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

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The present study was commissioned by the European Trade Union Technical Bureau for Health & Safety (TUTB) in December 2004. On 1 April 2005, the three research bodies attached to the ETUC (European Trade Union Confederation) namely TUTB, ETUI (European Trade Union Institute) and ETUCO (European Trade Union College) were merged into the European Trade Union Institute for Research, Education and Health & Safety (ETUI-REHS).

Preface

Since the White Paper on Chemicals was published 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 of the European Union hosted a seminar to review the many studies done up to then. It proved to be an unprecedented volume for a single piece of draft legislation: thirty-six impact assessment studies at the time! And even more have been published since.

So why did the European Trade Union Confederation's Institute (ETUI-REHS) feel the need to add yet another study to the list?

A close reading of the Dutch Presidency's report shows that by far most of the impact assessment studies done on this draft reform are on the direct and indirect cost burdens on business. Few address the REACH reform's benefits for human health.

When adopting its proposal, the Commission published what it called an "Extended Impact Assessment" of the economic, social and environmental impacts in line with its "better regulation" pledge. This study assessed the benefit to public health at 50 billion euros over 30 years, from the thousands of deaths that would avoided each year thanks to the useful information on chemicals that will be generated by REACH.

Only one other study looked specifically at the occupational health benefits of REACH – that done by RPA Ltd for the European Commission. This study shows that almost the entire benefit of REACH to workers – between 18 and 27 billion euros over 30 years – would come from future avoided fatal cancers, with other chemical-related occupational diseases contributing only very little to the expected benefits.

But a close look at the most recent data published by Eurostat on recognized occupational diseases in Europe (one in three of which are chemical-related) reveals a much higher frequency of work-related skin and respiratory system diseases than cancers. And the causal links between chemicals and these diseases are closer than for cancers.

That is why we commissioned the University of Sheffield to do an impact assessment study on the benefit of REACH for workers' health, purely on non-cancerous work-related respiratory system and skin diseases.

The study's findings, presented to the European Parliament on 17 October this year, show that Europe could be spared 50,000 cases of work-related respiratory diseases and 40,000 cases of work-related skin diseases, all due to workers being exposed to dangerous chemicals, each year through REACH.

That would amount to average savings of 3.5 billion euros over 10 years for the EU-25, and more than 90 billion euros over 30 years when the full effects of the reform filter through.

The savings will benefit social security systems through reduced costs, workers through an improved quality of life, and employers across all sectors through avoidance of sickness absence-related lost productivity.

This is a major study on several counts. First, because it underscores something pointed out by the European Parliament's lead rapporteur, Guido Sacconi – that REACH may have a cost, but also prospective benefits for human – and especially workers' – health. That is a key objective of the reform. But also because, in addition to its scoreboard of occupational health benefits of REACH, the study gives a forensic survey of work-related skin and respiratory system diseases in Europe – diseases that tend to slip through the net of existing reporting and recognition systems in the 25 Union countries.

It is also important to point out that the expected potential benefits depend not just on the various actors involved applying the regulation, but even more so on the information that the system will generate on the hazards of chemicals and means of managing the risks related to their uses.

REACH is an instrument for producing and transmitting useful data on chemicals. But both it and the investments will seriously under-perform unless manufacturers are required to produce a minimum amount of relevant information. Basic information on which to take action without extra foot-dragging and endless procedural wrangling is crucial.

The European Trade Union Confederation (ETUC) has put forward specific proposals for optimising the expected cost-benefit ratio, in particular for workers' health. One essential is to beef up the information requirements for the many low-volume chemicals workers are exposed to. That's why the ETUC thinks the acute toxicity test and the obligation to produce a chemical safety reports should be extended to the 20,000 substances in the 1-10 tonne range.

Finally, a debt of thanks is due to all those involved in producing this study: the University of Sheffield's research team, the experts from the European Commission's Enterprise, Environment and Employment DGs, RPA Ltd and Beratungs und Informationsstelle Arbeit & Gesundheit, who did the crucial job of validating the study, but also all the members of our institute's staff who worked on this project from design to production of the final report.

Marc Sapir,
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Executive summary

Background

In October 2003, the European Commission adopted a proposal for a new EU regulatory framework for chemicals called REACH, which stands for **R**egistration, **E**valuation, and **A**uthorisation of **CH**emicals (Commission of the European Communities, 2003a). 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 used 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, analyses have been conducted for assessing the human health benefits that may arise from REACH – Commission Extended Impact Assessment, RPA study on occupational health, Danish Study, and the TUTB report – but all have some limitations.

Focus of this research

The School of Health and Related Research (ScHARR), University of Sheffield was commissioned to analyse the impact of the 2003 European Union 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, COPD). Calculations carried out by the TUTB using EODS compensation statistics suggest that 88% of occupational skin disease (OSD) cases and 36% of occupational respiratory disease (ORD) cases are related to chemical exposure (Musu, 2004). A further reason for focusing on these conditions specifically 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. Rhinitis, urticaria and fibrosing alveolitis were also excluded.

A number of approaches were adopted to obtain an accurate assessment of the burden of occupational respiratory and skin diseases in the EU-25. The triangulation of data from several different sources was used to obtain a more robust estimate for the number of cases, with lower and upper bounds, 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 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 – 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. All 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;
- sections of the working population.

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

1. Obtain incidence rates (per million) using different methods:
   a. obtain incidence rate of new cases of each occupational disease using incidence data where available;
   b. calculate incidence rates using proportion attributable to work where the diagnosis is generic;
   c. 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, calculations of costs per case 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 without REACH for asthma, COPD and dermatitis has been estimated at 400, 500 and 400, of which the proportion of cases potentially preventable by REACH is 50%, 10% and 50%, respectively. Using a working population figure for EU-25 of 200 million, the number of future cases per year that might be avoided thanks to REACH is 40,000 for asthma, 10,000 for COPD and 40,000 for dermatitis.

Incidence, proportion and number of cases avoided by REACH

	Incidence: nr. of cases / million / year	Proportion of cases avoided by REACH	Nr. of cases per year avoided by REACH
Asthma	400	50%	40,000
COPD	500	10%	10,000
Dermatitis	400	50%	40,000

Cost analysis

The analysis of the costs associated with 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 (the traditional approach) and the friction-cost method. 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 (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.

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;

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

Total costs	10 year time horizon				30 year time horizon			
	Asthma	COPD	Dermatitis	Total	Asthma	COPD	Dermatitis	Total
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

- 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 COPD and asthma due to 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 chemical-related occupational diseases and the associated costs for both industry and society. REACH total costs for the chemical industry and the downstream users, as estimated by the Commission, are in the range €2.8 to 5.2 billion over 15 years (Commission of the European Communities, 2003b).

From the analyses in this report, we conclude:

- REACH benefits for occupational skin and non-malignant respiratory diseases only, in the first ten years: €0.66 – €6.2 billion.
- REACH benefits for occupational skin and non-malignant respiratory diseases only, in the 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. They are however in line with several EU studies suggesting that occupational disease costs are equivalent to between 3 and 5% of Gross Domestic Product. REACH has the potential to impact on these.

Section 1
Introduction

1.1 Background to the study

In February 2001, the European Commission adopted a White Paper (COM(2001) 88 final) setting out its strategy for a future Community Policy for Chemicals. The aim of this strategy is to ensure a high level of protection for human health and the environment, while ensuring the efficient functioning of the internal market, and stimulating innovation and competitiveness in the chemical industry.

The White Paper proposes that, in the future, new and existing substances should be regulated under the same procedures and within a single system called REACH, which stands for the **R**egistration, **E**valuation and **A**uthorisation of **CH**emicals. The European Commission adopted the proposal for a REACH regulation in October 2003 (COM(2003) 644 final), and it is currently being examined by the European Parliament and the Council in a co-decision procedure.

Under the proposed new system manufacturers or importers of one tonne or more per year of a chemical substance will be required to register information on it in a central database. Some of the substances will be subject to evaluation by competent authorities in member states and substances of very high concern will be subject to authorisation.

REACH will reverse the "burden of proof" from authorities to industry. The producers will have to supply the appropriate information required to ensure the safe use of their products before those products can be marketed within the EU.

The REACH proposals describe a new method of controlling the risks for human health and the environment arising from the manufacture, import, placing on the market and use of substances. It is expected that REACH has the potential to realise a range of benefits associated with the provision of additional test and risk assessment data on chemicals, which would then lead to improved classification and labelling and earlier restrictions on substances of concern.

A number of studies have been carried out to determine the impacts of REACH (Workshop REACH Impact Assessment, The Hague, 2004). These studies differ in terms of focus, methodology and structure. Most of these impact assessments have focused on costs (mainly for the business sector), very few on benefits.

The main study available that addresses the impact of REACH on occupational diseases has been prepared by Risk and Policy Analysts Associates (RPA) at the request of the European Commission (RPA Inc, 2003). One of the main findings of the RPA study is that more than 99% of the reduction in occupational health impacts that may arise at EU-15 level from the implementation of the REACH regulation comes from the avoidance of future cancer deaths. The estimated value of reducing skin and respiratory diseases only accounts for approximately €16 million of the total €27 billion benefits expected over a 30 year time period.

At the request of the European Trade Union Institute for Research, Education and Health and Safety (ETUI-REHS) attached to the European Trade Union Confederation (ETUC), a team from the School of Health and Related Research (ScHARR), University of Sheffield, have carried out a further study.

1.2 Aims and scope of the study

The School of Health and Related Research, University of Sheffield, was commissioned to provide a further assessment of the impact of REACH on occupational health with a focus on skin and respiratory diseases.

The study reanalyses for these two endpoints the potential REACH benefits calculated by RPA. Although both studies are built on a similar structure, this study tries to refine the RPA methodology by using alternative approaches in some steps.

It addresses the following issues for the EU-25 workforce:

- The prevalence and incidence of occupationally-related respiratory and skin diseases that could be affected under REACH
- The proportion of cases of disease preventable under REACH
- Costs of respiratory and skin diseases
- Cost savings and health benefits due to REACH.

This study does not challenge the REACH benefits calculated by the RPA which are linked to the prevention of occupational cancer deaths, it just reassesses the potential benefits for work-related skin and respiratory diseases.

Section 2
REACH impact on workers' exposure to chemicals

2.1 Links between REACH and the worker protection legislation

In order to better understand the impact of REACH on workers' exposure to chemicals, it is important to examine the linkages, differences and interactions between REACH and the existing legislation designed to protect workers exposed to hazardous chemicals in the workplace.

The European legislation on chemicals can be divided into two categories: one dealing with the functioning of the internal market (ie, trade in these substances) and the other concerning the protection of workers exposed to these substances. These two sets of legislation differ in their legal basis, scope and actors involved.

2.1.1 Legal base

The European directives laying down rules for the marketing of substances establish **total harmonisation** of national legislations (Articles 94 and 95 of the Treaties) whilst those on the protection of workers' health and safety aim for **minimum harmonisation** of the different member states' legislative provisions (Article 137 of the Treaties).

The REACH proposal belongs to the first category. It will repeal, take over or amend the existing Community Directives and Regulations on the marketing and use of chemicals (see Table 1). REACH will replace Regulation 793/93 on the evaluation and control of the risks of existing substances as well as Directive 76/769/EEC and all the other associated directives concerning restrictions on the marketing and use of certain dangerous substances and preparations. The existing restrictions will remain in force and will be listed in an annex to REACH. Directives 67/548/EEC and 1999/45/EC on the classification and labelling of dangerous substances and preparations will be amended to align them with REACH. Finally, REACH will also take over the current safety data sheet requirements (Directive 91/155/EEC).

Table 1 **How REACH will affect the two systems for chemical legislation**

Legal Basis			**After REACH entry into force**
Internal market legislation (articles 94 and 95 EC Treaty)	Classification & Labelling (C&L) Directives		
	▪ Dangerous Substances	67/548/EEC	Amended
	▪ Dangerous Preparations	1999/45/EC	Amended
	Safety Data Sheets Directive	91/155/EEC	Inclusion in REACH
	Existing Substances Regulation	793/93	Repealed
	Restrictions Directives on the marketing and use of dangerous substances and preparations	76/769/EEC	Repealed + existing restrictions taken over by REACH
	REACH Regulation	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

As far as chemicals are concerned, the second category mainly consists of two directives: the Chemical Agents Directive (98/24/EC) and the Carcinogens Directive (2004/37/EC). These directives compel employers to carry out a risk assessment for all chemicals present at the workplace and to take the necessary prevention and

protection measures. The provisions of those directives will remain unchanged after REACH is enforced, and as REACH will coexist with the worker protection legislation, the requirements of both legislations will need to be met.

2.1.2 Scope

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

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 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
Chemicals Directive	All substances present in the workplace
Carcinogens Directive	All carcinogens and mutagens (categories 1 and 2) present in the workplace

* CMRs: carcinogenic, mutagenic, toxic for reproduction; PBTs: persistent, bioaccumulative and toxic; vPvBs: very persistent and very bioaccumulative, ie, toxic substances which could accumulate irreversibly in the body and the environment

Nor is there any volume exemption to the worker protection legislation: the Chemicals Directive applies to all chemicals, and the Carcinogens Directive to all substances classified as carcinogenic or mutagenic (categories 1 and 2), regardless of how little is used in the workplace.

2.1.3 The actors involved

Each body of legislation lays down legal obligations that are to be met by different actors in the supply chain, although the same actor may wear different hats (see Table 3).

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, ie, not applicable to end-users
C&L: Classification and labelling
WPL: Worker protection legislation

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 get less onerous the further away the actor is from the starting point (manufacture or import).

- **Manufacturers and importers** must register their substances above one tpa, and from ten tpa upwards they must draw up a chemical safety report to show

that the risks the substances may present for humans (workers and consumers) and the environment are properly managed. Any risk management measures deriving from the chemical safety report must be annexed to 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 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 supplied 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 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 can be exposed to them. Employers also have an obligation to provide information and training for their workers.
- **Workers** must make correct use of the dangerous substances and protective equipment supplied to them as they have been trained to do.

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 present in the workplace.

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 comply with the REACH authorisation rules.

2.2 REACH impact on OHS legislation

The differences in the scopes, actors involved and their obligations make it readily evident that there is no duplication of work between REACH and the worker protection legislation. It is expected rather that REACH will have a positive impact on the existing occupational health and safety legislation.

2.2.1 Impact on employers

The manufacture and use of chemicals in workplaces takes a heavy toll of workers. About one in three of all occupational diseases recognised each year in Europe is due to exposure to dangerous chemicals (Musu, 2004). 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 from smaller firms) are unwittingly or deliberately flouting their Chemicals Directive or Carcinogens Directive obligations. REACH will provide a good opportunity to remind employers that they have obligations to fulfil under worker protection legislation.

2.2.2 Impact on classification and labelling

The effectiveness of worker protection legislation depends very much on the information required by the legislation that governs trade in them. The employer's primary obligation is to identify whether dangerous substances are present in his workplace. His main means of doing so is from the 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 are placing on the market. If needs be, they will have to update the classification and labelling of their substances. These provisions should lead to earlier restrictions on substances of concern and improve the quality of labels for the benefit of all users. Specifically, it 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 ten tpa and upwards, because the information required for registration of substances between one and ten tpa is not enough to significantly improve their classification and labelling.

2.2.3 Impact on the safety data sheets

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 ten tpa upwards, so only safety data sheets for chemicals in this bracket will carry the additional safety information.

2.2.4 Impact on communication

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 the 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[3]. All actors in the supply chain also have a duty to communicate certain information upstream[4].

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.

3. See article 30 of the REACH proposal. http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0644en.html.
4. See article 31 of the REACH proposal.

2.2.5 Impact on substitution

Having to apply for authorisation for substances of very high concern should prompt manufacturers and importers to replace them by less dangerous alternative substances, not least because it 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.

2.3 Exposures affected by REACH

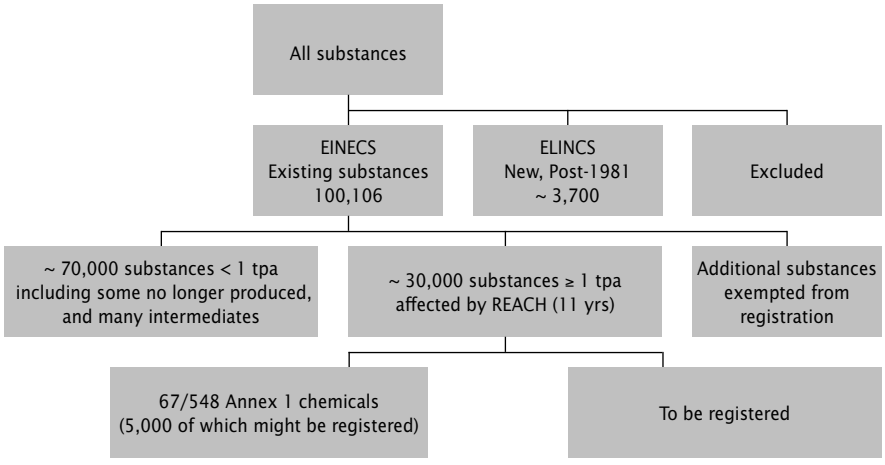
Through the above-mentioned impacts, REACH will therefore significantly boost the effectiveness of the existing legislation on the protection of workers exposed to chemicals, lead to a reduction of exposure and lower future incidence of chemicals-related occupational diseases.

The effect on different substances will vary according to the areas in which the deficits to be made up by REACH lie, ie, data generation, communication, substitution or restrictions.

Chemical substances produced and marketed in the EU are listed in two databases (see Figure 1):

- EINECS (European INventory of Existing commercial Chemical Substances) lists 'existing' substances in use prior to 1981. There are about 100,000 substances on EINECS. Most existing substances have not been thoroughly tested for their risks to human health and the environment.
- ELINCS (European LIst of Notified Chemical Substances) is for 'new' substances introduced since 1981. From that year, importers and manufacturers of chemicals have been obliged to notify the substances they wish to place on the market in accordance with an amendment of Directive 67/548/EEC. Approximately 3,700 'new' substances have been notified in 24 years and entered onto ELINCS. These substances have been quite rigorously tested and are considered as registered under REACH. However, if the quantity of a notified substance reaches a higher tonnage threshold, additional information must be submitted. It can be suggested that a quarter of ELINCS substances are sensitisers, but this result should be treated with caution, as ELINCS substances are not likely to be representative of existing chemicals.

