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JATC2 Task 7.4 / Information sheet 3:

Hazardous substances in the aerosol from e-cigarettes and heated tobacco products

General information about e-cigarettes and heated tobacco products

E-cigarettes and heated tobacco products are devices that produce an inhalable vapour/aerosol by heating an e-liquid or a tobacco stick respectively. E-cigarettes contain a wick that transfers the e-liquid from the cartridge or a reservoir to a battery powered heating element (coil). The e-liquid generally contains propylene glycol and vegetable glycerine, flavourings, other additives, and nicotine but not tobacco. E-liquids without nicotine are also available. Heated tobacco products (HTP) use sticks of processed tobacco leaves that are heated by a battery powered device. There is an increasing trend in the use of both e-cigarettes and heated tobacco products in Europe. The use of these products shows close associations with dual and polyuse of conventional cigarettes and other tobacco products.

Substance exposure from the use of e-cigarettes or heated tobacco products

A recent JATC-2 report identified a total of approximately 2.000 substances in the ingredients or emissions from e-cigarettes and heated tobacco products. The identified substances were grouped according to their health hazard.

The JATC-2 report (WP7 M7.6) identified 1585 substances associated with e-cigarettes. Of these, 1301 were ingredients (in the e-liquid) as notified by manufacturers. The other 284 were substances identified in e-cigarette emissions, as described in literature. The JATC-2 report also identified 468 substances associated with heated tobacco products. Of these, 88 were ingredients notified by manufacturers and 380 were emission substances based on data collected from a literature review. The consulted literature included all relevant publications published between January 2010 and May 2020.

The substances were grouped based on existing classifications of health hazards by various national and international organizations into three categories (see figure 1). Category 1 substances were regarded as high-priority substances for research and quantification, with the highest health hazard potential. Of the ingredients in e-cigarettes and HTP, 44 and 4 substances respectively were in category 1. In the emission from e-cigarettes and HTP, 102 and 84 substances respectively were in category 1. Category 2, which was classified as potentially harmful substances, included 208 substances in total for both products . Category 3, for which no data was available at the time of categorization, included a total of 1610 substances for both products.

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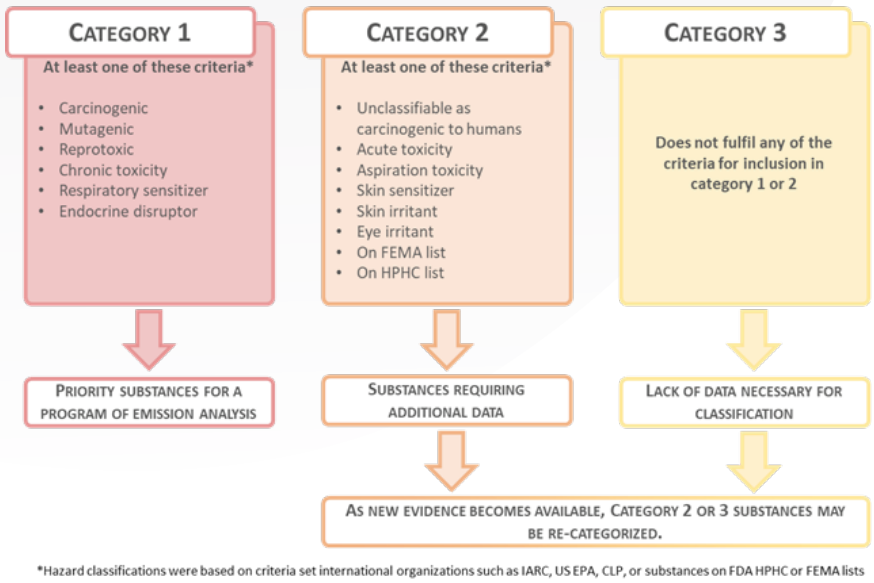

Figure 1. Categorization of substances in ingredients and emissions of e-cigarettes and HTP's based on health hazard.

Health hazards

The inhalable aerosol from e-cigarettes or heated tobacco products, contains hazardous substances. Several of these substances are associated with health hazards such as carcinogenicity, mutagenicity, and reproductive toxicity (CMR properties)

The 133 category 1 substances grouped with the highest health hazard potential belong to different chemical classes. These include volatile organic compounds (VOCs), phenolic compounds, metals, polycyclic aromatic hydrocarbon (PAH) and other tobacco related substances (for heated tobacco products). According to national and international organizations such as IARC and ECHA, most of these high-priority substances are categorized as human carcinogens, mutagens, or reproductive toxicants (CMR properties). According to TPD articles 7 and 20, substances with CMR properties are prohibited as additives in tobacco and related products. In addition, for e-cigarettes, only ingredients that are used in nicotine-containing liquid and that do not pose a risk to human health in heated or unheated form is allowed. The majority of the other high priority substances were categorized as having endocrine disrupting properties.

