

BH 2:2021

BAHRAINI TECHNICAL REGULATION
Electronic Nicotine Products (Equivalents of Traditional Tobacco Products)

ICS: 65.160

English Language

Edition 1 – 11 November 2021



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National Foreword

Ministry of Industry, Commerce and Tourism has adopted the (National Technical Regulation) No. **(BH 2:2021)** concerning (Electronic Nicotine Products (Equivalents of Traditional Tobacco Products)).

National Adoption Date	11 November 2021
Publication Date in the Official Gazette	11 November 2021
Implementation Date <i>*(For technical regulations only)</i>	12 May 2021

Bahraini Regulation**BH: 2:2021****Electronic Nicotine Products (Equivalents of Traditional Tobacco Products)****1. Scope**

This Bahraini Technical Regulation applies to the requirements that must be met in the electronic nicotine products that are designed in the form of the equivalent traditional tobacco products (such as cigarettes, cigars, pipes, cigarillos, or hookah/shisha), which include the following products:

- Electronic vape products that do not contain tobacco (and may or may not contain nicotine) and cartridges designated to refill it, such as (e-liquid) containers.
- Electronic heated tobacco products that contain tobacco (whether processed or unprocessed) that is heated using an electronic device (without combustion).

It also specifies the requirements of its import, manufacture, packaging, display, circulation, weights, and the explanatory statements on its label, but it does not include the products that are consumed by being lighted and smoked through combustion, or any other products containing nicotine such as nicotine patches and tobacco products used through mouth.

2. Supplementary References

- 2.1 GSO ISO 9001: Quality Management Systems – Requirements
- 2.2 GSO IEC 60335-1: Household Electrical Appliances and the Like – Safety – Part One: General Requirements
- 2.3 GSO ISO 8317: Child-resistant Packaging - Requirements and Testing Procedures for Re-closable Boxes (packages).
- 2.4 IEC 62133-1: Secondary Cells and Batteries Containing Alkaline or Non-acid Electrolyte – Safety Requirements for Portable Sealed Secondary Cells, and for Batteries Made from Them, for Use in Portable Applications – Part One: Nickel (NI) Systems.
- 2.5 IEC 62133-2: Secondary Cells and Batteries Containing Alkaline or Non-acid Electrolyte – Safety Requirements for Portable Sealed Secondary Cells, and for Batteries Made from Them, for Use in Portable Applications – Part Two: Lithium (LI) Systems.
- 2.6 GSO IEC 60086-4: Primary Dry Batteries - Part Four: Safety of Lithium Batteries
- 2.7 GSO IEC 60335-2-29: Household Electrical Appliances and the Like – Safety – Part 2-29: Special Requirements for Battery Chargers.
- 2.8 GSO 2500: Additives Permitted to be Used in Food Stuffs.
- 2.9 GSO 707: Flavorings Permitted to be Used in Food Products.
- 2.10 GSO 9: Labels of the Packaged Materials Used in Manufacturing Food Products.
- 2.11 European Pharmacopoeia for Non-Sterile Inhalation Products.
- 2.12 European Pharmacopoeia – Nicotine Study (Monograph).
- 2.13 European Pharmacopoeia – Purified Water Study (Monograph).
- 2.14 European Pharmacopoeia – Propylene Glycol Study (Monograph).
- 2.15 European Pharmacopoeia – Glycerol Study (Monograph).
- 2.16 GSO IEC 61558-1: Safety of Power Transformers, Power Supplies, Reactors and Similar Products - Part One: General Requirements and Tests.

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3. Definitions

3.1 Tobacco:

Leaves and other natural processed or unprocessed parts of tobacco plant, including processed tobacco that is reconstituted or reformulated.

3.2 Nicotine

Nicotinic alkaloids

3.3 Ingredients

Tobacco, any additive, or any element present in the finished product or related products, including paper, filter, ink, capsules and adhesives.

3.4 Flavor

An Additive that imparts smell and/or taste.

3.5 Characterizing flavor:

Means a noticeable smell or taste, resulting from an additive or a combination of additives, including, but not limited to, fruits, spices, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the product.

3.6 Electronic Vape Products

Electronic devices (and its accessories) which operate through batteries and can be used to heat the e-liquid to be vaporized, inhaled and exhaled by mouth as a simulation of smoking, and they are free of tobacco.

The typical electronic cigarette consists of the battery that is used to heat the solution tank containing the so-called "e-liquid" that may be in a disposable cartridge or a tank that can be refilled from external cartridges.

3.7 E-liquid:

A liquid formula (or gel) in the Electronic Vape Products or in a replaceable cartridge (which may or may not contain nicotine) and some other additives, such as distilled water, solvents, vegetable glycerin and propylene glycol.

3.8 External Cartridges (Single Container):

Any container used for refilling the electronic nicotine products, whether in the form of rolls, tanks, small containers, capsules containing granules or other forms, and whether it is disposable or can be used for refilling each time.

3.9 Electronic Tobacco Heating Device:

An electronic device used to heat tobacco products and operated by electronic heating or by other means to be used in the consumption of heated tobacco products through mouth.

3.10 Heated Tobacco Products:

A product consists of tobacco and non-tobacco substances specially prepared for use with or without an aerosol-generating device that contains nicotine without the combustion of tobacco.

3.11 Toxicity:

The adverse effects that the product may have on the human organism, including the effects that occur over time, whether through consumption or frequent or continuous exposure to the effects of the product.

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3.12 Pack (packet):

The single pack of the product (with its accessories) sold to the consumer as an integrated product unit, including the carton (the box containing the single packs).

3.13 Label:

Any label, mark, trademark, picture, or any other descriptive statements written, printed, stamped, placed, engraved, or embossed on the pack in a non-removable manner.

3.14 Explanatory Statements:

Any writing, pictures or graphics on the label related to the product qualities, properties, nature or consumption, or one of its ingredients or any other characteristics.

3.15 Main Display Area:

The front and back sides of the pack, if it is not possible to be known, the largest area is considered the front side and the next largest area is considered the back side.

3.16 Health Warning:

A warning concerning the adverse effects on human health or other undesired consequences of its consumption, including text warnings, attached health warnings, general warnings, and information messages.

3.17 Outside Packaging:

Any package in which the products or the related products are placed, which contains a unit packet or a set of unit packets. Transparent packaging shall not be considered a part of the outside packaging.

3.18 Production Code (Batch Number):

A code for a quantity of the product that was produced under the same conditions during a specific period of time, it is usually for a specific product line or production unit.

4. Requirements

4.1 General Requirements

4.1.1 The manufacturing facilities must meet the requirements of the standard specification contained in Clause (2.1).

4.1.2 The appliances (electronic and electrical) must meet the related requirements of the standard specification mentioned in Clause (2.2) (or its equivalent) regarding safety of electrical equipment and devices, including the drop test, contact temperature and the electromagnetic compatibility (EMC) test.

4.1.3 Batteries, energy accumulators, secondary cells and chargers must meet the requirements of the standard specifications applied to each one of them and mentioned in Clauses (2.4), (2.5), (2.6) and (2.7).

4.1.4 The product and/or cartridges must meet the requirements of child protection set forth in Clause (2.3), so that they do not pose any potential health risks to children. It is necessary to ensure that these products are protected, tightly closed, and have a child-resistant packaging, including the place of marks for protection from children and protection by appropriate mechanisms for opening and closing the packages.

4.1.5 The product and cartridges must remain in conformity with the requirements of this standard specification throughout the shelf life indicated on the package.

4.1.6 No modification or change in the ingredients or characteristics of the product and cartridges may be made unless the official approval is obtained from the responsible entity.

4.1.7 It is not allowed to import, manufacture, or introduce the product and cartridges in the markets of the state unless the official approval is obtained from the responsible entity and the following documents are submitted:

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4.1.7.1 Reports of the tests of safety of electronic components / drop test / leakage test / contact temperatures / electromagnetic efficiency, from the scientific agencies or laboratories accepted by the responsible entity.

4.1.7.2 A list of all ingredients and their quantities used in the product in descending order according to the weight of each ingredient, with indicating the trade name, type, and relevant quantities, accompanied by a statement specifying the reasons for adding these ingredients to the products concerned, in addition to the level of emissions arising from the use and any other emissions.

4.1.7.3 The results of the toxicological studies required for the product ingredients before and after use and its emissions, including when heated, issued by the scientific agencies or laboratories accepted by the responsible entities.

4.1.7.4 Data on nicotine doses and absorption when consumed in the normal or reasonably expected conditions.

4.1.7.5 Acknowledgment that the manufacturing company and importer assume full responsibility for the quality and safety of the product when introduced to the market and used in normal or expected conditions.

4.1.7.6 A description for the instructions of using the product and refill containers, including the product opening and re-filling mechanism.

4.1.7.7 A description of the production process, including the sequence of production processes, with ensuring that the production process conforms to the requirements of this standard specification.

4.1.7.8 Stability studies supporting the product's shelf life specified on the product label, wherever applicable.

4.1.7.9 Laboratory reports from the agencies accepted by the responsible entity, including information on nicotine concentration in the product and cartridges, the quality and safety of the product, post-marketing and post-consumption analyses, electrical safety, and any other similar information upon request.