Figure 1 **Breakdown of chemicals to be registered under REACH**



REACH will cover the registration of EINECS substances manufactured or imported in volumes starting at one tonne per year per manufacturer or importer. EINECS substances exempted from registration are mainly substances manufactured or imported in volumes under one tpa and substances covered by other legislations. The number of substances to be registered is estimated at 30,000. These are, in bulk terms, responsible for most exposure, but the nature of skin and respiratory sensitisation means that sensitisers often initiate adverse health effects in very low

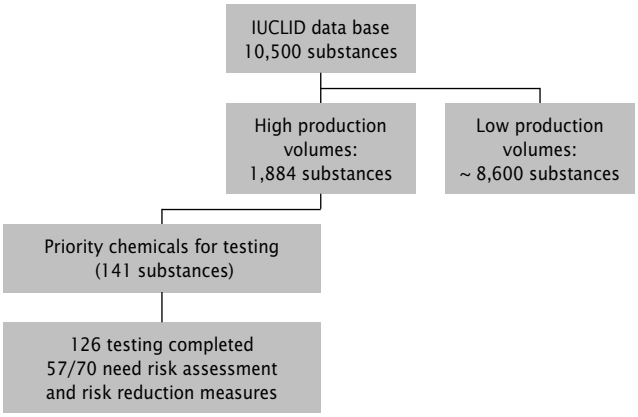
concentrations, so that this prioritisation by volume is unlikely to have an effect on the burden of occupational respiratory and skin diseases (ORSD) directly proportional to the volume of chemicals in use.

A series of pieces of legislation to control the use of chemicals and to protect human health and the environment have introduced requirements for different, often overlapping, groups of existing (and new) chemicals. Because of this, the REACH regulations are likely to impact on the use of EINECS substances in several different ways.

Certain existing (EINECS) and new (ELINCS) substances are classified under Directive 67/548/EEC, which also covered classification and labelling of dangerous substances and introduced risk and safety phrases. In Annex 1 of this directive, seven thousand or so substances are listed as being dangerous (about 5,000 are existing substances and 2,000 are new substances). For the purposes of REACH, existing substances over one tpa that are listed in Annex 1 of 67/548/EEC will need to be registered. As already mentioned, REACH will not interfere with the classification process, but classification will have to be changed where registration shows that this is necessary.

Other EINECS substances have been fairly thoroughly tested. Data sets in the Harmonized Electronic Data SET (HEDSET) format are held in the International Uniform Chemical Information Database (IUCLID) database (see Figure 2) on 10,500 substances, of which 1,884 are High Production Volume Chemicals (HPVCs, those produced in more than 1,000 tonne quantities per annum during the period 1984 to 1994). Of the 1,884, 48% had data on sensitisation, 73% on skin irritation, and 50% on acute inhalation toxicity. The additional substances making up the 10,500 are lower volume (10-1000 tonne) substances listed in 1998. Complete information is available for approximately half of these, and of these, roughly 25% are skin sensitisers and 10% respiratory sensitisers (see Figure 2 in Allanou, 1999).

Figure 2 **The IUCLID database**



Forty-seven substances or groups of substances, covering 900 individual substances are covered by Directive 76/769/EEC (Restrictions Directive) which restricts the marketing and use of certain dangerous substances and preparations. The restricted substances listed on Annex 1 of the Directive (so known as Annex 1 substances) are generally mutagens, carcinogens or substances with reproductive effects. However, some of them are powerful sensitisers as well (chromates, nickel and compounds, certain Polycyclic Aromatic Hydrocarbons – PAHs). Restrictions arising from the Restrictions Directive are responsible for a decline in exposure and sensitisation to chromates. REACH is likely to have least impact on exposure to these chemicals.

One hundred and forty-one substances – all HPVCs – have been prioritised for thorough risk evaluation and management under Existing Substances Regulation 793/93. Of these, risk assessment has been concluded on 70, and 57 of the 70 were found to require additional risk reduction measures. The impact of REACH for these, and other substances for which there is relatively complete information in the HEDSET format, will be an improvement in communication of information to end-users and between end-users, the authorities, and producers on risks and risk reduction measures.

Other substances with this standard data set still require further testing and evaluation. The impact of REACH should be to complete the data sets for these substances and, as in the case of the HPVCs so far tested, this is likely to lead to the introduction of additional risk reduction measures and improved communication between the authorities, producers and end-users.

The greatest impact may well be on the 30,000 substances, prioritised on the basis of volume, which have not already been listed for testing. From the testing of EINECS substances, HPVCs and ELINCS substances, we expect these to include many sensitisers and irritants.

REACH is intended to give an overarching structure for the control of chemical risks 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?

- If the substance is in ELINCS, then REACH may affect the restrictions placed on its use and will introduce, in some cases, new communication requirements in the supply chain.
- If the substance is in EINECS and has been adequately tested and restrictions put in place (ie, one of the 76/769 Annex 1 substances) then the influence of REACH will be small.
- If the substance is in EINECS and has been adequately tested and restrictions required (ie, one of the Priority substances), the impact will be via communication.
- If a substance has already been recognised as a sensitiser or irritant but is not in ELINCS or among the relatively few tested EINECS substances, REACH might add weight to the prevention measures to be taken, as REACH will improve the information for users by specifying the risk reduction measures that are required.
- If the substance is among the 30,000 substances to be registered and is not among the substances for which there are already data on sensitisation and irritation, the effect will be on testing, classification, communication and risk reduction; ie, the greatest impact on current use. However, for 20,000 of these, produced in lower volumes, the lack of acute toxicity testing required by REACH for these substances will potentially reduce effects on the prevention of ORSD.
- If the substance is produced in very small volumes then REACH would not affect its classification within the first 11 years.
- A number of classes of exposure are outside the terms of REACH. If the substance is an excluded substance, its use would not be influenced by REACH. Classes include:
  - substances which occur as natural metabolites in the human body (glucose, for example);
  - polymers in pure form (rarely encountered in work – most polymers in use are mixtures of additives);
  - biological substances unmodified, biocides and pesticides (these are covered by other legislation);
  - naturally occurring mineral dusts.

In contrast to the method used in the RPA study, for our estimates of effect, we take all cases of diseases attributable to chemicals likely to be affected by the REACH structure. Setting an upper and lower bound is difficult using existing statistics. If we take out substances for which data is relatively good then we are generally taking out the substances responsible for the majority of cases of disease; skin sensitisers like chromium or epoxy resins, and respiratory sensitisers like isocyanates. But since these substances continue to be responsible for more cases of

the respective diseases than any others, then eliminating them from the estimate implies that REACH will have no impact on communication and compliance of risk reduction measures and no impact on the major chemical causes of ORSD. A good example of this is the occupational asthma caused by isocyanates. Ten to twenty percent of asthma cases recorded in EU compensation statistics are due to isocyanates; this proportion has changed little over 20 years. It is not unreasonable to expect regulation of isocyanate use to improve through the introduction of REACH.

We therefore assume 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. In this, our approach differs from that adopted by RPA. Given the impact of assumptions built into estimates of the number of cases of disease we think it may be preferable to set upper and lower bounds based on a range of estimates for the burden of disease rather than for the scope of REACH. These estimates of burden take into account both the case count and the case severity for each disease.

Section 3
Previous studies

Most of the impact assessments for REACH have focused on costs (mainly for the business sector), very few on benefits. A review of these studies can be found in the final report of a Workshop held in October 2004 by The Netherlands Presidency (REACH Impact Assessment, The Hague, 2004). We are aware of only four previous studies that have taken into account the benefits to human health that might result following implementation of REACH.

3.1 Extended impact assessment of REACH

In its October 2003 *Extended Impact Assessment of REACH*, the European Commission offered an estimation of the possible costs and benefits of REACH (Commission of the European Communities, 2003b). REACH total costs for the chemical industry and the downstream users were estimated to be in the range €2.8 to €5.2 billion over 15 years.

In order to illustrate the possible magnitude of the benefits of REACH for human health, the Commission employed a World Bank analysis of the total amount of disease attributable to harmful chemical exposures. Drawing from the conservative end of the range of World Bank estimates, the study assumed that 1% of all disease is attributable to chemical exposures. It estimated that 10% of these impacts could be addressed by REACH, implying that 4,500 lives could be saved each year by REACH. With the value of a statistical life at €1 million, and assuming that public health benefits would begin ten years after REACH goes into effect and continue for only 20 years, it found that, as an illustration of the potential scale of the benefits of REACH, the present value of total benefits over the next 30 years is around €50 billion.

The potential scale of benefits may be even larger. The effects of hazardous chemicals often last more than 20 years, so the benefits of reducing exposure would last longer as well. Some cancers associated with chemical exposure have a latency period of 20 years or more, so the benefits of reduction would not be visible within a 20-year window.

3.2 The RPA study for the European Commission

The RPA study, *Assessment of the Impact of the New Chemicals Policy on Occupational Health* (RPA Inc, 2003) was commissioned by the European Commission to provide an assessment of the potential reduction in occupational health impacts that might arise at the EU-15 level from the implementation of REACH. This is the main study available dealing with the impact of REACH on occupational diseases.

The approach used comprises three steps. First, scenarios were developed on the number of cases reduced under REACH for five health end-points. Secondly, the economic costs per case per year were estimated. Thirdly, by combining step 1 and 2, the economic value of the future diseases avoided under REACH was calculated (see Table 4).

Table 4 **Occupational disease impact scenarios on the number of cases reduced under REACH and cost assumptions used**

Health end-point	Cases associated with exposure to unknown chemicals – LOWER BOUND	Cases associated with exposure to non-specific chemicals – UPPER BOUND	Cost assumptions per case per year (€)
Skin diseases	1,350	12,000	640
Respiratory diseases	275	3,680	1,180
Eye disorders	50	50	600
CNS diseases	50	485	11,570
Cancers	2,167	4,333	1.3 to 2.14 million

Source: RPA Inc, 2003

The RPA study concluded that the estimated health impact reductions arising from REACH ranged from around €18 billion to €27 billion for the lower bound assumptions on the number of cases that will be reduced through increased test data and authorisation.

One of the main conclusions of the RPA study is that more than 99% of the reduction in occupational health impacts that may arise at EU-15 level from the implementation of the REACH regulation comes from the avoidance of future cancer deaths. The estimated value of reducing skin and respiratory diseases only accounts for approximately €16 million of the total €27 billion benefits expected over a 30 year time period.

The RPA studies concentrate on occupational diseases that are caused by chemicals, and use the numbers of new cases of occupational disease reported by social protection/compensation bodies to measure the number of cases that could potentially be prevented following the introduction of REACH. Where authorities failed to provide RPA with the statistics, the figures were extrapolated from those that were provided by other EU member states. The effect is that the total estimated by RPA for the EU15 is significantly higher than that produced by the European Occupational Disease Statistics survey that gathered statistics from 12 member states (Eurostat, 2004). This is presumably because the countries that provided RPA with statistics were those with the most effective surveillance systems. We have subjected this source of data to analysis in Section 5.3.1 below. The use by RPA of social protection systems as the sole source of data on occupational morbidity is likely to have led to large scale underestimation of the number of preventable cases. This is because the scope of social protection for occupational disease sufferers in the EU is limited and the application of administrative rules limits recognition of cases amongst eligible workers.

RPA calculates the number of preventable cases, by analysing the chemicals named as the cause of disease cases that are recorded in government statistics. The RPA analysis takes a narrow view of the purposes of REACH, excluding the effects of REACH on the use of chemicals, which have already been evaluated. RPA assumes that chemicals named as causes in compensation analyses are already known to be hazardous and are unlikely to be controlled better post-REACH, and that the cases that are preventable are those where the chemical responsible is stated either as unknown or unspecified in the statistics.

The RPA analysis makes distinctions between:

- disease cases due to known substances, which it argues will not be prevented by REACH measures;
- cases described in statistical tables as due to unknown substances, which may or may not be covered by REACH and therefore, RPA assumed, mark the lower bound of expected effects of REACH;
- cases due to unspecified or non-specific substances (Table 4).

There is no detailed discussion of what the terms unknown, unspecified and non-specific mean either in the sources from which RPA draws its statistics or in the RPA analysis itself.

If a cause is unknown, then it may or may not be chemical-related. Unspecified may mean that a case is thought likely to be due to a chemical, but the identity is not known. Non-specific has different connotations: a substance may for example belong to a group, such as the isocyanates, without the specific isocyanate being known. Whatever is intended by these terms, it is unlikely that they can be applied with consistency, and we feel that they are an unreliable basis on which to set upper and lower bounds of effect.

The RPA analysis models the effects of REACH following the stepwise introduction of REACH measures over the initial 11 years, to generate a model of increasing power to prevent illness. The first years after introduction show smaller benefits in terms of illness cases prevented than when the measures are fully in place.

3.3 Danish study

A Danish government report (Miljoeministeriet, 2004) used RPA estimates of case numbers and cost estimates based on an earlier Danish report (Serup-Hansen N *et al.*, 2004). This report estimated the health benefits for Denmark alone, due to improvements in the working environment, to be worth between 675 and 5,260 million Krone (€95 million and €737 million) over a 30-year period at 2002 prices. Since the study is based on the RPA methodology, the above-mentioned limitations also apply to the Danish government report.

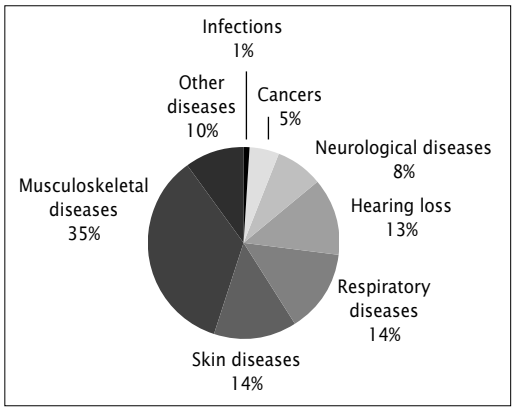
3.4 The TUTB report

5. Now Health and Safety Department of the ETUI-REHS.

The European Trade Union Technical Bureau for Health and Safety (TUTB)[5] has produced a short report on the gains to be made by workers in the European Union from the introduction of REACH (Musu, 2004), from which the figures below are drawn. Skin and respiratory diseases comprise over a quarter of the occupational diseases recognised each year in Europe (Figure 3, below). On the basis of these data, the TUTB has estimated, for each category of diseases with a possible link to chemicals, the proportion of them that may indeed be related to exposure to chemicals (Table 5, below). These calculations suggest that 88% of occupational skin disease cases and 36% of occupational respiratory disease cases are related to chemical exposure.

The limitation of this report is that it only provides an indication of the percentage of occupational diseases related to chemicals exposure. No estimation is given of the proportion of these diseases that may be avoided in the future due to REACH implementation.

Figure 3 **Recognised occupational diseases in Europe 2001**



Source: EODS Eurostat, 2004

Table 5 **Estimated percentage of occupational diseases related to exposure to chemical substances**

Occupational diseases	% linked to chemicals exposure	% amongst all recognised diseases	% chemicals related amongst all recorded diseases
Cancers	4 – 90% *	5%	0.2 – 4.5% *
Neurological diseases	2%	8%	0.2%
Respiratory diseases	36 – 89% *	14%	5.0 – 12.5% *
Skin diseases	88%	14%	12.3%
Total			**~ 18% to 30% ***

* including chemical dust (asbestos, silica dusts, wood dusts)
Source: Musu, 2004

Section 4
The research brief

To analyse the impact of the 2003 European Union REACH proposal, three tasks have been carried out.

Task 1

Burden of occupational skin and respiratory diseases: estimation of the actual number of cases of occupational skin and respiratory diseases in different member states :

- Review of the total number of recognised cases of occupational skin and respiratory diseases in the 25 European member states.
- Propose a methodology for assessing the extent of under-declaration and under-recognition of these occupational diseases.
- Estimate the actual number of cases of occupational and respiratory diseases in the 25 countries.

Task 2

Development of occupational disease scenarios on the number of cases reduced under REACH :

- Estimate the percentage of occupational skin and respiratory diseases related to chemicals exposure.
- Develop impact scenarios for the number of these cases that may be avoided in the future due to implementation of the REACH legislation.

Task 3

Economic benefits :

- Calculation of the economic benefits associated with the estimated number of skin and respiratory diseases avoided under REACH.

Section 5
Methods

5.1 Diseases included and excluded by this report

We have narrowed the scope of this project 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 compensation statistics suggest that 88% of occupational skin disease cases and 36% of occupational respiratory disease cases are related to chemical exposure (Musu, 2004). A further reason for focusing on these conditions specifically 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 have been 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 (see Appendix 3 for details).

Rhinitis: Relatively few cases of occupational rhinitis occur each year compared with the number of occupational asthma cases. In the UK, there were 100 assessed cases of this condition in 2002/03 (HSE, unpublished).

Urticaria: Finnish registry figures for 1990-1994 found 815 cases of contact urticaria; 29.5% of allergic occupational skin conditions (Kanerva *et al.*, 1996). The vast majority of contact urticaria cases resulted from exposure to biological materials. Only 14 were caused by low molecular weight substances (similar statistics are available in the UK). For this reason the following discussion looks only at contact dermatitis resulting from exposure to substances at work.

Fibrosing Alveolitis: In comparison with occupational dermatitis or asthma, fibrosing alveolitis is a rare condition (HSE, unpublished; FIOH, 2004).

If these diseases were included the calculated impact of REACH would be higher than we have estimated.

We have also excluded cases of disease made worse, rather than caused by exposure to chemicals because of the paucity of studies. However 20% of asthma sufferers in a Finnish study stated that their asthma was aggravated by work at least weekly in the preceding month (Saarinen *et al.*, 2003).

5.2 Calculating the disease burden

We have adopted a number of approaches to obtaining an accurate assessment of the burden of occupational respiratory and skin diseases (ORSD) in the EU-15. By triangulating the data from several different sources we hope to obtain a robust estimate for the number of cases with lower and upper bounds, using more or less conservative assumptions.

