

REACH Implementation Opinion Statement  
Issue Number 2 Dated 3<sup>rd</sup> May 2006

Lake Chemicals and Minerals Ltd. recommends that customers and suppliers (manufacturers and importers) of substances, and, importers of formulations and articles continue to gather independent advice on the implementation of REACH (**R**egistration, **E**valuation, **A**uthorisation of **C**hemicals).

If the legislation passes through the European Parliament and Council this year (as expected) then REACH will come into force in spring 2007 (T=0). The European Chemical Agency (Helsinki) will be operational in spring 2008 and will oversee the implementation of REACH in concert with existing national organisations e.g. HSE.

The fundamental requirement of REACH is that an EU legal entity e.g. UK Company Ltd., importing a (chemical) substance into the EU or manufacturing a substance in the EU or importing a formulation of substances (preparation or article) into the EU must register the substance.

Some substances are exempt from REACH at present e.g. polymers, substances notified under ELINCS, some natural substances not chemically modified.

The first stage of REACH will be pre-registration by each legal entity of substances that are placed on the EU market in volumes > 1 tonne per annum (tpa). Information required will be substance name, EINECS #, CAS#, registrant contact details, projected registration deadline and tonnage band. Substance Information Exchange Forums (SIEFs) will be formed by companies with the same interests in the same substances.

For each legal entity registration at T+3 years (2010) will be for substances > 1,000 tpa, and, substances classified as category 1 & 2 carcinogens, mutagens and reproductive toxicants (CMRs) manufactured or imported at > 1 tpa, and, substances classified as N R50/53 and manufactured or imported at >100 tpa (R50/53 very toxic to aquatic organisms and potentially persistent, bioaccumulative and toxic (PBT)).

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Further registrations will take place at T+6 years (>100 tpa per legal entity) and T+11 years (>1 tpa per legal entity).

Costs will arise for the collation of data in the 12 to 18 months following REACH enforcement. There are likely to be few technical consultants available to hire and those that are available will cost a premium. At least for SMEs a contribution to the cost of the ECA in Helsinki has been wavered.

The data required for the Registration Dossier includes a Technical Dossier and depending on substance a Chemical Safety Report. The Technical Dossier for each substance is in part readily available from existing safety data sheets and specific animal testing information will be available in original format for some. The ECA has the power to fine companies who refuse to share animal test data with other companies. Cost sharing proposals will be made.

For substances >10 tpa that are PBT/vPvB a Chemical Safety Report will include risk and waste management measures recommended for safe use and disposal. This includes an exposure assessment, risk characterisation for manufacture and for each use. Standard free software will be made available to collate and report this information.

The SIEFs facilitate One Substance One Registration (OSOR) although companies can elect to work alone. A chosen company (or third party) of the SIEF may submit the common technical issues of the registration dossier but each legal entity will register the company, substance, volume and uses.

Calculated guesses abound as to the cost of registration per substance and the figure depends on the final decisions in the latter stages of REACH approval depending on which expensive tests are required for each tonnage category. As an order of magnitude we can expect per substance 1 – 10 tpa @ \$15,000; 10 – 100 tpa \$150,000; 100 – 1000 tpa \$300,000; > 1000 tpa \$400,000.

The aim of REACH is to minimise the use of dangerous chemicals in the EU market and the ECA will place dangerous substances on a “sunset” list where

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specific uses must be applied for authorisation more than 18 months prior or the substance will be banned. There are clear opportunities for companies developing more harmless and natural substances for use in the EU market.

After evaluation of the Registration Dossier the ECA will directly grant authorisation, or, will ask for more information to be gathered (for the highest volume/most toxic), or, will not authorise the substance. The authorisation applies to the specific applicant company and the specific identified uses for the substances and mixtures, and, each substance is given a review period.

If you are a customer of an EU company e.g. Lake Chemicals and Minerals Ltd., you need to decide whether you register the identified use through Lake and help to prepare a joint Chemical Safety Assessment or you prepare the CSA yourself to submit to the ECA. The categories of use are still to be finalised and will be an important aspect of confidentiality.

Some customers of Lake will also be importers of substances or preparations or articles from outside of the EU and it is your responsibility to register each substance depending on volumes. Already there are consortia (pre-SIEFs) sprouting up around us and it is important for us all to keep abreast of these opportunities to share the cost and time burden of registration so that we can make the right decision for our companies when the time comes. It is clear that the longer you take to join a consortium (and start to share the costs) the higher will be the entrance costs to the consortium.

There will be a great deal of work carried out in the next 24 months not only gathering data on the substances we buy and their uses but we also need to modify our business operational procedures to incorporate decisions based on the need to fulfil REACH. This is nothing new for companies who have implemented ISO9001:2000, ISO14001 and some may see REACH as an opportunity rather than a burden.

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