Principles of Tobacco and Nicotine Products, Including Electronic Products, of 2019 Issued by the Jordan Food and Drug Administration based on the Council of Ministers Decision No. 4569 of May 8, 2019, and Article 7(I) of Jordan Food and Drug Administration Law No. 41 of 2008

Article 1:

These Principles are called "Principles of Tobacco and Nicotine Products, Including Electronic Products, of 2019" and they are effective as of the date of their publication in the Official Gazette.

Article 2:

For the purposes of these Principles, the words and phrases mentioned in them in have the meanings given to them as follows, unless indicated otherwise by the context:

JFDA:	The Jordan Food and Drug Administration.
The Unit:	The Unit of Tobacco, Tobacco Products, and Tobacco and Nicotine Products, including E-Cigarettes, which is responsible for overseeing the electronic tobacco and nicotine products sector.
The Director General:	The JFDA Director General.
The Director:	The Director of the Unit.
The Committee:	The Committee on Tobacco and Tobacco Products, Nicotine, and E-cigarettes responsible for giving recommendations for the registration and importation of, and trade in, electronic tobacco and nicotine products.
Tobacco:	The leaves and other natural parts, artificial or not artificial, from the tobacco plant, including artificial tobacco, which is reformed or reconstituted.
Tobacco product:	Any product made or derived from tobacco designated for human consumption, including any constituent, part, accessory, or element of the tobacco product (except for non-tobacco raw materials used in the manufacture).
Nicotine:	Nicotine alkaloids in their two forms, free or linked to salts.
Components:	Tobacco or any additive material or element found in the final product or related products.
Flavoring:	An additive or a combination of additives that imparts an aroma and/or taste, including: fruit, spices, herbs, alcohol, sweets, menthol, vanilla, and the like, which is perceived before or during consumption of the product.

Electronic vaping products: Electronic devices and/or their accessories that are battery operated and which can be used to heat an electronic liquid to cause vaporization for inhalation and exhalation through the mouth, like smoking, but do not contain tobacco. These products traditionally consist of:

- The device that contains the batteries, either non-replaceable or replaceable (vape pen or mod), and which provides the power needed for heating.
- The coil, which is responsible for the heating operation.
- The liquid tank, which contains what is called the "electronic liquid," which may be in a single use cartridge (pod or cartridge) or in a tank that can be refilled from external refills.
- The electronic liquid

The electronic liquid: A liquid compound or gel in electronic vaping products or in the refill cartridge which may or may not contain nicotine and some other additives, such as distilled water, solvents, vegetable glycerin, and propylene glycol.

External refill cartridges (individual container): Any container used to refill electronic tobacco and nicotine products, whether in the form of covers, tanks, small containers, or capsules that contain granules or other shapes which can be refillable at any time or for one-time use only.

Electronic tobacco heating products: Electronic battery-operated devices used to heat the tobacco (processed or unprocessed) in the form of wrappings, powder, or granules within capsules) by heat contact (heat not burn) and inhaling and exhaling it through the mouth like smoking. The complete system of these electronic devices usually consists of:

- The electric charger
- The inhalation device and/or the heating device charger
- The inhalation device and/or heating device, which contains an electronic battery that powers the heating.
- Processed or unprocessed tobacco intended for use with the device, either in the form of tobacco sticks or tanks or small capsules that contain granules or objects of other shapes.

Accessories: Any part expected to be used in electronic vaping products or electronically heated tobacco products.

Toxicity: The harmful effects that the product can cause to a human being, including effects that occur over time, whether through consumption or repeated or continual exposure to the effects of the product.

Package (Packet): The individual package of the product (with its accessories) which is sold to the consumer as an integrated product unit. The package includes the container for the individual cartridges.

Information card: Any card, logo, mark, picture, or other descriptive information written, printed, stamped, placed, engraved, or embossed on the package in a way that cannot be removed relating to the quality, characteristics, nature, or consumption of the product or one of its components or any other characteristics.

Main display area: The front and back panel of the package, or, if that cannot be determined, then the largest area on the front panel and the next largest area on the back panel.

Health warning: The warning regarding the product's harmful effects on human health or other undesirable results of its consumption, including written warnings, supplementary health warnings, general warnings, and informational messages.

Outer wrapper: Any package in which the products or related products are placed and which contains a unit or group of packs of units. Transparent wrappers are not considered part of the outer wrapper.

Production symbol (batch number): The code indicating the quantity of the product that was manufactured under the same circumstances during a specified period of time, usually from a production line or a certain production unit.

