions of use marketed electronic cigarettes shall release nicotine in equal doses.

Art. 43g. Marketed electronic cigarettes and refillable containers shall be resistant to damage by children, shall not be prone to counterfeiting, shall be protected from breakage and leaks and shall have a mechanism which ensures filling without leaks.

Art. 43h. (1) As part of the unit packet of electronic cigarettes and/or refillable containers a leaflet shall be included with:

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

2. Contraindications;

3. Warnings for certain risk groups;

4. Possible side effects;

5. Warnings about the dangers of addiction and toxicity;

6. Details of the manufacturer and/or importer, as well as the contact person (legal or natural person) within the European Union.

(2) The unit packet and any outside packaging of electronic cigarettes and refillable containers shall include:

1. A list of all product ingredients in descending order of weight;

2. An indication of the product's nicotine content and the absorbed amount of nicotine per dose;

3. A batch number;

4. A recommendation to keep the product away from children;

5. Information on the content of nicotine and flavourings.

(3) The unit packet and any outside packaging of electronic cigarettes and refillable containers shall not include elements or distinctive markings that:

1. Promote the corresponding product or encourage its consumption by misleading about its characteristics, health effects, risks or emissions;

2. Mislead that a particular product is less harmful or aim to reduce the effect of some harmful components of smoke or has vitalising, energising, healing, rejuvenating, natural or organic properties, or has other health or lifestyle benefits;

3. Refer to taste, smell or other additives or the absence thereof;

4. Resemble a food or a cosmetic product;

5. Mislead that a specific product has improved biodegradability or other environmental advantages.

(4) On the unit packet and on each outside packaging of electronic cigarettes and refillable containers the following health warning shall be placed: "This product contains nicotine, which is highly addictive. It is not recommended for use by non-smokers."

(5) The health warning shall be governed by art. 35 l, par. 2."

**§ 19.** Article 46 shall be amended as follows:

"Art. 46. (1) Whoever stores, offers or sells at commercial warehouses or stores tobacco and/or related products, or new tobacco products in violation of art. 26 a, 26c, 29, art. 30, par. 2, items 1—8, and items 10—18, art. 31, 31 a, art. 35 a, par. 1—4, art. 35f—35r, art. 35 s, par. 1—4 and par. 9, and art. 35 t, shall be fined 1,000 to 3,000 BGN, or a property sanction of 2,000 to 5,000 BGN respectively shall be imposed.

(2) For a repeated violation under par. 1 the fine shall be 2,000 to 5,000 BGN, and the property sanction—of 4,000 to 8,000 BGN."

**§ 20.** A new art. 46 a is hereby added:

"Art. 46a. When in violation of art. 30, par. 2, item 9, storage, offering or sale of tobacco products in commercial warehouses or stores has been found, the Commission for Consumer Protection (CCP) shall notify the National Customs Agency and shall send them a certified copy of the protocol, containing all established facts and circumstances. The National Customs Agency shall check the facts and impose an administrative sanction under the Law on Excise Duties and Tax Warehouses."

**§ 21.** Article 49 shall be amended as follows:

"Art. 49. Whoever violates the provisions of art. 32 shall be fined 1,000 to 3,000 BGN, or a property sanction of 2,000 to 5,000 BGN respectively shall be imposed."

**§ 22.** Article 50 shall be amended and supplemented as follows:

1. The existing text is hereby remunerated as par. 1.

2. A new par. 2 is hereby added:

"(2) For a repeated violation under par. 1, or a breach of the provisions of art. 52 a, par. 6, a fine in the amount of 50,000 to 100,000 BGN shall be imposed, and a property sanction of 100,000 to 150,000 BGN."

**§ 23.** Article 51a shall be amended and supplemented as follows:

1. In par. 1 the words "art. 35c, par. 2 and art. 35 d" are hereby replaced by "art. 35b, par. 1—5 and art. 35c, par. 1—4".