5.2.1 Literature search

A literature search was carried out using the following databases: PubMed, NIOSHTIC, CISDOC. All references cited in identified sources were followed up. Search terms included: occupational dermatitis/eczema, asthma, chronic obstructive lung/pulmonary/airways disease, burden, prevalence, incidence, compensation, cost, outcome, name of EU state. An example of how many papers were located is shown in Table 6. Given the short time scale and limited budget, any publications 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.

Table 6 **Number of papers located on PubMed**

	Disease	Prevalence	Incidence	Prevalence and incidence	Europe	Occupational
Asthma	32,666	2,100	2,110	2,307	1,958	298
Dermatitis	17,337	2,477	2,582	2,895	839	194
COPD	22,714	2,100	2,110	2,307	500	55

5.2.2 Public health organisations

We also addressed this problem by making contact with public health organisations, institutes of occupational health, and national health and safety institutes in the 25 member states to collect local data from them. We have also made contact with individuals with an interest in this field, through networked discussion lists (public health, evidence-based health, human biology).

5.3 Sources used

We used three main kinds of data to triangulate our estimates of the disease burden.

5.3.1 Social protection systems

A review was made of the total number of recognised cases of occupational skin and respiratory disease in the 25 European member states. Routine statistics collected through both social protection and notification systems reporting cases of occupational respiratory and skin disease are a primary source of data on occupational disease burden and cases collated by disease and occupational exposure.

The EU-15 systems are divided into three kinds:

- Those which have a fixed list of diseases covered by the compensation system, such that if the claimant has the disease, it is for the assessors to show why the disease is not occupational and he/she should not be assessed for compensation.
- So-called individual proof systems where the onus is on the claimant to make the case that the condition has been caused by work. In systems of this kind, claimants frequently lack the expert support required to prove that a disease is occupational in their individual case.

- Many EU-15 systems use a mixed system, with, typically, chronic obstructive pulmonary disease being covered by an individual proof system, occupational dermatitis by a disease list system, and occupational asthma using either one or the other (see Table 7). In principle, mixed or individual proof systems should allow all ORSD cases to be compensated. However, claimants, and sometimes the relevant administrative and medical authorities, lack the resources to decide the complex issues that are often involved.

In spite of attempts to harmonise the reporting of occupational diseases in EU member states (CEC, 2003c), the social protection systems use individual definitions with little consistency across the EU. The differences in the case of occupational asthma are more fully discussed in EUROGIP (2002b).

Table 7 describes the characteristics of the data collected, and demonstrates that the data collected in different countries describe different:

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

Table 7 **Comparison of social protection systems in the EU-15**

	AT	BE	DE	DK	GR	ES	FI	FR	IE	IT	LU	NL	PT	SE	GB
Route of access	Doctor or E	R, e or Doctor	Doctor or E	R				e	e	e-E			R	E	e
Method of proof	M	M	M	M	L	L	M	M	L	M	M		M	O	L
Qualifying degree of disability % ST	1	None	5	15	1	33	10	1	1	11	1		15		
LT	20	None	20%	15%	50%	33	10/5	None	1%	11%: none	None		None	1/15	14%: 1% for pneumo-coniosis
Qualifying kind of disability	W	W	W	W	W	W	W	W	O	O	W		W	W	O
Excluded occupational groups		s/e	Civil servants	Some s/e		s/e	Some s/e		s/e						s/e (public sector)
Time limits	None	None	Immediate	1 yr		Imme-diate	1 yr	2 yrs	For asthma, deafness and tuberculosis	3 yrs			1 yr	Immediate	Only for asthma, deafness
Qualifying exposure time	Only knee problems	Not fixed	Not fixed		Varying			Some fixed	For certain diseases						Only for deafness, COPD
Waiting time	3 days	15 days	None	None	None		3 days	None	3 days	None					15 weeks

Key: Route of access: via registry (R), by employee (e), Employer (E)
Method of proof: Disease list (L), Mixed disease list and individual proof (M)
Qualifying kind of disability: Work disability (W), Other (O), Short term (ST), Long term (LT)
Excluded occupational groups: (s/e self-employed)

Source: EUROGIP (2002a), EUROGIP (2002b), HVBG (1995), http://europa.eu.int/comm/employment_social/missoc2001/ir_part8_en.htm

These differences are discussed below.

1. Access to systems varies in the different countries. In some cases, the employee first contacts the employer who must then report the case; in others the employee, or a doctor providing health care, makes contact with the occupational disease reporting system or registry, which must then assess the case before passing the information on to the insurance provider. Reluctance on the part of workers to reveal a disabling health condition to the employer is often reported, and is likely to be a particularly powerful limitation on the validity of social protection statistics, where access is via the employer, or where the level of work disability required for award of compensation is defined as being unable to carry out current job.

2. Methods of proof vary. For COPD, only certain occupations may be covered in a list of recognised diseases, whereas for asthma and dermatitis an open or individual proof system is generally used. However, a necessary condition for recognition of an asthma case in some state systems is that there has been exposure to a known respiratory sensitiser. In all schemes, recognition is dependent on the opinion of a specialist medical assessor, which minimises the likelihood of any over-estimation. Medical opinions can be challenged with reference to a further medical assessor leading to additional cases being recognised.
3. The degree of disability required for short-term or long-term benefits varies from 1 to 50%.
4. The method of assessing disability differs. In all but two EU member states it is based on working capacity; in Ireland and the UK it is a measure of general disablement.
5. Civil servants (20% of those in work) are outside the schemes in Germany, and the public sector (18% of those in work), is separately provided for in the UK. Policy on the self-employed – up to 15% of the workforce in some countries, varies widely; they are exempted wholly or partly in six member states.
6. Time limits within which a claim must be made exist in seven member states.
7. Qualifying periods of disability vary. They are generally short, apart from the UK.
8. Qualifying lengths of exposure exist for miners seeking social security payments for COPD in the UK.
9. The Netherlands has no system equivalent to those reported on above. It has 10.5 million people of working age; 7 million in work. This is 4% of the total EU-15 population on which RPA's estimates were based.

The internal inconsistencies and incompleteness of statistics on claimants in social protection systems make them a poor basis for assessing the total burden of ORSD. The same consideration would apply to the other occupational diseases caused by exposure to chemicals, which are not included in this report.

Table 8 **Incidence and prevalence figures from EODS and ELFS surveys in the EU-15**

	RPA study (estimated incidence of recognised cases/year) *	**ELFS** (self-reported cases prevalent) *
Respiratory diseases	17,000	600,000
Skin diseases	18,000	200,000

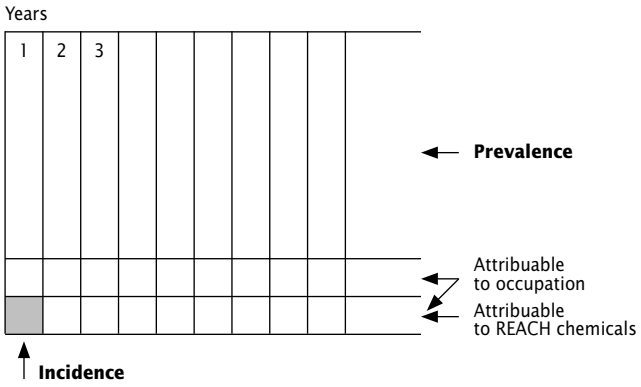
* In the EU-15
ELFS: European Labour Force Survey, Eurostat 1999 ad hoc module published on the Eurostat website (Eurostat, 2004)

The RPA study estimated disease burden using routinely collected statistics in different member countries collected by social protection systems but which the authors collected in their own research exercise. The contrast between the RPA figures and the results of the European Labour Force Survey (ELFS) carried out for the European Agency for Safety and Health at Work (European Agency, 2000) and Eurostat (Eurostat, 2004) is shown in Table 8 for 15 member states.

5.3.2 Incidence and prevalence

The burden of work-related ill-health is described either in terms of incidence, or of prevalence. Incidence is the occurrence of a new case of a disease during a defined time interval, whereas prevalence is the existence of a case during a defined time interval or at a given time (point prevalence). The prevalence of a disease at a given time is the accumulated incidence of new cases, corrected for the proportion of cases that will have resolved prior to that time.

Figure 4 **Schema to illustrate disease incidence and prevalence attributable to REACH**



For the purposes of this report the relationship between point prevalence and incidence is taken to be: **incidence x duration = prevalence**.

Figure 4 illustrates the relationship over time of incidence and prevalence for a specific health condition overall, the proportion attributable to occupational exposure, and within that, attributable to REACH chemicals.

5.3.3 Self-reported work-related ill-health

In self-reporting surveys individuals are interviewed about what effects they think work has had on their health. The major surveys of this kind are the EU Labour Force Survey carried out in 1999, the series of European Surveys of Working Conditions carried out by the European Foundation, and the UK occasional Labour Force Survey. These and a few other national self-reporting schemes provide a primary source of data for comparison.

There are limitations to self-reporting methodology, which have been discussed in some detail in the UK (Abba *et al.*, 2004). Self-reporting could over-estimate the burden of occupational disease if respondents made strategic responses, on the basis of an expectation of how the results of the survey were to be used. There may also be a cognitive dissymmetry between attribution to different causes of the same condition; such that, for example, a 'lifestyle' cause is downplayed, or a cause over which the respondent feels they have less control could be exaggerated. Respondents may mistakenly over-estimate the burden of occupational disease because of wrong information about causation. Abba and colleagues discuss the way in which attribution by individuals can be affected by social pressures and how this can lead to under- and over-estimation of the true number of cases.

In response to these possible sources of bias, the UK Labour Force Surveys have used a number of checks to assess the likely validity of responses. These include obtaining the views of treating physicians on the attribution; experts' views on the plausibility of association between self-reported ill-health and particular occupations; linkage to self-reported and expert-assessed exposures; and existence of other cases known to the respondent. None of these forms of non-rigorous confirmation have undermined the validity of self-reporting. Indeed, research carried out to assess occupational disease prevalence has tended to demonstrate that self-reporting understates the burden.

In the UK, two community prevalence surveys on occupational deafness and hand-arm vibration syndrome have demonstrated levels of ill-health attributable to work several fold higher than those emerging from the UK Labour Force Surveys (Palmer K *et al.*, 2000, Palmer K *et al.,* 2002). It is likely that these arise from the limited knowledge of respondents, and perhaps from the context in which the labour force surveys are carried out; a small number of occupational disease questions are added to a much longer questionnaire about other labour force participation issues.

5.3.4 Population attributable risk (PAR)

To provide a third set of estimates of the prevalence of occupational respiratory and skin diseases, we have reviewed the published literature from EU member states on the proportion of the total societal burden of asthma, chronic obstructive lung disease, and non-malignant skin disease that can be attributed to work.

Estimates of the population attributable risk (PAR) or attributable fraction (AF) are based on a calculation of the proportion of the population exposed to a hazard and the relative risk of developing the disease associated with exposure where the prevalence of the condition in the population is known. Exposure can be assessed using self-reported exposure – which can give rise to reporting bias – or a job-exposure matrix or occupational title. When combined with the prevalence of a condition in the population it can be used to estimate the proportion of cases of the disease that would not occur if the hazard were absent. One weakness of PAR methods is the difficulty of defining exposures in a population in such a way that the relative risks that have been calculated in other studies can be applied to them, or conversely, carrying out studies of relative risk on a population for which relevant exposure data is available.

Attributable fractions are not strictly comparable to numbers of cases of occupational disease because they take into account the complex aetiology of the conditions being considered here. In any one case, removal of one or more causal factors might lead to avoidance of illness. For this reason, the fractions of cases attributable to different factors in a disease process may add up to more than 100%. The strength of the attributable fraction method is that it looks at the total burden of disease related to work; the weakness of the method is the difficulty of obtaining reliable estimates of risk and of exposure, given that both are continuous rather than discrete variables.

In Karjalainen's study of occupational asthma in Finland (Karjalainen *et al.*, 2001), the proportion of cases of adults on medication for asthma attributable to exposures at work was calculated taking the exposure of administrative staff as posing no risk. The PAR was calculated using the excess of cases in other occupational groups based on this assumption as a proportion of the total. Karjalainen's study is described in more detail in the section on asthma.

5.4 Modelling

The basic approach to calculating the burden of occupational disease is given below.

Step 1
- Obtain incidence rates (per million) using different methods.
- Obtain incidence rate of new cases of each occupational disease using incidence data where available.
- Calculate the incidence rates using proportion attributable to work where the diagnosis is generic.
- Calculate incidence rates from prevalence rates for occupational or generic disease using an estimated mean duration.

Step 2
Estimate the proportion of cases attributable to exposure to substances affected by REACH.

Step 3
Apply proportion from Step 2 to Step 1.

Step 4
Use incidence rate of REACH-affected disease to calculate preventable disease for the EU-25 workforce (200 million).

Calculations of costs per case were recalculated using the method described in Section 8, but the timing of the impact of REACH on the working environment and hence on disease incidence is that used in the RPA study.

Section 6
Results

The aim of this section is to derive the actual number of cases of occupational skin and respiratory disorders in the 25 countries. We looked at different sources of statistics and chose the best estimate from amongst them. A few countries have provided the majority of the studies used in this section because of their detailed data sets and robust methods of data collection. They were Denmark, Sweden, Germany, Finland, UK and France. The totals are based on the assumption that incidence rates across the EU-12, EU-15 and EU-25 are broadly the same; an approach supported by the results of the two European Surveys of Working Conditions for EU-15 and EU-25 (European Foundation, 2001, 2002), which show broadly similar levels of self-reported work-related lung and skin disease in EU member states. Appendix 6 shows the levels for the new accession states.

6.1 Asthma

As outlined above, entry to compensation schemes is restricted in terms of populations eligible (status, occupational group, type of asthma) and for the award of compensation, limited by degree and nature of disablement. In addition, there are sharp differences in occupational groups contributing to the burden assessed in compensation statistics and population studies (Karjalainen *et al.*, 2001).

6.1.1 Incidence of asthma

Table 9 (see below) shows published incidence data for occupational asthma for five member states (DE, FI, SE, FR, GB) for each kind of estimate of ORSD burden (social protection, self-reporting and attributable fraction).

EODS data covers certain recommended occupational diseases. Included on the standard list are exposure-specific groups of conditions, such as isocyanate and chromium effects on skin and lungs, as well as occupational asthma. The occupational asthma (and dermatitis) statistics may therefore slightly underestimate the actual reportable cases from member states.

None of these sources include cases merely made worse by work environment factors. However Saarinen *et al.* (2003) found 20% of adult asthma sufferers to have asthma made worse at work each week in the month preceding the survey.

Self-reporting studies are a poor source of data on occupational asthma because they are generally on too small a scale for meaningful figures to be gathered for different kinds of occupational lung disease.

Confirmed cases lie in the range 25-394 per million per year. The upper end of this wide range of incidence estimates reflects the better ascertainment and reporting

Table 9 **Incidence of occupational asthma in selected EU member states, EU-12 and EU-15** (per million unless otherwise stated)

	DE	SE	FI	FR	GB	EU-12	EU-15
Confirmed occupational asthma cases (Eurostat, 1999)	40		394 (a)	25	53		35
EODS number of cases 2001						N = 1075	N = 1780*
Compensated cases incidence/million	10 (b)		175 (a)	4	7 (c)		
Registry incidence					37-43 (c)		
Self-reporting incidence		80 (d)		25.7 (e)			
Incidence of all asthma		2.2/1000 per yr age 30-54 (f)					

N: number of cases/ people
* extrapolated from EU-12

(a) Karjalainen, 2001; (b) Baur *et al.*, 1998; (c) HSE, 2005; (d) Toren *et al.*, 1999; (e) Kopferschmitt-Kubler, 1992; (f) Toren, 2004

in Finland. Asthma incidence amongst adults in a number of recent surveys lies in the range 2-5,000 per million per year (Toren *et al.*, 2004).

6.1.2 Prevalence of occupational asthma

Studies have been carried out in several EU-15 states on the proportion of adult asthma attributable to work (see Table 10). These and similar studies in other industrialised countries point to an attributable risk of between 5 and 20%. The prevalence of asthma and of cases attributable to occupation increases with age. The proportion attributable to occupation is higher for men than women.

There are six-fold differences between the prevalence of asthma symptoms in European countries covered by the European Community Respiratory Health Survey (ECRHS) project (Janson, 2001; ECRHS, 2002). The ECRHS studied men and women aged 20-44 in 13 of the EU-15 plus three other European and five other non-European countries. The median value was 5%, which is likely to be lower than the adult population prevalence because of the increase in prevalence with age.

Table 10 **Prevalence of asthma and occupational asthma**

	DE	SE	FI	FR	GB	EU-15	EU-10
Self-reporting occupational asthma (most-serious disease)					23/1000 (a)	6% occupational lung disease, 4% allergies (b)	4.2/1000 (c)
PAR prevalence	10% (d)	11% (e)	29% M 17% F (f)	9-14% (g)			
Prevalence of asthma (wheeze at work) (ECRHS)	5.2%	9.2%			11.6%		

(a) HSE, 1998; (b) European Foundation, 2001; (c) Eurostat, 2004; (d) Kogevinas *et al.*, 1999; (e) Toren, 1999; (f) Karjalainen, 2001; (g) Le Moual *et al.*, 2000

Several of the European PAR studies are for small areas within an EU state and may not be fully representative of the state as a whole. PAR results quoted in Table 10 are figures reported in articles reviewed in Balmes *et al.* (2003). Studies reviewed by Balmes on adult populations from most industrialised countries find PARs of 10-20%. In the European Community Respiratory Health Survey, the PAR for occupational factors was 10%; exposure to gas and fumes had a PAR of 3.5%. However this latter study was carried out only on adults below the age of 44.

The most likely reason for the differences between sources of incidence and prevalence data are:

1. Social protection systems exclude certain sections of the workforce, require particular kinds of proof and qualifying kinds of incapacity. They are not well-known and tend to compensate workers with asthma caused by well-established asthmagens.
2. Registry statistics are slightly higher (Ameille *et al.*, 2003; Kopferschmitt-Kubler *et al.*, 2002; HSE, 2004), implying that not all patients satisfying respiratory disease specialists and occupational health specialists that they have occupational asthma are successful in making claims under social protection systems. Registries are more inclusive, but are the endpoint on a referral path that can include managers, occupational health personnel, and family practitioners. Poor coverage of occupational health services, and low levels of knowledge on the part of family practitioners – or lack of inclination to refer – play a role in keeping registry figures low.
3. Self-reporting figures are slightly higher than registry figures allowing for plausible assumptions about the relationship between incidence and prevalence. The UK Labour Force Survey (HSE, 1998) includes a five minute section on occupational accidents and ill-health in a much longer questionnaire on labour force issues and the European Labour Force Survey includes a few questions on disease at the end of a much longer questionnaire (Eurostat, 2004). The statistics from the labour force surveys are for diseases listed as the most serious suffered by the interviewee.
4. The very large differences between the prevalence figures from compensation, registry and labour force surveys on the one hand, and the ESWC and PAR analysis on the other, (roughly ten fold), can be accounted for in a number of ways. It may be that only more serious cases are compensated or reported. However this is unlikely to be the main reason for the disparity between results. The ESWC and PAR analyses are likely to be more sensitive to work-related symptoms and to multifactorial aetiology than compensation or reporting systems which miss substantial numbers of cases of asthma attributable to work (Karjalainen *et al.*, 2002). Occupation-specific investigations have shown that many cases of occupational asthma occur in jobs and in sectors of the workforce where knowledge of occupational asthma and the relevant reporting and compensation systems are poor.

Outliers in this survey of sources include the UK Labour Force Survey for 1995, the European Working Conditions Surveys and the Finnish studies of Karjalainen and colleagues (Karjalainen *et al.*, 2001, 2002). Self-reporting surveys conducted as part of Labour Force Surveys produce estimates in the region of 1000/million population and the European Working Conditions Survey conducted every three years by the European Foundation is an investigation by interview of working conditions throughout the EU (European Foundation, 2001, 2002). The latter surveys do not discriminate between different kinds of work-related lung disorder but find a prevalence of 6% for non-malignant lung disorders and 4% for allergies (not explained). These could include pneumoconioses, COPD, occupational asthma and work-aggravated lung conditions.

Karjalainen *et al*'s study provides the strongest evidence available for work-related asthma prevalence at the levels indicated by these two self-reporting surveys. Karjalainen compares observed and expected numbers of asthma cases in different occupational groups in the Finnish population. Even when cases reported to the Finnish Registry were excluded, there were still excess cases in acknowledged high-risk occupations. However the Karjalainen studies also highlighted occupations in

which excess risk had not been expected, for example, amongst cleaners. Increased risk of asthma amongst cleaners has been confirmed by occupation-specific studies (Zock *et al.*, 2001a; Karjalainen *et al.,* 2002). The reason for the difference between the pattern of registrations and the pattern in the Karjalainen studies may be reporting bias. Cleaners with asthma may not be aware of compensation systems or may consider that reporting it would place their employment at risk. The study also showed that large occupational groups with slightly raised risk of occupational asthma could contribute more cases than small, well-known, high-risk groups, like bakers or painters.

The reasonably close agreement between self-reporting in the EWCS and PAR calculations provides some support for the argument that these are the most satisfactory estimates of the prevalence of occupational asthma.

Table 11 **Incidence of REACH-affected asthma per million per year**

Source	Incidence
Compensation statistics	4 – 175 (EU15=35)
Registries	37 – 43
Self-reporting (LFS)	200 – 1000
PAR method (Toren, Balmes)	200 – 400
ESWC (P = half of all ORD, i.e. 3%, duration = 25 years)	1200
ESTIMATE	200 – 400
Proportion of cases affected by REACH	50%

The picture that emerges from the sources reviewed here is that the PAR for occupation is in the range 10-20%. There is correspondingly an approximate 5-10 fold difference between incidence rates of asthma and occupational asthma. The figures presented in Table 11 above are compatible with incidence rates of occupational asthma of 200-400/million/year. This is equivalent to 40,000-80,000 new cases per year in the EU-25. It is of note that the UK Health and Safety Executive, summarising data on occupational asthma, has stated that incidence rates of occupational asthma could be 5,000 per year (HSE, 2004). The UK labour force is roughly one-tenth that of the EU-25.

6.1.3 Proportion affected by REACH

The proportion of occupational asthma cases resulting from REACH-affected chemicals in the best investigated cases is about 50%, though with some variation from country to country (See Table 12), i.e. 100-200 new cases/million/year or for a European base population of 200 million (see Appendix 5 for definition), between 20,000 and 40,000 new cases each year. For the costs analysis below the figure of 40,000 is used.

Table 12 **Percentage of implicated exposures related to chemicals affected by REACH**

Author	Country	Proportion of REACH affected exposures
Meyer, 1999	GB	90% inhalation injuries
Di Stefano, 2004	GB, W. Midlands	44% (71% including other and unknown)
McDonald, 2000	GB	61% (69% including other or unknown)
Kopferschmitt-Kubler, 2002	FR	28% (41% with other)
Ameille, 2003	FR	37% (60% including other and undetermined)
Toren, 1999	SE, Gothenburg	84% (urban population, NB not mutually exclusive)
Swedish Work Environment Authority, 2000	SE	37% (all respiratory diseases, only known substances)
FIOH, 2004	FI	32% (registry)

Excludes biological dusts (wood, grain, latex, laboratory animals, farm animals, colophony), but not enzymes

6.2 Chronic obstructive pulmonary disease

6.2.1 Incidence

There is little firm data on the occurrence of new cases of work-related chronic obstructive pulmonary disease. The principal reason for this is that the main

Table 13 **Compensated cases of COPD**

	DE	GB	EU-12	EU-15
Compensated cases	6 per million (a)	570,000 registered of which 205,000 paid over the last 6 years (b)	N = 497 Chronic bronchitis (c)	N = 820 * Chronic bronchitis (c)

N: number of cases/ people
* extrapolated from EU-12
(a) HVBG, 2005; (b) DTI, 2005;
(c) Eurostat, 2001

source of incidence data; social protection systems, recognise and compensate only a small proportion of cases, with restrictive conditions or an individual proof system in operation. Compensation for COPD is largely confined to traditional jobs such as mining and work in steelworks and foundries (Baur *et al.*, 1998), where the exposures are process-generated mixtures of mineral dusts. Where these jobs involve exposure to substances likely to be influenced by REACH, the effect of the exposure has proved difficult to assess. Few claims are successfully acknowledged on an individual proof basis for other occupations in which the REACH proposals would have a greater effect, even though epidemiological studies find excesses of COPD in numerous other occupational groups. The figures for the UK reflect a loosening of restrictions that has allowed ex-miners to claim compensation for pre-existing emphysema and bronchitis (DTI, 2005) and illustrate a potential weakness in the use of compensation statistics for a single year.

6.2.2 Prevalence of work-related COPD

In the absence of good incidence data, the preferred method is to derive incidence figures from data on the prevalence of work-related COPD using direct and indirect (PAR) methods.

Prevalence figures for COPD in the population have a wide range, with the higher prevalence figures being from studies involving spirometry and clinical examination. Even with standard case-definitions, the choice of definition is critical, as airway obstruction is a progressive phenomenon. Mild, moderate and severe COPD can be defined spirometrically. Further problems ensue because the link between disability and objective lung function measurements is not a simple one, and because many individuals have several diagnoses including asthma and COPD concomitantly.

The burden of chronic obstructive lung disease is 4 to 10% in the general population according to a recent review (Halbert *et al.*, 2003*)*. All studies were of adults, though some were of older age-groups only. The lowest prevalence figures were from studies using expert opinion or self-reporting with a ten-fold increase for self-reporting. The highest prevalence figures were based on standardised symptom-reporting or lung function measurements. This gradation from small numbers of expert-acknowledged cases to larger numbers of self-reported cases and yet larger numbers of cases identified by more thorough investigations confirms the findings for occupational diseases in the surveys described in the preceding section.

In Rennard *et al.* (2002) the burden of COPD amongst adults aged 45 years or more was 6 to 8%. While COPD is much more prevalent amongst smokers than non-smokers, many studies have confirmed that the combination of workplace exposures and smoking produce additive effects. There was no simple relationship between the prevalence amongst smokers and the prevalence overall for each country.

Estimates of the contribution of occupational factors to COPD depend heavily on PAR methods because of the shortage of data of other kinds. The figures presented below are for productive cough, because of the difficulty of distinguishing

between COPD and asthma 'cases' in population studies. However Balmes and colleagues present estimates for productive cough, spirometrically defined COPD and asthma, in their review of studies of the population attributable risk for occupational factors in lung disease.

Table 14 **Population attributable risks and burden for productive cough and COPD**

	DE	DK	ES	FI	FR	IT	NL	GB	P
PAR productive cough % (Balmes *et al.*, 2003)			20		15/20 M/F	17 M	15		19/9 M/F
Burden of COPD % (Rennard *et al.*, 2002)	8		6		6	6	8	6	
COPD % (Other studies)		3.7 (a)		3.7 (b) 22.1:7.2 M:F (c)				16.7: 7.1 M:F (d) 3.9:2.1 M:F (e)	

(a) Lange, 1989; (b) Pallasaho, 1999; (c) Von Hertzen, 2000; (d) Medical Research Council Criteria; (e) Self-report, Littlejohns, 1989

The above PARs in Table 14 are for productive cough, as the lung function measurements used in population surveys do not discriminate well between asthma and COPD.

Table 15 **Prevalence of occupational COPD**

	DE	DK	FI	EU-15 EU-25	EU-15	EU-11+HU
Reporting/million prevalence	60 per million (a)					
Self-reporting prevalence (most-serious disease) ever-employed (Eurostat, 2004)				6%, 7.6% all respiratory conditions (b)	587,105 all ORD (c)	457,743 all ORD (c)

(a) Baur *et al*., 1998; (b) ESWC, 2003; (c) Eurostat, 2004

The European Survey of Working Conditions and the European Labour Force Survey, along with some of the UK Labour Force Surveys have not distinguished between different kinds of occupational respiratory disease, of which the two main groups of obstructive diseases, asthma and COPD, are much the most common.

Table 16 **Occupational pulmonary disorders, most serious disease (ever-worked), self assessment**

	No days lost	1-3 days	4-29 days	1 month +	Permanent incapacity	Unemployed/ inactive
%	23	7	24	11	0.7	33
Total	238,000	25,000	86,000	39,000	2,557	117,000

Source: Eurostat, 2004

If on a conservative estimate, 5% of the adult population has COPD and the PAR is 15%, then the prevalence of COPD attributable to work is 0.75% of the population. Age of onset is in the latter part of working life, with a mean duration of 10-20 years until the end of working life, giving an incidence rate of 0.05% per annum (for 15 years). The proportion attributable to REACH-affected substances cannot be accurately calculated. There is no analysis of the kind published for dermatitis or asthma, on the proportion of cases caused by one agent or another, though it is noteworthy that exposures to vapour, gases, and fumes were associated with an increased risk of COPD in the ECRHS (Zock, 2001). In this and studies elsewhere in the world (Balmes *et al.*, 2003) the PAR for vapours, gases and fumes is comparable to that for occupational factors in general; roughly 10%.

Table 17 **Incidence of REACH-affected COPD per million per year**

Source	Incidence
Compensation statistics	Not used
Registries	Not used
Self-reporting (ELFS – 300K)	130
PAR method (Balmes – 15%)	500
ESWC (P = 3%, duration = 10 years)	3,000
ESTIMATE	500
of which the proportion of cases affected by REACH	10%

6.2.3 Proportion affected by REACH

For the purposes of this analysis a very conservative estimate of the proportion of work-related COPD related to substances that could be controlled under REACH would be 10% (Table 17); a REACH affected incidence rate of 0.005% of the EU-25 base population (10,000 per year).

6.3 Skin disease

The main non-malignant skin disease resulting from exposures to chemicals at work is contact dermatitis.

6.3.1 Incidence and prevalence of occupational dermatitis

Tables 18 and 19 show estimates of the incidence and prevalence of occupational dermatitis from compensation statistics, general population surveys and epidemiological studies.

Table 18 **Incidence of occupational dermatitis** (cases per million unless otherwise stated)

	DE	DK	FI	FR	GB	EU-15
Confirmed cases (all skin diseases, N=) (EODS, 2004)	66	145	410	60	18	68 *
Reporting/million incidence p.a.	451 ICD 410 ACD (a) 670 (b)	800 (c)	362 ACD 444 ICD = 806 (d)		129 (e)	
Population survey/ million					3800 (f)	

* extrapolated from EU-12
ICD : irritant contact dermatitis;
ACD: allergic contact dermatitis
(a) Dickel, 2002; (b) Diepgen, 2003; (c) Halkier-Sorensen, 1996; (d) Kanerva, 2000; (e) Cherry, *et al.*, 2000; (f) HSE, unpublished

Table 19 **Prevalence of occupational dermatitis** (total cases unless otherwise stated)

	DE	DK	FI	GB	EU-15	EU-11+HU
Reporting/ million prevalence	680 (a)			710-880/ million ever-employed (b)		
Self-reporting (ELFS) prevalence (most-serious disease) ever-employed		7,000 (c)	29,000 (c)	28,000 (c) 31,000 2001-2 38,000 2003-4 (b)	6% (d)	118,000 152,000 (c)
Proportion of dermatitis that is occupational				57% all 42% of hand dermatitis (e)		

= Eurozone, EU-12 – Eurozone in 1997 (see Appendix 2)
(a) Dickel, 2001; (b) HSE, 2004; (c) Eurostat, 2004; (d) European Foundation, 2001; (e) HSE, 1992

6.3.2 Severity

The large differences in rates of disease reported in different studies can be explained by the methods of data collection used. General practice and general population surveys use standard questionnaires of presence or absence of symptoms. Compensation systems recognise cases on the basis of a standard investigation procedure and degree of disability and in most social protection systems this means the degree of work disability. Case definitions therefore differ significantly.

Table 20 shows the proportion of people reporting occupational skin disorders who were unable to work for periods of varying lengths.

Table 20 **Occupational skin disorders, most serious disease**

	Total	No days lost	1-3 days	4-29 days	1 month +	Permanent incapacity	Unemployed inactive
Number	118,000	57,000	9,000	18,000	11,000	690	21,000
%	100	48	7	15	9	0.5	18

Source: ELFS, Table 68

However an underlying cause of the differences is that only a certain proportion of cases defined symptomatically have consequences on work and income. Studies of workplace populations confirm that symptoms are relatively common, but compensation claims are much rarer. In Funke's (Funke *et al.*, 2001) study of 2,078 Audi apprentices, of 241 cases of dermatitis, 41% were seen by a doctor, 21% by a dermatologist, 1% took sick leave and only one individual was referred for compensation. In other studies the ratio of work effects to cases is much larger. Brisman *et al.* (1998) found that one in three of the bakers with hand eczema changed their jobs because of it.

6.3.3 Recognition and compensation

In Germany and the UK, far more cases are recognised than are compensated. In statistics provided by the state compensation office (HVBG, 2003) only 10% of recognised cases are compensated; the majority that are recognised but not compensated failed because less than a 20% drop in working capacity had resulted (Ruehl and Wriedt, 2004). Ruehl and Wriedt go on to argue that because of limited knowledge of the nature of dermatitis, reluctance on the part of workers to draw attention to work limitations, and problems with the documentation of disease by the authorities, the figures cited understate the true costs of occupational dermatitis. The potential benefits of REACH will extend to individuals who may not receive compensation, or be recognised by the compensation system as having occupational dermatitis.

As far as this analysis is concerned, we need to establish that the costs could be reduced by the introduction of REACH. In a large number of studies from EU states and in other industrialised countries (Cahill *et al.*, 2004), it is clear that for many individuals who do not get compensation, ill-health persists and financial losses affect even those who remain employed. Dermatitis is unusual among occupational diseases in having a peak incidence in younger age groups (Smith *et al.*, 2000), with the effect that its impact may be felt particularly strongly amongst trainees and apprentices in occupations with heavy chemical exposure. In a study of German hairdressing apprentices (Funke *et al.*, 2001), even using a conservative definition of hand dermatitis, the point prevalence amongst hairdressing trainees in 1994 was 23.9% after three years. Half of those who started the training dropped out. Whereas the asthma and COPD affect an individual's capacity to remain in their current job, dermatitis also has an impact on an individual's ability to start a job for which they are in training. The cost of reduced access to the labour market for these individuals has not been considered further in this report.

Table 21 **Contrast between incidence rates of occupational dermatitis and the overall burden of dermatitis**

	NL	SE
Reported occupational dermatitis cases	40/million (a)	158/100,000 (b)
Burden of dermatitis or hand eczema	Hand: 5.2% men, 10.6% women Total: 8.2% (c)	All dermatitis: 5.4% (d)

(a) NCB, 2002; (b) SWEA, 2000;
(c) Smit *et al.*, 1993; (d) Meding *et al.*, 1987

6.3.4 Indirect method of assessing OSD incidence

The population data on the burden of skin disease is notably poorer than for asthma and COPD, making indirect methods of assessing occupational skin diseases (OSD) incidence more difficult. There are fewer surveys of dermatitis or eczema prevalence in the adult population. Though most point to a prevalence figure of 5 to 10% (Brisman *et al*., 1998; Smit *et al.,* 1993; Meding and Jarvholm, 2004) and to incidence rates of 4-11 cases per 1,000 person years (Brisman *et al.,* 1998; Meding and Jarvholm, 2004), although the use of self-reporting in the latter studies was believed to have led to under-reporting. It is almost twice as common in women as in men.

In 80% of cases, contact dermatitis affects the hands. In their Swedish study, Meding and Jarvholm (2004) found the difference in hand eczema incidence per annum in men and women (4/1000 versus 7/1000) to be due to differences in incidence in young age groups. One analysis of cases suggested that 42% of hand dermatitis cases (hands are by far the most common site for contact dermatitis) were attributable to work (HSE, unpublished). The present study has not been able to locate any other analyses of the proportion of dermatitis cases in the general population that may have resulted from work exposures. A cautious estimate would be a quarter of such cases.

