

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.

REACH: economic impacts and workers' health

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

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Background and justification

In March 2004 the European Commission and the employers' representatives (UNICE/CEFIC¹) signed a Memorandum of Understanding² 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 KPMG³; 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, formulators⁴ and other user sectors with regard to the impact of the planned reform on employment and business competitiveness⁵.

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 assessment⁶ 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 Commission⁸.

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 perform-

ance 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 subject⁹.

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

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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 limitations¹.

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 EODS² 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 CISDOC³ – 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 approach⁴ (the traditional approach) and the friction-cost method⁵. 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 QALY⁶ (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, there-

fore, 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 rules¹. 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 agents² 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 legislation³. 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 chemicals⁴. 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 users⁵. All actors in the supply chain also have a duty to communicate certain information upstream⁶.

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 REACH⁸.

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>.

