LAW No. 9636 dated 6.11.2006

ON HEALTH PROTECTION AGAINST TOBACCO PRODUCTS

(amended by laws: no. 49/2013, dated 14.2.2013, no. 76/2014, dated 10.7.2014, no. 56/2019, dated 18.7.2019)

Pursuant to articles 78 and 83, item 1 of the Constitution, upon a proposal from the Council of Ministers,

THE ASSEMBLY OF THE REPUBLIC OF ALBANIA

DECIDED:

CHAPTER I GENERAL PROVISIONS

Article 1

Purpose

The purpose of such law remains is the protection of public health from the use of tobacco products and involuntary exposure to smoke.

Article 2 **Objectives**

The objectives of the law are:

- a) Designation of measures aiming at restricting the use of tobacco products and protecting the public from harms caused by involuntary exposure to smoke;
- b) Designation of measures aiming at raising the public awareness of tobacco harms and guaranteeing effective and continuous informing of tobacco users about such harms;
- c) Designations of measures to prevent starting of smoking, encourage and support quitting, and reduce consumption of tobacco products.

Article 3 **Definitions**

(item 12 was amended, wording was added to item 13, and item 18 was added under law no. 49/2013, dated 14.2.2013, amended

items 1 and 7, wording was added to item 18 and items 19-36 were added under law no. 56/2019, dated 18.7.2019)

- 1. "Tobacco products" means products that many be consumed and contain even partially genetically modified tobacco or not.
- 2. "Packet or package" means every retailed box or closed bag containing tobacco products.
- 3. "Tar" means dry and undiluted condensation, nicotine-free, of the smoke released from smoking.
- 4. "Nicotine" means toxic nicotinic alkaloids contained in tobacco smoke, which affect the nervous system.
- 5. "Carbon Monoxide" means a chemical substance produced during tobacco combustion and released together with tobacco smoke.
- 6. "Trading of tobacco products" means import and export of tobacco products, storing for sale and purchasing purposes.
- 7. "Smoking" means lighting, inhaling and holding a lit tobacco product in one's hand, a electronic cigarettes and shishas/hookahs, too.
- 8. "Tobacco products advertising" means every form of communication, recommendation or commercial action which has an impact on promoting a tobacco product or encouraging smoking directly or indirectly including even sponsorship or image of a tobacco product by mentioning its name or brand name.
- 9. "Brand" means distinctive signs attached to tobacco products to indicate their type, quality and the manufacturer including their names, letters, numbers, symbolic signs, combination of colors or shades as well as their combination.
- 10. "Tobacco sponsorship" means every form of contribution to an event, cultural or sports activity or to an individual, which leads to or may lead to promotion or utilization of tobacco products either directly or not.
- 11. "Tobacco promotion" means every kind of activity, event or action aiming at making the public aware of new tobacco products launched or to be launched in the market.
- 12. "Public setting" means any settings open to the public.
- 13. "Working environment" means any closed space, where employees perform the activities and duties assigned as well as meeting halls, corridors, staircases, elevators, restrooms, and any other closed setting.
- 14. "Ashtray" means a small container where tobacco ash is shaken off while it is being burned and where cigarettes butts are placed.
- 15. "Preventive measures against smoking" means regular activities aiming at protecting public health by prolonging life expectancy and improving its quality.
- 16. "CSCHPTP" means Cross-sector Committee on Health PROTECTION against TOBACCO PRODUCTS.
- 17. "ISO (International Standards Organization)" means a system of references which sets/provides specifications and criteria to be applied regularly while classifying industrial materials and providing products, testing and analyzing them, identifying the terminology and offering services.
- 18. "Closed setting" is:
 - a. Any venue with a roof or ceiling, doors, windows, or open or closed pathways, completely surrounded with permanent or temporary walls.
 - b. Any venue with a roof or ceiling, doors, windows, or open or closed pathways, completely surrounded with permanent or temporary walls, with permanently opening walls or with unchanging walls (that cannot open or close), with an area of 50 per cent less than the total wall area".
- 19. "Cigarette" means a wrapper filled with minced tobacco consumed through the combustion process, except of cigars, cigarillos and other tobacco wrappers.
- 20. "Roll-your-own-cigarettes" means rolling paper filled with fine-minced tobacco smoked without further industrial processing.
- 21. "Pipe tobacco" means the loose tobacco for smoking.

