

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

### The toxicological evaluation of novel heat-not-burn tobacco products: Second draft statement (**Reserved Business**)

1. The COT, with support from COM and COC, has been requested to assess the toxicological risks from novel heat-not-burn tobacco products, and compare these risks to those from conventional cigarettes. This will provide the Department of Health (DH) and Public Health England (PHE) with a general opinion on the toxicological risks of such products, and is not to fulfil any regulatory function of PHE.
2. The Committees have considered scoping papers on the topic at the COT meetings in December 2016 and February 2017 (papers TOX/2016/42 and TOX/2017/09), the COM meeting in February 2017 (MUT/2017/01) and the COC meeting in March 2017 (COC/2017/07). The two manufacturers of heat-not-burn products notified to DH were invited to a joint COT, COC and COM discussion session to present their data to address a list of data requirements compiled based on the comments provided by each Committee. This discussion was held at the May 2017 COT meeting (TOX/2017/25). Following the May 2017 meeting, one of the manufacturers has provided a further submission of information to address the requests of the Committee. This was discussed at the June 2017 COM meeting (MUT/2017/05), July 2017 COT meeting (TOX/2017/32) and July 2017 COC meeting (CC/2017/16).
3. The first draft statement was considered by COT and COC alongside the further information at the July 2017 meetings, and by correspondence after the COC meeting by COM and COC Members. This paper presents the second draft statement as a clean copy in Annex A, and with the comments from COM and COC members addressed and subsequent changes tracked in Annex B. A non-technical summary will follow as Annex C.
4. The Secretariat has been notified of a preliminary risk assessment of heat-not-burn tobacco products by the German Federal Institute for Risk Assessment (BfR). An English translation of the document provided by one of the tobacco manufacturers is attached at Annex D. In addition, the material currently available from the Dutch National Institute for Public Health and the Environment (RIVM) is attached at Annex E.

### Questions for the Committee

5. Members are invited to comment on the structure and contents of the draft statement and in particular:
  - (i) Are Members content with the wording of the conclusions of the statement?

This is a paper for discussion.  
It does not represent the views of the Committee and should not be quoted, cited or reproduced.

**TOX/2017/43 Annex A**

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

**The toxicological evaluation of novel heat-not-burn tobacco products: Second  
draft statement (**Reserved Business**)**

**Second Draft statement – clean copy**

This Annex contains the second draft statement.

This annex is not being made publicly available as it relates to information which is  
commercially sensitive

**Secretariat  
August 2017**

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**TOX/2017/43 Annex B**

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

**The toxicological evaluation of novel heat-not-burn tobacco products: Second  
draft statement (**Reserved Business**)**

**Second Draft statement – tracked changes version**

This Annex contains the second draft statement, with the comments from COM and COC members. The changes to the text suggested by Members have been accepted, and the tracked changes presented address the comments from COM and COC.

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August 2017**

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**TOX/2017/43 Annex C**

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

**The toxicological evaluation of novel heat-not-burn tobacco products: Second  
draft statement (**Reserved Business**)**

**Draft non-technical summary of statement**

This Annex will follow and contains the draft non-technical summary statement.

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TOX/2017/43 Annex D

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

**The toxicological evaluation of novel heat-not-burn tobacco products: Second  
draft statement (**Reserved Business**)**

**Preliminary Risk Assessment relating to Tobacco Heating Systems as  
Tobacco Products, by the German Federal Institute for Risk Assessment (BfR)**

This Annex contains an English translation of the BfR assessment available here:  
<http://www.bfr.bund.de/cm/343/vorlaeufige-risikobewertung-von-tobacco-heating-systemen-als-tabakprodukte.pdf>.

To note, this translation has been provided to the Secretariat by one of the  
manufacturers.

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TOX/2017/43 Annex E

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

**The toxicological evaluation of novel heat-not-burn tobacco products: Second  
draft statement (**Reserved Business**)**

**Alternative tobacco products: harm reduction? : Tobacco- and related  
products that may be less harmful than cigarettes, by the Dutch National  
Institute for Public Health and the Environment (RIVM)**

This Annex contains two webpages on the work undertaken by RIVM, available here:  
[http://www.rivm.nl/en/Documents\\_and\\_publications/Scientific/Reports/2016/september/Alternative\\_tobacco\\_products\\_harm\\_reduction\\_Tobacco\\_and\\_related\\_products\\_that\\_may\\_be\\_less\\_harmful\\_than\\_cigarettes](http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2016/september/Alternative_tobacco_products_harm_reduction_Tobacco_and_related_products_that_may_be_less_harmful_than_cigarettes) and here:  
[http://www.rivm.nl/en/Documents\\_and\\_publications/Common\\_and\\_Present/Newsmessages/2016/Assessment\\_of\\_health\\_effects\\_of\\_alternative\\_tobacco\\_products](http://www.rivm.nl/en/Documents_and_publications/Common_and_Present/Newsmessages/2016/Assessment_of_health_effects_of_alternative_tobacco_products).

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**Secretariat  
August 2017**