

European chemicals legislation will reach all parts of the PU industry

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Although the European chemical industry will bear the brunt of the extensive new regulations on the chemicals, major users of chemicals such as the polyurethanes industry must also prepare for the many changes. At a basic level, the cost of the new testing requirements will have to be absorbed by the chemical industry and its customers, while it is possible that some of the chemicals used in making polyurethanes will no longer be available, since the cost of testing and registration may far exceed their potential value.

The polyurethanes industry in Europe is the key part of the whole value chain based on MDI (methylene diphenyl diisocyanate), TDI (toluene diisocyanate), and the various associated polyols: it converts these basic chemicals into a myriad of end products used in virtually all industrial and consumer product sectors. Estimates suggest that as many as 3000 chemicals are used in the sector, making these new regulations an important concern for the industry's future.

More than 23 500 companies are involved in the sector, and most of these are SMEs (small and medium-sized enterprises). These companies employ well over 800 000 people and generate a market value of nearly €130 000 million, making the PU industry a key part of Europe's industrial infrastructure.

For these reasons, polyurethane processors should now be preparing for the various possibilities engendered by the proposed European regulations, encapsulated by the acronym REACH (Registration, Evaluation, Authorisation and Restriction

About this feature

The chemical industry is one of major European industries with a turnover of €530 000 million (\$643 000 million). The regulations and controls on its products have developed with time and there are various regulations in place—but these are not uniform in their applicability and there are different controls on existing (pre-1981) and 'new' chemicals which came into use after this deadline.

Pressure groups, and a changing regulatory environment, have called for greater control over the production and use of chemicals, aiming to create an over-arching legislative framework. The new regulatory proposals will require the Registration, Evaluation, Authorisation and Restriction of Chemicals, hence the acronym REACH;

of CHEMicals), as discussed here.

ISOPA, the European diisocyanate and polyol producers association, sees its role as communicating with the downstream polyurethanes industry and, upstream, with the suppliers of other essential components in the value chain—catalysts, surfactants, pigments, fire retardants and blowing agents.

Two-way communications

This has to be a two-way communication so that concerns can be taken up and data requirements shared. To this end, ISOPA is part of the REACH advocacy process alongside CEFIC (the European chemical industry association). It is actively engaged in preparing for registering the products produced by its members, including identifying and filling data gaps. Since the legislation is not finalised and data requirements may change along the road, this is a case of proceeding with a measured pace while aiming to be ready

they will replace all the existing controls.

The products of the chemical industry are used throughout manufacturing industry to create all the articles and items which we all use every day. Consequently, the impact of REACH will stretch far beyond the chemical industry itself: the cost burden looks likely to be significant and will, inevitably, have to be shared throughout the value chain. Because of this, obvious questions are being asked about the final cost/benefit balance.

The development of REACH is a very involved process which will take a few more years to complete. Whatever changes take place in the remaining legislative phases, the regulations will almost certainly be quite complex and very burdensome and it's a good time to start preparing now—if you are not already engaged.

on time with the right data.

To assist in this process, and ensure that all aspects of relevance are covered, the polyurethanes industry must play an active role in the various activities involved. There are four main points to start this process:

- Track the development of REACH legislation;
- Understand its implications for your business;
- Prepare a substance inventory; and
- Check that all your suppliers are preparing for REACH.

The aim should be to assemble all the information you can on your applications to share with your chemical suppliers in compiling the chemical safety reports (CSRs), which are a key part of the legislation, as discussed below.

In addition, it is vital that you talk to your representatives in the European Parliament and in your national government: Voice your concerns to them; ultimately they will be voting on the REACH proposals when they come before the European Parliament, it is vital that they know and understand your concerns.

The objectives of the new Chemicals Policy obviously include the protection of human health and the environment, sentiments with which all stakeholders undoubtedly agree, but it also requires "the maintenance and enhancement of the competitiveness of the European Union's chemical industry." Many people in the chemical industry have difficulty seeing how this latter goal can be achieved given that the industry is competing in a global market.

Recent history

The decision to review the existing set of controls on chemicals was taken at the meeting of the Council of Environmental Ministers in Chester, UK, in April 1998 during the last UK Presidency of the European Union. This discussion took place because a range of stakeholders voiced their opinions that the existing regulations were not adequate to control the chemical industry and the use of its products.

