

E-CIGARETTES



Current Regulation

- Currently there is no EU wide regulatory framework to guarantee the safety and quality of e-cigarettes. The application of the General Product Safety Directive is not sufficient.¹

Concentration and Size

- An e-cigarette with a concentration of 20mg/ml delivers approx. 1 mg of nicotine in 5 minutes (the time needed to smoke a traditional cigarette, which delivers 1mg of nicotine).²
- The most commonly sold strength of e-cigarettes is 17-18 mg/ml³ and strengths of 20mg/ml and lower were shown to be effective for the majority of smokers in their cessation efforts.⁴

Cartridges and Refills

- The market share for refillable cartridges and tanks varies across the EU. At this stage reliable independent studies on market shares are not available. A recent study of a stakeholder estimated the EU average of refillable e-cigarettes to slightly exceed 40%.⁵
- Refillable cartridges and refill bottles⁶ with liquid can be contaminated, expose users to toxic nicotine liquid⁷ and are a safety risk for children.⁸ These products also allow users to home blend higher nicotine strengths and flavour combinations.
- The majority of products on the market consists of disposable e-cigarettes and e-cigarettes with sealed cartridges. These limit the risk that users come into contact with nicotine liquid.⁹

Flavours

- Regulating flavours is important to ensure that products are not attractive to young people and non-smokers (risk of gateway into nicotine addiction *et alia*).
- Flavours currently in use in nicotine replacement therapies include tobacco (approx. 50% of the e-cigarette market), mint, fruit, lemon, toffee and liquorice.¹⁰

Uniform Dosing

- Users should receive consistent nicotine delivery when they use an e-cigarette.¹¹
- Devices should be designed to ensure that the same puff, for example 5 seconds consuming 0.003ml liquid, always delivers the same amount of nicotine.

¹ 14 notifications concerning (refill) liquids for E-cigarettes via the RAPEX system have been reported. DG Health and Consumers. Rapid Alert System for non-food products posing a serious risk (RAPEX) Brussels: DG SANCO; 2012.

http://ec.europa.eu/consumers/safety/rapex/index_en.htm

² Farsalinos et al. Evaluation of Electronic Cigarette Use (Vaping) Topography and Estimation of Liquid Consumption. Int J Environ Res Public Health. 2013;10: 2500-14.

³ Information from industry and the MHRA for UK market.

⁴ Farsalinos et al. Evaluating nicotine levels selection and patterns of electronic cigarette use in a group of 'Vapers' who had achieved complete substitution of smoking. Substance Abuse: Research and Treatment. 2013; 7:139-146.

⁵ Provided by industry. Estimates based on research conducted in UK, FR, DE, PL, IT, ES. In comparison, the market share in the US is approximately 10%. (http://www.cspdigitals.com/msa/MSA_CSP_Content_092613.pdf)

⁶ The commonly sold 10ml refill bottle of 18mg/ml liquid contains the equivalent of 180 smoked tobacco cigarettes.

<http://www.totallywicked-eliquid.co.uk/about-the-fluid.html>

⁷ Regulation (EC) No 1272/2008, OJ L 353.

⁸ <http://www.ipost.com/Breaking-News/Toddler-who-ingested-liquid-nicotine-passes-away-314683>. In the view of the BfR, refill solutions in particular pose an additional health hazard for children (http://www.bfr.bund.de/en/frequently_asked_questions_about_e_cigarettes-130598.html).

⁹ <http://www.e-cigarette-forum.com/infozone/Dr-Lynne-Dawkins>

¹⁰ Survey of MS (BE, DE, EE, ES, FI, HR, HU, IE, LT, LV, SI, SK and UK) on authorised flavours. Information from industry.

¹¹ "Analyses of nicotine levels delivered from electronic cigarettes suggest significant variability exists in the products tested to date." (<http://www.mhra.gov.uk/home/groups/commms-ic/documents/websitesresources/con286839.pdf>).