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**THE RA GOVERNMENT DECISION ON APPROVING THE TECHNICAL REGULATIONS FOR THE SAFETY OF TOBACCO SUBSTITUTE PRODUCTS**

**THE GOVERNMENT OF THE REPUBLIC OF ARMENIA**

**DECISION**
**No 155-N as of February 10, 2022**

# ON APPROVING THE TECHNICAL REGULATIONS FOR THE SAFETY OF TOBACCO SUBSTITUTE PRODUCTS

Based on Article 8, Part 1, Section 3, Paragraph "a" of the Law of the Republic of Armenia "On Technical Regulations", Article 4, Part 1 of the Law of the Republic of Armenia "On Reduction and Prevention of Health Damage Due to the Use of Tobacco Products and their Substitutes", the Government of the Republic of Armenia ***decides***:

1. To approve the technical regulations on the safety for tobacco substitute products in accordance with the annex.
2. To the Minister of Economy of the Republic of Armenia, within 1 week after the official publication of this decision, to ensure the publication of the list of standards enabling the implementation of the technical regulations approved by section 1 of this decision.
3. The given decision enters into force on the day following its official publication.
4. The product that is the object of these technical regulations, which was not subject to a mandatory assessment of compliance and was put into circulation before the entry into force of the given technical regulations, is allowed to circulate within the validity period of the latter without the compliance mandatory assessment documents and without the application of the national mark of conformity.

**The Prime Minister of the Republic of Armenia** **N. Pashinyan**

Yerevan

10.02.2022
APPROVED BY
ELECTRONIC SIGNATURE
Annex

to the Government
Decision No 155-N,
dated February 10, 2022

TECHNICAL REGULATIONS

ON THE SAFETY OF TOBACCO SUBSTITUTE PRODUCTS

## 1. FIELD OF APPLICATION

1. The operation of the technical regulations on the safety of tobacco substitute products (hereinafter referred to as the technical regulations) applies to products that do not contain tobacco raw materials and are electronic substitutes for tobacco products.

2. The operation of these technical regulations is extended to the tobacco product substitutes (hereinafter referred to as "NCP"), mentioned in section 1 and in the class 2404 of the unified commodity list of the foreign economic activity of the Eurasian Economic Union, that do not contain tobacco raw materials, are filler vaporized and electronically operated tobacco product substitutes, through which nicotine and propylene glycol or glycerin, in some cases, the aerosol generated by the vaporization of the filler containing various flavor or odor additives is also transferred to the consumer's body.

3. The technical regulations define the indicators characterizing the safety of the NCP, the requirements for their identification, production, marking, packaging, storage and transportation, as well as the conformity assessment procedures.

4. These technical regulations are developed in order to protect human life and health, the environment, as well as to prevent actions that mislead consumers in terms of the meaning and safety of NCP, and it applies to tobacco product substitutes put into circulation in the territory of the Republic of Armenia.

5. The products that are the object of the given technical regulations and put into circulation for domestic consumption are certified by conformity assessment in the form of declaration of conformity, with the exception of NCP samples that are imported into the territory of the Republic of Armenia for:

1) products intended for display at exhibitions, fairs and international meetings, as well as products used during such a display or exhibitions;

2) as test samples and samples intended for research and testing, on the condition of providing a copy of the contract or letter concluded with the certified conformity assessment body, which confirms the quantity (weight and volume) of the product (products) being imported (imported) necessary for these purposes, laboratories, manufacturers and (or) by importers (sellers), and are intended for the purpose of quality and safety control, measurements in accordance with international standards, inter-laboratory comparative tests, calibration of measuring instruments, comparative tests, tasting (degustation), design study;

3) previously used (exploited) products;

4) products being imported (imported) in unique copies (quantities) intended for one foreign trade contract for the importer's exclusive personal use (including for scientific research or representative purposes, as souvenirs or advertising materials).

6. The following products are not regulated by these technical regulations:

1) tobacco products, in particular products made entirely or partially from tobacco raw materials, tobacco leaves and (or) other parts, which are prepared to be used for smoking, sucking, chewing or inhaling through the nose;

2) medicated liquids;

3) products that are exported outside the territory of the Republic of Armenia according to foreign trade agreements;

4) food products containing natural nicotine.

