FuelsEurope position paper on REACH and the Refining industry

The contribution of the Refining Industry to the economy of the EU and Member States

The Petroleum Refining Industry is a key sector for the EU, fuelling more than 90% of transport and supplying vital products for many other areas of the economy. 140,000 people are directly employed on its sites and 600,000 more are involved with the distribution and sale of products, plus many more induced and indirect jobs. Beyond transport fuels, petroleum products are used as feedstocks for further downstream processes that contribute to a wide range of products that we use in our everyday lives. Additionally, it is very hard to replace such products and their feedstocks with valuable and sustainable alternatives.

The Petroleum Refining industry's approach to REACH

Petroleum Substances are under the scope of the REACH Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals, the European Union's instrument for managing the risks for human health and the environment of chemical substances. The refining industry has been deeply engaged in the registration phase of REACH and is fully committed to work with the Regulatory Authorities at European and national level to ensure effective compliance. The industry supports REACH's principles of risk management, scientific grounding and provide information on their safe use. However, the implementation of this regulation is a challenge due to the nature of petroleum substances. This creates concerns about the loss of competitiveness for European industry when the administrative burden and costs increase drastically, like in the authorisation process.

REACH and the implementation challenges for Petroleum Substances

Petroleum products are derived from crude oil and are characterised in REACH terms as 'UVCBs' (substances of Unknown or Variable composition, Complex reaction products or Biological materials). The fundamental aspect of this is that Petroleum Substances are both **complex and variable**: their exact composition can hardly be exhaustively described in analytical terms, particularly for the heavier substances, and furthermore will also vary across different samples of the same product, reflecting the specific refining process they underwent and the crude oils they are sourced from.

REACH allows grouping substances in categories and that principle has been developed by Concawe[1] for the registration of petroleum substances: the 200 currently registered petroleum substances are grouped into 18 categories. This 'category approach' is the most effective way[2] of using hazard data for a substance by applying it with read-across to other substances in the category. Using the worst case approach ensures the hazard level, and consequently the risks are not underestimated.

We are now at a critical juncture

As recognised by the European Commission[3] the implementation of REACH is challenging for simpler (well-defined) chemical substances and it is still undergoing a learning process; this is even more the case for more complex ones.
Today with REACH addressing the challenges of the Evaluation phase, dossiers and substances are being selected for evaluation based on data used in the registration dossiers, according to the timeline of the SVHC Roadmap[4]. At the same time, there are challenges for stakeholders needing to meet the final registration phases involving lower tonnage bands, implementation of new testing systems[5], and for Member States approaching the complex implementation and

[1] Concawe is the division for research on health, safety, and environmental (HSE) issues of importance to the European oil refining industry
[2] As compared to carrying out 200 separate tests
[3]The Commission document on REACH effects SWD (2013/0025) states that "the competitiveness of the EU chemical industry has been affected by the costs of registration which have been higher than expected"
[4] Substances of Very High Concern Roadmap
[5] The Extended One Generation Reprotoxicity Study was recently approved as a new standard for inclusion in test proposals

enforcement of REACH requirements. This phase presents a broad array of specific challenges for our industry, including the following:

- The "category approach" is a long-established method which underpins the hazard evaluation of Petroleum Substances in a way which avoids underestimation of hazard. This approach needs to be retained, but further developed, explained and justified in response to the challenges of REACH.
- An overly-conservative screening will result in having a large number of Petroleum Substances unnecessarily included in the SVHC[6] Roadmap, and will lead to demands for additional animal testing a; the SVHC Roadmap should not become a political target, rather than a guidance process for hazardous substances when risks aren't properly addressed.
- If the draft Implementing Act on Data Sharing[7] could result in forcing also the SIEFs[8] which are well-managed to comply with unnecessary and disproportionate requirements, this would result in additional burden and costs for new and existing registrants, including SMEs;
- If there is no consistent enforcement by Member States, the European Union may face a risk of fragmentation of the EU internal market and disruption of the level playing field. REACH implementation also needs to consider international competitiveness.

Uncertainty about time and costs of the evaluation will put pressure both on industry and authorities, thus a suitable approach with a realistic timeline is urgently called for, which complies with REACH while recognising the specific characteristics of Petroleum Substances and provides for a workable way forward for all involved.

Our proposed way forward

The refining industry recommends taking an integrated approach which includes the following:

- Using a category approach to group substances together is, in our view, the best way to deal with the UVCBs while complying with both the requirements and the intent of REACH in an efficient, scientifically proven and realistic manner for industry, ECHA and Member States. This would support eliminating unnecessary animal testing;
- Overhauling the registration dossiers according to a realistic timeline as proposed to ECHA which will ensure the necessary degree of certainty and provide all involved stakeholders with a pathway for joint cooperation;
- To keep the addition of Petroleum Substances to the "Candidate list" to a minimum by applying criteria that consider uses and hazard better. FuelsEurope is against any unjustified additions of substances to the priority list; we support an approach that focuses on substances having widespread, professional and consumer uses, and welcome working with stakeholders about the best way to implement this
- Prioritisation of the evaluation of petroleum substances should be prioritised in a way that allows Industry and authorities sufficient time to improve data and carry out testing in an efficient way; Consideration of alternatives for putting a substance on the SVHC list, such as restrictions or measures under the Chemical Agents Directive; Support for innovative testing methods for data gathering to improve experimental design, such as the toxicogenomics approach could help underpin the justification for read-across;
- Ensuring an Implementing Act on Data Sharing that will not disrupt the current organisation of the Petroleum Substances SIEFs, sharing all costs on a category level and respecting the principles of fairness, transparency, proportionality and non-discrimination.

Contact : **Alexander Ioannidis**
T +32 2 566 91 20
F +32 2 566 91 11
alexander.ioannidis@fuelseurope.eu
www.fuelseurope.eu

[6] Substances of Very High Concern: substances of potentially high concern regarding their impact on human health and the environment

[7] The Implementing Act on Data Sharing aims to establish a framework for the operation of SIEFs (Substance Information Exchange Forum, where registrants of the same substance can share costs), establishing principles such as transparency and cost sharing.

[8] Substance Information Exchange Fora