The impact of REACH on future skin and respiratory diseases

Simon Pickvance
School of Health and Related Research, University of Sheffield, UK

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.