



E-cigarettes in the context of the EU tobacco control

22nd BfR Consumer Protection Forum "Opportunities and risks of the e-cigarette"

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Introduction

Objectives: the opinion aimed to address the role of electronic cigarettes, focusing into potential impacts on the EU context, in relation to:

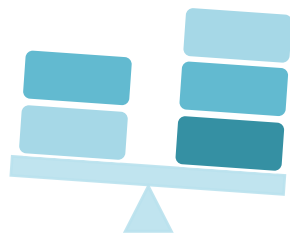
1. their use and adverse health effects (i.e. short- and long-term effects), risks associated with their technical design and chemical composition (e.g. number and levels of toxicants) and with the existing EU regulatory framework (e.g. nicotine concentration and limits).
2. their role as a gateway to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

Methodology: the members of the working group agreed to firstly use **review articles** published between **1 January 2015 and April 2019 for this Opinion**. If necessary, the primary sources were also used, as well as further articles of (end of the public consultation). Also inclusion of important published articles after **April 2019 until 26 October 2020**.

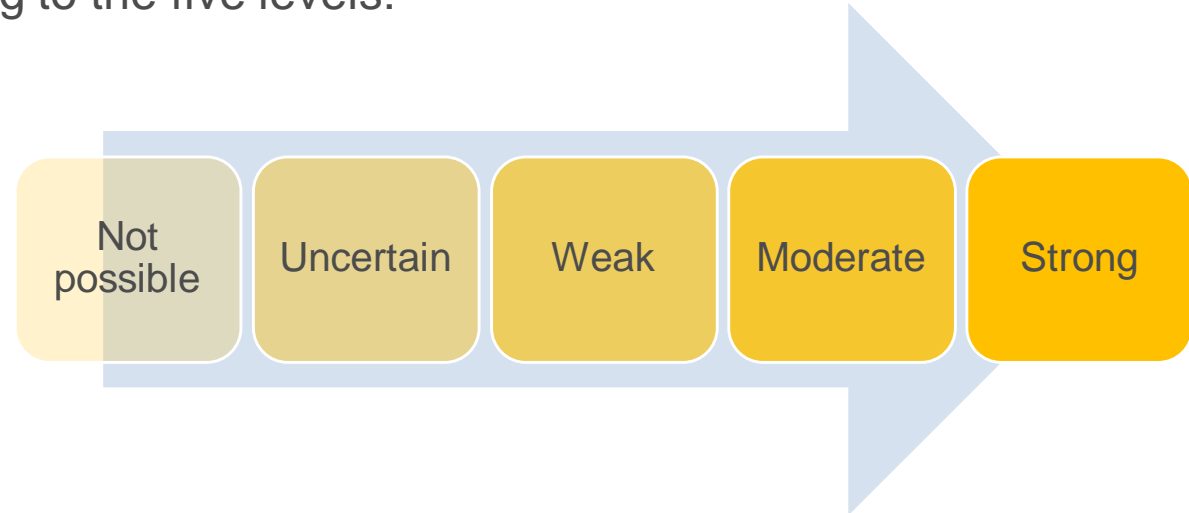
How did the SCHEER evaluated the health risks?

The SCHEER follows different lines of evidence, i.e. **information on exposure of users and second-hand exposed persons, hazards of ingredients in the aerosol and information from human experience** as well as from **epidemiological studies**. The SCHEER weighs the evidence for every line considered and provide an overall risk assessment based on all lines. The SCHEER weighs the evidence of its assessment according to the five levels:

Weight of evidence



Strength of the evidence



A weight of the evidence approach considers **all of the scientific evidence** that is relevant to a particular issue (positive and negative). Strength of evidence considers only **a subset of the evidence**, such as focusing on only those studies which have found a positive link between exposure and adverse condition.

