

Record no. V/35660/2022

18 November 2022

Electronic cigarettes, nicotine-containing liquids and nicotine-free liquids intended for vaporisation, and their unit packets

Guidelines for properties, requirements, labelling and other appearance



Valvira

National Supervisory Authority
for Welfare and Health

Contents

Introduction.....	2
1 Legislation.....	3
2 Labelling and other appearance of the unit packets	7
2.1 Mandatory labelling.....	8
2.1.1 The leaflet included in the unit packet	10
2.1.2 Language and size requirements for labelling	10
2.2 Permitted labelling and other appearance	11
2.3 Prohibited labelling elements	12
2.4 Marketing ban	13
3 Electronic cigarettes, refill containers and liquids	14
3.1 General information on the labelling of electronic cigarettes and refill containers.....	14
3.2 The labelling and appearance of refill containers.....	15
3.3 Properties of electronic cigarettes and refill containers.....	15
3.3.1 Delivering nicotine doses at consistent levels.....	16
3.3.2 Refilling without leakage	16
3.3.3 Child-proof.....	18
3.4 Properties of liquids	19
3.4.1 The properties and appearance of nicotine-containing liquids	19
3.4.2 The properties of nicotine-free liquids.....	20

Introduction

Based on section 6 of the Tobacco Act (549/2016), the National Supervisory Authority for Welfare and Health (Valvira) issues these guidelines for electronic cigarettes, nicotine-containing liquids and nicotine-free liquids for vaporisation, and their unit packets. These guidelines discuss the properties, requirements, labelling and other appearance of the product groups above and their unit packets.

These guidelines also address the plain packaging amendments that, however, include a transitional provision. Regulations on plain packaging and the layout of nicotine-containing liquids and refill containers will enter into force on 1 May 2023. These guidelines supersede the previous guidelines (record no. V/28695/2018).

Decision issued by Jussi Holmalahti

Presented by Taru Peippo

Disclaimer/clause:

Translation from Finnish – Valvira is not responsible for possible translation errors.

1 Legislation

According to section 2, subsection 18 of the Tobacco Act, **electronic cigarette** means a product that can be used for inhaling nicotine-containing vapour via a mouth piece, or any component of that product.

According to section 2, subsection 19 of the Tobacco Act, **nicotine-containing liquid** means a liquid that contains nicotine, is intended for vaporisation by means of an electronic cigarette, does not contain nicotine in excess of 20 milligrams per millilitre and is not intended for a purpose referred to in section 3(1) of the Medicines Act (395/1987).

According to section 2, subsection 20 of the Tobacco Act, **nicotine-free liquid intended for vaporisation** means a liquid other than nicotine-containing liquid that is intended for vaporisation by means of an electronic cigarette or a similar method.

According to section 2, subsection 21 of the Tobacco Act, **refill container** means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette.

According to section 22.1 of the Tobacco Act, manufacturers and importers shall ensure that electronic cigarettes, refill containers, nicotine-containing liquids or nicotine-free liquids intended for vaporisation that are intended for commercial sale or other supply comply with the applicable provisions.

According to section 23.1 of the Tobacco Act, electronic cigarettes may be sold or otherwise supplied to consumers only if they deliver the nicotine doses at consistent levels under normal conditions of use. Electronic cigarettes and refill containers shall be child- and tamper-proof, be protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

According to section 24.1 of the Tobacco Act, nicotine-containing liquids intended for use in electronic cigarettes may only be sold or otherwise supplied to consumers:

- 1) in refill containers, disposable electronic cigarettes or single use nicotine cartridges;

- 2) if the liquid does not have characteristics or contain additives that are prohibited in tobacco products under section 11(1)(1–6)¹;
- 3) if only ingredients of high purity are used in the manufacture of the liquid;
- 4) if, except for nicotine, only ingredients are used in the liquid that do not pose a risk to human health in heated or unheated form.

According to section 24.2 of the Tobacco Act, nicotine-containing liquids may not contain ingredients for which no prior notification has been submitted in accordance with section 26. This does not apply to traces that are technically unavoidable during manufacture.

According to section 24.3, the volume of a refill container shall not exceed 10 millilitres, and the volume of the tank of an electronic cigarette or a single use cartridge shall not exceed 2 millilitres. According to section 24.4, further provisions on assessing compliance with the requirements laid down in subsections 1 and 2 may be issued by decree of the Ministry of Social Affairs and Health.

According to section 25 of the Tobacco Act, the provisions laid down in section 24(1)(2–4) shall also apply to nicotine-free liquids intended for vaporisation.

According to section 31 of the Tobacco Act, electronic cigarettes, refill containers, nicotine-containing liquids and nicotine-free liquids intended for vaporisation may be sold and otherwise supplied to consumers only in unit packets that comply with the Tobacco Act and the provisions issued under it, as well as with relevant EU legislation.

¹ According to section 11.1 of the Tobacco Act, it is prohibited to sell or otherwise supply to consumers the following:

- 1) cigarettes or roll-your-own tobacco with a characterising flavour or aroma;
- 2) tobacco products containing additives that are liable to create the impression that the product has a health benefit or presents reduced health risks compared to other tobacco products;
- 3) tobacco products containing stimulant compounds or other additives that are liable to create an impression of energy and vitality;
- 4) tobacco products containing additives that have colouring properties for emissions;
- 5) tobacco products containing additives that have CMR properties in unburnt form;
- 6) tobacco products for smoking containing additives that facilitate nicotine uptake or the inhalation of smoke.

According to section 36.1 of the Tobacco Act, unit packets of electronic cigarettes and refill containers shall include:

- 1) a list of ingredients contained in the product in descending order of the weight;
- 2) an indication of the nicotine content of the product and the delivery per dose;
- 3) the manufacturer's batch number;
- 4) a recommendation to keep the product out of reach of children;
- 5) health warnings in Finnish and in Swedish;
- 6) a leaflet with information on the product and its use and the necessary contact details.

According to section 36.2 of the Tobacco Act, subsections 1(1), (2) and (5) shall not apply to electronic cigarettes that are not pre-filled with a nicotine-containing liquid.

According to section 36.3, electronic cigarettes, refill containers or unit packets thereof shall not include any of the prohibited labelling elements referred to in section 33². This shall not apply to information on the nicotine content, delivery per dose and flavourings.

According to section 36.4, the unit packet of an electronic cigarette and refill container may present the brand name of the product, the trade name and contact details of the manufacturer or importer and the packaging size, flavour, date of manufacture and barcode of the product in such a way that the unit packet is not distinguished from other unit packets of electronic cigarettes or

² According to section 33 of the Tobacco Act, the labelling of tobacco products and their unit packets shall not:

- 1) promote the product or encourage its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions;
- 2) include any information about the nicotine, tar or carbon monoxide content of the product;
- 3) suggest that the product is less harmful than others or aims to reduce the effect of some harmful components of smoke;
- 4) suggest that the product has vitalising, energetic, healing, rejuvenating, natural or organic properties or that its use has other health or lifestyle benefits;
- 5) refer to taste, smell, any flavourings or other additives or the absence thereof;
- 6) resemble a food or a cosmetic product;
- 7) suggest that the product has environmental advantages;
- 8) suggest that the product is fire safe or otherwise create an impression that the product is not dangerous or that it has a reduced fire risk compared to other similar products.

refill containers in terms of its labelling and the labelling does not promote the sale of the product.

According to section 36.5 of the Tobacco Act, unless otherwise provided by law, no markings other than those referred to in subsections 1 and 4 may appear on the unit packets of electronic cigarettes and refill containers.

According to section 36.6, the decree of the Ministry of Social Affairs and Health can lay down more detailed provisions:

- 1) the texts, font type and size, colour, surface area, location and other specifications concerning the health warning referred to in subsection 1, paragraph 5;
- 2) the information to be provided in the leaflet referred to in subsection 1, paragraph 6;
- 3) the font type and size, colour, surface, location and other specifications concerning labelling referred to in subsection 5; derogations from the uniformity requirement laid down in subsection 4 in respect of specifications concerning labelling may also be given by decree of the Ministry of Social Affairs and Health, if the exemption is minor and does not promote the sale of the product.

According to section 36 a, subsection 1 of the Tobacco Act, the unit packets of electronic cigarettes and refill containers shall not be distinguished in form, colour, material or other appearance from other unit packets of electronic cigarettes or refill containers, and the appearance of the unit packet must not be used to promote the sale of the product. According to section 36 a, subsection 2, further provisions on the permitted form, colour, material and other appearance of electronic cigarettes and refill containers shall be given by decree of the Ministry of Social Affairs and Health. Derogations from the uniformity requirement laid down in subsection 1 may also be given by decree of the Ministry of Social Affairs and Health in respect of the presentation of a unit packet if the exemption is minor and does not promote the sale of the product.

According to section 36 b, subsection 1 of the Tobacco Act, a refill container shall not differ in shape, colour, surface, colour of label or other appearance from other refill containers, nor shall the presentation of the refill container be used to promote the sale of the product. According to subsection 2, the refill container may be labelled with the brand name of the nicotine-containing liquid, the manufacturer or importer's trade name and contact details and the

packaging size, flavour and date of manufacture of the product, in such a way that the labelling is not distinguished from the corresponding labelling of other refill containers and is not used to promote the sale of the product. The filling container shall not bear any other markings except those referred to in Article 37.

According to section 36 b, subsection 3, the nicotine-containing liquid must not differ in colour from other nicotine-containing liquids and the colour of the liquid must not be used to promote the sale of the product.

According to section 36 b, subsection 4, further provisions on the permitted shape, colour, surface, colour of label and other presentation of the refill container, and on the font type and size, colour, surface, location and other specifications concerning labelling referred to in subsection 2, and on the permitted colour of the nicotine-containing liquid may be given by decree of the Ministry of Social Affairs and Health. Derogations from the uniformity requirement laid down in subsections 1-3 may also be provided for by decree of the Ministry of Social Affairs and Health in respect of the labelling and other presentation of the refill container and the nicotine-containing liquid, if the exemption is minor and does not promote the sale of the product.

According to section 37, provisions on the labelling of electronic cigarettes that are pre-filled with nicotine-containing liquid and of refill containers are laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP regulation), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

According to section 38 of the Tobacco Act, sections 36(1)(1) and 36(3) above also apply to nicotine-free liquids intended for vaporisation and the unit packets thereof.

2 Labelling and other appearance of the unit packets

Electronic cigarettes and liquids used in them (nicotine-containing or nicotine-free) may be sold or otherwise supplied to consumers only in unit packets in compliance with law. In practice, this means that, in addition to electronic cigarettes, their components, including atomisers, tanks, frames, holders and batteries, must be sold in a unit packet. Separate provisions are laid down on

the labelling of electronic cigarettes pre-filled with nicotine and refill containers. It should be noted that the refill container is not a unit packet as referred to in the Tobacco Act.

The Tobacco Act lays down provisions on the mandatory, permitted and prohibited labelling and other appearance of the unit packet. With regard to labelling, other acts that may apply to unit packets (e.g. chemical legislation) must also be addressed. In addition, the marketing ban laid down in the Tobacco Act regarding the unit packet and its labelling must be addressed especially with regard to products whose unit packets are not subject to the plain packaging requirement.

2.1 Mandatory labelling

The mandatory labelling of the unit packets of electronic cigarettes and liquids used in them vary depending on the product sold. The mandatory labelling is affected, for example, by whether an electronic cigarette is sold empty or pre-filled, whether the device is disposable or refillable, and whether the product contains nicotine.

Unit packets of electronic cigarettes and refill containers must include:

- 1) a list of ingredients contained in the product in descending order of the weight;
- 2) an indication of the nicotine content of the product and the delivery per dose;
- 3) the manufacturer's batch number;
- 4) a recommendation to keep the product out of reach of children;
- 5) health warnings in Finnish and in Swedish;
- 6) a leaflet with information on the product and its use and the necessary contact details.

