

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2015/744

of 8 May 2015

authorising the provisional measure taken by the Netherlands in accordance with Article 52 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council as regards additional packaging and labelling requirements for electronic cigarettes containing nicotine and refill containers

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ⁽¹⁾, and in particular Article 52 thereof,

Whereas:

- (1) On 10 March 2015, the Netherlands informed the Commission in accordance with Article 52(1) of Regulation (EC) No 1272/2008 that it has justifiable grounds for believing that electronic cigarettes and refill containers containing nicotine, although satisfying the requirements of this Regulation, constitute a serious risk to human health due to reasons of labelling and packaging. The Netherlands adopted a provisional measure regarding temporary regulations with regard to the electronic cigarettes on 24 November 2014. That measure was published in the Official Journal of the Kingdom of the Netherlands on 28 November 2014 ('the Decree') ⁽²⁾. The Netherlands informed the other Member States and the European Chemicals Agency of the Decree on 12 March 2015.
- (2) Article 4(1) of the Decree provides that nicotine containing electronic cigarettes and their refill containers must be childproof and Article 4(2) provides that refill containers must have a child-resistant fastening even if it is not required by Regulation (EC) No 1272/2008. In this context, it should be noted that, for the purposes of Regulation (EC) No 1272/2008, electronic cigarettes can be considered to be a mixture in a container. By subjecting both electronic cigarettes and refill containers to the requirement of child-resistant fastenings irrespective of the concentration limit of nicotine in the mixture, the Decree imposes additional requirements going beyond the provisions of Regulation (EC) No 1272/2008. Article 7(2) of the Decree requires that, in so far as the recommendation to keep a product outside the reach of children is not mandatory on the basis of Regulation (EC) No 1272/2008, a packaging unit and any outer packaging must contain that recommendation. Therefore, the Decree goes beyond the labelling obligations under Regulation (EC) No 1272/2008. For those reasons, the additional requirements provided by Article 4(1) and (2) and Article 7(2) of the Decree have the potential to impede the placing on the Netherlands' market of products which comply with the applicable rules under Regulation (EC) No 1272/2008.
- (3) The Netherlands have provided justifiable grounds for believing that e-cigarettes and refill containers containing nicotine represent a serious risk to human health. Whereas only 2 poisoning cases were recorded in the first half of 2013, the number increased in the second half of the year, taking the total to 33 reported cases for 2013 and to 43 cases for 2014. For 2013, in 27 cases, the mixtures were ingested orally, including 8 children between 0 and 4 years. The labelling and packaging measures in the Decree are of a nature that can prevent access of children to those mixtures, and consequently are appropriate to reduce the risk to health of children.

⁽¹⁾ OJ L 353, 31.12.2008, p. 1.

⁽²⁾ Besluit van 24 november 2014, houdende tijdelijke regels met betrekking tot de elektronische sigaret (Tijdelijk warenwetbesluit elektronische sigaret), Staatsblad van het Koninkrijk der Nederlanden, 28 November 2014, n° 456, p. 1.

- (4) The provisions of the Decree mirror the provisions of Article 20 of Directive 2014/40/EU of the European Parliament and of the Council ⁽¹⁾. Member States have to bring into force laws, regulations and administrative provisions necessary to comply with that Directive by 20 May 2016.
- (5) The Decree is a temporary measure which may remain applicable until the measures adopted by the Netherlands transposing Directive 2014/40/EU into Dutch national law become applicable. The measures should therefore be authorised until 19 May 2016.
- (6) In order for the Commission to comply with the 60-day period for taking its decision laid down in Article 52(2) of Regulation (EC) No 1272/2008, this Decision should enter into force on the day of its publication.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽²⁾,

HAS ADOPTED THIS DECISION:

Article 1

The provisional measure provided for in Article 4(1) and (2) and Article 7(2) of the Decree of 24 November 2014, regarding temporary regulations with regard to the electronic cigarettes, notified to the Commission by the Netherlands on 10 March 2015, is authorised until 19 May 2016.

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 8 May 2015.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ 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).

⁽²⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).