LUBE-TECH

The first part of a two-part feature No.45

EU STRATEGY FOR A FUTURE CHEMICALS POLICY: REACH

While the REACh legislation has still to be fully defined, and this process is now not expected to recommence until 2nd half 2006, this feature provided by SafePharm provides a substantial technical assessment of the detailed Registration Evaluation and Authorisation process for Chemical Substances, as it currently stands, with which companies will need to comply to satisfy REACh legislation.

1. BACKGROUND

On 13 February 2001 the European Commission adopted the much-discussed White Paper 'Strategy for a Future Chemicals Policy' [1]. This proposes a wide-ranging fundamental overhaul of EU chemical control legislation, ie the Dangerous Substances Directive (DSD) [2], including the notification scheme for new substances [3], the Dangerous Preparations Directive (DPD) [4], the Existing Substances Regulation [5] and the Marketing and Use Directive [6]. In essence, the legislation for new and existing substances would be merged. The current EU chemical control measures result in too great a disparity between new and existing substances, with the high cost of new substance notification stifling innovation. Furthermore, existing substances account for >99% by volume of chemicals in commerce, but are poorly assessed and controlled in comparison.

The European Commission published the first draft of legislation intended to implement the White Paper on 7 May 2003 [7]. This is the Registration, Evaluation and Authorisation (REACH) scheme for chemicals. There was an 8-week Internet consultation on the 'workability' of this legislation from 16 May to 10 July 2003 and about 6,400 contributions were received. A revised version emerged in September 2003, jointly from the Enterprise and Environment Directorates of the European Commission and after consultation within the Commission, the final proposed Regulation was presented on 29 October 2003 [8]. These formal legislative proposals have to be discussed by the Council of Ministers and the European Parliament, under the Co-decision Procedure. The European Parliament approved a compromise text developed by the UK Presidency on 17 November 2005 and the Competitiveness Council reached political agreement on 13 December 2005. This paves the way for REACH to enter into force in the summer of 2007, with the European Chemicals Agency (ECA) being fully operational a year later. Meanwhile, work on the REACH Implementation Projects (RIPs) continues, with the EU Joint Research Centre (JRC) gearing up to take a greater role in preparing the technical guidance documents. The new and existing substances regimes will continue until the REACH regime starts to become operational.

2. REACH: REGISTRATION, EVALUATION AND AUTHORISATION OF CHEMICALS

REACH will place a duty on companies that produce, import and use chemicals to assess the risks arising from their use (with new studies conducted in justified cases), and to take the necessary measures to manage any risks identified. Hence the burden of proof will be transferred from the regulators to industry for putting safe chemicals on the market. Testing results have to be shared to reduce any animal testing, and registration of information on the properties, uses and safe use of chemical substances will be an integral part of the new system. These registration requirements will vary depending on the volume in which a substance is produced, and on the likelihood of exposure to humans or the environment. A phase-in system lasting up to 11 years is planned. Higher tonnage substances would require the most data, and would have to be registered first; lower tonnage substances would require less data and be registered later.

Tighter controls will be introduced for the chemicals of highest concern, *i.e.* carcinogens, mutagens and reproductive toxicants (CMR's), persistent, bioaccumulative and toxic substances (PBT's) and very persistent and very bioaccumulative substances (vPvB's) will be subjected to an authorisation regime and hence will be registered early. Other substances of concern, such as endocrine disrupters, will be included on a case-by-case basis within the authorisation system. Substances subject to authorisation will have to be approved for a specific use, with decisions based on a risk assessment and consideration of socio-economic factors.

The REACH system will be administered by the new ECA in Helsinki.

3. THE COMPROMISE TEXT AND PLANNED DEVELOPMENTS

The first reading on 17 November 2005 of the proposed REACH Regulation by the European Parliament took place and considered over 1,000 tabled amendments. A compromise text was approved, in a deal brokered by Guido Sacconi. Pre-registration of all existing 'phase-in' substances will be in a single phase 18 months after the Regulation comes into force, but with a further 6 months allowed for SME's and downstream users. Earlier registration will be required for PBT and vPvB existing substances. Full safety data will only be required for registration of substances at 1 to 10 tonnes per annum if they are suspected to be classified as carcinogenic, mutagenic or toxic for reproduction (CMR) or are assessed as classified as dangerous to human health or the environment and are for dispersive or diffusive use, particularly if used by consumers. Reproduction toxicology data will normally be needed at 100 tonnes per annum and above instead of at 10 tonnes per annum. Waiving of studies on the grounds of low exposure is introduced for specific tests at all tonnages. The 'one substance one registration' (OSOR) requirement was agreed, but with the possibility of opting out if the cost would be disproportionate, where there would be a breach of confidentiality or a disagreement on the hazardous properties, but sharing of animal testing would still be mandatory and also sharing of non-animal testing if requested by one potential registrant. Authorisation of very high concern substances will now be subject to periodic review.