Contact dermatitis is a disease of relatively long duration; at least 40% of cases persist at follow-up, with follow-up periods of up to ten years (Cahill *et al.,* 2004). Meding and Swanbeck (1987) give a median duration of ten years and Skoet *et al*. (2004) of 4.4 and 4.9 years for men and women respectively in occupational cases from the Danish Registry. The relationship between incidence and prevalence rates of hand dermatitis in Brisman *et al.* (1998), Smit *et al*. (1993), and Meding and Jarvholm (2004), and other reports are consistent with a mean duration of 5-10 years. Using a five-year duration and the above figures for prevalence and work-relatedness gives an incidence figure for occupational dermatitis of 1-2.5 per 1,000 person years.

Using a five-year duration with the ELFS and ESWC prevalence estimates produces contrasting incidence estimates (200-12,000/million). The European Survey of Working Conditions (European Foundation, 2001) takes the loosest definition – 'skin problems related to work' – and generates much the highest incidence estimate. HSE's population study in family doctors' practices, where the criterion was presentation for medical care, falls in the middle of this range and is closer to the estimates generated from population studies of all-cause eczema described earlier. A value of 2/1000 is used here to take into account the likely under-reporting in the European Labour Force Survey, the under-compensation of cases in social protection systems on the one hand and the low levels of disability associated with responses in the European Survey of Working Conditions on the other. The cost estimates presented in Section 8 of this report are largely associated with indirect, employment-related losses. In the ELFS at least 31% of respondents said that they had had time off-sick with their work-related skin problem (interpreting the figure for those who were inactive at the time of the survey is difficult). In Meding (1990) 21.4% of people with hand eczema had had time off-sick with it. Using this 20% figure then, 0.4/1000 person years have occupational skin disease of this degree of severity.

There is relatively good information on the chemicals associated with individual cases of occupational dermatitis. This is compiled in many EU member states in the records of registries and social protection systems. It has been possible to analyse which of the listed agents is a substance likely to be covered by REACH. At least half of the thoroughly investigated cases of dermatitis reported in case series and registries

are due to REACH-affected chemicals (Table 22). This gives a figure of 200 cases per million per year for an EU-25 workforce of 200 million for the incidence of occupational skin disorders attributable to substances affected by REACH.

Table 22 **Percentage of cases due to REACH-affected exposures**

Author	Country	Proportion of REACH
Dickel, 2002	DE	98% allergic contact dermatitis, 73% irritant contact dermatitis clinic cases
Skoet, 2004	DK	50% compensation cases
Registry statistics, 1998	SE	82% occupational contact dermatitis
Registry statistics, 1997-1998	GB	80% occupational contact dermatitis
Swedish Work Environment Authority, 2000	SE	65% (skin diseases, only listed substances)
FIOH, 2004	FI	65% (Registry)

6.3.5 Proportion affected by REACH

Using the base population figure for EU-25 of 200 million generates an incidence figure for occupational skin disease, for the purposes of this report, of 40,000 cases per year potentially preventable by REACH (see Table 23).

Table 23 **Incidence of REACH-affected occupational skin disease per million per year**

Source	Incidence
Compensation statistics	68 (EU-15)
Registries	129 – 800
Self-reporting (ELFS), most serious disease (duration = 5 years)	200
HSE Community study	3,800
ESWC (P = 6%, duration = 5 years)	12,000
ESTIMATE	400
of which the proportion of cases affected by REACH	50%

Section 7
Number of cases reduced under REACH

The perspective used in the RPA study was to recognise the uncertainties in estimates of effect by setting upper and lower bounds. The lower bound assumed that only diseases caused by known chemicals for which information is incomplete are susceptible to change; while the upper bound includes as susceptible the effects of unknown chemicals as well. Our practice will be to exclude cases of disease where the cause was known to be a substance that is not covered by REACH.

7.1 Cases of occupational ill health caused by REACH-affected chemicals

Most of the information available on the proportion of cases resulting from REACH chemicals comes from registries and reporting systems, where the level of clinical investigation is highest. When the major non-REACH causes of dermatitis (wet work, friction, foodstuffs, biocides and pesticides) are removed at least 50% of cases remain. One impact of REACH will be to increase the testing of existing substances. Very large numbers of skin sensitisers have already been identified using animal toxicity testing models, but many untested chemicals are likely to be discovered to have skin sensitising properties. In other cases, test results may not be incorporated into data available to end-users. Checking known sensitisers against the data held in the IUCLID database shows that many substances well-known to dermatologists as sensitisers do not currently have skin sensitiser risk phrases.

Communication between end-users and the suppliers and manufacturers of chemicals will also be enhanced by REACH. Careful testing by clinicians often leads to apparent cases of irritant dermatitis being traced to a particular sensitiser in the workplace (Dickel *et al.,* 2001). It is noteworthy that occupational dermatologists who have greater resources to enable them to test for sensitisation are more likely to report allergic contact dermatitis than occupational physicians in the UK reporting systems. In two other studies, it was shown that an occupational cause of dermatitis was only established when substances from the workplace were tested in a clinical setting (Dickel *et al.*, 2001 quoted in Ruehl and Wriedt, 2004). This implies that REACH may have its effect on the prevention of dermatitis in a number of ways; through improving data files, through communication and through improved exposure control and restrictions on use of substances.

For asthma, several of the major causes of asthma are non-REACH substances; flour dust, animal dander, other biological dusts, etc. There are large differences in the main contributing causes of occupational asthma across EU states and the range of values for REACH susceptible cases of asthma is 40-67%. Without an animal model for recognition of substances as respiratory sensitisers, case reports and epidemiological studies are the major source of data on asthmagens. The recognition

of respiratory sensitisers without REACH is poor. Many causes of occupational asthma that appear on standard lists (see for example: www.haz-map.com), lack relevant risk phrases (eg, chlorhexidine, ethanolamine, ethyl cyanoacrylate, triethanolamine, zinc chloride fume). As with dermatitis, REACH is likely to have its effects at many different levels, with communication from users to suppliers and manufacturers a particularly important route of effect.

The proportion of COPD cases caused by REACH substances is difficult to estimate. Some of the major causes are mineral dusts (coal dust, silica dust).

Table 24 summarises the estimated proportion of exposures to be reduced through REACH.

Table 25 gives our summary statistics on the incident cases preventable each year through full implementation of the REACH proposals. For comparison, the figures used by the RPA and those obtained by using rates of self-reported ill-health are included.

Table 24 **Proportion of exposures reduced through REACH**

Condition	Social protection registries, etc
Occupational asthma	40% – 60%
COPD (ECRHS)	10% – 20%
Occupational dermatitis	50%

Table 25 **Incidence of the three major diseases**

	RPA EU-15	EODS EU-15	ELFS	Summary values EU-25
Occupational asthma	6,700	1,780	} 29,000	40,000
COPD		823		10,500
Occupational dermatitis	16,000	7,378	20,000	40,000

Source: RPA 2003, Eurostat 2004

7.2 Health impact reductions

We follow the RPA in estimating the number of cases preventable during the introduction of REACH on the following basis.

Table 26 shows the projected reductions in the number of disease cases on which the RPA report is based. According to the plan proposed in the draft regulations, testing and registration of chemicals under REACH would be completed within ten years. However, improvements in communication could occur sooner and authorisation could take longer. RPA Associates argue that most health impact reductions will not occur until near to or after the end of the 10-0 year time period. For cancer endpoints (not assessed here), there will be a further lag-time before the full impact occurs. For diseases caused by work with much shorter latencies, such as asthma and dermatitis, the effects will be earlier. For incremental diseases such as chronic obstructive pulmonary disease, the impact will start as soon as chemical controls are introduced. For existing disease aggravated by work, the impact will also be immediate.

Table 26 **Assumptions on timing of health impact reductions**

End-point	Year reductions in cases start	% of cases reduced per annum	Number of years to achieve reductions	Year scenario reductions realised
Skin disease	6	20	5	11
Respiratory disease	6	12.5	8	14

Source: RPA Associates, Table 5.2

Section 8
Cost analysis of occupational COPD, asthma and dermatitis

8.1 Introduction

The analysis of the costs associated with skin and respiratory diseases is 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.

The estimation of health service costs is relatively straightforward, though the current review is dependent on relevant cost estimates presented in the published literature.

Productivity costs refer to the value of production lost as a result of the ill health, disability or death of an individual. In a perfectly competitive market, the wage rate is an exact monetary measure of the productivity of employed individuals. Whilst few employment markets are perfectly competitive, it is commonly assumed that the wage rate is a reasonable proxy measure for the productive output of employed individuals. From the societal perspective, costs are incurred in all cases in which productive output is reduced, either as a result of reduced productivity in the same job, or due to an individual only being able to undertake less productive work.

The affected individual may or may not experience reduced income. Income may be reduced, for example, if occupational asthma results in the need to change occupation, whilst income may not be reduced if an occupational disease results in temporary sick leave. Transfer payments are defined as money given by the government to its citizens, including social security, unemployment compensation, welfare, and disability payments. These costs should not be included, as transfer payments shift the burden of the occupational ill health from the individual to society. Including transfer payments in the cost of illness would also result in double counting, counting first the individual's loss of productivity and then the redistribution of society's resources that attempts to compensate the individual for that loss.

Section 8.3 describes the different forms of productivity losses, though alternative methods of valuing production losses are described here.

The traditional approach is called the human capital approach, which simply assumes that production losses are irreplaceable, such that the value of the production lost by any individual is equal to the time off work up to the specified age of retirement multiplied by the pro rata wage rate. An example is a worker who is forced into early retirement at the age of 50, when the official retirement age is 65. If the average annual salary is €30,000, then the undiscounted productivity cost of the event that causes early retirement is 15 x €30,000 = €450,000.

The friction-cost method has been put forward as an alternative to the human-capital method as allowing more realistic estimates of productivity costs (Brouwer and Koopmanschap, 2005). The possibility of replacement of (long-term) absentees is

at the heart of the friction-cost method, which recognises that society will restore initial production levels after some period of adaptation, the length of which may depend on the availability of labour and, hence, on unemployment. The above example of enforced early retirement at age 50 may allow for the recruitment of a replacement worker from the pool of unemployed workers resulting, for example, in a period of 6 months in which the retired worker's productive output is not replaced. Thus, the friction cost estimate of the productivity cost would be 0.5 x €30,000 = €15,000.

The methods of estimating productivity costs described above account only for the production losses associated with the affected individual. It is recognised that the production effects of occupational ill health may be wider, particularly in small firms where the loss of a single (skilled) worker may have devastating effects on the whole company. In extreme cases, the productive output of the whole company may be lost. The estimation of such effects has not been identified in published studies of productivity losses, and without direct evidence, it is difficult to produce reliable estimates of these effects. Productivity losses beyond the production effects of affected individuals are not, therefore, included in the current analysis.

The final cost category is defined as the monetary value of the loss of health-related quality of life per se. The monetary values attached to lost health-related quality of life should only reflect the impact of the lost health on the non-financial aspects of individuals' lives and not any reduction in income (income effects are included in the estimated productivity costs category). The Quality Adjusted Life Year (QALY), a generic measure of the health impact of disease, is used to estimate the monetary value of lost health. One QALY describes a year of life spent in a health state that is equivalent to perfect, or best imaginable, health. In the UK, the National Institute for Health and Clinical Excellence (NICE) uses an implicitly accepted range of monetary values for a single QALY that is used to inform decisions around the approval of new health care technologies for the UK National Health Service (NHS). Estimates of the QALY losses due to occupational disease are multiplied by monetary values of a QALY to estimate the monetary value of the different forms of occupational disease.

Further details around each of these categories are presented in the following sections, which describe the identified data describing these costs, and the assumptions underpinning the analyses undertaken to estimate the costs of occupational COPD, asthma, and dermatitis.

8.2 Health service costs

Health service costs describe the costs of the resources used to treat the disease of interest, including inpatient stays, outpatient and general practitioner visits, and medications received. In the absence of primary data describing such resource use at an individual level, the costs presented in this analysis are based on published sources. The following sections describe the data used to inform relevant estimates of the health service costs.

8.2.1 Health service costs of occupational COPD

In Section 6.2, we estimated the incidence of new cases of COPD attributable to REACH-affected chemicals each year in the EU-25 base population as being 10,000 per year.

The most relevant data describing the costs of occupational COPD are derived from the Confronting COPD Survey, which presents detailed cost estimates for the Netherlands, France, Italy, Spain and the UK. (Britton, 2003; Izquierdo, 2003; Wouters, 2003; Dal Negro, *et al.,* 2003; Piperno *et al.,* 2003). These data are summarised in Table 27. The health care costs include the following resource items: inpatient, outpatient, emergency room, and general practitioner visits; medication use; and laboratory tests. Country-specific unit costs are applied to the respective resource use estimates. The average health care cost across the five countries is taken as the mean costs of COPD, whilst the lower and upper reported costs inform the range of uncertainty in the mean cost estimate.

Table 27 **Health care and productivity costs of occupational COPD, 2004 values** (€)

	NL	FR	IT	ES	GB	Average
Health care costs	614	530	1,261	3,238	1,270	1,383
Productivity costs	683	2,246	100	833	2,886	1,350
Proxied average wage productivity costs*	1,914					769
Ratio	0.36					
Proxied friction productivity costs*		801	36	297	1,030	569

* Productivity costs for the Netherlands were estimated using the friction cost method, productivity costs are estimated for all countries using both approaches (see text for details).

If required, health care costs for individual EU countries could be calculated by converting the presented cost estimates to US dollars using the respective Purchasing Power Parities (PPPs). The average health care costs in US dollars are then converted to the currency of the countries for which costs have not been observed using the respective PPPs of the unobserved countries.

Rutten-van Molken *et al.* (1999) present health costs for asthma and COPD in the Netherlands in 1993, based on family doctor and specialised physician contacts in outpatient clinics obtained from the Health Interview Survey. The number of inpatient admissions and inpatient days were obtained from the National Medical Registration, and respiratory medications were based on a 1990 survey on drug prescriptions. Costs presented as US$ are converted to Euros using the 1993 PPP of NLG 2.13 per US$ and the constant NLG:Euro conversion rate. The annual cost for COPD is €779 per patient. The health care cost for COPD is somewhat higher than the health care cost estimated by the Confronting COPD survey for the Netherlands ($553), especially as the 1993 cost has not been uprated. The advantage of the data presented by Rutten-van Molken *et al.* (1999) is that they are partly based on observed data, though the proximity of the Confronting COPD survey is considered a greater advantage and these estimates are preferred.

8.2.2 Health service costs of occupational asthma

In Section 6.1, we estimated the incidence of new cases of asthma attributable to REACH-affected chemicals each year in the EU-25 base population as being 40,000 per year.

As described in section 8.2.1, Rutten-van Molken *et al.* (1999) present health costs for asthma and COPD in the Netherlands in 1993 (not specific to occupational causes). The estimated annual cost per asthma patient is €281. As noted, the health care cost for COPD is higher than the corresponding health care cost estimated by the Confronting COPD survey for the Netherlands. It is also considerably higher than the €170 cost estimate used in the previous assessment of the impact of REACH (RPA Inc, 2003), which was based on a 2001 audit by the National

Asthma Campaign, though this figure reflected patients without an asthma attack in the last 12 months (National Asthma Campaign, 2001).

Brocklebank *et al.* (2001) present an evaluation of inhaler devices for asthma and COPD, though cost estimates are only presented for stable asthma. Pressurised metered dose inhalers (pMDIs) are shown to be the most cost-effective device and the estimated annual cost for asthma patients receiving these devices (hospital and general practitioner contacts) is estimated to be around £100 (*c* €140).

On the basis of the identified estimates, a range of €100 – €300 per asthma patient per year is specified.

8.2.3 Health service costs of occupational dermatitis

In Section 6.3, we estimated the incidence of new cases of dermatitis attributable to REACH-affected chemicals each year in the EU-25 base population as being 40,000 per year. We noted that the figure chosen appeared to be more sensitive to the criteria used for case definition than for occupational respiratory disorders discussed here. The source of data generating the highest estimates does not imply usage of medical services. We have therefore adopted lower estimates to reflect the burden of occupational skin disease likely to impact on individuals' health costs and employment experience.

Meding (1990) presenting the results of a survey of 20,000 individuals, which identified 1,238 with hand eczema, reports that 8% of individuals with occupational hand eczema changed jobs as a result of the eczema. Table 28 describes some of the cost effects of hand eczema. Visits to general practitioners comprise the majority of the health service costs associated with hand eczema. Applying a cost per visit of €28.5 (based on UK estimates), the annual cost is estimated to be around €70. Based on a recent review of topical corticosteroids for atopic eczema (Green *et al.*, 2005) appropriate medication costs are assumed to be less than €10 per year.

Table 28 **Annual cost consequences of hand eczema**

Nr. of visits/ episodes of sick leave	% affected individuals requiring	
	Family doctor visits	Periods of sick leave*
0	31	78.6
1	19.7	9
2-5	27.4	8
5+	21.9	4.4

* each period of sick leave is defined as being off work for at least 7 days

8.3 Productivity costs

Blanc (2004) defines disease-related work disability as:
1. Complete cessation of work due to health
2. Failure to enter the labour force
3. Lost work days (partial or total)
4. Decreased work productivity
5. Health-related change in job or job duties
6. Pay cut or reduced hours.

Productive output per unit of time is commonly valued as the wage rate received per unit of time. This assumption is based on the efficient working of employment markets that does not hold in reality, though it is as good an approximation as is possible.

Of the above six categories, (2) is clearly not relevant to the estimation of the costs of occupational disease. The cost to society of the remaining categories may be dependent on how employers are able to compensate for the loss of productivity in employees with occupational disease. The issues around each category are described below:

1. Complete cessation of work due to health
If a person retires from the workforce due to ill health before the normal age of retirement, then society has lost the productive output of that person over the remainder of their working life. However, if there is unemployment in society, it may be possible to replace lost workers from the pool of the unemployed. The extent to which workers may be replaced is dependent on the skills and experience required to produce the same productive output.

