

Introduction to Concawe UVCB workshop 8th November 2023

Analytical technology exchange to meet health & environmental regulatory challenges for UVCBs

The EU REACH Regulation requires registrants of UVCB⁽¹⁾ substances to provide detailed and comprehensive qualitative and quantitative information on the constituents present in these substances. Concawe currently manages over 140 registered hydrocarbon UVCB substances grouped into 20 categories ranging from light (e.g. naphtha) to heavy (e.g. bitumen) substances and such information is required both to assess the potential environmental and human health impacts of these substances in normal use and, owing to the variation in their composition, to assess the degree of similarity between substances such that results obtained from toxicity tests can be applied from one substance to another (read-across).

Naphthas (~C4-C12), which contain a few hundred constituents, are relatively straightforward to characterise by gas chromatography (GC). Kerosines (~C9-C16), which contain several thousand constituents, and middle distillate substances such as diesel fuels (~C10-C26), which contain hundreds of thousands of constituents, can be characterised with sufficient granularity by comprehensive two-dimensional gas chromatography (GCxGC). However, it becomes increasingly challenging to characterise the heavier (>C30) petroleum substances such as lubricating oils, heavy fuel oils and bitumens which can contain many millions of constituents; the complexity of such substances not only arises from the exponential increase in isomers with carbon number but also from the more varied chemical functionality (and multi-functionality) within the constituents present.

In Section 2.3.2 of <u>Advice on using read-across for UVCB substances (May 2022)</u>, ECHA accepts that for read-across purposes it might not be possible (or practical) to identify all the constituents present in some UVCB substances and in these cases other approaches for demonstrating similarity between substances can be applied. One suggested approach is "fingerprinting" the constituents present using an appropriate analytical technique, although a proviso of such an approach is that the measurement should cover >95% of the constituents present. The comments on page 10 and 11 of this <u>ECHA advice</u> are particularly pertinent to the challenges faced with heavier UVCB substances.

Concawe is aware of many publications describing analytical procedures and techniques which provide information on the identity of constituents present in the heavier petroleum substances but, from our perspective, these papers do not provide both qualitative and quantitative information and/or only provide such information on a small proportion of the total substance. A helpful overview of <u>Analytical chemistry solutions to hazard evaluation of petroleum refining products</u> by Roman-Hubers et al (Dec 2022) sets out the regulatory requirements and the analytical possibilities of evolving technologies.









In addition to the need for comprehensive analysis as described above, targeted analysis of specific constituents is also important (European Chemicals Agency, 'Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/VPvB Assessment, Version 3.0). From an environmental perspective, identification of substances of very high concern (SVHC) due to their Persistence, Bioaccumulation, and Toxicity (PBT or very P/very B) are made on a constituent level. The number of constituents in these UVCB substances pose co-elution challenges for the identification of individual constituents of interest for bioaccumulation and persistence. Regulatory obligations for analysis of degradation products of UVCB substances require a larger suite of analytical approaches to capture the evolving structures.

Further, additional analysis of specific constituents might provide further toxicological insights and support classification and labelling of the above-described heavier petroleum substances.

This workshop aims to bring together analytical chemists, ecotoxicologists, human health toxicologists and product stewards from regulators, academia and industry to exchange and develop expertise in the identification and quantitation of UVCB substance constituents/constituent groups to meet EU REACH regulatory requirements. We will start the day clarifying the regulatory requirements for health and environment that are not yet met by analytical technologies and how such data could be applied in EU REACH. A range of laboratories will then present their current and evolving analytical technologies to support comprehensive quantitation of constituents / constituent groups and the targeted resolution and identification of constituents. We will end the day synthesizing all we have learnt, identifying the opportunities and gaps for delivery of the required data. The event will also kick off the "All Constituent Challenge" a Concawe project to understand the capabilities of a wide range of analytical technologies to quantify UVCB substance constituents / constituent groups.

Should you have any questions about the workshop, please contact reachworkshop@concawe.eu

- 1. Unknown or Variable composition, Complex reaction products or Biological materials
- 2. The Concawe ACC project aims to: determine specific analytical approaches that can most fully quantify constituents/constituent groups of hydrocarbon substance streams with carbon range >C30; identify constituents that fill data gaps of potential biodegradation and bioaccumulation and human toxicology interest and provide information to regulators regarding the limits of analysis of hydrocarbon substance constituents.

Analytical laboratories will be invited to analyse the same set of hydrocarbon substance samples (gas oil, residual aromatic extract, lubricant base oil, bitumen, heavy vacuum oil and paraffin wax) with the analytical approach of their choice to provide as much quantitative information about constituents of the samples as possible. Data from each analytical approach will be collated by Concawe.

For further information about the Concawe ACC project, please contact evangelia.tzoumani@concawe.eu

