

Note: document includes the following laws:

Law No. 349-2002;

Ordinance No. 13/2003;

Law No. 275/2003;

Law No. 90/2004;

Law No. 553/2004;

Emergency Ordinance No. 58/2006;

Ordinance No. 5/2008;

Correction in Official Gazette No. 116, 14 February 2008;

Law No. 203/2008;

Law No. 15/2016.

## **LAW No. 349 of June 6, 2002**

### **On preventing the consumption of tobacco products and combating its effects**

*Text enters into force on March 17, 2016*

- Government Ordinance No. 13/2003;
- Law No. 275/2003;
- Law No. 90/2004;
- Law No. 553/2004;
- Emergency Government Ordinance No. 58/2006;
- Government Ordinance No.5/2008;
- Correction published in the Official Gazette of România, Part I, No. 116 of 14 February 2008;
- Law No. 203/2008;
- Law No. 15/2016.

#### **ART. 1**

This law sets forth certain measures on preventing and combating the consumption of tobacco products, by completely prohibiting smoking in all enclosed public spaces, enclosed spaces at the place of employment and children's playgrounds, by means of labeling the packages of tobacco products, by carrying out public information and education campaigns, informing consumers about tobacco products they are about to purchase, by indicating on the final product the tar, nicotine and carbon monoxide content, and by certain measures relating to the use of ingredients in tobacco products, with the goal of protecting the health of smokers and non-smokers from the harmful effects of smoking, preventing the spreading of smoking among minors and ensuring an adequate quality of life for the population of România.

#### **ART. 2**

For purposes of this Law [the following definitions shall apply]:

- a) tobacco products means products intended for smoking, snuffing, sucking or chewing made entirely or partly of tobacco, whether genetically modified or not;
- b) tobacco for oral use means all products intended for oral use, with the exception of those that are smoked or chewed, made entirely or partly of tobacco, in powder or particulate form or in any combination thereof, particularly those presented in sachet portions or porous sachets, and those having a form that resembles a food product;
- c) chewing tobacco means processed tobacco cut or minced intended for chewing;
- d) snuff tobacco means a processed tobacco product, ground to a fine powder, intended for snuffing;
- e) smoking means willingly inhaling the smoke that emanates from burning tobacco contained in cigarettes, cigars, cigarillos and pipes;

- f) cigarettes means tobacco products that contain processed tobacco, cut tobacco, wrapped in a longitudinal paper roll, having a round or oval cross section that contains processed tobacco configured to be smoked directly;
- g) “trabucuri” – generic term for cigars;
- h) cigar means a tobacco product obtained by wrapping filler tobacco (cut or minced) in one or more processed tobacco leaves;
- i) cigarillo means a small cigar;
- i<sup>1</sup>) electronic cigarette means a device used to inhale nicotine-containing vapors by means of a mouthpiece or any component thereof including a cartridge, a tank or the device without cartridge or tank;
- j) tar means the raw anhydrous nicotine-free condensate of smoke;
- k) nicotine means nicotinic alkaloids;
- k<sup>1</sup>) starting substance means flavors, solvents, humectants, adhesives and thickening agents, additives, sauces, colorants and coloring agents, preservatives;
- l) ingredient means any substance or any constituent, with the exception of tobacco leaves, and other natural or unprocessed tobacco parts used in the preparation or manufacture of tobacco products and still present in the finished product, even if it appears under different forms including paper, filter, ink and adhesives;
- m) enclosed public space means any space accessible to the general public or intended to be used by a community, regardless of ownership type or means of access, that has a roof or ceiling and is enclosed by at least two walls, regardless of the material used in construction or whether such construction is permanent or temporary;
- n) enclosed space at a place of employment means any space that has a roof or ceiling and is enclosed by at least two walls, regardless of the material used in construction or whether such construction is permanent or temporary as defined in the Occupational Safety and Health Law No. 319/2006, as subsequently amended;
- n<sup>1</sup>) public transport means any vehicle used for public passenger transport, usually for a fee;
- n<sup>2</sup>) children’s playground means any enclosed or outdoor space intended for use by children;
- o) packet means the smallest sale packet of a tobacco product;
- p) outside packaging means the material or object used to package several tobacco product packages for the purpose of retail sale of the tobacco product;
- q) transparent exterior wrapper means the transparent material or object additionally used to wrap one or more tobacco product packages.