Device properties affecting emissions, specifically for e-cigarettes

Some e-cigarettes have options for personalized settings. Increasing the power may increase the e-liquid vaporized, thereby potentially increasing the exposure to hazardous substances. For heated tobacco products, there is a limited number of devices with few or no options for adjustment.

There is a wide variety of e-cigarette devices on the market. Many devices have the possibility for personalized adjustments, such as different coil designs and power settings (wattage, voltage, or temperature). The composition of the aerosolized e-liquid that a user inhales, may be affected by the composition of the e-liquid, type of device used, device settings (watt, volt, temperature), user patterns (puff duration, puff frequency) and the lifespan of e-cigarette components which are affected by use, such as coil ageing. Predicting the hazardous effects of the aerosol and its constituents is therefore challenging, due to the limited information available for most products about the chemical characteristics of the aerosols and the e-liquids.

Increasing the power of the device, if such an option is available, may increase the amount of e-liquid

vaporized and consumed. This may increase the user's exposure to hazardous substances. When using modifiable devices, using a power outside the recommended settings of the coil may also increase the level of harmful substances in the aerosols. Malfunctioning e-cigarettes and dry puffing (puffing with very little e-liquid) may increase the formation of hazardous substances, such as formaldehyde and acrolein. in the case of heated tobacco products, there is a limited number of devices, with few or no options for adjustment.

Do-it-yourself practices and storage

Do it your self-practices, homemade mixture of e-liquids, and chemical reactions occurring in the e-liquids during their storage may impact the types and levels of inhaled substances.

A growing appeal of do-it-yourself products is closely related to the attractiveness of characterizing flavours, as e-cigarette users can create their own blends. This practice, as well as the possibility to add any type of substances, may increase the complexity and health hazard of the resulting aerosol.

The shelf-life of e-liquids may be limited. Constituents may deteriorate or react with other constituents forming new substances. In cases where the e-liquid is in contact (e.g., cartridges or pods) with metal components of the e-cigarette device, transfer of metals from the device to the e-liquid may occur.

Regulatory recommendations

Regular updates and adjustments to regulations, coupled with educational initiatives, can contribute to a safer and more informed use of these products.

E-cigarettes and heated tobacco products contain harmful ingredients, some of which fall under the categories that are prohibited by the TPD (art 7 and 20). Therefore, regulators are recommended to strengthen the implementation and enforcement of ingredients bans and consider applying the precautionary principle to substances in category 2, potentially harmful substances. In addition, European policy makers may consider the following:

- Current regulations only prohibit ingredients. However, users of e-cigarettes and HTP are exposed to substances in the emissions which are not necessarily present as ingredients, as hazardous substances may form during heating. Therefore, regulators should consider enforcing emission bans or maximum levels of hazardous emissions in tobacco products and e-cigarettes.
- E-cigarettes without nicotine may contain the same harmful ingredients and similar emissions as e-cigarettes containing nicotine. Therefore, regulation of ingredients and emissions should be extended to nicotine-free products.
- Different device settings and components used in modifiable devices may increase exposure to hazardous substances. We recommend that Member States consider requiring manufacturers to provide the recommended settings, such as wattage and/or temperature range for the device or components, such as the coil, to avoid excess exposure to hazardous substances.
- We recommend that Member States develop software for monitoring manufacturers declarations of ingredients and emissions that is able to automatically identify hazardous substances and is regularly updated with new scientific knowledge.
- Besides product regulation, it is important to strengthen health literacy and user education among the public to create more risk awareness and discourage use.

Summary

E-cigarettes and heated tobacco products and their aerosols contain substances with CMR properties. The hazards associated with these substances highlight the need to better characterize and regulate emissions from these products.

Regulations, notably on CMR compounds, currently apply to additives and not emissions. There are proportionally fewer high priority substances in the e-cigarette ingredients dataset than in the emissions dataset. This may be due to the decomposition of substances present in the e-liquids during heating, creating new substances. These may further react with other constituents, further increasing the chemical complexity of the aerosol.

How the products are used, may also impact the resulting emissions. The "do it yourself" practice among e-cigarette consumers, in which users make their own e-liquid, adds a further layer of complexity.

The policy recommendations aim to address the enforcement of existing bans, proactively manage potential risks, and continually improve the regulatory framework by considering new ingredient bans and emission standards.