

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

Potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes). First draft statement.

1. During 2018 and 2019, the COT reviewed the potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes). A first draft statement bringing together the discussions and conclusions of the Committee during this period has been prepared and is presented in Annex A.

2. Aspects covered in the statement include:

- the background and scope of the COT review
- review methodology, including a table listing the discussion papers that have been considered by the Committee on this topic
- an overview of E(N)NDS products, their contents, and use
- an overview of regulations and guidance relating to E(N)NDS, with a focus on the current situation in the UK
- summaries of toxicological and clinical data on E(N)NDS aerosol components, as well as some other constituents that have been reported from analytical studies:
 - particulate matter
 - propylene glycol (PG)
 - glycerol
 - nicotine
 - flavourings and their degradation products
 - other constituents, and products formed on aerosolization
 - E(N)NDS aerosol

3. The toxicological summaries for the principal E(N)NDS constituents, PG, glycerol, and nicotine, include preliminary risk assessments of potential adverse health effects associated with product use based on the COT discussions. These risk assessments address 'best-guess' general exposure scenarios for users and for bystanders, based on the evidence base that was available to the COT during the review. However, it is of note that E(N)NDS is a rapidly developing market and, in addition, the rate of new scientific publications in this field is high. These two aspects will impact on the applicability of the COT risk assessments to the real-time E(N)NDS market.

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4. The statement is currently structured with synthesis and conclusions of the Committee's discussions relating to each of the E(N)NDS aerosol components and constituents given in bullet points at the end of each individual section. The overall findings and conclusions of the COT review are then drawn together at the end of the statement.
5. The final summary highlights main exposure groups that may need to be taken into account when considering adverse health effects of E(N)NDS, with note that the assessment of risk will not be the same for all of these different groups. The main focus of the COT review was the use of E(N)NDS as a replacement for conventional cigarettes (CC) to aid smoking cessation for current smokers. Another important consideration was the potential for adverse health effects to bystanders associated with any emissions into ambient air from E(N)NDS use. Although not the main focus, the statement also includes consideration of risk that may be associated with taking up E(N)NDS by individuals who are naïve to tobacco product use.
6. The summary section also comments on the breadth and suitability of the evidence base on which the COT review was based, highlights important data gaps, and comments on the importance good manufacturing standards and quality control as the E(N)NDS market develops.
7. The overall conclusions of the COT review of E(N)NDS are summarised in the two final paragraphs, with note that this is a topic that the Committee intends to keep under review in the future.

Questions for the Committee

8. Members are invited to comment on the first draft statement, and in particular:
 - Is the structure, length, and narrative style of the statement on E(N)NDS appropriate?
 - Are there any aspects that have been addressed during the COT review of E(N)NDS that are not covered in the draft statement but which should be included?
 - Do the conclusions drawn throughout the text accurately represent the findings of the COT review of the potential adverse health effects of E(N)NDS? Where this is not the case, can these aspects be addressed to establish the Committee's agreed conclusions.

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- iv. Members are invited to make comments on the findings and conclusions, and to address the additional questions that are included in red-type throughout the text.

**NCET at WRc/IEH-C under contract supporting the PHE COT Secretariat
January 2020**

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TOX/2020/08 – Annex A

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First draft statement

The attached document is a draft. It should not be cited and does not necessarily represent the views of the Committee. The final version of the statement will be published in due course on the COT website: <https://cot.food.gov.uk/>

**NCET at WRc/IEH-C under contract supporting the PHE COT Secretariat
January 2020**