### **ART. 3**

(1) Smoking shall be completely prohibited in all enclosed public spaces, enclosed spaces at the place of employment, public transport, and children’s playgrounds. Inmate cells in maximum-security prisons are exempted from these provisions.

(1<sup>1</sup>) Smoking shall be completely prohibited in state-owned or private health care and education facilities, and those providing child protection and assistance.

(1<sup>2</sup>) Use of electronic cigarettes is also prohibited in spaces set forth in art. 2 let. n<sup>1</sup>).

(2) Smoking is permitted in specially designated rooms only in the transit area of international airports provided the following requirements are met:

- a) [the space] is used exclusively for smoking;
- b) is not a passageway or access to enclosed public spaces;
- c) is equipped with working ventilation systems that ensure that smoke is exhausted by negative pressure;
- d) is equipped with ashtrays and fire extinguishers and set up in compliance with the legal provisions in force regarding fire prevention and fire fighting;
- e) is marked in a visible place by signs reading: “Smoking room”, “Smoking area”.

(2<sup>1</sup>) \*\*\* Repealed

- (3) \*\*\* Repealed
- (4) \*\*\* Repealed
- (4<sup>1</sup>) \*\*\* Repealed
- (4<sup>2</sup>) \*\*\* Repealed"
- (5) The sale of individual cigarettes, cigars and cigarillos shall be prohibited.
- (5<sup>1</sup>) Cigarette packets that contain fewer than 20 cigarettes may be placed on the market until 31 December 2004.
- (5<sup>2</sup>) The sale of cigarette packets that contain fewer than 20 cigarettes is prohibited.
- (6) The sale of tobacco products through vending machines shall be prohibited.
- (6<sup>1</sup>) The sale of tobacco products to youth under 18 years of age shall be prohibited.
- (7) The sanitary certificate for establishments that sell tobacco products will contain a special clause stating that selling tobacco products to youth under 18 years of age is prohibited.
- (7<sup>1</sup>) The sale of tobacco products on the premises of state-owned or private health care and education facilities is prohibited.
- (8) Manufacture and import for the domestic market and placing on the market of any packet of cigarettes that does not bear the inscription on measured tar, nicotine and carbon monoxide content shall be prohibited.
- (8<sup>1</sup>) \*\*\* Repealed
- (9) Manufacture and import for the domestic market and placing on the market of any packet of cigarettes that does not bear the warnings set forth by law shall be prohibited.
- (10) Placing on the market of any tobacco products for oral use shall be prohibited.

### **ART. 3<sup>1</sup>**

Tobacco, tobacco products and the ingredients used to manufacture tobacco products must meet at least the minimum conditions set forth in legal regulations in force.

### **ART. 3<sup>2</sup>**

- (1) Cigarettes placed on the market or manufactured shall not exceed:
  - a) 10 mg per cigarette for tar;
  - b) 1 mg per cigarette for nicotine;
  - c) 10 mg per cigarette for carbon monoxide.
- (2) The import of cigarettes manufactured in Member States of the Union, which comply with Community regulations concerning the maximum content of tar, nicotine, and carbon monoxide is permitted.
- (3) The tar, nicotine and carbon monoxide content from cigarettes is measured by laboratories approved and monitored by the Ministry of Public Health, or by laboratories duly accredited and monitored by the competent authorities of other Member States of the European Union.
- (4) The Ministry of Public Health will make publically available a list of laboratories approved and monitored by the Ministry of Public Health, specifying the criteria used for approval and the methods of monitoring applied, and a list of laboratories accredited and monitored by the competent authorities of other Member States of the European Union.
- (5) The tar, nicotine and carbon monoxide content from cigarettes is measured based on the following standards: ISO 4387- for tar, ISO 10315 - for nicotine, and ISO 8454- for carbon monoxide. The accuracy of the tar, nicotine and carbon monoxide measurements on packets is determined in accordance with ISO 8243.
- (6) The Ministry of Health may request that manufacturer or importers submit any supplementary tests to determine the concentration of other substances contained in tobacco products, by brand and type, in order to evaluate the effect these substances have on health, especially as regards their potential to cause addiction.
- (6<sup>1</sup>) Supplementary tests performed in accordance with para. (6) shall be carried out by approved or duly accredited laboratories as provided for in para. (3).