Country of origin: The country that produces or supplies electronic tobacco and nicotine products.

Food class: A material of a quality that is fit for human consumption or for use in food production or storage according to the international Codex Alimentarius.

Pharmaceutical grade: A material of a quality that meets the requirements of an internationally recognized agency, such as the European Pharmacopoeia, the United States Pharmacopoeia (USP), or the British Pharmacopoeia (BP).

Importation and trade permit: Approval to import and trade the product after a study of its components, its information card, its use, and any other documents that the Unit believes are appropriate to ensure the product's safety.

The manufacturer: The company that produces, packages (primary or secondary wrapper), or markets electronic tobacco and nicotine products.

Good Manufacturing Practices: That part that ensures quality control of the manufactured products in accordance with the requirements of the permission to market them. Therefore, Good Manufacturing Practices in production mean quality control.

Trade: Manufacture, transport, procurement, distribution, display for sale, delivery, purchase, import, introduction, or use.

Article 3: Scope

These Principles concern the requirements that must be met to register and approve for trade electronic tobacco and nicotine products that are used as substitutes and are designed to resemble traditional cigarettes, and include the following products:

- Electronic vaping products that contain tobacco but also contain an electronic liquid (that may or may not contain nicotine) and refill containers designed to be refilled.
- Electronically heated tobacco products that contain tobacco (processed or unprocessed) and which are heated by an electronic device (without burning).
- Any other similar products are included in the concept of electronic tobacco and nicotine products.

The requirements for importation, manufacturing, packaging, display, trade, weights, and descriptive data are also specified on their information card.

Article 4:

A. Trade in electronic tobacco and nicotine products is prohibited without being registered with the JFDA.
B. Registration of electronic tobacco and nicotine products requires that they conform to the general and specific requirements mentioned in these Principles.

Article 5:

A. The "Tobacco, Tobacco Products, and Tobacco and Nicotine Products, Including Electronic Cigarettes, Unit" shall be formed in the JFDA. The Unit shall be responsible for the following tasks and have the following powers:
    1. Perform an oversight and governance role over tobacco and tobacco products, including e-cigarettes.
    2. Govern the registration, importation, trade, and manufacture of tobacco and tobacco products, including e-cigarettes.
    3. Ensure that the JFDA's prior approval is obtained in the case of importation of any primary material used in the manufacture of any part of the product.
    4. Ensure that the JFDA's prior approval is obtained in the case of a refill size change, addition of a new size, or addition of a new flavor.
    5. Ensure that the JFDA's prior approval is obtained in the case of a change in the concentrations of the ingredients of the electronic liquid as well as flavors and additives, or the commercial name, or a change in the manufacturing site or the country of manufacture.
    6. Approve sales locations for electronic tobacco and nicotine products.
    7. Cooperate with official agencies and security agencies in controlling unlicensed sales.
B. In its work, the Unit will maintain the following goals:
    1. Coordinate with other concerned divisions in conducting various monitoring programs.
    2. Protect individuals under 19 years of age and non-smokers from exposure to or dependence on electronic tobacco and nicotine products by restricting and limiting access to them.
    3. Prevent public deception and misinformation in connection with the risks of using electronic tobacco and nicotine products.

4. Support awareness programs in connection with electronic tobacco and nicotine products and educate the young generation about the risks of smoking.

Article 6:

A. The JFDA's director general shall form the "Tobacco, Tobacco Products, Nicotine, and E-Cigarettes Committee" to be headed by the Unit's director. In the decision to form it, he shall designate the number of members, what constitutes a quorum for its meetings, and how decisions and recommendations are to be made.
B. The committee will review applications for approval to import and trade in tobacco, tobacco products, nicotine, and e-cigarettes, and determine the extent to which they conform to the instructions for these products.
C. The committee can request necessary information and documents from applicants to use for its work.
D. The committee will submit its recommendations to the Director General for acceptance or rejection of the application for registration and/or importation and/or trade and/or manufacture and/or display of tobacco, tobacco products, nicotine, and e-cigarettes.
E. The Director General will issue his decision to accept or reject the application for registration and/or importation and/or trade and/or manufacture and/or display of tobacco, tobacco products, nicotine, and e-cigarettes on the basis of the committee's recommendations.
F. The applicant can submit an objection to the committee's decision within one month of the date of his notification of the decision. The objection shall be submitted to the committee, and the committee will review it within a maximum of one month and submit its recommendations to the Director General.
G. The Director General shall issue his decision about the objection on the basis of the committee's recommendations.