In a primary research study, involving a representative (random) sample of the working population, it would be possible to assess the 'replaceability' of each observed case of occupational disease that led to early retirement. In the case of the secondary REACH evaluation, it is necessary to make judgements about the replaceability of workers based on the characteristics of the work affected by the REACH regulations. Ideally, this would require estimates of the proportion of workers in each sector who will leave their job due to the incidence of occupational disease and the proportion of jobs in each sector for which it will be possible to replace workers from the pool of the unemployed. In reality, there may be a chain reaction, such that a currently employed person replaces the lost worker, who is replaced by another currently employed person, who is then replaced by a currently unemployed person. This does not affect the theory of the approach.

If there are shortages of potential workers from the pool of the unemployed, one can either assume that the lost worker is not replaced, or that a non-qualified new worker is trained to the sufficient level to undertake the lost position. In this case, the costs of training and the lost output over the time required to train a new worker should be estimated.

3. Lost work days (partial or total)
The impact of lost work days is dependent on how the work that would have been undertaken by the missing worker is handled. There are three options. Firstly, if the worker catches up with the missed work by working longer hours upon returning to work such that their total output is not affected, then no productive output is lost. Secondly, if other workers compensate for the absence of the missing worker (presumably by working longer hours, though not necessarily) and total output is not affected, then no productive output is lost. Thirdly, if the worker does not catch up or the other workers do not compensate for the absence of the missing worker and total output is affected, then productive output is lost. The fact that extra wages may have to be paid in order that total output remains unaffected is not considered a cost to society as these additional payments may be interpreted as compensation payments for the absent worker, which are defined as transfer payments across society. The estimated value of the lost productive output due to lost days should be based on the proportions of lost output that is compensated and the average wages in the relevant employment sectors affected by REACH.

4. Decreased work productivity
The process for estimating the impact of decreased work productivity is similar to that for lost work days. If the decrease in productivity per unit of time is compensated by longer working hours or by increased activity of work colleagues and total output is not reduced, then there is no impact on productive output. If output

is affected, then the value of the lost output may be estimated by multiplying the wage rate by the time worked by the percentage of lost productivity.

5. Health-related change in job or job duties
If ill health leads to a change in job or job duties, the impact of productive output is determined by whether the original job is undertaken by someone else (as described for category 1), or whether the lost duties arising from a change in job duties are undertaken by another worker. If the job or the lost duties are not replaced, then the productive loss is approximated as the difference in the wage rate between the old and the new position. Otherwise, no productive loss is assumed. For the REACH evaluation, this requires estimates of the proportion of lost jobs or job duties that are replaced, as well as estimates of differential wage levels between original jobs and subsequent positions for workers who change jobs.

6. Pay cut or reduced hours
The impact of a pay cut or reduced hours is incorporated within the above categories; for example, a person undertaking fewer duties within a job is likely to receive a pay cut and the methods for estimating the impact of the pay cut are described above.

A primary research study would try to account for all of the above factors through the collection of data describing the individual circumstances of each episode of productivity costs. The current analysis is based on a review of the literature and is constrained by the level of detail published. The following sections describe the data used to estimate productivity costs associated with occupational COPD, asthma, and dermatitis.

8.3.1 Productivity costs of occupational COPD

Estimates of the productivity costs of COPD, as presented in Table 27 above, are adapted from the Confronting COPD survey to describe such costs only for individuals of working age. (Britton, 2003; Izquierdo, 2003; Wouters, 2003; dal Negro *et al.*, 2003; Piperno *et al.*, 2003). Two approaches to the estimation of productivity costs are observed in the Confronting COPD survey. The traditional human capital approach is reported by four of the five country-specific studies (estimating the productivity cost of illness based on the predicted remaining lifetime earnings in the absence of occupational disease).

The Netherlands study team apply the friction cost method, which recognises that society will restore initial production levels after some period of adaptation. The Netherlands study presents the total number of work days lost and the average wage rate, so it is possible to estimate productivity costs assuming the human capital approach. Conversely, the friction cost method is approximated in the other four countries by applying the ratio of the productivity costs using the two methods in the Netherlands to the human capital estimates in the other countries. The resulting cost estimates are presented in Table 27. Excluding the presented costs for Italy, which are extreme outliers, the costs range between €833 and €2,886 for the human capital approach, and between €297 and €1,030 for the friction cost approach.

8.3.2 Productivity costs of occupational asthma

Table 29 (below) summarises the findings of seven European studies of the impact of asthma on occupational activity. The assumptions used to estimate the productivity costs of asthma are described below. The range of daily wage costs reported in the Confronting COPD survey is applied to the assumed productivity effects.

Table 29 **Studies of work impact of asthma** (adults of working age)

Study	Country	n	Findings
Schwenkglenks, 2003	CH	10	26% work absence (year)
Balder, 1998	SE	332	12% change job, 4% change duties
Abramson, 1995	AU	159	5% quit work
McClellan, 1990	NZ	821	7% work choice limited
Axon, 1995	GB	29	21% changed jobs
Sibbald, 1991 *	GB	460	3% long term sick leave
Goh, 1994 *	SG	802	21% >1 week absence per year

* as reported by Blanc (2004)

Abramson (1995) in the European Community Respiratory Health Survey (ECRHS) found that 5% quit work. This figure is used to estimate an associated annual cost of between €450 and €1,750 based on the human capital approach. Approximate friction cost estimates of productivity costs (based on the reported ratio estimated from the Confronting COPD survey) are between €167 and €612.

Costs are also attached to the work absence rates reported by Schwenkglenks *et al.* (2003), which are approximately confirmed by Goh, as reported by Blanc (2004). Twenty-six percent of individuals with occupational asthma are assumed to have a related 2-week absence from work. The estimated cost of these absences is between €390 and €1,430.

Balder *et al.* (1998) present a mean work ability of 90% based on a survey of 332 individuals remaining in work following diagnosis with occupational asthma. These data are used to estimate the productive effect in individuals remaining in work by multiplying 'one' minus the work ability percentage by the average wage rate. The annual cost impact of reduced work ability is estimated to be between €900 and €3,500.

The combined productivity costs estimate for occupational asthma is between €1,500 and €6,500. These estimates appear high relative to the productivity cost estimates for COPD that were reported in the Confronting COPD survey, though the survey was restricted to days of work lost, which would not include work ability effects. If these effects are excluded the range reduces to €600 and €3,000.

8.3.3 Productivity costs of occupational dermatitis

Cahill *et al.* (2004) identified two studies reporting similar proportions of patients with occupational contact dermatitis self-reporting a diminished earning capacity (58-59%). Adisesh *et al.* (2002) surveyed 510 individuals with occupational contact dermatitis who were reported to the EPIDERM database in the UK. They found that 6.3-7% had been unemployed, and 16.8-20.1% had taken sick leave (4% had done both).

As described in section 8.2.3, Meding (1990) presents more representative data for the population of individuals experiencing occupational dermatitis, as it is based on a random sample of the population. Data describing time off work due to hand eczema are presented in Table 28. The mean total sick leave time for the proportion of workers taking sick leave (0.214) is described as being four weeks, ie, each period of sick leave due to occupational hand eczema is four weeks.

Productivity costs due to work absences are estimated as the expected number of days sick leave, based on the data presented in Table 28 (3 days per case of occupational dermatitis), multiplied by a lower and an upper bound for the annual wage (based on the rates reported in the Confronting CPOD survey publications).

The annual cost impact is estimated to be between €75 and €277.

If the impact of an assumed 20% reduction in earning capacity for 58% of the affected population is reflective of reduced productivity (ie, the human capital approach), then an additional €1,000 – €4,000 can be added to the productivity cost estimates.

The combined productivity costs estimate for occupational dermatitis is between €1,161 and €4,258 using the human capital approach. Applying the ratio of friction costs to human capital cost estimates observed in the Confronting COPD survey, the friction cost estimates are between €418 and €1,533.

8.4 Health-related quality of life costs

The monetary values of the prevention of reductions in the health-related quality of life (excluding income effects) for individuals with occupational COPD, asthma, and dermatitis are approximated by multiplying an estimated utility decrement over an assumed duration of symptoms by the value of a QALY.

There is such wide variation in the reported utility values associated with the diseases of interest (Harvard Cost Effectiveness Analysis CEA Registry) that a range of utility decrements of 0.05 to 0.2 is specified for all three diseases. The mean duration of the diseases is assumed to be between 20 to 30 years. The assumed monetary value of a QALY is estimated to be €28,000 – €43,000 (based on the £20-30,000 implicit threshold used by NICE in the UK). Discounting the utility effects at 3.5% per year, the range of health-related quality of life costs is estimated to be in the range of €21,000 to €163,000. The annual health-related quality of life costs are estimated to be between €1,400 and €8,600.

8.5 Disease cost summary

The above sections have described the available data and assumptions that have been used to estimate the total cost impact of three forms of occupational disease – COPD, asthma, and dermatitis.

Table 30 summarises the cost estimates by category, as well as presenting the aggregate annual cost estimates for each disease.

Table 30 **Cost impact summary** (€)

Disease	Health service costs	Productivity costs*		Health-related quality of life costs	Aggregate annual costs	Mid-point of cost estimates
		HC	Friction			
Asthma	100 - 300	1,800 - 6,600	1,500 - 5,500	1,400 - 8,600	4,800 - 21,000	12,900
COPD	530 - 3,238	833 - 2,886	297 - 1,030	1,400 - 8,600	2,337 - 13,651	7,994
Dermatitis	70 - 80	1,161 - 4,258	418 - 1,533	1,400 - 8,600	1,888 - 12,938	7,413

* HC: Human Capital Approach; Friction: Friction Cost Approach

No better estimate of the average cost for each disease can be defined than the mid-point of the estimated ranges for each disease, as even within the COPD category there remains significant uncertainty around the cost estimates as demonstrated by the range of estimates across the five European countries included in the survey. The main potential discrepancy between the cost categories is the difference in the estimated productivity costs across the three occupational diseases, as it might be expected that individuals with COPD would have higher productivity

costs relative to the other diseases. The survey asked respondents to describe the number of days lost from work in the previous 12 months, and so is directly comparable with the survey data collected for occupational dermatitis. It is less comparable with the asthma data, which included reductions in work ability and were based on more assumptions. However, if similar costs of reduced work ability are applied to the COPD, then the productivity cost estimates are similar.

One further caveat around the estimated productivity costs is that they are based on average wage rates and those workers at risk of occupational diseases relating to the REACH regulations are likely to be employed in jobs that offer lower than average wage rates. Thus, the estimated productivity costs may be at the high end of the true range.

8.6 REACH cost impact summary

Table 31 describes 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. The cost estimates are presented over a 10-year and a 30-year time horizon after the implementation of REACH compared to a scenario in which REACH is not implemented. The costs are based on the low and high cost estimates for each of the diseases presented in the previous sections, and the estimated incidence rates presented for the three diseases. The incidence of dermatitis is set at 40,000, whilst the incidence of COPD and asthma are kept constant at 10,000 and 40,000, respectively.

Table 31 **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**
Productivity costs	Without REACH	7,274	715	7,384	15,373	39,050	3,095	18,920	61,065
	With REACH	6,786	667	6,717	14,170	19,362	1,345	7,329	28,036
	Cost savings	488	48	667	1,203	19,688	1,750	11,592	33,030
Health care costs	Without REACH	359	846	180	1,385	1,975	4,541	462	6,978
	With REACH	335	789	164	1,288	1,003	2,252	179	3,433
	Cost savings	24	57	16	97	972	2,290	283	3,545
Health-related quality of life costs	Without REACH	8,981	2,245	15,284	26,510	49,369	12,052	39,164	100,586
	With REACH	8,378	2,095	13,904	24,377	25,063	5,976	15,170	46,209
	Cost savings	603	151	1,380	2,133	24,306	6,076	23,994	54,376
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

The REACH impact assumptions are based on those reported in the RPA report, that REACH has no impact on incidence for six years, followed by a constant decline in the number of new cases (20% per annum decline for dermatitis and a 12.5% decline for COPD and asthma). It is assumed that the mean age at incidence is 50 years and 40 years for COPD and asthma, respectively. Productivity costs are assumed to continue for the remainder of each affected persons working life (to 65 years) and health-related costs continue to age 75 years. The effects and costs associated with dermatitis are assumed to continue for 5 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. Allowing for the staged uptake of REACH across the EU, the midpoint

estimate for the cost savings due to REACH over a 10-year time horizon are estimated to be around €3.5 billion. Over the longer 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, almost half of which is derived from savings due to reductions in the incidence of occupational asthma.

Table 32 describes the range of potential cost savings due to reduced productivity losses, health care costs, and monetary valuations of the impact of lost health after the implementation of REACH from which the midpoint estimates are derived. The ranges incorporate the effect of high and low cost estimates for each component of each disease, high and low incidence figures for dermatitis, and alternative time horizons over which the impact of REACH is predicted (10 years and 30 years).

Table 32 **Range of estimated cost savings due to implementation of REACH over 10- and 30-year time horizons** (€ millions)

10 year time horizon		Productivity cost savings	Health care cost savings	HRQoL* cost savings	Total cost savings
Asthma	Low	181	12	169	362
	High	795	36	1,036	1,868
COPD	Low	9	16	42	67
	High	87	98	259	444
Dermatitis	Low	50	8	169	228
	High	1,283	24	2,591	3,898
Combined	Low	240	36	380	656
	High	2,165	158	3,887	6,210
30 year time horizon					
Asthma	Low	7,292	486	6,806	14,584
	High	32,084	1,458	41,806	75,348
COPD	Low	327	644	1,701	2,672
	High	3,174	3,935	10,452	17,561
Dermatitis	Low	876	147	2,934	3,956
	High	22,307	419	45,054	67,781
Combined	Low	8,494	1,277	11,441	21,212
	High	57,565	5,813	97,312	160,689

* Health-related quality of life

The estimated cost savings over a 10 year time horizon due to REACH range from €67 – €444 million for COPD to €284 – €3,898 million for dermatitis. If the monetary values of the health effects of disease are excluded, the estimated cost savings decrease to €25 – €185 million for COPD and €74 – €1,307 for dermatitis. The values over the 30-year time horizon are much larger, with a total saving across the three disease categories of between €21.5 – €158 billion including the monetary valuations of the health effects, and €9 – €60 billion without such valuations.

Section 9
Summary and conclusion

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 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 the downstream users, as estimated by the Commission, are in the range 2.8 to 5.2 billion over 15 years (Commission of the European Communities, 2003b).

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. They are, however, in line with several EU studies suggesting that occupational disease costs are equivalent to between 3 and 5% of Gross Domestic Product. REACH has the potential to impact on these.

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Appendices

Appendix 1
Available statistical data on occupational disease

- EODS and EUROSTAT data. Available from: http://epp.eurostat.cec.eu.int > Population & social conditions > Data > Health
- MISSCEEC data. Available from: http://europa.eu.int/comm/employment_social/missceec/index_en.html
- EUROGIP data. Available from: http://www.eurogip.fr/en/bref/index.htm
- RIDDOR data. Available from: http://www.riddor.gov.uk

Appendix 2
Abbreviations used

List of countries and their abbreviations

Australia	AU	Greece	GR	Norway	NO
Austria	AT	Hungary	HU	Poland	PL
Belgium	BE	Iceland	IS	Portugal	PT
Canada	CA	Ireland	IE	Singapore	SG
Cyprus	CY	Italy	IT	Slovakia	SK
Czech Republic	CZ	Latvia	LV	Slovenia	SI
Denmark	DK	Lithuania	LT	Spain	ES
Estonia	EE	Luxembourg	LU	Sweden	SE
Finland	FI	Malta	MT	Switzerland	CH
France	FR	Netherlands	NL	United Kingdom	GB
Germany	DE	New Zealand	NZ	United States	US

Other abbreviations

- CEA Cost effectiveness analysis
- CISDOC Centre international d'information de sécurité et de santé au travail documents (ILO Documentation Centre).
- COPD Chronic obstructive pulmonary disease
- ECRHS European Community Respiratory Health Survey
- ELFS European Labour Force Survey (EUROSTAT)
- EODS European Occupational Disease Statistics (EUROSTAT)
- EPIDERM Epidemiology of dermatitis (reporting system)
- ESWC European survey on working conditions
- EU-11 DE, DK, ES, FI, GB, GR, IE, IT, LU, PT, SE
- EU-12 AT, BE, DK, ES, IE, FI, GB, IT, LU, NL, PT, SE
- EU-15 AT, BE, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, NL, PT, SE
- EU-25 EU-15+ CY, CZ, EE, HU, LV, LT, MT, PL, SK, SI

- FEV1 Forced expiratory volume in one second
- FVC Functional vital capacity
- LFS Labour Force Survey
- MISSCEEC II Mutual Information System on Social Protection in the Central and Eastern European Countries Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovak Republic and Slovenia
- MISSOC Mutual Information System on Social Protection Systems
- ORSD Occupational respiratory and skin diseases
- ORD Occupational respiratory diseases
- OSD Occupational skin diseases
- PPP Purchasing power parities
- QALY Quality-adjusted life year
- REACH Registration, evaluation and authorisation of chemicals
- RIDDOR Reporting of Incidence in Disease and Dangerous Occurrences Regulations
- SWI Self-reported work-related illness

Appendix 3
Disease definitions

Diseases included in the study

The respiratory and skin diseases (ORSD) included in this study are to be defined using ICD9 or ICD10 codes where possible or as defined in state compensatory systems where they are not linked to an ICD code.

Malignant respiratory and skin diseases have been specifically excluded as most of the substances responsible for malignant disease are unlikely to be significantly affected by REACH. Malignant effects are, in any case, unlikely to occur within the 30-year time span considered here.

- **Occupational asthma** : There is no single definition in universal use for occupational asthma. For the purposes of this report, occupational asthma is asthma (variable airway limitation and/or bronchial hyper responsiveness) resulting from or aggravated by exposure to an agent at work. Occupational asthma may first appear in adulthood and symptoms may vary across the working shift or week. It may take weeks or years after starting to work in an environment containing a sensitiser or irritant. Acute exposures resulting in onset of asthma are referred to as Reactive Airways Dysfunction. There is little doubt that there is a large group of distinct or overlapping patterns of reversible airways dysfunction that result from work exposures.