More detailed provisions on health warnings on unit packets of electronic cigarettes and refill containers, and the information contained by leaflets, are laid down in the Decree of the Ministry of Social Affairs and Health on the labelling and other layout elements of tobacco product and related products and their unit packets (591/2016, later the Decree on unit packets)

According to the Decree on unit packets, unit packets of electronic cigarettes and refill containers shall include the following nicotine warning label with the text **“Tämä tuote sisältää nikotiinia, joka on voimakkaasti riippuvuutta aiheuttava aine”** (in Swedish: **“Denna produkt innehåller nikotin som är ett mycket beroendeframkallande ämne”**; in English: “This product contains nicotine which is a highly addictive substance”). The warning label should be on the unit packet in both Finnish and Swedish. The warning label shall cover 32 % of the surface on which it is placed. The text shall be printed in black Helvetica bold type on a white background in a font size ensures that the text occupies the greatest possible proportion of the surface reserved for it. The above-mentioned warning label shall be placed on the two largest surfaces of the unit packets of electronic cigarettes and refill containers. The text of the of the warning label shall appear in the centre of the area reserved for it and be parallel to the main text on the surface.

In the case of an electronic cigarettes that is not pre-filled (sold empty) or an electronic cigarette component that do not contain any nicotine, the unit packet must carry:

- 1) the manufacturer’s batch number;
- 2) a recommendation to keep the product out of reach of children;
- 3) a leaflet with information on the product and its use and the necessary contact details.

The unit packet of a nicotine-free liquid intended for vaporisation must include a list of ingredients contained in the product in descending order of the weight.

As a result, the unit packet of an electronic cigarette pre-filled with a nicotine-free liquid (refillable) must include: a list of ingredients contained in the product in descending order of the weight; the manufacturer’s batch number; a recommendation to keep the product out of reach of children; and a leaflet with information on the product and its use and the necessary contact details. The unit packet of a disposable device containing a nicotine-free liquid for vaporisation (e.g. “e-shisha”) must only include a list of ingredients contained in the product in descending order of the weight.

A table of the mandatory labelling of electronic cigarettes and liquids used in them in different situations is presented at the end of these guidelines.

2.1.1 The leaflet included in the unit packet

All electronic cigarettes (including electronic cigarettes sold empty or pre-filled with a nicotine-free liquid, and electronic cigarette components) and refill containers must include a leaflet with information on the product and its use and the necessary contact details. According to section 15 of the Decree on unit packets, the leaflet must contain the following in Finnish and in Swedish:

- 1) instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;
- 2) information about illnesses and other health-related conditions which preclude use of the product;
- 3) warnings for specific risk groups;
- 4) information about possible adverse effects;
- 5) information about addictiveness and toxicity;
- 6) contact details of the manufacturer or importer and a contact person within the European Union.

The instructions for use on the leaflet must include appropriate instructions and diagrams for filling, as well as instructions for opening a child-proof electronic cigarette and refill container.

2.1.2 Language and size requirements for labelling

The Tobacco Act and the provisions issued under it regulate the requirements for the use of Finnish and Swedish languages only with regard to health warnings and the leaflet supplied with unit packets.

With regard to all labelling on the unit packet, it must be taken into account that information on consumer goods must be in Finnish and Swedish as provided in Section 34 of the Language Act (434/2003)³, unless the information is provided using commonly known instruction and warning labels.

³ When the law requires that a product to be sold is labelled, in accordance with commercial practice, with a name, with a description of the product, instructions or warning, the text on a product to be sold in a unilingual municipality shall be at least in the language of this municipality and the text on a product to be sold in a bilingual municipality shall be at least in

With regard to the product groups covered by these guidelines, the plain packaging requirement applies to electronic cigarettes and refill containers. However, the font size requirement related to plain packaging does not apply to the mandatory labelling of unit packets defined in Section 2.1 above.

Considering the aforementioned and the product groups covered by these guidelines, the Government Decree on information provided on consumer goods and services (613/2004) must also be taken into account regarding the size of information provided on a unit packet. According to section 8 of the Decree, information on consumer goods must be provided in a clear and comprehensible form and using a clear font and sufficiently large font size.

2.2 Permitted labelling and other appearance

A unit packet of an electronic cigarette and refill container may present the brand name of the product and possible version name, the trade name and contact details of the manufacturer or importer and the packaging size, flavour, date of manufacture and barcode of the product in such a way that the unit packet is not distinguished from other unit packets of electronic cigarettes or refill containers in terms of its labelling and the labelling does not promote the sale of the product. According to the justification of the Government proposal (141/2021), information on social media channels, for example, cannot be regarded as permitted contact details.