4.1.8 Risk assessment studies of the consumable part of the products.

4.1.9 Products and cartridges must meet the safety and quality requirements, so that they do not break or liquids leak during use and refilling.

4.1.10 The following substances must not be added to the product, cartridges, and e-liquids:

- Vitamins or other additives that give the impression that the product has a health benefit or reduces health risks.
- Caffeine, taurine or other additives and stimulants associated with stimulating performance and vitality.
- Colored additives with emission coloring characteristics.
- Carcinogens, substances cause genetic mutations or produce toxins before and after use.
- Substances classified as legally prohibited substances, such as psychotropic, narcotics, hallucinogens, depressants and stimulants, etc.
- Ethylene glycol, diethylene glycol, formaldehyde, acetaldehyde, acrolein, crotonaldehyde, acetone, diacetyl, acetylpropionyl, pentane 3,2, dione, and related ketones, as well as long chain paraben preservatives.
- Acrylonitrile, benzene 3,1-butadiene, isoprene, and toluene.
- 4 amino-diphenyl, aminonaphthalene-1, aminonaphthalene-2.
- Ammonia.
- Cinnamic compounds.
- Respiratory allergens.
- Residues of heavy metals such as lead, cadmium, mercury, chromium, nickel, iron, arsenic and tin.
- Multipolar hydrocarbons, carbon monoxide, and nitrosamines of tobacco (e.g. NNK and NNN).
- Mineral oils, vegetable oils and fats such as (olive oil).

4.1.11 It is allowed to use the materials necessary for the manufacture of products and cartridges, such as sugar to replace the sugar lost during the treatment process, provided that they do not increase addiction or toxicity.

4.1.12 Other product components such as filters, paper, parcels, capsules or any other related components shall not contain flavors that modify the smell or taste of the products or the emissions' intensity, nor shall they contain tobacco, tobacco extracts or nicotine.

4.1.13 The packs or their outer packaging shall not contain printed vouchers, discount offers, a reference to free distribution, two offers together or any other similar offers that may suggest economic advantages to consumers and thus induce them to purchase the products.

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- 4.2.1 The electronic liquid shall be fully manufactured according to the requirements of the standard specification mentioned in Clause (2.1).
- 4.2.2 The ingredients of the electronic liquid, such as nicotine and solvents, shall be of high purity and conforming to its pharmaceutical properties as per the requirements of the European Pharmacopoeia mentioned in Clauses (2.11 – 2.15).
- 4.2.3 The microbiological limits of nicotine in the electronic liquid shall not exceed what is specified in the European Pharmacopoeia for Non-Sterile Inhalation Products mentioned in Clause (2. 11).
- 4.2.4 The content of nicotine in the electronic liquid shall be less than or equal to 20 milligrams per milliliter.
- 4.2.5 The capacity of the electronic liquid tank integrated to the same product shall not exceed 10 ml.
- 4.2.6 The capacity of the electronic liquid's refill containers shall not exceed 50 ml per single container.
- 4.2.7 The electronic liquid containers shall not be easily breakable, damageable, or destroyable.
- 4.2.8 Electronic liquid containers shall operate in a manner ensuring that the electronic liquid does not leak to the mouth during inhalation.
- 4.2.9 The ingredients used in electronic liquids shall not pose a health hazard (except for nicotine and tobacco extracts if used), before and after use, at the concentration level used and under the conditions of use for which they are intended.
- 4.2.10 Substances prohibited under Clause (4.1.10) shall not be added to the electronic liquid.
- 4.2.11 It is allowed to add the following moisturizing substances:
- 4.2.12 Glycerol (of food grade and not manufactured from the petroleum products), propylene glycol 1-2, butylene glycol 1-3, triethylene glycol (with a minimum purity of 99.5%) and they shall be fit for human consumption and conforming with its pharmaceutical characteristics as per the requirements of the European Pharmacopoeia.
- 4.2.13 The additives used in the product shall be of the food grade and permitted in accordance with the standard specification mentioned in Clause (2.8).
- 4.2.14 The substances with flavoring characteristics shall be permitted in accordance with the standard specification mentioned in Clause (2.9).
- 4.2.15 If hyper-allergens are used, this should be indicated on the label of the product in accordance with the standard specification mentioned in Clause (2.10).

