Editorial

Trade unions want a more ambitious REACH

The European Trade Union Confederation (ETUC) called a major conference on the 11th and 12th of March on the REACH proposal to overhaul European chemicals legislation. The conference was both part of the wider agenda set by the ETUC's declarations[1], and constructive input by European workers to the development of the future European regulation. It gave the main stakeholders an opportunity to trade views, and be informed by a very wide range of positions.

Nearly 200 people attended the two-day discussions – a hundred-plus delegates from ETUC member organizations, along with many invited guests, including European Commission and Member State officials, MEPs, and representatives from industry, consumer groups and leading environmental lobbies.

The single concerted message that the ETUC and its members aimed to get over at the conference is crystal clear: European workers back the reform, but want specific provisions put back in or tightened up.

This special report on our conference proceedings starts with a review of the messages brought by our invited guests: Stavros Dimas, the European Environment Commissioner, Guido Sacconi, lead rapporteur on REACH for the European Parliament, Lucien Lux, Minister of State of the Grand Duchy of Luxembourg, representing the Council presidency, Jean-Paul Mingasson for UNICE, and John Hontelez for the European Environmental Bureau (EEB).

The first section, on the impacts of REACH, looks at the findings of the further impact assessment studies done by the chemical industry, and those of a study commissioned from the University of Sheffield showing that the economic benefit of REACH for European workers' health could outweigh its total implementation cost.

John Monks
General Secretary, ETUC

In parts two and three, papers given by a series of experts first set REACH in its European industrial policy context to inform the linkages with innovation and competitiveness, and go on to explore possible ways to achieve a smooth implementation of the reform.

The conclusions spell out and argue the case for the ETUC's proposals for improving the text adopted by the Commission in October 2003. The product of extensive discussions and dialogue between all ETUC member federations and confederations, the workers' proposals aim to optimize the expected cost/benefit ratio, especially the outcomes for workers' health and safety.

[1] Declarations on REACH adopted by the ETUC Executive Committees of 17-18 March and 1 December 2004. Published in the brochure *REACHing the workplace* and downloadable from www.etui-rehs.org/hesa > Main topics > Chemicals.

Since last March's conference, other sources have further informed the REACH debate: a KPMG impact assessment study published in May showed that the costs of REACH are easily manageable, while the outcomes of the SPORT exercise showed the reform was workable in practice.

This latest information strengthens the ETUC's case for the co-decision procedure to move forward, and for the European chemicals legislation reform to be adopted without delay.

European trade unions call on the European Parliament and Council to take their proposed improvements and resulting amendments into account.

The ETUC will continue tracking the REACH process, and seek to leverage it as a full part of the construction of a socially responsible Europe committed to developing a dynamic labour market with a plentiful supply of good quality jobs. ■

John Monks,
General Secretary, ETUC

IN THIS ISSUE

The European Trade Union Confederation brought together some 200 experts, trade union leaders and European politicians in Brussels on 11 and 12 March 2005 to assess the overhaul of European chemicals legislation currently under way. It was an opportunity to clarify the positions of the many players involved in the highly complex and controversial REACH issue.

REACH: getting the balance right between competitiveness and health

"We back REACH, but are still looking for improvements to the present proposal," said **John Monks**, General Secretary of the European Trade Union Confederation (ETUC), opening the two-day debate held last March on European chemicals legislation reform. The trade union leader cited the stark tragedy of asbestos that typified the risks faced by millions of workers who have to handle substances that can have devastating health consequences. The risks are particularly high for chemical industry workers and those employed by downstream user industries.

"One in three occupational diseases is due to exposure to chemicals", claims the ETUC's research institute (ETUI-REHS) from its examination of a Eurostat survey. John Monks puts this alarming figure down to "the lack of knowledge and information about chemicals, and the manifest unwillingness of some industry employers to improve their employees' working conditions". The ETUC leader said that REACH is an opportunity for employers to improve the industry's image and promote innovation.

Stavros Dimas
European Commissioner
for the Environment

Three million working days lost each year

The EU's Environment Commissioner, **Stavros Dimas**, also believes that REACH should open up a new chapter in Europe's industrial history by "bridging a knowledge gap". A lack of information that can have tragic consequences, as the Greek Commissioner pointed out, citing the Ardystil case, the Spanish firm where the incorrect use of a chemical in 1992 led to six workers dying of lung disease.

If REACH had already been in place at the time, this tragedy could have been avoided, because information on how to use the product would have been available, said Mr Dimas. "Those parts of industry that still have doubts on REACH need to think about the money they would have saved if sick workers continued to be fit and able to work", added the Commissioner, going on to recall the high social costs incurred by chemicals: "Three million working days are lost in the EU due to occupational skin diseases caused by chemicals". In his speech, Commissioner Dimas also cited a study by the Commission's research centre, which put the cost of dredging and cleaning up contaminated soil in the EU at more than €7.5 billion in the next ten years. If these chemicals had been treated under REACH, these high costs could have been avoided, he said.

Recent scares about some consumer goods that have rocked European public opinion have done untold damage to brands and the industry, went on Stavros Dimas. REACH will allow safer substances to be launched on the market, create new market opportunities, stimulate growth and create jobs, while respecting the environment and health, he argued. In short, the EU policymaker said, REACH is in line with the Commission's re-launch of the Lisbon strategy. And he gave this reassurance about the future of the chemicals legislation reform: "There has been speculation that the Commission is planning to withdraw the proposal. This speculation is unfounded!"

Employers say "yes, but..."

Jean-Paul Mingasson
General Adviser to UNICE

Jean-Paul Mingasson, General Adviser with the Union of Industries of the European Community (UNICE), offered reassurance on European employers' attitude to REACH. "UNICE supports REACH", he said. But while the European employers' organisation seemingly backed the principle and aims of the reform, it nevertheless felt that changes were needed to the current text, which "poses some major problems".

UNICE believes the reform will be too bureaucratic and costly. "Tens of thousands of chemicals will have to be evaluated in too short a time, when the chemical industry cannot manage to evaluate more than 100 substances a year at present", said Jean-Paul Mingasson. UNICE is also unhappy that the reform "will force businesses to compile a large amount of useless information on the use of substances that are not hazardous", and argues that there is no linkage between the European proposal and the international programmes and strategies developed by the OECD and UN (Johannesburg Summit).

UNICE is particularly concerned about how REACH will affect SMEs, and claims that the costs of implementation could undermine their profitability and be an obstacle to innovation.

Environmental organisations see things very differently. The European Environmental Bureau (EEB) argues that the current text does not give workers and consumers enough protection.

John Hontelez
EEB Secretary General

"The substitution principle must be made mandatory", argued **John Hontelez**. The EEB Secretary General also pointed to the wide information gap between substances produced or imported in large volumes and those of less than ten tonnes. "The information required on small quantities is not enough for them to be classified properly. This is a major failing of the current text", he said.

The environmental lobby representative also pressed for the information supplied by industry to come under independent scrutiny, to be as full for imported substances as for those produced in Europe, and for risk information to be published throughout the supply chain, right down to the final consumer.

"We must find a compromise!"

Such a barrage of wide-ranging criticism means that the Commission text, already heavily watered down in a concession to employers, is likely to undergo further overhaul. This prospect was confirmed by MEP **Guido Sacconi** (socialist group), the European Parliament's principal rapporteur on REACH. "I believe that the final version of the Commission proposal strikes an acceptable balance between environmental, social and competitiveness aspects, but it could still do with being strengthened and improved", the Italian MEP told the conference. He said that in working towards that improved balance, he had taken account of the ETUC's positions, citing a series of proposed amendments that would tighten up the vigilance requirements and ensure authorization procedures more favourable to the substitution principle.

Guido Sacconi
European Parliament's principal rapporteur on REACH

"We must find a compromise!" he went on to say, comparing his role as rapporteur to that of a traffic policeman. "My experience as a trade unionist - I come from the union movement - has taught me that compromises emerge when they are ready, i.e., when all

Lucien Lux
Luxembourg's Environment Minister

the interested parties are willing to give up at least a little ground", he added, going on to express his belief that Parliament would be overwhelmingly in favour of this middle way approach.

Arguing that REACH was an opportunity to combine economic growth with quality of life, the Italian MEP concluded that, "Europe will either have quality growth or none".

That combination of growth and quality of employment was also central to the speech given by Luxembourg's Environment Minister, **Lucien Lux**.

"I firmly believe that only a future European industry based on the development and use of chemicals that protect the environment as well as workers and consumers' health will deliver a long-term sustainable industry, which will obviously contribute to the fight against unemployment", said the Minister, who holds the presidency of the EU's Environment Council for the first half of 2005.

Reviewing the work of the ad hoc working group on REACH set up to help the Council hammer out a common position, Lucien Lux said the ultimate aim was to eliminate and progressively replace dangerous substances and preparations in the belief that it "will encourage innovation and research into substitutes by producers of these particularly worrying substances".

The proposal is now back with the European Parliament and Council for agreement on a final "new look" version - probably by 2007. The key issue is which way the final balance will tip: towards the chemical industry's immediate interests or, with more far-reaching consequences for the community, workers and consumers' health?

Denis Grégoire, ETUI-REHS

Part 1

REACH: economic impacts and workers' health

Since the Chemicals White Paper was published nearly five years ago, most of the debate on REACH has focused on the prospective costs and benefits of the proposed reform. In October 2004, the Dutch Presidency hosted an overview workshop of the many available studies done to date by industry, the different Member States and environmental groups.

Thirty six impact studies were looked at. As the issues addressed and methods used differed widely from one study to another, the exercise reached the somewhat bland conclusion that: "The impacts of REACH on society as well as on business cannot be estimated with certainty".

The Dutch review bore out the Commission's estimates of the approximate direct costs of REACH implementation at 2.3 billion euros over 11 years. Different studies vary wildly as to the predicted indirect cost burden on business.

The studies also found that the benefits for human health were undeniable, but hard to cost out: the Commission estimated that the thousands of deaths avoided each year would produce savings of 50 billion euros over 30 years.

An entire session of the ETUC conference, chaired by Reinhard Reibsch, General Secretary of the European Mine, Chemical and Energy Workers' Federation (EMCEF), was given over to an analysis of the REACH impact assessment studies. To move the discussion on, the results of two recent major impact assessment studies are described here.

In the first article, Marc Sapir, Managing Director of ETUI-REHS, takes a close look at the findings of the further impact assessment study done by industry to evaluate the effects of REACH in the supply chain. As a member of the multi-party working group that supervised these studies, he also gives a trade-union take on the exercise and the conclusions that can be drawn from it.

In the second article, Simon Pickvance of Sheffield University's School of Health and Related Research summarises the results of a study done by him for ETUI-REHS to cost out the benefits of REACH for workers' health. The study confirms that the information generated by REACH could avoid many chemical exposure-related occupational diseases in the future. The medical cost and lost productivity savings, and quality of life benefits, would outweigh the total implementation costs of REACH.

A third article, co-written by Tony Musu and Henning Wriedt, highlights the impact of REACH on the European legislation to protect workers from chemical risks.

Trade union view on supplementary economic impact studies

Marc Sapir
Director of the Health and Safety Department, ETUI-REHS

Background and justification

In March 2004 the European Commission and the employers' representatives (UNICE/CEFIC[1]) signed a Memorandum of Understanding[2] intended to serve as a framework for further studies on the impact of the Commission's proposal to reform the European legislation on trade in chemicals (REACH), adopted in October 2003.

By signing this Memorandum of Understanding, the Commission was responding to the demands of the European Council held on 16-17 October 2003, and in particular to its decision to entrust scrutiny of the REACH proposal to the Competitiveness Council. By the same token, the Commission was also acknowledging the need to investigate the potential impact of REACH on the supply chain, on innovation and on the new Member States.

The studies on the supply chain and on innovation were to be entrusted to the accounting and business advisory company KPMG[3]; the one concerning the new Member States to the Institute for Prospective Technological Studies (IPTS), a body linked to the European Commission's Joint Research Centre.

The Council, for its part, had fed into its exploratory debates the criticisms and campaigns conducted by chemicals producers, formulators[4] and other user sectors with regard to the impact of the planned reform on employment and business competitiveness[5].

Reservations as to the methodology used

Roles of the different players

By signing a Memorandum of Understanding with industry, the Commission took the decision – for the first time since the publication of its Communication on impact assessment[6] in 2002 – to entrust representatives of the companies directly affected by REACH with conducting and financing some of the further work on economic impact assessment.

For the purposes of monitoring these new impact studies, the Commission established a Working Group comprising specialists from various Commission departments, from industry, NGOs and the European Trade Union Confederation (ETUC)[7]. The entire process was headed up by a High Level Group bringing together high level representatives of industry, the Commission, Parliament, Council, trade union organisations and NGOs.

Even though the players included not only industry representatives but also trade unions, NGOs and experts appointed by the Commission, the working method relied exclusively on data supplied, selected and validated by companies.

Business participation in the KPMG studies was voluntary. The Working Group had no say in the selection of either the companies or the materials.

It is also important to point out that this approach did not permit any macro-economic conclusions to be drawn in relation to the effects on employment or GDP (gross domestic product).

Concerning the transparency of the process, the Memorandum envisaged that the reports would be published but guaranteed that individual company data would remain confidential.

The Working Group met on nine occasions and complied with the terms of the Memorandum, monitoring the work in progress and holding overarching discussions about the work commissioned from KPMG by CEFIC and UNICE (supply chain and innovation) and that carried out by the IPTS (impact in the new Member States).

Both reports are available on the Directorate-General (DG) Enterprise website, along with comments from the departments of the Commission[8].

Case studies (micro-economic level)

The KPMG report examines cases in a number of industries, highlighting the existing relationships between chemicals suppliers and end users, and seeking to identify mechanisms which might be affected by REACH, especially aspects related to registration and testing costs.

[1] UNICE: Union of industrial confederations in the European Community. CEFIC: European Chemical Industry Council.
[2] Viewable at http://europa.eu.int/comm/enterprise/reach/eia_en.htm.
[3] In August 2004 KPMG, in association with the companies TNO and Sira, published a study, carried out at the request of the Dutch government, concerning the impact of REACH on business competitiveness in the Netherlands (see the document produced by the Netherlands presidency at http://hesa.etui-rehs.org/uk/dossiers/files/eu2004reach.pdf).
[4] Companies which blend different substances in order to produce preparations.
[5] On this point see industry's responses to the 2003 internet consultation as well as the impact studies commissioned by the national federations belonging to CEFIC. www.cefic.org > REACH > Our Views & Activities.
[6] Commission Communication on impact assessment, 5 June 2002, COM(2002) 276 final.
[7] The ETUC delegation consisted of three representatives: one from the ETUC itself, one from the German trade union confederation (DGB) and one from the European Mine, Chemical and Energy Workers' Federation (EMCEF).
[8] www.europa.eu.int/comm/enterprise/reach/eia_en.htm.

This meant looking at the following points:
- the availability of substances and potential repercussions on users;
- European manufacturers' abilities to compete with their non-EU rivals;
- the preconditions for innovation (particularly expenditure on research and development);
- financial benefits.

The following companies and materials were investigated (10 case studies in all):
- two automobile manufacturers, where the materials examined were engine oils, metal working fluids and paint;
- four inorganic sub-sectors: steel, paper, cement and zinc;
- two flexible packaging manufacturers, where inks, varnishes and adhesives were examined;
- two printed circuit board assembly firms (owing to delays, these data were not put through the verification procedure and were not discussed at the meeting of the High Level Group. The data were however included in the final report).

In all, 164 substances were examined but only 78 underwent a full evaluation.

Results of the work done by KPMG

"Vulnerability" of substances

Chemical industry representatives fear that the registration costs for some substances will be so high that they will force manufacturers to stop producing them, consequently leading to the disappearance of important substances required for the production of certain goods.

