

Unofficial
Translation

Kingdom of Saudi Arabia
Saudi Food & Drug Authority



المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Controls and Requirements for Electronic Smoking Devices

Version No. 1

18/9/1440 AH

Introduction:

In reference to Supreme Decree No. 38621 dated 11/7/1440 AH, on lifting the ban on importing, selling and trading of e-cigarettes, and collecting the selective tax, following the example of tobacco and its derivatives; Also in reference to Telegram No. 51691 dated 19/11/1438 AH received from the Chief of the Royal Court, on assigning to the Authority the tasks of inspecting tobacco products, establishing standard specifications for tobacco and its products, issuing and approving such standard specifications;

Accordingly, temporary requirements were developed for the importation and trade in electronic smoking devices, pending the issuance of special binding regulations for electronic smoking devices.

First: Definitions:

▪ **Electronic Smoking Devices:**

Products that function using electronic heating for smoking tobacco designed to be heated, or e-liquid, through the mouth. These products are single or multiple use items.

This includes, but is not limited to: E-Cigarettes and electronic tobacco heating products.

Such products consist of several parts, such as: Mouthpiece, integrated cartridge, battery and electric charger.

▪ **Tobacco Designed to be Heated:**

Manufactured or non-manufactured tobacco in the form of rolls, powder or granules in capsules, which is used through thermal heating without burning.

▪ **Tobacco:**

A product produced from a combination of plants of the species of *Nicotiana tabacum*, *Nicotiana rustica* and/or any combination of the two. It is processed afterwards by exposing it to smoke, sunshine, air, fire or by maturation.

▪ **E-Liquid:**

A liquid solution or gel (may contain nicotine) and some additives, such as distilled water or solvents and glycerin and propylene glycol.

▪ **External filling containers (single container):**

External container contains tobacco designed to be heated or e-liquid, and used for filling electronic smoking devices.

▪ **Integrated Cartridge:**

The part designed to be filled by e-liquid, which is integrated within the electronic smoking device and can be refilled.

▪ **Emissions:**

The substances emitted or released during the consumption of electronic smoking products.

▪ **Additives:**

Any substance added to tobacco or e-liquid during its manufacturing, and has a specific function in the final product.

▪ **Health Warning:**

The warning about the harmful effects of the product which appears on the container and includes warning statements and health messages.

Second: General Requirements:

1. The electronic smoking devices shall meet the quality requirements for the safety of the electric appliances and their parts, including:
 - GSO IEC 62133: Secondary cells and batteries containing alkalis and non-acidic electrolytes - Safety requirements for secondary sealed portable cells, and for batteries made from them, for use in portable applications.
 - GSO IEC 60335-1: Household and similar electric appliances– Safety – Part 1: General Requirements.
 - GSO IEC 60086-4: Primary Dry Batteries – Part 4: Safety of Lithium Batteries.
 - GSO IEC 60335-2-29: Electric and similar Appliances – Safety – Part 2-29: Requirements for battery chargers.
2. The electronic smoking devices and the external filling containers shall be protected against breakage and be tightly sealed, so it does not break or leak liquids. Further, designed to withstand the damage caused by children, so that it does not cause health risks to children, by placing markings to protect from children and setting appropriate mechanisms for opening and closing the containers.

3. The packaging of the product or the product itself shall not contain or cause any of the following:
 - Promoting the product or encouraging its consumption through messages or implications regarding its characteristics, health effects, risks, or emissions.
 - An implication that the product is less dangerous than other products, or that it aims to reduce the harmful effect of smoking.
 - Any element or publication promoting the product or containing promotional offers.
4. The electronic smoking devices and the external filling containers shall contain leaflets of the instructions for use and storage, including the mechanism of opening the product and re-filling it.
5. The outer packaging of the electronic smoking devices and the external filling containers shall contain health warnings on the front and back sides covering 65% of the whole surface. The following health warning statement shall be written in white, Helvetica font and in a size covering the specified section on a black matte background:
(The product contains nicotine which causes addiction)
6. It is forbidden to add the following substances:
 - Vitamins or other additives which give the impression that the product has a healthy benefit.
 - Caffeine, taurine or other additives and stimulants associated with stimulating performance and vitality.
 - Color additives that add color to the emissions.
 - Substances with carcinogenic, genetic mutation-causing or toxin-producing properties before burning.
 - Substances that are specified as illegal to trade in such as psychotropics, narcotics, hallucinogens and stimulants.

Third: Requirements for E-Liquid:

1. The nicotine amount in the e-liquid shall not exceed 20 mg/ml.
2. The capacity of the integrated cartridge shall not exceed 2 ml.
3. The capacity of the external filling containers shall not exceed 10 ml in the single container.
4. Permitted Flavors for E-Liquid:
 - It is permitted to use fruit flavors and menthol or a mixture of them only. It is prohibited to use some flavors such as cocoa, vanilla, coffee, tea, spices, candy, chewing gum, cola and alcohol.
5. Toxic solvents shall not exceed 0.10% for both ethylene glycol and diethylene glycol.

6. The concentration of the following heavy metals shall not exceed the permitted limit:

| Metal | Maximum limits (µg/g) |
|--------------|------------------------------|
| Cadmium | 0.2 |
| Lead | 0.5 |
| Arsenic | 0.2 |
| Mercury | 0.1 |
| Chromium | 0.3 |
| Nickel | 0.5 |
| Tin | 6 |

7. Must pass the laboratory testing for the following microbes:

| Microbiological testing | Maximum limits |
|--------------------------------|------------------------|
| APC | 10 ² CFU/mL |
| Yeast and Mold | 10 ² CFU/mL |
| S.aureus | Should be absent |
| P.aeruginosa | Should be absent |
| Enterobacteriaceae | Should be absent |

Fourth: Requirements for Tobacco Designed to be Heated Electronically:

1. The nicotine amount shall not exceed 6.0 mg/cigarette.
2. It is not allowed to use flavors with tobacco designed to be heated.
3. Single container capacity is 20 cigarettes.