Executive summary

- The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) has an ongoing review of the toxicological risks of e-cigarettes, which will continue into 2018.

- There are a number of aspects and gaps in knowledge with respect to e-cigarettes which the COT plans to consider as part of this review, including: the composition of particles produced, bystander exposure to key analytes, the effects of long term inhalation of the main constituents and emissions, the effects of the flavourings used, and the exposure to metals from the device components.

- The COT is due to publish a statement on the toxicological risks of heat not burn tobacco products on 12th December 2017. The overall conclusion of this statement is that: “while there is a likely reduction in risk for smokers switching to heat-not-burn tobacco products, there will be a residual risk and it would be more beneficial for smokers to quit smoking entirely. This should from part of any long-term strategy to minimise risk from tobacco use.”

Introduction

1. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) is an independent scientific committee that provides advice to the Food Standards Agency, the Department of Health and other Government Departments and Agencies on matters concerning the toxicity of chemicals.

2. Most of its members are appointed as scientific and medical experts on the basis of their special knowledge and expertise. In addition, two non-specialist members of the committee are appointed for their broader knowledge of consumer affairs.

3. The COT is supported in its work by a secretariat provided jointly by the Food Standards Agency and Public Health England. The secretariat has scientific expertise that enables them to provide members with comprehensive background information and briefing papers that inform the decision-making processes of the Committee.

4. Over the past two years, the COT has considered and is continuing to consider two topics of relevance to the Science and Technology Committee’s inquiry on e-cigarettes. These are: the potential toxicological risks from e-cigarettes, and the toxicological risks from novel heat not burn tobacco products, both of which are described further below. The COT work on e-cigarettes is ongoing, while the work on

1 Full terms of reference: https://cot.food.gov.uk/moreinfo/cotterms
Written evidence submitted by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (ECG0082)

heat not burn tobacco products is complete. The Science and Technology Committee should be aware that the COT remit covers risk assessment, and thus any assessment of benefit including a combined risk-benefit assessment is outside of the Committees remit.

**Ongoing COT review of e-cigarettes**

5. In respect to the Science and Technology Committee’s request on “The impact on human health of e-cigarettes—themselves and relative to ‘conventional’ smoking—and any gaps in the science knowledge-base in this area”, the Committee should be aware of the COT’s ongoing review of e-cigarettes.

6. In February 2016 the potential risks from e-cigarettes were discussed as part of the Committee’s annual horizon scanning\(^2\), and it was agreed that it would be timely for the COT to review the toxicity of both nicotine-containing and nicotine-free electronic delivery systems\(^3\). A scoping paper on e-cigarettes was discussed in July 2016\(^4\), highlighting issues with respect to additives, nitrosamines produced, and secondary exposure to exhaled products. From this discussion, the Committee agreed that further consideration should be made of: the composition of particles produced, bystander exposure to key analytes, the effects of long term inhalation of the main constituents and emissions, the effects of the flavourings used, and the exposure to metals from the device components\(^5\).

7. These areas have been highlighted as important for further consideration for a number of reasons. For flavouring agents, while many of these are present in food, there is a lack of information on the effects of exposure from inhalation. The particles are of interest because there is little information on the composition and solubility of these particles. The scoping literature provided in July 2016 on bystander or secondary exposure was sufficient to indicate a possible concern for health, but not conclusive enough to fully evaluate the risk and the Committee will carefully consider exposure to vulnerable populations.

8. The COT has noted that the settings, such as voltage and temperature, on some e-cigarette devices can be modified by the user, which will result in variations in the composition of the vapour. The settings on devices used in studies are often not reported in the literature. It will be difficult to establish a worst case scenario that is representative of human exposure, for the Committee’s evaluation.

9. The Committee’s work on e-cigarettes has been on hold from July 2016 to December 2017 due to the referral on heat not burn tobacco products from Department of Health, described below. However, the Committee now has the time

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\(^2\) See paper TOX/2016/01: [https://cot.food.gov.uk/sites/default/files/tox2016-01.pdf](https://cot.food.gov.uk/sites/default/files/tox2016-01.pdf)

\(^3\) See minutes TOX/MIN/2016/01, Item 4: [https://cot.food.gov.uk/sites/default/files/finalminutes02feb2016.pdf](https://cot.food.gov.uk/sites/default/files/finalminutes02feb2016.pdf)


and resources to consider e-cigarettes further, and a series of discussion papers is planned for consideration starting at the COT meeting on 13 December 2017 and continuing through meetings in 2018. These will cover the topics of concern raised at the July 2016 meeting.

