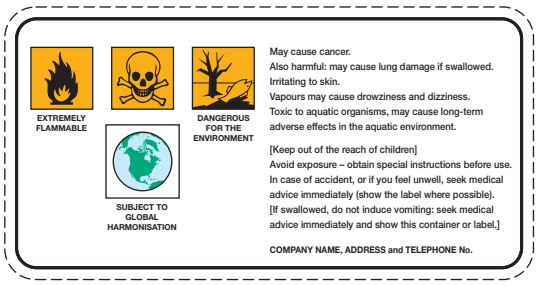
Petroleum products

From Classification and Labelling to Risk Assessments

The field of 'Petroleum Products' in CONCAWE deals with product stewardship and chemical control legislative issues relating to the production, marketing and use of petroleum substances. Since its early days, CONCAWE has provided guidance to its member companies for compliance with emerging and evolving EU legislation related to the control of chemicals. At present, the key legislation affecting the control of chemicals consists of the ***Dangerous Substances Directive*** (issued in 1967), the ***Existing Substances Regulation*** (issued in 1993), and the ***Dangerous Preparations Directive*** (revised in 1999).

The ***Dangerous Substances Directive*** establishes criteria for classification and labelling of chemicals based on the inherent health and environmental hazards that a chemical presents. In 1985 CONCAWE published its first guidance on the classification and labelling of petroleum products marketed in the European Community, at a time when the European Commission had yet to undertake a formal evaluation of petroleum substances. Since then, EU legislation for the classification and labelling of petroleum substances has evolved considerably. Requirements for the environmental classification of substances and preparations have been introduced, as have new criteria for evaluating health hazards. CONCAWE has kept abreast of these legislative changes, updating its classification recommendations to enable industry to adopt a harmonized approach to the classification and labelling of petroleum substances. A stand-alone report has also been published providing the rationale for the environmental classification of petroleum substances. As this article goes to press, work is under way on a new update of the classification recommendations, in response to the 29th ***Adaptation to Technical Progress to the Dangerous Substances Directive***, which is soon to be published.



Although they are regulated by the same legislation as single-component chemicals, petroleum substances are different. Unlike 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 is still a need for petroleum substances to be classified and, in response to this need, CONCAWE has 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.

The ***Dangerous Preparations Directive***, provides criteria for the classification and labelling of preparations (i.e. mixtures). First published in 1988, the Directive was revised in 1999 to include criteria for the classification and labelling of preparations on the basis of environmental hazards. As a consequence of revisions to the Dangerous Preparations Directive, the Safety Data Sheet Directive was also amended in 2001. CONCAWE has issued reports giving guidance on the implementation of these revised Directives.

The ***Existing Substances Regulation***, published in 1993, required all producers and importers to supply certain information (i.e. classification, toxicity and eco-toxicity information, physico-chemical properties and production volumes) on high production volume chemicals to

Towards a new approach to chemicals control

Over the past few years, the perceived slow progress of the ***Existing Substances Regulation*** has prompted considerable debate, amongst the Commission, 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 the Registration, Evaluation, and Authorisation of Chemicals (REACH) that would, if enacted into law, radically transform the responsibilities of industry and the authorities for the control of chemicals. In particular, the REACH consultation document calls for a shift of responsibility for undertaking the health and environmental risk assessment on substances from the authorities to industry. Given the ambitious deadline proposed by the Commission for completing risk assessments on high production volume substances (i.e. three years after adoption of the legislation) the challenge to industry appears daunting.

the Commission. The objective was to include this information in a database at the European Chemicals Bureau at Ispra, Italy. The database, known as IUCLID (International Uniform Chemical Information Database), is now used as the source of information for subsequent risk assessments by the Member States in accordance with the ***Existing Substances Regulation***.

In the 1990s, CONCAWE initiated a massive activity in the coordination, compilation and submission of health and environmental information on petroleum substances into harmonised electronic datasets (HEDSETS), as required by the ***Existing Substances Regulation*** for high production volume chemicals. This work is particularly noteworthy in that it was carried out on behalf of the entire industry, including manufacturers and importers that were not members of CONCAWE.

CONCAWE has also summarised the available health, environmental and safety information on petroleum substances, and published the results in a series of product dossiers that continue to serve as a valuable source of information to regulatory authorities, companies and users.

The risk assessment process (Figure 1) 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 the product of its inherent toxicity coupled with the actual exposure, of either man or the environment, to the substance.

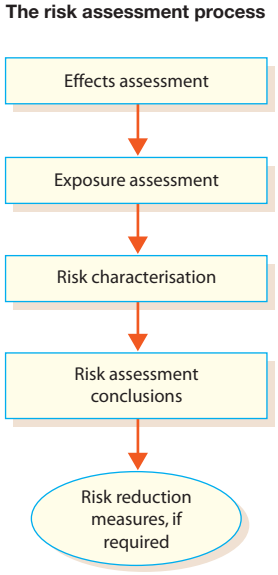


Figure 1
The risk assessment process builds on the inherent toxicity/eco-toxicity of a substance (i.e. effects assessment) and introduces the aspect of exposure.

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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 attached to such complex products is in many ways entering uncharted territory.

Recognizing the magnitude of the effort and time required, and the need to develop an appropriate methodology, CONCAWE has, ahead of legislation but in consultation with the Commission, taken the initiative to conduct health and environmental risk assessments of all petroleum substances by 2010 on behalf of its member companies.

It is clear that the risk assessment process requires a multi-disciplinary input. Accordingly, a coordination group has been formed in CONCAWE, bringing together experts from virtually all disciplines represented in the CONCAWE work portfolio. The group's task is to coordinate the risk assessment programme and to develop and manage a multi-year plan for completing this programme by the target date of 2010.

The European Inventory of Existing Commercial Chemical Substance (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 risk assessments consists of 13 product groups, 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 thirteen product groups because the oil industry is a major producer of sulphur as a consequence of product de-sulphurisation.

Table 1 Grouping scheme for risk assessment

- Crude oil
- Petroleum gases
- Gasoline streams
- Kerosine streams
- Gas oil streams
- Fuel oil streams
- Lubricant base oils
- White mineral oils
- Aromatic extracts
- Petroleum waxes
- Bitumen
- Petroleum coke
- Sulphur

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 has recently 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 now launched a project to further develop this generic environmental risk assessment methodology.

As of September 2003, risk assessments on gasoline and gas oils are under way and work on kerosines is planned to start later in the year. Though 2010 is still a number of years away on the horizon, there is much to be done.