(7) Test results carried out in accordance with provisions in para. (6) shall be communicated annually to the Ministry of Health.

(8) The Ministry of Health may request that test results carried out in accordance with provisions in para. (6) be performed at greater intervals than those set forth in para. (7), when the characteristics of tobacco products are not modified.

(9) The Ministry of Health shall be notified every time the characteristics of tobacco products are modified.

(10) The Ministry of Health, the Ministry of Agriculture, Forests and Rural Development and Romanian Standards Association - ASRO – will ensure the adoption of ISO standards as Romanian standards until the entry into force of this law.

### **ART. 3<sup>3</sup>**

In the manufacture of tobacco products only starting substances from the list approved by joint order of the minister of health and the minister of agriculture, forests and rural development issued by 31 December 2004 may be used.

### **ART. 3<sup>4</sup>**

(1) Manufactures or importers of tobacco products generate a record for the product that will contain the following:

- a) a list of all ingredients used in the manufacturing process of tobacco products, and the quantities thereof by type and brand name. The list will be compiled in descending order of weight of each ingredient in the tobacco product;
- b) a statement on the reasons for using the listed ingredients in the tobacco product, indicating the function and categories thereof;
- c) toxicological data available to the manufacturer or importer regarding the ingredients used, regardless of their form of presentation, with special reference to their effect on health, and addictiveness;
- d) tar, nicotine and carbon monoxide content in the case of cigarettes.

(2) The record drawn up in accordance with the provisions in para. (1) shall be submitted annually, by 1 September, by the manufacturer or importer, as notification to the competent authority designated by the Ministry of Public Health.

(3) Information on tar, nicotine and carbon monoxide content, the results of supplementary tests conducted upon request by the Ministry of Health, and the statement, toxicological data of the product record, the list of ingredients used during the manufacture process, with the exception of data on specific product formulae that are deemed by the manufacturer to constitute a trade secret, are public information.

(4) The Ministry of Health ensures that consumers are informed about data set forth in para. (3), by any appropriate means. The list of ingredients for each product and the tar, nicotine and carbon monoxide content will be made publically available by the Ministry of Health.

(5) The standards for the implementation of provisions under para. (1) - (4) are determined in accordance with applicable Community regulations in the field, by order of the minister of public health.

### **ART. 4**

(1) Advertising of tobacco products is permitted in accordance with the legislation in force.

(2) The use of a tobacco logo or band name to promote or market other products is prohibited.

### **ART. 5**

Persons in charge of institutions and facilities who manage spaces under art. 2 letters m), n), n<sup>1</sup>) and n<sup>2</sup>) will develop and implement in-house regulations for the implementation of art. 3 paragraphs (1) and (1<sup>1</sup>), including provisions whereby violations constitute a serious disciplinary offence, and marking the mentioned spaces with signs indicating “No Smoking” and by using the international sign i.e., a cigarette with a diagonal bar through it.

**ART. 6**

(1) When placed on the market, each packet that contains cigarettes must indicate printed on one side of the packet, in Romanian, the tar, nicotine and carbon monoxide content measured in accordance with the legal provisions in force, in such a way that at least 10% of the corresponding surface of the packet is covered.