- 22. "Cigars" means cigarette smoke, wrapped in tobacco leaves or tobacco-color wrappers, with or without filter, consumed by the combustion process.
- 23. "Shisha tobacco" means tobacco consumed in the form of smoke or steam, necessarily passing through a water container, which may or may not be flavoured, or mixed with fruit sugar or molasses.
- 24. "Burnot" means a smokeless tobacco product consumed by smelling.
- 25. "Tobacco for oral use" means all tobacco products for oral use, with the exception of those products consumed by inhalation or chewing, wholly or partly made of tobacco, in the form of dust, particles or combined, packed in porous bags.
- 26. "Smokeless tobacco" means a non-combustible tobacco product, including chewing tobacco, nasal inhalation tobacco, oral tobacco, and heated tobacco.
- 27. "Smoke" means solid or liquid particles in the air and gases created when a material is burned together with the amount of air absorbed or mixed with the mass, including smoke extracted from the lungs during smoking.
- 28. "Combustion" means a chemical process of oxidation that occurs quick enough to produce heat and usually incandescent light or flame.
- 29. "New tobacco products" means tobacco products which:
 a) do not fall into any of the following categories: cigarettes, roll-your-own-cigarette, hookah tobacco, cigars, cigarillos, chewing tobacco, inhaling tobacco, oral tobacco; b) they shall enter the market after the entry into force of this law.
- 30. "Electronic cigarette" means a product that may be used for the consumption of vapor containing nicotine by means of a mouth piece placed near the mouth or any other parts of that product, including a container, a tank and a mouth piece without a container or tank. Electronic cigarettes can be disposable, refilled by a re-filler tank, or they can be recharged by a disposable cartridge.
- 31. "Rechargeable cartridge" means an instrument with a nicotine-containing liquid that can be used to refill an electronic cigarette.
- 32. "Heated tobacco" means a tobacco product, specially designed for heating, used to release aerosol containing nicotine and other substances which are orally inhaled by the user.
- 33. "Characteristic taste" means a clearly distinct taste or aroma other than that of tobacco due to the use of an additive or a combination of additives, including but not limited to: fruit, spices, herbs, alcohol, candy, menthol or vanilla, which are perceivable before or during the tobacco products consumption.
- 34. "Cigarillo" means a type of cigar, weighing not more than 3 grams.
- 35. "Extra substance" means a substance other than tobacco, which is added to a tobacco product, a package unit or any external packaging.
- 36. "Flavoring" means an additional substance that adds flavor and/or taste.

CHAPTER II

MANDATORY HEALTH WARNINGS ON TOBACCO PRODUCTS

Article 4

(wording was added in the first paragraph and words were amended in the second paragraph under law no. 49/2013, dated 14.2.2013)

Every package unit or packet of tobacco products should contain warning messages with regard to health harms caused by smoking. Such messages should be written clearly, legibly, and visibly in Albanian. They should cover 50% or more of the area they appear on, but not less than 30% of the main area.

Messages type and content shall be determined by CSCHPTP on regular bases.

Article 5

(items 4, 5 and 6 were added under law no. 56/2019, dated 18.7.2019)

- 1. On packages and packets, containing tobacco products, the following shall appear in written form in Albanian:
 - a) name of product;
 - b) name, address of manufacturer and name of license holder;
 - c) number of pieces/units of tobacco products per package or packet;
 - ç) amount of nicotine in the smoke;
 - d) amount of tar in the smoke;
 - dh) amount of carbon monoxide in the smoke.
- 2. If the product has not been packaged by its manufacturer, it should also bear the name of packager. The data mentioned in items 1 and 2 of the current law should cover 10% of the outside area of the packet and be placed on the lateral areas.
- 3. It is banned to domestically manufacture, import, and trade tobacco products containing more than:
- 10 mg of tar per cigarette;
- 1 mg of nicotine per cigarette;
- 10 mg of carbon monoxide

Tests measuring the amount of tar, nicotine, and carbon monoxide shall be conducted in laboratories accredited by competent authorities based on ISO standards.

- 4. Each electronic cigarette packaging unit and packaging of nicotine refill cartridges shall contain an information sheet in Albanian, including information on instructions for use and storage of the product, including a reference that this product is not recommended for use by young people and non-smokers; contraindications to use; warnings for particular risk groups, side effects; the degree of addiction and toxicity; manufacturer or importer details.
- 5. Nicotine liquid shall only be placed on the market when it is in dedicated cartridges at the amount of not more than 10 ml or in the form of disposable electronic cigarettes, at the amount of not more than 2 ml.
- 6. The placing on the market of a liquid containing more than 20 mg/ml of nicotine is not permitted.

Article 6

Writing expressions such as "low tar content", "light", "super light", "mild" or terms, figures, photos, drawings, and other similar elements on packets or packages, aiming at giving the wrong impression that a certain tobacco product is less harmful than other products, shall be banned.