  The criteria used for inclusion of cases in the papers discussed differ in their inclusiveness. Reversible respiratory symptoms include, wheezing or whistling sounds, coughing, attacks of shortness of breath, or airflow limitation measured with a spirometer.

- **COPD** : COPD includes chronic bronchitis and emphysema, diseases that cause chronic airway narrowing. Symptoms are cough, sputum production and dyspnoea. Clinical diagnosis is confirmed by spirometric tests in the presence of not-fully-reversible airflow limitation. The major symptom of COPD is exertional dyspnoea. COPD is a major cause of chronic morbidity and mortality and represents a substantial economic and social burden. The predominant factor explaining the development of COPD is tobacco smoking and the prevalence

of the disease in different countries is related to rates of smoking and time of introduction of smoking. The contribution of occupational risk factors is quite small, but may vary depending on a country's level of economic development (de Marco, 2004).

- **Occupational skin disease – contact dermatitis** : The lack of a standard case definition of occupational contact dermatitis leads to difficulties in obtaining accurate epidemiological data as case definitions vary from one data source to another. Contact dermatitis is an altered state of skin reactivity induced by exposure to an external agent. Substances that produce this condition after single or multiple exposures may be irritant or allergic in nature and will often appear as an inflammatory process. Direct tissue damage results from contact with irritants (irritant contact dermatitis; ICD). Tissue damage by allergic substances or sensitisers is mediated through immunologic mechanisms (allergic contact dermatitis; ACD). Contact dermatitis is characterised by a reaction by the skin to produce a number of changes including erythema, papules, vesicles, exudation and itching. Standard questionnaires list the symptoms and ask for how long, or how often, they have occurred. They are based on self-reporting of diagnoses (Susitaival *et al.*, 2003). The clinical diagnosis of occupational contact dermatitis is made on the basis of:
  - history of onset;
  - appearance;
  - exposure to known irritants or sensitisers;
  - patch-testing;
  - exclusion of other causes.

  Patch-testing by itself is not a sufficient diagnostic test for occupational contact dermatitis because positive reactions to certain sensitisers are common in the general population. The final diagnosis is made by a clinician assessing the occupational relevance of the patch-test result using occupational exposure data, history, and exclusion of other causes.

Diseases excluded from the study

- **Rhinitis:** Perennial allergic rhinitis starts in early childhood and occurs all year round. Allergic rhinitis is caused by the body producing increased amounts of a specific antibody, IgE, which reacts to a specific allergen. This binds to body cells, the mast cells, which release irritant chemicals, in particular histamine, causing symptoms at the site of release. Common allergens are droppings of house dust mites or pet skin flakes, indoor mould spores and, in rare cases, food allergy. There is often a family predisposition to developing rhinitis and other allergies. The symptoms are: symptoms of a 'permanent cold'; blocked stuffy nose; headaches and earache; constant sore throats and postnasal drip; sleep disturbances and snoring; loss of taste and smell and poor concentration.

- **Urticaria:** Contact urticaria is also known as hives and is the eruption of red marks on the skin that are usually accompanied by itching. This condition can be caused by an allergy (eg, to food or drugs), stress, infection or physical agents (eg, heat or cold). Urticaria is much less common than contact dermatitis, and most cases are caused by large molecular weight biological molecules.

- **Fibrosing alveolitis:** Fibrosing alveolitis is a condition caused by cells that are normally involved in the body's own defence against infection, instead causing inflammation, injury, and scarring in the lungs. Scar tissue prevents the lung performing its normal function. The most common age at which the disease

strikes is in the 50s, and men and women are equally affected. Exposure to certain occupational dusts (eg, asbestos, hard metal alloy), can produce disease which is identical to fibrosing alveolitis, and most people with the disease are, or have been, cigarette smokers. However, for most people the specific cause or provoking factors cannot be identified. The most common symptom is breathlessness, particularly on exercise such as walking up hills or stairs. If it remains untreated, the condition can often worsen and lead to permanent and progressive breathlessness. Less common symptoms include a dry cough.

Appendix 4
Severity and duration of disease

- **Asthma** : The hallmark diagnostic tool of asthma is the pulmonary function test (PFT). Pulmonary function testing will determine airflow obstruction severity and the degree of reversibility. Spirometry measurements (FEV1, FEF25-75, PEFR, FVC, FEV1/FVC) before and after the patient inhales a short-acting bronchodilator are instrumental in diagnosing asthma. Bronchial challenge testing not only aids in determining the presence of airflow obstruction, but also determines the degree of reversibility after a bronchodilator. Spirometry values achieved during forced expiratory manoeuvres are compared to predicted values. Generally, significant reversibility is indicated by a 12% or greater and / or 200 ml increase in a patient's FEV1.

  The risk of long-term/persistent asthma is directly related to the severity and duration of symptoms at the time of diagnosis, and to the duration of exposure to the initiating cause after the onset of respiratory symptoms. In a study in the USA, remission of asthma is 22% during 9 years (Bronniman *et al.*, 1986). In a study in the Netherlands of asthmatics aged 13–44 years 21% did not have bronchial hyper-responsiveness after 25 years, 11% were in remission if normal lung function and freedom from symptoms were required (Panhuysen *et al.*, 1997). In Sweden, remission of asthma (no symptoms without using asthma medicine) in the middle aged and elderly was found to be 6% during 10 years (Rönmark *et al.*, 1999).

- **COPD** : Severity is measured by pulmonary function FEV_1 (The amount of air that can be expired as quickly as possible in one second after a maximal inhalation) and by a carbon monoxide diffusion test (CO diff. Transfer capacity).

  GOLD Guidelines [online]
  Stage 0 chronic cough and phlegm without airway obstruction, at risk of developing disease and $FEV_1/FVC \leq 70\%$
  Stage I mild: $FEV_1/FVC < 70\%$ and $FEV_1 \geq 80\%$ predicted
  Stage II moderate: $FEV_1/FVC < 70\%$ and FEV_1 50-80%
  Stage III severe: $FEV_1/FVC < 70\%$ and FEV_1 30-50%
  Stage IV very severe: $FEV_1/FVC < 70\%$ and $FEV_1 < 30\%$

  COPD is most often diagnosed in the fifth or sixth decade of life. It is generally a chronic and progressive disease. Smoking cessation is the only intervention shown to slow the decline.

- **Dermatitis** : Contact dermatitis is usually a mild self-limiting condition but recurs with repeated exposure and may become long lasting and chronic. Meding (1990) found a mean duration of 11.6 years. Funke (2001) found two-thirds were recurring or continuous, one-third isolated incidents amongst apprentices.

Almost any substance can be an irritant, depending on the circumstances. Furthermore, more than 2800 substances have been identified as contact allergens. A number of other non-malignant skin diseases caused by chemicals at work are recorded in national disease statistics, including occupational vitiligo and contact urticaria. If contact with the causing agent continues, dermatitis may become chronic, disabling, and a serious threat to continued work and the activities of daily living. ICD accounts for more days lost from work than any other occupational disorder apart from musculo-skeletal conditions (HSE 2002, HSE unpublished).

After prolonged and repeated episodes of dermatitis, the condition may become severe, persistent, job-threatening, and sometimes life-threatening. If the agent or agents causing the dermatitis can be found and successfully avoided, recovery can be anticipated; but if contact continues, the dermatitis may become chronic and disabling. After prolonged and repeated episodes of dermatitis, a few patients may not fully recover, even with adequate medical care and following avoidance of its causes.

Appendix 5
Nature of primary survey sources used in the report

Survey	Sample base	Age range	Employed/inactive/ ever	Work related ill health: Main/any	Question
SWI, 1990	74,000 England & Wales	Adults	Ever worked	Most serious	Respondents disease descry Within the last 12 months have you suffered any illness, disability or other physical or mental problem that was caused or made worse by your job or work done in the past ?
SWI, 1995	40,000 GB	Adults	Ever worked	All/most serious	Illnesses classified
SWI, 1999	69,000 GB	Adults	Had worked in the last 12 months	Most serious	Illnesses classified
ELFS, 1999	650,000 EU-10 +HU	Adults	Ever worked with age restrictions in some countries Rates: illnesses linked to current employment/100,000 employed 1999	Most serious; detail All	5 variables on diseases, disabilities and other physical or psychological health problems
ESWC, 2000	EU-15		Working, self-employed or employed	Health affected by work	Generic part of the body affected
EODS, 2004	EU-12 extrapolated to EU-15	Adults With exclusions	Mainly without employment conditions Rates /100,000 employed 2001	Restricted 68	Disease entities, rec by national compensation authorities EU Rec 90/236

Because of the variety of populations used in the studies cited here and elsewhere in the report we have adopted a base population figure of 200 million for use in generating our REACH estimates.

Most population studies refer to people of working age when stating the prevalence figure. Others use 'ever worked' populations or those currently in work, or those who have worked in a fixed period prior to the survey. For the diseases of concern to us, most cases are likely to arise while the individuals are in work. In principle incidence rates should then be calculated using the specific figures for the active workforce relevant to each study. These incidence rates would be correspondingly higher than they would be if they were based on the much larger working age population. To avoid recalculation of incidence rates and to provide

a common basis for calculation, we have adopted a figure of 200 million which we refer to as the base population. Eurostat figures give the EU 25 population in 2005 as 469 million, the proportion between 15 and 65 as 49 % (230 M) and the proportion of those between 15 and 65 in work as 63% (145 M).

European Union population statistics can be found on: http://europa.eu.int/comm/employment_social/news/2005/mar/demog_gp_en.html

Appendix 6
Evidence tables

Key: Attributable risk (AR), Incidence (I), Occupational asthma (OA), Odds ratio (OR), Occupational health diseases (OHD), Prevalence (P), Prevalence rate (PR), Relative risk (RR)

Table 33 **Evidence table for occupational asthma**

Country	Year	Nr.	Method	Test	Findings	Substances	Reference
FR	1996	559	cross-sectional questionnaire	clinical	I=25.7 per m workers. Considerable variation by region from 4 to 73 per m.	suspected: flour, isocyanates, latex, aldehydes, persulphates, wood dust, enzymes, dust mite, glues and resins, mammals, grain, amines, colophony, acids	KOPFERSCHMITT-KUBLER MC, AMEILLE J, POPIN E, CALASTRENG-CRINQUAND A, VERVLOET D, BAYEUX-DUNGLAS MC, PAULI G (2002)
FR	1996-1999	2,178 new cases over 3 years			annual rate 24/million	flour, isocyanates, latex, etc.	AMEILLE J, PAULI G, CALASTRENG-CRINQUAND A, VERVLOET D, IWATSUBO Y, POPIN E, BAYEUX-DUNGLAS MC, KOPFERSCHMITT-KUBLER MC (2003)
FR	1975	20,310 aged 25-59	cross-sectional questionnaire	questionnaire	AR=14% for self reported exposure to dusts, gases, fumes and asthma onset after current job. AR=3% for exposure to any asthmagens and asthma onset after current job. AR=8% for exposure to any asthmagens and asthma with airflow limitation	dusts, gases, fumes	LE MOUAL N, KENNEDY SM, KAUFFMAN F (2004)
FI	1986-1998	960,497 men; 892,351 women	Register Registry		attributable fraction of occupation 29% (CI 25-33) for men and 17% (CI15-19) for women	various	KARJALAINEN A, KURPPA K, MARTIKAINEN R, KLAUKKA T, KARJALAINEN J (2001)
FI			cross sectional /register questionnaire	clinical	20% reported work aggravated symptoms		SAARINEN K, KARJALAINEN A, MARTIKAINEN,R, UITTI J, TAMMILEHTO L, KLAUKKA T, KURPA K (2003)
FI	1988-2000	3,637	prospective Register		I:420 cases of A in those with rhinitis and 972 in reference pop		KARJALAINEN A, MARTIKAINEN R, KARJALAINEN J, KLAUKKA T, SAARINEN K, UITTI JUKKA (2003)
FI	1986-1998	49,575 new asthma cases in 5.8m population	cohort Register	lung function	significant RR for adult onset asthma for 125 non-administrative occupations. Significant RR for confirmed male and female occupational asthma cases for farmers etc., fur farmers (men only), agricultural workers, painters etc., bakers, butchers (men only), plastic production workers, cooks (men only) livestock breeders (women only), plywood etc. workers (women only)		KARJALAINEN A, KURPPA K, MARTIKAINEN R, KARJALAINEN J, KLAUKKA T (2002)
FI	1986-1998	cleaners: 54,000 admin: 203,000	cross sectional		work related attributable fraction of A among cleaners = 33%. 25/2414 cases of A in cleaners recognised as OA		KARJALAINEN A, MARTIKAINEN R, KARJALAINEN J, KLAUKKA T, KURPPA K (2003)
FI	1997	521 cases, 932 controls	case control recruit new cases in 1 hospital district, plus new registrants to Nat Soc Insurance list	clinical	OR = 5.69 (95% CI 1.08, 29.8) for chemical occupations, both sexes; 4.52 (2.35, 8.70) for metal work, men; 3.03 (1.10, 8.31) for waiters, women.		JAAKKOLA JJ, PIIPARI R, JAAKKOLA MS (2003)
GB	1990-1997		Registry	bronchial challenge	Annual incidence= 41.2 / million	various	DI STEFANO F, SIRIRUTTANAPRUK S, MCCOACH J, DI GIOACCHINO M, BURGE PS (2004)

Country	Year	Nr.	Method	Test	Findings	Substances	Reference
GB	1996-1997		SWORD 98. Monthly data from 24 chest physicians + single month report from 405 chest physicians for 1998. Register		1998 - 986 cases of ORD adjusted = 2966 incident cases A=822, COPD=58 etc.	enzymes, flour, isocyanates, etc.	MEYER JD, HOLT DL, CHERRY NM, MCDONALD JC (1999)
GB	1999		Registry		1999 - 1168 A, 73% male mean age 43 New cases of OA 1992: 312, 26%; 1993: 257, 23%; 1994: 279, 28%; 1995: 284, 29%; 1996: 229, 26%; 1997: 274, 27%; 1998: 204, 22%; 1999: 259, 25%		MEYER JD, HOLT DL, CHEN Y, CHERRY NM, MCDONALD JC (2001)
GB	1993		Registry		Table of A by suspected agent and occupation. Estimated I for 1993 A 879, Bronchitis 58	various	SALLIE BA, ROSS D J, MEREDITH SK, MCDONALD JC (1994)
GB		6,077	Clinic Questionnaire		182 with adult onset asthma now aged 45.4 ± 12. Diagnosis at mean age 33.9 ± 12.8 157 had at least one occupation noted. Of these 157, 50 were in occupation of known potential exposure. A firm diagnosis of OA was made in 7 of 182 (4%)		DE BONO J, HUDSMITH L (1999)
GB	1989-1997	7,300	clinical			half not an official sensitiser	MCDONALD JC, KEYNES HL, MEREDITH SK (2000)
GB	1992	188	Cross sectional Questionnaire		20/188	irritants, allergens	
AU, BE, DE, IS, IE, IT, NZ, NO, US, ES, SE, GB		15,637	OR for occupations, Questionnaire, Risk assessed for occupational GPs + exposures	metacholine challenge	AR = 5-10% DE highest. Highest if Q + methacholine challenge combined. Food and bakery very low! Smoking status adjustment made little difference	biological dusts and mineral dusts 3-4% each AR. Gases and fumes 3.5%	KOGEVINAS M, ANTO FM, SUNYER J, TOBIAS A, KROMHOUT H, BURNEY P *et al.* (1999)
FI, SE, GB					Incidence rates vary from 16 - 175/million in medico-legal studies. Attributable fraction 15%. Annual incidence 400/106 - 710/106 Analysis big difference between Registry studies in Finland		GAUTRIN D, NEWMAN-TAYLOR AJ, NORDMAN H, MALO J-L (2003)
IE, EE, GB, BE, DK, SE, ES, DE, PL, IT, NO, IS			Cross sectional questionnaire	none	PR=2.1 (95% CI 1.8, 2.4) for exposure to vapours, gas, dust, fumes; 1.3 (1.04, 1.7) for high risk asthma job	non-specific vapours, dust, gas, fumes	BLANC PD, BURNEY P, JANSON C, TOREN K (2003)
AU, BE, DE, IS, IE, IT, NZ, NO, ES, SE, GB, US		15,637			proportion of A attributable to occupation = 5-10%	dust, gases, fumes	KOGEVINAS M, ANTO FM, SUNYER J, TOBIAS A, KROMHOUT H, BURNEY P *et al.* (1999)
IS, NO, SE, DK, EE	1999-2001	16,191 (74% response)	Follow-up questionnaire Questionnaire	not clear, as ECRHS used clinical but not reported here	I for all symptoms=1.5 (1.0, 2.0), by country 3.6/1000 pt years in Iceland (95% CI 3.0, 4.9), lowest in Estonia 0.5/1000 pt years (0.2, 1.1).		TOREN K, GISLASON T, OMENAAS E, JOGI R, FORSBERG B, NYSTROM L, OLIN AC, SVANES C, JANSON C (2004)
CA		phase 1: 18,701; phase 2: 2,974 of whom 383 had A	Questionnaire		P of probable OA and possible OA = 36.1% (CI 31.3-41.0)	industries given	JOHNSON AR, DIMICH-WARD HD, MANFREDA J, BECKLAKE MR, ERNST P, SEARS MR, BOWIE DM, SWEET L, CHAN-YEUNG (2000)

