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Modifiers and Incorporations

DECISION OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA ON THE APPROVAL OF THE TECHNICAL REGULATIONS ON TOBACCO SAFETY AND ON DECLARING INEFFECTIVE DECISION No 540 OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA DATED APRIL 28, 2005

Armenian State Government

DECISION

No 219 DATED March 5, 2015, OF

THE GOVERNMENT OF THE REPUBLIC OF ARMENIA ON THE APPROVAL OF THE TECHNICAL REGULATIONS ON TOBACCO SAFETY AND DECLARING INEFFECTIVE THE DECISION No 540 OF THE GOVERNMENT OF THE REPUBLIC OF ARMENIA DATED APRIL 28, 2005

Pursuant to Art. 8, Part 1, Paragraph 3, Subparagraph (a) of the Law of the Republic of Armenia "On Technical Regulation", the Government of the Republic of Armenia *decides* [as follows]:

- 1. Approve the Technical Regulations on Tobacco Safety according to the Appendix.
- 2. Declare ineffective the Decision No 540 "On the Approval of the Technical Regulation on Tobacco" of the Government of the Republic of Armenia dated April 28, 2005.
- 3. To the Head of the Office for Coordination of Inspection Bodies of the Office of the Prime Minister of the Republic of Armenia: Within one month after the entry into force of this Decision, ensure the approval of state control checklists for tobacco products defined by this Decision.

(Paragraph 3 ed. per No 297 dated 29.03.19)

3.1. Establish, that only in the territory of the Republic of Armenia, the tobacco products are circulated in accordance with the requirements defined by this Decision, until January 1, 2024, and (or) in accordance with the requirements set by the Technical Regulations of the Customs Union: "Technical Regulations on Tobacco Products" (CU TC 035/2014).

(Paragraph 3.1 amended per No 297 dated 29.03.19)

4. This Decision shall enter into force 18 months after its official publication, except for Paragraph 3 of this Decision, which shall enter into force on the day following its official publication.

March 10, 2015 Yerevan

Appendix to the RA Government Decision No 219 dated March 5, 2015

TECHNICAL REGULATIONS ON TOBACCO SAFETY

I. FIELD OF APPLICATION

1. The provisions of the Technical Regulations on Tobacco Safety (hereinafter, the Technical Regulations) apply to the following tobacco products which are tobacco product types in accordance with the codes of the Commodity Nomenclature of Foreign Economic Activity:

Cigars, cigarillos (cigarita)	2402 10 000 0
Cigarette, kretek, beedi [bidi]	2402 20 100 0
	2402 20 900 0
Finely chopped smoking tobacco	2403 11 000 0
Hookah tobacco, smoke cylinder	2403 19 100 0
	2403 19 900 0

(Paragraph 1 ed. per No 297 dated 29.03.19)

2. This Technical Regulations defines the indicators characterizing the safety of tobacco products presented in Paragraph 1 of this Technical Regulations, their labeling, packaging, storage requirements, as well as the compliance assessment procedures.

(Paragraph 2 amended per No 297 dated 29.03.19)

3. This Technical Regulations is designed to protect human life and health and the environment, as well as to prevent misleading actions in terms of the significance and safety of tobacco products, and it applies to tobacco products circulating in the territory of the Republic of Armenia.

(Paragraph 3 ed. per No 297 dated 29.03.19)

4. The tobacco products presented in Paragraph 1 of this Technical Regulations are subject to conformity assessment.

(Paragraph 4 amended per No 297 dated 29.03.19)

- 4.1 This Technical Regulations does not apply to the following tobacco products:
- 1) Samples of tobacco products, which are imported into the territory of the Republic of Armenia by laboratories, producers (or) importers (vendors) of tobacco products, which are intended for quality and safety control, measurements in accordance with international standards, interlaboratory comparative tests, in accordance with the requirements of the legislation of the Republic of Armenia, for measurements, equipment calibration, comparative tests, tasting, design study.