Article 7

It is the task of Ministry of Health to notify the public about tar, nicotine, and carbon monoxide levels in the production of tobacco products, their impact on health as well as every effect which brings about or is thought to bring about addiction

Article 8

(amended under law no. 56/2019, dated 18.7.2019)

It is mandatory for manufacturers and/or importers of new tobacco products including electronic cigarettes and heated tobacco to notify the Ministry responsible for Health regarding tobacco products circulating in the domestic market as well as whenever they launch a new tobacco product in the market. This notification shall be submitted electronically not later than 30 days before the product enters the market. The notification shall include:

- a) Manufacturer or importer contacts in Albania;
- b) Detailed product description;
- c) Instructions of its use;
- d) A list of all components used during the manufacturing of such product and their respective amounts, the reason or purpose such components were used as well as their functions and categorization. Such a list should be accompanied with toxicological data made available by the manufacturer or importer regarding such combustible or non-combustible components, emphasizing in particular their impact on health and assessing every effect which brings about or is reckoned to bring about smokers' addiction.
- e) Available evidence, risk of addiction and withdrawal of the product.

CHAPTER III RESTRICTING MEASURES ON CONSUMING TOBACCO PRODUCTS

Article 9

(wordings were added under law no. 56/2019, dated 18.7.2019)

It is forbidden to trade or supply, for commercial purposes, tobacco products, electronic cigarettes, shishas/hookahs to people under 18.

All outlets shall be provided with a visible and legible sign reading: "It is forbidden to trade tobacco products to people under 18."

Article 10

(wordings were added under law no. 56/2019, dated 18.7.2019)

It is forbidden to trade tobacco products, electronic cigarettes, shishas/hookahs:

- a) in state institutions:
- b) in educational institutions;
- c) in sports institutions;
- c) automatic vending machines;
- d) as a self-service;
- dh) at the street by vendors;
- e) by mail service.

Article 11

(paragraphs were added after the first paragraph under law no. 56/2019, dated 18.7.2019)

Retailing of packaged or damaged packets of tobacco products is prohibited. It is forbidden to market tobacco products with a characteristic taste. Use of additives necessary to manufacture tobacco products shall not be banned such as the sugars replacing the sugar lost during the tobacco processing process, provided that these additives do not cause characteristic taste and do not boost significantly and measurably the addiction, toxicity or carcinogenic, mutagenic and toxicity characteristics for tobacco product reproduction.

The Ministry responsible for Health determines whether a tobacco product is considered of characteristic taste. The procedure for determining tobacco products of characteristic taste shall be drafted by a decision of the Council of Ministers.

It is prohibited to place on the market tobacco products containing flavorings in any of the components, such as filters, paper wrappers, packaging, capsules or any technical modification that permits the modification of the flavor or taste of the tobacco product or the smoke intensity. Filters, paper wrappers, and capsules should not contain tobacco or nicotine.

One cigarette package unit shall contain at least 20 cigarettes. One roll-your-own-cigarette unit shall contain not less than 30 grams of net tobacco product.

Article 12

Manufacturer, importers or trader of tobacco products are banned from offer them for free.

CHAPTER IV

ADVERTISEMENT, PROMOTION, AND SPONSORSHIP

Article 13

(the last sentence of the first paragraph was amended under law no. 56/2019, dated 18.7.2019)

It is forbidden to advertise or promote tobacco products by means of the written media, television or radio broadcastings, and information companies' services. It is forbidden to advertise tobacco products in any other form or way, including indirect promotion through color representing company logos or promotion by displaying products imitating the external package of a tobacco product.

It is forbidden to publish photos, drawings etc for advertisement or promotion purposes which reveal people smoking or create wrong public impression about the features of tobacco products, health impacts, risks and/or harms.

Scientific books, magazines and other professional tobacco publications shall not be considered as means of advertisement or promotion.

Article 14

It is forbidden for companies whose activity is manufacturing, importing or trading of tobacco products to sponsor radio and television programs and any other activity when such a sponsorship aims at promoting or advertising tobacco products.

Article 14/1

(added under law no. 76/2014, dated 10.7.2014)

- 1. The Albanian Broadcaster shall broadcast educational shows on a monthly basis on health PROTECTION against TOBACCO PRODUCTS pursuant to the law on the Audio Visual media in the Republic of Albania. These educational shows shall be aired for 90 minutes between 8:00 and 22:00. One of these shows, lasting for 30 minutes shall be aired mandatorily from between 17:00 and 22:00.
- 2. The official websites of public institutes shall post visible information messages on health risks from smoking and tobacco products.

