Petroleum products: looking back over the past 50 years

Petroleum product stewardship: to REACH and beyond

The field of petroleum products in CONCAWE has historically been concerned with product stewardship and chemicals control legislation relating to the production, marketing and use of petroleum substances. In 1977, the Petroleum Products Management Group issued its first report, titled *An assessment of precautionary labelling systems relating to the movement of petroleum products in bulk*, the objective of which was to promote the harmonisation of labelling for dangerous goods. Over the years CONCAWE has continued to provide guidance to its member companies on compliance with emerging and evolving EU legislation related to the control of chemicals.

Classification and labelling of chemicals—from DSD/DPD to CLP

The Dangerous Substances Directive (DSD), originally issued in 1967 and which entered into force in 1970, established criteria for the classification and labelling of chemicals based on their inherent physico-chemical and health properties. Since its original publication, the DSD was amended 31 times through Adaptations to Technical Progress (ATPs), which introduced requirements for the environmental classification and revisions/additions to human health effects. In 1980, CONCAWE published its first guidance on the classification and labelling of petroleum products marketed in the European Community, in advance of any formal evaluation by the European Commission on the classification of petroleum substances. Harmonized classifications for the carcinogenicity of petroleum substances were incorporated into the DSD beginning with the 19th and 21st ATPs in 1993. In 1995, CONCAWE updated its recommendations for classification and labelling of petroleum substances and introduced the concept of 'grouping'. The Dangerous Preparations Directive (DPD), first published in 1988 and recast in 1999, provided criteria for the classification and labelling of preparations. CONCAWE has kept abreast of subsequent legislative changes, updating its classification recommendations to enable industry to adopt a harmonized approach to the classification and labelling of petroleum substances.

Although petroleum substances are regulated by the same EU legislation as single-component chemicals, petroleum substances have a complex and varying composition, generally consisting of hundreds, if not thousands, of individual chemical components. For that reason, test methods developed for the classification of 'chemicals' cannot always be suitably applied to petroleum substances. Nevertheless, there was still a need for petroleum substances to be classified; in response to this need, CONCAWE had been instrumental in developing appropriate test methods for determining the aquatic toxicity and the inherent biodegradability of petroleum substances, and has published reports describing these.

At the United Nations Conference on Environment and Development, held in Rio de Janeiro in 1992, agreement was reached on the development of an international programme for the classification of chemicals based on their physicochemical, health and environmental properties. This vision was realised with the publication of the first edition of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) in 2003.

In 2007, the European Union issued a Regulation on the Classification, Labelling and Packaging (CLP) of Chemicals which incorporated major elements of the GHS. The CLP Regulation entered into force for substances in 2010 and will enter into force for mixtures (i.e. preparations) in 2015. At the time of writing this article, the CLP Regulation had been amended three times. CONCAWE continues to periodically update the report on classification and labelling recommendations, keeping it aligned with changes in the legislation and also with new information which becomes available on petroleum substances.

Restrictions/risk assessment—from MUDS/ESR to REACH

The Marketing and Use Limitations Directive (MUDS), first issued in 1976, introduced a framework for placing restrictions on the marketing and use of certain dangerous substances and preparations. Of particular note, the 14th ATP to the Directive, issued in 1994, banned substances classified as category 1 or category 2 carcinogens, mutagens and/or reproductive toxicants from sale to the general public. This ATP also included an

exemption for the sale of motor fuels, mineral oil products intended for use as fuel in mobile or fixed combustion plants and for fuels sold in closed systems. These exemptions have been carried forward into the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) which is discussed in more detail later in this article. Other restrictions impacting on petroleum substances that were introduced under MUDS include a restriction on the sale of lamp oils to the general public and restrictions on the level of certain polyaromatic hydrocarbons used in extender oils for the production of tyres. As before, these restrictions have also been carried forward into REACH.

The Existing Substances Regulation (ESR), published in 1993, required all producers and importers to supply certain information (i.e. classification, toxicity and ecotoxicity information, physico-chemical properties and production volumes) on high production volume chemicals to the European Commission. The ESR reflected the consolidation of petroleum substances into 'groups' based on their refining process. The objective was to compile the information into a database named IUCLID (International Uniform Chemical Information Database) which would be used as the source of information for subsequent risk assessments carried out by the Member States in accordance with the ESR.

