

Chemicals control legislation

What are the implications of the REACH proposal for the downstream oil industry?

The future of chemicals control in the EU (under which petroleum substances are regulated) has been under discussion for several years. Following the EU Commission's White Paper on a Strategy for a Future Chemicals Policy (February 2001), the Commission issued its formal legislative proposal for a Regulation on REACH (Registration, Evaluation and Authorisation of Chemicals) on 29 October 2003. REACH is intended to provide a new framework for the control of chemicals in the EU, replacing the Existing Substances Regulation, the Dangerous Substances Directive, the Dangerous Preparations Directive and the Limitations on Marketing and Use Directive. REACH will introduce a fundamental paradigm shift in the traditional roles that authorities and industry have assumed. In contrast to the existing EU chemicals regime in which responsibility lies with the authorities to demonstrate that a chemical poses a risk to human health or the environment, under REACH responsibility will be shifted from the authorities to industry to demonstrate that a chemical can be handled safely without endangering human health or the environment.

The aim of this article is to summarise the legislative status and key elements of the Commission's proposal, activities CONCAWE has undertaken on behalf of its members to prepare for REACH, and suggestions for how member companies can begin to prepare to meet their obligations under REACH.

Legislative status

The Commission's legislative proposal for a regulation on REACH is now with the EU Parliament and the EU Council. In the Parliament the Environment Committee will have the lead role, and in the Council the Competitiveness Council will assume the lead. An ad-hoc Council working group with representatives from both the Competitiveness and Environment Councils was formed in spring 2004 to assist the Competitiveness

Council. Although discussions are under way, the Council has indicated that it is unlikely a common position will be agreed before the second half of 2005. The EU Parliament is expected to begin its first reading of the proposed Regulation during autumn 2004.

To assist industry and regulatory authorities in meeting their responsibilities under REACH, the Commission launched an Interim Strategy in February 2004 to develop guidance documents on the practical implementation of REACH. The Interim Strategy will run until Q1 2006. Based on the Commission's current timeline, REACH would come into force Q2 2006. However, based on the status of discussions in the Council and Parliament, it is unlikely that this deadline will be met.

At this point in time, neither the precise details of the REACH regulatory text that will emerge from the legislative process, nor the date at which it will come into force are known. Consequently, it is not currently possible to understand fully the impact that REACH will have on CONCAWE member companies. Although the detailed requirements may change, there are nevertheless three fundamental building blocks for REACH which are likely to remain and which will provide the overall framework for the future control of chemicals in the EU. These are *Registration, Evaluation and Authorisation*.

It is important to realise that REACH will impact not only upon manufacturers and importers of chemical substances (i.e. imports from outside the EU), but also on downstream suppliers and users, as well as producers and importers of preparations and articles. Member companies are likely to find themselves in more than one of these categories and will need to be aware of their obligations under REACH. It is also important to recognise that, once adopted, this Regulation will apply to the EU-25 and be implemented on one date rather than needing to be adopted into National legislation.

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What will CONCAWE do on behalf of its member companies to meet the requirements under REACH?

There will be an obligation under REACH for manufacturers and importers to submit a registration dossier for all substances manufactured in the EU and/or imported in quantities above 1 tonne per annum (t/a). Based on the current Commission proposal, registration deadlines for existing substances will depend on the annual production/import quantity. For example, substances produced in amounts greater than 1000 t/a will need to be registered 3 years after REACH comes into force, whereas the deadline will be 11 years for substances produced in amounts of between 1 and 100 t/a.

The registration dossier will include a Chemical Safety Report (CSR) (based on a risk assessment), technical dossier, summaries of health and environmental studies, an enhanced Safety Data Sheet (SDS) and recommendations for classification.

To assist member companies in preparing for the submission of a Chemical Safety Report under REACH, it has been agreed that CONCAWE will undertake risk assessments on all existing petroleum substances represented by the following 13 groups:

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| ● aromatic extracts | ● kerosenes |
| ● base oils | ● petroleum coke |
| ● bitumen | ● petroleum gases |
| ● crude oil | ● sulphur |
| ● gas oils | ● waxes |
| ● gasoline | ● white mineral oils |
| ● heavy fuel oils | |

As a first step, CONCAWE has developed a methodology for conducting the risk assessment of gasoline. This same methodology is being applied to the risk assessments on gas oils, kerosenes and petroleum gases which are all currently under way. For higher boiling point petroleum substances (i.e. base oils, heavy fuel oils, etc.) detailed compositional information cannot be obtained. An alternative generic environmental risk assessment

methodology is therefore being developed and will be available in 2005.