According to the Decree on unit packets, the aforementioned labelling may not be printed more than once on two surfaces of the unit packet. The labelling shall be printed in the Helvetica font, which is matte and in the colour Pantone Cool Gray 2 C. The labels shall have a maximum point size of 10. The labelling shall not be indicated in bold, italics, underlined or otherwise highlighted.

The barcode differs from aforementioned so that it shall be either black on a white background or a matte Pantone Cool Gray 2 C or Pantone 448 C on a white background. The barcode shall be printed on the bottom, back or side of the unit packet and it shall be printed on the unit packet only once.

The product name may not be presented in more than one row. The possible version name may not be displayed in more than one row immediately below the product name. The wording of the product name and, where applicable, the

Finnish and Swedish. In providing the information here referred to, Finnish and Swedish shall be dealt with on an equal basis. (Language Act, section 34)

version name shall be in line with the warning label for nicotine. The labelling shall consist of lower case letters, except for the first letter.

The unit packets of electronic cigarettes and refill containers shall not be distinguished in form, colour, material, or other appearance from other unit packets of electronic cigarettes or refill containers, and the appearance of the unit packet must not be used to promote the sale of the product. Further provisions on the permitted form, colour, material, and other appearance of the unit packets of electronic cigarettes and refill containers shall be given by the Decree on unit packets.

According to the Decree on unit packets, the unit packets of e-cigarettes and refill containers must be cuboid in shape, Pantone 448 C in colour and made of cardboard with a smooth and matte texture. The colour of the inside of the unit packet shall be Pantone 448 C or white. The wrapping of the unit packet shall be smooth, transparent, colourless and shall not bear any markings. The tear-off strip of the wrapping shall be smooth and transparent and colourless or black. It shall not be more than 3 mm wide and shall be parallel to the upper edge of the package. The tear-off tape shall have a continuous transparent, colourless or black line not exceeding 23 mm in length, marking the starting point of the tape.

2.3 Prohibited labelling elements

According to section 36.3 and 38 of the Tobacco Act, electronic cigarettes, refill containers, receptacles containing a nicotine-free liquid intended for vaporisation or their unit packets shall not include any of the prohibited labelling elements referred to in section 33. This shall not apply to information on the nicotine content, delivery per dose and flavourings.

In view of the above, the labelling of unit packets shall not:

- 1) promote the product or encourage its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions;
- 2) include any information about the nicotine, tar or carbon monoxide content of the product;
- 3) suggest that the product is less harmful than others or aims to reduce the effect of some harmful components of smoke;

- 4) suggest that the product has vitalising, energetic, healing, rejuvenating, natural or organic properties or that its use has other health or lifestyle benefits;
- 5) refer to taste, smell, any flavourings or other additives or the absence thereof (this prohibition does not apply to information on product flavourings);
- 6) resemble a food or a cosmetic product;
- 7) suggest that the product has environmental advantages;
- 8) suggest that the product is fire safe or otherwise create an impression that the product is not dangerous or that it has a reduced fire risk compared to other similar products.

According to the Tobacco Act, characterising flavour or aroma means a smell or taste other than one of tobacco. As the liquids used in electronic cigarettes may have a tobacco taste, unit packets may have labelling that mentions the product's tobacco flavouring in accordance with paragraph 5 above. Even in this case, the labelling on the unit packet of the smell or taste of tobacco in the product must be expressed as neutrally as possible (e.g. tobacco, cigar). The list of ingredients must also include information about the flavourings with which the flavour in the product has been achieved.

Section 33 remains relevant for unit packets of electronic cigarettes and refill containers in accordance with the plain packaging requirements, since for example a product name that suggest that the product is less harmful or that the product has vitalising, and energetic properties is still prohibited in accordance with section 33.

2.4 Marketing ban

According to section 68 of the Tobacco Act, the marketing of tobacco products, tobacco substitutes, smoking accessories, tobacco imitations, electronic cigarettes or nicotine-containing liquids is prohibited.⁴

⁴ Section 3 defines restrictions on the scope of application. The scope of application of the Tobacco Act has been restricted so that, if a product is with the scope of the Medicines Act, the Narcotics Act or the Medical Devices Act, the Tobacco Act does not apply to it. For example, if a product has received a licence in accordance with the Medicines Act, the marketing provisions of the Medicines Act will apply to it.