- 2) Samples of tobacco products imported by the organizers (or) participants of international exhibitions and (or) participants as samples and exhibits into the customs territory of the Customs Union.
- 3) Tobacco products exported outside the territory of the Republic of Armenia in accordance with foreign trade agreements.

(Paragraph 4.1 amended per No 297 dated 29.03.19)

II. BASIC CONCEPTS

- 5. This Technical Regulations applies the following concepts provided for by the Law of the Republic of Armenia "On Restrictions on the Sale, Consumption and Use of Tobacco" in this section.
 - 1) (Subparagraph has become ineffective per No 297 dated 29.03.19)
 - 2) (Subparagraph has become ineffective, per No 297 dated 29.03.19)
- 3) **Consumer container**: a container in which the product is sold, and which is not a transporting container.
 - 4) Transporting container: a container which forms an independent transporting unit.
 - 5) **Box**: unit of a consumer container which contains a certain quantity of tobacco product.
 - 6) (Subparagraph has become ineffective per No 297 dated 29.03.19)
- 7) **Block**: a group consumer container unit which contains a certain quantity of boxes of cigarettes or smoke cylinders, either wrapped in paper or polymer film, or wrapped in paper tape.
- 8) **Tobacco product brand**: the name of a tobacco product with certain consumer properties, which identifies each individual type (subtype) of tobacco product.
- 9) **Batch of Tobacco Product types**: A quantity of Tobacco Product type of the same brand and packaging subject to inspection.
 - 10) **Tobacco Products**: Tobacco product types packaged in consumer packaging.

(Paragraph 5 amended and supplemented per No 297 dated 29.03.19)

III. RULES GOVERNING CIRCULATION RELEASE, INCLUDING SALES

6. The manufacturer or his/her authorized representative in the Republic of Armenia, shall take the necessary measures to ensure that the tobacco products released for circulation are manufactured in accordance with the safety requirements prescribed by this Technical Regulations, that they do not constitute a source of danger for the human life and health; natural and legal persons and state property; life and health of fauna and flora; the environment; nor do they contain elements of safety that mislead consumers.

(Paragraph 6 amended per No 297 dated 29.03.19 and ed. per No 1040 dated 08.08.19)

7. The release for circulation, including the sale, of the tobacco products in the territory of the Republic of Armenia, mentioned in Paragraph 1 of this Technical Regulations without compliance assessment and (or) national compliance mark, shall be prohibited.

(Paragraph 7 amended and supplemented per No 297 dated 29.03.19)

8. Tobacco products in the territory of the Republic of Armenia shall be accompanied by a declaration of compliance and (or) a national compliance mark.

(Paragraph 8 amended and supplemented per No 297 dated 29.03.19, and ed. per No 1040 dated 08.08.19)

9. The utilization (destruction) of tobacco products and the production waste from the tobacco products shall be governed in accordance with the legislation of the Republic of Armenia.

(Paragraph 9 amended per No 297 dated 29.03.19)

IV. SAFETY REQUIREMENTS APPLICABLE TO TOBACCO RAW MATERIALS AND TOBACCO PRODUCTS (title amended per No 297 dated 29.03.19)

10. Indicators characterizing the safety of tobacco raw materials and tobacco products are presented in Paragraphs 10.1, 11 and 12 of Table No 2 of this Technical Regulations.

(Paragraph 10 amended per No 297 dated 29.03.19)

10.1 In tobacco raw materials and tobacco products, the maximum content of carbon monoxide in each cigarette smoke shall not exceed 10 mg / per cigarette.

