



30. May 2016.

No 499.

## Order on quality, labelling, age checking systems, and advertising etc. of electronic cigarettes and refill containers etc.<sup>1)</sup>

Pursuant to § 7, clause 2, § 8, § 9, clause 2, § 15, clause 3, § 18 and 22, and clause 2, in the Act 426 of 18th of. May 2016 regarding electronic cigarettes etc. the following is hereby decreed:

### Chapter 1

#### *Term definitions*

§ 1. The following terms in this Order are defined as:

- 1) Nicotine-containing liquid: Liquid with nicotine alkaloids that can be used in an electronic cigarette or refill container.
- 2) Dedicated refill containers: Refill containers produced for use with electronic cigarettes and filled with a nicotine containing liquid.
- 3) CMR properties: Substances that have carcinogenic, mutagenic or reprotoxic properties.
- 4) Emissions: Substances released, when electronic cigarettes are used as intended.
- 5) Flow control mechanism: A mechanism that ensures the refill container only releases a certain number of liquid drops per minute, when held vertically.
- 6) Docking system: Coupling system, which is fitted tightly and links the electronic cigarette and refill tank, ensuring that liquid is only released into the tank in the electronic cigarette.
- 7) Advertising: Every action that has the aim of promoting the sale of electronic cigarettes and refill containers with or without nicotine, or which has this direct or indirect effect.

### Chapter 2

#### *Product quality and properties*

§ 2. Nicotine-containing liquid may only be marketed:

- 1) in dedicated refill containers with a volume of at most 10 ml,
- 2) in electronic single use cigarettes, and
- 3) in cartridges for single use.

*Clause 2.* Highest volume for cartridges and tanks- 2 ml.

§ 3. Highest nicotine content in nicotine-containing liquid -20 mg/ml.

§ 4. Nicotine-containing liquid must not contain:

- 1) vitamins or other additives, which give the impression, an electronic cigarette or refill container has a health advantage or a limited health risk,
- 2) caffeine or taurine or other additives and stimulating compounds associated with energy and vitality,
- 3) additives whose emissions have coloring characteristics, or
- 4) additives that have CMR properties in an unburned state.

§ 5. Only ingredients of high cleanliness may be used in production of the nicotine containing liquid, cf. however clause. 2.

*Clause 2.* Traces of substances other than the ingredients declared to the Danish Safety Technology Authority cf. Order on declaration of electronic cigarettes and refill containers etc. § 2, clause 1, cf. appendix 1, that are included in, and emissions, emerging from, the product, may only occur in the nicotine containing liquid if, such traceable amounts are technically unavoidable during manufacture.

§ 6. Apart from nicotine, only ingredients that do not pose a risk to human health in a heated or unheated state may be used in the nicotine containing liquid.

§ 7. Electronic cigarettes containing nicotine shall deliver nicotine doses in constant volumes when used.

§ 8. Electronic cigarettes and refill containers containing nicotine must be child-safe, highly robust, and also secured against manipulation and liquid leakage.

§ 9. Electronic cigarettes and refill containers containing nicotine may only be marketed, if the mechanism via

1) The Order implements parts of the European Parliament's and Council's directive 2014/40/EU of 3rd of April 2014 on mutual harmonization of member state laws and administrative orders on the production, presentation and sale of tobacco and related products and the abrogation of directive 2001/37/EU, Official Journal of the European Union 2014, no. L 127, p. 1.

which the electronic cigarette is refilled complies with the following conditions:

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

2) It functions by means of a docking-system that only releases refill liquid to the tank in the electronic cigarette, when the cigarette and refill container are connected.

**§ 10.** The user guide, cf. § 11, no. 1, for refillable electronic cigarettes and refill containers containing nicotine shall contain the requisite instructions for refilling, including diagrams.

*Clause 2.* The user guide for refillable electronic cigarettes and refill containers containing nicotine that use the refill mechanism, cf. § 9, no. 1, shall state the width of the nozzle or tank opening in a way that helps consumers to assess whether the refill container and electronic cigarette fit together.

*Clause 3.* The user guide for refillable electronic cigarettes and refill containers containing nicotine that use the refill mechanism, cf. § 9, no. 2, shall state the type of docking systems with which such electronic cigarettes and refillable containers fit together.

### Chapter 3

#### *Labelling and health warnings*

**§11.** Each single packet of electronic cigarettes and refill containers containing nicotine shall contain information on:

- 1) A user guide in Danish on storage of the product including a notice that the product is not recommended for young people and non-smokers.
- 2) Contraindications.
- 3) Warnings to specific risk groups.
- 4) Possible harmful effects.
- 5) Addictive properties and toxicity and
- 6) Contact details for manufacturer or importer and a responsible legal or physical person.