Two concepts were used in the KPMG study to address these business concerns: that of "critical" substances and that of "vulnerable" substances.

"Critical" substances are ones regarded by user companies as essential for the technical performance of the product or process into which they are incorporated.

A substance is deemed "vulnerable" when the estimated cost of registering it exceeds the net value of the anticipated profit, obliging the producer to withdraw this unprofitable substance from the market. Depending on the withdrawal circumstances, such a decision could have consequences for user companies.

Main conclusions of the study

1. Following the proposed methodology, it emerges from the study that substances regarded as "critical" by users are not "vulnerable". In other words, there is no risk that the production of substances which users consider essential will be halted.

2. Substances manufactured or imported in large quantities are unlikely to be withdrawn from the market, since the costs occasioned by REACH can be absorbed by the volumes produced. Substances produced in small tonnages, on the other hand, may well be "vulnerable". It should however be recalled that the obligation to register these low-volume substances (between 1 and 100 tonnes per year) will not come into effect until, at the earliest, six years after the entry into force of REACH. In short, given the lifecycles of many products, manufacturers of small quantities should have sufficient time to adapt to the requirements laid down in the text.

3. Business should derive certain benefits from REACH:
- the reform should help them to rationalise their product portfolio by abandoning the production of non-"critical" substances and of those which are harmful to health and the environment;
- thanks to the data generated by REACH, risk management should be simplified owing to the elimination of the most hazardous substances.

It is moreover crucial to point out that, in the main, suppliers decide whether or not to continue manufacturing a given substance on the basis of factors other than those analysed in the KPMG study. The level of demand, the nature of relations with the customer and the profitability of the substance, for example, are other key factors entering into the equation.

Other lessons learnt from the study

- **Passing-on of registration and testing costs to industry**: according to the KPMG study, manufacturers and formulators intend to cover the costs themselves or else pass them on to their customers. Formulators expect to recoup the costs by placing on the market new products associated with new functionalities. Transferring the costs to users will manifestly have a limited effect on the profitability of these companies.

- **REACH and SMEs**: small manufacturing firms could find it difficult to finance the measures required by REACH. In assessing the financial capability of an SME to implement the reform, account should in particular be taken of its situation on the market and in the industry under consideration: something the KPMG report did not look into. An SME working as a subcontractor does not have the same market knowledge and scope for price-setting as a small firm which holds a portfolio of new substances.

- **Outsourcing and R&D**: the report proves reassuring in respect of two major concerns of the trade unions. It considers that outsourcing is unlikely to occur purely as a consequence of REACH and that there is little risk of resources earmarked for research and development (R&D) being diverted.

- **Business concerns**: companies have expressed anxiety above all about the following points: protection of intellectual property, uncertainty over how to interpret certain provisions in the text (especially those concerning its application to inorganic substances), unease about a method of impact analysis that relies excessively on case studies, simultaneous implementation of the legislation, and risks arising from inadequate communication between the various players in the industry.

Some of these points relate directly to the wording of the regulation and its implementing rules. Other comments refer to the actual content of the requirements, for example those concerning the obligation to register and the data to be supplied. Suppliers and formulators, for instance, are concerned about the fact that REACH could threaten the protection of intellectual property. On this issue, the study confines itself to presenting the views of the companies concerned but does not describe any aspects of the methods of protection currently used by these companies. Nor does it take account of the various practices described in the literature on this subject[9].

Several surveys have shown that there are different protection methods for processes and for products. Generally speaking, protection operates on the basis of technological progress for processes and commercial practices for products. It is also worth noting that Annex IV of the REACH proposal stipulates: "Precise details of the process, particularly those of a commercially sensitive nature, are not required".

- The KPMG study highlights the imbalance in power existing throughout the supply chain and demonstrates that technical information is a key element in this connection.

Do these reports fulfil the aims of the Memorandum?

The IPTS report: impact on the new Member States

At the request of CEFIC and UNICE, the study focused on the speciality chemicals sector. The report confined itself to profiling the sector in the new Member States and describing the outcome of the interviews conducted in several countries.

This study finds that the cost of implementing REACH in the new Member States is modest, including in the worst case scenario. Nevertheless, in some regions companies using products imported from third countries could experience difficulties. These findings should however be treated with caution since not all the data were fully validated.

[9] See: "Protection de la propriété intellectuelle en concurrence avec d'autres stratégies", *Problèmes économiques*, dossier no. 2869, February 2005, Paris, La documentation française.

The KPMG reports: supply chain and innovation

The reports set out to cover four areas, from a micro-economic perspective: the availability of substances, business competitiveness, innovation and benefits. It is evident that the first two areas – availability and competitiveness – have been explored, albeit with the limitations mentioned above. Very little attention has been devoted to aspects concerning innovation and benefits, on the other hand, since the methodology chosen was geared to aspects such as costs and product value.

What lessons has the ETUC learnt from its involvement in this study?

From the very outset, we in the trade unions voiced our hope that the work undertaken would lead to a better understanding of companies' circumstances. Moreover, we expressed reservations about the lack of transparency in the process, in terms of both the data and the industries and products selected. We also, at every meeting, stressed the need to distinguish clearly between economic data and company managers' opinions about REACH.

Ultimately, we have concluded from this exercise that the main argument of UNICE and CEFIC – namely the risk that "critical" substances may disappear, with a knock-on effect on downstream sectors – is vitiated. The report does however give us a better grasp of the concerns expressed by business. These relate to vagueness in the current text and uncertainty as to the agenda for implementing the authorisation procedure. This last point will depend on the political will of the Member States and the pace of work at the future European Chemicals Agency, to be established in Helsinki, which will be responsible for managing the REACH system.

The study likewise shows that the REACH proposal draws attention, for the benefit of manufacturers, to the importance of communication and the need for the authorities to take into account the precarious situation of a number of operators on the market. In this context, the capacity of the national public authorities to effectively implement REACH will be crucial to such companies.

Following these efforts to assess the impact of REACH, there is obviously no need to conduct any more of these studies on the proposal. It is now high time that the legislator finalised its scrutiny of the text and took a decision in the not too distant future. A vital part of this legislative process is the development of tools to monitor the implementation of REACH by business and any repercussions it may have. Indeed, it has become apparent that the chemicals market lacks transparency, especially in terms of the way prices are set and of communication between the various players in the industry.

The ETUC's proposals (see article p. 39) to improve the draft legislation focus on giving greater prominence to the benefits expected of it.

Lessons learnt for future impact studies

In the wake of the EU White Paper on governance, the Commission adopted in June 2002 an Action Plan entitled "Simplifying and improving the regulatory environment"[10]. Among the measures put forward with a view to improving the Community's legislative cycle was an undertaking by the Commission to conduct economic, social and environmental impact assessment studies on each of its major legislative initiatives. These impact studies were scheduled to begin in 2003, and guidelines have gradually been developed with a view to carrying them out.

We believe that the work undertaken by means of the studies presented above should not constitute a model for future impact studies, since it is based on an imbalance between the different parties involved.

The growing use of the practice of impact assessment means that the Commission needs to have a broader knowledge base than under the regulatory approach. This entails gathering information from sources other than business. The Commission absolutely must develop a policy of acquainting itself with market forces and practices for the purpose of regulating the market. ■

[10] COM(2002) 278 final/2, downloadable from http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0278en01.pdf.

The impact of REACH on future skin and respiratory diseases

Simon Pickvance
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In October 2003, the European Commission adopted a proposal for a new EU regulatory framework for chemicals called REACH, which stands for Registration, Evaluation, Authorisation of CHemicals. The two most important aims of REACH are to improve protection of human health and the environment from the risks of chemicals, and to enhance the competitiveness of the EU chemicals industry.

REACH requires manufacturers and importers of chemicals to obtain relevant information on their substances, assess the risks arising from their uses, and ensure that the risks the substances may present are properly managed. By generating additional data, REACH will help close the gaps in our knowledge about many of the chemicals on the European market. Better information on hazards and risks, and how to manage them, will be passed down and up the supply chain through improved labelling and safety data sheets. REACH reverses the burden of proof so that the chemical industry must demonstrate the safe use of substances before they can be marketed within the EU. It will replace or modify the existing framework of regulations and directives governing chemical trade and use in the European Union. In addition, REACH will complement and improve the effectiveness of the existing occupational health legislation.

REACH is intended to give an overarching structure for the control of risks arising from chemicals use in the EU, and its effects are not intended to be limited only to substances about which there is currently too little data. The research question for this study is: what proportion of exposures leading to occupational diseases might be prevented by the introduction of REACH?

In four previous studies – Commission Extended Impact Assessment, RPA study, Danish study and the TUTB report – analyses have been conducted for assessing the human health benefits that may arise from REACH, but all have some limitations[1].

Focus of this research

The University of Sheffield's School of Health and Related Research was commissioned to analyse the impact of the European Union's 2003 REACH proposal on the health of the EU-25 workforce, by:

- determining the burden of occupational skin and respiratory diseases: estimation of the actual number of cases of occupational skin and respiratory diseases in different member states;
- developing occupational disease scenarios on the number of cases reduced under REACH;
- calculating the economic benefits.

Method

The scope of the project was narrowed down to two broad groups of occupational diseases; non-malignant diseases of the skin (dermatitis) and of the respiratory system (asthma and chronic obstructive pulmonary disease or COPD). Calculations carried out by the TUTB using EODS[2] compensation statistics suggest that 88% of occupational skin disease cases, and 36% of occupational respiratory disease cases, are related to chemical exposure. A further reason for focusing specifically on these conditions is that there is a short time lag between exposure and effects, therefore reflecting current work conditions, where early gains might be made following the introduction of REACH.

Malignant respiratory and skin diseases were specifically excluded, as most of the occupational causes of malignant respiratory and skin disease are either not covered by REACH (for example, UV light, asbestos dust, wood dust) or the impact on them would not be within a 30-year time span. We also excluded rhinitis, urticaria and fibrosing alveolitis.

We adopted a number of approaches to obtaining an accurate assessment of the burden of occupational respiratory and skin diseases in the EU-25. By triangulating the data from several different sources, we tried to obtain a robust estimate for the number of cases with lower and upper boundaries, using more or less conservative assumptions.

In contrast to the method used in the RPA study, for our estimates of effect we have taken all cases of diseases attributable to chemicals likely to be affected by the REACH structure. To set upper and lower bounds we have assumed that the effects of REACH are likely to be proportional to the theoretical and actual effects of chemical substances wherever they fit into the existing framework of chemical legislation. Given the impact of assumptions built into estimates of the number of cases of disease, we have set upper and lower bounds based on a range of estimates for the burden of disease rather than for

[1] *Extended Impact Assessment (EIA)*, European Commission, 2003. Available from http://europa.eu.int/comm/enterprise/reach/docs/reach/eia-sec-2003_1171.pdf.
RPA Inc., *Assessment of the impact of the new chemicals policy on occupational health*, March 2003. Available from www.chemicalspolicy.org/downloads/ImpactsOccupationalHealth.pdf.
Serup-Hansen, N., Gudum, A., Munk Sorensen, M., *Valuation of chemical related health impacts*, Copenhagen, Miljoeministeriet, 2004.
Musu, T., *REACHing the workplace. How workers stand to benefit from the new European policy on chemical agents*, European Trade Union Technical Bureau (TUTB), 2004. Available from http://hesa.etui-rehs.org/uk/publications/pub33.htm.
[2] EODS : European Occupational Diseases Statistics.

the scope of REACH. These estimates of burden take into account both the case count and the case severity for each disease.

Results

To determine the disease burden, three databases – PubMed, NIOSHTIC and CISDOC[3] – were searched for relevant peer-reviewed publications using a range of search terms including: occupational dermatitis/eczema, asthma, chronic obstructive lung/pulmonary/airways disease, burden, prevalence, incidence, compensation, cost, outcome, name of EU state, and reference citations were also followed up. The number of hits on PubMed ranged from over 32,000 for "asthma and disease" down to 55 for "occupational and COPD". Any relevant publications obtained but not available in English were translated internally, where possible, by members of the research team. The grey literature and the web were also searched for references using the search terms listed above. This information was triangulated with data obtained from routine data sources, such as those of social protection systems in the EU member states, which may involve either self-reporting or state monitoring. Public health organisations in all 25 member states were also contacted.

The outcome from this data search was that, of the data collected, different countries describe different:

- definitions for each disease;
- qualifying exposures or occupational histories;
- degrees of disability;
- definitions of disability; and
- sections of the working population.

Using the following approach, we calculated the burden of occupational disease from the information obtained as follows:

1. a) obtain incidence rates (per million) using different methods;
   b) obtain incidence rate of new cases of each occupational disease using incidence data where available;
   c) calculate the incidence rates using proportion attributable to work where the diagnosis is generic;
   d) calculate incidence rates from prevalence rates for occupational or generic disease using an estimated mean duration.
2. Estimate the proportion of cases attributable to exposure to substances affected by REACH.
3. Apply proportion from Step 2 to Step 1.
4. Use incidence rate of REACH-affected disease to calculate preventable disease for the EU-25 workforce (200 million).

For costs of occupational diseases, calculations of costs per case from the RPA study were recalculated but the timing of the impact of REACH on the working environment, and hence on disease incidence, was that used in the RPA study.

From the evidence, the incidence per million per year, and the proportion of cases avoided by REACH for asthma, COPD, and dermatitis, has been estimated at 200 and 50%, 50 and 10%, and 200 and 50%, respectively (see table 1).

Table 1 Incidence and proportion of cases avoided by REACH

	Incidence: nr. of cases avoided / million / year	Proportion of cases avoided by REACH
Asthma	200	50 %
COPD	50	10 %
Dermatitis	200	50 %

Cost analysis

The analysis of the costs associated with work-related skin and respiratory diseases was divided into three categories that cover the health service costs; productivity costs; and the value of the lost health-related quality of life to the individual.

Health service costs were calculated using evidence from other studies in the published literature. For valuing production losses, two alternative methods were used: the human capital approach[4] (the traditional approach) and the friction-cost method[5]. The monetary values of the prevention of reductions in health-related quality of life for individuals with occupational asthma, COPD, and dermatitis was approximated by multiplying an estimated utility decrement over an assumed duration of symptoms by the value of a QALY[6] (quality-adjusted life-year). The mid-point estimates of costs incurred due to productivity losses, health care costs, and monetary valuations of the impact of lost health relating to chemicals covered by REACH were calculated for 10-year and 30-year time horizons following implementation of REACH, compared to a scenario in which REACH has not been implemented (see table 2, p. 14).

[3] PubMed: PubMed, a service of the National Library of Medicine of the United States, includes over 15 million citations from MEDLINE and additional life science journals for biomedical articles back to the 1950's. www.ncbi.nlm.nih.gov/entrez/query.fcgi?DB=pubmed.
NIOSHTIC is the National Institute for Occupational Safety and Health's (NIOSH) electronic, bibliographic database of literature in the field of occupational safety and health. www.cdc.gov/niosh/nioshtic.html.
The CISDOC database, a product of the International Occupational Safety and Health Information Centre of the International Labour Organisation in Geneva, contains references from over 35 countries to key literature on safety and health at work. www.ilo.org/dyn/cisdoc/index_html.

[4] A measurement method that assigns an economic value to ill health as a function of lost productivity. Periods of illness, care, remission and relapse are valued only by reference to their implications for the individual's lost future earnings. Using directly available data, the human capital approach estimates the direct (expenditure) and indirect (lost income and opportunities) costs for each state of ill health.

[5] A method that assesses the impact of illness on productivity and production by measuring the costs of adaptation – the "friction period" – to compensate for work time and productivity lost due to ill health.

[6] The number of years of life saved weighted by the quality of life during the years added.