Once the Commission has issued the technical guidance document for Chemical Safety Reports (CSRs), CONCAWE will convert the risk assessments into the specified CSR format. It is also proposed that CONCAWE will compile the non-confidential elements of the registration dossiers on behalf of its members.

What will individual companies need to do?

Submission of a registration dossier under REACH will be a legal obligation on the manufacturer and/or a lead company representing a consortium of manufacturers/importers. Under the Commission's proposal, it will not be possible for CONCAWE, as an association, to submit Registrations.

It is also important to note that the risk assessments undertaken by CONCAWE would cover only those uses which have been identified or agreed within CONCAWE. For unique uses not covered, member companies will need to supplement the risk assessment.

CONCAWE will not prepare risk assessments or Chemical Safety Reports for chemicals that are purchased and used on site (e.g. catalysts, water treatment chemicals, laboratory chemicals, etc.) or additives used to formulate finished products (e.g. fuels and lubricants). Where member companies are either importers or manufacturers of these chemicals, they will be responsible for the preparation and submission of the appropriate registration dossiers. Where member companies are users of chemicals, they should confirm with their suppliers that the chemicals will be registered for the intended use.

Companies should develop an inventory (including the CAS No¹ and annual volumes) of all chemicals they either manufacture or import, to determine whether and when a registration dossier would need to be

¹ CAS Registry Numbers (often referred to as CAS RNs or CAS Numbers) are unique identifiers for chemical substances

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Activities companies could already undertake in preparation for REACH

Produce an inventory of chemical substances

- Establish annual volumes produced or imported into the EU (including substances in preparations) that will be subject to REACH
- Identify the CAS numbers of these substances
- Establish a list of customers and their uses
- Establish what information already exists:
 - (i) hazard property information (i.e. any available studies according to Annexes V through VIII of REACH or other types of hazard information such as human data or QSARs)
 - (ii) exposure information across the supply chain (i.e. exposures in the member companies workforce, customers' workplaces and by the consumer).

Table 1

It is by no means too soon for companies to start making preparations for REACH.

submitted. It should be recognised that import of a formulated product/preparation may require the importer to register *all* the chemicals present in the mixture. Companies should also begin to identify all downstream uses of the products they supply.

Though this is not included in the Commission's current legislative proposal, the Commission is giving consideration to the adoption of the United Nations Globally Harmonised System (GHS) for classification and labelling at the same time that REACH comes into force. This will introduce further work, as current classification and labelling advice will need to be updated to meet the revised criteria. In any event, once REACH comes into force, member companies will need to update their SDSs and labels based on the CSRs for substances they produce and/or import. Additionally, SDSs/labels for preparations marketed in the EU will need to be updated.

Evaluation of selected registration dossiers will be the responsibility of either a Member State or the Central Agency foreseen in the proposal. Companies submitting registration dossiers should be aware that submission is not necessarily the end of the road and that further information may be requested by the evaluating authority.

Certain substances meeting the criteria for classification for carcinogenicity, mutagenicity or reprotoxicity (CMR) or meeting the criteria for persistence, bioaccumulation and toxicity (e.g. PBT or vPvB) will fall under the scope of Authorisation and could be subject to a restriction or a ban under REACH. Member companies should identify these 'at risk' substances, particularly those used in business-critical applications or requiring lengthy product approvals, and seek assurance from their suppliers that they will take the necessary steps to obtain authorisation for the chemicals concerned. For substances covered by the 13 groups of petroleum substances, it is proposed that CONCAWE could prepare the relevant authorisation dossiers.

Though the precise details of what will need to be done are still unclear, it is likely that the future of EU chemicals control will bring with it many challenges and much work for the downstream oil industry. CONCAWE will do its part to assist member companies to meet their obligations under REACH, but it can't do it all. Individual companies will need to do their part. It's not too soon to begin preparing (Table 1).