## 2. DEFINITIONS

7. The following concepts and their definitions are used for the purposes of administration of these technical regulations:

1) **consumer packaging:** for products sold to the final consumer or packaging intended for sale;

2) **a capsule (cartridge)**: a component of a nicotine delivery system (hereinafter referred to as a nicotine delivery system), which is a liquid container industrially filled for a nicotine delivery system, and which can be built into a nicotine delivery system;

3) **component**: an ingredient (except for a mixture, liquid, gel, powder, etc.) used in the production of a filler for a nicotine-containing product and present in a finished nicotine-containing product, including in a modified form;

4) **aerosol**: a suspension of solid and (or) liquid particles in a gaseous state, including cigarette vapor, obtained from the filler in any way, except for the combustion (smoke) of the filler;

5) **container**: a container intended for the NCP, which is used for charging the NCP, is not a component of the NCP and cannot be placed in the NCP;

6) **filler**: the main element of the NCP (including mixture, liquid, gel, powder, additive, flavorant, etc.), from which and (or) through which an aerosol containing nicotine or nicotine salts inhaled by the consumer is formed during the operation of the NCP;

7) **nicotine-containing products (hereinafter - NCP)**: a product intended for use by the consumer by inhalation of an aerosol containing nicotine or nicotine salts generated during the operation of the NDS;

8) **nicotine delivery system (NDS)**: a device necessary for the use of a NCP (including an electronic vaporizer, a device for heating an electronic vapor generator, etc.), which is necessary to obtain an aerosol inhaled by the consumer from the filler (the NDS can be structurally connected with NCP);

9) **liquid for NDS:** a type of NCP, a solution (liquid or gel) that, when used with NDS as intended, turns into a nicotine containing aerosol inhaled by the consumer;

10) **NCP exploitation**: inhalation by the consumer of an aerosol containing nicotine or nicotine salts, which is obtained from the NCP filler through the NDS;

11) **flavorant**: an additive designed to give taste and (or) aroma;

12) **harmful or potentially harmful substances**: released substances that harm or may harm human health;

13) **released substances** - chemical elements or compounds that are released during the intended use of the product, including substances contained in the nicotine-containing aerosol, which the consumer inhales;

14) **additive**: any raw material or substance added to the main filler of the NCP;

15) **supplier**: producer of NCP or NDS (a person authorized by the manufacturer), importer or seller;

16) **expiration date:** a period of time intended for the intended use of the NCP, after which the NCP is no longer suitable for the intended use.

## 3. RUSES FOR PUTTING INTO CIRCULATION

8. The NCP subject to mandatory assessment of conformity and being in circulation in the territory of the Republic of Armenia must be accompanied by a declaration of conformity, an Armenian marking and a national mark of conformity.

9. The circulation of NCP that is subject to mandatory assessment of conformity in the territory of the Republic of Armenia without the requirements defined in section 8 is prohibited.

10. It can be imported to the Republic of Armenia and sold in the territory of the Republic of Armenia for the purpose of realization, to produce the NCP corresponding to these technical regulations.

11. NCPs produced for export outside the territory of the Republic of Armenia may be produced in accordance with the requirements of the legislation of the importing country.

## 4. NCP IDENTIFICATION PROCESS

12. Identification of the NCP in order to place it within the scope of application of these technical regulations is performed by the supplier (producer (person authorized by the manufacturer), importer, importer-dealer, seller), the customs body within the framework of the requirements set by the customs legislation, the inspection body exercising state control over compliance with the requirements of these technical regulations, the conformity assessment body and the persons provided by the legislation, via visual examination, and instrumentally.

13. For the purpose of NCP identification, the following documents are used as a document on the product: operating instructions, guiding insert-sheet, information sheet, contract, product accompanying documents, conformity assessment certifying document, as well as other documents provided by the supplier (if necessary).

14. The visual identification of the NCP by inspection is carried out according to its name, characteristic features and method of application by comparing the appearance of the NCP with the characteristics set forth in the definition in accordance with these technical regulations.

1) by name in the information included on the NCP consumer package and on the leaflet and (or) in the accompanying documents (originals of the supply contract (approved copies), documents attached to the product or an NCP declaration of conformity) the name of the specified NCP by comparing it with the definitions in accordance with these technical regulations;

2) according to the composition of the ingredients on the consumer packaging or in the documents of the product being examined by checking the information posted about the NCP.

3) according to the method of application, as indicated in the consumer packaging or operating documents by checking its availability, for the application of nicotine products (type, brand, model), the designation of the device with which the NCP should be used.

15) In the case of the impossibility of carrying out the identification by visual inspection, the NCP identification can also be done instrumentally.