SCHEER conclusions on health effects

For users of electronic cigarettes

1. The overall weight of evidence is **moderate** for risks of local irritative damage to the respiratory tract of users due to the cumulative exposure to polyols, aldehydes and nicotine. However, the overall reported incidence is low.
2. The overall weight of evidence for risks of long-term systemic effects on the cardiovascular system is **moderate**.
3. The overall weight of evidence for risks of carcinogenicity of the respiratory tract due to long-term, cumulative exposure to nitrosamines and due to exposure to acetaldehyde and formaldehyde is **weak to moderate**. The weight of evidence for risks of adverse effects, specifically carcinogenicity, due to metals in aerosols is **weak**.

LIMITED evidence

SCHEER conclusions on health effects

For users of electronic cigarettes

4. The overall weight of evidence for risks of poisoning and injuries due to burns and explosion, is **strong**. However, the incidence is low.
5. The overall weight of evidence for risks of other long-term adverse health effects, such as pulmonary disease CNS and reprotoxic effects based on the hazard identification and human evidence, is **weak**, and further consistent data are needed.
6. To date, there is **no specific data** that specific flavourings used in the EU pose health risks for electronic cigarette users following repeated exposure.

LIMITED evidence

LIMITED database

Most flavourings are listed as generally recognized as safe (GRAS) by the FDA and approved by EFSA as food additives showing low toxicity after oral uptake. However, their toxicity after inhalation, the major route of exposure for electronic cigarette users, is largely untested.

SCHEER conclusions on health effects

For **second-hand** exposed persons

Second-hand exposure may be **through exhaled air following a puff**. The reported concentrations of **aerosol ingredients** are orders of **magnitude lower** than those reported for exposure of electronic cigarette users.

1. The overall weight of evidence is **moderate** for risks of local irritative damage to the respiratory tract mainly due to exposure to glycols.
2. The overall weight of evidence for risks of systemic cardiovascular effects in second-hand exposed persons due to exposure to nicotine is **weak to moderate**.
3. The overall weight of evidence for carcinogenic risk due to cumulative exposure to nitrosamines is **weak to moderate**.

LIMITED evidence

Lack of evidence on acute and long-term effects on cardiovascular and other health outcomes **in children and adolescents**. Further research is needed on whether children and adolescents are at greater risk than adults of being adversely affected by regular second-hand exposure to electronic cigarettes within their home environments.

SCHEER conclusions on health effects

Initiation and quitting

1. **Weak** evidence for the support of electronic cigarettes' effectiveness in helping smokers to quit while the evidence on smoking reduction is assessed as **weak to moderate**.
2. **Moderate** evidence that electronic cigarettes are a gateway to smoking for young people.
3. **Strong** evidence that nicotine in e-liquids is implicated in the development of addiction and that flavours have a relevant contribution for attractiveness of use of electronic cigarette and initiation.

LIMITED evidence

Small number of trials, low event rates and wide confidence intervals around estimates result in weak evidence for electronic cigarettes' effectiveness in helping smokers to quit while the evidence on smoking reduction is assessed as weak to moderate

LIMITED database

Many of the studies are from the **US**. **Products** on the US market may **differ** considerably from those sold in the **EU** and conclusions drawn for the US may not be directly transferable to the EU.

What aspects of e-cigarettes to consider when protecting public health?

Chemicals present in the **aerosol** are mainly responsible for possible health effects, which have different origins:

E-liquids (e.g. propylene glycol, glycerol, nicotine, water, flavourings, preservatives)

Formed by **chemical reaction or thermal decomposition** in the heating element of some constituents or solvent carriers (e.g. aldehydes, free radicals, reactive oxygen species, furans, acetic acid)

Originating from the **device** (e.g. metals) and **device-liquid** interaction



Lack of harmonised hazard classification (CLP), especially via inhalation, the relevant route of exposure.

Variability of exposure: Strong evidence that exposure to nicotine from electronic cigarettes is highly variable, depends on product characteristics and that there is **substantial evidence** that nicotine intake among experienced adult users can be comparable to cigarettes. A very high variability is confirmed also for the exposure to other aerosol constituents.

Behavioural aspects: depending on duration of use and user puffing topography

Thank you