

# Order on the quality, labelling and age verification system, etc. of electronic cigarettes and refill containers, etc.<sup>1)</sup>

Pursuant to Section 7(2), Section 8, Section 9(2) and Section 15(4) of the Act on electronic cigarettes etc., cf. Consolidated Act No 1166 of 4 November 2024, the following is laid down:

## Chapter 1

### *Definitions*

**Section 1.** The following definitions apply to this Order:

- 1) Nicotine-containing liquid: liquid containing nicotine alkaloids that can be used in an electronic cigarette or refill container.
- 2) Special refill containers: refill containers manufactured to be used for an electronic cigarette and to contain a nicotine-containing liquid.
- 3) CMR properties: substances which have carcinogenic, mutagenic or reprotoxic properties.
- 4) Emissions: substances released when electronic cigarettes are used as intended.
- 5) Flow control mechanism: a mechanism that allows the refill container to discharge only a certain number of drops of liquid per minute when the refill container is held vertically.
- 6) Docking system: a coupling system that is tightly connected and connects the electronic cigarette and the refill container so that only liquid can be released into the tank of the electronic cigarette.

## Chapter 2

### *Quality and composition*

**Section 2.** Nicotine-containing liquid may only be placed on the market:

- 1) in special refill containers with a volume of not more than 10 ml;
- 2) in single-use electronic cigarettes; and
- 3) in single-use cartridges.

*Paragraph 2.* Cartridges and tanks may have a maximum volume of 2 ml.

**Section 3.** A nicotine-containing liquid may not contain more than 20 mg/ml of nicotine.

**Section 4.** A nicotine-containing liquid may not contain:

- 1) vitamins or other additives which give the impression that an electronic cigarette or refill container presents a health benefit or a limited health risk;
- 2) caffeine or taurine or other additives and stimulant compounds associated with energy and vitality;
- 3) additives having colouring properties for emissions;
- 4) additives facilitating inhalation or nicotine uptake; and
- 5) additives which have CMR properties in unburnt form.

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<sup>1</sup> This Order implements parts of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1). A draft of this Order has been notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification).

**Section 5.** Without prejudice to Paragraph 2, only high purity ingredients may be used in the manufacture of the nicotine-containing liquid.

*Paragraph 2.* Traces of substances other than the ingredients notified to the Danish Safety Technology Authority, cf. Section 2(1) of the Order on notification of electronic cigarettes and refill containers, etc., cf. Annex 1, which are contained in, and emissions arising from, the use of the product, may only be present in the nicotine-containing liquid if such traceable quantities are technically unavoidable during manufacture.

**Section 6.** Except for nicotine, only ingredients which do not pose a risk to human health in heated or unheated form may be used in the nicotine-containing liquid.

**Section 7.** Electronic cigarettes with nicotine shall deliver nicotine doses in constant quantities when used.

**Section 8.** Electronic cigarettes and refill containers containing nicotine shall be child- and tamper-proof and protected against damage and leakage of liquid.

**Section 9.** Electronic cigarettes and refill containers containing nicotine may be placed on the market only if the mechanism by which the electronic cigarettes are refilled meets one of the following conditions:

1) It includes the use of a refill container with a securely attached nozzle at least 9 mm long, which is narrower than and easily fits into the opening of the reservoir of the electronic cigarette for which it is used, and which has a flow control mechanism that discharges no more than 20 drops of refill liquid per minute in a vertical position and at atmospheric pressure alone at 20 degrees Celsius  $\pm$  5 degrees Celsius.

2) It works by means of a docking system that releases refill liquids to the reservoir of the electronic cigarette only when the electronic cigarette and refill container are connected.

**Section 10.** The instructions for use, cf. Section 11, No 1, for refillable electronic cigarettes and refill containers containing nicotine shall be accompanied by appropriate instructions for refilling, including diagrams.

*Paragraph 2.* The instructions for use for refillable electronic cigarettes and refill containers with nicotine using the refill mechanism referred to in Section 9, No 1, shall indicate the width of the nozzle or the width of the opening on the reservoir in a way that enables consumers to judge whether the refill containers and electronic cigarettes fit together.

*Paragraph 3.* The instructions for use for refillable electronic cigarettes and refillable containers with nicotine using the refill mechanism referred to in Section 9, No 2, shall indicate the types of docking systems that allow such electronic cigarettes and refillable containers to fit together.

