Guidelines on the properties and requirements for electronic cigarettes and the liquids used in electronic cigarettes and the labelling of unit packets

The National Supervisory Authority for Welfare and Health (Valvira) publishes, on the grounds of Section 6 of the Tobacco Act (549/2016), guidelines on the properties and requirements for electronic cigarettes and the liquids used in them and on the labelling of unit packets.

Legislation

According to Section 2(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(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(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(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 and 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 as well as 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.

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 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 the reach of children;
5. health warnings in Finnish and in Swedish;

---

\(^1\) 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.
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 33.2 This shall not apply to information on the nicotine content, delivery per dose and flavourings. According to Section 36(4), further provisions on the text, font and font size, colour, surface area, position and other properties of the health warning referred to in subsection 1(5) as well as on the information to be included in the leaflet referred to in subsection 1(6) may be issued by decree of the Ministry of Social Affairs and Health.


Labelling of unit packets

Electronic cigarettes and liquids (nicotine-containing and nicotine-free) used in them may be sold and otherwise supplied to consumers only in unit packets that comply with the law. This means, in practice, that electronic cigarettes and their parts, such as atomizers, cartridges, bodies, mouthpieces and batteries, as well as refill containers containing liquid for use in electronic cigarettes, such as bottles containing nicotine-containing liquid, must be sold in unit packets. Refill containers (e.g. bottles) are not unit packets as referred to in the Tobacco Act and their labelling is regulated separately.3

The Tobacco Act provides for mandatory and prohibited labelling elements for unit packets. In addition, with regard to unit packets and their labelling,

---

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.

3 Please see section Labelling of electronic cigarettes and refill containers p. 8
other issues to be considered include the ban on marketing stipulated in the Tobacco Act and any other laws that apply to the unit packets of these products (legislation on consumer products and chemicals, for example).

**Mandatory labelling elements**

The mandatory labelling elements of unit packets of electronic cigarettes and the liquids used in them vary depending on the product. The mandatory labelling elements may be affected by issues such as whether the electronic cigarette is pre-filled or not, whether it is a disposable or refillable device and whether or not the product contains nicotine.

Unit packets of **electronic cigarettes and refill containers**, such as refill bottles containing nicotine-containing liquid, must carry:

1. a list of ingredients contained in the product in descending order of 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.

The health warnings and information included on unit packets of electronic cigarettes and refill containers are specified in the Decree of the Ministry of Social Affairs and Health on the warning labels on unit packets of tobacco products and similar products (591/2016, hereinafter the Decree on unit packets).

According to the Decree on unit packets, the unit packets of refill containers for electronic cigarettes must carry a nicotine warning label, the text of which reads “This product contains nicotine which is a highly addictive substance.” (in Finnish: “Tämä tuote sisältää nikotiinia, joka on voimakkaasti riippuvuutta aiheuttava aine.”; in Swedish: “Denna produkt innehåller nikotin som är ett mycket beroendeframkallande ämne.”). The text must be printed in black Helvetica bold type font on a white background, in a font size that ensures that the text occupies the greatest possible proportion of the surface reserved for it. The above-mentioned warning label must be placed on the two largest surfaces of the unit packets of electronic cigarettes and refill containers. The text of the warning label must appear in the centre of the area reserved for it and be parallel to the main text on the surface.\(^4\)

In the case of an **electronic cigarette that is not pre-filled or an electronic cigarette part**, 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.

---

\(^4\) Sections 11-13 of the Decree on unit packets (591/2016)
The labelling on unit packets of **nicotine-free liquid intended for vaporisation** must include a list of ingredients contained in the product in descending order of weight.

This means that unit packets of electronic cigarettes pre-filled with nicotine-free liquid (refillable) must include: a list of ingredients contained in the product in descending order of 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 labelling on unit packets of **disposable electronic cigarettes** that contain nicotine-free liquid intended for vaporisation (e.g. "e-shisha") only needs to include a list of ingredients contained in the product in descending order of weight.

The table in the appendix to these guidelines shows the mandatory elements of the labels of electronic cigarettes and the liquids used in them in various circumstances.

*The leaflet supplied with unit packets*

All electronic cigarettes (incl. electronic cigarettes that are not pre-filled, that are pre-filled with nicotine-free liquid, and parts of electronic cigarettes) 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 the 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 refilling the electronic cigarette, as well as instructions for opening a child-proof electronic cigarette and refill container.5

*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.

---

5 Please see section *Characteristics/conformity to law of electronic cigarettes and refill containers, i.e. bottles containing nicotine-containing liquid*, in particular the headings *Refilling without leakage and Child-proof packaging.*
With regard to all labelling elements on unit packets, 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 (423/2003), unless the information is provided by well-known instruction and warning elements.

With regard to the size of the information on unit packets, the Decree on information to be provided on consumer goods and consumer services (613/2004) must be taken into account. According to Section 8 of the Decree, the information to be provided on consumer goods must be provided in a clear and comprehensible form and using a clear font and sufficiently large font size.

