

**COMMITTEE ON MUTAGENICITY OF CHEMICALS IN FOOD, CONSUMER  
PRODUCTS AND THE ENVIRONMENT**

**RESERVED BUSINESS**

**Toxicological evaluation of novel heat-not-burn commercial products:  
Overview summary of genotoxicity data submitted (Confidential)**

1. The Committee is asked to consider the current scoping document, which provides an overview of technical and scientific data on the toxicity of heat-not-burn (HNB) products. The data for these products was submitted prior to their entry into the UK market, as per the requirements of the Tobacco & Related Products Regulations 2016 (SI, 2016).
2. It is hoped that this summary will facilitate the identification of key areas for discussion, in addition to any data gaps that would preclude a future COM risk assessment of the data. Members should note that the subsequent COM evaluation of this data would be required solely to provide PHE with a general opinion on their safety, and not to fulfil any regulatory function of PHE.
3. The Committee is reminded that certain data contained in this summary (and its Annex's) constitute trade secrets and confidential information. Therefore, the data presented in this report should be treated as commercially sensitive.

**Questions for the Committee**

- (i) Do Members consider the data submitted is sufficient to conduct a thorough assessment of these products? What data gaps exist?
- (ii) What additional information is required before a considered view on the genotoxicity of their HNB products could be provided. What level of detail would be required to evaluate the data?
- (iii) What are Members opinions on the data matrix and the proposed list of data requirements?

**Secretariat/ PHE-Supported Imperial College Toxicology Unit  
February 2017**

**Schaller et al (2016). Evaluation of the Tobacco Heating System 2.2. Part 2: Chemical composition, genotoxicity, cytotoxicity, and physical properties of the aerosol. Regulatory Toxicology and Pharmacology Volume 81, Supplement 2, Pages S27–S47**