(Paragraph 10.1 supplemented per No 297 dated 29.03.19)

Table No 1

PHYSICAL AND CHEMICAL INDICATORS OF TOBACCO RAW MATERIALS (table has become ineffective per No 297 dated 29.03.19)

Table No 2

PHYSICAL AND MECHANICAL INDICATORS OF TOBACCO PRODUCTS (title amended per No 297 dated 29.03.19)

Tobacco product type	Indicator name	Norm
Cigarette	Humidity, %	11 – 15
	Maximum nicotine content in the smoke of one cigarette (with filter and without filter) should not exceed, mg / cigarette	1
	Maximum tar content in the smoke of one cigarette (with filter and without filter) should not exceed, mg / cigarette	10
Cigar, cigarillo		10 – 14
Smoke cylinder	Homeidite 0/	11 – 15
Smoking tobacco	Humidity, %	12 – 16
Pipe tobacco		11.5 –15.5

(the table was amended per No 297 dated 29.03.19)

- 11. (Paragraph has become ineffective, per No 297 dated 29.03.19)
- 12. (Paragraph has become ineffective, per No 297 dated 29.03.19)
- 13. (Paragraph has become ineffective, per No 297 dated 29.03.19)
- 14. During the manufacturing of tobacco products, it shall be prohibited to use as ingredients such substances that are described in in Table No 3 of the Technical Regulations:

No	Prohibited substances
1	Laricic acid (Acidum agaricinicum) Birch resin oil (Oleum Betulae empyreumaticum) Bitter almond oil (Oleum Amygdalarum amarum), alone or containing hydrocyanic acid Sassafras oil (Oleum Sassafratis) Juniper resin oil (Oleum Juniperi empyreumaticum) Camphor oil (Oleum camphoratum) Camphor Coumarin Safflower Thujone
2	Such substances the circulation of which is prohibited in accordance with the international treaties of the member states of the Eurasian Economic Union and the Common Economic Space.
3	Fragrances and flavors produced from: Woody stem of bitter-sweet nightshade (Stipites Dulcamarae) Wood of the camphor tree (Lignum Camphorae) Rhizome of the common centipede (Rhizoma Poiypodii) Leaves of swamp mint (Herba Pulegii) Quassia wood (Lignum Quassiae) Soap tree bark (Cortex Quillaja) Tansy herb (Herba Tanaceti) Satap [Rue] grass (Herba Rutae) Stalks, leaves and bark of sassafras (Stipes, Folium, Cortex Sassafratis) Medicinal clover (Millilotus officinalis) Tonka beans (Semen Toncae) Odoriferous Liatris (Liatris odoratissima) Woodruff (Asperula odorata)

(Paragraph 14 ed. per No 297 dated 29.03.19)

15. (Paragraph has become ineffective, per No 297 dated 29.03.19)

V. REQUIREMENTS FOR THE BRANDING AND PACKAGING OF TOBACCO PRODUCTS AND STORAGE TERMS

(title amended per No 297 dated 29.03.19)

16. (Paragraph has become ineffective, per No 297 dated 29.03.19)

- 17. Each unit of the tobacco box containing tobacco products, as well as the block and the insert sheet in the transparent packages of pipe and smoking tobacco, must contain the following information:
- 1) Product name ("Cigarettes", "Smoke cylinders", "Cigars", "Cigarillos", "Pipe tobacco" or "Smoking tobacco");
 - 2) Brand or trademark;
- 3) The names and location of the manufacturer and licensor (if any) or the name and location of the company that controls the production of its own brand of tobacco products, the raw materials used and the quality, in which case the manufacturing country shall also be indicated in the label;

- 4) The name and location of the organization receiving consumer complaints in the Republic of Armenia (if the manufacturer is located in another country);
 - 5) The presence or absence of a filter;
 - 6) The quantity in pieces or mass in grams (for pipe and smoking tobacco);
 - 7) The presence or absence of menthol;
- 8) Basic and additional warnings on the harmfulness of smoking in accordance with Paragraph 18 of this Technical Regulations;
- 9) Nicotine, tar content in one cigarette smoke (for cigarettes only) in accordance with Paragraph 10 of this Technical Regulations.

(Paragraph 17 amended per No 297 dated 29.03.19)

17.1. The box of the tobacco product must be marked with its maximum retail price in accordance with the procedure established by the Decision No 817 of the Government of the Republic of Armenia dated July 6, 2017.