**§ 12** Each single packet and any outer packaging of electronic cigarettes and refill containers containing nicotine must contain a list of:

- 1) all the ingredients contained in the product in descending order based on weight,
- 2) a statement of the product's nicotine content and its dosage release, batch number, and
- 3) a recommendation to store the product away from children.

*Clause 2.* Each single packet and any outer packaging of electronic cigarettes and refill containers containing nicotine must not contain features which:

- 1) give the impression that a particular electronic cigarette is less harmful than other electronic cigarettes, or is intended to reduce the effect of specific harmful components in the vapor or have revitalizing, energy giving, healing, rejuvenating, natural, ecological properties, or other positive health and lifestyle effects,
- 2) makes the electronic cigarette or refill container containing nicotine resemble a foodstuff or et cosmetic product,
- 3) gives the impression a particular electronic cigarette or refill container containing nicotine has an enhanced biological degradability or other environmental advantages,, or
- 4) gives the impression of financial advantages by containing printed coupons offering discounts, free samples, disbursement, two for one offers, or other similar offers.

*Clause 3.* The banned elements and features, as per clause 2 nos. 1-4, can cover, but are not restricted to, text, symbols, names, brands, figures or other signs.

**§ 13.** Each single 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 an extremely addictive substance«.

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

- 1) be placed on the two largest surfaces on the single packet and any outer packaging,
- 2) cover 30% of the surface of the single packet and any outer packaging,
- 3) be printed in bold Helvetica font on a white background,
- 4) be designed with a text size that covers the greatest possible share of the surface area reserved for the health warning, and
- 5) is centered in that area reserved for the warning and on box shaped packets and any outer packaging shall be placed parallel with the side edge of the single packet or outer packaging.

**§ 14.** The labelling of each single packet and any outer packaging of electronic cigarettes and refill containers containing nicotine must be in Danish.

### Chapter 4

#### *Age checking system*

**§ 15.** Those who wish to market electronic cigarettes and refill containers containing nicotine to consumers in this country, or in another EU/EEA country via cross border distance selling, shall provide the Danish Safety Technology Authority with more detailed information on age checking system, the seller has

30. May 2016.

3

No. 499.

put in place as per the Act's § 15, clause 2. The information shall describe the age checking system's content and application.

Chapter 5  
*Advertising/Marketing etc.*

§ 16. All forms of advertising, cf. the Act's § 16, for electronic cigarettes and refill containers is forbidden.

*Clause 2.* The advertising ban, as per clause 1 involves a ban on:

1) Use of a name, brand, symbol or other characteristic, that is primarily known from electronic cigarettes and refill containers, in advertising for other goods and services.

2) Marketing of electronic cigarettes and refill containers by use of a name, brand, symbol or other characteristic that is known as, or in use as, a brand for other goods and services.

3) Marketing of electronic cigarettes and refill containers by use of names, brands, symbols, figures or similar, and which, are primarily aimed at children and young people under 18 years of age.

4) Use of layout, design, or particular color combinations associated with particular electronic cigarettes and refill containers.

5) Use of recognizable electronic cigarettes and refill containers in advertising for other goods and services.

*Clause 3.* The ban in clause. 1, however, does not apply to:

1) Communications exclusively aimed at professionals within the trade sector.

2) Price lists for electronic cigarettes and refill containers in retail outlets.

3) Notices in a retail outlet with the text "Electronic cigarettes"

4) Advertising aimed at purchasers at sales outlets which specialize in the sale of electronic cigarettes and refill-containers, with the exception of internet sales

5) Use of a name that before the 7<sup>th</sup> of June 2016 was used both for electronic cigarettes and refill-

containers and other goods or services as advertisements for these other products, where the name appears in a form that clearly differs from the name displayed on the electronic cigarette and refill container.

6) Use of name that is associated with electronic cigarettes, in advertising for other goods and services, if the other item or service is only marketed in a limited geographical area.

*Clause 4.* The ban in clause. 1, applies does not, furthermore apply to neutral placements of electronic cigarettes and refill containers in relation to payment tills, bars and the like. Electronic cigarettes and refill containers may only be placed:

1) on shelves and in cabinets behind or below the till, counter, bar, or similar places,  
2) in boxes above the till, bar or similar places, or  
3) in special automats that take cards which can only be obtained and paid for at the till.

*Clause 5.* The shelves, cabinets and boxes must not be of such a size or design that they have the effect of advertising.

Chapter 6  
*Penalties*

§ 17. Unless a more serious penalty, as per another Act, is warranted, persons concerned incur fines if they contravene §§ 2-10 and §§ 11-14, or contravene the ban in § 16.

*Clause 2.* Companies etc. (legal persons) can face criminal liability charges as per the stipulations in Chapter 5 of the Criminal Law Act.

Chapter 7  
*Coming into force*

§ 18. This order comes into force on the 7th of June 2016.

*Ministry of Health, 30th of May 2016*

SOPHIE LØHDE

/ Erich Erichsen