

A Toxicological Risk Assessment Strategy for the Responsible Development of Next Generation Product Device Materials

Eurotox | LP-25 | 14-17th September 2025

Natalie Firth¹*, Ourania Komini¹, Georgiana Cava¹, Konstantinos Papikinos¹
*Presenting author
¹ Imperial Brands PLC, 121 Winterstoke Road, BS3 2LL, Bristol UK

FIND OUT MORE



INTRODUCTION

As a responsible manufacturer, Imperial Brands acknowledges the importance of understanding how our products may interact with consumer health and remains committed to proactively evaluating potential risks associated with their use. This approach underpins our product stewardship strategy, which is guided by two key principles: prioritising consumer safety and supporting regulatory compliance across the diverse markets in which we operate. Next Generation Products (NGP), like Heated Tobacco Products (HTP) and E-Vapour Products (EVP), deliver nicotine without burning tobacco and so have the potential to play a key role in Tobacco Harm Reduction (THR). Here, we describe a structured approach to assess NGP device materials, combining desk-based toxicological risk

evaluation and analytical testing. The approach aims to mitigate potential risks associated with device materials, contributing to enhanced consumer safety. Our assessment also ensures compliance with relevant regulations (e.g. REACH and RoHS) and internal product safety standards. Our process starts with a thorough review of safety documentation (as shown below) to assess potential hazards of device materials that come into direct contact with the consumer, e.g. the mouthpiece or outer shell of the device. This includes screening for any Carcinogenic, Mutagenic or Reprotoxic (CMR) substances according to Classification Labelling and Packaging Regulation (EC) No 1272/2008. To fully characterise device components, we incorporate

analytical reports on extractables and leachables, operating conditions, analysing system temperature and material thermal tolerance. The analytical data is assessed to determine how components interact under real-use conditions, ensuring the entire device functions within expected safety parameters. Our comprehensive approach enables us to maintain high safety standards and produce a product consumers can trust. Our assessment approach ensures product integrity through Pre-Market Stewardship and ongoing Post-Market Surveillance. Continuous review and refinement of our approach maintain rigorous assessment standards and promote innovation in next-generation products whilst supporting potentially less harmful alternatives to conventional cigarettes.



CONCLUSIONS

Following toxicological assessment of the above data, manufacturing quality documentation and additional information may also be considered. Combining the desk-based assessment along with the temperature reports, ACM data, Extractables & Leachables studies and manufacturing reports, forms a robust assessment strategy which Imperial adopts to support the products potentially reduced risk when in use.

As a responsible manufacturer, we apply our expertise in product science to ensure robust product safety standards and to support confidence in quality of device innovations. Our comprehensive approach for devices contribute to our Scientific Assessment Framework (SAF). Through the application of the device assessment strategy, along with the assessment of EVP liquids and heated tobacco consumables, Imperial aims to generate scientific insights

that contribute to a potentially reduced harm alternative to smoking cigarettes, and the potential to make a meaningful contribution to tobacco harm reduction.



IMPERIAL
BRANDS

SCIENCE