

Implementing REACH

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Although EU legislators have yet to agree on the final text, regulatory activities for implementing REACH continue to gain momentum. As the most complex single piece of chemical regulation ever devised, understanding and tracking the technical aspects of the legislation prove fundamental to improving corporate preparedness. Preliminary Technical Guidance Documents, published on the European Chemicals Bureau website, offer practical insight on the system for the Registration, Evaluation and Authorisation of EU Chemicals (REACH).

Noteworthy developments in the REACH-Implementation Projects (RIPs) include work on the format of Chemical Safety Reports and the criteria for Exposure Scenarios. These risk management tools will guide decision-making under REACH. A Chemical Safety Report will document Exposure Scenarios that describe the safe handling of dangerous substances produced or imported above 10 tonnes per annum in the EU subject to Registration, including Very Persistent and Very Bioaccumulative chemicals. Responding to the limited ability of many Safety Data Sheets to effectively communicate risk reduction measures, relevant Exposure Scenarios will then need to be detailed in an Annex to the European equivalent of a Material Safety Data Sheet. In addition to general exceptions offered under REACH, reduced reporting duties should be expected for use-specific Exposure Scenarios involving less than 1 tonne per annum. REACH could otherwise present an excessive administrative burden to many companies, especially when combined with the procedures for Registration, Evaluation, Restriction and Authorisation.

Chemical users may define and even report their own Exposure Scenarios. In practice, that responsibility will often be conferred onto a producer or importer. Establishing Exposure Scenarios will therefore depend on communication through supply chains. A wide Exposure Scenario that covers many chemical applications could minimise the amount of data submitted by a downstream user to its chemical supplier. On the other hand, a more elaborate use-specific Exposure Scenario may avoid over-protective safety measures.

A new version of the International Uniform Chemical Information Database (IUCLID) should provide a mechanism for the creation and management of various aspects of a Chemical Safety Report. Developing a set of Exposure Scenarios that interlinks with hazard data is challenging, especially as it requires translation capabilities for all EU Member State languages. As IUCLID will serve as the primary platform for data-exchange between companies, it must be operational for the six-month pre-Registration stage anticipated to begin in April 2008. Following this timeline, companies could begin sharing test data for any substance subject to Registration through Substance Information Exchange Fora (SIEF) before the end of 2008. The first Registration deadline for high volume phase-in substances would however still happen in Spring 2010. New substances within the scope of REACH will probably either need to be registered immediately or one year after regulatory enactment, again depending on the final regulatory demands.

In order to ensure anonymity, a representative could comply with Registration for a company on its behalf. Once in a SIEF, a company will retain opportunities to 'opt-out' and register a substance separately, for instance when necessary to safeguard confidential business information. In the event of missing a pre-Registration deadline, a company will need to directly register the given phase-in substance unless entering the market for the first time. Companies must therefore prioritise their preparatory activities according to the potential advantages and drawbacks of each Registration option.

REACH is already affecting the business environment. Examples of recent corporate responses range from updating product management systems for compatibility with IUCLID software to identifying Exposure Scenarios of potential regulatory concern. Nevertheless, many companies around the globe may still be relatively unprepared; a fact that draws the attention of investors and insurers. As the official start to implementation draws near, corporate and regulatory activities will intensify.

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