2. A new par. 3 is hereby added:

"(3) In case of an offence under par. 1, the Tobacco and Tobacco Products Institute shall notify the Ministry of Agriculture and Food and send a certified copy of the protocol, containing all established facts and circumstances."

**§ 24.** Art. 51b, 51c and 51 d are hereby added:

"Art. 51b. (1) Whoever stores, offers or sells electronic cigarettes and/or refillable containers in violation of art. 43 a, par. 1, 2 and 6, art. 43b, par. 1 and art. 43c—43h shall be fined 1,000 to 3,000 BGN, or a property sanction of 2,000 to 5,000 BGN respectively shall be imposed.

(2) For a repeated violation under par. 1 the fine shall be 2,000 to 5,000 BGN, and the property sanction—of 4,000 to 8,000 BGN.

Art. 51c. A person who violates art. 35b, par. 8, unless subject to a more severe penalty, shall be fined 100 to 1,000 BGN.

Art. 51 d. In case of a violation or a suspected violation of the law in carrying out obligations, customs authorities shall immediately notify the relevant authority under art. 52, par. 1."

**§ 25.** Article 52 shall be amended as follows:

"Art. 52. (1) Violations of the law shall be established by acts issued by:

1. The officials, authorised by the Director of the National Customs Agency—for violations under art. 46 in relation to art. 32, 35p—35r, art. 35 s, par. 1—4 and par. 9 and art. 35 t, as well as art. 49;

2. The officials, authorised by the Minister of Agriculture and Food—for violations under art. 51 a;

3. The directors of the regional directorates "Agriculture" or the officials, authorised thereby—for violations under art. 44 a and 44b;

4. The officials, authorised by the Minister of Economy—for violations under art. 46 in relation to art. 26 a, par. 1 and 2, art. 26c and art. 51b in relation to art. 43 a, par. 1, 2 and 6, art. 43b, par. 1 and art. 43h;

5. The officials, authorised by the Chair of the Commission for Consumer Protection—for violations under art. 46 in relation to art. 29, art. 30, par. 2, items 1—8, and items 10—18, art. 31, 31 a, 35, art. 35 a, par. 1—4, art. 35f—35o in relation to art. 50 and art. 51b in relation to art. 43c—43h.

(2) The penalty decrees shall be issued by:

1. The Director of the National Customs Agency or by an official, authorised by him/her—under par. 1, item 1;

2. The Minister of Agriculture and Food or by an official, authorised by him/her—under par. 1, items 2 and 3;

3. The Minister of Economy or by an official, authorised by him/her—under par. 1, item 4;

4. The President of the Commission for Consumer Protection or by an official, authorised by him/her—under par. 1, item 5."

**§ 26.** Article 52a is hereby amended as follows:

"Art. 52a. (1) The Commission for Consumer Protection shall enforce compliance with the requirements under art. 26 a, par. 1 and 2, art. 26c, 29, art. 30, par. 2, items 1—8, and items 10—18, art. 31, 31 a, 35, art. 35 a, par. 1—3, art. 35f—35o, art. 43 a, par. 1 and art. 43c—43h.

(2) When an inspection has found a non-compliance with the requirements under art. 30, par. 2, items 17 and 18, art. 35 a, par. 1, art. 43e, 43f and 43g, the cost of said inspection shall be borne by the inspected. Where a non-compliance has been found, the cost of said inspection shall be borne by the Commission for Consumer Protection.

(3) Where marketed tobacco products, new tobacco products, electronic cigarettes and refillable containers do not meet the requirements of art. 26a, par. 1 and 2, art. 26c, art. 35 a, par. 1—3, art. 35f—35 t, art. 43e—43h, control authorities shall issue an order with mandatory instructions to manufacturers, importers and retailers to withdraw the products from the market.

(4) Where manufacturers, importers and traders have not complied with the instructions, the control authority shall seize and destroy their products.

(5) In cases of violation of art. 26 a, par. 1 and 2, art. 26c, art. 43 a, par. 1 and 2, art. 43c, 43 d, the Commission for Consumer Protection shall notify the Ministry of Economy and send a certified copy of the protocol, containing all established facts and circumstances.

