

FuelsEurope Position Paper on REACH and the Refining industry

Brussels, July 2015

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. The Commission Communication of May 2014 on European Energy Supply Security stated that *“it is important to maintain competitive refining capacities in Europe to avoid overdependence on imported products and to be able to process crude oil stocks with sufficient flexibility”*¹. Refineries are located in most Member States and are important contributors to GDP, high-skill jobs, technical know-how and are a valuable, integrated part of the industrial supply chain. Across the EU, the sector generates 23 billion euro a year of added value and 270 billion in revenue from fuel taxes.

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: from plastics used in packaging to synthetic fibres in clothing, from detergents used in domestic cleaning to agricultural fertilisers. The close integration with sectors such as petrochemicals strengthens those valuable industries. 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 with the scope and objectives of REACH. 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 when the administrative burden and costs (for example data generation and dossier management) 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 material). The fundamental aspect of this is that Petroleum Substances are both **complex and variable**: their exact composition can never be exhaustively described in analytical terms, particularly for the heaviest 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.

For many years, petroleum substances have been identified under a number of definitions each of these corresponding to a different CAS² and EINECS³ entry. These typically identify the starting material and the last process step that a substance underwent during its production. In many cases an indication of important physico-chemical parameters such as either a boiling range or a carbon number range or both will be included in the CAS definition. This approach has

¹ COM (2014) 330 final, page 11

² Chemical Abstracts Service

³ European INventory of Existing Commercial chemical Substances

however resulted in large overlaps in definitions and in a disconnect between those definitions and the way petroleum substances are marketed (e.g. the Fuels Quality Directive doesn't refer to any EINECS definition).

To deal with that diversity, even before REACH, petroleum substances have been grouped for classification and labelling purposes (Council regulation (EEC) 793/93). Grouping allows read across to all substances in the group of hazard data from one of the member substances. The worst health and environment results for any of the group members is applied to all other members of the group.

REACH allows grouping substances in categories and that principle has been developed by Concawe⁴ 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 of using hazard data for a substance by applying it to other substances in the category. Using the worst case approach ensures the hazard level, and consequently the risks are not underestimated.

As recognised by the European Commission⁵ 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. To achieve effective implementation of REACH for Petroleum Substances a suitable approach is required, involving:

- An improved collaborative approach among ECHA⁶, the European Commission and industry, based upon a shared appreciation of both the key principles of REACH and the technical and economic challenges of its application to Petroleum Substances;
- An improved dialogue between industry and Member States throughout the process of evaluation, screening of petroleum substances, risk management options on both the technical challenges and also their potential negative consequences on the competitiveness of the EU industry; REACH is also supposed to enhance competitiveness⁷ and innovation (both in methodology as well as products);
- Sufficient time for the industry - based on the above prioritisation - to develop scientifically robust methodologies and data to ensure REACH compliance of Petroleum Substances.

We are now at a critical juncture

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 SVHC⁸ roadmap. At the same time, there are challenges for stakeholders needing to meet the final registration phases involving lower tonnage bands, implementation of new testing systems⁹, and for Member States approaching the complex implementation and enforcement of REACH requirements. Adequate and aligned prioritisation of future work, both from industry, Member States and ECHA is essential.

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

⁴ Concawe is the division for research on health, safety, and environmental (HSE) issues of importance to the European oil refining industry

⁵The 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" and identified needs for additional action in several areas.

⁶ ECHA: European Chemicals Agency

⁷ Article 1 of REACH: "This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own... **while enhancing competitiveness and innovation.**"

⁸ Substances of Very High Concern: substances of potentially high concern regarding their impact on human health and the environment

⁹ The Extended One Generation Reprotoxicity Study was recently approved as a new standard for inclusion in test proposals

developed, explained and justified in response to the challenges of REACH. The revisions required by ECHA and/or Member States should be limited to those that are suitable and proportionate;

- Rejection of a suitable and reasonable revision of the category approach will adversely impact the classification scheme used throughout the EU for Petroleum substances, with consequent confusion for customers and along the supply chain;
- excessive and premature limitation on the applicability of data read-across¹⁰, which does not take into account the data that Concawe will develop to support categories and read across, will result in the need to increase animal testing and to the unnecessary proliferation of data generation;
- An overly-conservative screening will result in having a large number of Petroleum Substances unnecessarily included in the SVHC roadmap, and will lead to demands for the generation of data that are not needed for the safe management. This will also include animal testing and unnecessary constraints in the marketing and use of such substances ([see annex](#)). We support an approach that focuses on widespread, consumer uses of hazardous substances, and welcome working with stakeholders about the best way to implement this;
- If the draft Implementing Act on Data Sharing¹¹ could result in forcing well-managed SIEF¹²s 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 as proposed to ECHA: the programme to do this provides a realistic timeline which will ensure the necessary degree of certainty (thereby removing a key concern of industry) 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, in order to avoid unnecessary testing. FuelsEurope is against any unjustified additions of substances to the priority list; the SVHC Roadmap should not become a political target, rather than a guidance process for hazardous substances when risks aren’t properly addressed. The PetCo (Petroleum and Coal coordination group) should understand and recognise the clear difference between petroleum and coal substances when considering the approach to take with them;

¹⁰ Read across is defined by ECHA as “a technique for data-gap filling where endpoint information from one chemical is used to predict the same endpoint for another chemical which is considered to be similar in some important aspect relating to that endpoint”, http://echa.europa.eu/documents/10162/13655/pg_report_readacross_en.pdf

¹¹ 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.

- A realistic implementation of REACH principles in the **Evaluation phase**, which is key. The evaluation of petroleum substances should be prioritised in a way that allows Industry and authorities sufficient to improve datasets and carry out testing and in an efficient way;
- Where current risk management measures are deemed insufficient as the result of substance evaluations, alternatives for putting a substance on the SVHC list should be considered, such as restrictions or measures under the Chemical Agents Directive;
- Support for **innovative testing methods** for data gathering to improve experimental design, leading to a better understanding of the relationship between chemical properties and biological responses, and further reduce the level of animal testing. For example, the toxicogenomics approach could help underpin the justification for read-across;
- An Implementing Act on Data Sharing that does 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;
- As requested by Italy and supported by other Member States at the Refining Forum¹³ of December 2014, REACH should be included in a future update of the Refining Fitness Check's¹⁴ cumulative analysis of impact of EU legislation.

See our views on the specific aspects of REACH in the annex available on www.fuelseurope.eu

FuelsEurope, the voice of the European petroleum refining industry

FuelsEurope represents with the EU institutions the interest of 42 companies operating refineries in the EU. Members account for almost 100% of EU petroleum refining capacity and more than 75% of EU motor fuel retail sales.

FuelsEurope aims to promote economically and environmentally sustainable refining, supply and use of petroleum products in the EU, by providing input and expert advice to the EU institutions, Member State Governments and the wider community and thus contributing in a constructive and pro-active way to the development and implementation of EU policies and regulations.

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¹³ The EU Refining Forum, organised by DG Energy, is twice-yearly event bringing together the industry with the EU institutions and other stakeholders to discuss regulatory proposals that may affect the refining industry and the EU's secure supply of petroleum products: <http://ec.europa.eu/energy/en/topics/oil-gas-and-coal/oil-refining>

¹⁴ The Fitness Check is a study, carried out by DG GROW, analysing the impact EU legislation has had on the competitiveness of the industry.