



Petroleum products and REACH: looking ahead

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Concawe is continuing to strengthen the support it provides to guide registrants through the successive stages of REACH; however, it remains essential that member companies recognise the need to maintain their own REACH expertise.
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The petroleum refining industry successfully met the first REACH¹ deadline in December 2010 with the registration of all petroleum substances. This was a commendable achievement in view of the complexity of REACH itself and the additional difficulties of dealing with UVCBs² and was possible only thanks to the extensive involvement of Concawe contracted and member experts.

After the 2010 registration deadline, many companies seemed to think that compliance with REACH was achieved. However, it has become clear that REACH will require substantial and sustained efforts, probably through to 2020. This review highlights the work we can currently identify to successfully navigate the successive stages of Evaluation, Authorisation and Restriction that follow the registration of our products. Whilst 2018 (the date of the last REACH registration deadline) will be an important milestone, the Evaluation, Authorisation and Restriction work to follow up is likely to continue for several years thereafter.

In recognition of the ongoing work required to support our members and all registrants of petroleum substances through these successive stages, Concawe reorganised its REACH focused activities in 2013, adding additional resources to strengthen the support we provide. However, the Concawe team is just the tip of the iceberg, as much of the work has to be done by member company staff dedicated to REACH, and here we emphasise the need for member companies to maintain their REACH expertise.

Under the REACH legislation, all registrants of the same chemical substance are obliged to collaborate with each other through Substance Information Exchange Fora, or SIEFs. ECHA's guidance introduced the concept of a SIEF Formation Facilitator (SFF) for facilitating the pre-registration of substances by companies. Concawe volunteered to act as the SFF for all petroleum substances. Concawe's SFF role has already proved to be of great value to registrants by coordinating the scientific

and specialist aspects of the REACH process and substantially simplifying their involvement in the SIEFs.

Although these activities have gone relatively smoothly, much more effort will be required over the coming years to ensure that the common elements of Concawe's registration dossiers remain compliant under REACH. Some information on this was already provided in the spring 2013 Concawe *Review* article titled 'Petroleum products: looking back over the past 50 years'. The current article extends this discussion by reviewing the main drivers for REACH activities between now and 2020.

Testing proposals

In preparing the 2010 registration dossiers, Concawe proposed that petroleum substances should be grouped and registered in a limited number of well-defined 'categories' that would recognise the variability in composition that can be observed among similar products covered by the same substance description and CAS number. Where important gaps in the scientific information were identified, REACH required submission of Testing Proposals to generate the missing data when the testing involves vertebrate animals. The Concawe registration dossiers include testing proposals for pre-natal developmental and/or reproductive toxicity for certain categories. ECHA issued draft decisions on these testing proposals which were discussed by the Member State Committee (MSC) in November 2013.

The draft decisions on the testing proposals relate to the two following elements:

1. Categories of petroleum substances

Concawe proposed grouping petroleum substances into categories to provide a common data set for all substances within each category. Where there were insufficient data Concawe proposed to test a single substance from each category, as representative of the worst actor³ within that category.

¹ REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

² UVCB, or 'substances of unknown or variable composition, complex reaction products or biological materials', is used to describe these substances in the REACH Regulation.

³ A worst actor is defined as a substance most likely to demonstrate the highest effect for the hazard under consideration.



ECHA and the MSC have not accepted this grouping as they considered that there were insufficient data to demonstrate chemical similarity between the different substances within a category.

The MSC agreed an alternative approach in which testing on a single substance from a category would be allowed and the results then read across to other members of the category (one-to-one read-across). This outcome is favourable in that we can proceed with testing a single substance as per our testing proposals and could only be reached thanks to the hard work invested to demonstrate the chemical similarity of petroleum substances. However, ECHA will only accept the applicability of the data to the whole category if the testing results support the read-across hypothesis.

ECHA is requesting additional information to be included in the dossiers when, after completion of the testing, they will have to be updated. This information would need to ensure that the results of the testing do not underestimate the toxicity of other substances and can be applied to all members of the same category. ECHA may request more testing to be carried out after reviewing the updated dossiers with the outcome of the testing.

In addition to the testing programme, Concawe will need to improve the characterisation of all petroleum substances that have been registered. This will involve a comprehensive analytical and data collection programme from all registrants of petroleum substances, due to be launched in 2014. At the same time, there will be a need for further discussions with ECHA and Member States regarding their concerns with the category approach. Doing so will provide additional support to the category approach as well as for the use of read-across in addressing both eco-toxicity and human health endpoints.

ECHA has also launched two new projects on the substance identification of UVCBs. These include the characterisation, chemical representation and modelling of UVCB substances which will further develop ECHA's understanding on the issues of categories and substance identification. Petroleum substances have been specifically identified as one class of UVCBs ECHA will focus on.

2. Testing method for reproductive toxicity

REACH stipulates the use of a standard methodology for reproductive toxicity testing, based on two-generation testing. Several Member States are promoting an alternative methodology based on the Extended One Generation Reproductive Toxicity Study (EOGRTS). The MSC did not reach unanimous decision regarding the method to be used for testing reproductive toxicity and hence the draft decisions were referred to the Commission for a decision. Whilst this has been an issue for several months, we understand that the Commission is likely to revise the testing regulations to stipulate the EOGRTS as the preferred method. This is not unique to petroleum substances as it will apply to any substance that requires reproductive toxicity testing under REACH.

It is not clear at this time when the Commission will issue its decision and therefore when the proposed testing can be started. Once final decisions are issued, it is expected to take 24 to 45 months to complete the testing and to update the dossiers. Concawe is already preparing for the testing programmes by working with the specialised laboratories and planning sample collection.