(1<sup>1</sup>) The name carbon monoxide shall be printed in full, i.e. "carbon monoxide" and not CO.

(1<sup>2</sup>) A packet of cigarettes is a rectangular parallelepiped composed of six surfaces/sides: two larger surfaces or main surfaces, two medium surfaces or laterals, and two small surfaces.

(2) Each packet that contains tobacco products, with the exception of tobacco for oral use, or other smokeless tobacco products shall be labeled in Romanian with a general warning, and an additional warning, as follows:

- a) the general warning shall be printed alternatively, to ensure regular appearance, using one of two texts, such as: "Smoking kills", with the alternative: "Smoking can kill" and "Smoking severely harms you and those around you";
- b) the general warning shall be printed on the most visible surface of the packet and on any outside packaging, with the exception of the additional transparent exterior wrapper used in the retail sale of the product;
- c) the most visible surface of the packet means one of the two large visible surfaces, selected as a reference;
- d) the general warning shall cover at least 30% of the external area of the visible surface of the packet on which it is printed;
- e) the additional warning printed alternatively, to ensure regular appearance, of one of the 14 texts on the list included in the annexe which constitutes an integral part of this law;
- f) the additional warning is printed on the other large visible surface and any exterior packaging with the exception of the additional transparent exterior wrapper used in the retail sale of the product;
- g) the additional warning shall cover no less than 40% of the external area of the surface of the packet on which it is printed;
- h) A combined warning consists of the text of an additional warning and a color photograph or other illustration that shows the consequences smoking has on health and shall be printed on cigarette packets and the exterior packaging thereof with effect from 1 July 2008, and on the packets and exterior packaging of the other tobacco products intended for smoking, with the exception of individually wrapped cigars, with effect from 1 January 2009, respectively. The technical standards for printing and the selection of the graphic elements shall be determined by order of the minister of public health in accordance with Community regulations in force;
- i) in the case of packets containing tobacco products other than cigarettes, where the most visible surface exceeds 75 cm<sup>2</sup>, warnings set forth in this law shall cover an area of at least 22,5 cm<sup>2</sup> on each surface.

(2<sup>1</sup>) Smokeless tobacco products shall be labeled in Romanian with the following warning: "This tobacco product can damage your health and causes addiction."

(2<sup>2</sup>) The text warning set forth in (2<sup>1</sup>) shall be printed on the most visible surface of the packet and on any outside packaging, with the exception of the additional transparent exterior wrapper used in the retail sale of the product, and shall cover at least 30% of the external area of the visible surface of the packet on which it is printed.

(3) Text warnings and tar, nicotine and carbon monoxide content shall be:

- a) printed in black Helvetica bold type on a white background; the font size shall occupy the greatest possible portion of the area reserved for the text;
- b) printed in lower-case type except for the first letter of the message;
- c) printed centered, parallel to the top edge of the packet;
- d) framed by a black border not less than 3 mm and not more than 4 mm in width that does not interfere with the text or graphics of the warning or the information given, with the exception of

smokeless tobacco products.

(3<sup>1</sup>) The border set forth in para. (3) let. d) is placed centered, parallel, with the edge of the packet or exterior packaging, and outside of it, above the health warnings, shall be printed centered the text: “Council Directive EC2001/37/EEC (in abbreviated form)”, text size, color and font used to be determined by the manufacturer. This border shall not be included in the surface allocated for the text which it frames; said surface shall be 10%, 30%, respectively 40% of the exterior area of the visible surface of the packet, depending on the type of warning.

(3<sup>2</sup>) \*\*\* Repealed

(4) The printing of the text warnings and the tar, nicotine and carbon monoxide content on the stamp shall be prohibited.

(5) The text shall be printed in such a way as to be irremovable, indelible, and shall not be obscured or hidden or interrupted by other texts or pictorials or by the opening of the packet.

(5<sup>1</sup>) In the case of tobacco products other than cigarettes, the warning texts may be irremovably affixed with adhesives.