(Paragraph 17.1 amended per No 558 dated 25.05.17)

- 18. The warning texts about the negative effects of tobacco on human health are the following:
- 1) The main warning texts:
- a. "Smoking is harmful to health."
- b. "Smoking can cause death."
- c. "Smoking seriously harms you and those around you."
- 2) The complementary warning texts:
- a. "Smoking causes lung cancer."
- b. "Protect children, do not let them breathe tobacco smoke."
- c. "Smoking during pregnancy harms your future baby."
- d. "Smoking causes cardiovascular diseases."
- e. "Smoking causes blockage of blood vessels and leads to heart attack and brain stroke."
- f. "Quitting smoking can reduce the risk of fatal heart and lung diseases."
- g. "Smoking harms sperm and reduces fertility."
- h. "Smoking causes lethal lung cancer."

(Paragraph 18 amended per No 297 dated 29.03.19; ed. per No 1040 dated 08.08.19)

- 19. The main warning text on the harmfulness of smoking shall be placed on one of the 2 largest areas of any box and the additional warning text, on the other. (Sentence removed per No 297 dated 29.03.19) Warning texts should be surrounded by a black frame and they, including the frame, should cover not less than 30% of the surface area of each of the 2 largest sides of the consumer package (tobacco box and block) used in the wholesale and retail sale of tobacco products (examples are given in Forms 1 and 2 of this Technical Regulations), and they shall meet the following requirements:
- 1) Warning texts must be printed in such a way as to exclude the possibility of removing them, and they must be printed:
 - a) clearly and legibly;
 - b) with dark ink on a contrasting background;
- c) in Arial Armenian bold font, the main warning texts in uppercase, the additional warning texts in lowercase except for the first letter in uppercase.
 - 2) The thickness of the frame around the main and additional warning texts should be 3-4 mm.
- 3) The font size should be chosen so that the warning texts occupy the maximum possible area for them.
- 4) The warning texts should be in the center of the surface intended for them, parallel to the top edge of the box and when opening it shall be possible to avoid damaging it.
 - 5) The warning texts should not contain the following:
 - a) be printed or affixed to paper as a transparent or outer packaging element;
 - b) be hidden or covered by other printed information or by an image;

- c) be printed on excise stamps of a consumer package (tobacco box and block).
- 6) In the case of transparent packs of pipe and smoking tobacco, the text of the warning on the harmfulness of smoking provided for in Paragraph 18 of this Technical Regulations should be placed on an insert sheet and it should cover an area of not less than 30% of its surface area.
- 7) The additional warning texts in 8 versions provided for in Paragraph 18, Subparagraph 2 of this Technical Regulations, should be indicated on the consumer package of tobacco products (tobacco box and block), offering the possibility of exchanging them on the consumer package of tobacco products (tobacco box and block).

(Paragraph 19 amended and ed. per No 297 dated 29.03.19)

- 20. In the Republic of Armenia, information on the organization receiving consumer complaints may be placed inside the box in a convenient place for reading (if the manufacturer is in another country).
- 21. Texts on the nicotine and tar content should be surrounded by a black frame and should cover at least 10% of the side area of the consumer package (tobacco box and block) used in wholesale and retail trade, including the frame, and comply with the examples included in this Technical Regulations (diagrams No 1 and 2) and the following requirements:
- 1) texts relating to nicotine and tar must be printed in such a way as to exclude the possibility of their removal and they must be printed:
 - a) clearly and legibly;
 - b) with dark ink on a contrasting background;
- c) In "Arial Armenian" bold font, the words "NICOTINE", "TAR" in capital letters, units of measurement for the nicotine and tar in small letters.
 - 2) The thickness of the frame around the texts on nicotine and tar content shall be 3-4 mm;
- 3) The font size shall be chosen so that the text on the nicotine and tar content occupies the maximum possible area;
- 4) The text of the nicotine and tar content shall be printed in the center of the surface intended for them, parallel to the side edge of the box and it shall be possible to avoid damaging this text when opening the box.
 - 5) The text on the nicotine and tar content shall not:
 - a) be printed or affixed to paper as a transparent or outer packaging element;
 - b) be hidden or covered by other printed information or by an image;
 - c) be printed on excise stamps of a consumer package (tobacco box).