CHAPTER V

PROTECTION FROM INVOLUNTARY EXPOSURE TO TOBACCO SMOKE

Article 15

(letter "dh" was amended under law no. 49/2013, dated 14.2.2013 and amended under law no. 76/2014, dated 10.7.2014)

- 1. Smoking shall be banned in:
 - a) the work place;
 - b) health institutions, except of mental health institutions (only by patients);
 - c) educational institutions, including nurseries;
 - c) public means of transport, including taxis;
 - d) closed marketing settings, bars, restaurants, discotheques, and night clubs;
 - dh) closed culture and sport settings
 - e) shared premises under mandatory ownership
 - ë) other closed public settings;
- 2. The above-mentioned settings/institutions shall issue internal regulations emphasizing the banning of smoking in such settings and identify the person that will take actions in cases of any violations of the regulation.

Article 16

(a sentence was added at the end of the Article under law no. 49/2013, dated 14.2.2013 and amended under law no. 76/2014, dated 10.7.2014)

The owner or manager of settings mentioned in article 15 of the current law or the person hereto appointed shall be responsible for posting in visible areas the list of inspectorate authorities on protection of health from tobacco products, for placing visible signs which indicate that smoking in such settings is banned and for not permitting the placement of ashtrays in such settings. The form and content of warning signs shall be developed by the

Cross-sector Committee on Health PROTECTION against TOBACCO PRODUCTS CSCHPTP.

CHAPTER VI

ORGANIZATION OF STRUCTURES FOR HEALTH PROTECTION AGAINST TOBACCO PRODUCTS

Article 17

A Cross-Sector Committee for Health Protection against Tobacco Products (CSCHPTP) shall be established at the Ministry of Health. CSCHPTP shall be chaired by the Minister of Health.

Its organization, operation, composition and remunerations for Committee members shall be determined by a decision of the Council of Ministers.

Article 18

CSCHPTP shall be responsible for:

- a) guiding public health protection policies and strategies against tobacco products;
- b) revising the existing acts regarding public health protection from tobacco products and proposing amendments to the law;
- c) proposing programs and projects in order to ensure the reduction of tobacco products consumption and protection of citizens, monitoring and assessing such programs and projects;
- ç) directing sources towards programs and projects aiming at reducing tobacco products consumption and health protection.
- d) ensuring collaboration with state and private institutions both at home and abroad regarding tobacco control policies;
- dh) submitting annual reports to the relevant parliamentary commission.

CHAPTER VII

INSPECTION, MONITORING OF LAW ENFORCEMENT AND ADMINISTRATIVE VIOLATIONS

Article 19

(nominations were amended and a new paragraph was added under law no. 49/2013, dated 14.2.2013 and amended under law no. 76/2014, dated 10.7.2014, nominations were amended under law no. 56/2019, dated 18.7.2019)

1. The responsible law-enforcing institutions are:

- a) The health inspection responsible structures, customs administration bodies, and the Tax Offices shall be responsible for any violations to articles 4, 5, and 6. In events these institutions conduct joint inspections they shall coordinate their duties to serve this purpose.
- b) Tax authorities shall be responsible for any violation to article 9;
- c) Health inspection structures shall be responsible for any violation to paragraphs "a", "b", and "c" of article 10,
- ç) Education Inspectorate shall be responsible for any violation to paragraphs "b", and "c" of article 10;
- d) Tax authorities shall be responsible for any violation to paragraphs "ç", "d" e "dh" of article 10;
- dh) Health inspection structures and the tax authorities shall be responsible for any violation to articles 11, 12, 13, and 14;
- e) Labor, and health inspection inspectorate and Fire Security Inspectorate shall be responsible for any violation to paragraph "a", of article 15;
- ë) Health inspection structures, for any violation to paragraph "b", of article 15;
- f) Education Inspectorate and Health Inspectorate shall be responsible for any violation to paragraph "c", of article 15;
- g) The State, municipal/communal police shall be responsible for any violation to paragraph "ç", of article 15;
- gj) Labor Inspectorate, health inspectorate and National Food Authority shall be responsible for any violation to paragraph "d", of article 15;
- h) Health inspection structures and the police in the area shall be responsible for any violation to paragraph "dh", of article 15;
- i) Municipal/commune police and the police inspector in the area shall be responsible for any violation to paragraph "e", of article 15;
- j) Health inspection structures shall be responsible for any violation to paragraph "ë", of article 15.
- 2. The inspectorate authorities, pursuant to paragraph 1 of this article, shall certify that the legal requirements deriving from the current law are met pursuant to Law no. 10 433, dated 16.6.2011, "On Inspection in the Republic of Albania".
- 3. The Central Inspectorate shall coordinate the activities of all inspectorate authorities, defined in paragraph 1 of this article. The Health inspection structures shall be in charge of monitoring the law enforcement and collection information by the other inspectorate authorities.

