

Annex No 1

Regulation for the requirements on the labelling, marking and layout of tobacco products and for defining standards for completing an evaluation on the relevant tar, nicotine and carbon monoxide content in the tobacco products

(Title, amended, - Official State Gazette, issue: 92 from year 2013, in effect from 22.10.2013)

Accepted by the Council of Ministers Decree No. 184 from 27.07.2004, published in the official state gazette, issue: 69 from 6.08.2004, in effect from 1.01.2005, amended and supplemented , issue: 2 from 7.01.2005, in effect from 1.01.2005, amended, issue: 92 from 22.10.2013, in effect from 22.10.2013

Code of statuses - APIS office (Bulgaria) 9/2004 year, page: 208; office. 2/2005 year, page: 390

Section I
General positions

Clause: 1 These regulations have been defined:

1. (amended - Official state gazette, issue: 92 from year 2013, in effect from 22.10.2013) the requirements for the labelling, marking and layout of tobacco products in view of ensuring the health of the consumers;

2. standards for evaluating the tar, nicotine and carbon monoxide content in the cigarettes.

Clause: 2 Under the regulation, the labelling requirements apply to all tobacco products intended for smoking, chewing and sniffing, which even if only partially, are produced from tobacco.

Clause: 3 The labelling of the tobacco products is to be completed subject to the requirements for labelling non-food goods, introduced by the current legislation.

Section II
Requirements for the labelling, marking and layout of tobacco products

(title, amended - Official state gazette, issue: 92 from year 2013, in effect from 22.10.2013)

Clause: 4 (1) (amended - Official state gazette, issue 92 from year 2013, in effect from

22.10.2013) The consumer packages of all types of cigarettes shall indicate the defined tar and carbon monoxide content in a cigarette in mg as a whole number and the nicotine content in a cigarette in mg as a decimal number, pursuant to the relevant standard under clause: 9. The accuracy upon marking the tar and nicotine content on the consumer packaging of cigarettes is to be assessed under standard ISO 8243.

(2) (amended - Official state gazette, issue 92 from year 2013, in effect from 22.10.2013) The inscription with the tar, nicotine and carbon monoxide in a cigarette is to be printed on one of the narrow long sides of the consumer packaging and should cover no less than 10% of the relevant surface.

Clause: 5. (1) Each consumer and outer packaging of tobacco products, with the exception of the packages of tobacco products for chewing and sniffing, as well as additional transparent wrappers, should bear one of the main warning inscriptions on their wide sides: "Smoking kills" or ""Smoking seriously harms you and others around you". The warning inscriptions should be printed upon an equal number of consumer packages.

(2) On the other wide side of each consumer and outer packaging, with the exception of additional transparent packaging, used in retail sales, with the exception of tobacco products for chewing and sniffing, an additional warning inscription from the list in the annex is to be placed. The additional warning inscription should be printed upon an equal number of consumer packages.

(3) Each consumer and outer packaging of tobacco products for chewing and sniffing, with the exception of additional transparent packages, used in retail sales, bear the warning inscription "This tobacco product may damage your health and lead to addiction", printed upon the most visible surface.

(4) The main warning inscription pursuant to article: 1 should take up no less than 30% of the relevant surface and the additional warning inscription on the consumer packages of cigarettes should take up no less than 40% of the relevant surface.

(5) On the consumer packages, designed for other tobacco products other than cigarettes, where the visible surface exceeds 75cm², the main and additional warnings pursuant to article: 1 and 3, cover no less than 22.5 cm² of the relevant surface.

Clause: 6. Except in the cases under clause: 7, the inscription with the contents of harmful substances under clause: 4 and the text of the main and additional warnings under clause: 5, not including tobacco products for chewing or sniffing, should comply with the following requirements:

1. to be printed in Bulgarian using black, bold Helvetica font on a white background, the size of the font is to be selected so that the inscription takes up the largest possible part of the area intended for the text;

2. they are to be written in small letters, except for the first letter of the inscription and the first letters of "You" and "Your".

3. they are to be centred in the area where they should be printed, parallel to the upper edge of

the consumer packaging;

4. they are to be surrounded by a black line, no less than 3mm and no more than 4mm wide, which does not cross the warning text or the information on the harmful substance contents;

5. they are not to be placed in an area which may be defected upon opening the packaging;

6. they are not to be printed upon the wrapper, which is removed when opening the packaging, or upon the wrapper signs (the stickers), they are not in any circumstances to be covered, overlapping or interrupted by other text or pictures.

Clause: 7. The main warning and the additional warnings pursuant to clause: 5, as well as the inscription with the harmful substance contents in clause: 4 upon tobacco products, designed for commercial outlets licensed for free trade, may be printed in English as well, as they must comply with the requirements in clause: 6 and the remaining provisions of the regulation.

Clause: 8. (1) The consumer packaging of tobacco products is to be marked in an appropriate way (by indicating the batch number or in another way), which ensures the identification of the place and time of the product manufacturing and the possibility to track it.

(2) Texts, names, trade marks and figurative or other signs cannot be placed upon consumer packaging of tobacco products, defining a product as less harmful.

Section III

Standards for evaluating the tar, nicotine and carbon monoxide content in the cigarettes

Clause: 9. (1) (amended - Official state gazette, issue 92 from year 2013, in effect from 22.10.2013) The tar content is determined according to standard ISO 4387.

(2) The nicotine content is determined pursuant to standard ISO 10315.

(3) The carbon monoxide content is determined pursuant to standard ISO 8454.

Section IV

Control and sanctions

Clause: 10. (amended - Official state gazette, issue 92 from year 2013, in effect from 22.10.2013) The control on applying the regulation is to be implemented by the Commission for Consumer Protection.

Clause: 11. For violations against the provisions of the regulation, the sanctions under clause: 46 from the Law for Tobacco and Tobacco Products apply.

TRANSITIONAL AND FINAL PROVISIONS

§ 1. Tobacco products, which are covered with stickers at the time of the regulation coming into effect and are not labelled according to the requirements, can be sold whilst stocks last but by no later than 32st December 2005.

§ 2. - New - Official state gazette, issue 2 from year 2005). The warehouse stocks of tobacco products up until 31st December 2004, designed for commercial outlets and licensed for free trade, which towards the date of the regulation coming into effect are not labelled according to the requirements, can be sold whilst stocks last but by no later than 32st December 2005.

§ 3. (Previously § 2 - Official state gazette, issue: 2 from year 2005.) The regulation is issued upon the grounds of clause: 35a, article: 2 and clause: 356, article: 1 from the Law for Tobacco and Tobacco Products.

§ 4. (Previously § 3 - Official state gazette, issue: 2 from year 2005.) The regulation comes into effect from 1st January 2005.

DECREE No. 237 from 17.10.2013 for amending the Regulation for the requirements on the labelling, marking and outer layout of tobacco products and for defining standards for completing an evaluation on the relevant content of harmful substances in the cigarettes.

- Official state gazette, issue 92 from year 2013, in effect from 22.10.2013)

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Additional provision

§ 8. The decree introduces the provisions of the Directorate 2012/9/EU of the Commission from 7th March 2012 for amending Appendix I towards Directorate 2001/37/EC of the European Parliament and of the Council for the approximation of laws, regulations and administrative provisions of the state members regarding the manufacturing, presentation and sale of tobacco products (text relevant to the EEA) (OJ, L 69/15 from 8th March 2012).

Transitional and final provisions

§ 9. Tobacco products that are labelled according to the requirements of the regulation up until the time of the decree coming into effect, can be sold whilst stocks last but by no later than 28th March 2016.

§ 10. The warehouse supplies of tobacco products, designed for commercial outlets and licensed for free trade, which are labelled according to the requirements of the regulation up until the time of the decree coming into effect, can be sold whilst stocks last but by no later than 28th March 2016.

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Annex

towards clause: 5, article: 2
(amended - Official state gazette, issue 92 from year 2013;
in effect from 22.10.2013)

List of additional warning inscriptions

1. Smoking causes 9 out of every 10 cases of lung cancer.
2. Smoking causes mouth and throat cancer.
3. Smoking damages your lungs.
4. Smoking causes heart attacks.
5. Smoking causes strokes and leads to disabilities.
6. Smoking leads to blocked arteries.
7. Smoking increases the risk of blindness.
8. Smoking damages your teeth and gums.
9. Smoking can kill your unborn child.
10. Cigarette 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 (telephone: 0700 10 323
or on the website: www.aznepusha.bg).
13. Smoking reduces your chances of having children.
14. Smoking increases the risk of impotence.