

Amendment to Government Decree 39/2013 of 14 February 2013 on the manufacture, placement on the market and control of tobacco products, combined warnings and the detailed rules for the application of the health-protection fine

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§ 2 of Government Decree 39/2013 of 14 February 2013 on the manufacture, placement on the market and control of tobacco products, combined warnings and the detailed rules for the application of the health-protection fine (hereinafter referred to as the 'Implementation Decree on the Protection of Non-Smokers') is supplemented with the following point 24:

(For the purposes of this Decree:)

'24. nicotine-containing liquid: liquid utilised in the course of using electronic cigarettes or for refilling them that contain any amount of nicotine, however small.'

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The Implementation Decree on the Protection of Non-Smokers is supplemented with the following sub-heading 9/A:

'9/A Rules governing electronic cigarettes, electronic smoking imitation devices and refill containers

§ 19/A(1) The notification referred to under § 7/D(1) of the Act on the Protection of Non-Smokers shall be submitted to the National Institute of Pharmacy and Nutrition (hereinafter referred to as the NIPN). The notification shall contain the following information:

- a) the name and contact details of the manufacturer and the importer;
- b) a list of all product ingredients and emissions created when using the product, and their respective quantities, by brand name and type;
- c) toxicological data on product ingredients and emissions, primarily on their impact on consumers and users exerted through inhalation, taking into account any impacts potentially causing addiction;
- d) information on the product's valid nicotine dose and nicotine absorption when used for its intended purpose or under conditions which can reasonably be foreseen;
- e) a description of product components, including the mechanism of the electronic cigarette and of the opening and refilling of the refill container;
- f) a description of the manufacturing process, including whether the product is serially manufactured, and a declaration on whether the manufacturing process ensures compliance with legislative requirements;
- g) a declaration that the manufacturer and the importer assume full responsibility for the product's quality and safety in the context of its placement on the market and use for its intended purpose or under conditions which can reasonably be foreseen.

(2) In the case of electronic smoking imitation devices, the notification shall be made with the data content specified in paragraph (1)(a)-(c) and (e)-(g).

§ 19/B(1) Electronic cigarettes and refill containers may not contain flavourings.

§ 19/C(1) Electronic smoking imitation devices may be placed on the market and distributed subject to the following conditions:

- a) the liquid used in the electronic smoking imitation devices may not contain nicotine;
- b) the liquid may not contain flavourings;
- c) the liquid may not contain:
 - ca) additives specified in Annex 4;
 - cb) vitamins or other additives giving the impression that the product has a beneficial physiological impact or is less harmful to health;
 - cc) caffeine, taurine or other additives and stimulant compounds that give a feeling of improved energy and vitality;
 - cd) additives causing a discolouration of the emissions;
 - ce) additives facilitating inhalation; and
 - cf) additives with CMR properties;
- d) the liquid may not contain ingredients containing more than 0.1% impurities;
- e) the liquid may only contain ingredients that are not harmful to human health, whether in reaction to heat or not;
- f) electronic smoking imitation devices shall be fitted with a child safety lock system;
- g) electronic smoking imitation devices shall be protected against breakage and leakage, and fitted with the mechanism allowing leakage-free refilling.

(2) An information leaflet containing the elements specified in § 19/B(2) shall be appended to the unit packets of electronic smoking imitation devices.

(3) Unit packets and the outside packaging of electronic smoking imitation devices shall include:

- a) all product ingredients listed in descending order by weight,
- b) the manufacturing batch number,
- c) the following text warning: 'Keep out of reach of children.'

(4) Unit packets and the outside packaging of electronic smoking imitation devices shall comply with the requirements laid down in § 6/A(1)(b), (d) and (e) and paragraphs (2) and (3) of the Act on the Protection of Non-Smokers.

(5) The following health warning shall be displayed, in the manner specified in § 19/B(6), on the two largest surfaces of unit packets and the outside packaging of electronic smoking imitation devices, covering at least 30 % of both sides:

'This product is an electronic smoking imitation device. Not recommended for children.'

Final provisions

The requirement for the preliminary notification of this draft Decree, as stipulated in Articles 5–7 of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9

September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, has been complied with.