Article 20

(letters "c" and "d" were amended, a new paragraph was added after letter "ë" and the last paragraph was amended under law no. 49/2013, dated 14.2.2013 and amended under law no. 76/2014, dated 10.7.2014, letter a/a and item 1/1 were added under law no. 56/2019, dated 18.7.2019))

- 1. Violations of provisions of the current law, when not qualified as criminal offenses, shall be considered as civil offenses and punished as follows:
 - a) violation of article 4, article 5, paragraph 1, letters "ç", "d" e "dh" and paragraph 3, as well as article 6 shall be punished by confiscation, disposal of goods, and a fine of LEK 5,000,000 (five million), as appropriate, for the importer of the product or domestic manufacturer:
 - a/a. Violation of article 8 shall be fined by LEK 500,000 for the importer of the product or domestic manufacturer;
 - b) violation of article 9 shall be punished by confiscation of tobacco products and a fine of LEK 100,000 (one hundred thousand), as appropriate, for the retailers or wholesalers;
 - violation of article 10 shall be punished by confiscation of tobacco products and a fine of LEK 100,000 (one hundred thousand), as appropriate, for the retailer or taxable business operator;
- ç) violation of article 11 shall be punished by confiscation of tobacco products and a fine of LEK 20,000 (twenty thousand) for the retailer.
- d) violation of article 12 shall be punished by confiscation of tobacco products and a fine of LEK 100,000 (one hundred thousand), as appropriate, for the manufacturer, importer, or trader who has committed the offence.
- dh) violation of article 13, paragraph 1 and 2, shall be punished by a fine of LEK 3,000,000 (three million) for the taxable person of advertising company, printed press, radio or television airing, or information company's service;
- e) violation of article 14 shall be punished by a fine of LEK 3,000,000 (three million) for the manufacturer, importer or trader of tobacco products who has committed the offence;
- ë) violation of article 15 shall be fined as follows:
- i) 300,000 LEK (three hundred thousand) to the taxable person;
- ii) 50,000 LEK (fifty thousand) to the person in charge in public institutions;
- iii) 50,000 LEK (fifty thousand) to the manager of dwelling premises of mandatory coownership;
- iv) 5 000 LEK (five thousand) to the smoker;
- f) violation of article 16 shall be fined as follows:

- i) 300,000 LEK (three hundred thousand) to the taxable person;
- ii) 50,000 LEK (fifty thousand) manager of person in charge.

1/1 For a violation of article 15 twice within a three-month period, the taxable person shall be fined equally to twice the fine imposed in subdivision "i" of letter "h" of this Article.

If the taxable person fined twice is found to be in breach of article 15 again within a one-year period, a fine of six times the fine set in subdivision "i" of letter "ë" shall be imposed, followed by a suspension of activity until the fine is paid.

- 2. Confiscation and disposal of goods shall be primary measure of punishment whereas fining shall be a primary measure of punishment where foreseen as separate measure, and complementary punishment where given simultaneously with the confiscation and disposal measure.
- 3. Appeal against the decisions of the relevant inspectorate authorities shall be handled under the law on inspection whereas appeal against tax authorities, customs authorities, State Police, municipal/communal police shall be handled under the legislation in force. Upon the termination of procedures of administrative appeals, court appeal procedures shall be initiated within the deadlines and procedures foreseen in the provisions of the law no. 49/2012, "On Organization and functioning of administrative/civil courts and ruling over civil disagreements".
- 4. The revenues generated by fines, pursuant to this article, shall be delivered to the State Budget.

Article 21

Paragraph 3 of article 19/a and paragraph 3 of article 19/b of law no. 8691 dated 16.11.2000 "On Manufacturing and trading of tobacco and cigarettes", amended, shall be repealed.

Article 22

It is the task of Council of Ministers, as provided for by articles 17 and 19 of the current law, to issue bylaws.

Transitional provision

(decided under law no. 49/2013, dated 14.2.2013)

The current inspecting authority shall exert its duty based on the current structure until a new authority is established as foreseen in the amendments to this law.

Article 23

The current law shall enter into force 6 months after its publication in the Official Journal, whereas article 6 of the current law shall be enforced as of January 1, 2009.

Declared upon decree no. 5122 dated 20.11.2006 of the President of the Republic of Albania, Alfred Moisiu