Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)

Request for a scientific Opinion on

Electronic cigarettes

1. Background

Tobacco Products Directive

The Tobacco Products Directive 2014/40/EU (TPD)[1] lays down rules for tobacco and related products placed on the EU market. It aims to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of health protection for European citizens.

Article 20 of the Tobacco Products Directive introduces for the first time a comprehensive regulatory framework for electronic cigarettes with a focus on safety, quality, consumer protection and collection of information. It also sets out requirements for nicotine containing liquid, including the prohibition of certain additives.

Under Article 28, the European Commission has been tasked with reporting to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the application of the Directive by 20 May 2021. Further, the Commission shall be 'assisted by scientific and technical experts in order to have all the necessary information at its disposal' and the report shall indicate, 'elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments'. Article 28 also further emphasises that the Commission shall pay special attention to electronic cigarettes (e-cigarettes) and the report shall be followed by proposals for amending the Directive. E-cigarettes are recent products on the EU market and evidence concerning their potential risks and benefits is emerging. While some work has been carried out outside of the EU[2&3], research performed in a European context and focused on EU policy needs is still limited. At this stage, the Commission and Member States are monitoring scientific evidence, user profiles and market developments regarding all types of e-cigarettes. Open questions particularly include the role of e-cigarettes in relation to their use and adverse health effects (i.e.; short- and long-term effects), their role as a gateway to smoking / the initiation of smoking (particularly focusing on young people), their role in harm reduction / cessation of traditional tobacco smoking, as well as risks associated with their chemical composition (e.g.; number and levels of toxicants).

E-cigarettes and Article 20 of the Tobacco Products Directive

Article 20 of the TPD sets down a number of safety and quality requirements for nicotine-containing e-cigarettes and the relevant nicotine-containing liquid intended for the consumer market. These consumer e-cigarettes may be disposable, rechargeable with a cartridge or refillable by means of refill containers containing e-liquid.

Manufacturers and importers must notify their products to Member State competent authorities (Article 20(2)). This notification must include information on ingredients and emissions, toxicological data, information on nicotine doses and uptake, and a description of the device and production processes. Manufacturers must also submit sales data and information on consumer preferences annually to Member States (Article 20(7)).

[1] https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf
[2] http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx
[3] https://www.nap.edu/resource/24952/012318ecigaretteConclusionsbyOutcome.pdf

Manufacturers and importers must collect information on suspected adverse effects on human health and take immediate corrective action if they believe their products to be unsafe (Article 20(9)).

The TPD contains provisions on the ingredients that can be used in e-cigarettes and sets limits on the amount of nicotine that can be sold in consumer electronic cigarettes and refill containers (Article 20(3)). E-liquids must not contain more than 20mg/ml nicotine (Article 20(3)(b)), tanks and cartridges must not be larger than 2ml, and refill containers must not be larger than 10ml (Article 20(3)(a)). Refill containers and electronic cigarettes must also be child-resistant and tamper-proof, and sold with instructions for use and health warnings (Article 20 paragraphs 3(g), 4(a) and (b)).

Cross-border advertising and sponsorship of e-cigarettes is not allowed (Article 20(5)) and Member States may choose to prohibit cross-border distance sales in the same manner as for tobacco products (Article 20(6)). The regulation of flavours, local advertising and age limits are left to Member States.

2. Terms of reference

The main purpose of the scientific opinion is to assist the Commission in assessing the most recent scientific and technical information on e-cigarettes. Findings presented in the scientific opinion will feed into the Commission's reporting obligations under Article 28 of the TPD and also help the Commission in assessing the potential need for legislative amendments under the Directive or other regulatory/enforcement measures.

The assessment should include and address the role of e-cigarettes, looking into potential impacts on the EU context, in relation to:

- their use and adverse health effects (i.e.; short- and long-term effects)
- risks associated with their technical design and chemical composition (e.g.; number and levels of toxicants) and with the existing EU regulatory framework (e.g. nicotine concentration and limits)
- their role as a gateway to smoking / the initiation of smoking (particularly focusing on young people)
- their role in cessation of traditional tobacco smoking

While drawing-up the scientific opinion, the committee should take into consideration the most recent and up-to-date scientific evidence and technical developments and, as appropriate, the existing provisions concerning e-cigarettes under the TPD (in particular Article 20(3)) and the evolution of new products on the market. The scientific opinion should address considerations relevant both at individual level and at a population level, from a public health perspective.

3. Deadline

Article 28 report needs to be submitted to the EU Parliament by 20 May 2021. In this respect the SCHEER should deliver the final opinion in September/October 2020 at the latest.