

Inspired thinking



Substitution should remain within REACH

Introduction

The European Commission is due to approve this autumn new regulations to control the use and marketing of chemicals. REACH is considered by some experts to be the most complex and technical piece of EU environmental legislation ever devised. Insight is concerned that the EC may miss the opportunity REACH presents to improve the sustainability of the chemicals sector and to promote innovation.

Background

Several years ago, the EC recognised that data on chemical hazards and the chemical contents of products in the EU market was lacking. It therefore proposed the Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation.

REACH seeks to reverse the 'burden of proof' for identifying chemical risks away from regulators and towards companies. In other words, under REACH, companies will have to demonstrate the safety of a chemical, rather than it being the job of regulators to identify that the chemical is too dangerous to be approved for use.

REACH is still in draft form, but it is expected to be finalised in late 2006 following a second reading in the European Parliament. Once in force, any chemical produced or marketed in any quantity over 1 tonne per annum (tpa) in the EU will be subject to a Registration procedure that establishes a 'no data, no market' approach to chemical control. Put simply, if a company does not provide safety data for a product – including those that have been sold for many years – then it will not have permission to market or sell the product. In addition, any substance that is identified by regulators

as being of 'very high concern' to human health or the environment may also be regulated under REACH through procedures for Authorisations or Restrictions.

Anticipated to come into force in April 2007, the Regulation will be implemented progressively over 11 or more years, ultimately leading to the creation of an inventory of hazard and use data for the vast majority of chemicals on the EU market. With around 30,000 substances included in its scope, the regulation potentially covers up to one hundred thousand intermediates, several hundreds of thousands of formulations and, conceivably, well in excess of one million finished products. REACH therefore presents a significant administrative challenge for many companies.

What happens with REACH in Europe is also important for other countries as the United States, China, Russia, and Canada are all looking to learn lessons from REACH for potential reforms to their own chemical policies.

Key principle at risk

A central objective of the proposed REACH policy framework is to stimulate the application and development of 'safer substitute' chemicals. This is known as the 'Substitution Principle,' (a principle that already exists under EU occupational health legislation). In the context of REACH, it means that a company should give strong preference to using the least hazardous alternative when selecting a chemical for a specific use.

The Substitution Principle is critical to REACH because the ongoing replacement of hazardous substances and processes with less dangerous alternatives is fundamental to catalysing much needed innovation

throughout the manufacturing supply chain. Substitution should also help to stimulate competition, create new markets and support consumer confidence in the chemical sector. Conversely, in the absence of a Substitution Principle, REACH may increase barriers to market entry and intensify economies of scale because of the projected high costs of the Authorisation and Registration processes. Smaller companies or new market entrants may therefore be disadvantaged, and deterred from developing new, safer chemicals or putting them forwards for European approval. Recent legislation aimed at tightening environmental protection has been noted to have had similar effects.

Substitution is now a critical issue that needs to be resolved in order to achieve political agreement on the final legislative text between the Council of Ministers of the European Union and the European Parliament during the so-called Co-Decision process. Differences exist on how to define and evaluate the appropriateness of potential alternative substances and processes during Authorisations. In this respect, it is unfortunate that a definition of 'substitution' or 'safer alternative' does not exist in the legislative text.

A number of REACH Implementation Projects are being piloted under the auspices of the EU. They are intended to produce the tools, technical guidance and infrastructure necessary to make REACH a reality. As the technical guidance will be critically important to future regulatory decision-making, Insight is keen that the Substitution Principle is fully considered in these preparatory activities. This will ensure that substitution is fully integrated into future decision-making for both Authorisations and Restrictions.

Limited business impact assessments

In our view, a significant weakness of many Business Impact Assessments of REACH conducted for the European Commission is that they do not take sufficient account of the commercial opportunities for companies arising from the Substitution Principle. This is particularly surprising as: (i) substitution is a primary objective of the original European Commission Proposal for a new EU Chemicals Strategy; (ii) it is seen by some stakeholders as a cornerstone for building public trust and consumer confidence in chemicals; and (iii) it has been identified by some companies as a source of future revenue. Overall, there appears

to have been a very limited exploration of different implementation scenarios for REACH and how substitution may be best incorporated into this new regulatory regime.

Company case studies

Insight has been monitoring the responses of companies in the European chemical sector to REACH since 2003. During this time we have seen increased recognition among sector leaders of the commercial opportunities under REACH. Examples of companies identifying such opportunities include AkzoNobel, Ciba, DSM and ICI. In particular, companies are increasingly pointing to specific competitive advantages under REACH from their R&D and product stewardship programmes. DSM and ICI have both predicted business benefits linked specifically to the Substitution Principle within REACH.

Insight's position

Insight fully supports the new REACH proposal. In general, we believe that it will: (i) help clarify existing European chemicals legislation for investors; (ii) improve public confidence in the EU chemical sector; (iii) stimulate innovation in the sector; and, (iv) support the sustainability of the sector.

Insight sees the further development and application of substitution as critical to future competition and innovation in the European chemical sector. We are therefore concerned to ensure that the Substitution Principle remains an integral part of REACH. While substitution features as a major objective in the White Paper that formed the initial policy behind REACH, few mechanisms for its practical application currently appear to be available.

Recognising the importance of corporate demands for clear and predictable regulation, we propose that:

1. Substitution should remain a key principle within REACH and underpin future regulatory decision-making;
2. Substitution should be integrated into the REACH Implementation Projects from the earliest opportunity;
3. Substitution should guide corporate chemical safety management by both upstream producers and downstream users;

4. Substitution should revolve around the principles of sustainability. In other words, it should: (i) fully consider the socio-economic costs and benefits associated with alternative substances and technologies, and (ii) take a life cycle approach by considering impacts resulting from manufacture, use, and disposal;
5. As well as those chemicals that are banned for use, those substances Authorised for use should be clearly communicated to stakeholders. This transparency should limit the potential 'black listing' of substances based on hazard instead of risk thereby alleviating one of the concerns of industry; and,
6. The new European Chemicals Agency should facilitate the application of substitution by providing a mechanism for stakeholders to communicate potential substitutes for substances subject to Authorisations and Restrictions.

Conclusion

Overall, we believe that promoting a move towards knowledge-based products and services through substitution should be a key component of the contribution that REACH makes towards sustaining the international competitiveness of the European chemical industry. We therefore hope that Substitution becomes an integral part of REACH. The tools and methods for incorporating Substitution into decision-making and regulatory compliance still need to be developed, emphasising the importance of the REACH Implementation Projects. Further regulatory impact studies and forthcoming reviews should examine how REACH can promote best practice and the application of substitution. We hope that the European Commission, Council and Parliament will come to similar conclusions.

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