(6) Where the inspections under par. 1 have found a non-compliance with the requirements of art. 35, the Chair of the Commission for Consumer Protection or an officer, authorised thereby, shall issue an order with mandatory instructions to remedy the non-compliance issue within a specified period.

(7) If electronic cigarettes and refillable containers meet the requirements of the law, but the Commission for Consumer Protection has reasonable grounds to believe that the product in question may cause a serious risk to human health, CCP may apply the measures under par. 3.

(8) The Commission for Consumer Protection shall notify the European Commission, the competent authorities of the EU Member States and the Ministry of Economy of the measures taken under par. 6, as well as the reasons for taking them."

**§ 27.** The following supplements and amendments are hereby made to the additional provision:

1. The name "Additional provision" is hereby amended as follows: "Additional Provisions".

2. In § 1:

a) A third sentence is hereby added to item 1: Tobacco leaves and other natural processed or unprocessed parts of the tobacco plant, including bloated and reconstituted tobacco, shall also be referred to as "tobacco";

b) New items 5, 6, 7, 8 and 8 a are hereby added:

"5. "Tobacco products for smoking" are tobacco products other than smokeless tobacco products.

6. "Tobacco for water pipes" is a tobacco product for smoking which can be consumed by means of a water pipe. If the product can be used for consumption in a water pipe, as well as for roll-your-own cigarettes, it shall be referred to as roll-your-own tobacco.

7. "New tobacco product" means a tobacco product that:

a) Does not fall within the scope of items 4a—4e, 4 g—4i and item 6;

b) Was marketed later than May 19, 2014.

8. "Products, related to tobacco products" means electronic cigarettes, refillable containers and liquids, containing nicotine.

8 a. "Tobacco products other than cigarettes and roll-your-own tobacco" means the devices that fall within the scope of items 4b—4 d, 4e—4i, items 6 and 7";

c) Previous item 5 is hereby remunerated as item 9 and is amended as follows:

"9. "Ingredients" means tobacco, an additive, as well as all substances or elements contained in the finished tobacco or related product, including paper, filters, inks, capsules and adhesives.";

d) previous item 6 is hereby remunerated as item 10 and the words "tobacco smoke" are hereby replaced by "smoke";

e) previous item 7 is hereby renumbered as item 11;

f) new items 12, 13, 14 and 15 and items 16, 17 and 18 are hereby added:

"12. "Emissions" means substances that are released while a tobacco product and/or a related product is being used for its intended purpose, such as substances in smoke or substances emitted when using smokeless tobacco products.

13. "Additive" means any substance, other than tobacco, which has been added to the tobacco product, to its unit packet or any outside packaging.

14. "Flavouring" means an additive that gives smell and/or taste.

15. "Characteristic flavours" means clearly detectable smell or taste different from that of tobacco, and obtained by means of an additive or a combination of additives, including but not limited to, fruit, spice, herb, alcohol, sugar confectionery, menthol or vanilla, which can be tasted before or during the use of tobacco.

16. "Maximum level of emissions" means the maximum concentration or emissions of a substance in a tobacco product, including zero content, measured in milligrams.

17. "Addictiveness" means the pharmacological potential of a substance to induce addiction—a condition that affects a person's ability to control his/her behaviour—usually by creating a feeling of satisfaction or relief of withdrawal symptoms, or both.

18. "Toxicity" means the extent to which a substance can have adverse effects on the human body, including the consequences occurring over time, usually upon repeated or prolonged use or exposure to that substance.";

g) Previous item 8 is hereby remunerated as item 19 and is amended as follows:

"19. "Unit packet" means the smallest individual packaging of a marketed tobacco product and/or related product.";

g) Previous item 8 is hereby remunerated as item 20 and is amended as follows:

"20. "Unit packet of hand-rolled cigars" means the smallest individual packaging that a manufacturer, importer or wholesaler supplies to retailers, licensed to trade in tobacco products. In cases where the unit packet of hand-rolled cigars from limited editions has added value due to its special workmanship or the cost of the material used, then the outside packaging of that specific product shall be considered a unit packet.";

s) Items 21—31 are hereby added:

"21. "Limited edition" means a product under item. 20 which is produced in a limited or specific quantity over a certain period of time and is designated exclusively for collectors.