This debate resulted in the publication in February 2001 of a White Paper titled 'Strategy for a future chemicals policy.' A fundamental aim of the proposal is a single, coherent, set of controls which will

cover the 30 000 'existing chemicals' which are marketed in the EU but are not subjected to the same controls and data requirements as the 2700 'new' chemicals which have been put on the market since 1981.

In the European Commission, the development of a regulation stemming from this White Paper has been jointly led by DGs Environment and Enterprise.

Following intensive work in the summer of 2003 by the Commission, its proposal for a Regulation—COM(2003) 644—was published at the end of October, first in English and then in the other EU languages. The details of this are discussed in the main article. **UT**

There is genuine concern in the chemicals industry that all of the extensive costs involved in meeting the requirements of the proposed legislation cannot be absorbed, which could result in vital chemicals being withdrawn from the market, and the regulations are an obvious brake on the development of new, possibly safer or more effective chemicals.

REACH to apply across the EU

The mammoth 1328-page REACH proposal is split into six volumes and includes some 800 pages detailing the test methods to be used in generating data on physical-chemical properties, toxicity, and ecotoxicity of all chemicals. The fundamental legal text is contained in about 250 pages.

One important point is that it will be set up under Article 95 of the EC Treaty which requires its uniform application across the EU.

The regulations will also apply equally to chemicals produced in the EU and those chemicals imported and made outside the EU's boundaries. It will apply to all chemicals manufactured or imported in quantities of one tonne or more. The registration step of REACH carries a time-prioritisation based on the annual tonnage marketed per producer with strongly increasing data requirements for larger volumes (see Table).

Many chemical producers may register

Impact assessments

The White Paper of 2001 listed the costs of REACH testing to industry as only €2100 million over 11 years or a mere €200 million per year. This is only €70 000 per chemical. Against this it claimed, for illustration, that there would be a reduction in the costs of allergies, which run at €29 000 million across the EU.

There are several points that can be made against this initial assessment and several that have followed. The key point is that the testing costs are just the beginning, and even these are grossly underestimated in the White Paper's assessment. ISOPA has experience that just a single designated test for one chemical can cost more than €70 000. Estimates indicate a cost of up to €1 million for the testing needed to support the registration of a large-volume substance.

But the real costs impact far more than the chemicals industry. The whole value chain—including makers of, for example, foams and other polyurethane products used in buildings, cars, refrigerators and the myriad of other applications and products—will be impacted. There will be additional costs, for example, for the re-formulation and re-certification of systems if additives are withdrawn from the market because the costs of REACH far outweigh the potential income from the chemical.

As noted at the start of the main article,

their substances well ahead of these deadlines and the date limit for downstream users to submit data concerning their usage of the material in question is 12 months after receiving the registration number from their supplier.

One positive response to the consultation process is that the need to register polymers has been withdrawn—at least temporarily.

Producers and importers have to pre-register their substances 18 months before the registration deadline so that authorities can indicate where data can be shared and so reduce costly animal-testing requirements.

Chemical Safety Reports

As noted earlier, a key part of the REACH process is the creation of documents called 'Chemical Safety Reports.' These will be required for all substances manufactured or imported/marketed in amounts greater than 10 tonnes per year. The CSRs will include evaluations of all the applications known to the producer/importer—in this respect they seem to be very similar to the risk assessment documents which EU Member States and the chemical industry have been labouring over for several years now.

If an entrepreneurial end user has developed a new use for the chemical concerned he may have to produce the CSR himself—the costs of which will be a major

the polyurethanes industry uses up to 3000 different chemicals as part of a complex value chain. Any lack of data on any one of these chemicals, or suppliers that opt out of the whole process, could result in serious disruptions.

There have been numerous impact assessments over the years. These show the gaps between the modest impacts which Commission assessments show and the much bigger impact that national and industry assessments indicate.

One example is the study carried out for several French ministries and industry associations by the Mercer consultancy. This study examined the impacts on downstream industries and estimated that the costs to the French industry alone would be €28 000 million over 10 years, which could result in 360 000 job losses across a range of industries.

There have been fewer studies on the potential benefits, but Denmark has estimated the health sector benefits as in the range €90 million to €707 million over 30 years, including the gains from reduced production loss through workers being ill.

Clearly, this cost/benefit imbalance shows there has to be better information and agreement between all stakeholders on the economic and social impacts before bridges are crossed. We hope that the new studies promised for late 2004 and early 2005 will bridge the gap. **UT**

Data reporting requirements

Usage, t/y	1-10	10-100	100-1000	1000+
Annex ¹	V	V & VI	V-VII	V-VIII
Deadline ² , y	11	11	6	3

1 Location of data requirements;

2 Registration after entry into force

block to invention and progress.