5. Explanatory Statements**5.1 General Requirements**

- 5.1.1 It is prohibited to use any names, symbols, marks, images, or phrases that violate public order.
- 5.1.2 The product and its accessories shall not be described or presented with labels, explanatory statements, names, shapes or symbols that may lead to an erroneous, misleading or promotional impression, inside or outside the package, about their qualities, or that may mislead consumers, and in a false or deceptive manner, or that may lead to erroneous impression about their qualities in any way, suggest that they are less harmful than any other type of products, or indicate a reduced risk of smoking-related diseases, including, but not limited to: low or no tar and/or nicotine; light, very light, mild, moderate, natural, organic; no additives; no (or very little) flavors; or claims about the economic advantages compared to the traditional cigarettes, or suggestion of therapeutic benefits in terms of weight loss, attraction, social status, social life, or qualities such as femininity, masculinity or elegance, or improved biological performance, or the size and appearance of the products in terms of their resemblance to food or cosmetics.
- 5.1.3 The statements shall be clear and easy to read, and the colors used for writing shall be distinctly different from the background colors and not close or overlapping with them.
- 5.1.4 The explanatory statements (in Arabic or English for Clauses 5.2.1 through 5.2.7) shall be placed directly on the package and may be placed on a non-removable sticker.
- 5.1.5 No statements, names, images, marks, symbols, or data may be written on the outer cellophane wrapper.
- 5.1.6 The health warning shall be on the package directly and on the outer cover of the package, which is apparent before the eyes of the consumer on the main display area, and shall be printed in a fully visible way and cannot be erased or removed, this includes that it must not be partially or totally hidden or completely covered by tax stamps, price marks, security features and wrappers, etc.

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5.2 The following explanatory statements shall be written on the label of the product single packs and the label of the cartridges:

- 5.2.1 Product name and trade name.
- 5.2.2 Number of units inside the single pack.
- 5.2.3 Validity or packing dates by month and year (according to the stability studies of validity).
- 5.2.4 Production code (batch number)
- 5.2.5 Ingredients of the product (name or type of the flavor used shall be fixed near the product name).
- 5.2.6 Country of origin, manufacture, or packing.
- 5.2.7 Writing the statement of (For sale in the Kingdom of Bahrain).
- 5.2.8 For products that contain nicotine, the following health warning shall be written in both Arabic and English on the packs (literally):

(This product contains nicotine which causes severe addiction, increased heart rate and high blood pressure. Nicotine is harmful to the health of pregnant and nursing women, and people suffering from chronic pulmonary diseases such as asthma and pulmonary embolism.)

- 5.2.9 The health warning shall be in conformity with the following requirements:
 - 5.2.9.1 The producing companies may increase or decrease and maintain the health warning (provided for in Clause 5.2.8) to suit the different sizes of product packs, provided that it covers more than 50% (without the frame) of the main display area and shall be placed on the outside of the package on (the lower front part/ in English) and on (the lower back part /in Arabic).
 - 5.2.9.2 The health warning, its place, form, and measurements shall be in accordance with the appendix (1) included in this Standard Specification, and it may not be changed, modified or reworded in any way.
- 5.2.10 To write the following statement in both Arabic and English on the packs of the product, in addition to age restriction symbol (18+), which should not be less than 1 cm x 1 cm:

(It is prohibited to sell and consume this product by individuals under the age of 18, and non-smokers are not advised to use it).



- 5.2.11 For the products that contain (e-liquid), the following statement shall be written on the product packs in both Arabic and English:

(This product may pose a health hazard when inhaled, swallowed, or contacted with the skin)

- 5.2.12 The health warning requirements shall be complied with in accordance with appendix (1) contained in this Standard Specifications and shall be changed in accordance with the requirements of the public interest.

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5.3 Each (integrated system) pack of the product shall include a leaflet containing the following information printed in Arabic or English:

- 5.3.1 Instructions for using and storing the product; including a reference stating that the product is not recommended for use by young people or non-smokers.
- 5.3.2 Contraindications to the use of the product, warnings specified in Clause 5.2 and any warnings related to certain populations of the consumers.
- 5.3.3 Instructions for using and storing the product.
- 5.3.4 Addiction and toxicity.
- 5.3.5 Potential adverse effects.

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Appendix – 1: Health Warnings

Health Warning: This product contains nicotine which causes severe addiction, increased heart rate and high blood pressure. Nicotine is harmful to the health of pregnant and nursing women, and people suffering from chronic pulmonary diseases such as asthma and pulmonary embolism.

It is prohibited to sell and consume this product by individuals under the age of 18, and non-smokers are not advised to use it.



This product may pose a health hazard when inhaled, swallowed or contacted with the skin.

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References

- United Arab Emirates Mandatory Standard Specifications for Electronic Nicotine Products (UAE.S. 5030: Electronic Nicotine Products – Equivalents of Traditional Tobacco Products)