

LAW
No. 56/2019

**ON SOME AMENDMENTS AND ADDITIONS TO LAW NO. 9636, DATED
11.6.2006, “ON THE PROTECTION OF HEALTH FROM TOBACCO PRODUCTS”,
AS AMENDED¹**

Pursuant to Articles 78 and 83, point 1 of the Constitution, with the proposal of the Council of Ministers,

**THE ASSEMBLY
OF THE REPUBLIC OF ALBANIA**

DECIDED:

In the Law No. 9636, dated 11.6.2006, “ON THE PROTECTION OF HEALTH FROM TOBACCO PRODUCTS”, as amended, the following amendments and additions will be made:

Article 1

At Article 3 the following amendments and additions are made:

1. Point 1 and 7 are changed as follows:

"1. ‘Tobacco products’ means products that can be consumed and which must contain, even partially, tobacco whether it is genetically modified or not”.

"7. ‘Smoking’ is the lighting, inhaling and keeping in one’s hand a lit tobacco product, as well as of electronic cigars and waterpipes/Hookahs.”

2. At point 18, after the words: “Completely with walls”, the following words are added: “And any other kind of material”.

3. After point 18, points 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35 and 36 are added with the following content:

"19. ‘Cigarette’ means a roll of a minced tobacco, which is consumed through the combustion process, except of cigars, cigarillos and rolls of tobacco.

20. ‘Roll-your-own-tobacco’ means finely minced tobacco, which can be used for smoking by consumers without further industrial processing.

21. ‘Tobacco for pipe’ means ground tobacco for use with pipe.

22. ‘Cigar’ means minced tobacco, which is covered with, rolled tobacco leaves or with cover paper with tobacco color, with or without filter, which is consumed through the combustion process.

23. ‘Hookah tobacco’ means a tobacco product that can be consumed as a smoke of vapor, by having to pass through a waterpipe, which may or may not be flavored, or mixed with sugar fruit or molasses.

24. ‘Nasal tobacco’ means a smokeless tobacco product that can be consumed via the nose.

¹This draft law partially approximates with Directive 2014/40/EU, of the European Parliament and the Council, dated April 3, 2014, “On the approximation of the law, regulations and administrative provisions of member states on the production, introduction and sale of tobacco and tobacco products and the repeal of Directive 2001/37/EC.

Official journal of the European Union, L 127/1, dated 4.29.2014, CELEX, no 32014L0040.

25. 'Tobacco for oral use' means all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets;

26. 'Smokeless tobacco product' means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;

27. 'Smoke' means solid or liquid particles in the air and the gases created when a material is combusted together with the amount of air that is inhaled or mixed, including also the smoke exhaled by the lungs during smoking.

28. 'Combustion' means a chemical process of oxidation, which occurs with such a fast, speed as to produce heat and usually light in incandescent form or as a flame.

29. 'Novel tobacco products' means a tobacco product which:

(a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, Hookah tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use;

(b) is placed on the market after the entry into force of this law.

30. 'Electronic cigarette' means a product that can be used for consumption of nicotine-containing vapor via a mouth piece, or any other component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges;

31. 'Refill container' means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette;

32. 'Tobacco by heat' means a tobacco product, especially created for heating purposes, which is used to exhaust aerosol containing nicotine and other substances, which is inhaled from the user through the mouth.

33. 'Characterizing flavor' means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product;

34. 'Cigarillo' means a kind of cigar weighting no more than 3 grams.

35. 'Additive' means a substance, other than tobacco that is added to a tobacco product, a unit packet or to any outside packaging;

36. 'Flavoring' means an additive that imparts smell and/or taste".

Article 2

In article 5, after point 3, points 4, 5 and 6 are added with the following content:

"4. Any packaging unit of electronic cigarettes and nicotine liquid refill packages must contain an information sheet in Albanian language, which should include information about: instructions for the use and storage of the product, including a reference that this product is not recommended for use by young people and by non-smokers; contra-indications for its use; warnings to special risk groups; warnings for side effects; the level of addiction and toxicity; the contact details for the manufacturer and the importer.

5. Nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml.

6. Nicotine-containing liquid should only be allowed to be placed on the market where the nicotine concentration does not exceed 20 mg/ml.