Table 2 Midpoint estimates of the cost impact of REACH (€ millions)

		10 year time horizon				30 year time horizon			
		Asthma	COPD	Dermatitis	Total	Asthma	COPD	Dermatitis	Total
Total costs	Without REACH	16,615	3,806	22,848	43,268	90,394	19,689	58,546	168,629
	With REACH	15,500	3,550	20,785	39,835	45,428	9,572	22,678	77,678
	Cost savings	1,115	255	2,063	3,433	44,966	10,116	35,868	90,951

Our REACH impact assumptions were based on the following assumptions:

- that REACH has no impact on incidence for six years, followed by a constant decline of new cases (as used in the RPA report);
- that mean age at incidence is 50 years and 40 years for COPD and asthma respectively;
- that productivity costs for asthma- and COPD-affected persons continue to the remainder of each affected person's working life (to 65 years);
- that health-related costs for COPD- and asthma-affected persons continue to 75 years;
- that the effects and costs associated with dermatitis continue for five years in all affected persons;
- costs are discounted at an annual rate of 3.5%.

The results show that occupational asthma and dermatitis have the greatest effect on productivity costs, but that occupational COPD has a larger effect on health care costs. The midpoint estimate for cost savings due to REACH, over a 10-year time horizon is estimated to be around € 3.5 billion. Over a 30-year time horizon, when the full effects of REACH are in place for the majority of the time period, the aggregate cost savings are estimated to be just over € 90 billion.

The uncertainties in this study mean that the benefits of the introduction of REACH are impossible to predict with a high degree of precision. There is a considerable amount of evidence on the burden of chronic obstructive pulmonary disease and asthma due to chemicals exposure at work, and more limited evidence on the burden of occupational skin disease. The impact of REACH on this burden is difficult to assess, not because of lack of clarity about the mechanisms proposed, but because of uncertainty about their implementation. However, REACH is clearly an opportunity to reduce the number of chemicals-related occupational diseases and the associated costs for both industry and society. REACH total costs for the chemical industry and downstream users, as estimated by the Commission, are in the range € 2.8 to 5.2 billion over 15 years (Extended Impact Assessment, 2003).

From the analyses in this report, we conclude:

- REACH benefits for occupational skin and non-malignant respiratory diseases only in first ten years: € 0.66 – 6.2 billion;
- REACH benefits for occupational skin and non-malignant respiratory diseases only in first thirty years: € 21.2 – 160.7 billion.

What is certain is that chemical exposures in the workplace are responsible for a very large burden of disease, the costs of which, to society, to enterprises and to the individual, greatly exceed earlier estimates but are in line with several EU studies suggesting that occupational disease costs are equivalent to between three and five percent of Gross Domestic Product. REACH has the potential to impact on them. ■

The full version of the Sheffield University study will be published shortly by the ETUI-REHS. Publication will be announced on our website and in our email newsletter: *HESAmail*.
See: www.etui-rehs.org/hesa.

REACH and worker protection legislation

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There are two related areas of European chemicals legislation: one covering the marketing of chemicals, and one protecting the workers who use them. REACH is concerned with the first area. The reform, when it comes into force, will bring changes to existing legislation on trade in chemicals: some directives will be subsumed under REACH, while others will be amended or repealed (see table 1). The worker protection legislation, by contrast, will remain untouched and so continue to apply alongside the commercial legislation. But REACH will still have positive spin-offs for worker protection. This article highlights the differences, linkages and the interplay there will be between the two areas of legislation when REACH is implemented.

Differences between the two sets of legislation

Legal base

EU chemicals marketing legislation aims at total harmonization of national laws (articles 94 and 95 EC Treaty), while worker protection legislation requires only a minimum harmonization of Member States' laws (article 137 EC Treaty). For the former, therefore, the Member States cannot in theory impose further limitations at national level, whereas for the latter, they can impose national rules that set stricter standards than the European ones.

Scope

After implementation of REACH – currently scheduled for 2007 – all substances manufactured or imported in quantities of 1 tonne or more a year (tpa) will be progressively registered on an 11-year timetable. Substances covered by other legislation, like pesticides, and those manufactured or imported in quantities below 1 tpa will not need to be registered. Significantly, however, (see table 2) there is no volume exemption to the authorisation and restriction provisions under REACH, or indeed to the requirement to supply a safety data sheet for substances that are classified as dangerous, or to the classification and labelling rules[1]. Thus, these requirements will apply regardless of production volume.

Nor is there any volume exemption to the worker protection legislation: the Chemical Agents Directive applies to all chemicals, and the Carcinogens Directive to all substances classified as carcinogenic

Table 1 How REACH will affect the two areas of chemicals legislation

Legal basis			After the entry into force of REACH
Trade legislation (articles 94 and 95 EC Treaty)	Classification and Labelling (C&L)		
	- Dangerous Substances Directive	67/548/EEC	Amended
	- Dangerous Preparations Directive	1999/45/EC	Amended
	Safety data sheets	91/155/EEC	Inclusion in REACH
	Existing Substances Regulation	793/93/EEC	Repealed
	Restrictions on Use and Marketing Directive	76/769/EEC	Repealed + Inclusion of existing limitations in REACH
	REACH	COM(2003) 644	Planned for 2007
Worker protection legislation (article 137 EC Treaty)	Chemical Agents Directive	98/24/EC	Unchanged
	Carcinogens Directive	2004/37/EC	Unchanged

Table 2 Scope of legislation (post-REACH)

Classification & Labelling (C&L)	All substances and preparations
REACH	
• Registration	All substances ≥ 1 tpa
- Chemical Safety Report	All substances ≥ 10 tpa
• Authorisation	All substances of very high concern
• Restriction	All substances
• Safety data sheets	All dangerous substances and preparations containing dangerous substances
Chemical Agents Directive	All substances present in the workplace
Carcinogens Directive	All carcinogens and mutagens (categories 1 and 2) present in the workplace

[1] A Globally Harmonised System (GHS) for classification and labelling was recently adopted at international level. The Commission is drafting legislation to implement it.

Table 3 The actors in the supply chain, their role(s) and governing legislation

	Suppliers	Users	Employers	Obligations under
Manufacturers	X	X	X	C&L, REACH, WPL
Importers	X		X	C&L, REACH, WPL
Downstream users	X *	X	X	C&L, REACH, WPL
Distributors	X		X	C&L, REACH, WPL
Workers		X		WPL

* not in every case, i.e. not applicable to end-users
C&L: Classification and labelling / WPL: Worker protection legislation

or mutagenic (categories 1 and 2), regardless of how little is used at the workplace.

The actors involved

In each area of legislation legal obligations are laid down that are to be met by different actors in the supply chain, although the same actor may wear different hats (see table 3).

REACH lays down obligations on manufacturers, importers, downstream users (formulators, industrial and professional users, etc.) and distributors (those who take substances or preparations in storage and place them on the market). These obligations differ widely according to where the actor stands in the supply chain. The main obligations of the different actors are described below. They become less onerous the further away the actor is from the starting point (manufacture or import).

- **Manufacturers and importers** must register their substances above 1 tpa, and from 10 tpa upwards they must draw up a chemical safety report to show that the risks the substance may pose to humans (workers and consumers) and to the environment are properly managed. Any risk management measures indicated in the chemical safety report must be included in the safety data sheet supplied to all downstream users of the substance. Manufacturers and importers must also apply for authorisation for the use or marketing of substances "of very high concern".

- **Downstream users** must check whether the safety data sheet accompanying the substance supplied actually covers the intended uses. If it does, they must apply the safety measures described; if not, they can ask their suppliers to include their uses in the chemical safety report. The suppliers can then revise the safety data sheet. But downstream users can also choose to keep their uses confidential. If they do so, they must draw up their own chemical safety reports and apply any resulting risk management measures. They must also document their recommended risk management measures in the safety data sheets they supply with the preparations intended for their downstream customers.

- **Distributors** must supply recipients of the substance or preparation with the accompanying safety data sheet if applicable.

The worker protection directives place obligations on employers and on workers.

- **Employers** must identify whether dangerous chemical agents[2] are present in the workplace, assess the risk to the health and safety of workers exposed to them and, if necessary, take appropriate preventive and protective measures. There is a clearly defined hierarchy of obligations: elimination of dangerous substances, substitution by less dangerous substances, reduction of the exposure level, compliance with existing occupational exposure limits, etc. Risk assessments are specific to each workplace, and deal with the dangerous substances and all activities in which workers may be exposed to them. Employers also have an obligation to provide information and training to their workers in this regard.

- **Workers** must make correct use of the dangerous substances and protective equipment supplied to them as they have been trained to do.

Some of the actors with obligations under REACH can obviously also be employers; if so, they must fulfil both the REACH and worker protection legislation obligations (see table 3). If a carcinogen is to be used in a workplace, the employer must first apply the hierarchy of obligations laid down in the Carcinogens Directive (elimination, substitution, control) before using it. If, after this, they still have to use those carcinogens, they must then also comply with the REACH authorisation rules.

Will REACH duplicate the Chemical Agents Directive?

This is a reasonable question that frequently cropped up in the debates on European chemicals legislation reform. It was specifically picked over at a tripartite workshop on the relation between chemicals legislation and worker protection legislation[3]. Some employers fear having to carry out the risk assessment twice over, since both the REACH chemical safety report and the Chemical Agents Directive require it. It was also argued that as both sets of legislation have the same aim, the Chemical Agents Directive should be repealed when REACH comes into force.

But the differences in the scopes, actors involved and their obligations make it readily evident that

[2] The definition of a dangerous chemical agent goes beyond the dangerous substances and preparations classified under the classification and labelling directives and includes all substances that may present a risk to workers because of the way they are used or are present in the workplace.

[3] Final report of the tripartite workshop on the relation between chemicals legislation and worker protection legislation, London, 14-15 June 2004. Downloadable from: http://hesa.etui-rehs.org/uk/dossiers/files/WORKSHOPReport.pdf.

there is no duplication, and that repealing the Chemical Agents Directive would have disastrous consequences for the health and safety of workers.

What REACH will add to worker protection legislation

- **REACH will remind employers that they have obligations to fulfil under worker protection legislation.** The manufacture and use of chemicals in workplaces takes a heavy toll on workers. About one in three of all occupational diseases recognised each year in Europe is due to exposure to dangerous chemicals[4]. This suggests that the legislation to protect workers from exposure to hazardous chemicals is only patchily applied in workplaces, if at all. One of many reasons for this may be that many employers (especially smaller firms) are unwittingly or deliberately flouting their obligations under the Chemical Agents Directive or the Carcinogens Directive. REACH is a good opportunity to remind them that these laws must be applied.

- **REACH will generate extra information on chemical hazards and improve "hazchem" labelling.** The effectiveness of worker protection legislation depends very much on the information required by the legislation that governs trade in chemicals. The employer's primary obligation is to identify whether dangerous substances are present in his workplace. His main means of doing that is product labels and, for products that are classified as dangerous, the safety data sheets supplied with them, if any.

  The REACH registration system will force industrial suppliers to provide extra information on the intrinsic properties of the substances they place on the market. If need be, they will have to update the classification and labelling of their substances. These provisions should improve the quality of labels to the benefit of all users. Specifically, they will help employers to identify dangerous products.

  A word of caution, however: improved classification and labelling are likely to be seen mainly for substances in volumes of 10 tpa and upwards, because the information required for registration of substances between 1 and 10 tpa is not enough to significantly improve their classification and labelling.

- **REACH will improve the quality of safety data sheets and help employers meet the requirements of Directive 98/24/EC.** The chemical safety report will require manufacturers, importers and some downstream users to establish what risk management measures are needed for the substance to be used safely. This information will have to be produced for each identified use of the substance and attached to its safety data sheet. In this way, REACH should improve the quality of safety data sheets and in so doing, help employers to carry out the risk assessment required by Directive 98/24/EC.

  Once again, chemical safety reports are required only from volumes of 10 tpa upwards, so only safety data sheets for chemicals in this bracket will carry the additional safety information.

  REACH will improve transmission of safety data and communication down the supply chain. Under the current legislation, suppliers have to transmit safety data sheets to users. This is a one-way communication. REACH will introduce two-way communication into the supply chain by enabling users who receive a safety data sheet that does not cover their use of the substance to notify their supplier of this fact. The supplier will then be able to draw up a new safety data sheet using the data communicated by the user.

  Even where a safety data sheet does not have to be supplied for a substance or preparation, the supplier must still communicate all manner of information to downstream users[5]. All actors in the supply chain also have a duty to communicate certain information upstream[6].

  This increased upstream and downstream communication in the supply chain will help employers to take the preventive and protective measures that worker protection legislation demands.

- **REACH should promote application of the substitution principle.** Having to apply for authorisation for substances of very high concern should prompt manufacturers and importers to replace them with less dangerous alternative substances, not least because authorisation can be a costly procedure with no guarantees of success. As CMR substances (categories 1 and 2) are classed as substances of very high concern, REACH should encourage employers to apply the substitution principle laid down in the Carcinogens Directive.

How worker protection legislation will add to REACH

Worker protection legislation can also help the actors in the supply chain to draw up the chemical safety reports required under REACH. The employer can extract from his own workplace risk assessment and communicate to his supplier the information he needs to prepare a chemical safety report. This will particularly be the case with downstream users looking to pass this obligation on to their suppliers.

The occupational exposure limits set for many chemicals could also be useful in establishing DNELs (Derived No-Effect Levels)[7] in exposure scenarios when drawing up a chemical safety report.

[4] Musu, T., *REACHing the workplace. How workers stand to benefit from the new European policy on chemical agents*, TUTB, 2004. Downloadable from our website: www.etui-rehs.org/hesa > Publications.
[5] See article 30 of the REACH proposal. http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0644en.html.
[6] See article 31 of the REACH proposal.
[7] Levels of exposure to a substance above which human beings should not be exposed.

Whether effective synergies can be created between the REACH and Directive 98/24/EC assessments of risks to workers will depend on the guidelines for drawing up the chemical safety reports. These guidelines are currently being worked out, and aim at helping industry fulfil its obligations under REACH[8].

Conclusions

REACH is an opportunity to tighten up existing European legislation on the protection of workers exposed to chemicals and to reduce the future incidence of chemicals-related occupational diseases.

Its principal benefit relates to the requirement of the Chemical Agents Directive to assess the risks to the health and safety of workers. Not only will REACH fill the information gap on the properties of chemicals and the means of controlling risks in use; it will also improve the transmission of that information throughout the supply chain, enabling employers to implement more effective preventive and protective measures.

In return, the workplace risk assessment employers must do should also be a help to them in discharging some of their obligations under REACH.

How far REACH will benefit workers' health and safety will depend mainly on the final contents of the reform, that is what improvements are made to it in the negotiations between the European Parliament and the Council.

After that, whether any benefits accrue will depend on enforcement of the obligations both under REACH and worker protection legislation on the factory floor. The national authorities, as well as the two sides of industry through the national and European sectoral and intersectoral social dialogue will play key roles here. ■

[8] See the RIPs (REACH Implementation Projects): http://ecb.jrc.it/REACH.

Part II

REACH and the industrial dynamic

The planned REACH reform of European chemicals marketing legislation has stirred up a debate full of complexities that is not always easy to unravel. While there is now general consensus around the objectives of REACH – ensuring a high level of protection for human health and the environment while strengthening the competitive position of the European chemical industry – exactly how to strike that delicate balance, and hence the concrete contents of the reform, remain riven with controversy. What further complicates it is the number and often conflicting interests of the parties concerned.

To try and see a clearer way through the issues in the reform and the terms of the debate, the ETUC commissioned a study from the Syndex experts to set REACH in the context of current chemical industry policy in Europe.

In their article, Bernard Bordes, Fabrizio Giacalone and Patrick Roturier provide insights into how compatible REACH is with sustainable development, the backcloth to the Lisbon strategy, and how it ties in with innovation and competitiveness, but also the uncertain economic effects REACH may have, especially for SMEs.