In response to the obligations placed on industry, CONCAWE served to coordinate the compilation and submission of the required health and environmental information on petroleum substances into Harmonised Electronic Datasets (HEDSETS), as required by the ESR. This activity was particularly noteworthy in that it was carried out on behalf of the entire industry, including manufacturers and importers that were not members of CONCAWE.

Guidance for conducting risk assessments of single component chemicals has been developed under the Existing Substances Regulation. Though administered as a 'substance' under EU legislation, petroleum substances are, as mentioned earlier, different from single component chemicals. Assessing the risks to human health, and particularly to the environment, associated with such complex products was an entry into uncharted waters. In this context, CONCAWE introduced the concept of the Hydrocarbon Block Methodology which was accepted by the regulators and incorporated into the guidance for the ESR.

Recognizing the magnitude of the effort and time required to develop the detailed methodology for applying the Hydrocarbon Block Methodology to the environmental risk assessment of petroleum substances, CONCAWE embarked on a multi-year programme to develop PETRORISK to enable environmental risk assessments for petroleum substances using an EU decision-support instrument (EUSES). A second model, PETROTOX, was also developed to allow the prediction of aquatic toxicity of petroleum substances. Both models are publicly available and can be downloaded from the CONCAWE website (www.concawe.org).

Over the ensuing years, the slow progress under the ESR generated considerable debate amongst the European Commission, EU Member States, NGOs and industry with regard to the need to overhaul the existing legislative framework of chemicals control in the EU. In late spring 2003, the EU Commission issued a consultation document for REACH which proposed to shift the responsibility for undertaking the health and environmental risk assessment on substances from the authorities to industry. REACH was adopted by the EU Council and Parliament in 2006 and required the registration of chemicals manufactured or imported in quantities above 1,000 tonnes (and carcinogens above 1 tonne or substances classified as very toxic with long-term effects in the aquatic environment above 100 tonnes) to be submitted to a newly created European Chemicals Agency (in Helsinki) by 1 December 2010. For substances in lower tonnage bands, the regulation established two subsequent registration deadlines of 2013 and 2018.

The REACH regulation is extremely ambitious and complex. One of the basic principles of REACH is that there should be one registration per substance. Registrants were expected to organize themselves into Substance Information Exchange Fora (SIEF) to exchange the information required and to agree the common parts of the dossier that would be submitted by a Lead Registrant. As with the ESR, CONCAWE played a lead-

ing role in coordinating the industry response, and served as the Substance Information Exchange Facilitator of all SIEFs for petroleum substances that required registration.

The risk assessment process builds on the inherent toxicity/eco-toxicity of a substance (i.e. effects assessment) and introduces the aspect of exposure. The actual risk that a substance presents is characterized as its inherent toxicity coupled with the actual exposure, of either man or the environment, to the substance.

One of the core information needs for environmental risk assessments is a speciated compositional analysis which, in practice, is feasible only for light products. For high boiling substances (i.e. heavy fuel oils, base oils for lubricants, etc.), even state-of-the-art analytical techniques do not deliver a compositional analysis with the required level of detail. To overcome this limitation, CONCAWE proposed an alternative methodology, making use of physico-chemical properties rather than compositional information. The proposed methodology was presented to various European regulatory authorities and academics at a workshop in spring 2003. Response was favourable and CONCAWE has adopted this methodology for environmental risk assessment under REACH.

Table 1 Grouping scheme for petroleum substances

Stand-alone substances	MK1 Diesel Fuel
	Oxidized Asphalt
	Sulfur
Categories	Low Boiling Point Naphthas (Gasolines)
	Kerosines
	Straight-run Gas Oils
	Other Gas Oils
	Cracked Gas Oils
	Vacuum Gas Oils, Hydrocracked Gas Oils & Distillate Fuels
	Heavy Fuel Oils Components
	Other Lubricant Base Oils
	Highly Refined Base Oils
	Slack Waxes
	Foots Oils
	Petrolatums
	Paraffins and Hydrocarbon Waxes
	Untreated Distillate Aromatic Extracts
	Residual Aromatic Extracts
	Treated Distillate Aromatic Extracts
	Unrefined / Acid Treated Oils
	Bitumen