Prohibited labelling elements

According to Section 36(3) and Section 38 of the Tobacco Act, electronic cigarettes, refill containers, receptacles that contain nicotine-free liquid intended for vaporisation and 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 (the ban does not apply to information about flavourings in the product)\(^6\);
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, a 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.

\(^6\) 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 Finnish and Swedish. In providing the information here referred to, Finnish and Swedish shall be dealt with on an equal basis. (The Language Act, Section 34)

\(^7\) Judicial practice has established that the expression ‘Iceflow’\(^+\), for example, refers to taste and is therefore a prohibited term. (The Market Court, 84/18)
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 obtained.

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.\(^8\)

According to Section 2(35) of the Tobacco Act, the concept of marketing means advertising, indirect advertising and other promotion efforts as well as tobacco sponsorship.\(^6\)

This is a total ban on marketing, with certain exceptions to be defined separately, and all measures designed to create or promote the consumption and demand for products covered by the Tobacco Act are illegal. The marketing ban provision is platform-neutral.

Due to the scope of the marketing ban and it being platform-neutral, the method used in marketing or in the advertising space used is irrelevant. All marketing messages on the product’s packaging, on the product itself or executed in any other way are, therefore, prohibited. No part of the unit packet of electronic cigarettes or liquids that are used in electronic cigarettes is allowed to contain elements that are in breach of the marketing ban.

On the basis of the marketing provision, elements that have been considered to be prohibited on the packaging of products subject to the Tobacco Act include promotional images, colours and fonts, promotional descriptions of the product’s characteristics, manufacturing or origin, as well as texts directing users to websites selling products, for example.

Judicial practice (MAO 84/18) has established that information offered to consumers, which might be considered relevant in itself, may also be considered to be in breach of the marketing ban if images, colours, logos or other marketing elements have been added to the message.

---

\(^8\) Section 3 of the Tobacco Act provides for restrictions on the scope of application of the Tobacco Act. The scope of the Tobacco Act is limited so that it does not apply to products that are subject to the Medicines Act, the Narcotics Act or the Medical Devices Act. For example, a product that has been granted authorisation under the Medicines Act would be subject to the marketing provisions of the Medicines Act.

\(^6\) The amendment to the Tobacco Act’s marketing rule in the Tobacco Act that entered into force in 2016 is conceptual, and it was intended not to change the scope of the concept of marketing. In Government proposal 180/2009, it was pointed out that the messages contained in the packaging of tobacco products can be divided into informative and those promoting sales. The Government proposal states, for example, that any measure relating to the marketing of tobacco which presents the packaging as attractively as possible to the purchaser may justifiably be equated with tobacco advertising.
The Tobacco Act provides detailed regulations on labelling, restrictions and bans concerning unit packets of products that are subject to the Tobacco Act. These detailed provisions are complemented by the extensive marketing ban in the Tobacco Act. Additional labelling elements on unit packets easily breach the limit set for prohibited marketing efforts.

For example, the English text “new design same taste” printed in capital letters on the packaging of a tobacco product has been found to be in breach of the marketing ban. Firstly, the text is in English and, secondly, it resembles a slogan and allows for different interpretations. (The Market Court, 505/12).

Labelling of electronic cigarettes and refill containers

The Tobacco Act provides not only for the labelling on unit packets of electronic cigarettes and refill containers, but also for the labelling on the product itself.

According to the Tobacco Act, electronic cigarettes that are 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, 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.

Prohibited labelling elements

Electronic cigarettes and refill containers shall not carry any prohibited labelling elements or elements in breach of the marketing ban described in the Tobacco Act (see “Labelling of unit packets”, sections Prohibited labelling elements and Marketing ban, pp. 6-7).

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 containers; or
b) in disposable electronic cigarettes; or
c) in single use nicotine cartridges.

The volume of a refill container shall not exceed 10 millilitres.
The volume of the tank of an 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 shall be child- and tamper-proof, be protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

Electronic cigarettes and their components, such as 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.

*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, safety and quality, and to avoid the risk of accidental consumption of large doses. An electronic cigarette delivers nicotine doses at consistent levels if the same make and model of the electronic cigarette always delivers the same amount of nicotine during the same period of use and when used with the same intensity. Electronic cigarettes that deliver unpredictable doses of nicotine are in particular in breach of this paragraph. ⑩

*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 governing the mechanism that ensures the refilling of electronic cigarettes and refill containers without leakage are laid down in Commission Implementing Decision (EU) 2016/586 on technical standards for the refill mechanism of electronic cigarettes.

According to paragraph 3 of the introduction to Commission Implementing Decision (EU) 2016/586, in view of the toxicity of the nicotine-containing liquids used in electronic cigarettes and refill containers, it is appropriate to

⑩ Government proposal 15/2016, p. 91
ensure that electronic cigarettes can be refilled in a manner that minimises the risk of dermal contact and accidental ingestion of such liquids.