We also asked Michael Warhurst, an NGO expert who has been tracking developments in European chemicals legislation for many years, for his view on what REACH will do for the future of European industry. His article explains why, contrary to the popular industry argument, environmental legislation does not undermine competitiveness.

REACH, lever for a sustainable chemical industry: on what basis and how?

The full Syndex study is available on our website: www.etui-rehs.org/hesa > Main topics > Chemicals.

The draft Regulation's aims are now accepted by all the stakeholders, partly because a more demanding societal context needs regulations to move on, and partly because the rolling multi-year dialogue of stakeholders and transparency on REACH has brought the chemical industry itself to admit the need for fundamental changes in chemicals management. Big adjustments have been made to the project to accommodate a range of issues (costs, innovation, SMEs, etc.). The debate is now mainly focused on how REACH is to be implemented and what kinds of balances are being struck.

The work presented here is an attempt to take existing thinking on the impacts of implementing REACH further, and identify areas for further investigation. The aim was to shift perceptions and open up perspectives by re-contextualizing REACH and offering new insights in light of the current debates on the project.

The work is centred on three issues: REACH's compatibility with sustainable development; its interaction with the dynamic of innovation; addressing competitiveness issues, especially for SMEs.

Bernard Bordes, Fabrizio Giacalone and Patrick Roturier
Syndex

REACH AS A LEVER FOR A SUSTAINABLE CHEMICAL INDUSTRY

REACH, sustainable development and corporate social responsibility

REACH is a chemicals aspect of the sustainable development policy that underlies the Lisbon strategy aimed at turning the European Union (EU) into "the most competitive and dynamic knowledge-based economy in the world capable of sustainable economic growth with more and better jobs, and greater social cohesion and respect for the environment" by 2010.

Sustainable development is about bringing various dimensions – economic, social, environmental, governance[1] – that are in a state of permanent tension into an overall balance that requires trade-offs and compromises. The quality of a sustainable development policy is gauged not only by the objectives to be achieved in each dimension, but also by how the stakeholders join together in addressing the areas of tensions that inevitably exist between them.

In this respect, the challenge of REACH is to deliver a high level of (health and environmental) protection for all chemicals, while ensuring the smooth running of the internal market and stimulating innovation and competitiveness.

REACH is also a framework within which to develop corporate social responsibility (CSR) – i.e., the contribution firms make to sustainable development through improved control of their environmental impacts.

The REACH project offers certain guarantees as regards sustainable development policy and CSR. It sets up a specialized independent agency with extensive expertise, which should improve transparency. The process engaged since the first draft reflects an aim to preserve specific sustainable development balances through wide-ranging, extended consultation. Reversing the burden of proof onto companies is also logical and a good thing. Lastly, REACH can bring clarity and transparency to the implementation of the Responsible care agreement adopted by the chemical industry.

The REACH dynamic and the new competitive framework

REACH is only one of other components (competitiveness, innovation, SMEs) in the dynamic of a European chemical industry going through a crisis that long predates the current project, and results from complex, structural tensions. Also, criticism of any attempt to regulate disregards the fact that regulatory standards, especially in environmental matters, can benefit the community without putting the long-term future of the industries concerned at risk.

[1] An aspect that is increasingly entrenched in sustainable development and draws the other aspects together.

Crisis and change in the European chemical industry

The chemical business has been particularly affected by deregulation of the world economy from the 1980s onwards. All chemical industry groups have engaged with ongoing rationalization and flexibility strategies to address this new environment. In practice, this has led to a refocusing of the scope of businesses, organizational restructuring (questioning of internal coordination/integration systems, bigger sales and marketing focus, networking) and increasingly finance-driven trade-offs.

The chemical industry is therefore faced with major upheavals:

- a relatively radical questioning of resource ownership structures (formation of new players) and the internationalization of shareholding structures;
- financial segmentation of assets by growth potential / profitability criteria driving strong trends towards the repositioning of operators;
- questioning of internal coordination / integration systems and the roll-out of market-driven approaches and an increasing organization into business units;
- changes in innovation, increasingly driven by the need for shorter times to market and applied uses (business requirements);
- increasingly prevalent short-termism which has strongly influenced market assessments.

Business conditions in recent years have piled the pressure on the European chemical industry to perform:

- upstream, the rising cost of raw materials (where Europe is not well positioned) penalizes the processing industries, including the chemical industry, by increasing pressure on prices;
- downstream, the globalization and offshoring of chemical industry customer bases is reflected in strong downward pressures on prices and increasingly far-removed markets;
- the rising euro has also produced a 30 to 40% shrinkage in the industrial bases of Europe's chemical industry since the start of 2002.

The dynamics created by standards: experience feedback

Public rules (national, regional or international) are traditionally needed to regiment and provide private sector activities with a legitimate framework for action. They also aim to compensate for failings in letting the market alone provide for complex issues, especially balancing many mutually-conflicting dimensions. They can also aim to prompt behavioural change so that players deliver objectives outside their own self-interest.

Standards and groups of actors: processes of adjustment

Any standard necessarily challenges vested interests and behaviours, so stakeholders use their varying clout and resources to bring pressure to bear on standards developers in the development phase.

The newly-adopted standard then informs a reworking of the ground rules, impelling all actors to change their strategy to maximize the benefits to them.

The two phases tend to overlap, and the skill lies in each predicting the right time to develop an independent strategy: when the standard is stabilized, to optimize preparations for its economic application; when it makes sense to pre-empt the standard itself, for actors who have a vested interest in the development of the new constraint.

Also, some mechanisms of disseminating standards may be outside the methods prescribed by the standard itself, especially when a shift occurs from the standard as an object of contention to the standard as a framework for competitive action. This propagation of the standard tends to go beyond the initial geographical framework in which it was designed.

Industrialists most exposed to public opinion back REACH

These actors are affected by REACH. We are now in a phase where the discussion on the various elements of REACH will start going round in circles, because all the arguments have already been repeatedly rehearsed and expanded on by the stakeholders. As a result, the players are starting to position themselves within the emerging new framework according to their own specific interests.

First among these are those under the strongest strategic pressure to take up the new regulation, who have already brought in REACH-like practices (mainly firms in the Scandinavian countries). It is no coincidence that groups like Ikea, Skanska, Marks & Spencer, Procter & Gamble, Unilever, Electrolux, Ericsson, Boots, etc. have come out with a positive take on REACH.

Firms who market products that include chemicals are most exposed to consumer pressure, and their strategy must accommodate that. To that extent, they will most likely be the standard bearers for REACH in the industry. With their economic clout and the importance of their brands, they can encourage producers to move towards substitution of products.

REACH AND INNOVATION, A CORE ISSUE

Essential to delivering success, but complex

Lisbon and the global issues around innovation

Making up lost ground

The European chemical industry's competitive position in innovation has declined relative to its other main rivals. There has been a structural fall-off in the company research and development (R&D) effort in recent years. The difference between the United States, Japan and Europe is the product of a decade's widening gap in R&D spending between these three zones. It reflects a structural, non-accidental deterioration that is more down to business than States.

The last ten years' fall in proactive spending is not due to shortage of funds or business resources (15 of the world's top 30 chemical groups are European), but to new financial strategies.

To deliver the Lisbon objectives, therefore, it was decided to increase investment in R&D to 3% of GDP by 2010 (against 1.9% in 2003-2004), with a greater percentage of funding (2/3 against just over half now) coming from the private sector by 2010[2]. It is an ambitious aim for Europe, bearing in mind the wide research effort gap between the various Member States ("catching up by Southern Europe").

The challenges of innovation are not just about the R&D effort

Restoring competitiveness through innovation is a challenge that cannot be reduced to simply stepping up the R&D effort. The nature and dynamism of innovation involve broader institutional mechanisms: the linkage between technology, science and industry, which in particular shapes the relationship between public and private research; education and training are at the basis of the systematic adaptation and ongoing renewal of skills and abilities; public intervention in protecting innovation; the financial system, which can act as a "facilitator" by enabling long-term risk-taking.

The challenge is also one of the paradigm shift in innovation. The issue is now about promoting a more socially acceptable innovation policy that better accommodates sustainable development.

A complex chemical industry context

An inherently innovative industry...

The chemical industry depends heavily on scientific research. Research and dissemination on the one hand, and the knowledge-based economy on the other, are central to its organization and performance. The industry's history is one of big technological leaps and bounds. Cases in point are polymer chemistry and chemical engineering, which pushed back the bounds of science in chemical products and substances, and chemical processes, respectively, while bringing big changes to the industry's organization and structure.

The chemical industry's innovation-mindedness is particularly reflected in its response to environmental constraints, which have gradually increased in influence on two fronts: growing pressure from public opinion and consumers about quality, and public regulations. Companies have transformed their technologies and products to adapt them to the new requirements, at the same time seeking to leverage the changes in terms of greater energy efficiency, improved recovery and recycling rates, reducing inputs, efficiency and productivity gains, etc. But, it is an area where US groups have out-innovated European groups through a bigger process focus.

... but differentiated problem situations

• **By subsector[3]**

The basic chemicals industry is not much affected by REACH because it is generally a high volume producer (limited scope for substitution, cost depreciation on high volumes). It is not particularly R&D-intensive, and is more process- and cost reduction-centred.

The fine and speciality chemicals industry is most affected by REACH, but ostensibly more innovative; it is more R&D-intensive, focused mainly on processes, fine chemical product development, and the development of new products and applications in the speciality chemicals industry.

• **By geographical zone**

REACH's R&D impact is not evenly distributed between zones. The bulk of Europe's chemical industry (92%) and R&D capacities are concentrated in eight countries that are more materially affected by REACH: Germany, France, the United Kingdom, Italy, Belgium, Spain, the Netherlands and Ireland. The new entrants to the EU are relatively marginal and much more vulnerable (lagging behind West European industry in many different ways).

• **By company size**

Their size and resources give big companies a big influence on the innovation process. The bigger the company, the more researchers are spatially concentrated (R&D resources consolidated in a small number of world centres); and the more extensive the networks of researchers involved in innovation

[2] The higher levels of private funding in the USA having been identified as the reason for the country's competitive edge.
[3] Except the heavily-regulated pharmaceutical sector.

(linkages between different private and public sector players), the more firmly interdisciplinary the resulting patents.

R&D is also about centres of technological competitiveness - a key issue for SMEs, which have relatively few in-house R&D resources.

• Doubly segmented organization and investment

Organizationally-speaking, an increasingly clear separation is made between the strategic core of global research laboratories, application and process improvement spheres (local development centres), and what are regarded as more ordinary, outsourceable, relocatable R&D activities. There is a shift from business line organization to a business unit organization.

The R&D investment effort is focused on the most promising product lines (in terms of profitable growth) with a bigger focus on downstream (time to market, areas of application, more product- than process-oriented) than upstream research (more fundamental and long-term).

The challenge: creating a dynamic of innovation in health, safety and the environment

The R&D impact of REACH: highly uncertain

The various impact studies of REACH on innovation come to widely differing conclusions. Some claim highly positive impacts from the improvements delivered by REACH: the five-year exemption for substances used in R&D processes; the raising of the exemption threshold from 10 kg to 1 ton for new substances; the removal of the penalizing distinction between old and new substances to the latter's disadvantage; the withdrawal of hazardous substances, which will necessarily entail developing alternatives.

By contrast, some industrialists see REACH as an obstacle to innovation. The costs of evaluation and registration would divert resources from R&D (more significantly so for SMEs with fewer resources). The product portfolio rationalizations that would result from REACH (shedding small volume manufactures and/or products too strongly impacted by REACH) would commensurately restrict the range of substances usable by R&D.

The uncertainty about how the REACH project will impact innovation is due to two things. One is the lack of reliable evidence on the measures and timing of the implementation of corporate innovation strategies. The other is that mechanisms that typify R&D, especially the process going from the decision to step up the R&D effort to the impact in economic performance terms, are still poorly understood despite the many academic and applied studies of recent years.

REACH and Community R&D policies: including sustainable chemical industry issues in instruments to stimulate innovation

Boosting the R&D effort and innovation-led competitiveness does not *per se* guarantee the emergence of a sustainable chemical industry with a competitiveness based on economic and societal performances, focused on abilities to protect and preserve human and environmental health. REACH brings to light strong linkages between economic performance, social wellbeing and environmental protection. It can also be a delivery system for an approach to a genuinely open, knowledge-based economy that works for all stakeholders (not just for the benefit of companies and the highly-skilled).

So, one issue is to engage in a new way with the instruments currently being deployed (some in the definition phase) by the EU because of the big challenges facing all branches of industry, by branding them with this linkage approach, and so breaking down the barriers between economic innovation and social/societal innovation. This is a monumental challenge, insofar as, even where planned, opening-up to all stakeholders is seldom done where it counts (upstream), and in practice is restricted to a fairly lax "feeder system" working for chiefly private interests.

THE UNCERTAIN ECONOMIC EFFECTS OF REACH – A VITAL ISSUE

The economic impact of REACH: 36 studies leading to a paradox[4]

Consensus on an affordable total cost of REACH…

Despite the mixed findings, the expected long-term social benefits far outweigh the costs of implementing REACH in most cases.

The total direct cost assessments vary between three possible scenarios, none of which seem likely to put the future of the European chemical industry at risk (between 0.05% and 0.2% of annual industry turnover over ten years).

A scenario in which all cost saving opportunities would be exploited (in vitro replacing animal testing, information sharing and co-operation) produces a total all-EU cost of 2.4 billion euros (i.e., 0.5% of the European chemical industry's 2003 turnover for the full ten year implementation period).

A scenario in which these opportunities were only very partially exploited results in a cost of 4 billion euros, i.e., 0.7% of the European chemical industry's 2003 turnover.

[4] What follows is informed by the review of impact studies commissioned from the ECORYS and Opdenkamp Adviesgroup by the Dutch Presidency in October 2004.

A study of the Dutch chemical industry identifies extra costs in developing specific know-how on which all parties seem to be agreed: extrapolated EU-wide, these added costs would amount to nearly 1% of industry turnover, increasing the direct costs to just short of 2% of turnover.

...but wide variations in indirect effects and assumed business behaviour

By contrast, the controversy over the indirect effects seems to preclude any possible consensus. It is clear from the studies that opinion is mainly divided on two things: the number of products that would be pulled from the market, and the view of competition taken by those who commissioned the studies.

- The critical parameter is the number of products withdrawn for health, safety and environmental (HSE) or economic reasons (with knock-on job losses).

The Commission and pro-REACH camp assume that this number will be small, as any product withdrawn from a market would leave a place free that could be taken by a competitor. The anti-REACH camp extrapolate (in a way widely criticized as misleading by the other players) from case studies and surveys to disaster scenarios.

- The loss-v-gain of competitiveness argument (both in and downstream of the chemical industry) stems from two differing approaches to competition that remain to be supported: by costs versus by differentiation.

The pro-REACH camp are banking on a social demand for HSE becoming a major source of competitive advantages while precluding the problems of "localized" added cost burdens (especially for low volume and/or low value products), whereas the anti-REACH camp gloss over the social demand for HSE and play up the domino effect of the localized added cost burdens.

- There are also two diametrically opposed views about business behaviour on two other parameters: R&D (cf supra) and co-operation.

The pro-REACH camp rightly focuses on co-operation in the implementation of REACH as being key to reducing the costs of implementation. The anti-REACH camp rule it out of court...

It is worth noting that no serious study seems to have been done on any of these aspects. Those that have, are either based on ingoing assumptions about business reactions, or on surveys of industry leaders which, clearly carried out in connection with lobbying campaigns on REACH, have every likelihood of returning biased replies.

The main paradox: small causes, big effects?

Arguably, the big question raised by all these studies can be framed as: could a marginal added administrative cost (at most 0.2% of turnover) produce a macro- or meso-economic near disaster[5]? This question cannot be dismissed out of hand, nor receive a reliable response as part of a lobbying exercise which, whatever the quality of the studies, is by nature wholly unscientific.