Since the plain packaging requirements applies to unit packets of electronic cigarette and refill container (contains nicotine liquid), the marketing ban concerns, regarding the products covered by these guidelines, especially nicotine-free liquid intended for vaporisation that meet the definition of tobacco substitute.

3 Electronic cigarettes, refill containers and liquids

The Tobacco Act provides not only on the labelling and appearance of unit packets of electronic cigarette and refill container, but also on the properties and labelling of electronic cigarette and refill container, layout elements of refill container and nicotine-containing liquid, and the properties of liquids.

3.1 General information on the labelling of electronic cigarettes and refill containers

According to the Tobacco Act, electronic cigarettes pre-filled with nicotine containing liquid and refill containers must bear warning labels in accordance with the CLP (Classification, Labelling and Packaging of Chemicals) regulation. The requirement for warning labels that comply with the CLP regulation depends on the nicotine content of the liquid and the other ingredients in the liquid and their concentrations.

It should be noted that, if the product itself, such as a refill container, has to be labelled in accordance with the CLP regulation, the unit packet of the product must also bear the warning labels required by the CLP regulation.

The Finnish Safety and Chemicals Agency (Tukes) acts as the competent authority under the REACH and CLP regulations and maintains the chemical advice service and monitors compliance with the CLP regulation. More detailed advice and guidance on the requirements of the CLP regulation can be obtained from Tukes.

Furthermore, it should be noted that electronic cigarettes and refill containers are subject to the same prohibited labelling elements or elements breach of the marketing ban as their unit packets.

3.2 The labelling and appearance of refill containers

The refill container shall not differ in shape, colour, surface, colour of label or other appearance from other refill containers, nor shall the presentation of the refill container be used to promote the sale of the product.

According to the Decree on unit packets, the refill container shall be in the shape of a right circular cylinder with a funnel-shaped nozzle. The refill container shall be transparent and colourless and shall have a smooth, flat surface. The refill container cap must be transparent, white or black. If the refill container contains a label, its background shall be of the same colour as the unit packet of the product. However, this requirement does not apply to labelling under CLP regulation.

The labelling referred to in section 36 b, subsection 2 of the Tobacco Act, i.e. the brand name of the nicotine-containing liquid, the manufacturer or importer's trade name and contact details, the packaging size, flavour and date of manufacture of the product, may not be printed on the refill container or its label more than once, in such a way that the labelling is not distinguished from the corresponding labelling of other refill containers and is not used to promote the sale of the product. Same applies to possible version name printed on the refill container or its label. The labelling shall be printed in the Helvetica font, which is matte and black or Pantone Cool Gray 2 C in colour. The labels shall have a maximum size of 10 points and the labelling shall not be indicated in bold, italics, underlined or otherwise highlighted.

The product name may not be presented in more than one row. The possible version name may not be displayed in more than one row immediately below the product name. The labelling shall consist of lower case letters, except for the first letter.

3.3 Properties of electronic cigarettes and refill containers

Nicotine-containing liquids intended for use in electronic cigarettes may only be sold or otherwise supplied to consumers:

- a) in refill container; or
- b) in disposable electronic cigarette; or
- c) in single use nicotine cartridge.

The volume of a refill container shall not exceed 10 millilitres.

The volume of the tank of electronic cigarette or a single use cartridge shall not exceed 2 millilitres.

Electronic cigarettes may be sold or otherwise supplied to consumers only if they deliver the nicotine doses at consistent levels under normal conditions of use. Electronic cigarettes and refill containers must be child- and tamper-proof, be protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

Electronic cigarette devices and their components, including batteries and chargers, are also subject to the Low Voltage Directive, the Restriction of Hazardous Substances (RoHS) Directive, the Electromagnetic Compatibility (EMC) Directive and the Battery Directive. For these, the competent authority in Finland is Tukes.