16) Instrumental identification of the NCP is performed according to the following identification indicators:

1) Determination of nicotine content in the aerosol generated from the use of NCP.

2) Determination of the maximum nicotine content in the liquid of NCP.

3) Determining the elements present in the NCP filler.

4) Determination of the prohibited components during the production of NCP, defined by these technical regulations.

5) Absence of combustion during the use of NCP.

17. The result of identification is considered to be whether or not to classify the identified product as an NCP.

## 5. NCP SAFETY REQUIREMENTS

Depending on the filler, there is a distinction between liquids intended for combined NCP and NDS.

18. The NCP must be produced in accordance with the requirements of these technical regulations, the manufacturer's technological instructions and specifications for the specific types of NCP products.

19. The NCP must be manufactured in such a way that the intended use of the appropriate filler material result in the generation of a nicotine containing aerosol.

20. In the process of liquid production for NDS, the following raw material shown in table N 1 is used.

Table N1

| Product Name | Indicator Name | Norm |
|---|---|---|
| Liquids for NDS | nicotine, nicotine salts %, not less | 98 |
| | distilled glycerin, %, not less | 95 |
| | propylene glycol, %, not less | 95 |

21. It is allowed to use in production only those components that ensure their use based on the characteristics of the liquid of the NDS defined by these technical regulations.

22. Nicotine containing liquid may not contain the following additives:

1) vitamins or other additives that create the impression that the tobacco product substitute is beneficial to health or presents reduced risks to health;

2) caffeine or taurine or other additives and stimulant compounds; which are related to energy and vitality;

3) additives with emission coloring properties;

4) additives that facilitate inhalation or absorption of nicotine;

5) Additives that are carcinogenic, mutagenic or reprotoxic (toxic substances affecting human reproductive system) properties in the unheated state.

23. The maximum content of nicotine in the liquid of the NDS should not exceed 20 mg/g.

24. The volume of the liquid of the NDS in a unit capsule (cartridge) intended for consumption cannot exceed 2 ml.

25. It is allowed to use only those additives that comply with the specification for NCP defined in the given regulations.

26. Additives used during the production of NCP must be in accordance with the requirements for additives established by the legislation in force in the territory of the Republic of Armenia and adopted in accordance with international agreements.

27. The manufacturer is obliged to carry out a risk assessment in accordance with the requirements established by the legislation and the standards ensuring the implementation of these technical regulations.

28. During the risk assessment, the properties of raw materials and microbiological, manufacturing process and control features, packaging conditions and the life cycle of the NCP throughout the supply chain are taken into account.

29. Based on the results of the risk assessment, storage conditions and shelf life are determined.

30. Storage conditions or shelf life are set by the manufacturer, based on their own studies.

31. During its operation, the NDS must comply with the requirements established by the legislation in force in the territory of the Republic of Armenia and adopted in accordance with international agreements.

32. Any substance released in a nicotine-containing aerosol during the operation of the NCP must comply with the requirements set by the standards ensuring the implementation of these technical regulations.

33. In a nicotine-containing aerosol the nicotine content is calculated in mg per 100 cm3 of nicotine-containing aerosol by gas chromatography, in accordance with the requirements established by the legislation of the Republic of Armenia and the standards ensuring the implementation of these technical regulations.

34. The list of prohibited components during the production of NCP is as follows:

1) substances:

a. agaric acid (Acidumagaricinicum),

b. birch tar oil (Oleum Betulaeempyreumaticum),

c. bitter almond oil (Oleum Amygdalarumamarum): prussic acid-free or with its content,

d. oil of Sassafras (Oleum Sassafratis),

e. juniper tar oil (Oleum Juniperi Empyreumaticum),

f. camphor oil (Oleum Camphoratum),

g. camphor,

h. coumarin,

i. carthamus,

j. thuja biota,

k. safflower,

l. thujone.

2) those substances circulation of which is prohibited in accordance with the international agreements of the Republic of Armenia.

3) flavorants and flavoring substances made of:

a. Bittersweet Nightshade Stems (Stipites Dulcamarae), Camphorwood (Lignum Camphorae),

b. Polypody Rootstock (Rhizoma Poiypodii),

c. Pennyroyal Herb (Herba Pulegii),

d. Quassia Wood (Lignum Quassiae),

e. Soap Bark (Cortex Quillaja),

f. Tansy Herb (Herba Tanaceti),

g. Rue Herb (Herba Rutae),

h. Sassafras Leaves, Sassafras Wood, Sassafras Root Bark (Stipes, Folium, Cortex Sassafratis),

i. Yellow Sweet Clover (Millilotus officinalis),

j. Tonka Beans (Semen Toncae),

k. Vanilla plant (Liatris odoratissima),

l. Sweet Woodruff (Asperulaodorata).