Article 7: Registration procedures

The applicant or his representative will submit an application to register electronic tobacco and nicotine products or any part of them in accordance with the general and specific requirements and the conditions mentioned in these Principles and their appendixes.

Article 8: General requirements

The following general requirements must be complied with for approval of registration or trade in tobacco and nicotine products, including electronic ones:

A. The manufacturing facilities must meet the requirements of good manufacturing practices (GMP).
B. The product and refill cartridges and the vaping and tobacco devices must satisfy the requirements for the protection of children so that they do not constitute any potential health risks to children.
C. The product and the refills must remain consistent with the requirements of these Principles throughout the shelf life stated on the package.
D. The product and refills can be imported, manufactured, or offered in the country's markets only after obtaining the official approval of the JFDA and submission of the necessary required documents.
E. Laboratory reports are accepted from parties accredited by the JFDA, which include information about the concentration of nicotine in the product and the refills and about the product's quality and safety, and post-marketing analyses of consumption, electric safety, and similar data, upon demand.
F. The products and refill cartridges must meet the requirements of safety and quality, so that they do not break or leak liquids during use and refilling.
G. The products' other components, such as filters, papers, packages, capsules or any other accessories must be free of flavors that alter the smell, taste, or density of the emissions, and they must not contain any tobacco or nicotine.

H. The packages or their outer wrapper must not include printed coupons, discount offers, or reference to free distribution or any other similar offers that can give the impression of economic benefits to the consumers, or through cultural occasions, or with false claims that encourage consumption or use as a lifestyle.

I. It must be stated that the licensee is responsible for the safety of electronic tobacco and nicotine products or any part of them when they are used under normal circumstances.

J. Every importer or manufacturer must apply a system for monitoring the materials that he imports into the Kingdom or manufactures and he must keep records that show the parties that sold them the imported or manufactured goods.

K. No person or public or private agency, including the media, may print, display, or publish any advertisement for the purpose of publicity for any electronic tobacco and nicotine products or distribute any leaflet or tools or materials to introduce it or advertise its products without obtaining the necessary approval from the JFDA.

L. The manufacturer, importer, sales locations, or any other concerned party must notify the JFDA about any factory harm or harm resulting from trade of the product (vigilance).

M. Consumption of electronic tobacco and nicotine products must not be encouraged by creating the false impression of their characteristics or health effects or risks, or their emissions. For example:
   1. Claiming that they have vital, active, curative, revitalizing, natural, or organic characteristics.
   2. Claiming that they have other health or lifestyle benefits.
   3. Not indicating the taste, smell, or other added substances (except for flavorings).
   4. Claiming that they are like food.
   5. Claiming that they are less harmful to the environment.
   6. Adding the phrase “causing little harm / less harmful.”

Article 9: The requirements of electronic nicotine product devices, including electronic vaping products and electronically heated tobacco products

A. Trade in electronic nicotine product devices, including electronic vaping products and electronically heated tobacco product devices is prohibited unless they have been registered and have received approval for trade from the JFDA.

B. For the purposes of registration and obtaining authorization for trade, the final products and refill cartridges for electronic nicotine products, including electronic vaping products and electronically heated tobacco products, must meet the special requirements mentioned in Appendix 1 of these Principles.

Article 10: Requirements of the electronic liquid

A. Trade in electronic liquid is prohibited unless it is registered and has obtained authorization for trade from the JFDA in accordance with the registration requirements mentioned in Appendix 5 of these Principles.

B. For the purposes of registration and obtaining authorization for trade, the electronic liquid must fulfill the special requirements mentioned in Appendix 2 of these Principles.

Article 11: Requirements of electronically heated tobacco

A. Trade in electronically heated tobacco is prohibited unless registered and having obtained authorization for trade from the JFDA in accordance with the registration requirements mentioned in Appendix 5 of these Principles.

B. For the purposes of registration and obtaining authorization for trade, electronically heated tobacco must meet the following special requirements mentioned in Appendix 3 of these Principles.

Article 12: Descriptive statements and health warnings

A. The descriptive statements that are used to identify the product and the health warnings must conform to the requirements mentioned in Appendix 6 of these Principles.

B. The JFDA can approve the specifications and technical regulations of the country of origin until the issuance of Jordanian standards or technical regulations that contain health warnings related to the Kingdom and are applicable by law.

