

All information, including estimated costs, is provided in good faith and without warranty. 1 of 3

REACH Implementation Opinion Statement
Issue Number 3 Dated 18th July 2006

The final version of the REACH legislation will be passed by the European Parliament in Autumn 2006 but many details are known today. The European Chemical Agency located in Helsinki will administer REACH and is expected to be fully operational in 2008. The following summary is an interpretation of the practical consequences of REACH and is provided in good faith with no warranty.

Registrations of your substances/preparations for specific uses/applications can only be made through European Legal Entities. You have to register either through a European company, subsidiary, or, through your designated European agency, or, through your European distributor. The European Legal Entity then has the rights to use and sell the substances and preparations under the registration number which links "product + company + use".

Substances are single synthetic chemical substances. Preparations can be physical mixtures of substances, modified substances e.g. clay treated with silane, resin containing surfactant.

There are exceptions to REACH e.g. food ingredients, natural products (minerals), biocides (as these are already controlled by the Biocidal Product Directive). However since the final decisions on exclusions have not yet been taken we recommend that you list all your products including polymers and their monomers. All preparations that are chemically active must be registered e.g. imported oils and paints.

Since the registration deadlines and costs for a substance/preparation depend on volumes:

- >1 to <10 tpa 2007 to 2018
- >10 to <100 tpa 2007 to 2018
- >100 to <1000 tpa 2007 to 2013
- >1000 tpa, and, substances classified R50/53 and >100 tpa 2007 to 2010

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it is important to comprehend if it is less expensive to register one large volume or many smaller volumes. Confidentiality and the subsequent rights to sell also have to be considered.

Pre-registration data will be entered via an internet portal within 18 months from the REACH implementation.

New substances/preparations must be registered and authorised before commercial sales. Pre-registration data will include the simple data you are now being asked to collate.

The pre-registration data will allow the REACH Authority to create and publish tables of common companies and substances to facilitate the creation of a Substance Information Exchange Forum (SIEF). The SIEF will elect a lead company to register valid substance data on behalf of the SIEF. The SIEF will become a consortium and facilitates One Substance One Registration (OSOR). This OSOR approach avoids the multiple testing for a single substance and most importantly tests on animals will be minimised. Available animal test data must be shared and the costs apportioned among the Consortium.

Consortia will not be allowed to exchange commercially sensitive company and market data in accordance with European Anti-Competition laws. Opting out of a consortium (e.g. to retain confidentiality) will only be allowed under exceptional and proven circumstances.

Depending on sales volumes the test data required per substance will be:

- Physico-chemical data (non Good Laboratory Practice)
- Toxicological data (GLP)
- Environmental data (GLP)
- Use and exposure data
- Chemical Safety Assessment/Chemical Safety Report (>10 tons)
- Classification

Once registered a substance/preparation will be evaluated and may have to be authorized. It will have to be demonstrated that the risks connected with the use of the substance are acceptable and controlled. It is certain that the following will have to be authorized for volumes >1tpa:

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- CMR Cat. 1 and 2
- vPvB – PBT – POP
- Possible endocrine disruptors and other substances regarded to be in a similar danger category

For the highest volume substances and also for the highest risk substances, the REACH Authority can create specific test regimes according to the perceived risks to users.

The costs of REACH implementation will include internal company costs (data collation, consortia attendance), external costs (data measurement costs or cost sharing within consortia) and the registration fee (as yet unknown cost).

For example, if you start from zero information for a new substance (you will of course be able to start with your safety data sheet information) a full set of registration data for a substance volume of 1 to 10 tpa costs ca. €20,000 and for 10 to 100tpa an additional €120,000 and if the REACH Authority insists on specific toxicological tests add an additional €115,000 and if some tests are to be conducted under GLP conditions then add another €20,000. Total worst case for the cost of test data for a substance sold in volumes of 10 to 100tpa is €250,000. However, expected or likely costs per substance could be €120,000.

It is therefore important to understand whether 10 x 9.99tpa registrations is less expensive compared with 1 x 99.99 tpa registration. Understanding your REACH registration strategy is an important senior management task as your company will have to evaluate return on investment criteria.

In addition to REACH implementation and as a separate but related issue, the classification, labeling and hazard communication/information for chemicals will come under the auspices of the Global Harmonised System (GHS) from 2008.

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