3.3.1 Delivering nicotine doses at consistent levels

Electronic cigarettes may be sold or otherwise supplied to consumers only if they deliver the nicotine doses at consistent levels under normal conditions of use.

Delivering nicotine doses at consistent levels is necessary for purposes of health protection, safety and quality, and to avoid the risk of accidental consumption of large doses. According to the justification of the Government proposal (15/2016), a device delivers nicotine doses at consistent levels when a device of a certain brand or model always delivers the same amount of nicotine over the same time and at the same intensity of use. Especially devices that deliver an unforeseeable amount of nicotine are in breach of section 23 of the Tobacco Act.

3.3.2 Refilling without leakage

Electronic cigarettes and refill containers shall have a mechanism that ensures refilling without leakage.

The provisions governing the technical standards for the refill mechanism and the standards according to which the fulfilment of other requirements referred to in section 23.1 of the Tobacco Act are assessed are further specified in the Decree of the Ministry of Social Affairs and Health on standards and

notifications concerning tobacco products and similar products (592/2016), hereinafter the Product Decree.

As stated in section 8 of the Product Decree, the provisions on mechanisms governing the mechanism that ensures the refilling of electronic cigarettes and refill containers without leakage are laid down in Commission implementation Decision (EU) 2016/586 on technical standards for the refill mechanism of electronic cigarettes.

According to Recital 3 of the Commission Implementing Decision, in view of the toxicity of the nicotine-containing liquids used in electronic cigarettes and refill containers, it is appropriate to ensure that electronic cigarettes can be refilled in a manner that minimises the risk of dermal contact and accidental ingestion of such liquids.

Furthermore, according to article 2, paragraph 1, Member States shall ensure that refillable electronic cigarettes and refill containers are only placed on the market if the mechanism by which the electronic cigarettes are refilled meets one of the following conditions:

- a) it entails the use of a refill container possessing a securely attached nozzle at least 9 mm long, which is narrower than and slots comfortably into the opening of the tank of the electronic cigarette with which it is used and possessing a flow control mechanism that emits no more than 20 drops of refill liquid per minute when placed vertically and subjected to atmospheric pressure alone at $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$;
- b) it operates by means of a docking system which only releases refill liquids into the tank of the electronic cigarette when the electronic cigarette and refill container are connected.

As set out in article 2, paragraph 2, Member States shall ensure that refillable electronic cigarettes and refill containers include appropriate instructions for refilling, including diagrams, as part of the instructions for use. Refillable electronic cigarettes and refill containers with a refill mechanism of the type referred to in point a above shall indicate the width of the nozzle or width of the opening of the tank in the instructions for use in a manner that enables consumers to identify the compatibility of refill containers and electronic cigarettes. Refillable electronic cigarettes and refill containers with a refill mechanism of the type referred to in point b above shall specify, in the instructions for use, the types of docking system with which such electronic cigarettes and refill containers are compatible.

3.3.3 Child-proof

According to the Tobacco Act, electronic cigarettes and refill containers must be child-proof. According to the justification of Government proposal 15/2016, this means, among other things, that a product must have child-proof labelling and fastenings and opening mechanisms. Furthermore, the products must not resemble or contain elements which, in the light of common knowledge, appeal to children.

Child-proof fastenings and opening mechanisms have been in use for a long time, for example in pharmaceutical and chemical products. In practice, child-proof fastenings and opening mechanism are generally required to be such that opening the package requires various combinations of movements that require strength and cognitive skills. An example is a mechanism that needs to be simultaneously pushed down and turned, such as a cap on a pharmaceutical bottle.

The requirements for and the testing of child-proof packaging are at least defined in ISO standards (ISO 8317:2015 and 13127/2012). In addition, the CEN/TS 17287:2019 standard covers the child-proof of electronic cigarettes and refill containers to some extent. It should be noted that the CLP regulation requires that the packaging of products classified for certain hazardous properties to be fitted with a child-proof fastening that complies with the requirements of ISO 8317:2015. The CLP regulation also requires the inclusion of a tactile warning of danger on the packaging if the product is classified for certain hazardous properties. The requirements for child-proof fastenings and tactile warnings of danger can be found in Annex II to the CLP regulation.

