

**Statement by the German Cancer Research Center
(Deutsches Krebsforschungszentrum, DKFZ)**

Subject: A "Technical Report" available on the Internet entitled:
„Peering through the mist: What does the chemistry of contaminants
in electronic cigarettes tell us about health risks?"

A study by the Department of Environmental and Occupational
Health School of Public Health Drexel University Philadelphia,
July–August 2013

[www.publichealth.drexel.edu/SiteData/docs/ms08/
f90349264250e603/ms08.pdf](http://www.publichealth.drexel.edu/SiteData/docs/ms08/f90349264250e603/ms08.pdf)

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1. The Technical Report (TR) was carried out on behalf of the lobby organization "The Consumer Advocates for Smoke-free Alternatives Association (CASAA)", which also provided the funding. The author of the report is Igor Burstyn, a scientist at the Department of Environmental and Occupational Health of the School of Public Health at Drexel University in Philadelphia, USA. The TR is an assessment of the toxicological data found in the existing literature on electronic cigarettes (measurements of substances present in the liquids used in e-cigarettes as well as in the mist (aerosol) when inhaled and in indoor air). These are being related to exposure limit values effective at workplaces in the United States. The result of this comparison is that most of the toxicological values of e-cigarettes measured so far are below these occupational exposure limits. Higher values found are considered negligible due to "unrealistic levels of heating".
2. The TR uses a scientific construct to make the use of e-cigarettes appear acceptable in no-smoking areas. The basic assumption of this construct is not valid and must strongly be rejected, because occupational exposure limits were set to protect workers from toxic substances from industrial production processes, i.e., for exposures that arise at the workplace as a result of the work process. In the following we will discuss the relevance of occupational exposure limits and the regulatory practice in Germany with respect to the results of the report:
 - 2.1 Occupational exposure limits only apply to exposures that arise during economically indispensable processes and cannot be avoided by state-of-the-art technology. (To give an example: the emission of benzene during coke production). Due to the health risks involved, these hazardous substances are strictly regulated. This means, for example, that they must be reduced or replaced by less hazardous alternatives employing economically justifiable means.
 - 2.2 According to legal regulations effective in Germany, the scope of the Ordinance on Hazardous Substances ("Gefahrstoffverordnung") and the resulting definition of exposure limits for hazardous substances are exactly defined:

"(1) This regulation applies to bringing into circulation of substances, preparations and products; for the protection of workers and other persons from risks to their health and safety ..."

"(3) The third to sixth section apply to the protection of employees against actual or potential risks to their health and safety due to effects of substances, preparations and products used to carry out activities or which are formed during such activities ..."

"§ 3 Definitions" specifies: "(1) Hazardous substances within the meaning of this provision are 1. dangerous substances and preparations according to § 3a of the Chemicals Act as well as substances and preparations which have other chronic damaging properties, ..."

Under "§ 2 Scope", the Chemical Act states: "(1) The provisions of the second and third section ... shall not apply to ... cosmetic products ... and to tobacco products within the meaning of the Draft Tobacco Act. ..."

In short: Neither electronic cigarette aerosol nor tobacco smoke are produced in a manner comparable to hazardous substances; they are not packaged and marketed; their generation is not unavoidable but can be prevented by simply banning the use of e-cigarettes or tobacco smoking at the workplace. Regulations created for hazardous substances may therefore not be misused for tobacco smoke or aerosol generated by e-cigarettes.
 - 2.3 There is another important specification pertaining to occupational exposure limits: Exposure limits were defined for single chemicals and cannot be transferred to mixtures (German Research Foundation, DFG 2013). Only in exceptional cases, where an identical toxicity mechanism has been proven for various members of the same substance class, is it permissible, for practical reasons, that the toxic effects of the individual substances be summed (for example: dioxin derivatives are multiplied by their toxic equivalency factors (TEF) (Fried & Rozman, 2008)).

This approach is not valid for tobacco smoke or aerosol from e-cigarettes, because the numerous compounds identified up to now in both mixtures do not have identical modes of action.

To date, there is only little information available concerning the pathophysiological response of bronchopulmonary tissue to the aerosol generated by electronic cigarettes. There have been reports of respiratory irritations, of which even vendors caution on their websites. Compounds in the aerosol are gaseous or particle-bound. Like when inhaling tobacco smoke, it is possible that these compounds dissolve, for the most part, in the fluid coating the walls of the alveoli of the lungs (lung surfactant – a fluid containing proteins and lipids) and their content is absorbed by the bronchial and alveolar epithelium. Depending on the depth of inhalation, the substances hence reside in the airways of e-cigarette users. However, large quantities of aerosol are also exhaled back into ambient air appearing as a visible vapor.