Compliance checks

ECHA performs compliance checks on the REACH registration dossiers to validate the completeness and adequacy of the information submitted by registrants, e.g. regarding substance identification. These compliance checks can result in draft decisions being sent to registrants.

Following compliance checks, ECHA issued draft decisions in October 2013 that questioned the derivation of the environmental effects endpoints. ECHA's reservations concern the suitability of the tool (PETROTOX) developed by Concawe for the prediction of eco-toxicity endpoints and the undertaking of environmental risk assessments for petroleum substances. Concawe has prepared an action plan that will be discussed with ECHA before the draft decisions are submitted to the Member State Competent Authorities (MSCAs).



In anticipation of further compliance checks, Concawe has initiated discussions with ECHA on several topics, e.g. substance identity, and will continue this dialogue to develop a common understanding. The results of all this work will be included in a thorough revision of the dossiers submitted in 2010. A work plan to address this major activity has been developed for discussion with ECHA.

Evaluation, Authorisation and Restriction

Member States perform 'substance evaluations' under the Community Rolling Action Plan (CoRAP) to scrutinise substances for potential concerns. The outcome of these evaluations could lead to requests for even more testing or the identification of substances as Substances of Very High Concern (SVHCs). This may lead to some substances being added to the REACH candidate list, causing these to potentially fall under the REACH Authorisation process.

In 2013, the Commission issued its SVHC roadmap to define a process for ensuring the incorporation of all SVHCs in the REACH candidate list by 2020. Petroleum substances are explicitly mentioned in the SVHC roadmap, with a 'development of an approach' phase through 2013–2015 and a 'systematic assessment' beginning in 2016. Whilst uses of petroleum substances as fuels or intermediates are exempt from Authorisation, non-fuel uses will be scrutinised. A revision of the uses currently supported in the Concawe registration dossiers will probably be necessary to ensure that the Evaluation of petroleum substances is driven by realistic end-use applications.

Any petroleum substances which are classified as CMR (Carcinogens, Mutagens or Reproductive toxicants) or those containing constituents above 0.1% which are identified as PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative) may be included in the REACH candidate list. One possible outcome for a petroleum substance that is included on this list could be to restrict some of the non-fuel uses of that substance.

The Commission will launch a Working Group, the 'Petroleum Substances Expert Group', in 2014 which will require the involvement of Concawe experts. Concawe also participates in the ECHA PBT Working Group to ensure that the identification of substances as PBTs is based upon robust application of the available science.

The Commission is considering the use of Risk Management Options (RMOs) and is in debate with Member States on how this may be included as a step before Authorisation. Concawe needs to understand and, if possible, influence how the RMO process will be developed and applied.

The Authorisation process under REACH is intended to stop the manufacture and marketing of substances that are deemed to pose an unacceptable risk to human health or the environment, unless it can be demonstrated that the risk associated with handling such substances can be managed safely. While there are provisions in the regulation for obtaining 'authorisation' to continue manufacturing and marketing substances that are subject to the Authorisation process, the process itself is very complicated and demanding, requiring significant effort and resources. Concawe must be prepared to help registrants of petroleum substances manage this Authorisation process.

Dossier updates

Chemical Safety Assessments (CSAs) are required by REACH for substances manufactured in quantities in excess of 100 tonnes per annum. For substances classified as hazardous, these CSAs must include risk assessments for human health and for the environment. 'Exposure scenarios' were developed by Concawe in 2010, to identify the conditions under which the substance can be used in a safe manner without causing harm to humans or the environment. ECHA, in collaboration with industry partners, formed the Exchange Network on Exposure Scenarios (ENES) and has issued a roadmap for 2013–15 work to improve the overall quality of exposure scenarios. In addition to participating in the ENES Steering Group, Concawe is also prepared to provide significant effort and resources if there is a need to fundamentally re-work the exposure scenarios for petroleum substances.



In late 2015, ECHA will once again radically overhaul IUCLID, the software used to submit and update dossiers to ECHA under REACH. The next version of IUCLID (IUCLID6) is expected to require more information on exposure scenarios and the assessment of PBT properties in highly structured data-entry fields to facilitate the automated screening by ECHA of exposure data and other information. Consequently, Concawe will have to update all of the dossiers to allow registrants of petroleum substances to keep their registrations compliant and up-to-date.

Communication with registrants

Most of the issues described above also require an ongoing and intensive communication with the registrants of petroleum substances, i.e. with the members of the respective SIEFs. Because Concawe is acting as SFF for all petroleum substances, this communication will also involve substantial work. Following the initial registrations in 2010, there have now been over 4,300 registrations of petroleum substances and this figure provides a good estimate of the communication effort required. Concawe's SIEF Team will continue to manage this communication and the ongoing process of licensing dossiers to non-Concawe members. The costs involved in dossier preparation and updating must be shared amongst all registrants in a fair and transparent manner. This is another important aspect of Concawe's role as SFF

Conclusions

Concawe now has a better understanding of where the petroleum substances dossiers have to be improved to ensure their ongoing compliance with REACH. By addressing the draft decisions, and thanks to our ongoing dialogue with ECHA and the Commission, Concawe will be best placed to support all registrants through the successive stages of REACH. This has allowed us to develop long-term work and resource plans needed to support registrants of petroleum substances. In developing these plans we have had to make assumptions, particularly around the cost and duration of testing.

Concawe will update these plans reflecting the learnings from our dialogues with ECHA and others. We would like to stress once more that this work will only be possible with the continuing commitment of our member companies.