It is possible to improve the child-proof properties of a product with the selection of the material used in the unit packet of electronic cigarettes and refill containers. In the case of cartons, for example, there are materials that have higher tear resistance than normal.

The Tobacco Act requires that the unit packet of an electronic cigarette and refill container must include a leaflet with information on the product and its use and the necessary contact details. This leaflet must include instructions for opening a child-proof electronic cigarette and refill container.⁵

⁵ Article 2.2 of Commission Implementing Decision (EU) 2016/586

3.4 Properties of liquids

The liquids used in electronic cigarettes subject to the Tobacco Act fall into two categories: nicotine-containing liquids and nicotine-free liquids intended for vaporisation.

3.4.1 The properties and appearance of nicotine-containing liquids

Nicotine-containing liquids intended for use in electronic cigarettes may only be sold or otherwise supplied to consumers:

- a) in refill container; or
- b) in disposable electronic cigarette; or
- c) in single use nicotine cartridge.

The maximum content of nicotine in a nicotine-containing liquid is 20 milligrams per millilitre.

Nicotine-containing liquid cannot have a characterising flavour or aroma. According to section 2, subsection 25 of the Tobacco Act, characterising flavour or aroma means a smell or taste other than one of tobacco, resulting from an additive or a combination of additives, which is clearly noticeable in a tobacco product, nicotine-containing liquid or nicotine-free liquid intended for vaporisation before or during its consumption.

Furthermore, nicotine-containing liquid must not contain additives:

- a) that are liable to create the impression that the product has a health benefit or presents reduced health risks compared to other (tobacco) products;
- b) or stimulant compounds that are liable to create an impression of energy and vitality;
- c) that have colouring properties for emissions;
- d) that have CMR properties in unburnt form;
- e) that facilitate nicotine uptake or the inhalation of smoke.

According to section 2, subsection 30 of the Tobacco Act, CMR properties means the carcinogenic, mutagenic or reprotoxic properties of a tobacco product or any other product referred to in the Tobacco Act.

Only ingredients of high purity can be used in the manufacture of nicotine-containing liquid. Except for nicotine, only ingredients that do not pose a risk to human health in heated or unheated form, can be used in nicotine-containing liquid.

Nicotine-containing liquid must not contain ingredients that have not been included in the prior notification to Valvira regarding the electronic cigarette or refill container (except for traces that are technically unavoidable during manufacture).

Nicotine-containing liquid must not differ in colour from other nicotine-containing liquids and the colour of the liquid must not be used to promote the sale of the product. According to the Decree on unit packets the nicotine-containing liquid may only be slightly yellow in colour or colourless.

3.4.2 The properties of nicotine-free liquids

Nicotine-free liquid intended for vaporisation must not have a characterising flavour or aroma. It is also not allowed to contain additives:

- a) that are liable to create the impression that the product has a health benefit or presents reduced health risks compared to other (tobacco) products;
- b) or stimulant compounds that are liable to create an impression of energy and vitality;
- c) that have colouring properties for emissions;
- d) that have CMR properties in unburnt form;
- e) that facilitate nicotine uptake or the inhalation of smoke.

Only ingredients of high purity can be used in the manufacture of the nicotine-free liquid. Only ingredients that do not pose a risk to human health in heated or unheated form, can be used in nicotine-free liquid.

Table 1. Mandatory packaging labelling for electronic cigarettes and liquids used in them

Products	List of ingredients	Nicotine content and delivery per dose	Batch number	Recommendation to keep the product out of reach of children	Health warnings	Leaflet
Empty electronic cigarette/electronic cigarette component			X	X		X
Refill container (incl. nicotine-containing liquid)	X	X	X	X	X	X
Nicotine-free liquid	X					
Disposable electronic cigarette with nicotine-containing liquid	X	X	X	X	X	X
Disposable device with nicotine-free liquid	X					



Valvira

National Supervisory Authority
for Welfare and Health

National Supervisory Authority
for Welfare and Health, Valvira

Ratapihantie 9, 00520 Helsinki, Finland
P.O. Box 43, FI-00521 Helsinki, Finland
Koskenranta 3, FI-96100 Rovaniemi

Tel. +358 295 209 111
kirjaamo@valvira.fi
valvira.fi