Reach will start to be implemented in June and companies are being urged to prepare for it. This is easier said than done, with many areas of the legislation still decidedly fuzzy, as Sean Milmo reports.

Reach will start to be implemented on 1 June. Its registration procedure will take 11 years to be completed but companies need to pre-register chemicals within 12–18 months. Trade associations are urging companies to prepare for Reach as soon as possible. Gathering data for Reach will depend on cooperation down the supply chain, from end-users to chemical producers.

European chemical producers, importers and their customers can be forgiven for thinking that they can take their time with Reach, the EU scheme for the registration, evaluation and authorisation of chemicals. Reach will start to be implemented in June but the registration procedure, which comprises the core of the project, will take 11 years to be completed.

In fact, trade associations representing chemical producers and downstream users of chemicals are advising their members to start preparing themselves for Reach as quickly as they can. A delay in responding to Reach could mean that a company will have to spend far more time and money than is necessary to ensure that it is complying with the legislation.

‘On the whole, companies should be getting ready for Reach as soon as possible,’ says Steffen Erler, technical manager at REACHReady, the help desk of the UK Chemical Industries Association (CIA).

‘There will be registration dossiers for low-volume chemicals without any health or environmental hazards whose producers and importers will not have to worry too much about being prepared for Reach early on,’ he says. ‘But others will not want to be landed with the extra costs of providing registration data because they were slow in finding out what safety information would be needed for the registering of their chemicals.’

The warnings about the dangers of deferral are aimed in particular at small and medium sized companies (SMEs) who could be hit the hardest by Reach because they tend to know much less about the safety profiles of their products than larger players. Larger companies, both chemical producers and users, have long been organising themselves in anticipation of Reach.

All in the tonnage SMEs are responsible for a large majority of the chemicals that are manufactured or imported by individual companies in amounts of between one and 10 tonnes a year and which account for most of the estimated 30 000 chemicals due to be registered under Reach.

In short

● Reach will start to be implemented on 1 June. Its registration procedure will take 11 years to be completed but companies need to pre-register chemicals within 12–18 months.

● Trade associations are urging companies to prepare for Reach as soon as possible.

● Gathering data for Reach will depend on cooperation down the supply chain, from end-users to chemical producers.

Producers of low-volume and relatively benign chemicals needn’t lose sleep over Reach.

Reach
This is the lowest of the four tonnage ranges – the others being 10–100 tonnes, 100–1000 tonnes, and other chemicals at or above 1000 tonnes. The registration deadline for substances in the tonnage bands from 1–100 tonnes is 11 years, for 100–1000 tonnes six years and for those above 1000 tonnes and categories of high concern three and half years.

The data requirements for chemicals produced or imported in small quantities are the least restrictive. Nonetheless in some circumstances their registration, particularly for those inexperienced in handling safety data, could be fraught with difficulties.

Even more vulnerable to pitfalls in acquiescing with Reach will be SMEs that are users of chemicals, particularly formulators such as coatings or inks manufacturers. They will have to gather safety data on the use of chemicals they apply and process while they could also be obliged to provide detailed safety information to their own customers about the chemicals in their products.

A key reason why companies have to react early to the demands of Reach is that gathering of registration, as well as authorisation, data will depend a lot on cooperation down the supply chain. Much of the information on the effects of chemicals on health, safety and the environment will come from the users of the chemicals, even though most of the registration dossiers will be drawn up by the chemical producers themselves.

**Disappearing from market**

A relatively large number of chemicals could be withdrawn from the market as a result of Reach, either due to the cost or difficulties of the registration process or problems in gaining authorisation.

‘If a chemical is no longer going to be available, a coatings or inks producer, for example, will want to know about it as soon as possible,’ explains Jacques Warnon, technical director at the European trade association of coatings (Cepe). ‘It may take time to find a suitable replacement because the coatings manufacturer will want to make sure it is not dangerous and that it works well in the company’s formulations. The company will also want to ensure there is a suitable supplier of an alternative.’

When the European Commission put forward its first proposals for Reach around eight years ago, both chemical producers and their customers became worried about the possibility of large quantities of chemicals being taken off the market as a result of the project.

The likely number of withdrawals is still not clear. Although the Reach legislation was finally approved by the European Parliament and the Council of Ministers representing the EU governments at the end of last year (see *Chemistry World*, January 2007, p8), some important features of the scheme have yet to be finalised.

