

REACH - Update on Progress

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A great deal of 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 [36 impact assessments](#) (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

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.

European Parliament REACH Hearing Breaks New Ground

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On 19 January, the European Parliament launched the first phase of its legislative review of the Commission's REACH proposal with a full-day public Hearing. The Hearing was organized jointly by the three Committees¹ sharing responsibility for formulating the Parliament's opinion. The Hearing drew one of the largest audiences ever attracted by such an event at the Parliament, including presentations from the past Dutch and current Luxembourg Presidencies of the Council, the Enterprise and Environment Commissioners and responsible services of the European Commission, a range of industry representatives, environment/health NGOs and various other experts. The turnout confirmed REACH as one of the most important legislative initiatives undertaken by the EU. From the perspective of an observer at numerous Parliament Hearings over the years, this Hearing also was notable because the debate was highly substantive, testifying to an underlying current of commitment to making REACH a reality. The hearing also revealed that the current proposal is likely to undergo important amendments before finally being considered for joint adoption by the Council and Parliament.

There are several developments to highlight.

Prospect of Amendments to Avoid Undue Impacts on Industry

European Commissioner Verheugen (Enterprise, Competitiveness) personally confirmed that the Commission is open to making changes in REACH, will take full account of impact assessments and related studies that are still being carried out (principally those focusing on industry costs and impacts on competition to be concluded over the next few months) and will introduce appropriate amendments to the current proposal. Both Commissioner Verheugen and Environment Commissioner Dimas emphasized the importance of further studies and the need to understand the real burdens that would be placed by the current proposal on industry, particularly on small and medium-sized enterprises (SMEs). They pledged to developing appropriate solutions while still maintaining the proposal's environmental and health objectives. Commissioner Verheugen, however, suggested a greater need for amendments than did Commissioner Dimas.

The Commission's views on openness to changes were largely supported by the representatives of the Luxembourg Presidency, who intend to put the theory of "better regulation" into practice. The representatives confirmed that the Presidency would organize a stakeholders Workshop this May and welcome "practical" proposals to make REACH more workable (real improvements) without imposing undue costs. They appealed for "creative" proposals to this end. We would note that the Presidency is fully open to consideration of "alternative proposals" on key issues (see analysis of REACH's unresolved issues in "[Excessive Costs or Crying Wolf](#)" in this issue of *Chemical Regulation Alert*) and openly mentioned at the Hearing, as did the Commission, the prospect of introducing, at least in part, the "one substance one registration" ([OSOR](#)) proposal of the U.K./Hungary.

Interestingly, Parliamentary reaction to these comments was one of initial surprise followed by some alarm. Some Members of the European Parliament ("MEPs") directly questioned Commission representatives why its Committees should spend time studying the current

¹ Committee for the Environment, Public Health and Food Safety; Committee on Industry, Research and Energy; Committee on Internal Market and Consumer Protection.

proposal over the next months if the Commission was already intending to introduce major changes. MEPs also asked whether the Commission was intending to draft the amendments itself (with the knowledge that changes in one chapter could require a number of related amendments in other chapters and in the annexes) or if the Commission would rely on the Parliament to draft the changes. The Commission responded carefully (!), indicating that it would introduce amendments to its proposal in the normal legislative sequence, i.e. following the Parliament's first reading and taking account of the Parliament's requests for amendments. While this position does not undercut Parliament's right to propose amendments, neither does it preclude the possibility of the Commission formally tabling amendments not addressed by the Parliament.

Key Substantive Issues

Apart from the standard disputing of views on the cost impact of REACH, there was a good, substantive exchange of opinions regarding how REACH's impact on industry might be lessened while still fulfilling its high environmental and health objectives. Several substantive questions areas were addressed.

Is REACH duplicating vertical legislation?

Commissioner Verheugen confirmed that the operative principle for REACH is "no duplication." If there is duplication with vertical legislation that adequately regulates the product (question raised by a MEP concerned the EU cosmetics legislation), then this is a basis for amending the REACH proposal.

Is a volume-based approach alone the most effective approach for registration requirements? Should the EU give priority to risk assessment?

Commissioner Verheugen indicated that there is "broad consensus" that the substances of greatest risk should be assessed first. A representative of SME chemical suppliers confirmed that a volume-only approach is wrong and would not be bearable for SMEs - volume bands must be combined with prioritization-based on risk assessment (see also CEFIC's alternative proposal). A retailer panellist, responding to a question whether Article 6 (registration / notification of substances released from articles) is workable, suggested that it is not and should be restricted to only priority chemicals. The Volvo representative confirmed the need to restrict Article 6 to only a very few, hazardous substances (the RoHS Directive was mentioned several times as an appropriate model).