(6) To ensure product identification and traceability, tobacco products shall be marked appropriately by batch number or equivalent on the packets containing tobacco products, enabling the place and date of manufacture to be determined.

6<sup>1</sup>) The manufacturer shall mark the manufacture date using his own internal coding system to identify the batch; the control authorities will request from the manufacturer his proprietary coding system.

(7) The manufacture and import of tobacco products intended for the internal market and the placing on the market of any tobacco product which bears any text, names, trademarks, drawing, photographs or any other sign that suggests that a tobacco product is less harmful than others, shall be prohibited

(7<sup>1</sup>) \*\*\* Repealed

#### **ART. 7**

(1) Economic operators who manufacture and import for the internal market and those who market tobacco products shall take necessary measures for the implementation of the provisions under Art. 3 para. (5), (5<sup>2</sup>), (6), (6<sup>1</sup>), (7<sup>1</sup>), (8), (9), (10) and of Art. 6.

(1<sup>1</sup>) \*\*\* Repealed

(1<sup>2</sup>) Upon the entry into force of this law\*, manufacture, import and marketing of tobacco products which do not comply with the present law shall be prohibited.

(1<sup>3</sup>) The stock of tobacco products already in the commercial circuit on the date the law\* comes into force that does not comply with the present law shall be liquidated within 12 months.

(2) State health inspections will include mandatory monitoring of compliance with the provisions under this law.

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\* The texts are to take effect the date Law No. 90/2004 enters into force.

#### **ART. 7<sup>1</sup>**

Any tobacco product imported from a Member State of the European Union shall be admitted into the territory of România if such product was legally manufactured and marketed in the Member State of origin and provides an equivalent degree of protection.

#### **ART. 8**

The Ministry of Education and Research, the Ministry of Health and the National Youth Authority develop and implement national education programs, including through mass media, on preventing and combating the consumption of tobacco products.

#### **ART. 8<sup>1</sup>**

\*\*\* Repealed

#### **ART. 9**

National radio and television stations make available to the Ministry of Education and Scientific Research, the Ministry of Health and the Ministry of Youth and Sport, and to nongovernmental organizations independent from the tobacco industry and whose activities are aimed at reducing tobacco use as set forth in paragraph (1) of art. 44 of Law No. 95/2006 on healthcare reform, republished, as subsequently amended and supplemented, a broadcasting slot of minimum 30 minutes weekly, for the broadcasting of promotional materials to prevent and combat the consumption of tobacco products.

#### **ART. 9<sup>1</sup>**

Failure to comply with the provisions of this law results in contraventional, civil or criminal liability, depending on the case according to the law.

#### **ART. 10**

The following acts constitute violations and shall be sanctioned as follows:

- a) failure of a physical person to comply with the provisions of art. 3 paragraphs (1) and (1<sup>1</sup>) shall be sanctioned with a fine from 100 lei to 500 lei;
- b) failure of a legal entity to comply with the provisions of art. 3 paragraphs (1), (1<sup>1</sup>), (5), (5<sup>2</sup>), (6), (6<sup>1</sup>), (7<sup>1</sup>) and art. 4 paragraph (2) shall be sanctioned with a fine of 5,000 lei on a first violation, with a fine of 10,000 lei and the additional sanction of suspension of operations until the situation that led to the suspension of operations is remedied on a second violation; subsequent violations of this law shall be sanctioned with a fine of 15,000 lei and the additional sanction of shutting down the facility;
- c) failure to comply with the provisions of Art. 3 para. (8), (9), (10), of Art. 3<sup>2</sup> para. (1), (3), (6<sup>1</sup>), (7), (9), of Art. 3<sup>3</sup>, of Art. 3<sup>4</sup> para. (1) and (2) and of Art. 6 shall be sanctioned with a fine from 10,000 la 50,000 lei;
- d) failure of manufacturers and importers to comply with the requests made by the Ministry of Public Health as set forth in Art. 3<sup>2</sup> para. (6) and (7) shall be sanctioned with a fine from 10,000 la 50,000 lei.