The European Commission considers that work on existing substances under the Existing Substances Regulation [5] will be completed. New substance notifications made in the run up to REACH will be handled as their equivalents under REACH. Similarly work will carry on for classification and labelling, but with a shift towards using the REACH documentation from 2006, and the 31st Adaptation to Technical Progress (ATP) of the Dangerous Substances Directive is planned for November 2006.

The European Commission plan to bring into force a new Regulation implementing the Global Harmonised Classification Scheme (GHS) [9] at the same time as REACH becomes operational, which would align with the stated political intention to implement GHS by 2008. A draft Regulation to implement the GHS is in preparation and a three-month internet consultation is planned to start in the first quarter of 2006, after which the European Commission will publish a formal proposal.

4. REGISTRATION

All substances manufactured or imported in the EU at ≥ 1 tonne per annum will be registered with the ECA, who will assign a registration number and performs a completeness check using an automated process, normally withing three weeks. The registrations are forwarded to Member State competent authorities and entered onto a database of registered substances. Under the compromise text, at least 5% of registration dossiers are to be checked in more detail by the ECA.

Registration will be needed before new substances are manufactured or imported. Manufacture or import of new substances can begin 3 weeks after the registration date, unless the ECA informs the registrant that the registration is incomplete.

All phase-in substances, ie. those listed in the European Inventory of Existing Chemical Substances (EINECS) or manufactured in the EU 15 years before the Regulation comes into force, have to be registered in a prioritised review. The deadlines for registration of such 'phase-in' substances are based on the date the new Regulation comes into force (Table 1). The compromise text requires earlier registration of substances classified as very toxic to aquatic organisms that may cause adverse effects in the aquatic environment (ie. labelled with R50/53). A new manufacturer or importer of a phase-in substance can participate in the review and enter the EU market under the compromise text. It is important to note that new substances already notified under the current DSD scheme are considered as registered under the new REACH system, but further information is required under REACH if the manufacture or import quantities are triggered. It is anticipated that ca 30,000 substances will be registered, with at least 10,000 requiring new testing.

Table 1.

- Register new substances at ≥ 1 t.p.a. before manufacture or import.
- Pre-registration of all phase-in substances within a 6-month period, beginning 12 months after the Regulation comes into force.
- Registration for phase-in substances (from date Regulation in force):
  - CMR's (> 1 t.p.a.): 3 years
  - > 100 t.p.a (R50/53).: 3 years
  - > 1,000 t.p.a : 3 years
  - > 100 t.p.a.: 6 years
  - > 1 t.p.a.: 11 years
- Draft decisions for phase-in substances for further testing:
  - CMR's (> 1 t.p.a): 5 years
  - > 100 t.p.a (R50/53).: 5 years
  - > 1,000 t.p.a.: 5 years
  - > 100 t.p.a.: 9 years
  - > 1 t.p.a. (if any): 15 years

5. EVALUATION

It is estimated that around 80% of the registered substances will not proceed to the next stage of evaluation. However, the registration information for the ca 5000 substances exceeding a manufacture or import volume of 100 tonnes per annum will have to be evaluated. The registration dossier for substances at 100 tonnes per annum includes a proposal for Annex VII testing, and some substances at below this tonnage will also have additional proposed testing. For new substances, the ECA evaluate the proposal and produce a draft descision within 180 days. Evaluation of testing proposals for phase-in substances has to be completed as shown in Table 1, with priority being given to substances with CMR, PBT, vPvB or sensitising properties. The registrant is set a deadline to submit the additional studies for examination by the ECA. At 1,000 tonnes per annum an equivalent procedure is followed for Annex VIII testing.

There is also a procedure for evaluating substances. The ECA select substances for evaluation base on a risk-based approach, taking into account the hazardous properties, including of analogous substances, exposure and tonnage, including aggregated tonnage from all registrants. Such substances are evaluated by Rapporteur Member States, who select substances from the EU rolling action plan. The outcome may be EU harmonised classification, restrictions or adding to the list for authorisation.