‘The approval of the legislation has now enabled us to understand the strategy and direction behind Reach,’ says Peter Newport, director of the UK Chemical Business Association (CBA), which represents chemical distributors, many of them importers. ‘But the devil is in the detail, which is still to come. Until more is known about how Reach will operate exactly, producers and importers cannot make decisions about which chemicals and uses they will register.’

Under the deal thrashed out by EU negotiators on 1 December 2006, the parliament agreed to drop a proposal by its environment committee to have stricter requirements for the registration data for chemicals within the 1–10 annual tonnage range. As a result, registration of these chemicals will only have to include detailed information on the assessment of risks to human health and the environment if the chemicals have properties of ‘very high concern’. This concession should be a major benefit to SMEs because of the expense and time needed to collect the extra data on potential risks.

The biggest component of the deal related to the estimated 5 per cent of the 30 000 chemicals to be registered which would require separate authorisation. These could be substances categorised as being carcinogenic, mutagenic and toxic (CMRs), persistent, bioaccumulative and toxic (PBTs) and very persistent and very bioaccumulative (vPvBs).
Almost every day, we hear news of terrorist attacks and conspiracies, highlighting the need for security technologies to keep pace with the changing threat.

To support the UK’s Counter Terrorism Strategy the Home Office, Department for Transport, Centre for the Protection of National Infrastructure and Metropolitan Police Service are inviting companies and academic institutions to submit innovative proposals in the field of explosives and weapons detection.

If you convince us that have the relevant research and development capability you will be invited to our bidders’ conference to hear about our requirements. And, later, you can submit your ideas for funding.

Visit http://science.homeoffice.gov.uk/hosdb/ to see further details of the process and to request a Pre-Qualification Questionnaire. The deadline for receipt of questionnaires is 30 April.

For security reasons the organisers reserve the right to refuse admittance to the bidders’ conference and further participation.

Malcolm Campbell Memorial Prize 2007

The Biological and Medicinal Chemistry Sector of the RSC is proud to announce the winner of the Malcolm Campbell Memorial Prize for 2007. This year’s award attracted the largest number of high quality entries to date and the prize has been awarded to the team from Organon, Scotland for the discovery of sugammadex (Org 25969), the first selective relaxant binding agent (SRBA). Sugammadex is specifically designed to quickly and safely reverse the effects of muscle relaxants used during general anaesthesia and is currently in late Phase III development.

The Malcolm Campbell Memorial Prize commemorates Professor Campbell’s outstanding contributions in a broad range of chemistry and their applications to the understanding of bioactivity. The prize is awarded bi-annually, and the 2007 prize will be formally presented to the winning team during the RSC/SCI Medicinal Chemistry Symposium to be held in Cambridge, 23rd-26th September 2007.

The BMCS Committee wishes to express its gratitude for all the nominations received from both industry and academia for the 2007 award.

www.rsc.org/bmcs

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The parliament and council decided that the authorisation of these chemicals would be allowed only when safer and economical alternatives are not available. Applicants for authorisation would have to demonstrate that the use of the chemicals is adequately controlled so that their use remains within approved safety thresholds. Those without safety thresholds would only be authorised if a social-economic analysis (SEA) confirms that the advantages of their remaining on the market outweigh the impact of a ban.

Companies requiring authorisations will have to submit substitution plans for the products, including, if necessary, details of R&D programmes to find suitable alternatives. The European Chemical Industry Council (Cefic) has claimed that this arrangement could lead to mandatory substitutions.

### Identity crisis

For the EU legislators, Reach’s major objective is to replace chemicals that arouse the biggest worries about their safety. ‘The substitution principle is clearly the cornerstone of the whole of this legislation on chemicals,’ says Guido Sacconi, the rapporteur on Reach for the parliament’s environment committee, who had a strong influence on the wording of the text of the final draft.

Exactly how the substitution principle will be applied has yet, as with several aspects of Reach, to be laid down in detail in guidelines being drawn up by Reach Implementation Projects (RIPs) (see box above).

One of the RIPs has the task of clarifying the identity of substances, which will be an important consideration for companies wanting to be ready early for Reach. ‘You have got to know first of all which chemicals you are making, selling or using, which is not as easy as it might seem’, says Erler.