Article 13:

Trade

A. Trade in electronic tobacco and nicotine products is prohibited other than in accordance with the approved requirements and at locations that have obtained the JFDA's approval for such purpose.

B. These Principles apply to locations that sell, store, manufacture, and maintain electronic tobacco and nicotine products, and locations that have been approved to do so by the JFDA.

C. The following requirements for trade in electronic tobacco and nicotine products have been approved:

1. The following conditions are imposed on the display and sale of electronic tobacco and nicotine products:
    a. The sale and display of electronic tobacco and nicotine products shall be in designated locations after obtaining the JFDA's approval for such purpose.
    b. The products must be displayed in areas away from direct sunlight and sources of contamination.
    c. Electronic tobacco and nicotine products must be separated from any other materials such as chemicals and other substances.
    d. The sale of electronic tobacco and nicotine products to anyone under 19 years of age is prohibited under penalty of legal liability, and a copy of the purchaser's ID card must be made and kept in a special file at the sales location.
    e. Delivery of electronic tobacco and nicotine products to anyone under 19 years of age is prohibited under penalty of legal liability.
    f. The sale or delivery of electronic tobacco and nicotine products to other than sites licensed for such purpose, such as restaurants, etc., is prohibited.
    g. The mixing or preparation of the electronic liquid for direct sale to the consumer, combining electronic tobacco and nicotine products, or making any change to the ingredients of these approved products is prohibited.
    h. The provisions of the General Requirements apply to the requirements for display and sale.

2. The following requirements are imposed on the transport of electronic tobacco and nicotine products:
    a. Electronic tobacco and nicotine products must be transported on clean vehicles that are covered during transportation and they must be protected against moisture or any environmental factors that could damage the product.
    b. They must be transported at a temperature that is appropriate for the nature of the electronic tobacco and nicotine products.
3. The following requirements are imposed on the storage of electronic tobacco and nicotine products:
    a. The rooms and areas used to receive and store electronic tobacco and nicotine products must always be clean and must be cleaned in sanitary ways. The storage rooms must have good lighting and ventilation and an easily accessible thermometer must be available.
    b. The storage rooms must be resistant to the entry, presence, or proliferation of rodents, insects, and birds, and effective steps must be taken to prevent the occurrence of such.
    c. The materials must be disposed of before their expiration date and expired materials must be stored separately.
4. Electronic tobacco and nicotine products or any part thereof must be manufactured in compliance with the requirements imposed on them in these Principles and in accordance with the approvals required from the JFDA. The electronic tobacco and nicotine product manufacturing sites, facilities, and production lines must fulfill the following good manufacturing practices:
    a. Clear specification and identification of all phases of manufacturing.
    b. Submission of all required documents:
        - The building site must be in accordance with the Committee for Inspection of Facilities that Manufacture Electronic Tobacco and Nicotine Products.
        - The design, construction, and equipping of the building must be in conformity with the requirements of the concerned agencies and their necessary requirements.
    c. A suitable functional and effective training device must be available.
    d. Appropriate services and equipment must be available.
    e. Materials and vessels suitable for the manufacturing process must be available.
    f. There must be approved measures and instructions.
    g. There must be appropriate means for storage and transport.
    h. The methods and principles relating to the manufacturing process must be clearly written.
    i. Preparation of records during the manufacturing process will show all the manufacturing steps and the methods used during the manufacturing process, and all these records through which the history of the batch can be tracked, must be retained.
    j. There must be an adequate system for recovery of all the batches either before they are supplied or [after they are] sold.
    k. The necessary approvals and licenses must be obtained from the concerned agencies in connection with the requirements for manufacturing and production.
    l. Every factory that develops, leads, controls, and monitors the production processes must ensure that the electronic tobacco and nicotine products comply with the requirements, including the trade procedures such as production, manufacturing, packaging, wrapping, and distribution in accordance with good manufacturing practices procedures.

m. The manufacturer must establish systems for final product inspection with regard to examinations of stability and conformity to the requirements by taking samples of the final product for examination to ensure conformity with the requirements.
n. All the requirements mentioned in ISO 9001 quality management systems must be fulfilled.
o. The requirements and procedures of these Principles and their appendixes with regard to good manufacturing practices must be implemented at the factory.
p. Products can be manufactured with the specifications of the importing country in accordance with the technical regulations and requirements of the importing country with the objective of their exportation with the proviso that they are not traded locally and that the JFDA's required approval has been obtained.

