The authorisation of substances under REACH

What is the process?

The main elements of the REACH regulation (EU Official Journal L396, Vol 49, 30.12.2006) which enters into force on 1 June 2007, are the registration, evaluation, restriction and authorisation of chemical substances. With the exception of crude oil, which is regarded as a naturally occurring substance, all other petroleum substances will be subject to registration. After a volume band dependent deadline (30 November 2010 for practically all petroleum substances), a registration will be required to manufacture a substance in the EU or to import it from outside the EU, hence the slogan 'No data, no market!'

Whereas the registration of substances and their safe use is the sole responsibility of industry, evaluation, restrictions and authorisations are tasks for the new European Chemicals Agency (ECHA), the Member States and/or the Commission. This includes identifying exactly which substances are to be subject to an authorisation procedure. The decision whether certain uses of a substance identified for an authorisation procedure will be granted authorisation is the sole responsibility of the Commission.

The most immediate priority for CONCAWE and its member companies is the assessment of petroleum substances and the demonstration of their safe use throughout the supply chain so that they can be pre-registered by 1 December 2008 and subsequently registered by the volume-specific deadlines. However, it is also important to understand whether petroleum substances will, or could be, subject to authorisation and if so, what the process would be.

Which substances are affected?

Article 57 of REACH defines which substances could be subject to an authorisation procedure:

1. Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMRs) category 1 or 2 in accordance with Directive 67/548/EEC.
2. Substances which are persistent, bioaccumulative and toxic (PBTs) or substances which are very persistent and very bioaccumulative (vPvBs) in accordance with the criteria set out in REACH itself.
3. Substances, such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria under 1 and 2, and for which there is scientific evidence of probable serious effects to humans or the environment which give rise to an equivalent level of concern to those of other substances described above and which are identified on a case-by-case basis in accordance with the procedure set out in REACH.

These substances are also referred to as substances of very high concern (SVHCs).

Whereas the criteria for SVHCs in the first two groups, i.e. CMRs, PBTs and vPvBs will, in principle, be well-defined and sufficiently transparent, and the consequences therefore predictable, the criteria for substances in the third group, often referred to as 'substances of an equivalent level of concern', are more obscure and will leave room for interpretation by the authorities. This has already become apparent in the Technical Guidance Document that is currently in preparation.

Known CMRs category 1 or 2 already have mandatory 'Community harmonised' classifications under existing law, and restrictions for their marketing and use are already in place. This includes a number of petroleum substances, for example gasoline.

However, there are exemptions from the need for authorisation. For the petroleum industry the most important exemptions are in Article 56(4):

- use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council; and

- use of mineral oil products as fuel in mobile or fixed combustion plants and in closed systems.

The term 'combustion plant' is defined in Directive 2001/80/EC, article 2(7) as 'any technical apparatus in which fuels are oxidised in order to use the heat thus generated' and includes home heating appliances.

Petroleum substances that are known CMRs category 1 or 2 will not become subject to an authorisation procedure as long as they are exclusively used as fuel.

Whether petroleum substances are PBTs or vPvBs in the definition of REACH will be established in the mandatory PBT assessment, which is part of the registration dossier that registrants will have to submit. This is currently work in progress and it is too early to say whether the application of the REACH criteria will lead to the identification of PBTs or vPvBs among the petroleum substances.

The identification of substances of equivalent concern is not an obligation for industry. This will be done by the authorities. In view of the wide margin for interpretation of the criteria, the outcome of the evaluation by the authorities is totally unpredictable.

Petroleum substances identified as PBTs, vPvBs or substances of an equivalent level of concern will not be affected by authorisation if used exclusively as fuel, as the exemption discussed above would still apply.

What triggers an authorisation dossier?

The decision making process, which triggers an authorisation dossier, can be summarised as follows:

- The registrant, a member state (MS) or the ECHA identifies or suspects that a substance is a CMR 1/2, PBT vPvB or of equivalent concern.
- An MS selects such substance and prepares an Annex XV dossier.
- The MS submits the Annex XV dossier to the Agency.
- The ECHA informs stakeholders, including registrants, that an Annex XV dossier has been submitted. It should be noted that the registrants have no access to the Annex XV dossier.
- If they wish to do so, the stakeholders formally submit comments to the Agency.
- The ECHA includes the substance in the candidate list, which will be published.
- The ECHA recommends priority substances (priority criteria are: PBTs, vPvBs, wide dispersive use, high volume), selects substances for its work programme and informs the stakeholders. The capacity of the ECHA to handle authorisations will be taken into account.
- If they wish to do so, the stakeholders formally submit comments to the Agency.
- The ECHA finalises its recommendations.
- The Commission amends Annex XIV (the list of substances which will then need to undergo an authorisation procedure) and sets a sunset date, i.e. the date after which a substance may no longer be manufactured/imported and put on the market without an authorisation.
- The registrant(s) submit(s) an application for authorisation at least 18 months before the sunset date.

What is the process by which an authorisation is granted?

Substances for which exposures are below their 'Derived No Effect Level' (DNEL) and their 'Predicted No Effect Concentration' (PNEC) are deemed to be adequately controlled. For these cases an authorisation will be granted.

To obtain an authorisation for substances where it is not possible to establish a DNEL, as well as those identified as PBTs and vPvBs (i.e. substances for which adequate control cannot be shown) it will have to be demonstrated that their socioeconomic benefits outweigh the risk.

All authorisations will be time limited. Before an authorisation expires the manufacturer/importer may apply for an extension. However, already in the first authorisation round the applicant is obliged to submit a substitution plan as part of his application for an authorisation.