Substances, defined as chemical elements and their compounds which are made through a manufacturing process, are categorised in the legislation as either being ‘phase in’ or ‘non phase-in’. The former are chemicals registered on the European Inventory of Existing Commercial Chemical Substances (EINECS) before September 1981. New chemicals introduced after 1981, of which there are around 3000, are not covered by Reach because they are already considered to have gone through an equivalent rigorous approval process. Non phase-in chemicals are those launched on the EU market after Reach comes into force, requiring prior registration and approval.

Some chemical companies might find that certain chemicals have not...
been properly registered in EINECS, so that their identity will need to be clarified as soon as possible,’ explains Erler.

Once the standing of a substance within Reach has been verified, the next major step is to assess its health and environmental safety and the availability of test data. This could be particularly important for users, as well as producers, of chemicals because new rules on safety data sheets (SDSs) for both chemicals and preparations will be immediately implemented when Reach comes into force.

SDSs will be needed for vPvBs and for some preparations containing certain hazardous chemicals. Companies may have to inform their customers if an article or finished product they sell contains hazardous substances categorised as being of very high concern.

Identifying substances is also necessary for companies to pre-register chemicals, which has to be done within 12 to 18 months of the scheme coming into force. The basic information required for pre-registration includes the name and identity code of the substance (like that in EINECS), the name and address of a contact person, the envisaged deadline for the registration in line with the tonnage band, and information on the status of the substance in respect of the need for data sharing and possible safety tests.

The main objective of pre-registration is to alert downstream users to the likelihood of substances being withdrawn from the market because their producers or importers are not planning to register them. However, a significant omission from the obligatory data for pre-registration is the identification of uses of substances. So for purchasers of a chemical, its pre-registration will not be a guarantee that its supplier will be registering their use of it.

Instead, downstream users will have to keep in close contact with producers and importers to find out their plans for registration of uses. One important means of doing this will be through substance information exchange forums (SIEFs) which will be set up following pre-registration. There will be one forum per substance with an estimated average of five participants on each one.

In the Commission’s original proposals for Reach, membership of SIEFs was to be restricted to chemical producers and importers. But downstream users, led by the Downstream Users of Chemicals Co-ordination group (DUCC), comprising mainly representatives from the paints, detergents and cosmetics trade associations, lobbied successfully for chemical purchasers to be allowed to be members of the forums.

Data sharing
In order to help to reduce registration costs, Reach lays down arrangements for sharing safety and test data. These are based on the principle of one substance, one registration (OSOR), under which registration of single substances producers or importers will have to be done jointly. Companies will, however, have a right to opt out of sharing some data mainly on the grounds of confidentiality of information. But sharing animal test data will be obligatory.

The main vehicle for implementation of OSOR will be SIEFs, which will have a major role to play in sharing hazard data on substances, especially those in tonnage bans above 10 tonnes a year. Their registration dossiers will have to contain chemical safety reports (CSR), based on chemical safety assessments and exposure scenarios. SIEFs should also help companies to decide how far they want to share data. But they will also provide a means for selling and buying safety data for completing registration dossiers.

‘Companies will need to be ready for participation in SIEFs as soon as they can,’ says Erler. ‘They will want to find out what they may be able to sell and what they might have to buy through the forums.’

Since SIEFs will include representatives from the full length of the supply chain – even retailers who may be classified as importers of substances – they will provide a platform for close communication between chemical producers and downstream users. But as with much of the rest of Reach the groundwork for the forums will have to be established at an early stage to ensure that they work effectively.

Businesses scratching their heads over Reach can spare a thought for the EU member states having to deal with the legislation. Each member state must set up a system of controls and penalties for breaches of Reach. The UK Department for the Environment, Food and Rural Affairs has launched a consultation document which considers who should enforce Reach requirements and the powers they will need (see further information).

It would seem that chemical producers and importers are stuck between a rock and a hard place. Should they wait until all the grey areas of Reach are scrubbed clean or make assumptions and get cracking on collecting data? Best follow the CIA’s advice and get ready for Reach ‘as soon as possible’.

Sean Milmo is a freelance journalist based in Braintree, UK

Further information
- The CIA’s REACHReady offers advice and information on Reach: www.reachready.co.uk
- UK Health and Safety Executive helpdesk: UKREACH@hse.gsi.gov.uk

RSC and GDCh cooperate

As part of the RSC and the German chemical society’s (GDCh) collaborative work, Chemistry World and Nachrichten aus der Chemie are publishing a series of articles simultaneously in both magazines. This article continues the series.

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