- 2.4 In Germany, the concept of technical reference concentrations (TRC, in German: “TRK-Werte”) for carcinogenic substances was abolished years ago. However, for want of knowledge of the facts, TRCs are frequently still being used as a standard for reducing carcinogens. Among the reasons for abolishing the concept were violations of the rigorous regulations relating to TRCs, including a strict mandate to replace the substances or minimize their concentrations. TRCs will be replaced by “risk-based substance-specific exposure limits” (in German: “risikobasierte stoffspezifische Grenzwerte”), which are based on an “acceptable risk” (Klein et al., 2007).

The reasoning behind these exposure limits is that people who occupy a workplace must be prepared to take a higher risk than the general population.

- 2.5 So far, only very few exposure limits have been defined for carcinogens that cause damage to the genetic material DNA (genotoxic carcinogens). However, even if not exceeding these limits, these carcinogens are presumed to contribute slightly to the cancer risk of humans (German Research Foundation, DFG 2013) .

Consequently, for the vast majority of carcinogens identified so far in e-cigarettes it is not possible to name any exposure limits that do not pose any health risks.

- 2.6 Aside from a few exceptions, the reference values for indoor air are not based on toxicology but on statistical evaluation of large collectives of measurements that were carried out in indoor spaces of widely varying use (Schleibinger et al., 2002; Schlechter et al., 2004). They only describe a state as it is, providing a sort of orientation which, of course, must not automatically be turned into a standard. (For example, offices that are located near busy roads will have a high basic air pollution level). In any case, these guidance values for orientation must be evaluated relating to single substances (Ad-hoc-Arbeitsgruppe, 1996). Furthermore, genotoxic carcinogens are exempt from this reference value approach. Wherever possible, carcinogens in indoor air must be eliminated or avoided.

- 2.7 It must be pointed out that the MAK Commission (MAK = “maximale Arbeitsplatzkonzentration”; maximum workplace concentration) of the German Research Foundation (DFG) has not defined an exposure limit for propylene glycol, the main ingredient of e-cigarettes, because for this substance “sufficient information for setting MAK values is not available, neither from experience with humans nor from animal experiments” (Deutsche Forschungsgemeinschaft, 2013). In other words, there is no reference base for a comparative assessment of health hazards, not even if – inappropriately – related to the workplace.

In addition to the inappropriateness of an exposure limit approach for mixtures such as the aerosols from e-cigarettes, it must be noted that non-smoker protection at the workplace and in no-smoking areas ideally aims to ensure that ambient air is kept as pure and clean as possible. This measure is based on the concept of protection of public health in public places. Smoking of cigarettes of any kind is an interference with air purity. The use of e-cigarettes also changes indoor air quality: Aerosol vapours filling the air deteriorate air quality due to inhalable finely dispersed liquid particles. The aerosol carries varying concentrations of dissolved nicotine and other

substances (depending on the product and intensity of use). It is irrelevant whether concentrations lie below a limit value that may have been set for an industrial workplace. In individuals with increased vulnerability such as elderly or chronically ill people, asthmatics, children and youth the aerosols can cause airway irritations and a general sense of feeling unwell. Therefore, the use of e-cigarettes should be banned in smoke-free areas and at the workplace.

In our society, acceptance of cigarette smoking in the presence of bystanders has declined substantially in recent years. More and more smokers are willing to quit and also avoid smoking in their homes. This trend towards an increased responsibility for one's own health and that of others should not be counteracted by new products such as the e-cigarette.

Should the use of e-cigarettes be permitted in no-smoking areas, this might propagate a new lifestyle product that will make smoking once more appear more attractive. Children and youth may become curious to try it out and become addicted.

3. The Technical Report banalises the presence of tobacco-specific nitrosamines (TSNAs) in e-cigarettes, even though these substances can cause cancer. The presence of TSNAs in e-cigarettes may be caused by the fact that the ingredient used is not pure nicotine. Instead, the alkaloid nicotine is isolated by extraction or steam distillation from nicotine-rich tobaccos. Depending on tobacco type and curing process, carcinogenic tobacco-specific nitrosamines may develop. The U.S. Food and Drug Administration (FDA) has detected these compounds in e-cigarette liquids. To protect consumers, we demand that liquids for use in e-cigarettes have to be completely free of TSNAs and of carcinogens in general.
4. An e-cigarette consumer inhales an average of 150 times a day from the e-cigarette which contains large quantities of propylene glycol and glycerin. Never before has a consumer generation consumed such high doses of a mixture of chemicals on a long-term basis. Most e-cigarette users are smokers willing to quit smoking, mostly for health reasons, or former smokers. They all have in common that their bronchopulmonary tissue is already adversely affected. This affected tissue is being exposed by 150 inhalations to the mixture of chemicals contained in e-cigarettes. At the present time, neither scientists nor doctors are able to assess the long-term effects of this exposure. Short-term effects that have been described include airway irritations, dry cough, dizziness and adverse effects on pulmonary function.

To conclude, it must be stated that the Technical Report does not provide any "proof" for stating that e-cigarettes are safe for users and bystanders, as the e-cigarette lobby in Germany assumes. The Technical Report has not provided any data or facts of its own; it only interprets existing literature in favour of the consumption of e-cigarettes.

Literature

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