Country	Year	Nr.	Method	Test	Findings	Substances	Reference
CA	over 19 years	900 referred 682 of the with diagnosed A, 51 A worse at work	Prospective survey Questionnaire		P: 7% for worsening aA at work, 16% in all working adult onset A		TARLO SM, LEUNG K, BRODER I, SILVERMAN F, HOLNESS (2000)
CZ	1996-2000	2,127 new cases of respiratory disease	Registry	physician, challenge tests etc	numbers of incident OA =258 (12.1%). incident rhinitis =121, incident OA & rhinitis = 65 (3.1%). tot=444	dusts, flours, textiles, etc.	BRHEL (2003)
IT	1989-1993	387 (203 OA, 184 non-occ)	Case-control occupation				MASTRANGELO G, BOMBANA S, PRIANTE E, GALO A, SAIA B (1997)
NO	1985 &1996	1985: 3,370 1996: 2,819	Questionnaire		cumulative 11 year I of A: 4.1 (quartz), 7.5 (asbestos), 5.3 (dust/fumes)	dust, fumes, asbestos, quartz	EAGAN TOMAS ML, GULSVIK AMUND, EIDE G E, BAKKE PS (2002)
SE			cross-sectional questionnaire	skin tests, lung function tests for some	PR=4.3 (95% CI 2.2, 8.6) for those exposed to vapours, gas, dust, fumes; 1.8 (1.1, 3.0) for exposure to high asthma risk job	non-specific vapours, dust, gas, fumes	BLANC PD, ELLBJAR S, JANSON C, NORBACK D, NORRMAN E, PLASCHKE P, TOREN K (1999)
SE	1996	407 asthma, 1,904 controls	case control previous study	clinical	OR=2.0 (95% CI 1.5, 3.4) for welding fumes, 2.6 (1.4, 7.3) for man made mineral fibres, 2.2 (1.4, 3.7) for solvents in painting, 2.1 (1.3, 3.3) for solvents in mechanical industry.	solvents, fumes	TOREN K, BALDER B, BRISMAN J, LINDHOLM N, LOWHAGAEN O, PALMQVIST M, TUNSATER A (1999)
SE	1990-2002	1,010	Register	questions	I=80 per million (95% CI 70, 90); for men 91/million (84, 98); women 70/million (63,77). Age stratified, higher I in older age groups (45-64 vs 20-44). I for male bakers, furnace men, welders, spray painters (599/m), chemical process workers (585/m), metal casters (567/m), wood processing workers (455/m). I for women chemical process workers (952/m), dairy and poultry (602/m), plastic production (566/m), wood workers (494/m).		TOREN K (1996)

Table 34 **Evidence table for COPD**

Country	Subjects	Year	Nr.	Method	Test	Findings	Substances	Reference
EU-15		1994-2002		self report		820 cases of chronic bronchitis, 410 cases allergic rhinitis 600,000 workers have respiratory problems		EUROSTAT (2004)
DE		1995		compensation stats Registry		I: of OA& COPD =51/million Number of compensations = 4128= P:136 per million		BAUR X, DEGENS P, WEBER K (1998)
DE	random	random digit dialling	14904			8%	not occ	RENNARD S, DECRAMER M, CALVERLEY PMA, PRIDE NB, VERMEIRE PA, VESTBO J (2002)
DK	cohort of 20-59 year olds	1981, 1986 & 1991		standard hospitalisation ratios		RR between unskilled and senior staff = 2.31 (CI2.13-2.51) for men and 1.62 (CI 1.38-1.92) for women		TUCHSEN F, HANNERZ H (2000)
DK	random sample of Copenhagen residents 20 - 90 year olds	1989	12698			P=3.7%		LANGE P, GROTH S, NYBOE J, APPLEYARD M, MORTENSEN J, JENSEN G, SCHNOHR P (1989)
DK	survey ECRHS among working adults aged 20-45		273			P of wheeze at work. DK=10.6%		BLANC PD, BURNEY P, JANSON C, TOREN K (2003)

Country	Subjects	Year	Nr.	Method	Test	Findings	Substances	Reference
FI	random sample of Helsinki residents 20 -69	1999	6062	patient report		P of chronic bronchitis =3.7%		PALLASAHO P, LUNDBACK B, LASPA SL, JONSSON E, KOTANIEMI J, SOVIJAN AR, LAITINEN LA
FI	older than 65	1990-1991	1196		spiro-metry or bronchodilator and clinical exam	12.5% men, 3.0% in women		ISAHO R, PUOLIJOKI H, HUHTI E, KEVELA SL, LAIPPALA P, TALA E (1994)
FI	random sample of Finnish adults aged 30+	2000	7217	clinical exam		P of chronic bronchitis/ emphysema= males 22.1%, females 7.2% P of clinically relevant airways obstruction= 11% in men, 5% in women		VON HERTZEN L, REUNANEN A, IMPIVAARA O, MALKIA E, AROMAA A (2000)
FR	random sample mean age 63.3	2000-2001	18165	random digit dialling		P of COPD =6%	not occ	RENNARD S, DECRAMER M, CALVERLEY PMA, PRIDE NB, VERMEIRE PA, VESTBO J (2002)
GB	SWORD	1999		Registry		1999 - 1168 Bronchitis/ emphysema 129, 97% male mean age 65		MEYER JD, HOLT DL, CHEN Y, CHERRY NM, MCDONAL JC (2001)
GB	Survey ECRHS among working adults aged 20-44		1,299	Questionnaire Occupation		P of wheeze at work=11.6%		BLANC PD, BURNEY P, JANSON C, TOREN K (2003)
GB	General practice group 40 -74	1989	1,444	spirometry	MRC criteria	P= 16.7% males, 7.1 %females	not occ	LITTLEJOHNS P, EBRAHIM S, ANDERSON R (1989)
GB	General practice group 40 -74	1989	1,444	patient report	self report	P= 3.9% males, 2.1% females	not occ	LITTLEJOHNS P, EBRAHIM S, ANDERSON R (1989)
GB	General practice group 60-75	1999	353	patient report		P= 9.9%	not occ	DICKINSON, JA, MEAKER M, SEARLE M, RATCLIFFE G (1999)
GB	SWORD 97	1997				23 I cases of bronchitis/ emphysema		ROSS DJ, KEYNES HL, MCDONALD JC (1998)
GB		random digit dialling	12,020	self report		6%	not occ	RENNARD S, DECRAMER M, CALVERLEY PMA, PRIDE NB, VERMEIRE PA, VESTBO J (2002)
GB	COPD patients on GPRD register age 20-65	1990-1997	50,714 Incident COPD patients	FU retrospective cohort	physician	1.36% in women, 1.62% in men	not occ	SORIANO JB, MAER WC *et al.* (2000)
ES	40-69 years	1996-1997	4,035	Population Questionnaire	spiro-metry	P=9.11% (8.1-10.2) females =3.9%, males = 14.3%		PENA VS, MIRAVITLLES M, GABRIEL R, JIMENEZ-RUIZ CA, VILLASANTE C, MASA JF, VIEJO JL, FERNANDEZ-FAU L (2000)
ES	ECRHS survey age 20-44			Cross sectional Questionnaire	fev1	35% exposed to gas and fumes	mineral dusts, gases fumes	SUNYER J, KOGEVINAS M, KROMHOUT H, ANTO JM, ROCA J, TOBIAS A, VERMEULEN R, PAYO F, MALDONADO JA, MARTINEZ-MORATALLA J, MUNIOZGUREN N (1998)
IT						6%		RENNARD S, DECRAMER M, CALVERLEY PMA, PRIDE NB, VERMEIRE PA, VESTBO J (2002)
IT	8-73 years	1988-1991	2,841	Cross sectional, Questionnaire	fev1	P COPD:ERS=11%, Clinical = 18.3%, ATS=40.4%		VIEGI G, PEDRESCHI M, PISTELLI F, DI PEDE F, BALDACCI S, CARROZZI L, GIUNTINI C (2000)
NL	Report to National centre for occupational diseases			Registry		in 2002 41 lung diseases reported		NETHERLANDS CENTER FOR OCCUPATIONAL DISEASE ANNUAL REPORT (2002)

Country	Subjects	Year	Nr.	Method	Test	Findings	Substances	Reference
NL	Zutphen study, men randomly selected 40 -59 years	1960	878	Cohort, Follow-up for 25 years	non specific lung disease medical exam	Incidence Density Ratio of 1.4 (CI 1.07, 1.85) for population with exposure to dusts, fumes or gases in their occupation		HEEDERIK *et al.* (1990)
NL	45 + years					8%		RENNARD S, DECRAMER M, CALVERLEY PMA, PRIDE NB, VERMEIRE PA, VESTBO J (2002)
SE	male construction workers	1971-1999	317,629	Prospective cohort, Death statistics		10.7% of those exposed had COPD. 52.6% of non-smokers had COPD	inorganic dust	BERGDAHL (2004)
NO	male tunnel construction workers	1989-2002	651	Prospective cohort follow-up	fev1 adjusted for smoking	nitrogen dioxide exposure showed strongest association with decreased FEV1	dust, gases	BAKKE B, ULVESTAD B, STEWART P, EDUARD W (2004)

Table 35 **Evidence table for dermatitis**

Country	Subjects	Year	Nr.	Study type	Test	Findings	Substances	Reference
DE	Registration scheme subjects	1990-1999	5,285	Registry	Using a standard Series of skin sensitisers	on patients with OSD, 29% of patients had occupationally related sensitisation to 21 known allergens	nickel sulphate, etc.	DICKEL H, KUSS O, SCHMIDT A, DIEPGEN TL (2002)
DE	Construction workers			Registry	patch tested	I: 5.1/10,000 over 10 years(CI 4.5-5.6) 21/152 ACD cases d.f. unidentified materials at work	potassium dichromate & epoxy resin	BOCK M, SCHMIDT A, BRUCKNER T, DIEPGEN TL (2003)
DE		1990-1999	5,285	Prospective cohort		3097 cases of OSD Rise in I from 10.7/10,000 p.a. in 90-92 to 4.9 in 93-99		DICKEL H, KUSS O, BLESIUS CR, SCHMIDT A, DIEPGEN TL (2001)
FI	Finnish register of occupational disease	1991-1997	25,543	Registry, substance and occupation		2543 ACD 3113 ICD 1247 urticaria 14% of ACD due to 3 metals: Co, Ni, Cr	metals, chromium, nickel cobalt	KANERVA L, JOLANKI R, ESTLANDER T, ALANKO K, SAVELA A (2000)
GB	Patients reporting to 12 dermatologists as a sample group EPIDERM and OPRA	1993-1999		Registry occupation		1993-99 12574 cases of OSD reported I:198 cases of OCD/year from nickel 12% of cases of OCD due to nickel	nickel	SHUM KW, MEYER JD, CHEN Y, CHERRY N, GAWDRODGER DJ (2003)
GB	Analysis of registers EPIDERM & OPRA		12,574 OSD cases			6.4 /100,000 workers from dermatologists, 6.5 per 100,000 from Occupational physicians=12.9/100,000	variety of substances	MEYER JD, CHEN Y, HOLT DL, BECK MF, CHERRY NM (2000)
GB	Working age patients in GPs practices (94) over 6 months	1981/2				P 3.8/1000. 57% work related = 2.1 cases/1000 = 57400 - 828000 of GP morbidity stats		DIEPGEN (2003)
GB	Dermatology clinic patients	1983-1997	6,849 HD /24,386	Analysis of clinic records clinic		42% OHD M:F=1:1 (if non occupational 0.7)		SMITH HR, ARMSTRONG DK, WAKELIN SH, RYCROFT RJ, WHITE IR, MCFADDEN JP (2000)
GB	OD registries EPIDERM & OPRA			Occupation		2096 cases per year from dermatologists 2,134 cases per year for Occupational physicians. Overall annual incidence =12.9 cses/100,000		CHERRY N, MEYER JD, ADISESH A, BROOKE R, OWEN-SMITH V, SWALES C, BECK MH (2000)
NL	report to national centre for occupational diseases			registry		in 2002, 854 occupational dermatoses reported		NETHERLANDS CENTER FOR OCCUPATIONAL DISEASE ANNUAL REPORT (2002)
NL	occupational dermatology patients , diverse jobs	follow up 5 years after original diagnosis	124/172	questionnaire clinic		50% still had medium ICD, 32% severe. 57% changed jobs, 46% permanently		JUNGBAUER FH, VAN DER VLEUTEN P, GROOTHOFF JW, COENRAADS PJ (2004)

Country	Subjects	Year	Nr.	Study type	Test	Findings	Substances	Reference
SE	patients of dermatology dept of hospital	1978-2001	22/15141 7F, 15M	clinic		8,117 (53.6%) have contact allergy to one or more substances, 26 were allergic to isocyanates or polyurethanes. 22 were occupational (of the 26). 10 reacted to isocyanate and MDA. 9 reacted only to MDA. 3 reacted only to isocyanates	isocyanates MDA, MDI, HMDI	GOOSSENS A, DETIENNE T, BRUZE M (2002)
SE	bakers trained in schools	1961-1989	2226/ 2923	questionnaire retrospective cohort		Male bakers I: 16.7/1000 person years Male controls 4.4-5.4/1000 Female bakers 34.4 Female controls 11.3-14.1 RR Males 3.5 (95CI 2.8-4.5) Females 2.8 (2.2-3.6)	flour and moisture	BRISMAN J, MEDING B, JARVHOLM B (1998)
SE	factory workers		9/88 had OD	questionnaire & clinical exam cross sectional		9/66 cases of skin disease traced to materials at work. 4 d.f. new resin . 39 unknown relation to work. 18 no relation to work.	phenol formaldehyde-resin and melamine formaldehyde-resin	ISAKSSON M, ZIMERSON E, BRUZE M (1999)
SE	dentists		3500	questionnaire + exam		1 year P=14.9% HE (95% 12-16). ICD=67% ACD=28%. 41/78 dentist with	variety	WALLENHAMMAR LM, ORTENGREN U, ANDREASSON H, BARREGARD L, BJORKNER B, KARLSSON S, WRANGSJO K, MEDING B (2000)
SE			16584/ 20000 question-naires	questionnaire + exam for those who answered positive to eczema		I: 11% (1 year). 5.4% Point Prevalence 2% continuous		MEDING B, SWANBECK G (1987)

Appendix 7
Reported effects of work on health in the new EU member states

Health affected by work (%)		Countries												Total
		Bulgaria	Cyprus	Estonia	Lithuania	Latvia	Hungary	Malta	Poland	Romania	Slovenia	Slovakia	Czech Republic	Col
1. No, it does not affect my health	–	70.2	60.7	77.9	76.0	78.4	62.5	69.5	74.1	60.6	64.4	73.6	71.0	69.0
	+	29.8	39.3	22.1	24.0	21.6	37.5	30.5	25.9	39.4	35.6	26.4	29.0	31.0
Different ways health is affected (%)														
2. Yes, hearing problems	–	94.6	90.1	92.4	91.4	93.4	90.4	95.0	89.2	92.9	88.2	89.4	88.6	90.8
	+	5.4	9.9	7.6	8.6	6.6	9.6	5.0	10.8	7.1	11.8	10.6	11.4	9.2
3. Yes, problems with your vision	–	87.9	89.1	79.6	80.8	83.1	85.0	92.8	86.1	85.4	80.7	84.4	82.0	85.0
	+	12.1	10.9	20.4	19.2	16.9	15.0	7.2	13.9	14.6	19.3	15.6	18.0	15.0
4. Yes, skin problems	–	95.6	87.4	89.0	89.3	92.3	92.6	96.4	89.6	93.1	92.4	91.3	91.6	91.5
	+	4.4	12.6	11.0	10.7	7.7	7.4	3.6	10.4	6.9	7.6	8.7	8.4	8.5
5. Yes, backache	–	75.7	63.1	62.9	65.6	65.0	67.5	66.5	64.0	69.7	60.8	52.7	60.5	65.6
	+	24.3	36.9	37.1	34.4	35.0	32.5	33.5	36.0	30.3	39.2	47.3	39.5	34.4
6. Yes, headache	–	80.4	72.0	79.1	81.4	79.6	82.7	85.1	80.4	79.2	81.4	74.9	77.1	79.7
	+	19.6	28.0	20.9	18.6	20.4	17.3	14.9	19.6	20.8	18.6	25.1	22.9	20.3
7. Yes, stomach ache	–	97.0	93.2	96.6	94.2	94.0	93.6	98.4	93.6	93.0	94.7	90.0	93.3	93.6
	+	3.0	6.8	3.4	5.8	6.0	6.4	1.6	6.4	7.0	5.3	10.0	6.7	6.4
8. Yes, muscular pains in shoulders and neck	–	80.1	72.8	68.9	79.1	75.0	76.2	77.4	74.3	81.0	75.3	74.1	76.5	76.9
	+	19.9	27.2	31.1	20.9	25.0	23.8	22.6	25.7	19.0	24.7	25.9	23.5	23.1
9. Yes, muscular pains in upper limbs	–	81.6	74.7	75.4	78.8	85.1	82.8	78.7	74.3	82.9	86.6	79.5	84.8	79.8
	+	18.4	25.3	24.6	21.2	14.9	17.2	21.3	25.7	17.1	13.4	20.5	15.2	20.2
10. Yes, muscular pains in lower limbs	–	83.9	77.3	76.3	76.7	83.4	82.8	79.2	72.3	79.4	85.2	80.8	84.3	78.3
	+	16.1	22.7	23.7	23.3	16.6	17.2	20.8	27.7	20.6	14.8	19.2	15.7	21.7
11. Yes, respiratory difficulties	–	94.8	92.8	94.4	91.6	92.6	95.6	97.0	93.6	88.8	93.4	90.5	93.6	92.4
	+	5.2	7.2	5.6	8.4	7.4	4.4	3.0	6.4	11.2	6.6	9.5	6.4	7.6
12. Yes, heart disease	–	97.8	97.8	95.7	93.3	95.0	96.9	99.7	95.0	92.2	98.5	96.8	98.2	95.2
	+	2.2	2.2	4.3	6.7	5.0	3.1	0.3	5.0	7.8	1.5	3.2	1.8	4.8
13. Yes, injury(ies)	–	95.1	96.6	94.0	91.0	93.5	92.4	95.9	92.0	91.8	92.0	90.3	89.6	91.9
	+	4.9	3.4	6.0	9.0	6.5	7.6	4.1	8.0	8.2	8.0	9.7	10.4	8.1

Source: European Foundation. *First survey of Working Conditions in Candidate Countries*. Dublin: European Foundation, 2002

Appendix 8
Summary of assumptions

	% work-related	Duration in years	% REACH chemicals	High:Low estimate of costs	30:10 year estimate ratio	% 10 year total associated with disease	% 30 year total associated with disease
Asthma	10%	20	50%	4.3	40	32%	49%
COPD	15%	15	10%	5.9	50.5	7%	11%
Skin disease	50%	5	50%	7.1	10.5	60%	40%

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HESA Department, 2005

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