

# Registration of petroleum substances under REACH

## *How CONCAWE can support its Members in the registration process*

### **Introduction**

In 1993 the Council adopted Regulation (EEC) 793/93 or the 'ESR' (Existing Substances Regulation), thus introducing a comprehensive framework for the evaluation and control of 'existing' chemical substances. The ESR foresaw comprehensive risk assessments and, where necessary, risk reduction measures for priority substances. This Regulation complemented the existing rules governed by Directive 67/548/EEC for 'new' chemical substances, which required approval by the competent authorities of EU Member States prior to being put on the market. In the late 1990s legislators and industry alike concluded that chemicals safety legislation needed a fundamental overhaul. The notification of new substances within the European Community had declined, falling significantly below the number of new substances notified in the USA. The risk assessment programme for existing chemicals under Regulation 793/93, the 'Existing Substances Regulation', was disappointingly slow. Since the adoption of the Existing Substances Regulation by the Council in 1993, work had started on 141 of the 2,700 or so high production volume chemicals produced within, or imported into the Community at volumes above 1,000 t/a, and risk assessments were completed for only a fraction of these 141 chemicals. The comprehensive risk assessment approach had turned out to be too heavy and too slow. Moreover, since the Existing Substances Regulation had not foreseen an involvement of downstream users of chemical substances as such (or as used in preparations), it was notoriously difficult to obtain the use and exposure information needed to assess the risks over the full life cycle. In parallel, the view emerged among authorities that responsibility for demonstrating the safe use of chemical substances ought to be moved from governments to industry.

This was the backdrop against which the European Commission published, in February 2001, its 'White Paper on the Strategy for a Future Chemicals Policy'. The White Paper introduced 'a new system of chemicals

control—the REACH system', where REACH stands for Registration, Evaluation and Authorisation of Chemicals.

The proposed REACH system foresaw the shift of responsibility from Member State governments to industry (manufacturers, importers and downstream users), often referred to as the 'paradigm shift'. REACH was intended to merge legislation for new chemicals and existing chemicals under a common registration scheme, and to maintain the possibility of restrictions of marketing and use. In addition it introduced the authorisation of certain chemicals of very high concern, for example carcinogens, mutagens and reprotoxins class 1 and 2. Implementation of REACH would be managed by a new Chemical Agency, located in Helsinki, but with a strong involvement of the Member States in the evaluation and authorisation process.

Industry noted the improvements for the notification of new chemicals but, on balance, was concerned about: the economic impact of the heavy REACH regime, particularly on small- and medium-sized enterprises (SMEs); the 'loss of chemicals' for applications as a consequence of the authorisation scheme; the possible negative effect on the innovation capability of manufacturers and downstream users; and the potential 'loss of market' as a consequence of relocating manufacturing to regions outside the EU.

In this debate the fact is often overlooked that REACH will stretch even the resources of big companies to the limit. SPORT, the Strategic Partnership on REACH Testing concluded that parallel work on the registration of a large number of chemicals within a relatively short period would be an unprecedented challenge to registrants (see [www.sport-project.info](http://www.sport-project.info)). Moreover, a significant number of registrants produce large volumes of substances with a limited market share and limited human resources. Although they are not usually regarded as SMEs, they will find it as difficult as any 'low

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volume manufacturer' type of SME, if not impossible, to fully comply in time. Several players in the oil industry fall into this category of registrants.

After an internet consultation, the European Commission adopted, on 29 October 2003, its proposal for a new EU regulatory framework for chemicals, i.e. REACH, thus kicking off the legislative process which involves both the European Parliament (EP) and the European Council of Ministers (Council) in the co-decision procedure.

The first reading in the EP took place on 17 November 2005. The EP voted for a number of improvements in the registration scheme benefiting small and medium enterprises and giving the Chemical Agency an overall stronger role, but at the same time it voted for a drastic tightening of the authorisation scheme that foresees the substitution of authorised substances after the authorisation period has expired.

The Council reached a political agreement on 13 December 2005. Again there were improvements in the registration scheme, a stronger role for the Chemical Agency, and a tightening of the authorisation scheme. However, with respect to registration there were fewer improvements, while as regards authorisation there was less tightening than had been voted for by the EP in its first reading.

Both the EP and the Council extended the scope for collective sharing of information by registrants beyond vertebrate animal testing results under the slogan 'One Substance, One Registration' (OSOR).