Article 14:

A. The Director General shall form a committee to be called "the Committee for Licensing Factories for Tobacco and Nicotine Products, Including Electronic Ones" to be chaired by a member of the JFDA and with the membership of representatives of the following:
    1. The Ministry of Environment
    2. The Department of Customs
    3. The Ministry of Industry, Trade, and Supply
    4. The Jordan Standards and Metrology Organization
    5. Income Tax
    6. The Ministry of Local Administration
    7. The Ministry of Health
    8. The Jordan Free and Development Zones Group (if the factory to be licensed is in the free zone)
B. Whenever necessary, the committee can seek the help of anyone it deems appropriate from within the JFDA or from outside, without that person having the right to vote on the committee's recommendations.
C. In the decision to form the committee, the Director General shall determine a legal quorum for the committee's meetings and submission of its recommendations and he will name a JFDA employee as rapporteur for the committee, who will be responsible for preparing agendas, recording meeting attendees, and keeping files and records, and tracking the implementation of recommendations without that person having the right to vote.
D. The Director General will issue his decision about license applications based on the committee's recommendations.

Article 15:

The Committee for Licensing Factories for Tobacco and Nicotine Products, Including Electronic Ones is responsible for the following tasks:

A. Reviewing applications for licensing and submitting recommendations to the Director General.
B. Recommending to the Director General to approve specific requirements for manufacturing sites.
C. Any other tasks related to licensing assigned to it by the Director General.

Article 16:

Tobacco and nicotine products, including electronic ones, are considered counterfeit and non-compliant in any of the following cases:

A. If they are manufactured at an unauthorized site or not by the original company and without its approval.
B. If they do not contain the active material or the concentration specified for it or it contains a substance that is different from what is specified in the information card.

C. If it carries a forged or counterfeit commercial name, trademark, or information card.
D. If the name of the country of manufacture mentioned on its inner packaging or its accessories is different from the real country of manufacture.

Article 17: Monitoring and inspection procedures:

In implementation of these Principles, the Director General can take any of the following measures:

A. Withdraw the license of any location that trades in electronic tobacco and nicotine products if there is repeated violation of these Principles.
B. Destroy any electronic tobacco and nicotine products that constitute a hazard to the health and safety of the consumer and are in violation of the directives and requirements and of approvals that have been obtained.
C. Impound any quantity of electronic tobacco and nicotine products until confirmation that they comply with the directives for e-cigarettes and their products.
D. Prevent the display of electronic tobacco and nicotine products if they have not obtained the necessary approvals from the JFDA and other relevant authorities.
E. Impound electronic tobacco and nicotine products in a designated location until a decision about it is issued.
F. Prevent any changes to be made to electronic tobacco and nicotine products stored in the free zones which may lead to violation or manipulation of the information mentioned in their information card, with the exception of manufacturing procedures that have been approved by the relevant competent agencies.
G. Refer the violators to the competent courts.

Article 18:

Facilities that sell or trade in electronic tobacco and nicotine products shall be responsible for all costs that result from violation of the provisions of these Principles.

Article 19:

The JFDA will cooperate with the Jordan Standards and Metrology Organization in monitoring, inspection, and quality compliance in accordance with the applicable principles, taking samples for laboratory testing of tobacco and sweetened tobacco when it is imported or manufactured, or from the local markets, an average of four times a year for each type, and in accordance with their operations and pursuant to a decision issued by the Director General.

Article 20:

The inspection mechanism, including post-trade inspection of tobacco and nicotine products, including electronic ones, will be specified pursuant to a decision issued by the Director General.

Article 21:

The Director General can, at the violator's expense, publish in the daily newspapers and official media the names and addresses of facilities that are in violation when they have been sequestered and the measures that have been taken with regard to them after the issuance of the decision regarding them.

General Provisions

Article 21: [sic]

The Director General can coordinate with any ministry, organization, or other department in performing the oversight and governance role for tobacco and tobacco products, including e-cigarettes, including authorizing any of these agencies to do any tasks and work related to oversight of these products and for a duration that he deems appropriate.

Article 23:

A. The Director General can assign any of the powers vested in him in these Principles to any JFDA employee he chooses, each according to his area of specialization, as long as the assignment is in writing and specific.
B. The Director General can form any committees he deems necessary to implement the provisions of these Principles.