6. AUTHORISATION AND RESTRICTIONS

Substances of very high concern will have to be authorised before being used for specific purposes that have been demonstrated to present a negligible risk. It is estimated that ca 1,400 substances will

Table 2. Criteria for Identification of PBT and vPvB

Criterion	PBT criteria	vPvB criteria
P	Half-life > 60 d in marine water or > 40 d in fresh or esturine water or half-life > 180 d in marine sediment or > 120 d in fresh or esturine water sediment or half-life in soil > 120 d	Half-life > 60 d in marine, fresh or esturine water or > 180 d in marine, fresh or esturine water sediment or half-life in soil > 180 d
B	BCF > 2,000 in fresh or marine aquatic species	BCF > 5,000
T	Chronic NOEC < 0.01 mg/l for fresh or marine water organisms, Category 1 or 2 carcinogen or mutagen or Category 1, 2 or 3 toxic for reproduction or chronically toxic (*i.e.* classified as T or Xn with R48)	Not applicable

(a) BCF is bioconcentration factor, NOEC is no-observed effect concentration and CMR is a substance classified as carcinogenic, mutagenic or toxic for reproduction

(b) For marine environmental risk assessment, half-life data in freshwater sediment can be overruled by data obtained under marine conditions

(c) Substances are classified when they fulfil the criteria for all three inherent properties for P, B and T. However, there is certain flexibility, for instance in cases where one criterion is marginally not fulfilled but the others are exceeded considerably.

be subject to authorisation. There will be a published list of these very high concern substances that are candidates for authorisation. Very high concern substances are substances classified as category 1 or 2 carcinogens, mutagens or toxic for reproduction (CMR's) or persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). The PBT and vPvB criteria given in Annex XII of the Regulation are summarised in Table 2. Endocrine disruptors not covered by these criteria will be added to the list of very high concern substances on an ad hoc basis.

The first step is to identify existing substances, or particular uses of substances, requiring authorisation, and to decide on a deadline for authorisation and any uses exempted from authorisation. As additional very high concern substances are identified, largely from testing for registration and evaluation, they will be fed into the authorisation system.

Particular uses of very high concern substances will be authorised in the second step on the basis of a risk assessment covering all stages of the life-cycle for that particular use submitted by industry. The risk assessment will focus on exposure assessment for the use, and generally no new studies would be required. There is the possibility of authorisation based on adequate control of exposure, but not for PBT's, vPvB's and 'non-threshold' CMR's. However, the ECA can take into account socio-economic factors in deciding if the use of the substance can nevertheless be authorised in the EU. The compromise text gives greater emphasis to the substitution principle, and applications for authorisation have to be accompanied by an analysis of possible alternatives with their risks and the technical and economic feasibility of substitution.

The compromise text introduced an amendment to require authorisations to be subject to time-limited review, to allow further consideration of alternative substances. Authorisation is also reviewed if information on possible substitutes is submitted to the ECA.

Restrictions for persistent organic pollutants (POP's) required under the Stockholm Convention will also be implemented through the restrictions provisions of the Regulation.

7. REGISTRATION OBLIGATIONS

Substances manufactured or imported, either neat or in a preparation, at > 1 tonne per annum have to be registered, unless exempted. There is the option for a non-EU manufacturer to appoint an EU representative to register the substance on behalf of the EU importer(s).

Some substances in articles are subject to registration, and the provisions have been clarified under the compromise text. Substances in articles have to be registered if they are intended to be released from the article and are supplied at > 1 tonne per annum. Instead of registration, a less onerous procedure of notification applies to substances present in articles at above 0.1% unless release of the substance is excluded. Under the compromise text articles manufactured in the EU are treated the same as imports. However the ECA can require a substance in an article to be registered if it poses a risk to human health or the environment.

Substances notified under the DSD are considered as having been registered, as are active substances used only for products covered by the Plant Protection Products Directive [10] or the Biocidal Products Directive [11] or for coformulants of Plant Protection Products.

The Regulation as a whole does not apply to radioactive substances, substances under customs supervision, substances in transit and non-isolated chemical intermediates or waste. Member states can exempt substances in the interest of defence. Substances are also exempt from registration if regulated by equivalent EU legislation (human and veterinary pharmaceuticals, food additives and flavourings, animal feed and substances used in animal nutrition). Furthermore, certain categories of substance are exempt from registration (Table 3).

Table 3. Categories of Substance Exempt from Registration

- The specific substances listed in Annex II of the Regulation
- Substances covered by Annex III:
  - Degradants from environmental factors
  - Chemical degradants from storage
  - Products from use
  - Products from reaction with additives
  - By-products
  - Hydrates, providing the anhydrous form is registered
  - Non-dangerous natural substances
  - Hydrogen, oxygen, nitrogen and the noble gases
  - Minerals, ores and ore concentrates, natural gas, crude oil and coal
- Monomers bound into polymers, but note that registration is required if the monomer is present at ≥ 2% (w/w) in the polymer and is at ≥ 1 tonne per annum
- Polymers
- Food and food ingredients
- Waste and certain recycled materials
- Substances needed in the interests of defence.