The Council is expected to agree a 'common position' in May 2006 after which REACH will go through the second reading in the EP. Assuming that a compromise is reached between the EP and the Council, REACH could enter into force as early as April 2007. However, the new European Chemicals Agency is only expected to be fully operational in April 2008, 12 months after entry into force of the legislation.

### How will petroleum substances be affected?

Refinery streams are regarded as substances. They will have to be registered if their annual production or import volume per manufacturer or importer is 1 t/a or more and if their manufacturers/importers wish to continue their business. Although the authorisation process may yield the most severe consequences, the bulk of the work for industry will most likely be related to registration.

There are only a few differences between the REACH versions of the EP and the Council as far as the basic principles of the future registration scheme are concerned, and the Commission has indicated that they support the Council position. The development of guidance and tools for both industry and authorities is in progress in the form of REACH Implementation Projects (RIPs) under the auspices of the Commission. Hence many details are still unclear and tools not yet ready, let alone tested and validated. Nevertheless, CONCAWE believes that its Members would be well-advised to prepare themselves without delay for the implementation of REACH. CONCAWE is supporting its Members in that preparation, in particular through the on-going programme of risk assessments of petroleum substances.

REACH foresees three phases for the registration depending on the volume band. Substances with a production/import volume of 1,000 t/a or more (and those classified as carcinogenic, mutagenic or reprotoxic) will have to be registered within three years after REACH enters into force. The deadline for registration could therefore be as early as April 2010. Lower production volume substances will have to be registered thereafter. The whole registration process for existing substances will be completed by 2018.

Practically all petroleum substances fall into the  $\geq 1,000$  t/a volume band and will therefore have to be registered during the first phase, i.e. before April 2010. Figure 1 illustrates the registration process.

Both the EP and the Council foresee that all registrants of a substance must collaborate for the preparation of certain elements of the registration dossier. These elements

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concern substance information, the testing proposal (where required) and the classification and labelling proposal<sup>1</sup>. A lead company is supposed to submit the documentation on behalf of all the other registrants.

This mandatory collaboration and sharing of information does not apply to use and exposure and thus risk-related elements of the registration dossier, although some of these elements, notably the Chemical Safety Report (CSR) may be submitted jointly by registrants.

In any event, any specific information will have to be prepared and submitted separately by each registrant.

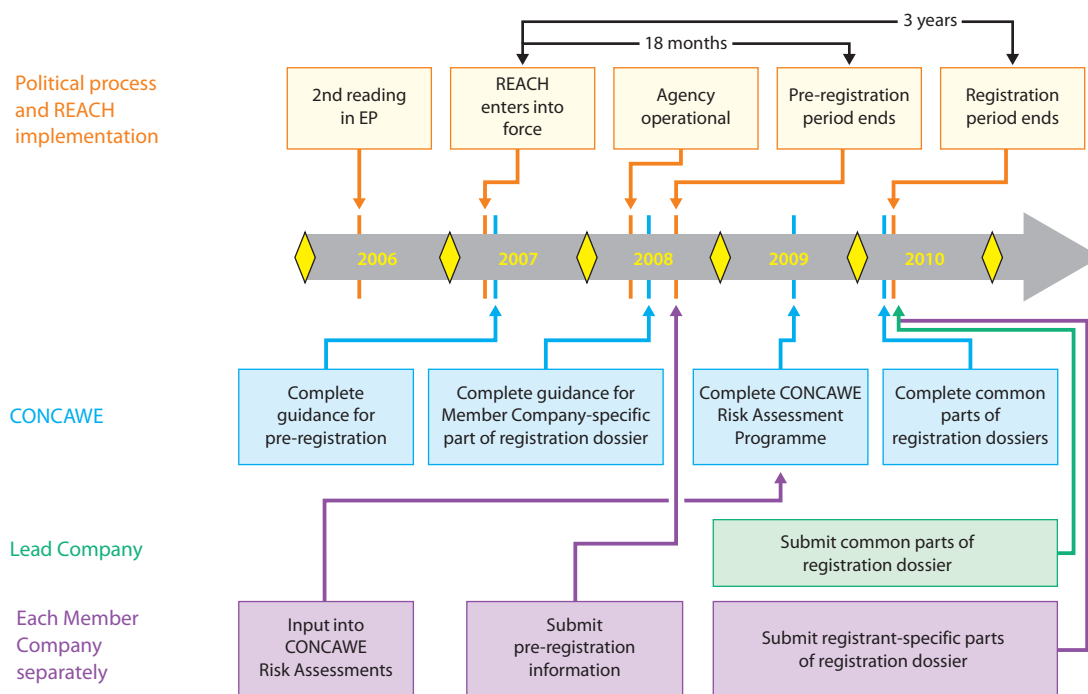
The registration process starts with a pre-registration step. Each individual registrant will have to submit its name and address and the CAS number of the substance. The Chemical Agency will inform other registrants for the same CAS number, to enable them to work collectively on the common elements of the registration dossier and to share the relevant information for these elements.