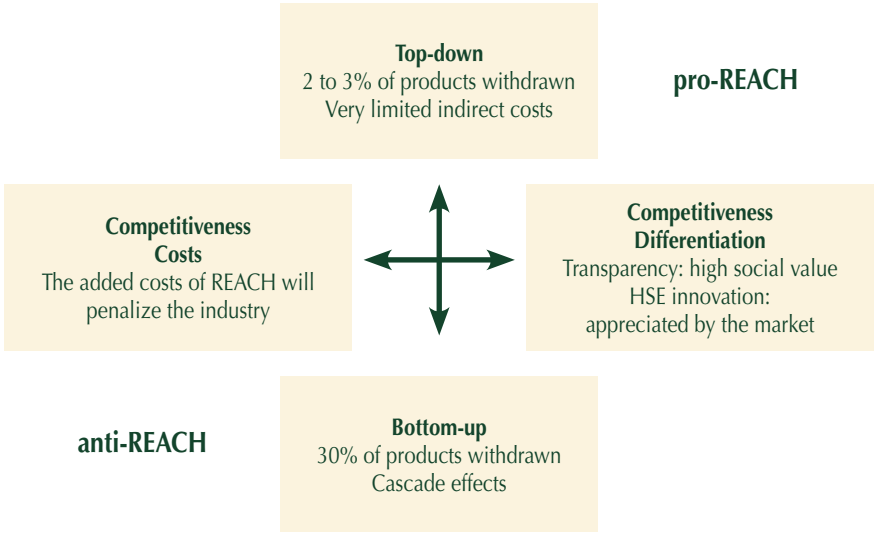
We would argue that the way to resolve this paradox is by contrasting the two models of competitiveness referred to earlier, and two concepts of the implementation of REACH with very differing outcomes (see figure).

In the "bottom up" model advanced by "disaster scenario" studies, the costs of implementing REACH are borne unaveraged by individual product and producer. Without averaging of the direct costs of REACH, the impacts will vary widely with the "volume/unit value" parameters specific to each product. In this model, distribution of the direct costs of REACH as well as the level of indirect costs – generated mainly by the withdrawal of products for economic reasons – will be dictated by the "invisible hand" alone on the basis of juxtaposed micro-economic decisions with highly complex interactions.

The "top down" model, by contrast, is based on a total cost of REACH expressed as a percentage of industry turnover, which holds water only if concrete cost-averaging measures are taken across the board. These studies hypothesize an across-the-board cost-averaging over all productions, and, unsurprisingly, rule out any product withdrawal for other than HSE reasons.

These considerations prompt a meta-economic question: given the minimal total cost of REACH, is it reasonable to leave REACH implementation purely to market forces driven by micro-economic calculations, if it is to be seen as a collective investment by European industry likely to bring a sustainable chemical industry significantly closer?

[5] A loss of 1.6% of French GDP and 360 000 jobs according to Mercer, a loss of 3% of German GDP and 1 to 1.2 million jobs according to ADL; a significant undermining of the European printing inks sector which, according to EUPIA-CEPE, would incur a total cost burden from REACH of 631 million euros (including 475 million euros in reformulation costs from product withdrawals), plus major risks of increased offshoring along the downstream supply chain.



REACH and SMEs

Impacts of uncertain nature and scope

Direct potential impacts: registration costs

Most chemical sector SMEs are in the fine chemicals industry, as small volume, high margin producers. In terms of chemical substances, they are at a potential disadvantage to big companies on two counts: they produce a greater number of substances, and in smaller quantities. That increases the number of tests required, while the low volumes makes it harder to absorb their cost.

It should be noted that SME chemical substance users (most) are not exposed to the direct cost impacts.

Indirect potential impacts through the disappearance of inputs for chemical substance users[6]

Downstream users may lose access to chemical substances for economic and/or environmental reasons.

As regards the former, producers and/or importers may find sales and profits too low to justify the costs of testing and registration. The likely overall impact of these withdrawals will be very low[7] (it bears pointing out that turnover of chemical substances is already very much an economic reality, with or without REACH): the main risk relates to low volume substances where profitability is already an issue (where REACH would simply speed up an existing process of rationalization). But specific problems may arise for users.

Attention must also be paid to the possibilities of substitution for substances withdrawn from the market: Is there a substitute available? What are its technical performances and cost compared to the old substance? If there is no substitute available, can one be developed within the REACH deadlines (industrial substitution rates and regulations working to same time frames) ?

A product may also be withdrawn for health or environmental reasons. This has health and environmental protection benefits, but may impose a cost burden on downstream users, if the substance concerned is economically important and there is no real substitute.

The benefits of REACH for downstream users must also be taken into account, because while it imposes specific costs on them, it helps to reduce the subsequent recurring costs connected with the use of dangerous substances for which information is incomplete. Furthermore, the disappearance of a substance from the market may be an opportunity for a company that manufactures a substitute (competitive weapon).

Addressing the risks of REACH for SMEs: more a problem of implementation than regulation

Most SMEs will not be immediately concerned by REACH (theoretically, it will be seven years before they are affected), which leaves time to identify and make arrangements to address the most vexed issues. Also, REACH includes provisions for adapting the regulations to lighten the cost burden on SMEs. So, registration costs for substances produced in low quantities (under ten tons) are reduced, which mainly benefits SMEs[8]. REACH has also provided a cost-saving mechanism for firms to mutualize testing by forming consortia, and authorization arrangements that weigh up the socio-economic effects against the health and environmental impacts: "an authorization is granted if it is shown that the socio-economic benefits outweigh the risks to human health and the environment and that there are no suitable alternative substances or technologies". Two committees with decision-making responsibilities have been set up by REACH: a committee for socio-economic analysis and a committee for risk assessment.

The REACH regulation is well-equipped in general terms, therefore. So the issue is to put the provisions into effect through a policy by which to identify the problems and work out appropriate ways of addressing them. This would involve, among other things, a differential approach according to the status and place of SMEs in the industrial fabric using a range of means: time periods, financial assistance, mutualisation, etc.

The principles for addressing the issues should be situation-specific and clearly distinguished between two broad types of measure:

- collective accountability systems for SMEs that are either part of a group (subsidiary companies) or in a relation of economic dependence (subcontracting): the impacts of REACH and the related issues should be dealt with uniformly in a way that encompasses the whole business (subsidiary/parent company; client/subcontractor);
- systems of assistance for independent SMEs.

CONCLUSION: UNCERTAINTIES AND SUPPORT PROVISIONS FOR A SUSTAINABLE CHEMICAL INDUSTRY

From our analysis, we have identified three key points about the process initiated by REACH.

One is that much of the health and environmental effects of chemicals are and will remain uncertain[9],

[6] The analysis of the impacts of REACH on downstream users is equated here to the impacts on SMEs, which although an approximation has some relevance given the importance of SMEs in the downstream industrial sectors.
[7] Subject to using a coherent model for implementation of REACH (see below).
[8] Adapted arrangements could be considered for those that produce or import substances in quantities of more than 1 000 tons a year, or CMR (carcinogenic, mutagenic, reprotoxic) substances in quantities over one ton.
[9] Uncertainty is not to be confused with hazard which refers to an identified danger associated with the occurrence of perfectly describable events.

which means taking particular care over defining the procedures and provision that will go best in hand with the long-term life-cycle of chemicals.

Second, it is also not possible to fully predict the dynamic of REACH on the chemical industry, because it comes down to the largely unknown strategies of actors, competing dynamics and innovation breakthroughs. It also involves potentially strong local risks, which must be addressed.

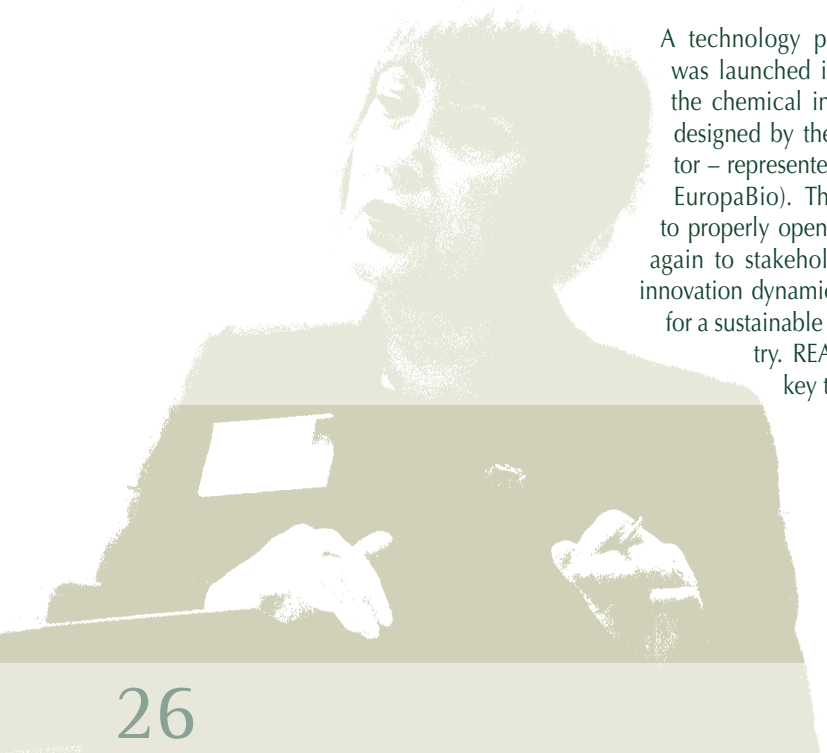
Finally, the implementation of REACH will have to ensure that ongoing balances are maintained between dimensions (economic / social / environmental) and between actors (private / public, representation of the various stakeholders, etc.).

Beyond the difficulty of getting REACH into existence, the main issue is therefore the procedures for implementing it, in two areas in particular: linking REACH into the other European policies; and management of the process dynamics, which involves controlling the economic disparities and implementing a proactive European chemical industry policy on sustainable development.

Implementation must be coordinated with the European policies

Technology platforms and the 7th Framework Programme for research and development: a practical opportunity to involve stakeholders

European technology platforms are being set up, bringing together business, research institutions, the financial community and regulatory agencies. The scheme was brought in with a view to the 7th Framework Programme for research and development (FP7) (2007-2011), and originally defined in a way heavily focused on and working for business (using public funds).



A technology platform project was launched in June 2004 in the chemical industry (initially designed by the industrial sector – represented by CEFIC and EuropaBio). The challenge is to properly open up the scheme again to stakeholders and to an innovation dynamic that will work for a sustainable chemical industry. REACH can be the key to do that.

SMEs: a cross-cutting issue in industrial policy

An analysis of the relations between REACH and SMEs shows up both how little is known about the realities of the situation, and the difficulty of pinning them down due to the wide range of concrete situations between sectors, business lines, countries, and regions. REACH cannot produce this knowledge, but should be able to use what is done elsewhere. REACH must be decompartmentalized.

European policies and measures taken for SMEs range across different areas.

For R&D, provision was made to enable SMEs to participate in FP6. At least 15% of the programme budget (i.e., approximately 1.7 billion euros) is earmarked for SMEs to take part in the seven new thematic fields of research (via "networks of excellence" and "integrated projects"), and also to benefit from a series of special measures intended to encourage their participation. They also benefit from two specific programmes on "co-operative research" and "collective research" (with an aggregate specific budget of 430 million euros).

A number of European programmes have also been launched to step up co-operation between SMEs, and innovation development can be one of the objectives.

These policies seem to suffer from the same problems as REACH, i.e., compartmentalization. The dispersal of what are largely designed as standalone measures may be the way the Commission works, but is not the best way of putting as central a focus on SMEs as the Lisbon strategy wanted.

Two implementation issues still need to be considered

What averaging is needed to even out disparities between sectors?

Limited, informal averaging left to the initiative of the players: REACH as it stands

Unaveraged, the extreme relative cost differentials of REACH may produce adverse chain reactions.

At a strictly micro-economic level, the direct costs of REACH are significant and can have product by product impacts that may result in decisions to halt production or downstream offshoring. An initial, admittedly highly simplistic, calculation illustrates the problem: over the existing 30 000 substances, the total direct cost of REACH of 4 billion euros means an "average investment" of 133 000 euros per substance. This level is not neutral for continuation or abandonment of production.

So, while low volume products may benefit from streamlined procedures, the cost of the studies required may become prohibitive and produce unwanted side-effects.

The Commission's urging for producer consortia to set up for these substances arguably falls well short of the mark, because without a preset framework, such consortia will be complex (and costly) to negotiate.

Comprehensive and centralized averaging of registration costs: economically feasible, but may undermine business accountability

An across-the-board averaging by levying a 0.2% turnover tax on chemicals to finance centralized registration would clearly preclude the forecast disaster scenarios.

Distributing that levy equally across all productions would prevent abandonment of products for economic reasons, and so incur no indirect costs.

The cost of REACH would therefore be no higher than 0.2% of annual turnover, and neutral for the "cost competitiveness" of a chemical industry which would remain profitable (approximately 10% of turnover over the long term) and R&D budgets (the costs of REACH amounting to approximately 3 to 4% of these budgets).

Downstream, the economic effects would probably be positive:

- where there is no product withdrawal for economic reasons, the reformulation costs become either non-existent, or a major source of differentiation;
- the 0.2% added cost burden would probably be more than comfortably offset by the savings from improved HSE and certainly unlikely of itself to prompt offshoring of downstream activities other than those for which the finished product transport costs were less than 0.2% of the value of the chemicals they contain…

An intermediate averaging: OSOR "plus"

The OSOR (one substance, one registration) amendment enables a case-by-case averaging to be introduced which could do much to facilitate cost sharing for the problematic low volume substances.

By creating a much more specific procedure than a simple call to form consortia, it can help reduce the transaction costs that are the main obstacle to co-operation.

Arguably, it could be reinforced by the introduction of a chemicals tax (an annual rate of 0.02% for 10 years could be enough) to finance a fund to facilitate the financing of registration studies for low volume/low value products by reintroducing obligations to carry out studies for products between 1 and 10 tons. ■

A proactive sustainable development policy: a REACH label

A REACH label could provide European chemical industry companies with a strategic opportunity as a means of differentiating and leveraging products on the world market. The REACH label would stand for the efforts companies were making to be transparent and improve the quality of their products. REACH has the qualities necessary – independence, expertise and transparency – to give the certification process public credibility. The future central chemicals agency could be the European one-stop shop for label certification and awarding.

But a series of constraints need to be overcome for a REACH label to be effective:

- **The scope of the label**: there are two possible scenarios. The REACH label applies only to chemical substances (the information is intended for user companies). This scenario flouts the spirit of REACH, which is based on the need to inform the public about the health and environmental risks of substances contained in consumer products (floor coverings, paint, detergents, etc.). The REACH label applies to chemical substances and the finished products that contain them. This goes beyond the central agency's powers, since it would mean certifying many categories of products in sectors downstream from the chemical industry. It would mean setting up several certification bodies which might, for example, be approved by the central agency.
- **The meaning of the label:** REACH labelling could operate at several levels: REACH 1 for registered substances, REACH 2 for authorized substances and, possibly, REACH 3 for particularly innovative substitutes.
- **Consistency between the REACH label and the Ecolabel set up in 1992**: the Ecolabel goes beyond the REACH system as currently planned and takes account of the entire product life cycle. Considerations of effectiveness and cost to companies clearly argue in favour of looking at ways of bringing the two labels together.
- **Promoting a REACH label worldwide**: the REACH label will deliver a competitive advantage in quality on the world market only if the European benchmark becomes the accepted standard. This is not an unrealistic aim, given the influence of the European chemical industry on the world market. Promoting REACH certification would therefore have to be largely a proactive policy by the industry, supported by all stakeholders in the system (government, NGOs, trade unions). This should then create leverage to bring the rest of the world chemical industry into line with European standards.