Article 24:

The JFDA shall collect the following service charges:

1. 500 dinars service fee for registration of electronic nicotine product devices, including electronic vaping product devices and electronically heated tobacco products for the first time.
2. 100 dinars service fee for registration of electronic liquid or heated tobacco.
3. 100 dinars service fee for examination of electronic nicotine product devices, including electronic vaping product devices and electronically heated tobacco products.
4. 50 dinars service fee for examination of electronic liquid.
5. 100 dinars service fee examination of heated tobacco.
6. The JFDA shall collect a service charge of 250 dinars for each examination of the operations of tobacco and sweetened tobacco.
7. 10,000 dinars licensing fee for a production line in a factory of tobacco and nicotine products, including electronic ones.
8. 500 dinars licensing fee for any facility for the sale of tobacco and nicotine products, including electronic ones.

Article 25:

Pursuant to these Principles, the JFDA will issue the requirements that must be implemented by facilities that trade in and manufacture tobacco and nicotine products, including electronic ones.

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Appendix 1

Requirements for Registration of Electronic Vaping Devices and Electronically Heated Tobacco Devices

1. A letter from the importer requesting registration that includes the commercial name of the product whose registration is being requested, and the type and number of units within the package (size), the name of the manufacturer and the country of origin.
2. The importer's valid commercial registration issued by the Ministry of Industry and Trade, which includes the purpose of the importation of / trade in tobacco.
3. The importer's valid professional license.
4. The original copy or a copy certified by a notary public or the Chamber of Commerce and Industry or any authorized official agency in the country of origin. Any of the following certificates is valid:
   - 4.1. CFR 21 USFDA certificate issued by the USFDA.
   - 4.2. CE certificate issued by an authorized agency in the countries of the European Union, in accordance with the following requirements:
   - 4.3. ROHS Directive (EU/65/2011): Restriction of the use of certain hazardous substances in electrical and electronic equipment.
   - 4.4. LVD (EU/35/2014): Low Voltage Directive
   - 4.5. EMC (EU/30/2014): Electromagnetic Compatibility Directive
5. A catalogue or data card for the product containing a description of the product's usage instructions, including the mechanism for opening and closing, refilling, and how to maintain it, safety instructions, etc.
6. The product's specifications or safety data sheet (SDS, MSDS, or PSDS), including the ingredients, uses, contraindications, warnings, etc.
7. Toxicity studies for the product's burning and non-burning ingredients and its emissions.
8. A picture of the product's outer and inner wrapper.
9. The internal leaflet, if any.
10. Test reports on the safety of the electronic components – drop test, leak test, contact temperatures, electromagnetic capacity – from scientific agencies or laboratories acceptable to the JFDA.
11. Confirmation that the manufacturer and the importer bear full responsibility for the product's quality and safety when placed on the market and used under ordinary and expected circumstances.
12. If any of the following changes are made to the material that was previously reviewed and licensed, a new application must be submitted for reexamination and relicensing:
13. There must be a bar code on the external package of the devices.
14. There must be a serial number on the devices and their accessories.

Appendix 2
Requirements for Registration of Electronic Liquid

1. Electronic liquid must be manufactured fully in accordance with good manufacturing practices (GMP).
2. A list of all the product's ingredients and the quantities used, in descending order by the weight of each ingredient, must be submitted with mention of the commercial name, the type, and the relevant amounts, accompanied by a statement specifying the reasons for including these ingredients in the relevant products, in addition to the level of emissions resulting from use and any other emissions.
3. The results of a toxicity study on the product's ingredients and emissions, including when heated, must be submitted and issued by scientific agencies or laboratories acceptable to the JFDA.
4. Statements about the dosages and absorption of nicotine when consumed under reasonably normal or expected circumstances must be submitted.
5. Stability studies for the product's shelf life stated on the product's information card must be submitted.
6. The ingredients of the electronic liquid, such as nicotine and solvents, must be of high purity and of pharmaceutical grade and in compliance with the requirements of the European pharmacopoeia.
7. The microbiological limits in the electronic liquid must not exceed what is specified in the European pharmacopoeia for unsterilized inhalation products.
8. The contents of free nicotine in the electronic liquid must not exceed 20 mg per ml.
9. The contents of nicotine linked to salts in the electronic liquid must not exceed 25 mg per ml.
10. The capacity of the tank allocated for refilling the electronic liquid must not exceed 2 ml.
11. The capacity of the refills for refilling the electronic liquid must not exceed 60 ml per package.
12. The containers of electronic liquid must be of food grade and must not be easily susceptible to breaking, damage, or crushing.
13. The electronic liquid containers must work in a way that ensures that the electronic liquid will not leak into the mouth during inhalation.
14. The ingredients used in the electronic liquids must not constitute a health risk (except for nicotine, if it is used) when heated or not heated, in the degree of concentration used, and pursuant to the conditions of their intended use.
15. The electronic liquid must be free of the materials mentioned in Appendix 4 of these Principles.
16. It is permitted to add the following related materials: glycerol (food grade and not made from petroleum products), 1-2 propylene glycol, 1-3 butylene glycol, triethylene glycol (minimum purity of 99.5%), etc., and they must be fit for human consumption and of pharmaceutical grade, and they must comply with the requirements of the European Pharmacopoeia.
17. Flavoring materials and additives used in the final product must be food grade and/or their use must be permitted in inhalation devices and mentioned in Jordan Technical Regulation No. 94 and its amendments.
18. The appropriate storage conditions for the electronic liquid must be mentioned on the product or in its attached informational leaflets.