#### **ART. 10<sup>1</sup>**

Tobacco and tobacco products that are the result of violations set forth in Art. 10 shall be seized and destroyed in accordance with the legal provisions in force.

#### **ART. 11**

Sanctions set forth in Art. 10 letters c) and d) shall apply to legal entities.

#### **ART. 12**

(1) Failure to comply with the provisions of Art. 3 para. (5<sup>2</sup>), (6), (8), (9), (10), of Art. 3<sup>2</sup> para. (1), of Art. 3<sup>3</sup>, of Art. 3<sup>4</sup> para. (1) and (2), of Art. 4 para. (2) and of Art. 6 shall be sanctioned with removal from the market of the product in question, for destruction by competent authorities in accordance with the law.

(2) \*\*\* Repealed

#### **ART. 13**

\*\*\* Repealed

#### **ART. 14**

The provisions on assessing violations and imposing sanctions under this law shall be supplemented by the provisions of Government Ordinance No. 2/2001 on the legal regime of contraventions approved as subsequently amended and supplemented by Law No. 180/2002, as subsequently amended and supplemented.

**ART. 14<sup>1</sup>**

Violations are assessed and sanctions are imposed by authorized persons from the Ministry of Health and the National Authority for Consumer Protection with the exception of provisions under letters a), b) and c) in art. 10 where violations are assessed and sanctions are imposed by representatives of the local police or the Ministry of Internal Affairs.

**ART. 14<sup>2</sup>**

The Ministry of Public Health shall communicate to the European Commission, annually or whenever there are changes:

- a) data and information resulting from the implementation of Art. 3<sup>2</sup> and 3<sup>4</sup>;
- b) list of laboratories approved to measure tar, nicotine and carbon monoxide content of tobacco products, and the criteria used for [lab] approval and the monitoring methods applied.

**ART. 15**

This Law shall enter into force six months after its publication in the Official Gazette of România, Part I, with the exception of the provision under Art. 3 paras. (8) and (9) and Art. 6, which enter into force on 31 December 2004.

This Law transposes Directive No. 2001/37/EC of the European Parliament and of the Council on the harmonization of legal regulatory or administrative provisions of Member States concerning the manufacture, presentation and sale of tobacco products, published in the Official Journal of the European Communities No. L 194 of 18 July 2001, pag. 26 - 35.

*sNOTE:*

Reproduced below are the provisions in Art. II and III of Government Ordinance No. 5/2008, as subsequently amended.

"ART. II

(1) The standards set forth in Art. 3<sup>4</sup> para. (5) of Law No. 349/2002, as subsequently amended and supplemented, and those in the present normative act, shall be developed and published within 90 days from the date of entry into force of the present ordinance.

(2) Regulations set forth in Art. 8<sup>1</sup> para. (2) of Law No. 349/2002, as subsequently amended and supplemented, and those set forth in this normative act shall be approved within 90 days from the entry into force of the present ordinance.

ART. III

The stock of tobacco products in the commercial circuit that fails to comply with the law shall be liquidated by 1 July 2009."

**ANNEX 1**

**LIST**

Comprising additional health warnings in accordance with Art. 6 para. (2) let. d)

1. Smokers die younger.
2. Smoking clogs the arteries and causes heart attacks and strokes.
3. Smoking causes fatal lung cancer.
4. Smoking while pregnant harms your child.
5. Protect children: don't let them breathe your smoke!
6. Your doctor or your pharmacist can help you stop smoking.
7. Smoking is addictive, don't start smoking!



8. Stopping smoking reduces the risk of fatal heart and lung disease.
9. Smoking can cause a slow and painful death.
10. To quit smoking consult your doctor/pharmacist.
11. Smoking reduces the blood flow and causes impotence.
12. Smoking causes ageing of the skin.
13. Smoking can damage sperm quality and reduces fertility.
14. Cigarette smoke contains benzenes, nitrosamines formaldehyde and cyanide.

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