According to Article 2(1) of the Commission Implementing Decision on technical standards for the refill mechanism of electronic cigarettes, 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 °C ± 5 °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(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. The instructions for use of refillable electronic cigarettes and refill containers with a refill mechanism referred to in point (a) above shall indicate the width of the nozzle or the width of the opening of the tank so that consumers can determine the compatibility of the refill containers with electronic cigarettes. The instructions for use of refillable electronic cigarettes and refill containers with a refill mechanism of the type referred to in point (b) above shall specify the type of docking systems that are compatible with the electronic cigarettes and refill containers in question.
Child-proof packaging

According to the Tobacco Act, electronic cigarettes and refill containers must be child-proof. This means that the products must have child-proof labelling, fastenings and opening mechanisms, for example. In addition, the products must not resemble or contain elements which, in the light of common knowledge, appeal to children. Such elements include toys, cartoon characters, watches, telephones, musical instruments, vehicles, guns, the human body or human body parts, animals, food, or beverage packaging.

Child-proof fastenings and opening mechanisms have been in use for a long time, for example in medical and chemical products. In practice, child-proof fastenings and opening mechanisms 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 of a medicine bottle.

There is currently no specific legislation or standard regarding child-proof fastenings and opening mechanisms for electronic cigarettes and refill containers. However, there is at least an ISO standard (ISO 8317:2015) on the requirements and testing of child-resistant packaging. It should also be noted that the CLP Regulation requires 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 unit packets of electronic cigarettes and refill containers to be supplied with a leaflet with information on the product and

---

11 Government proposal 15/2016 p. 91 and paragraph 40 of the introduction to the Tobacco Products Directive
12 Government Decree (780/2006) on ensuring child resistance of lighters placed on the market and prohibiting the placing on the market of novelty lighters prohibits all cigarette lighters that resemble objects other than cigarette lighters. These include cigarette lighters the design of which resembles cartoon characters, toys, guns, watches, telephones, musical instruments, vehicles, the human body or human body parts, animals, food, or beverage packaging, or that play musical notes, or have flashing lights or moving objects or other entertaining features. The purpose of the ban is to protect children from dangerous products. Government Decree (780/2006) has been revoked on 14 September 2017 but, factually, the same safety requirements apply to lighters as previously. This is due to the fact that the references of the European standards EN 13869:2016 on child safety requirements for lighters have been published in the Official Journal of the European Union and the safety requirements of the standard correspond to the safety requirements set previously by the Government Decree (780/2006).

13 More detailed advice and guidance regarding the CLP Regulation can be obtained from Tukes.
its use and the necessary contact details. The leaflet must include instructions for opening a child-proof electronic cigarette and refill container.\footnote{14}

Characteristics 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 vapourisation.

Characteristics of nicotine-containing liquids

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

\begin{enumerate}
\item in refill containers; or
\item in disposable electronic cigarettes; or
\item in single use nicotine cartridges.\footnote{15}
\end{enumerate}

The maximum nicotine content of nicotine-containing liquids is 20 milligrams per millilitre.

Nicotine-containing liquids must not have a characteristic aroma or flavour\footnote{16}. It is also not allowed to contain additives:

\begin{enumerate}
\item that are liable to create the impression that the product has a health benefit or presents reduced health risks compared to other (tobacco) products;
\item or stimulant compounds that are liable to create an impression of energy and vitality;
\item that have colouring properties for emissions;
\item that have CMR properties\footnote{17} in unburnt form;
\item that facilitate nicotine uptake or the inhalation of smoke.
\end{enumerate}

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

Nicotine-containing liquids must not contain ingredients that have not been included in the prior notification to Valvira regarding the electronic cigarette or refill container (except for residues that cannot be technically avoided during manufacture).

\footnote{14} Article 2(2), Commission Implementing Decision (EU) 2016/586
\footnote{15} Please see section Properties of electronic cigarettes and refill containers
\footnote{16} According to Section 2(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 vapourisation before or during its consumption.
\footnote{17} According to Section 2(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 said Act.
Nicotine-free liquids

Nicotine-free liquids must not have a characteristic aroma or flavour\(^\text{18}\). 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 are used in the manufacture of the nicotine-free liquid. Only ingredients are used in the liquid that do not pose a risk to human health in heated or unheated form.

For further information, please contact Senior Officer Reetta Honkanen, tel. +358 295 209 630.

Jussi Holmalahti
Director

Reetta Honkanen
Senior Officer

\(^{18}\) On 6 February 2018, Valvira issued guidelines, in Finnish and Swedish, entitled “Tupakkalain sovellaminen nesteisiin, joissa on tunnusomainen tuoksut tai maku” (“Application of the Tobacco Act to liquids with a characteristic aroma or flavour” (D. No. V/6284/2018)).
Appendix 1.

Table 1. The mandatory labelling elements in unit packets of electronic cigarettes and the liquids used in them

<table>
<thead>
<tr>
<th>Mandatory labelling elements</th>
<th>List of ingredients</th>
<th>Nicotine content and delivery per dose</th>
<th>Batch number</th>
<th>Recommendation to keep the product out of reach of children</th>
<th>Health warnings</th>
<th>Leaflet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Products</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronic cigarette that is not pre-filled/ electronic cigarette part</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Refill container (incl. nicotine-containing liquid)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Nicotine-free liquid</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposable electronic cigarette with nicotine-containing liquid</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Disposable electronic cigarette with nicotine-free liquid</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>