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Environmental regulation, innovation and competitiveness – making the link

The European economy has two major challenges: the need to create a sustainable economy, and the need to be competitive in the global market. It is well known that our current society is not sustainable; we need to achieve a major increase in the efficiency of resource use, whilst also preventing pollution. However, at the same time we must ensure that European businesses are able to compete globally, and that they are able to create and retain jobs. These two challenges are often seen as in contradiction to each other – but, for the sake of Europe and the rest of the world, they need not be.

This paper will examine how the challenges of competitiveness and innovation interrelate, and how they link with innovation and regulation. It also discusses the likely impacts of REACH on innovation in Europe.

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Regulation and competitiveness

Many stakeholders, particularly from the industry side, portray regulation as an enemy of competitiveness. This portrayal depends on the "common sense" approach that if industry has to conform with lots of regulations they are less likely to spend time innovating, and that they are likely to move their plants away from regions with more regulations.

However, these assumptions have been challenged by many of those who have studied the issue. For example, the Harvard economist Michael Porter suggested an alternative relationship in 1995 *[1]*:

"Companies can improve resource productivity by producing existing products more efficiently or by making products that are more valuable to customers – products customers are willing to pay more for. Increasingly, the nations and companies that are most competitive are not those with access to the lowest-cost inputs but those that employ the most advanced technology and methods in using their inputs.

"Environmental progress demands that companies innovate to raise resource productivity – and that is precisely what the new challenges of global competition demand. A truly competitive industry is more likely to take up a new standard as a challenge and respond to it with innovation. An uncompetitive industry, on the other hand, may not be oriented toward innovation and thus may be tempted to fight all regulation."

In reality, competitiveness involves many different factors, including issues as diverse as levels of education, the level of corruption and the macroeconomic environment. The World Economic Forum publishes an annual list ranking the "Growth Competitiveness Index" of many of the world's nations. The top 7 nations on this list in the 2004 study were as follows *[2]*: Finland > US > Sweden > Taiwan > Denmark > Norway = Singapore.

These ratings are particularly interesting as four out of the top seven countries are bound by EU product regulations – Finland, Sweden and Denmark are EU Member States, and Norway is a member of the European Economic Area and must apply all EU internal market legislation (including REACH). It is also interesting to note that these are Nordic countries – a region which has a tradition of strong environmental regulation and social support.

China is the country most often mentioned in the competitiveness debate in Europe. There is undoubtedly plenty of cheap labour available in China, but overall competitiveness relates to much more than labour costs, and the World Economic Forum places China at number 46.

Clearly, EU businesses must compete with those in China – but they will not do it by cutting wages or through a race to the bottom on regulation. As Digby Jones, the Director General of the UK business lobby group the Confederation of British Industry, put it *[3]*:

"We've got to drive toward getting everyone's skill levels up (…). If you're trying to compete only on

price, you will fail, and you will go bust and China will have your lunch. If you move into innovation, and high value-added [products], you have nothing to worry about. Britain has got a tremendous future."

Environmental regulation and relocation

The "common sense" claim that environmental regulations lead to companies moving abroad has not been supported by research by academics – primarily because environmental regulations are such a small part of business costs. For example, a 2004 study of the impacts of air pollution legislation carried out by the British consultancy company AEA Technology for DG Enterprise *[4]* found that:

"It is extremely difficult to assess the impacts of air pollution legislation on relocation from the other factors that determine location decisions, though it is clear that labour costs and access to market are much more important than environmental legislation.

"A review here has found that industrial relocation for reasons of different environmental standards is not found to be significant from OECD countries to non-OECD countries.

"However, the evidence data on movement within OECD countries does show some evidence both for and against an effect."

The lack of evidence for environmental regulation causing companies to relocate was also pointed out by DG Economic and Financial Affairs in their review of the European Economy in 2004 *[5]*:

"Evidence on crowding out of dirty industries to pollution havens in third countries seems to be very shaky and not convincing at all.

"This might not come as a surprise given that other factors normally drive decisions of investment locations, and given the convergence of environmental standards around the world, including developing countries."

Overestimation of regulatory costs

Studies that examine past debates over costs of environmental regulation have found that costs are generally overestimated by industry, and are often also overestimated by government *[6]*. A recent example is a report by AEA Technology for the UK Government, examining the costs and benefits of a number of past air pollution regulations *[7]*.

One of the regulations examined was improved vehicle emission standards:

- a cost for the UK of £16.1-22.8 billion for 1990-2001 was estimated before the regulations were put in place;
- AEA estimated the actual cost of the regulations to be £3 billion (€4.3 billion) over the 1990-2001 period.

This example gives a 5-fold difference between the predicted costs and the actual estimated cost, which means that costs were substantially over-estimated during the period when these standards were being politically debated.

It is also interesting to note that the cost of this legislation to the UK over 11 years was similar to the predicted total costs of REACH to the entire EU economy over 11 years – €2.8-5.2 billion *[8]*. This gives an idea of the small scale of REACH costs when compared to other regulatory actions.

AEA concludes: "The analysis of individual ex ante and ex post costs has shown that in most cases, ex ante costs were over-estimates. In many cases, these over-estimates were very significant. This also leads us to the conclusion that legislation itself acts as a spur to research and innovation.

"In cost-benefit analysis, the 'typical' assumption has been that the cost estimates are far more accurate than the benefits analysis. The data in this study shows that this conclusion is rarely valid."

Innovation – the key to both competitiveness and sustainability

It is clear that society needs to develop new ways of doing things, and new products to do them with – this will require considerable innovation. It is also clear that Europe will need to be innovative in order to be competitive. It is therefore important to understand what innovation is, and how it can be promoted.

Innovation has two components *[9]*:

- the rate of innovation is the quantity of innovations produced over a given period of time;
- the direction of innovation is related to the quality of innovation produced and its socially beneficial or damaging consequences.

Knowing the rate of innovation is not enough – the direction is crucial. An increase in unsustainable innovations (e.g., new disposable products) is not going to help achieve a more sustainable society.

Innovation is not evenly distributed – one company might be very innovative, whilst another might be more dependent on existing products. Innovation theory states that three factors are required for innovation to happen *[10]*:

- Willingness

- Including a company's capacity to change and the extent of its knowledge that change is possible

- Opportunity

- Supply side: technology exists or could be developed
- Demand side: regulatory requirement; opportunity to save costs or add to profits; pressure from workers or public

- Capacity

- Knowledge about better techniques, and the level of skill base at the company.

Regulation is important both to create the demand for innovation (and therefore the rewards for those companies that meet this demand), and to ensure that innovation is in the direction of sustainability. As the AEA report, above, concluded, innovation frequently acts to bring down the real cost of regulation to a level much lower than the predicted cost.

What will the effects of REACH be on innovation – positive or negative?

One of the arguments frequently used by industry is that the cost of complying with REACH will take resources away from research and development. Leaving aside the issue of whether research and development funds are really reduced as a result of regulatory compliance costs (rather than the funding coming from price changes, reduced profit, etc.), REACH is only likely to have such an impact if costs of compliance are significantly higher than normal variability in costs.

A few reports have claimed that REACH costs will be very high, for example the studies produced by Arthur D Little in Germany [*11*] and by Mercer consulting in France [*12*]. However, these studies have been widely condemned by economists [*9, 13, 14, 15*], though they have been remarkably persistent in the political debate.

However, other economic studies have found costs similar to those calculated by the European Commission [*8*], and have then compared these costs with other variable business costs, concluding that the changes in costs as a result of REACH will not be significant [*15*]:

"Price changes of the same magnitude as the costs of REACH are commonplace in industry, and do not prevent profitable operation.

"The spot price of crude oil varies by a greater percentage in almost every week, while the EU-15 price index for all intermediate manufactured goods varies by a greater percentage in almost every month."

Moving away from the issue of the cost of REACH, the key question becomes: To what extent can REACH promote innovation, and therefore competitiveness?

REACH includes a number of direct provisions which make innovation easier, and which should increase the rate of innovation, in particular:

- it reduces the burden of regulation on new chemicals, taking the threshold for notification from 10 kg / year at the moment, to 1 tonne / year under REACH;
- it creates new research and development exemptions of 5 years in the first instance, extendable by a further 5 years.

In addition, REACH has a number of measures which will affect the direction of innovation, increasing market pressure for safer products, e.g.:

- registration is simpler for chemicals not classified as dangerous, with no exposure assessment or risk assessment required. This will reward companies producing the safest chemicals;
- the new Authorisation process only affects chemicals meeting the criteria of very high concern, creating regulatory and market pressure away from these chemicals and towards safer alternatives;
- in certain circumstances, the Authorisation procedure will oblige companies to use available safer alternatives, assisting those companies that develop them;
- increased flow of information on chemical properties and risk management requirements will encourage downstream users to use the safest chemicals.

REACH will also have a substantial impact on the way chemicals are sold and used, for example promoting closer links between producers and users, as the producer will usually need to define safe use for downstream uses. Close contact between producers and customers has been shown to promote innovation [*9*].

REACH changes the distribution of costs in the value chain, as a result of increasing producer responsibility:

- chemical producers and importers will need to do more hazard and risk assessment of their chemicals, but they should have the expertise to do this;
- downstream users will be able to reduce their safety assessment costs, freeing them to focus on the service provided by chemicals, which is their area of speciality.

REACH will create new opportunities for innovation in the supply chain, as the players adjust their roles to take advantage of the new system, for example:

- chemical producers and importers will be encouraged to create and assess new exposure scenarios, promoting new uses of their products;
- formulators and distributors will have new opportunities to produce exposure scenarios to support their own customers, for example in sectoral or niche markets;
- downstream users will be able to innovate with uses of chemicals, knowing that the uses will be safe if they follow exposure scenarios in the Chemical Safety Reports.

Conclusions

The world faces a massive challenge in achieving a more sustainable future, and it is clear that Europe has a responsibility in leading this transformation as a major developed economy with a commitment to sustainability. However, this role as a leader should benefit rather than burden European companies, as they will be at the leading edge of the move to sustainability, as first movers into more sustainable technologies.

Europe is not going to compete in the global economy on the basis of low labour costs; it must instead provide more sustainable products. To encourage this transformation, Europe needs good, sustainability-orientated regulation, such as REACH. REACH will assist innovation through a combination of focussed deregulation, a re-ordering of the value chain and by promoting safer chemicals.

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REACH and the other European policies

Once the negotiations between Parliament and the European Council have been wrapped up and the contents of the reform finalized, the REACH regulation will have to be applied in the 25 Member States. To what effect will depend on a string of factors, including the level of preparedness of the different actors involved. First among these is industry, which will have to draw up the registration dossiers for the 30,000 substances covered by REACH. National and European industry associations have a key job here, and need to start informing and getting their members prepared for the REACH requirements right now. Then, the Member States will not just have to bring the regulation into force nationally, but also evaluate the dossiers submitted to them by industrialists operating inside their borders. Finally, the new Chemicals Agency, based in Helsinki, will see to the daily technical, scientific and administrative running of the REACH system.

The success of the REACH reform will also depend on whatever synergies can be developed with other existing European policies, like research and training.

The conference took a particularly close look at these latter aspects. Ake Ljunggren of the European Mine, Chemical and Energy Workers' Federation (EMCEF) discussed the importance of continuing training for workers (his presentation is available on our website). Below are the full texts of the other two papers delivered at this session.

Dominique Olivier of the French labour confederation, CFDT, reviews Community research and development policy and explains how it could be an enabler for implementation of the reform.

Following that, Giuseppe d'Ercole, of the Italian labour confederation CISL, outlines possible options for implementing REACH pre-emptively through social dialogue and voluntary agreements.

Research and REACH

Dominique Olivier
CFDT, France

Believing that Europe's future more than ever depends on a high level of skills and innovation, the European Trade Union Confederation (ETUC) gave its backing to the March 2000 Lisbon European Summit objectives.

This means that trade unions endorsed the European pledge to boost investment in research and development to 3% of GDP by 2010. Delivering this aim means pursuing proactive policies at both European and national level. Difficult economic times must not mean that the future goes by the board. But research and education are about more than the production and acquisition of new knowledge – they are fundamental to the economic, social and cultural development of our countries, and make an active contribution to increasing democracy.

Neither public nor private research, however, seems to be high on the government or business agenda. Public research is in a very shaky state, as can be seen from the resignations of 1000 research directors in France in March 2004. Commercial research is not hitting the targets set, is up against the growing influence of capital markets, and is often the first thing to go in cash-strapped firms.

Increased research also promotes job creation:
- direct jobs in research; jobs that need proper terms of employment, recognition and career prospects; and
- induced jobs created by research-driven innovation.

A closer look is needed at various areas that intersect these general problems of research and the challenges of the REACH project:
- bringing science closer to the public to achieve sustainable development;
- giving a new impetus to research through proactive measures in the European area;
- making jobs central to the Training – Research – Innovation triangle;
- making the case for a strong public research sector through cooperation with the private sector.

Bringing science closer to the public

The steadily-widening gap between science and the public must be closed to gain acceptance for substantial investment in research and credibility for its outcomes. Research can deliver fundamental rights and better access to basic items for all if it pays heed to social demand and respects a number of shared ethical principles.

Research and fundamental rights

We humans demand much of scientific research, but are also sceptical about its outcomes. We remember high-profile disasters, feel excluded from the benefits of science, or are directly affected by its unwanted effects. Younger people are disgruntled at the failure of scientific progress to deliver the expected jobs. The REACH project can and must address these questions and demands by providing more information to users and prompting them to make choices for a safe and sound environment through environment-conserving innovations.

Research, social demand and the precautionary principle

There is a real difficulty to creating social demand, which can reflect conflicting needs, and translating it into research issues. A new research governance is therefore needed which will take into account the demands of the different players in society (trade unions, but also voluntary organizations).

The precautionary principle has already become a benchmark in Europe, and European trade unions see it as a powerful guarantee for new research on big issues that are exercising society (GMOs, cloning, nuclear waste, stem cell research, homeopathy, etc.).

But the precautionary principle, which we see as positive, is not a principle of abstention. It must counsel prudent and responsible action when dealing with the unknown or uncertain.

Research and ethics

Research helps us to understand and address the big issues of our time and societal choices, especially food safety, experimentation on human beings, research on energy and global changes.

The players in civil society, especially the trade unions, must help leverage to the public the results of research in these big areas of social concern.

But the first place to address ethical issues is in the daily practice of research activities. The setting up of ethical committees open to civil society groups must be promoted.

These new approaches mean that research must properly accommodate the humanities and social sciences, and contribute to a real new governance of research and high-risk activities.

Proactive measures to give a new impetus to research

If Europe's future is dependent on innovation, investment in higher education and training and research is, along with collective bargaining, one of the main driving forces behind economic and social progress. So the agenda for today's Europe must be to develop company-funded research and innovation activity, and to create the conditions for a better interaction with public research. This means:

- clarifying the relations between public research and business with negotiated terms on patent ownership and exploitation;
- boosting the synergies between public and private research by increasing the number of combined laboratories and research partnerships;
- developing public research and higher education centres which, by brokering contract-based relations, will become a magnet for industrial and service activities;
- encouraging new innovative business creation, technology transfers, project promoters and venture capital investment in these firms;
- getting large firms to reintroduce the development of in-house research programmes into their strategies; and, at an industry level, consolidating vocational technology centres;
- transplanting the principles of transparency, prevention and responsibility into military research, because civil and military research cannot be mutually exclusive. This is a particular challenge for the scope of REACH.

Making jobs central to the Training – Research – Innovation triangle

The REACH project must be mainstreamed across education, life-long learning and upskilling policies to bring on quality jobs and work in research activities that, more than others, use potentially hazardous products and processes. This means:

- training workers in the skills for safe risk-taking inherent to research and innovation, and gaining recognition for these special skills in collective agreements;
- promoting credit for experience as another form of knowledge ownership, and hence creativity;
- reassessing the publicly-funded share of employment in R&D;
- assessing and taking account of how applied (or goal-directed) research in particular can contribute to improving working conditions and strengthening social dialogue.