The creation of these CSRs will require active involvement of all users of the chemicals concerned. They will contain information on likely exposure of workers and consumers as well as possible impact on the environment. They will also include risk management information.

There are evaluation requirements in which Member States will figure prominently, and then we have the controversial Authorisation step which could lead to the substitution or elimination of certain classes of chemicals.

The classes already identified include carcinogenic, mutagenic or reprotoxic (CMR) and chemicals that are harmful to the environment, but there are enough provisions and clauses in the proposal for Member States to introduce further requirements.

There are also provisions for the registration of substances in articles which are either intended or likely to be released and are harmful to human health or the environment. These provisions would be extremely difficult to operate in practice. For example, importers of articles such as toys would have to test their products to determine if any chemicals are released during use.

The administration of REACH will require a central agency, in Helsinki, to deal with the vast amounts of data which will have to be generated and shared.

In summary, for the polyurethanes industry, the first phase will require registration of in-depth data for most chemicals made in high volumes, including diisocyanates and some polyols plus many chemicals such as fire retardants and other additives. But, as noted above, extensive CSRs will be required and REACH will demand the active involvement of all users of chemicals—it cannot be left just to the chemical suppliers.

The REACH proposal has still to navigate its way through the normal EU institutional processes which include two readings in the European Parliament (EP) and corresponding sessions in Council.

The proposal was published just too late to have its first reading in the EP before the interruption caused by the enlargement of the EU and consequent changes of the EP elections as well as changes in the Council and in the College of Commissioners. This interruption is likely to significantly lengthen what would have been a long process due to the

complexity of the proposal and the involvement of many stakeholders.

Consequently, the voting on the first reading in the EP is now expected in the second half of 2005, according to Karl-Heinz Florenz, the new chairman of the Environment Committee, with final adoption in 2006/2007. This schedule means that the deadline for the registration of high-volume chemicals—2009-2010—is not so far away when there may be requirements for extensive animal testing.

What stakeholders think

The EP started its debate on the REACH dossier but did not get very far before the enlargement process began. The Environment Committee has the lead role and Guido Sacconi (Italy) is the Rapporteur.

Other Committees will have a strong say in the EP's procedure and both the Industry and Legal Affairs Committees within the EU have voiced their concerns about the administrative burden, the threat to innovation, the requirements for disclosure of commercially sensitive information, and, significantly, that data requirements and decisions should be based on risk and not just on tonnages.

The Council has set up a Working

Group to process the REACH dossier, and it has also expressed concern about the effect on industry and trade. To examine the latter concern it has asked the Commission for a further set of impact studies which are due by November 2004.

In a further recent move, some countries have suggested simplified processes including the UK's 'One substance, one registration' proposal.

On the other hand, pressure groups, led by Michael Warhurst of WWF (Worldwide Fund for Nature), have long been calling for strong comprehensive regulations to curb what they see as the worst excesses of industry. Additional elements are the groups representing animal rights who want to severely restrict animal testing within the REACH process.

Industry, led by CEFIC and the employer's organisation UNICE (the European Chemical Employers Federation), has been actively involved in the process from the very beginning.

While strongly supporting the political objectives of REACH, CEFIC's main concerns about the current proposals are:

- A less burdensome approach is needed;
- The REACH process should be based on risk and not mainly on volume or hazard;

- Inclusion of substances in Authorisation must be based on sound science;
- The preferred option for risk management should be based on restriction and not authorisation; and
- The Agency must be empowered to deliver harmonised implementation.

All parties likely to be impacted by these new regulations should do everything in their power to get these points across.

The polyurethanes industry, a key user of a wide range of chemicals, is likely to be heavily impacted by some of the likely changes under the REACH legislation. Make sure you are preparing for the changes while aiming to bring across your assessment of the likely impact on your business to all those involved in the legislative process. But start the process now. **UT**

About the author

Mike Jeffs is secretary general of ISOPA, the European Diisocyanate and Polyol Producers Association, which represents the producers of MDI (methylene diphenyl diisocyanate), TDI (toluene diisocyanate), and the associated polyols. Its members are Bayer, Elastogran (BASF), Dow, Huntsman, Repsol and Shell.