REACH: Excessive Costs or Crying Wolf?

Steptoe frequently works with the IBC to organize and identify speakers for conferences on chemical regulation. In December 2004, Graham Lloyd chaired and Jim Searles spoke at a high level conference on REACH that was held in Boston. The conference provided a forum for stakeholders to engage in a candid and at times pointed dialog. Commission representatives made clear that REACH ***will*** be implemented. Discussions reflected the industry view (shared by the US Commerce Department) that the requirements of the current text are likely to have a much larger impact than the Commission first thought. The Commission maintained that, in many areas of concern, industry is "crying wolf," and exaggerating the likely consequences of the REACH implementation. Among the most important and contentious issues discussed during these sessions were the following:

1. Multiple Registration and Duplicative Testing of Chemicals

While REACH is designed to encourage the formation of consortia and to make maximum use of available testing data, new chemical substances already face rigorous testing requirements, comparable to or greater than those called for by REACH. Duplicative testing remains a real possibility.

The "One Substance - One Registration" (OSOR) proposal, issued jointly by the UK and Hungary in July of 2004, opens one of several channels and opportunities to modify excessive risk assessment and testing requirements. Whilst this proposal is unlikely to be accepted in its present form, some aspects of it, including provisions to minimize duplication, may be incorporated into the final program.

2. Registration / Prioritization Mechanism

In the proposal's current form, regulation and data requirements are primarily volume/hazard-based rather than risk-based, potentially necessitating excessive and unnecessary testing. An industry theme emerged at the conference that any new regulation should work through a system that allows prioritization of chemicals for testing and a graduated scale of data requirements based on risk, enabling low risk substances to be exempted from costly analyses and resources to be concentrated on substances that are of real concern. The Commission did not agree with the idea that REACH is hazard-based, pointing out that only regulation of compounds that are persistent, bioaccumulative, carcinogens or reproductive hazards will be assessed on a hazard basis.

3. Hampering Innovation

Concern was voiced over potential negative impacts on innovation due to the inability of companies to finance the costs of REACH and a potential loss of competitive advantage for the European Chemical industry due to delays in bringing new products to market. Many specialty producers have indicated that the costs of REACH compliance are likely to cause them to withdraw from the market. The Commission and some industry members disagree, believing that REACH will ease burdens on innovators.

4. Potential disclosure of Confidential Business Information (CBI)

There was notable alarm that the public reporting requirements called for by REACH pose a substantial risk to the confidentiality of business information. Information would not be treated as confidential, being passed onto the European Chemicals Agency, recipients down

the supply chain, and potentially to competitors. Mandatory disclosure of confidential business information (e.g. name of the manufacturer of proprietary components and composition of proprietary preparations), including sensitive information such as physiochemical data and descriptions of uses, could impair protection of legitimate confidential business information.

Some industry representatives argued that the current disclosure obligations and non-confidential designation of proprietary information impairs companies' intellectual property rights and is disproportionate to the aims of the proposal. Industry seeks a narrower definition of the data classified as non-confidential and provision of generic information that will cont include confidential business information. Surprisingly, a consensus emerged that, to the extent that REACH requires companies to provide confidential data, this information should remain protected to the extent practicable.

5. Data Protection, Data Sharing, and Data Compensation

A topic related to CBI is the manner in which investments in toxicology and other data will be protected. Under the current proposal, Potential Registrants become members of a Substance Information Exchange Forum (SIEF), to which they must share their proprietary data. There is no real data protection under REACH as "exclusive use" rights are not acknowledged. Further, many ambiguities remain regarding data compensation rights. We address this issue further in a separate article of this issue of the *Chemical Regulation Alert*, below.

6. Possible Incompatibility with International Law

There was concern that REACH is incompatible with international initiatives and WTO rules and obligations. Some industry members have asserted that in its current form, REACH is inconsistent with the WTO Technical Barriers to Trade (TBT) Agreement. The Commission disagrees, stating that it has gone to great lengths to treat EU and non-EU producers equally and to minimize the impact of the program. Jim Searles (Partner, Steptoe & Johnson) pointed out that WTO compatibility will be assessed not on the face of the EU law but on the actual effects on trade in practice, and highlighted several specific areas where discriminatory effects on imports would arise from REACH as currently drafted.

7. Potential for Inconsistent Application by EU member states

Several speakers also raised the possibility that REACH may be interpreted differently by different EU Member States in a way that could lead to arbitrary and inconsistent decisions. Some criticism was voiced labeling REACH's enforcement structure as vague, which could present the possibility of excessive penalties. In addition to the potential for liability in each member state where a violation occurs (cumulative penalties), the fines for similar violations could vary widely between states.

Next Steps

As this short summary of concerns that emerged at the conference makes clear, there remain very serious areas of disagreement over the content and impact of the current REACH proposal. However, during the discussion of these differences, it also became apparent that the Commission is willing to entertain proposals from, and work with, industry on some aspects of REACH. While changes to some areas of REACH remain possible, changes to other areas are unlikely. In particular, the issues of data licensing and compensation were singled out by Commission officials to Steptoe's Graham Lloyd and Jim Searles. There is a

willingness to accept input from industry to develop a response to these issues that will be workable for REACH and may also be transferable to other areas of EU chemical regulation (such as for PPPs and Biocides). The opportunity to reach an agreement on data protection, sharing, and compensation, is examined in detail in the following article of this issue of *Chemical Regulation Alert*.