## 6. PACKAGING REQUIREMENTS

35. The packaging of the NCP must comply with the legislation in force in the territory of the Republic of Armenia and adopted in accordance with international agreements, as well as with the requirements set forth in this chapter.

36. For unit packaging of NCP and consumer packaging of products, the following are used:

1) cardboard labels;

2) boxes made of cardboard, paper and combined materials;

3) a flat cardboard product box that is glued;

4) wrapping paper;

5) polymer film;

6) consumer polymer packaging.

37. The list of visible defects in consumer packaging, as well as the methodology for evaluating such defects is defined by the manufacturer.

38. The volume of the container used for refilling the NDS cannot exceed 10 ml.

39. The manufacturer must ensure that children cannot open capsules (cartridges) and containers in accordance with the requirements of the interstate GOST ISO 8317 standard.

40. Unit packaging and industrially liquid-filled NDS must exclude liquid leakage.

## 7. REQUIREMENTS FOR THE PRODUCTION, TRANSPORTATION AND STORAGE OF THE NCP

41. The manufacturer is obliged to ensure the implementation of the periodic internal monitoring process during the entire production period.

42. The manufacturer's manufacturing processes, test results and monitoring must be documented.

43. In the case of different manufacturers of an NCP or an NDS or any component, the requirements of this chapter apply to each manufacturer separately, ensuring compliance of the combined product with the requirements of the given technical regulations.

44. The manufacturer ensures and is responsible for ensuring that each batch of raw materials and materials required for the production of any NDS component conforms to the manufacturer's technical specifications for the NDS component.

45. Conformity of the product is certified in accordance with the requirements established by national legislation, including a conformity assessment document provided by a third party (supplier of raw materials and materials), documents on periodic audits by the supplier of raw materials or material, or testing results of each batch of raw materials and materials performed by the manufacturer of the relevant component of the nicotine delivery system.

46. Each consumer package of NCP must have an identification by means of which the manufacturer can c determine the serial number of the product batch, the date of manufacture and the place of manufacture.

47. Transportation of NCPs is carried out in accordance with the rules of transportation of goods applicable to the certain type of vehicle.

48. Vehicles must be covered, dry, clean and free of extraneous odors.

49. The area intended for the storage of NCPs should be dry, clean and free of extraneous odors.

50. It is forbidden to store NCPs in the same area with perishable goods and smelly products.

## 8.REQUIREMENTS FOR THE MARKING OF CONSUMER PACKAGING

51. The following information should be marked on the packaging of liquids intended for NDS:

1) type of NCP or filler (e.g., "Liquid for nicotine delivery system," etc.);

2) product name, including trademark;

3) the number of pieces (portion or unit (pcs).

4) the name of the manufacturer and the importer, their location (legal address). The specified information may be placed on the outside or inside of the consumer package in a visible part of the package;

5) the name and address of the organization registered in the Republic of Armenia and authorized by the manufacturer to accept consumer claims;

6) nicotine content in the liquid (mg/g) for the NDS;

7) volume of liquid for NDS (ml);

8) the month, year and expiration date of manufacture;

9) notice about the inadmissibility of sales to minors;

10) for NDS liquids, a note to keep out of the reach of children in the form of the inscription "Keep out of the reach of children";

11) for the device, its name, including the indication of intended use and application with the NDS or capsule (cartridge);

12) warning label: "Contains nicotine, which is toxic and addictive." The inscription text is printed on a white background, in black, bold, clear, easy-to-read font size and Arial Armenian font. The font size should be chosen so that the warning texts occupy the maximum possible part of the surface intended for them. The information provided by this point is presented in a black frame with a thickness of not less than 3-4 mm3. The area limited by the frame, including the frame itself, must occupy not less than 30% of the surface of the front side of the consumer packaging.

13) product use and storage instructions;

14) contraindications;

15) warnings for special risk groups;

16) possible adverse effects;

52. The information to the labeling established by this chapter is inserted on the consumer packaging or may be placed in the consumer packaging through an insert in the information leaflet based on the impossibility of inserting the full volume of information related to labeling on consumer packaging.

53. Labeling information includes reliable information for the consumer about the product and its manufacturer, with the documents certifying the information.