(Paragraph 21 amended per No 297 dated 29.03.19, ed. per No 1040 dated 08.08.19)

22.It shall be permitted to post additional information on the transporting package of tobacco raw materials, as well as boxes of tobacco products, blocks, pipe and smoking tobacco, and on the inserts, which characterize the products and do not contradict the provisions of Paragraphs 16 and 17 of this Technical Regulations. However, it shall not be permitted to use the terms "low nicotine (tar)", "light", "very light" ("super light"), "soft", "unique filter" or any other misleading terms that directly or indirectly contribute to forming an opinion that the given tobacco product is less dangerous.

(Paragraph 22 amended per No 297 dated 29.03.19)

23. The manufacturer or his/her authorized representative shall ensure that the information on tobacco products manufactured or imported in the Republic of Armenia and sold in the Republic of Armenia referred to in Paragraphs 17 and 22 of this Regulation is provided in Armenian. The names of the manufacturer and licensor and the brands or trademarks of tobacco products may be represented in Latin letters.

(Paragraph 23 amended and comp. per No 297 dated 29.03.19)

24. Tobacco raw materials shall be stored in dry, clean, well-ventilated warehouses free from barn pests, which will have wooden floors without any cracks. If the floor is not wooden, the bundles and bales should be placed on a wooden deck.

25. To bacco products shall be stored in dry, clean buildings with a relative humidity of (60 \pm 10) % above ground level and shall be located at least 10 cm above the floor of the building.

(Paragraph 25 amended per No 297 dated 29.03.19, ed. per No 1040 dated 08.08.19)

VI. ENSURING COMPLIANCE WITH THE SAFETY REQUIREMENTS

26. Compliance of tobacco product types with this Technical Regulations shall be ensured by the application and direct implementation of the safety requirements included in the list of standards presented in Table No 4 of the Technical Regulations.

(Paragraph 26 ed. per No 297 dated 29.03.19)

27. The methods and measurements for testing tobacco raw materials and tobacco product types are defined by the standards included in Table No 4 of the Technical Regulations:

Table No 4

		Tuble No 4
1.	HST 294-2008 (ISO 10315:2000 MOD)	Cigarettes. Determination of nicotine content in smoke condensate. Gas chromatography method
2.	HST 325-2010 (ISO 8454:2007 MOD)	Cigarettes. Determination of carbon monoxide content in the gas phase of cigarette smoke (NDIR method)
3.	HST ISO 4387-2008	Determination of total and nicotine-free dry matter by a regular smoking machine
4.	GOST ISO 3308-2015	Laboratory ordinary machine for smoking cigarettes (smoking machine). Definitions and standard terms
5.	GOST ISO 3402-2003	Tobacco and tobacco product types. Atmospheres of improvement and testing
6.	GOST 30622.1-2003	Cigarettes. Determination of water content in smoke condensate. Gas chromatography method
7.	HST ISO 12863-2014	A standard test method for assessing the tendency of cigarettes to ignite
8.	HST ISO 16055-14 (ISO 16055:2012 IDT)	Tobacco and tobacco product types. Control sample. Requirements and application
9.	GOST 31632-2012	Cigarettes. Sampling
10.	ChIM 01-2009	Methodology for measuring the width of thin-walled tobacco and pipe tobacco
11.	ChIM 02-2009	Methodology for measuring the thickness of cigars and cigarillos

(Paragraph 27 ed. per No 297 dated 29.03.19)

VII. COMPLIANCE ASSESSMENT PROCEDURES

28. Compliance assessment of tobacco products with this Technical Regulations shall be carried out by one of the declaration procedures A1, A2, C1, C2, D, D1 approved by the Decision No 56 "On Defining Compliance Assessment Procedures" of the Government of the Republic of Armenia dated January 16, 2014.