Non-isolated chemical intermediates do not have to be registered. Site isolated intermediates at ≥ 1 tonne per annum are registered with information on the identity of the manufacturer and substance, classification and available test data. Registration also applies for transported isolated intermediates, which are transported between or supplied to other sites under contractual control (including for toll or contract manufacture) and for which there are strict conditions for manufacture and use to ensure only limited exposure. When transported at ≥ 1 tonne per annum these are registered with the same information as site isolated intermediates, but at > 1,000 tonnes per annum the basic Annex V test data are needed.

Although polymers do not have to be registered, if a polymer contains a monomer or other starting substance at ≥ 2% (w/w) in chemically bound form at ≥ 1 tonne per annum that has not been registered by another registrant, this monomer or starting substance has to be registered by the polymer manufacturer or importer.

Substances used only for process-orientated research and development (PORD) are exempt from registration for 5 years (extendable for a further 5 years on application in exceptional circumstances or 10 years for substances used exclusively to develop human or veterinary medicines). The manufacturer or importer has to inform the ECA of the substance identity, labelling and quantity and list the customers. Those customers can only use the PORD substance and it cannot be supplied to the public.

8. THE REGISTRATION DOSSIER AND CHEMICAL SAFETY REPORT

Annexes IV to VIII of the Regulation specify the information needed for registration. The general technical, commercial and administrative information needed for all registrations for the technical dossier is specified in Annex IV (Table 4) overleaf.

The technical dossier, including robust summaries of the study reports, for registration of chemicals under REACH is to be submitted to the ECA electronically using the International Chemical Information Database (IUCLID) format [12], which is a well-established database format for communicating and storing information on chemicals.

Table 4. General Annex IV Information Needed for Registration

- Technical dossier (in a specified electronic format):
  - Annex IV technical data on the registrant, identification of the substance, manufacture and use and guidance on safe use
  - Robust summaries of safety data
  - Proposed classification and labelling
  - Statement whether animal testing was conducted
  - Proposal for any further testing
- Chemical Safety Report , for subtances at > 10 tonne per annum. This is a risk assessment including PBT and vPvB assessment.

A Chemical Safety Report (CSR) is required for substances registered at 10 tonnes per annum unless the substance is present only on a preparation at below 0.1% or below the concentration limit(s) triggering classification as dangerous of the preparation. This is a risk assessment, following the general provisions of Annex I of the proposed REACH Regulation. Substances that are used only to formulate cosmetics or to manufacture food-packaging materials are dual regulated, they still have to be registered under REACH, although they are subject to separate EU measures that involve an evaluation of their safety to humans. Hence, in order to avoid duplication of work, the CSR only has to include an environmental risk assessment. The compromise text gives clarification on the CSR for special preparations such as alloys. These general risk assessment principles correspond with the current EU practice for notified new substances and priority existing substances [13]. The ECA will develop software to help registrants prepare the CSR. It is essential to have input from downstream users to prepare the risk assessment for the CSR, which in practice may prove problematic. The CSR also includes an assessment of whether the substance is classed as PBT or vPvB according to the Annex XII criteria (Table 2).

The CSR is a key element in communicating important safety information to users, and a summary of the CSR is to be included with the safety data sheet (SDS). Guidance on SDS's is given in Annex Ia of the Regulation. Annex XI of the Regulation advises downstream users on carrying out a chemical safety assessment and producing a CSR for uses not covered in the registrant's CSR.

The information on hazardous properties, as specified in Annexes V to VIII, is linked to the manufacture/import level, on the grounds that there is a potential for more exposure as more substance is in the EU (Tables 5 to 8).

Table 5 Annex V Data for Substances at ≥ 1 tonne per annum

Melting/freezing point	Granulometry
Boiling point	Acute oral toxicity
Relative density	Skin irritation or corrosivity evaluation or in vitro tests
Vapour pressure	Eye irritation evaluation or in vitro test
Surface tension	Skin sensitisation evaluation or local lymph node assay
Water solubility	Ames test
n-Octanol-water partition coefficient	Acute Daphnia toxicity
Flash point or flammability	Ready biodegradation
Explosivity	Possible additional studies:
Auto-flammability	Further mutagenicity tests
Oxidising properties	21-day Daphnia reproduction study

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The next issue of Lube-Tech will contain the second part of this feature.

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