

COMMITTEES ON TOXICITY, CARCINOGENICITY AND MUTAGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT, COC and COM)

Toxicological evaluation of novel heat-not-burn tobacco products – non-technical summary

Introduction

1. The COT, with support from the COC and the COM, was requested to assess the toxicological risks from novel heat-not-burn tobacco products, and compare these risks to those from conventional cigarettes.
2. To date, two novel heat-not-burn tobacco products have been notified to PHE in accordance with the Tobacco and Related Products Regulations 2016.

What are novel heat-not-burn tobacco products?

3. In heat-not-burn tobacco products, processed tobacco is heated in a controlled device instead of being burnt as is the case for conventional tobacco products.
4. A recent consultation by HM Treasury¹ noted there is a range of heat-not-burn tobacco products where:
 - a. processed tobacco is heated directly to produce vapour
 - b. processed tobacco is designed to be heated in a vaporiser
 - c. devices produce vapour from non-tobacco sources, where the vapour is then passed over processed tobacco in order to flavour the vapour
5. The two products assessed by the Committees fall into the first and last of these groups, and as a result the temperature to which the tobacco is heated varies considerably between them. For one product where the tobacco is heated directly, a maximum heating temperature of up to 350 °C was reported, while for the other product in which the tobacco is heated by a vapour, the maximum temperature of the tobacco was reported to be less than 50 °C. For comparison, when tobacco in cigarettes is burnt it reaches temperatures of at least 800 °C.

¹ Tax treatment of heated tobacco products, published 20 March 2017: <https://www.gov.uk/government/consultations/tax-treatment-of-heated-tobacco-products/tax-treatment-of-heated-tobacco-products> (accessed 19/06/2017)

Information obtained

6. The two manufacturers of products notified in the UK before November 2016 were asked to present the relevant toxicity data they hold. In addition to the manufacturers' data, a literature search was undertaken to identify any available independent data on these products. This was very limited.

Exposure

7. Investigations on both products that were assessed by the Committees, showed a decrease in the harmful and potentially harmful compounds (HPHCs) to which the user would be exposed, compared to the HPHCs from a conventional cigarette². For both products, there were some HPHCs where the reduction was approximately 50%, and the reduction in other HPHCs was greater than 90%.

8. The Committees also requested data on additional contaminants from the devices themselves. The available data presented and discussed with the manufacturers provided no evidence for exposures other than from compounds also present in conventional cigarette smoke.

9. The design of the devices means that any potential sidestream emissions from them will be very different to those from the burning tip of conventional cigarettes. In terms of environmental exposure to bystanders, assessments showed that while some of the measured components increased above background with the use of the heat-not-burn tobacco products, much greater increases occurred following use of conventional cigarettes.

Toxicity data

10. In compiling the list of information requested by the Committees for this evaluation, there was a focus on cancer, respiratory, cardiovascular and liver-related health effects.

Epidemiological data

11. Both products are already available on the market in the UK and other countries around the world. Post-marketing surveillance is being undertaken by both manufacturers in these countries, but it is too early for epidemiological information on health impacts to be available.

Committees' discussion

12. A number of differences were identified between the two products notified in the UK, the most obvious being the temperature to which the tobacco is heated, which will potentially have an impact on the number and amount of compounds that thereby become volatile and can be inhaled by the user. There is also a difference in the source of the nicotine. In the product where the tobacco is heated directly, the

² Throughout the statement, unless otherwise stated, comparison was between the product and the Kentucky 3R4F reference cigarette.

nicotine is derived from the tobacco in the device, while for the other product the nicotine is present within the liquid that is aerosolised and passed through the tobacco.

13. The Committees were unable to assess the absolute risk of heat-not-burn tobacco products given the nature of the data available.

14. The data indicated that the aerosol generated from these products contains HPHCs, some of which are mutagenic and carcinogenic, and therefore there will be some risk to health from use of these products. The normal recommendation of the Committees is that exposure to such chemicals is kept as low as reasonably practicable, but it was recognised that these products could provide harm reduction for people who would otherwise smoke cigarettes.