The European Inventory of Existing Commercial Chemical Substances (EINECS) includes nearly 700 petroleum substances. It would obviously not be feasible to conduct individual risk assessments on every one of them. CONCAWE is proposing a pragmatic methodology based on a refinement of the grouping scheme originally developed for classification purposes in the 1990s. The proposed grouping scheme for REACH consists of 18 'categories' and 3 'stand-alone substances', ranging from petroleum gases to bitumen, and grouping products and components of similar physico-chemical properties and uses (Table 1). Sulphur is also included as one of the 3 stand-alone substances because the oil industry is a major producer of sulphur as a consequence of product desulphurisation.

CONCAWE prepared registration dossiers for submission by the manufacturer/importer of the substance by the first deadline of 1 December 2010. The level of effort required to prepare these dossiers was significant; approximately 6,500 man-days of effort within a 3-year time-frame in the midst of new guidance being developed and/or revised in parallel. By February 2012, 4,194 registrations for 202 petroleum substances had been submitted to ECHA; 1,188 of these registrations were submitted by companies that are not members of CONCAWE. It must be mentioned that CONCAWE has provided all SIEF members with exhaustive guidance to support them throughout the REACH registration process; keeping this guidance updated in line with changes in, for example, the IT systems supporting REACH, remains a challenge which requires significant resources.

The categories have been developed to justify (e.g. for classification and labelling purposes) that tests carried out on samples of one category member can be considered applicable to all other category members, thus effectively reducing the number of expensive and time-consuming tests on petroleum substances. It must be noted that CONCAWE advocates applying the 'worst

case' approach, by which all substances in a category receive the most stringent classification arising from the available tests on any substance in the category.

Not only does REACH cover the registration of substances but it also provides for the possibility of compliance checks to be carried out by ECHA to validate the completeness and adequacy of the information submitted by registrants. At the time of writing this article, ECHA has put in place a semi-automated system able to identify pitfalls in the registration dossiers. For example, substances registered only as intermediates need to comply with certain requirements which were not explicitly available at the time of submitting the dossiers; CONCAWE is also helping SIEF members to address these compliance issues.

When a data gap is found for a toxicity endpoint and the respective test involves vertebrate animals, registrants must submit a 'testing proposal' in the registration dossier, to be evaluated by ECHA; the tests can only be initiated when they are accepted by ECHA and the EU Member States. CONCAWE has submitted testing proposals for five categories and one standalone substance. At the time of writing this article, ECHA has already issued draft decisions on these testing proposals; these draft decisions actually reject virtually all of the testing proposals and contain a number of concerns and requests for additional information. CONCAWE is working on addressing these concerns within extremely tight deadlines, to prevent having to conduct the tests for all substances in a category instead of, as proposed by CONCAWE, testing just one substance representative of the worst case within the category.

Looking ahead

Although registration under REACH was a major achievement by CONCAWE and its member companies, in essence it only served the primary objective of allowing companies to stay in the market by obtaining REACH registration numbers. Along the upcoming years, ECHA will be digging more and more deeply into the information contained in the registration dossiers for petroleum substances, under the umbrella of the 'dossier evaluation' and 'substance evaluation' processes set out in the REACH text. At the time of writing this article, this process has already started and is requiring an ever-increasing effort from CONCAWE staff and experts from member companies.

The main areas to be addressed to support the registration of petroleum substances under REACH are:

- Substance identity—how to describe the chemical composition of petroleum substances taking into account their complexity and intrinsic variability and the vagueness of many CAS number definitions for petroleum substances.
- Grouping approach—how to support the categories set out for REACH to be able to limit the number of tests to be carried out for petroleum substances.
- Risk assessment—how to carry out this process taking into account the specific properties of petroleum substances, and how to justify carrying out risk assessments at the category level instead of for each substance individually.

It is also likely that some uses for some petroleum substances will fall under the REACH authorisation process (use as fuel is exempted from authorisation in REACH). If this is the case, significant effort and resources will be required to deal with the highly complex authorisation process.

In summary, REACH has only started and a significant amount of effort, possibly in the same order of magnitude of that carried out until now, will be needed from CONCAWE and its member companies.