### Chapter 3

#### *Labelling and health warning*

**Section 11.** Each unit packet of electronic cigarettes and refill containers containing nicotine shall contain information concerning:

- 1) instructions for use and storage of the product in Danish, including a notice stating that the product is not recommended for use by adolescents and non-smokers;
- 2) contraindications;
- 3) warnings addressed to specific risk groups;
- 4) possible adverse effects;
- 5) addictiveness and toxicity; and
- 6) the contact details of the manufacturer or importer and a responsible legal or natural person in the EU.

**Section 12.** All unit packets and any outer packaging of electronic cigarettes and refill containers containing nicotine shall display the following nicotine cessation information: Stoplinien: 80 31 31 31  
[www.stoplinien.dk](http://www.stoplinien.dk).

**Section 13.** Each unit packet and any outer packaging of electronic cigarettes and refill containers containing nicotine shall contain a list of:

- 1) all the ingredients included in the product in descending order by weight;
- 2) an indication of the product's nicotine content and delivery per dose, batch number; and
- 3) a recommendation to keep the product out of the reach of children.

*Paragraph 2.* Each unit packet and any outer packaging of electronic cigarettes and refill containers containing nicotine may not contain any details which:

- 1) suggest that a particular electronic cigarette is less harmful than other electronic cigarettes or aims to reduce the effect of certain harmful components of the vapour or has vitalising, energising, healing, rejuvenating, natural, organic properties or other positive health or lifestyle effects;
- 2) refer to taste, smell, flavourings or other additives or state that the product does not contain them, with the exception of the words 'Tobacco-flavoured' or 'Menthol-flavoured';
- 3) make the electronic cigarette or refill container with nicotine look like a food or cosmetic product;
- 4) suggest that a particular electronic cigarette or refill container containing nicotine has improved biodegradability or other environmental benefits; or
- 5) give the impression of financial benefits by containing printed coupons offering discounts, free distribution, two-for-one offers or other similar offers.

*Paragraph 3.* The elements and details prohibited under Paragraph 2, Nos 1–5 may include, but are not limited to, text, symbols, names, trademarks, figures or other signs.

**Section 14.** Each unit packet and any outer packaging of electronic cigarettes and refill containers containing nicotine shall carry the following health warning:

'This product contains nicotine, which is a highly addictive substance'.

*Paragraph 2.* The health warning on each unit packet and any outer packaging of electronic cigarettes and refill containers containing nicotine shall:

- 1) be placed on the two largest surfaces on the unit packet and any outer packaging;
- 2) cover 30% of the area of the unit packet and any outer packaging;
- 3) be printed in black Helvetica bold type on a white background;
- 4) be written in such a way as to cover the largest possible proportion of the area reserved for the health warning; and
- 5) be placed in the centre of the area reserved for the warning. The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings. On box-shaped packets and any outer packaging, they shall be parallel to the side edge of the unit packet or of the outer packaging.

**Section 15.** The labelling on each unit packet and any outer packaging of electronic cigarettes and refill containers containing nicotine shall be in Danish.

#### Chapter 4

##### *Age verification systems*

**Section 16.** Anyone who wishes to market electronic cigarettes and refill containers containing nicotine to consumers in Denmark or in another EU/EEA country by means of cross-border distance selling shall provide the Danish Safety Technology Authority with details of the type of age verification system established by the retailer under Section 15(4) of the Act. The information shall relate to the content and use of the age verification system.

*Paragraph 2.* Retailers of electronic cigarettes and refill containers with and without nicotine shall operate, in the case of distance selling, an age verification system that effectively verifies that no sale is made to buyers below the specified age limit. This can be done, for example, through user creation with a passport or other valid form of identification or by using a national eID solution, such as MitID.

*Paragraph 3.* The requirement in paragraph 2 shall not apply to online platforms, including online platforms that allow consumers to conclude distance contracts with traders as referred to in Article 3(i) of Council Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC.

#### Chapter 5

##### *Penalties*

**Section 17.** Unless a more severe penalty is due under another act, anyone who breaches the rules in Sections 2–16 will be fined.

*Paragraph 2.* Companies, etc., (legal persons) may be held criminally liable in accordance with the regulations set out in Chapter 5 of the Penal Code.

#### Chapter 6

##### *Entry into force*

**Section 18.** This Order shall enter into force on 1 July 2025.

*Paragraph 2.* Order No 784 of 13 June 2023 on the quality, labelling and age verification system, etc. of electronic cigarettes and refill containers, etc. is hereby repealed.

*Paragraph 3.* For electronic cigarettes and refill containers containing nicotine manufactured before 1 July 2025, Section 12 and Section 13(2)(2), shall take effect from 1 April 2026.

The Ministry of the Interior and Health, 4 March 2025

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