

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT)

Statement on the potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes). Non-technical summary.

Background

1. The COT was requested by the Department of Health and Social Care (DHSC) and Public Health England (PHE) to assess the potential risk to human health from electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS) (collectively abbreviated to E(N)NDS), both from their use and in comparison with cigarettes. These products are commonly known as ‘e-cigarettes’ and their use is termed ‘vaping’.

What are E(N)NDS?

2. E(N)NDS are battery-powered devices in which a liquid (‘e-liquid’) is heated to produce aerosol (‘vape’) that is inhaled by the user (‘puffing’, ‘vaping’). E(N)NDS devices are available in many different forms; they are sometimes referred to as either ‘closed’ systems, with a disposable or replaceable e-liquid container which cannot be refilled, or ‘open’ systems that can be refilled with e-liquid. Some products allow the user to modify the operating characteristics. This is a rapidly changing market and product characteristics can change quite quickly.

3. The way these devices are used varies between individuals including when and how often they vape, the way they take a puff (for example, how deeply and for how long they breathe in), and the strength of nicotine, if any, used in e-liquid.

4. ‘ENDS’ (electronic **nicotine**-delivery system) products were developed to provide an alternative means of nicotine delivery that more closely mirrored the experience of cigarette smoking than other nicotine-replacement therapies such as skin patches or chewing gums. In the UK, E(N)NDS are suggested as an aid to quitting smoking, as it is considered likely their use would be less harmful to health than continuing to smoke cigarettes.

5. Some devices are used with an e-liquid that does not contain any nicotine, and so these products have been called ‘ENNDS’ (electronic **non-nicotine** delivery systems). These non-nicotine products may also help people to quit smoking by providing a substitute for the physical characteristics of smoking.

6. In the UK, the maximum strength of nicotine in e-liquid that is permitted for sale under the Tobacco and Related Products Regulations¹ is 20 mg/mL, but some

¹ <http://www.legislation.gov.uk/ukxi/2016/507/contents>

countries allow the sale of products containing higher levels, for example double this strength. This may affect how the different studies are interpreted in the context of likely UK use. ENNDS products are regulated under the General Product Safety Regulations².

Scope of the COT review

7. In compiling the information for review, the COT looked at the types of substances that users and bystanders may be exposed to, the level of exposure, and what is currently known about possible harm to human health from exposure to these substances. This was for both ENDS and ENNDS products. This information was also compared with that from the use of conventional cigarettes.

8. The COT review assessed the risks only from typical use of E(N)NDS products produced to good manufacturing standards and its conclusions do not apply to the use of the products in a non-standard manner, which may have additional risks.

9. The main aim of the COT review was to look at possible harm to human health that might occur when E(N)NDS are used to help people to quit smoking. For this, the Committee looked at how any possible health risks from using E(N)NDS compare with harm to health that is known to be linked with smoking cigarettes. The Committee also considered the possible health risks of E(N)NDS use in its own right.

Committee discussion

10. Common contents of e-liquids were identified as the 'carrier substances' propylene glycol and glycerol, nicotine, a range of flavourings, and other flavour-related chemicals. In addition, non-standard substances, including impurities within the e-liquid constituents, and metal particles were also identified for consideration. Studies assessed whether any of the aerosol components produced during vaping can be detected in the surrounding air, leading to bystander exposure. In general, analytical studies of e-liquids, the aerosols produced from E(N)NDS and emissions into surrounding air were often inconsistent in how they had been carried out, so it was difficult to draw firm conclusions.

11. It was thought likely that current smokers would reduce the risk of harm to their health if they switched completely to using E(N)NDS. The reduction in risk was likely to be different for different health effects. For example, the risk of developing lung cancer would be expected to decrease more than the likelihood of triggering asthma symptoms.

12. Some research showed that E(N)NDS are used to support the continued smoking of cigarettes (so called 'dual use'), such that there is no or only limited reduction in overall cigarette use, and as such this might increase the risk of harm to

² <http://www.legislation.gov.uk/ukxi/2005/1803/contents/made>

health compared with cigarette smoking only. However, this was something on which only limited information was available.

13. Data indicated that E(N)NDS use might increase the likelihood of users experiencing symptoms of irritation, including a burning sensation in the throat, nose, or eyes. In addition, it is possible that vaping may increase respiratory symptoms in people with respiratory disease or conditions, and adverse cardiovascular symptoms in people with cardiovascular disease. Such effects can also occur in those smoke conventional cigarettes.

14. The Committee was concerned about the possibility of harm to health from the flavouring ingredients, often approved food flavouring agents, used in e-liquids when heated and inhaled. This is because these substances may result in health effects after inhalation that do not occur when consumed in food. There was insufficient information to assess this risk. The Committee has therefore proposed the types of information that would be useful for assessment of the risk of inhalation of flavouring agents used in E(N)NDS³.

15. People who take up the use of nicotine-containing ENDS when they have not previously used nicotine-containing products were thought likely to experience immediate, short-lasting effects from nicotine exposure, such as increased heart-rate. This may also apply to some bystanders who are exposed to nicotine in the air around them, although levels of nicotine in air would mostly be relatively low. In the longer term, it was also considered that there would be a risk of those taking up ENDS becoming addicted to nicotine use. There is good evidence that exposure to nicotine during pregnancy, childhood, adolescence and young adulthood may adversely affect development. However, the Committee concluded that the information on this was not adequate to conclude on the level of risk from E(N)NDS use.

16. During 2019 and early 2020, there was an outbreak in the US of a respiratory illness related to the use of E(N)NDS products. This has been linked to the presence of vitamin E acetate which is banned from UK-regulated nicotine vaping products. Although outside the scope of the present COT review, this topic remains under review by the Committee.

17. As E(N)NDS products were developed only recently, it was acknowledged that there is a lack of information on possible adverse health effects following long-term use. It is currently not known what effects might occur, and whether these will be the same as the effects caused by cigarette smoking.

Overall conclusions

18. Overall, the COT concluded:

³ https://cot.food.gov.uk/sites/default/files/frameworkforriskassessingflavourings_0.pdf

- The use of E(N)NDS products, produced according to appropriate manufacturing standards and used as recommended, as a replacement for smoking cigarettes, is likely to lead to a reduction in harm to health. The amount by which the risk decreases will depend on the health effect in question.
- People who do not already use tobacco products who take up using E(N)NDS risk some negative health effects to which they would not otherwise have been subject.
- The use of flavouring products in e-liquids is an area of uncertainty, as very little information is available on whether these chemicals can damage human health when heated and inhaled. There is currently no information that this is happening, but this is an important data gap.
- E(N)NDS use leads to some emissions into surrounding air. The risks to bystanders in rooms where vaping takes place appears to be low in most situations, but some effects from exposure to nicotine in the surrounding air may occur, such as increased heart-rate.
- Much of the knowledge that is needed to assess the risks related to possible harm to human health from long term use of E(N)NDS is not currently available and can be obtained only from suitable epidemiology studies. This is reflected in the different policies on E(N)NDS across different countries.
- Information and science relating to E(N)NDS is changing rapidly and the COT will keep this area under review.

COT

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