

592/2016

**Decree of the Ministry of Social Affairs and Health
on standards and notifications concerning tobacco products and similar products**

By decision of the Ministry of Social Affairs and Health the following is enacted pursuant to the Tobacco Act (549/2016):

Section 1 – Methods for measuring emissions from cigarettes

- (1) The tar, nicotine and carbon monoxide emitted by cigarettes when smoked shall be measured in accordance with ISO Standards 4387 (tar), 10315 (nicotine) and 8454 (carbon monoxide).
- (2) The accuracy of the measurements referred to above in subsection 1 shall be verified in accordance with ISO Standard 8243.

Section 2 – Methods to be used in testing and verifying the fire safety requirements of cigarettes

The burning behaviour of cigarettes shall be tested and verified in accordance with the European standards EN 16156:2010 'Cigarettes — Assessment of the ignition propensity — Safety requirement' and EN ISO 12863:2010 'Standard test method for assessing the ignition propensity of cigarettes'.

Section 3 – Information to be reported in lists of ingredients for tobacco products

- (1) The following shall be reported in the list referred to in section 14(1)(4) of the Tobacco Act:
 - 1) the reasons for the inclusion of the ingredients in the product;
 - 2) the status of the ingredients including whether the ingredients have been registered in accordance with 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;
 - 3) the classification of the ingredients in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council 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;
 - 4) the relevant toxicological data regarding the ingredients in burnt or unburnt form, as appropriate, referring in particular to their effects on the health of consumers and taking into account, inter alia, any addictive effects.
- (2) The ingredients and quantities thereof shall be reported in descending order of the weight of each ingredient.

Section 4 – Time of notifying studies and sales volumes

The information referred to in sections 16, 27 and 28(1) of the Tobacco Act shall be notified to the National Supervisory Authority for Welfare and Health (*Valvira*) annually by 20 May. The information referred to in sections 16(2) and 27(1)(1) of the Tobacco Act must be notified for the previous calendar year.

Section 5 – Format for notifications concerning tobacco product ingredients and sales volumes

The provisions governing the format for notifying and making available the information referred to in sections 14(1)(1–5), 16 and 18 of the Tobacco Act are laid down in Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products.

Section 6 – Format for the prior notification concerning electronic cigarettes and refill containers

The provisions governing the format of the prior notification referred to in section 26 of the Tobacco Act are laid down in Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers

Section 7 – Verification laboratories

- (1) The laboratory which verifies the measurements and the accuracy of the measurements as referred to above in section 1 must be accredited to the standard SFS-EN ISO/IEC 17025.
- (2) The laboratory must notify the following information to Valvira when it applies for the approval referred to in section 85 of the Tobacco Act. Any changes in the said information shall also be notified:
 - 1) the name, contact details and Business Identity Code of the laboratory;
 - 2) the person responsible for the studies and his or her contact details;
 - 3) the time of the suspension, termination or resumption of the operations of the laboratory.
- (3) The grounds of approval of the laboratories as well as the control mechanisms employed must be notified in the list referred to in section 85(1) of the Tobacco Act.

Section 8 – Refill of electronic cigarettes and refill containers without leakage

The provisions governing the mechanism that ensures the refilling of electronic cigarettes and refill containers without leakage are laid down in Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes.

Section 9 – Entry into force

- (1) This Decree enters into force on 15 August 2016.
- (2) When the information referred to in section 16(2) and section 27(1)(1) of the Tobacco Act is first notified in accordance with section 4, information for 2015 shall also be notified.

Helsinki, 30 June 2016