Appendix 3

Requirements for Registration of Electronically Heated Tobacco

1. The product must be completely manufactured in accordance with good manufacturing practices (GMP).
2. A list of all the ingredients and quantities used in the product in descending order by the weight of each ingredient must be submitted with mention of the commercial name, the type, and the relevant amounts, accompanied by a statement specifying the reasons for including these ingredients in the relevant products, in addition to the level of emissions resulting from use and any other emissions.
3. The results of a toxicity study on the product's components and emissions when heated must be submitted and issued by scientific agencies or laboratories accredited with the JFDA.
4. Statements about the dosages and absorption of nicotine when consumed under reasonably normal or expected circumstances must be submitted.
5. Stability studies for the product's shelf life stated on the product's information card must be submitted.
6. The ingredients used in the product must not constitute a health risk (except for nicotine) when heated and pursuant to the conditions of their intended use.
7. The product's emissions must be free of substances mentioned in Appendix 4 of these Principles.
8. It is permitted to add materials associated with tobacco as long as they are fit for human consumption, are of pharmaceutical grade, and comply with the requirements of the European pharmacopoeia.
9. Flavoring materials and additives used in the final product must be food grade and/or their use must be permitted in inhalation devices and mentioned in Jordan Technical Regulation No. 94 and its amendments.
10. The amount of nicotine must not exceed 0.6 mg per cigarette.
11. The appropriate storage conditions for the product must be mentioned on the product or in its attached informational leaflets.

Appendix 4

Electronically heated tobacco and its emissions and the electronic liquid and its emissions must be free of the following substances:

1. Vitamins or other additives that give the impression that the product has a health benefit or reduces health risks.
2. Caffeine, taurine, or other additives and stimulants linked to stimulating performance and vitality.
3. Coloring additives with characteristics that color the emissions.
4. Carcinogenic substances or substances that cause genetic mutations or produce toxins in their burned or unburned form.
5. Substances classified as substances whose sale is prohibited by law, such as narcotics, hallucinogens, depressants, or stimulants.
6. Ethylene glycol, diethylene glycol, formaldehyde, acetaldehyde, acrolein, acetone, diacetyl, or acetyl propionyl.
7. Substances that maintain long chain parabens.
8. Substances that cause respiratory sensitivity.
9. Metals such as lead, cadmium, mercury, chromium, nickel, iron, arsenic, or tin.
10. Multipolar hydrocarbons, carbon monoxide, and nitrosamines in tobacco, such as NNN and NNK.
11. Any substance that is proven to be harmful to health or that the committee believes should be prohibited in this product.
12. In addition to the foregoing, electronically heated tobacco products and their emissions must be free of the following additional substances:
    - Crotonaldehyde and acrylonitrile, benzene, 1, 3-butadiene, isoprene, toluene.
    - 4-aminobiphenyl, 1 naphthylamine, 2 naphthylamine.
    - Ammonia and cinnamic compounds.

Appendix 5

Submission Attachments for an Application to Register Electronic Liquid and Electronically Heated Tobacco

1. A letter from the importer requesting registration, containing the commercial name of the product whose registration is desired, the type and number of units within the package (size), the manufacturer, and the country of origin.
2. A valid commercial registration of the importer issued by the Ministry of Industry and Trade containing the purpose of the importation of/trade in tobacco.
3. The importer's valid professional license.
4. An original certificate of free sale from the country of origin issued by the relevant official agency showing:
   4.1. The name and the trademark of the product whose licensing is being applied for.
   4.2. The name of the manufacturer and/or the packager.
   4.3. That the manufacturer is licensed to produce electronic liquid and is subject to health monitoring.
   4.4. That the product complies with the production specifications and is safe to use.
5. The certificate of ingredients issued by the manufacturer showing the internal materials in the product, including the percentage of nicotine.
6. A certificate issued by the manufacturer showing that the refills are food grade and safe to use in loading the electronic liquid.
7. A sample of the product and a copy of the information card.
8. The product licensing study fee.
9. If any of the following changes are being made to the material that has already been reviewed and licensed, a new application must be submitted for restudy and relicensing.

Appendix 6
Descriptive Data Requirements

A. The following general requirements must be adhered to with regard to the descriptive information that is used to explain the product:
   1. It must not use any designations, symbols, marks, pictures, or statements that violate public order.
   2. The product and its accessories must not be described or offered with a descriptive card or data, names, forms, or symbols, or any unapproved suggestive slogans on the inside or outside of the package that may lead to a false, misleading, or promotional impression regarding its characteristics.
   3. The information must be clear and legible, and it must use text in colors that are completely different from the background colors, and not similar or overlapping.
   4. The descriptive information mentioned in this article must be in Arabic or English, in accordance with the requirements, written directly on the packages or on stickers that are not removable.
   5. No statements, names, pictures, marks, symbols, or information may be written on the outer cellophane wrapper.
   6. A health warning must be printed on the package and any outer package, and it must be completely visible; it cannot be effaced or removed, including partial or full concealment or being completely covered, whether by price tags, security features, wrappers, or anything else.

B. The following descriptive information must be written on the product's single package information card and the information card for refills:
   1. The product's name and commercial name.
   2. The number of units in a single package.
   3. The product's ingredients and concentrations and the concentration of nicotine. This must be stated clearly and explicitly on the packages.
   4. The expiration date or packaging date using the month and year (pursuant to the shelf-life stability studies, if any).
   5. The batch number.
   6. The country of origin, manufacture, or packaging.
   7. The phrase "Designated for sale in Jordan."
   8. The following health warning must be written in Arabic (and it can also be added in English) on packages that contain nicotine (word for word):

      "Contains nicotine. Nicotine causes severe addiction, increased heart rate, and high blood pressure. It is harmful to pregnant and nursing women and people suffering from asthma."

      (Contains nicotine. Nicotine causes severe addictions, increased heart rate and blood pressure. Nicotine is harmful to pregnant and nursing women and people suffering from asthma)

9. The health warning must comply with the following requirements:
   a. Manufacturers can extend or shrink the health warning to match the various sizes of the product packages as long as it covers 30% of the main display area and on the lower front part in English and the lower back part in Arabic on the outer surface of the package.
   b. The health warning, its location, shape, and measurements must be in accordance with Appendix 4 – in this standard specification. It may not be changed, modified, or reworded in any way.
10. The following statement must be written in both Arabic and English along with the symbol of prohibition by age (19+), which must be at least 1 cm x 1 cm in size:

    "The sale and consumption of this product by people under nineteen years of age is prohibited and its use by non-smokers is not recommended."

    (It is prohibited to sell and consume this product by individuals under the age of 19, and it is not recommended for non-smokers)

11. In products that contain electronic liquid, the following statements must be written in both Arabic and English:

    "This product may pose a health hazard when inhaled, swallowed, or comes in contact with the skin."

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

12. Each package of the product must contain a leaflet that contains the following information printed in both Arabic and English:
    a. Instructions for use and storage of the product, including the explanation and notation that the product is not recommended for use by individuals under nineteen years of age or non-smokers.
    b. The product's contraindications and warnings for certain groups of consumers of the product.
    c. Addiction and toxicity.
    d. Potential adverse effects.

C. The health warnings mentioned in this appendix are based on the following forms:

Health warning: Contains nicotine, which causes severe addiction, increased heart rate, and high blood pressure. It is harmful to the health of pregnant and nursing women and people suffering from pulmonary diseases like asthma and pulmonary obstruction

Healthy Warning: 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

The sale and consumption of this product by people under nineteen years of age is prohibited and its use by non-smokers is not recommended

It is prohibited to sell and consume this product by individuals under the age of 19, and it is not recommended for non-smokers

This product may pose a health hazard when inhaled, swallowed, or comes in contact with the skin

This product may pose a health hazard when inhaled, swallowed, or gets in contact with the skin

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