22. "Outside packaging" means any package in which tobacco and related products are marketed, and which contains a unit packet or a set of unit packets. Transparent packaging shall not be referred to as outside packaging.

23. "Pouch" means a unit packet of roll-your-own tobacco in the shape of a rectangular pocket with a flap that covers the opening, or of a standing packet.

24. "Health warning" means a warning about adverse effects to human health or other adverse consequences of the use of a tobacco product, which includes text warnings, combined health warnings, general warnings and information messages, according to art. 35h, par. 1, art. 35k, par. 1, art. 35 l, par. 1, art. 35 m, par. 1 and art. 43h, par. 4 and Annex 3a.

25. "Combined health warning" means a health warning, which consists of a combination of a text warning under Annex 3a and the corresponding photograph from the picture library in Annex 3b.

26. "Consumer" means an individual, acting for purposes which are outside his business or profession.

27. "Manufacturer of tobacco and/or related products" means a natural or legal person who manufactures a product or assigns its creation or production, and markets this product under its own name or trademark.

28. "Importation of tobacco or related products" means the entry of tobacco and/or related products into the European Union unless the goods upon their entry into the European Union are placed under a customs suspensive procedure or arrangement, as well as their release from a customs suspensive procedure or arrangement.

29. "Importer of tobacco or related products" means the owner or the person who has the right to dispose of tobacco or related products that have been introduced within the European Union.

30. "Marketing" means the first placing, delivery or supply of tobacco and related products, irrespective of where they have been produced, at the disposal of consumers in the Republic of Bulgaria for a fee or free of charge, including through distance sales, cross-border distance sales and sales by using services of the information society.

31. "Outlet for retail sale" means a trade outlet (within the meaning of art. 90b, par. 1 of the Law on Excise Duties and Tax Warehouses), where tobacco products are marketed.";

k) Previous item 9 is hereby renumbered as item 32;

l) Previous item 10 is hereby renumbered as item 33 and the phrase "and/or a related product" is added to its end;

m) Previous item 11 is hereby renumbered as item 34 and the phrase "and/or a related product" is added to its end;

n) Previous items 12, 13 and 14 are hereby renumbered as 35, 36 and 37 respectively;

o) Items 38—45 are hereby added:

"38. "Economic operator" means a manufacturer, importer and distributor of tobacco and/or related products or his/her authorised representative, as well as every merchant under the Commerce Act, engaged in the wholesale of tobacco and/or related products.

39. "Electronic cigarette" means a device which can be used for the consumption of nicotine vapours through a mouthpiece or any component of this product, including a cartridge and a tank, as well as that device without a cartridge or a tank. Electronic cigarettes can be disposable or reusable (through a refillable container or a tank) or be reloaded with disposable cartridges.

40. "Refillable container" means a vessel with liquid containing nicotine, which can be used to reload the electronic cigarette.

41. "Systematic violation" means the performance of three or more offences of the same kind over a two-year period for which the person has been the subject of administrative penalties with effective penalty decrees.

42. "Modified tobacco product" means a product whose composition is altered in a way that affects the information provided under art. 35b, par. 1, items 1—3.

43. "Normal conditions of use" means the use of the product in accordance with the information provided in the instructions for use and storage of the product.

44. "Normal or reasonably foreseeable conditions" means using of the product in a way that is specified in the instructions for use and storage of the device and which may be the result of predictable human behaviour.

45. "Cross-border distance selling" means the distance selling to consumers, who—at the time of ordering tobacco or any related product—are located in the Republic of Bulgaria and are ordering from an outlet for retail sale, established in another EU Member State or in a third country; an outlet for retail sale shall be considered established in a EU Member State:

a) When the seller is a natural person and his/her place of business is in that Member State;

b) When the seller is a natural person and it has headquarters and registered office, central administration or principal place of business, including a branch, agency or other entity in that Member State."

