REACH - Update on Progress

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A great deal activity has revolved around REACH since the European Commission first proposed the revision of the EU chemical legislation in October 2003. The reality of the REACH regime's imminent implementation is now undeniable and stakeholders in all affected sectors are taking increasingly proactive approaches to the legislation's revision.

After industry criticism of the Extended Impact Assessment accompanying the initial proposal, a second series of impact assessments has been undertaken, the results of which should be known by March 2005. The formation of seven REACH Implementation Programmes ("RIP's") to assist industry and authorities marks an important development, As does the formation of a Strategic Partnership on REACH Testing ("SPORT"). Aligning industry, the Commission and EU authorities, REACH aims at assessing the precise needs and costs related to compliance with REACH requirements, including needs for additional guidance tools & IT to facilitate compliance.

Industry and NGO's worldwide also have advanced their REACH-related activities. During the Dutch Presidency of the EU Council, some <u>36 impact assessments</u> (see synthesis report) were reviewed in conjunction with a major conference on the subject. Direct costs are approximated to be €4 billion for the 25 EU member states (a figure that could be reduced by activities such as data sharing). The indirect impact of REACH is more difficult to quantify. The indirect costs have been defined as costs incurred due to the removal of non-viable substances and products from the market place, resulting in a requirement for downstream users to reformulate products and in some circumstances have products re-approved by end users. This process could take a considerable amount of time and resources.

The end of 2004 also saw comment on the "One substance one registration" (OSOR) proposal put forward jointly by the governments of UK and Hungary (see this issue's article, "REACH: Excessive Costs or Crying Wolf?").

The new year has seen an especially dramatic increase in REACH-related activity, much of which is associated with the Parliamentary debates on REACH. The European Parliament recently launched the first phase of its legislative review of REACH with a full-day public hearing on 19 January (see "REACH Hearing Breaks New Ground" in this issue of the *Chemical Regulation Alert*). Support for a stronger REACH came from the NGO Chemsec, the Swedish campaign group whose objective is a toxic-free environment. In their recent publication, "What we need from REACH," Chemsec emphasizes that downstream users with close contact with consumers must have access to the full spectrum of information required under REACH. Chemsec expressed concern over the dilution of the original proposal, which could lead to REACH failing to deliver its promise to downstream users and consumers.

Further support for a strong REACH came from the European doctors' association, CMPE. Writing to European MEP's, CMPE called for producers to take responsibility for harm caused by substances, to improve public access to information and to make chemical substitution requirements more stringent.

Again voicing support for the principles of REACH, an industry group composed of UNICE, Cefic, EUROMETAUX and ORGALIME came together to call for "the design of Reach to be improved without compromising the goals of the system." In a press release, they listed seven

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changes which they believe are necessary if REACH is to have a chance of success. Among the suggested changes are a call for a "lighter" registration system, a review of the draft rules on substances, greater emphasis on safety data sheets and the use of chemical exposure estimates for supply chain communication, and active commitment to voluntary data-sharing. Completing the list is a suggestion that REACH exclude some classes of substances and move toward a system in which restriction replaces authorisation as the tool for risk management.

Comments expressed at the recent Steptoe-sponsored IBC conferences on REACH (see discussion in "Excessive Costs or Crying Wolf?" in this issue of *Chemical Regulation Alert*) indicate the need for additional initiatives from industry to deliver viable alternatives to those elements of REACH which remain causes for concern. Areas where real progress could be made include: action taken before the pre-registration process begins; options available for sharing data costs (particularly where there is an uneven distribution among those interested in supporting the registration process); and distribution of technical and regulatory input.

Looking ahead, the Luxembourg Presidency will be focusing Council discussions on the issues of testing methods and downstream users. The Council has left open the possibility of returning to the OSOR proposal as well. Eight sessions of the Council's *ad hoc* chemicals working group are scheduled between now and the end of June (when the UK takes over Presidency of the Council) and major debates on REACH will be held on 6 June and 24 June in the Competitiveness and Environment Councils respectively. A workshop will be held on 10-11 May, during which the Commission is expected to present the preliminary results of its second impact assessment. A first reading by the European Parliament on the REACH proposal is not expected before September 2005.

The recent parliamentary hearing on REACH, examined in the following article, also testified to the immediate opportunity for stakeholders to proactively shape the REACH proposal so as to enable the legislation both to live up to its ideals and remain liveable for industry.