10. The COT will consider as relevant during its review of e-cigarettes, how the risk from these compare with that from heat not burn tobacco products.

11. In the process of considering e-cigarettes, the COT will also consult with the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) and the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM), as necessary.

COT statement on heat not burn tobacco products

12. In respect to the Science and Technology Committee’s request to “hear views on whether Government policy and regulation has kept up with the full range of ‘smoking’ and novel tobacco products (such as ‘heat not burn’) that are becoming available to the public, and if it takes account of their likely impact on human health”, the Committee should be aware of that the COT is due to publish a statement on the toxicological risks of heat not burn tobacco products on 12th December 2017.

13. The statement was requested by the Department of Health in late 2016 and will provide the Department of Health and Public Health England with a general opinion on the toxicological risks of such products.

14. In undertaking this assessment the COT, supported by the COC and COM, evaluated information provided by the two manufacturers of the two products notified in the UK by November 2016, in accordance with the Tobacco and Related Products Regulations 2016. A literature search was undertaken to identify any available independent data on the products.

15. The Committees noted a number of differences between the two products, and in addition there was a difference in the amount of available data of relevance for the Committees to evaluate.

16. The Committees’ conclusions and recommendations on novel heat not burn tobacco products are:

   a. Tobacco smoking and smokeless tobacco for oral or nasal use are carcinogenic to humans, and have been classified by IARC as Group 1 carcinogens.

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6 This will be available from: [https://cot.food.gov.uk](https://cot.food.gov.uk)
b. The aerosol generated by heat-not-burn tobacco products contains a number of compounds of concern, some of which are carcinogens, and there will be a risk to the health of anyone using these products.

c. For non-smokers who start to use these products, this will be an increase in risk, compared to if the products were not used. The Committees were particularly concerned for young people, who do not smoke, starting to use these products, due to the potential for longer exposure over the remainder of their lives compared to adults and to possible differences in sensitivity.

d. As the exposure to compounds of concern in the aerosol is reduced compared to conventional cigarette smoke, it is likely that there is a reduction in risk, though not to zero, to health for smokers who switch completely to heat-not-burn tobacco products.

e. The risks associated with use of heat-not-burn tobacco products cannot be quantified due to gaps in the information available and uncertainties in the dose-response relationship of the chemicals and potential adverse health outcomes. In addition, the levels of the different compounds in the aerosol vary compared to the levels in smoke from conventional cigarettes and therefore it is not possible to extrapolate from epidemiological data on smoking risks, particularly given the complexity of the interactions that occur between these compounds in producing adverse health effects.

f. As these products contain nicotine and are designed to deliver similar levels of nicotine to conventional cigarettes, their use will not reduce nicotine exposure or its risk to health and possibility of addiction from nicotine.

g. Most of the data on heat-not-burn tobacco products has been provided by the product manufacturers. To date there has been limited independent confirmation of the manufacturers’ findings, and for public health reassurance the Committees consider it important to obtain independent verification of the manufacturers’ results.

h. Further information on the population impact of availability of these products should be collected, including uptake of these products by smokers and non-smokers and their age profile, whether product switching or dual use occurs including with e-cigarettes, uptake of smoking as a result of use of these products by non-smokers, and overall population exposure, including bystanders, to compounds of concern.
i. In addition to the requested comparison of novel heat-not-burn tobacco products with conventional cigarettes, it is of interest to compare the risks from these products to those from e-cigarettes. This will be borne in mind when the COT considers e-cigarettes, but it is not possible to address this based on the data presented to the Committees as part of the current evaluation.

j. Overall, the Committees conclude that while there is a likely reduction in risk for smokers switching to heat-not-burn tobacco products, there will be a residual risk and it would be more beneficial for smokers to quit smoking entirely. This should form part of any long-term strategy to minimise risk from tobacco use.

*December 2017*