3. A new § 1a is hereby added:

„§ 1a. This Law introduces the requirements of:

1. 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 sale of tobacco and related products and repealing Directive 2001/37/EC;

2. Commission Delegated Directive 2014/109/EU of 10 October 2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products (OJ, L 360/22 of 17 December 2014).“

§ 28. Annex 3a to art. 35k, par. 2, item 1 is hereby added:

"Annex 3a to art. 35k, par. 2, item 1

#### List of Text Alerts

1. Smoking causes nine out of 10 cases of lung cancer
  2. Smoking causes cancers of the mouth and throat
  3. Smoking damages your lungs
  4. Smoking causes heart attacks
  5. Smoking causes strokes and disability
  6. Smoking clogs your arteries
  7. Smoking increases the risk of blindness
  8. Smoking damages your teeth and gums
  9. Smoking can kill your unborn child
  10. Tobacco smoke harms your children, family and friends
  11. Children of smokers are more likely to also become smokers
  12. Give up smoking—stay alive for your loved ones
  13. Smoking reduces fertility
  14. Smoking increases the risk of impotence."
- § 29. Annex 3b to art. 35k, par. 2, item 1 is hereby added:

"Annex 3b to art. 35k, par. 2, item 1

[SEE the Annex](#)

§ 30. Annex 3c to art. 35k, par. 7 is hereby added:

"Annex 3c to art. 35k, para. 7

STATEMENT

The undersigned \_\_\_\_\_

\_\_\_\_\_

(Given Name, Middle Name and Surname)

with PIN \_\_\_\_\_, ID card No \_\_\_\_\_,  
issued on \_\_\_\_\_ by the Ministry of Interior in the city of \_\_\_\_\_,  
with permanent address: \_\_\_\_\_

\_\_\_\_\_

in his/her capacity of \_\_\_\_\_  
\_\_\_\_\_

of \_\_\_\_\_ with headquarters and address of  
management—city of \_\_\_\_\_,  
registered in the Commercial Register with UIC \_\_\_\_\_,  
tel.: \_\_\_\_\_, fax: \_\_\_\_\_ and mailing address:  
\_\_\_\_\_  
\_\_\_\_\_

I HEREBY DECLARE THAT:

1. The Ministry of Economy has informed me (by means of a protocol annexed to this Declaration) of the technical specifications for the layout, design and format of the combined health warnings on tobacco products for smoking, adopted by Commission Implementing Decision (EU) 2015/1842 of the Commission of 9 October 2015 on the technical specifications for the layout, design and format of the combined health warnings for tobacco products for smoking (OJ, L 267/5 of 14 October 2015), hereinafter referred to as "Implementing Decision (EU) 2015/1842" for the sole purpose of preparing unit packets and outer packages for tobacco products for smoking. I hereby undertake to use those technical specifications.

2. I undertake not to use and not to distribute in any way the provided technical specifications for the layout, design and format of the combined health warnings, except for the purposes of item. 1.

3. In preparing to print unit packets and outer packages of tobacco products for smoking I undertake to include in the part of the technical specifications the information on cessation of tobacco use, and to add the following text: "Help to quit smoking: 0700 10 323", in compliance with the requirements of Implementing Decision (EU) 2015/1842.

I am aware of the responsibility under art. 172a, 172b and 313 of the Penal Code.

Date: \_\_\_\_\_ SIGNATURE: \_\_\_\_\_ “

Transitional and Final Provisions

§ 31. (1) When the excise stamp is attached to the upper corner of the carton unit packet, the combined health warning under art. 35k, par. 1, which must be located on the back surface of the packet, may until May 20, 2019 be placed just under the stamp.

(2) Where a unit packet is made of soft material, until May 20, 2019 a rectangular area with height greater than 13 mm may be retained for the excise stamp between the top edge of the packet and the beginning of combined health warnings.