A period of 18 months is foreseen for the pre-registration process, beginning with the date when REACH enters into force. Since the Chemical Agency is actively involved in the pre-registration process, it is worrying that it will only become operational one year after REACH has entered into force.

At face value the registration of petroleum substances appears to be a straightforward task. However, the REACH system is designed for the vast majority of registration cases, i.e. for single substances, whereas practically all petroleum substances are process streams of varying composition containing many different constituents.

CONCAWE's voluntary risk assessment programme for petroleum substances will enable CONCAWE and its members to prepare for the registration and, if and when required, the authorisation of petroleum substances under a REACH regime in a proper and timely fashion. For the risk assessments to serve these purposes, it is critical that member companies ensure

**Figure 1 REACH implementation timelines ( $\geq 1,000$  t/a volume band) and CONCAWE activities/actions**



*Practically all petroleum substances fall into the  $\geq 1,000$  t/a volume band and will therefore have to be registered before April 2010 assuming that REACH comes into force in April 2007. Figure 1 illustrates the registration process.*

<sup>1</sup> The GHS, i.e. the Globally Harmonised System of Classification and Labelling of Chemicals, will be implemented in parallel with REACH and replaces existing legislation. For registrants under REACH this implies additional work as the GHS is not identical to the current regime.

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that company-/site-specific information on manufacturing, storage and use is made available.

### What will CONCAWE do to support its Members?

For classification and labelling of petroleum substances, as well as for its voluntary risk assessment programme, CONCAWE has developed a methodology that allows grouping of substances for two purposes:

- a) to determine the inherent properties of refinery streams with a minimum of testing, vertebrate animal tests in particular; and
- b) for a common risk assessment.

Using the risk assessment for gasoline as an example, the methodology has been presented to, and discussed with, the TCNES (Technical Committee for New and Existing Substances). The TCNES has supported the methodology in principle.

The CONCAWE risk assessments for petroleum substances will form the basis for the various elements of REACH registration dossiers.

Moreover, the Commission has invited CONCAWE to draft technical guidance for petroleum substances, which will then be incorporated in the overall technical guidance for industry currently developed as part of the Commission's REACH Implementation Projects.

In terms of specific work for its Members CONCAWE will prepare:

- the common dataset;
- the common classification and labelling proposal; and, if required
- the testing proposal.

Under OSOR these elements will have to be common to all registrants, so registrants that are not CONCAWE Members will also benefit from this work subject to agreement on cost-sharing.

CONCAWE will also prepare Chemical Safety Reports for its Members. OSOR does not require these to be shared among all registrants.

In addition CONCAWE will develop specific guidance (and, where appropriate, templates) on the pre-registra-

tion of petroleum substances<sup>2</sup>; and the registrant specific elements of the registration dossier.

In parallel CONCAWE will determine whether, and if so which, petroleum streams may become subject to the authorisation scheme of REACH.

### Conclusion

It is essential to complete the CONCAWE Risk Assessments for Petroleum Substances within a time frame that allows for the preparation of registration dossiers well before the end of the registration period, currently expected to be spring 2010. This will be a major challenge but Members can contribute to a timely completion by providing the necessary information without delay. In view of the time pressure and the size of the task it will be impossible to adjust the risk assessments and to incorporate missing information at a later date.

Special Task Forces (STFs) have been formed in CONCAWE that will provide the input for the registration of petroleum substances and reclassify them in line with the Globally Harmonised System of classification and labelling as adopted by the EU. However, CONCAWE can only provide the input. Based on this input its member companies will have to prepare those elements of the registration that are specific for the registrant and they will have to carry out the registration.

It is therefore essential that all CONCAWE member companies fully understand their obligations under REACH and GHS, and that they proactively prepare the registrant-specific elements of the registration dossiers. Active participation in the CONCAWE Special Task Forces is the most efficient way to achieve this.

<sup>2</sup> *Determining the identity of substances is no trivial task. The Commission has recognised this and set up a specific REACH Implementation Project which has just completed draft guidance on substance identity.*