How to protect proprietary data, share other data and also share consortia costs ?

Through much of the day there were repeated references to data confidentiality issues, often in the context of questions on the OSOR proposal. Reflecting on the comments registered at the hearing, from the institutions and industry alike, there appeared to develop a general appreciation that OSOR will eventually become part of REACH, bringing about a substantial sharing of data beyond animal tests and a consequent reduction of registration costs. However, the details of the data sharing arrangement still need to be worked out carefully. One role of OSOR that was presented involved using the proposal as a means to help protect SMEs [SMEs, comprising a major segment of the chemicals industry, were frequently cited as on an "endangered list" due to REACH costs], enabling them to join consortia and share data with larger registrants whereas they could be squeezed out of purely voluntary registration consortia. On the other hand, broad support for OSOR was conditioned on the possibility of

an opt-out when properly justified, allowing for individual submission of proprietary data (considered to include specific/detailed use data).

To the extent that data is shared or submitted on behalf of other companies, compensation systems are clearly a major issue of concern. Indeed the issue of data compensation was cited by Commissioner Dimas as one of the current workability problems with OSOR. He noted that the current proposal would rely on cost sharing guidelines to be provided by industry, but that, so far, the industry guidelines do not yet exist. The U.K. environmental agency (DEFRA) representative, explaining OSOR and the complications of cost-sharing (noting that different companies have different volumes, different available data, etc.), indicated that the OSOR proposal provides provisionally for an ombudsman to resolve cost disputes but confirmed that industry guidelines are needed and that there are also other ways to deal with disputes.

Conclusions

The Parliament's Hearing significantly advanced an understanding of the EU institutions' collective planning concerning REACH. While the Luxembourg Presidency had earlier outlined its work plan, the new components from the Commission and Parliament help complete a picture that is largely positive and progressive. For industry, the Hearing confirmed for many participants that the institutions, notably including the Commission which has until now been very protective of its original proposal, are very open to consideration of specific amendments that will improve the workability of REACH. Thus, the hearing made it abundantly clear that REACH will not go away, but with real work and - as the Luxembourg Presidency put it - creativity, it can still be amended in important ways so as to enhance all three pillars of sustainability, including economic.

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 not 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*.

REACH-ing an Agreement on Data Protection, Data Sharing, and Data Compensation

The latest IBC conferences sponsored by Steptoe & Johnson on the European Union's proposed reform of chemicals legislation ("REACH"), held in Brussels and Boston, highlighted some of the most important and contentious issues facing industry. These include, multiple registration/duplicative testing, registration/prioritization mechanisms, impacts on innovation, confidentiality, data compensation, compatibility with international trade rules and overlapping international initiatives, and the potential for inconsistent application across the EU Member States.

The issue of data protection, in particular, has given rise to considerable debate. Objections concerning inadequate data protection have consistently been raised in response to proposed and/or adopted EU chemicals legislation, particularly those measures requiring the development of dossiers containing extensive information necessary for the assessment of risk to health and the environment.

Despite the fact that the EU Directives concerned with the approval for sale of biocides and plant protection products (PPPs) have been in operation for a number of years, debate about how data protection, data sharing and compensation should be addressed persists. The procedures that are being developed for REACH almost certainly will influence the pending revision of legislation on PPPs, which the EU Council agreed to fast-track last November, and may encourage revision of biocides legislation along similar lines. With regards to biocides, the European Court of Justice confirmed last December, in two cases, that Annex II of Regulation 2032/2002 (part of the second phase of the 10-year working programme examining all active substances already on the market) would not be suspended pending a final judgment on the legality of the programme. The programme includes controversial provisions regarding the data treatment and the status of "free riders." It is imperative that REACH properly addresses these issues.

Under the current REACH proposal, potential registrants become members of a Substance Information Exchange Forum (SIEF), to which they must share their proprietary data. There is no effective data protection under REACH as "exclusive use" rights are not acknowledged or protected. There are also many ambiguities regarding data compensation "rights."

A need exists for an effective and workable procedure to bring data owners together under approved cost sharing and data compensation formulas. With the details of REACH still very much open to debate (as discussed in this issue's [article on the recent European Parliament Hearing](#)), the time is ripe for affected stakeholders to fully develop a model for the procedures necessary to accommodate all aspects of data protection. Industry has experience, in the US and elsewhere, in this area, and is best-placed to develop and propose workable models. If this opportunity is not taken up it is highly likely that a system for the treatment of data will be imposed.