Article 3

Article 8 is changed as follows:

“Article 8

1. Manufacturers and importers of novel tobacco products, including electronic cigarettes and tobacco for heating products are required to submit a notification to the Ministry competent for Health of any such product they place on the national market, as well as in any instance when they place a new tobacco product in the market. The notification shall be submitted in electronic form no later than 30 days before the intended placing of the product on the market. The notification should contain:

- a) the contact information of the manufacturer or the importer in Albania;
- b) a detailed description of the product;
- c) user instructions;
- d) a list of all ingredients used in the manufacturing of the tobacco product and their quantities, the reason or purpose of their use as well as to define how the ingredients work and of what type are they. The list should be accompanied by toxicological data, available from the manufacturer or the importer, regarding the product's ingredients and emissions, including both in combusted and non-combusted form, referring in particular to their effects they cause on the health of consumers or are believed to cause any addictive effect to the consumer on the tobacco product.
- e) substances available for scientific research, the addictive risk and product recall.”

Article 4

At point 9, after the words: ‘Tobacco products’ the following words are added: “Electronic cigarettes, Hookah tobacco”.

Article 5

At point 10, after the words: ‘Tobacco products’ the following words are added: “Electronic cigarettes, Hookah tobacco”.

Article 6

At Article 11, after the first sentence, the following paragraphs with this content are added:

“The placement in the market of tobacco products with characterizing flavor is prohibited. The use of additives necessary for the manufacture of tobacco products, such as sugar to replace sugar that is lost during the tobacco curing process, is not prohibited, as long as these additives do not result in a characterizing flavor or increase the addictiveness, toxicity or mutagenic or carcinogenic properties for reproduction of the product to a significant and measurable level.

The Ministry responsible for Health determines whether a tobacco product is considered as one with characterizing flavor. The procedures for the way of determining the tobacco product with characterizing flavor are carried out through a decision of the Council of Ministers.

The placing in the market of tobacco products containing flavors in any of its components, such as filters, paper, packaging, capsules, or any other technical modification allowing the modification of the tobacco product flavor or taste or of the smoke intensity. Filters, paper and capsules should not contain tobacco or nicotine.

One cigarette-packaging unit should contain at list 20 cigarettes. On roll your own cigarette-packaging unit should contain no less that 30 grams net of tobacco product.

Article 7

At Article 13, the last sentence, first paragraph is amended as follows:

“Any other forms of advertisement of tobacco products, including indirect promotions through colors representing company logos, or promotion through the exposition of product that imitate outside packaging of a tobacco product are prohibited.

Article 8

At Article 19 and in the entire content of the law, the terms: “The inspectorate covering health” is replaced with the terms: “The responsible structure for inspecting in the area of health”.

Article 9

At Article 20 the following additions and amendments are made:

1. After letter “a” at point 2, the letter “a/a” with the following content is added:

“a/a. The violation of Article 8 is sanctioned with a fine of 500,000 ALL to the manufacturer and/or the importer of the novel tobacco products.”

2. In article a 5, after point 1, point 1/1 with the following content is added :

“1/1. For violations of Article 15 twice within a 3-month period the taxable subject is sanctioned with a fine twice as heavy compared with the fine imposed in subsection “i” of letter “ë” of this article.

If the taxable subject which is sanctioned for the second time is found once again in violation of Article 15 within a time period of one year, then a fine six fold higher than the fine sanctioned per subsection “1” of letter “ë”, of this article is imposed on him/her, as well as the suspension of his/her activity until the fine as been paid in full.”

Article 10

Within 6 months of the entry into force of this law the Council of Ministers is charged with issuing the bylaws enabling the implementation of the second paragraph of Article 6 of this law.

Article 11

Entry into force

This law enters into force 15 days after its publication in the Official Gazette, with the exceptions of the first, third and fourth paragraph of Article 6 of this law, which enters into force 24 months after its publication in the Official Gazette.

CHAIRMAN
Gramoz Ruçi

Approved on the date of 7.18.2019

Promulgated through Decree No. 11240, dated 7.26.2019 of the President of the Republic of Albania, Mr. Ilir Meta.