Making the case for a strong public research sector

Science and technology are part and parcel of our cultural heritage on a par with other forms of cultural expression. Research must not be just about improving economic competitiveness. It must take ownership of fundamental aspects that do not yield immediate returns, but can be important in later uses (e.g., sequencing the human genome).

This is the first duty of public research, which also makes an essential contribution to cultural and social progress by helping to inform flashpoint issues, debates and the decisions of our political and economic decision-makers about the big issues involved in social changes.

The public research sector must also provide objective information to the public, produced and put in perspective by coming from multiple sources, and the independent expertise required for making informed choices (cf., asbestos in France).

In conclusion

The trade unions want immediate strong and tangible indications to be included in the future Community framework programme for R&D, and a re-evaluation of the bodies and procedures of the debate on science and the role of research in society. The European trade union movement sees research as part of its sustainable development strategy. Without research there can be no significant environmental approach, without research no bold approach to work and employment, without research no improvement in economic governance, and without innovation, no economic growth. European research, with its priorities as laid down in the sixth Community framework R&D programme (2002-2006) and forthcoming programmes, can therefore both foster implementation of the REACH system and promote synergies between REACH and the broad areas of innovation and development.

For research to be as we want it also means fulfilling conditions on the terms of employment and working conditions of research personnel. The future of research is not about a GDP-related budget, but also the quality and long-term future of the jobs of researchers and laboratory workers.

Addressing all these issues properly can give a strong signal to youth, employees, businesses, and researchers, to allay misgivings about science and technology, or doubts about the willingness of the different countries, Europe and some businesses to develop research.

The chemical industry is not under threat from asking the right questions about its own sustainability. Because chemistry is a fundamental science, more than a collection of technologies and techniques, it contains within itself and in cooperation with other disciplines, the mainsprings of its own sustained progress.

Confronting these new challenges, public and private research can construct a new paradigm of economic and social development. ■

Proactive application of REACH through social dialogue and voluntary agreements

Giuseppe D'Ercole
CISL, Department of sustainable development policies, Rome

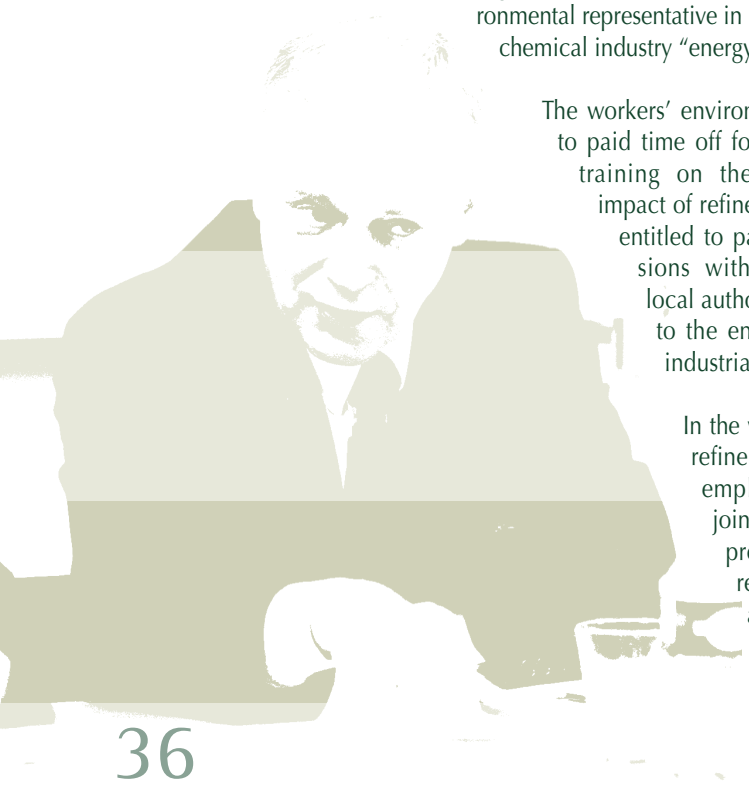
The chemical industry has often been blamed as the main culprit in a range of environmental hazards. But, to be fair, the chemical industry is the sector that is currently investing most to reduce the environmental impact of its activities and deliver better protection of workers' health at work. Even so, the consensus is that there is still a long way to go, and that REACH is a step in the right direction.

Successful delivery of the REACH objectives could be further improved if industrial relations and the whole labour relations set-up that in Europe goes by the name of "social dialogue", were carried out in accordance with each country's best practices, and if the clearest, most participatory and transparent voluntary agreements were to be implemented with the involvement of the stakeholders concerned.

Italy's national chemical industry monitoring centre – an Industry Ministry agency – has pointed out that the chemical industry has invested and is still investing most in innovation in both area and sectoral industrial relations and social dialogue systems.

Innovation in industrial relations

Among the most significant agreements recently concluded between trade unions and employers' organizations is that establishing a workers' environmental representative in refineries as a result of a chemical industry "energy" contract.



The workers' environmental rep has a right to paid time off for specific work-related training on the area environmental impact of refinery activities. He is also entitled to paid time off for discussions with the community and local authorities on issues relating to the environmental impact of industrial activities.

In the wake of this agreement, refinery industry unions and employers worked out a joint environmental training programme for workers' reps, and company safety and environment officers, which has recently gone into operation.

Workers' safety reps now also act as workers' environmental reps, therefore, helping to develop a function that promotes sustainable social, environmental and economic development. So, it could safely be said that the chemical industry is behind the creation of the workers' sustainable development rep.

He has gone from being a workplace representative arguing purely for shopfloor interests, even when they clash with the wider interests of the local community, to being a union rep conscious of his rights and responsibilities as a citizen in a specific area, working with the company to forge balances that are increasingly tipped in favour of sustainable environmental development and social acceptance of production activities. This helps business owners bring the social value of their activities into sharper focus and gain a wider acceptance in society for the idea that business is not just about providing jobs, but also about helping to prevent environmental damage that is as yet undetected or likely to appear only years or decades hence.

REACH provides a reference framework, and promotes real sustainability that is less about short-term profits than the ability to spot potential or future risks.

Sectoral agreement: sea transport of hazardous substances

The chemical industry is also behind another major agreement on the sea transport of hazardous substances. This is a voluntary agreement replacing binding legislation that has been challenged in the courts, leaving companies unsure of their rights and obligations.

Following the sinking of the oil tanker *Prestige,* which wreaked environmental, economic and social havoc to the Galician coastline in Spain, Italy's Environment Minister sought to create a statutory obligation to improve safety by using double-hull tankers.

The double-hull tanker legislation was already in force for the Venice lagoon, the site of one of Italy's biggest chemical complexes.

The Environment and Transport Ministers called joint national negotiations with chemical manufacturers and oil producers, shipping firms, trade unions and environmental groups to announce that the Venice

legislation was to be extended to all Italian ports, requiring double-hull tankers to be used for transporting and storing hazardous substances.

To their credit, the Italian environmental organizations, especially WWF Italy and Legambiente, did not stick to a hard line or political diatribes, but instead accepted the petrochemical industry's proposal to enter into a voluntary agreement which had the same effect by encouraging firms to charter only double-hull tankers, while shipping business associations pledged not to charter vessels without the double-hull safety structures for the carriage of hazardous substances.

This national agreement pre-empts by four years the entry into force of international legislation governing the carriage of hazardous substances by sea. The agreement was also supplemented with a training programme for crew on the management of waste in transit and a programme for port authorities to improve logistical facilities in this area for the efficient and prompt management and disposal of waste from the sea transport of hazardous substances.

The higher initial chartering costs of double-hull tankers was offset by the reduced cost of insurance premiums for accident and environmental damage risks, but especially by the increased security and certainty delivered for continuity of chemical plant and oil refinery production, and greater protection of other sea-related economic interests like fishing and tourism.

Once again, the chemical industry was proactive, bringing in a set of rules on the sustainability of its activity, in terms of the protection of the health and environment of those who could have been harmed by its activity, by putting the precautionary principle into practice.

REACH can be improved by this wealth of experiences, including more directly workplace-related ones, like *Responsible Care*, which can be incorporated into and developed within the REACH system.

Responsible Care is a global programme linking together chemical firms in an outreach initiative towards the families of workers and the local community where chemical plants are situated. It is a "factory open day" initiative where company executives and workers introduce their families, the local community and the authorities to the production process, the results they have achieved in terms of lessening the impact on the local environment, and safety systems that protect the health of workers and the surrounding community.

Far from trying to gloss over the dangers and risks of their production activities, these firms highlight the technologies and organizational systems that protect health and safety.

One thing is certain: it is an example to be followed for products used in production processes. What is needed is to communicate available state-of-the-art scientific and theoretical knowledge about their inherent dangers (registration), measures to protect workers and the local community (evaluation), and procedures for protection when using substances that are hazardous to humans and the environment.

Taking up the challenge of global competitiveness and sustainable development together

In this scenario of cooperation and transparency, the chemical industry can work with a greater will if institutions, stakeholders and especially European public opinion, become more aware of the global economic, industrial and financial challenges facing chemical industry firms.

Promote innovation

The European chemical industry is a world leader both in the market and in technologies for safety and lessening the environmental impact. Capital projects for innovative production processes and products can be brought in proactively without necessarily waiting for a payback which clears their written-down or investment cost.

Firms and sectors that are early innovators in production processes and products should be rewarded in line with the rules of the "Community guidelines on State aid for environmental protection", which could be further finessed and targeted in the first application of the REACH system.

Look at critical points

A special look must be taken at substances produced where European industry is structurally weak, both in terms of production, and levels of reliability for research and innovation.

Manage complexity

We believe that many firms are right now ready and able to work within the REACH system. But many fear it will be implemented and managed along unnecessarily bureaucratic, lines fixated on controls and penalties.

Various scenarios spring to mind:

- Firms with several substances to be subjected to the REACH procedure could find themselves under attack for one or two poorly analysed and notified substances, ignoring the dozen substances correctly notified.
- Allowance must be made for products that are marginally competitive on the market, where the REACH procedure could tip the balance in favour of stopping production in Europe.
- There are other substances where the market is already weak, and the possibility of resuming production in Europe may be ruled out.

We believe that the European chemical industry will gain more than it will lose from REACH, but if the winners keep silent, the bigger focus will obviously be on firms whose financial health is undermined to the point of collapse by their refusal to understand the damage that their activity may be doing to their workers, the local community and downstream users.

Introducing procedures to make REACH implementation more flexible based on good practice, especially in proactive registration, would enable the most critical and specific situations to be approached with equanimity through a balance between proactivity and possible derogations or staggered compliance periods for registrations, evaluations and authorizations.

Working assumptions
Voluntary agreements: programme contracts

Firms and sectors that claim to be ready to adapt to REACH, but which have critical points somewhere along the line, can set up voluntary technical discussions with official agencies, national authorities and workers' representatives, plus representatives of environmental and consumer groups, to work out a programme for positive REACH implementation. As part of this, proactive measures could be worked out for some substances, while others could be accorded more time, with checks carried out at regular intervals.

The rules remain, but opportunities for "voluntary" negotiation open up around which specific programme agreements can be formed; these can be national but also European where the activities concerned relate to multiple substances and/or production facilities present in at least three European countries, or again, if they relate to entire production sectors.

Programme agreements concluded by firms with the relevant official agencies, also signed up to by the unions, environmental and consumer protection groups, could possibly use a special label signalling that not only are the firms REACH-compliant, but also that their commitment and development schedules have been officially vetted and are supervised by the relevant stakeholders.

Finally, as well as specific national seats, stakeholder representatives could have a permanent seat in the European Chemicals Agency for consultation, supervision, evaluation and approval of the results of voluntary agreements. ■

The main proposals for improving REACH set out here are the product of detailed discussions held by the European Trade Union Confederation (ETUC) and its members (European industry federations and national trade union confederations) in an ad hoc working group initially tasked by the ETUC Executive Committee with preparing the unified European trade union position on REACH[1].

The ETUC's proposals for improving REACH

The ETUC's March 2005 conference gave over an entire session, chaired by Estefania Blaunt of the Spanish trade union Comisiones Obreras, to the presentation and discussion of trade union proposals for improving REACH[2]. Waldemar Bahr of the European Mine, Chemical and Energy Workers' Federation (EMCEF) presented the ETUC's proposals on the duty of care, Werner Schneider of the German Confederation of Trade Unions (DGB) those on registration, François Laurent of the Confederation of Christian Trade Unions of Belgium (ACV-CSC) those on evaluation, Francisco Blanco of Comisiones Obreras' chemical division those on the authorisation requirements, and Bernd Eisenbach of the European Federation of Building and WoodWorkers (EFBWW) those on downstream users and SMEs. Finally, Henning Wriedt of the German Work and Health consultancy looked at relations between REACH and the legislation to protect workers exposed to chemicals. These proposals follow directly on from the declarations adopted by the ETUC and its members, and aim to optimize the expected cost/benefit ratio of the reform in order to make the REACH system a more effective and paying proposition.

Duty of care

The proposed REACH Regulation adopted by the European Commission on 29 October 2003 seeks to deliver aims wholly congruent with all three pillars of the European Union's sustainable development policy: economic (industrial competitiveness), social (protection of human health and jobs) and environmental. REACH covers approximately 30 000 substances manufactured or imported into Europe in quantities of 1 tonne or more a year. These chemicals are part of our daily lives, being used in the manufacture of cosmetics, clothing, computers and other consumer goods. Chemicals contribute to European economic prosperity in terms of trade and jobs. The European chemical industry had an estimated turnover of 556 billion euros for the EU-25 in 2003, and the chemical sector employs 1.7 million people[3].

There are a hundred thousand different chemicals listed on the Community market, some of which can be harmful to human health or the environment.

Article 1.3 of the REACH proposal says that "this Regulation is based on the principle that it is up to manufacturers, importers and downstream users to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle"[4].

Furthermore, the States at the September 2002 Johannesburg World Summit on sustainable development pledged that by 2020, chemicals would be used and produced in such a way as to minimise the harm to human health and the environment.

[1] The declarations adopted by the Executive Committees of 17-18 March and 1 December 2004 are downloadable from www.etui-rehs.org/hesa > Main topics > Chemicals.
[2] Also downloadable from www.etui-rehs/hesa > Main topics > Chemicals.
[3] *Facts and Figures, The European chemical industry in a worldwide perspective*, CEFIC, June 2004, updated in July 2005. See: www.cefic.org/factsandfigures.
[4] The text of the REACH proposal can be downloaded from: http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0644en.html.

ETUC proposals on the duty of care

The European trade unions expect manufacturers, importers and downstream users to comply with article 1.3 and the Johannesburg pledges. But they believe that the text should clarify the responsibility of manufacturers and importers by reintroducing a general duty of care for all chemicals.

This is because manufacturers and importers must be responsible for documenting and communicating in an appropriate way all relevant safety information to downstream users and consumers. This principle would apply to all chemicals regardless of production volume, which means industry not only fulfilling its REACH obligations, but also shouldering the basic social, economic and environmental responsibilities that go with entrepreneurship.

There is a clear need for extra information and training for workers and their representatives on the risks and appropriate use of the substances they handle. That requires better communication on health and environmental protection between workers and their employers, and throughout the supply chain. That communication needs to be organised between trade unions and employers' organisations, and then spread through companies. The chemical industry's Responsible Care programmes are a good benchmark (see article page 36).

Registration

The REACH system requires chemical manufacturers and importers to submit a registration dossier for all substances produced or imported in quantities of 1 tonne or more a year, containing the information necessary for them to be used safely. Without a registration dossier, the 30 000 substances covered by the reform will not be able to be manufactured or imported on Community territory.

