

# 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.<sup>1</sup>

## 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, for which the maximum allowable delivery is 1mg of nicotine).<sup>2</sup>
- The most commonly sold strength of e-cigarettes is 17-18 mg/ml<sup>3</sup> and strengths of 20mg/ml and lower were shown to be effective for the majority of smokers in their cessation efforts.<sup>4</sup>

## 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%.<sup>5</sup>
- Refillable cartridges and refill bottles<sup>6</sup> with liquid can be contaminated, expose users to toxic nicotine liquid<sup>7</sup> and are a safety risk for children.<sup>8</sup> 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.<sup>9</sup>

## 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.<sup>10</sup>

## Uniform Dosing

- Users should receive consistent nicotine delivery when they use an e-cigarette.<sup>11</sup>
- 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.

<sup>1</sup> 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](http://ec.europa.eu/consumers/safety/rapex/index_en.htm)

<sup>2</sup> 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.

<sup>3</sup> Information from industry and the MHRA for UK market.

<sup>4</sup> 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.

<sup>5</sup> 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](http://www.cspdigitals.com/msa/MSA_CSP_Content_092613.pdf))

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

<http://www.totallywicked-eliq.com/about-the-fluid.html>

<sup>7</sup> Regulation (EC) No 1272/2008, OJ L 353. The minimum lethal dose of nicotine is estimated to be 40 to 60 mg.

<http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con062829.pdf>. This equals <1 mg/kg. In comparison, cocaine has been estimated to be lethal at 20 mg/kg (for a 70 kg individual). <http://archives.drugabuse.gov/pdf/monographs/108.pdf>

<sup>8</sup> <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](http://www.bfr.bund.de/en/frequently_asked_questions_about_e_cigarettes-130598.html)).

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

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

<sup>11</sup> "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/comms-ic/documents/websiteresources/con286839.pdf>).