15. There would likely be a reduction in risk for conventional smokers deciding to use heat-not-burn tobacco products instead of smoking cigarettes. However, stopping smoking entirely would lead to the greater reduction in risk.

16. A reduction in risk would also be experienced by bystanders where smokers switch to heat-not-burn tobacco products.

17. The Committees were concerned over the potential for non-smokers including children and young people, who would not otherwise start to smoke cigarettes, to take up using these products, as they are not without risk. There was also concern over whether the use of these products would lead to cigarette smoking by non-smokers. Information on this should be obtained before the overall impact on public health can be assessed.

18. The data considered by the Committees was not sufficient to comment on the relative risks of heat-not-burn tobacco products and e-cigarettes, though this is of interest.

19. The Committees considered the potential risks from use of these products during pregnancy. The current UK advice³ to pregnant women is to stop smoking entirely. However, the advice states: "If using an e-cigarette helps you to stop smoking, it is much safer for you and your baby than continuing to smoke". There is no direct data on the risk to the unborn child following use of heat-not-burn tobacco products by the mother. Based on reduced exposure to compounds of concern with heat-not-burn tobacco products compared to conventional cigarettes, the Committees considered that, though the aim should be for pregnant women to stop smoking entirely, the risk to the unborn baby is likely to be reduced if using these products during pregnancy instead of smoking.

20. The Committees emphasised that nicotine itself is addictive, and can have harmful effects on health. In addition, users of any nicotine product would use it in such a way, and in such quantity, as to achieve a similar effect to that they were used to from their previous smoking products. Depending on the concentrations of

³ Stop smoking in pregnancy. Available at: <http://www.nhs.uk/conditions/pregnancy-and-baby/pages/smoking-pregnant.aspx> (accessed 07/09/2017)

nicotine in different products, relative exposure to other compounds of concern could be increased or decreased in the process of achieving the desired nicotine effect. For example a user might take a fewer or greater number of puffs, or use these products more often or for longer than they did with conventional cigarettes.

Committees' conclusions

21. It is well recognised that using tobacco is carcinogenic and its use has other harmful effects on human health.
22. Using heat-not-burn tobacco products involves breathing in a number of compounds of concern, some of which are carcinogens.
23. The levels of the different compounds in the aerosol from heat-not-burn tobacco products are different to the levels in smoke from conventional cigarettes.
24. Heat-not-burn tobacco products contain nicotine and are designed to deliver similar levels of nicotine to conventional cigarettes; their use will not reduce nicotine exposure or the risk to health from and possibility of addiction to nicotine.
25. The Committees conclude that there will be a risk to health from using heat-not-burn tobacco products.
26. It is currently not possible to quantify this risk. Heat-not-burn tobacco products are new and there is insufficient data available to enable a full assessment.
27. The exposure to compounds of concern in using heat-not-burn tobacco products is reduced compared to that from conventional cigarette smoke. It is likely that there is a reduction in overall risk to health for conventional smokers who switch to heat-not-burn tobacco products.
28. While the Committees conclude there is a likely reduction in risk for smokers switching to heat-not-burn tobacco products, a risk remains and it would be more beneficial for smokers to quit smoking entirely.
29. A reduction in risk would be expected to be experienced by bystanders where smokers switch to heat-not-burn tobacco products.
30. The risk to the unborn child from use of these products by mothers during pregnancy is difficult to quantify and current NHS advice is to stop smoking entirely. The Committees consider that the risk to the unborn baby is likely to be reduced if these products were used during pregnancy instead of smoking, although the aim should be to stop smoking entirely.
31. Overall, the Committees conclude there are toxicological risks from novel heat-not-burn tobacco products though data on impacts to human health is very limited. Compared with the known risks from conventional cigarettes, they are probably less harmful. Even so, smokers would do better to quit entirely.