§ 32. The following shall be applicable to electronic cigarettes and refillable containers, manufactured or marketed before May 20, 2016: manufacturers, importers and persons, introducing electronic cigarettes and/or refillable containers to Bulgaria from another EU Member State, shall by November 20, 2016 submit a notification under the terms and conditions of art. 43 a, par. 1—4.

§ 33. Tobacco products which do not meet the requirements of this law, but have been labelled in compliance with the Ordinance on the labelling, marking and design of tobacco products and for setting standards for compliance assessment of tar, nicotine and carbon monoxide content in tobacco products (prom., SG, issue 69 of 2004; amend., issue 2 of 2005, issue 92 of 2013 and issue 22 of 2015) and have been manufactured or released for free circulation before May 20, 2016, may continue to be marketed until stocks have been exhausted but not later than May 20, 2017.

§ 34. Electronic cigarettes or refillable containers which do not meet the requirements of this law and were manufactured or released for free circulation by November 20, 2016, may continue to be marketed until stocks have been exhausted but not later than May 20, 2017.

§ 35. Article 30, par. 2, item 18 shall be applicable to tobacco products with distinctive flavours from May 20, 2020, if it is found that across the EU the volume of sales of tobacco products with distinctive flavours equals three or more than three per cent of a given product category.

§ 36. (1) Manufacturers, importers and persons, introducing tobacco products to Bulgaria from another EU Member State shall provide by November 20, 2016 the information under art. 35b, par. 1, pertaining to tobacco products marketed before May 20, 2016.

(2) Manufacturers, importers and persons, introducing new tobacco products, electronic cigarettes or refillable containers to Bulgaria from another EU Member State, shall notify by November 20, 2016 the Ministry of Economy of the new tobacco products, electronic cigarettes or refillable containers, marketed before November 20, 2016. The notification shall be made according to the terms and conditions of art. 26 and art. 43a, par. 1—4.

§ 37. Within the six-month period after the entry of this Law into force, the Council of Ministers shall align with it all regulations for its implementation.

§ 38. The Law on Seeds and Seedlings (prom., SG, issue 20 of 2003; amend., issue 27 of 2005, issue 30 and 97 of 2006, issue 36 and 43 of 2008, issue 25 and 41 of 2010, and issue 8 and 39 of 2011) in art. 1, par. 2 the words "and tobacco" are hereby replaced by "tobacco and related".

§ 39. In the Food Act (prom., SG, issue 90 of 1999, amend., issue 102 of 2003, issue 70 of 2004, issue 87, 99 and 105 of 2005, issue 30, 31, 34, 51, 55, 80 and 96 of 2006, issue 31, 51 and 53 of 2007, issue 36 and 69 of 2008, issue 23, 41, 74, 82 and 93 of 2009, issue 23, 25, 59, 80 and 98 of 2010, issue 8 of 2011, issue 54, and 77 of 2012, issue 68 of 2013, issue 26 of 2014, issue 14 and 56 of 2015), in art. 2, par. 3, item 6 the words "tobacco and made of tobacco" are hereby replaced by "tobacco, made of tobacco and related".

**§ 40.** This Law shall enter into force on the day of its promulgation in the "Official Gazette", except for:

1. Paragraph 5, § 7 in relation to art. 30, par. 2, item 12 and items 15—18, § 8 in relation to art. 31 a, § 9 in relation to art. 32, par. 2, § 10—16 and § 17 in relation to art. 35f—35o, § 18, § 19, § 21—26 and § 28—36, which enter into force on May 20, 2016;
2. Paragraph 17 in relation to art. 35p—35 t, which enter into force on:
  - a) May 20, 2019—for the manufacture and sale of cigarettes and roll-your-own tobacco;
  - a) May 20, 2024—for the manufacture and sale of tobacco products, other than cigarettes and roll-your-own tobacco.

The law was adopted by the 43rd National Assembly on March 24, 2016 and was affixed with the official seal of the National Assembly.

Chair of the National Assembly: **Tsetska Tsacheva**