The timetable for registration is phased over 11 years. Substances produced or imported in quantities of 1 000 tonnes or more a year (tpa), and CMR substances (carcinogens, mutagens and toxic for reproduction) from 1 tpa, will have to be registered the first, i.e., during the first three years after REACH comes into force. Substances between 100 and 1 000 tpa will have six years in which to be registered, and those between 10 and 100 and 1 and 10 tpa up to 11 years after the rules come into force.

The ETUC supports the volume-based approach

The ETUC strongly supports the volume-based prioritisation system proposed in the Commission's October 2003 text. It is a clear, objectively measurable criterion that gives firms the legal certainty it needs to easily programme their REACH obligations.

The approach has also been fine-tuned, as the legislation proposes that CMR substances – classified as extremely dangerous – be included in the first wave of registrations.

European trade unions believe that introducing risk-based prioritisation criteria into the registration phase, as the industry and some Member States[5] want, would doom the reform to failure because it requires risk and exposure data that are currently lacking for too great a number of substances, but which the REACH system itself is meant to generate. The upshot would be to perpetuate the failings of the current legislation, and allow substances to continue circulating on the market with no idea of their impacts on human health or the environment, and keeping the burden of proof on the public authorities instead of shifting it to producers as the REACH reform plans to do.

The ETUC supports the OSOR proposal

Approximately 30 000 substances will have to be registered under REACH. Some of these are manufactured or imported by more than one company, so there could potentially be more than one registration dossier per substance.

The ad hoc working group on REACH set up by the Council of the European Union is currently examining the Anglo-Hungarian OSOR (One Substance – One Registration)

[5] See the European Chemical Industry Council's (CEFIC) proposals: www.cefic.org. The governments of Malta and Slovenia recently put forward a joint proposal for to prioritize registration for substances between 1 and 10 tpa.

proposal. This would require manufacturers of the same substance to share all the data they hold and work out an arrangement for sharing the cost so as to submit a single registration dossier.

The ETUC supports this proposal as aiming to cut the costs to industry and the national authorities of implementing REACH. But the ETUC will maintain its support for OSOR when the practical details are known only if the legal liability of manufacturers, importers and downstream users remains intact. That would ensure that the responsibility of individual manufacturers is not diluted when submitting a joint dossier.

The ETUC proposes that a chemical safety report be required for all substances registered

An application to register a substance must always be accompanied by a technical dossier which includes information on the identity, properties or classification of the substance. But it does not require a chemical safety report, which is only required for substances from 10 tpa upwards.

That means that there will be no chemical safety report for 20 000 of the 30 000 substances registered under REACH (see table).

Obligation to produce registration dossiers

		Registration dossiers	
Volumes (tpa)	**Number of substances**	**Technical dossier**	**Chemical safety report**
1 – 10	20 000	yes	no
10 – 100	4 600	yes	yes
100 – 1 000	2 800	yes	yes
> 1 000	2 600	yes	yes

The good thing about the chemical safety report is that it has to include exposure scenarios for substances that are classified as dangerous, PBT or vPvB[6]. The exposure scenario describes the risk management measures necessary for safe use in each identified use of the substance, and must be annexed to the safety data sheet supplied to all downstream users of the substance.

The ETUC thinks the obligation to produce a chemical safety report should be extended to the 20 000 substances between 1 and 10 tpa.

There are three reasons why:

- It would improve the safety data sheets of a much greater number of substances by adding relevant risk management information to them;
- The extra costs of the measure would add only marginally to the total costs of registration[7]. Given the likely additional health and safety benefits to workers and consumers, this measure is definitely a paying proposition;
- It would help increase coherency and the synergies between REACH and existing worker protection legislation, because Chemicals Directive 98/24/EC requires employers to assess the risks to their workers of all dangerous substances present in the workplace regardless of the volume used.

It makes good sense, therefore, for the REACH chemical safety report to apply to all substances covered by the reform, not just those above 10 tpa. Especially so since, far from being a duplication of work, the REACH chemical safety report and the Directive 98/24/EC risk assessment have different scopes but can dovetail with and inform one another[8].

The ETUC wants an extra information requirement for substances between 1 and 10 tpa

The technical dossier for substances between 1 and 10 tpa must fulfil the requirements of Annex V of the Commission proposal. This means supplying data on 14 physico-chemical properties of the substance, and five basic toxicological tests[9].

The ETUC suggests that the information required by Annex V be expanded to include an acute toxicity test and a biodegradability test.

[6] PBT: persistent, bioaccumulative and toxic substances; vPvB: very persistent very bioaccumulative substances, i.e., toxic substances that may accumulate irreversibly in the body or the environment.

[7] Ackerman, F. and Massey, R., *The true costs of REACH*, TemaNord 2004:557, Nordic Council of Ministers, Copenhagen, 2004. See: www.norden.org/pub/miljo/miljo/sk/TN2004557.pdf.

[8] See the article on the relations between REACH and worker protection legislation, page 15.

[9] Skin and eye irritation, skin sensitization, bacterial mutation and short-term toxicity on Daphnia (crustaceans).

An acute toxicity test is a basic toxicological test which indicates the lethal concentration of the substance when accidentally swallowed or inhaled. This information is essential to ensure the proper classification and labelling of the 20 000 substances concerned, and so improve protection for the workers who use them.

The biodegradability test is a basic ecotoxicological test which more clearly identifies aquatic environmental hazards.

These extra tests, which would be made Annex V requirements, should not place an undue cost burden on industry because this information is already supposed to exist for very many substances. The chemical industry, in fact, has already committed to carrying out toxicological tests through voluntary agreements entered into under the Responsible Care programmes[10].

Evaluation

The evaluation procedure allows the competent authorities in each Member State to scrutinize the registration dossiers drawn up by manufacturers or importers.

Two types of evaluation are proposed: substance evaluation and dossier evaluation.

- **Substance evaluation: the authorities can require the industry to provide more information in order to clarify suspected risks that certain substances may present to human health and the environment. A system is provided whereby the competent authorities of Member States can split the work by distributing the substances for evaluation. The agency will develop risk-based criteria to determine in which order these substances will be evaluated. Substance evaluation can result in measures under the authorisation or restriction procedure.**
- **Dossier evaluation: the purpose of this is to check the quality of registration dossiers. There is a difference between the examination of testing proposals (article 39) and the compliance checking of registration dossiers (article 40).**

Under article 39, the competent authority has to give a decision on testing proposals made by the manufacturer or importer so as to avoid purposeless animal tests.

Article 40 allows but does not oblige the competent authorities to check whether a registration complies with the requirements of the regulation and its annexes.

The ETUC wants mandatory compliance checking for a minimum number of randomly selected dossiers

The ETUC makes the case that if article 40 is left optional, the aim of quality checking dossiers will not be fully delivered. A Member State could very well not take up the option for many reasons (understaffing, other priorities, etc), so that dossiers could go through without meeting all the regulation requirements or with poor quality information.

Looking at what is workable given the workload involved in checking, the ETUC suggests that the competent authorities in each Member State should have an obligation to spot check a minimum number (e.g., 5%) of dossiers.

This would mean that all registration dossiers were open to compliance checking, without adding too much red tape. This would be an incentive to all manufacturers and importers to submit good quality, compliant dossiers that contained the information needed to ensure a high level of protection of human health and the environment.

[10] For the voluntary agreements contracted by the chemical industry under Responsible Care programmes: www.responsiblecare.org.

Authorisation

Each use and placing on the market of substances of very high concern (CMR, PBT, vPvB, etc.) must be authorized by the Commission whatever their production volume. To get an authorisation, the applicant must show that the risks related to the use of the substance "are adequately controlled". But even if he cannot, an authorisation may still be granted if the applicant can show that the risks are outweighed by socio-economic benefits and there are no suitable alternative substances or technologies. An authorisation granted on socio-economic grounds will be limited in time.

The substance as such, or as used in a preparation or an article, may also be subject to a Community-wide restriction if it is shown that the risks are unacceptable to human health or the environment.

The ETUC wants to strengthen the application of the substitution principle in the authorisation phase

The ETUC argues that the authorization procedure should aim to promote substitution of the most dangerous chemicals, as required by European carcinogens legislation (Directive 2004/37/EC).

As the Commission proposal stands, an authorisation can be granted provided it is shown that the risks are adequately controlled, even where a safer alternative is available. This does not work in favour of eliminating the most dangerous substances.

The ETUC proposes that an authorisation should be granted only:
- if it can be shown that adequate alternative substances do not exist;
- if the socio-economic benefits outweigh the risks to human health or the environment;
- if the use of the substance is adequately controlled.

The ETUC wants all authorisations to be time-limited

There is at present no time-limit on the authorisations that can be granted under REACH where the risks are adequately controlled. Only authorisations issued on socio-economic grounds can be reviewed. The ETUC wants all authorisations to be time-limited in order to promote the development of substitution plans.

The ETUC wants to extend the list of substances subject to authorisation

Not just CMR, PBT and vPvB substances, but also those with similar properties, like endocrine disruptors, can require authorisation. The ETUC wants the list extended to include substances with highly sensitising properties that can also cause serious and irreversible effects in humans or the environment.

Downstream users and SMEs

REACH defines downstream users as, "Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities".

Distributors (who store chemical substances or preparations before placing them on the market) and consumers are not regarded as downstream users. Downstream users of chemicals, therefore, would be such things as formulators or industrial users of chemicals found across a wide range of sectors of industry, like construction, carmaking, textiles, etc.

The REACH system requires downstream users to assess the safety of their uses of chemicals in light of the information communicated by their suppliers, and to take appropriate risk management measures. Specifically, they must satisfy themselves that the safety data sheet accompanying the substance supplied covers their intended uses of it.

If it does, they must implement all the relevant risk management measures set out in the safety data sheet. If not (i.e., if the intended use of the substance is not covered by the manufacturer or importer's safety data sheet), the downstream user can either:

- **inform his supplier of his intended use of the substance. The supplier will then be able to undertake a chemical safety assessment and add appropriate risk management measures covering the "identified" use to the safety data sheet;**
- **keep the use of the substance confidential. In that case, he must himself prepare the chemical safety report and implement the measures resulting from it.**

The ETUC wants steps taken to inform SMEs of their obligations before REACH comes into force

There is great confusion surrounding the real obligations of the different actors in the REACH system. These obligations differ widely according to where the company stands in the supply chain. Downstream users, for example, have no obligation to register the substances they use (see above). Substances only have to be registered by their manufacturers or importers. The confusion stems from the fact that many manufacturers and importers, as well as by far most downstream users, are SMEs, and their REACH obligations are lumped together with the costs of it.

The ETUC therefore calls for a targeted information campaign to be run by the Member States and the Commission to inform SMEs of their real obligations. The early setting-up of help and information services on REACH in each Member State would be welcome.

The ETUC wants help for SMEs in fulfilling their REACH obligations

SMEs have more limited human and financial resources than large companies, and so will probably have more difficulties in implementing the reform. The ETUC calls on the Commission to take account of the specific characteristics of SMEs when drawing up the technical guidelines intended to help the different actors in the supply chain to fulfil their REACH obligations (see the different RIPs projects). It also calls on the different European industry associations to prepare their members before the reform takes effect, in particular by looking at an industry cost-sharing arrangement.

Links between REACH and worker protection legislation

There are two distinct bodies of European chemicals legislation: one covering the marketing of chemicals, and one protecting the workers who use them. REACH is concerned with the first of these. When it comes into force, it will bring changes to existing legislation on trade in chemicals. But REACH will also have positive spin-offs for worker protection legislation, which will continue to apply alongside the commercial legislation (see article page 15).

The ETUC's proposals

Particular attention should be paid to ensuring that the obligations laid down in the REACH system are consistent with those of the occupational safety and health directives.

A dialogue should be held on this issue between the social partners. This could be held in the tripartite Luxembourg Advisory Committee on Safety and Health at Work. The outcomes of the London workshop staged in June 2004 by the British, German, Dutch and Swedish governments would be a good starting point. Similarly, this should be the subject of social dialogue at sectoral level.

To avoid inconsistencies and increase synergies between both pieces of legislation, worker representatives should be consulted on framing practical guidelines to help industries comply with the REACH regulation. ■

REACH squares perfectly with the Lisbon Strategy approach. Making European business more competitive and enforcing workers' rights to health and safety in particular, are two key aspects of the debate around the proposed European chemicals legislation reform.

This reform obliges the political, social and economic actors to take a stand on society's imperative needs, and to ask questions about some of the ways in which they operate, especially as regards communication and transparency in decision-making.

Looking ahead

Joël Decaillon
Confederal Secretary, ETUC

Transparency and social responsibility

For trade unions, REACH prompts yet further thought about what they mean by "quality" of employment, reflected in the slogan *More and better jobs,* which was the European Trade Union Confederation's rallying call at its march through Brussels on 19 March 2005.

Arguably, the key challenge of globalization to the union movement may be that of defending jobs in a European area prey to high unemployment, while keeping up exacting demands about working conditions and the kind of new jobs created.

It is a fact that trade unionism is having to deal with changes in work organisation and workforces that are causing it difficulties. One instance of this that I am familiar with is the electricity sector in France, where the growth of subcontracting is pulling the union in different directions.

So, rank-and-file action in the EDF has helped preserve jobs with good terms and conditions of employment, but has been unable to stave off increasingly large-scale contracting-out of the most dangerous work, like having nuclear reactors cleaned by temporary workers. This assumption of the biggest risks by the most vulnerable workers is a big challenge to the union movement and calls the company to account about its social responsibilities.

Corporate social responsibility will only become reality if practical means are used to deliver information and transparency. REACH, when adopted, will be one such means.

Public opinion now demands transparency in decision-making, not only from the authorities, but also from the two sides of industry.

This demand for transparency, which is central to the REACH reform, calls into question the principle of data confidentiality. Industry must now bow to public demands and provide better information to its workers and consumers throughout the industrial process.

Furthermore, as the ETUC Executive Committee stressed in its declaration on REACH, the European trade unions strongly support the burden of proof being shifted from the authorities onto industry, and hence the volume rather than risk approach in the registration phase.

No sacrificing workers' rights

In the context of the Lisbon Strategy, REACH also prompts a rethink of the concept of competitiveness. The union movement is all for European businesses becoming more competitive, but only subject to certain conditions in terms of public and occupational health. The drive for competitiveness must not be at the expense of workers' rights to health and safety which, let us not forget, have been central to the labour movement from its very beginnings.

In the more specific case of the chemical industry, this means that where a substance puts the workers who produce it at risk, it has to be taken off the market. Competitiveness can never be a legitimate reason for keeping a product that damages workers' health. And trade unions would never in any circumstances agree to the debate being couched in those terms.

Co-operation between the ETUC, the European industry federations and national confederations may not always be plain sailing, but has proved effective. The union movement has spoken with a single voice, and that has got it listened to.

This intra-trade-union dialogue and the dialogue between industry workers' reps and the European authorities are essential, because the rules cannot cover all the issues. Involvement and initiatives by employers and trade unions to achieve the highest standards of health and safety are a prerequisite to implementing the European chemicals legislation reform.

The ETUC therefore wants workers' reps to be members of the future European chemicals agency that will be based in Helsinki. REACH will succeed only if there is a permanent, constructive social dialogue between the two sides of industry at the European and national levels. ■

REACHing the workplace

How workers stand to benefit from the new European policy on chemical agents

Tony Musu

TUTB, 2004, 36 pages, 17 x 24 cm
ISBN : 2-930003-44-8

Occupational health

Eight priority action areas for Community policy

Laurent Vogel

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Further assessment of the impact of REACH on occupational health with a focus on skin and respiratory diseases

A study by the School of Health and Related Research of the University of Sheffield to be published shortly by the ETUI-REHS.
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HESA NEWSLETTER

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