(Paragraph 28 amend. per No 297 dated 29.03.19)

29. The national mark of compliance shall be affixed to the consumer and transporting containers of tobacco products or to the accompanying documents by the manufacturer or his authorized representative in the Republic of Armenia in the manner prescribed in the Decision No 337 "On the Sample (Description) of the National Mark of Compliance Certifying Compliance with the Requirements of the Technical Regulations, Approving the Procedure of Application and Declaring Ineffective the Decision No 1281 of the Government of the Republic of Armenia" of the Republic of Armenia dated March 14, 2013.

(Paragraph 29 amend. per No 297 dated 29.03.19)

- 30. The following are evidence materials for declaration that tobacco products are in compliance with the requirements of this Technical Regulations:
 - 1) Consumer container sample or insert sheet;
- 2) Cigarette test reports performed by the designated compliance assessment body certifying the nicotine and tar content of one cigarette smoke and the carbon monoxide content of one filter cigarette smoke in accordance with the requirements of Paragraph 10 of this Technical Regulations.

(Paragraph 30 amend. per No 297 dated 29.03.19)

31. At the choice of the manufacturer or his authorized representative in the Republic of Armenia, other documents may be included, which serve as a basis for the latter to declare the compliance of the tobacco products with the requirements of this Technical Regulations, including the quality management system certificate.

(Paragraph 31 amend. per No 297 dated 29.03.19)

32. The manufacturer or his authorized representative in the Republic of Armenia may accept a declaration of compliance for each of the tobacco products released or for the whole assortment of one type of tobacco product.

(Paragraph32 amend. per No 297 dated 29.03.19)

- 33. The declaration of compliance shall include the following information:
- 1) The name and location (or place of residence) and signature of the manufacturer or his authorized representative in the Republic of Armenia;
 - 2) The following information presented on the consumer container and (or) the insert sheet:
 - a) The tobacco product;
- b) The names of the tobacco raw materials or tobacco product types or the names of the tobacco products;
- c) The presence or absence of a filter for cigarettes, as well as the content of nicotine and tar in the smoke of one cigarette [or] the content of nicotine and tar in the smoke of one filter cigarette;
- 3) Declaration of compliance with the requirements of the technical regulations with which the product must comply, including references to related national standards and compliance assessment procedures;
 - 4) Reference to specifications that are proof of compliance with the requirements (if applicable);
 - 5) Date of registration of the declaration;
- 6) The name, address and (if applicable) identification code of the designated compliance assessment body that carried out the compliance assessment procedure.
 - 7) Validity date of the declaration of compliance.

(Paragraph 33 amend. per No 297 dated 29.03.19)

34. The validity period of the declaration of compliance shall not exceed three years from the date of signing.

VIII. STATE CONTROL

35. State control over the compliance of tobacco products with the requirements of this Technical Regulations shall be carried out in accordance with the Law of the Republic of Armenia "On Technical Regulations".

(Paragraph 35 amend. per No 297 dated 29.03.19)

Chief of Staff of the Government of the Rep. of Armenia, Minister

D. HARUTYUNYAN

Diagram No 1

EXAMPLES OF PLACEMENT OF BASIC AND COMPLEMENTARY WARNING TEXTS ABOUT THE HARMFULNESS OF SMOKING, AS WELL AS TEXTS ON NICOTINE AND TAR, ON THE TOBACCO BOX (title amended per No 297 dated 29.03.19)

(diagram amended per No 297 dated 29.03.19; ed. per No 1040 dated 08.08.19)

Diagram No 2

EXAMPLES OF PLACEMENT OF BASIC AND COMPLEMENTARY WARNING TEXTS ABOUT THE HARMFULNESS OF SMOKING, AS WELL AS TEXTS ON NICOTINE AND TAR, ON THE BLOCK (title amended per No 297 dated 29.03.19)

(diagram amended per No 297 dated 29.03.19, ed. per No 1040 dated 08.08.19)

(Appendix supplemented per No 558 dated 25.05.17; amended, supplemented & edited per No 297 dated 29.03.19; ed. per No 1040 dated 08.08.19)