54. Information on consumer packaging must be clear and easy to read ensuring its stability during storage, transportation and sale.

55. Misleading terms such as "Low Nicotine", "Light", "Very light" (“Superlight”), “Soft”, “Special", "Less Hazardous” or any other term that directly or indirectly contributes to forming an opinion of the safety of the product are not allowed.

56. It is not allowed to insert the name, trademark or other information of the devices, which were not used for the evaluation of the NDS in accordance with the requirements of these technical regulations.

57. The information on the consumer packaging must be in the Armenian language, and the names of the producer and licensor and the name or trademarks of the NCP can be presented in Latin letters.

58. The product's transport packaging must contain the following information:

1) product type;

2) product name;

3) manufacturer's name and address;

4) in the case of a liquid, total amount or volume of NCP contained in consumer packaging in transport packaging;

59. There may be other additional reliable information on the transport packaging (if necessary and documents are available).

60. Transport packaging must be tightly closed to ensure the safety of the product during transportation and storage.

## 9. CLASSIFICATION OF THE NDS AND ITS COMPONENT PARTS

61. According to the method of use, the NDS is divided into the following groups:

1) a single-use or closed-type device with a built-in capsule (cartridge) NDS, without the possibility of replacing or refilling its used cartridge;

2) a reusable or open-type device – a NDS with the ability for the user to change the dosage package (e.g, rollers or cartridges) or to refill the cartridge with liquid.

62. NDS may include the following components: an atomizer, a dosage pack with NDS liquid (in the form of a capsule (cartridge), etc.), a container for the liquid of the NDS, a power supply, a charger, a pipe, a case, a power converter, a light indicator and other elements.

63. The products must be used only with the devices that are specified on the their packaging and (or) in the rules of their operation.

## 10. ENSURING COMPLIANCE OF THE NCP WITH THE REQUIREMENTS OF THE TECHNICAL REGULATIONS

64. Compliance of the NCP with these technical regulations is ensured by the direct application and fulfilling of its safety requirements, standards included in the list of standards ensuring the implementation of the technical regulations.

65. Compliance of NCPs to these technical regulations, test methods and measurements are defined by the standards ensuring the implementation of these technical regulations and the requirements established by the legislation in force in the territory of the Republic of Armenia and adopted in accordance with international agreements.

## 11. COMPLIANCE ASSESSMENT PROCEDURES

66. Before being put into circulation on the market of the Republic of Armenia, including importing, the NCP is subject to compliance assessment with declaration of compliance.

67. The compliance assessment of the NCP with these technical regulations is being carried out through any of the appropriate declaration procedures intended for batch and serial production and approved by the decision of the Government of the Republic of Armenia No. 56-N of January 16, 2014.

68. When declaring compliance with the NCP, the applicant:

1) compiles and analyzes the documents certifying the compliance of the NCP with the requirements of these technical regulations, including:

a) consumer packaging sample;

b) information sheet;

c) the protocol of tests of NCP samples for compliance with the requirements of these technical regulations;

d) supply contract and accompanying documents;

e) quality management system certificate (a copy of the certificate of conformity,

in the case of a requirement defined by the evaluation procedure);

f) other documents chosen by the applicant, which served as a basis for confirming the compliance of the NCP with the requirements of these technical regulations, as well as with the requirements of other technical regulations that apply to the latter (if any);

g) carries out the identification of the NCP in accordance with Chapter V of these technical regulations.

h) takes all necessary measures to ensure that the quality management system is functioning stable (if necessary);

i) adopts the declaration of compliance, which must comply with the legislation in accordance with the established requirements (in accordance with the requirements established by the order of the Minister of Economy of the Republic of Armenia No. 801-N of June 16, 2015), to be completed in Armenian, using electronic printing devices, in accordance with the requirements and format established by the legislation;

j) places the national mark of conformity on the consumer and transport containers of the NCP or in the accompanying documents in the manner defined by the decision of the Republic of Armenia N 337-N of March 14, 2013;

2) after completion of the compliance certification procedure, prepares a package of documents, which includes the documents specified in sub-clause 1 of this section and the declaration of compliance.

## 12. STATE CONTROL

69. State control regarding compliance of the NCP with the requirements of these technical regulations is carried out according to the law.

**Head of the Office of the Prime Minister of the Republic of Armenia**

**A. Harutyunyan**

10.02.2022
APPROVED BY
ELECTRONIC SIGNATURE

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