

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2016/586

of 14 April 2016

on technical standards for the refill mechanism of electronic cigarettes

(notified under document C(2016) 2093)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ⁽¹⁾, and in particular Article 20(13) thereof,

Whereas:

- (1) Article 20(3)(g) of Directive 2014/40/EU requires Member States to ensure that electronic cigarettes and their refill containers have a mechanism that ensures refilling without leakage.
- (2) Article 20(13) of Directive 2014/40/EU empowers the Commission to lay down technical standards for the refill mechanism of electronic cigarettes by means of an implementing act.
- (3) 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.
- (4) On the basis of feedback received from stakeholders and work carried out by an external contractor, technical standards have been identified which are intended to ensure that compliant refill mechanisms provide sufficient protection against leakage.
- (5) The technical standards identified also comprise measures ensuring that consumers are properly informed of how to operate the refill mechanisms in order to ensure leakage-free refilling.
- (6) Stakeholders may wish to provide the Commission with information on alternative mechanisms they have developed to ensure leakage-free refilling, which may lead to this Decision being revised.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 25 of Directive 2014/40/EU,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter

This Decision lays down the technical standards for the refill mechanism of electronic cigarettes manufactured in or imported into the Union.

⁽¹⁾ OJ L 127, 29.4.2014, p. 1.

*Article 2***Requirements for the refill mechanism**

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 $20\text{ °C} \pm 5\text{ °C}$;
- (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.

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 required by Article 20(4)(a)(i) of Directive 2014/40/EU.

Refillable electronic cigarettes and refill containers with a refill mechanism of the type referred to in paragraph 1(a) 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 paragraph 1(b) shall specify, in the instructions for use, the types of docking system with which such electronic cigarettes and refill containers are compatible.

*Article 3***Addressees**

This Decision is addressed to the Member States.

Done at Brussels, 14 April 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission