

# REACHing the workplace

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

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## Foreword

The Trade Union Technical Bureau has decided to focus in this brochure on the health and safety benefits inherent in the REACH legislative reform for the millions of European workers who are exposed to chemicals in the workplace on a daily basis.

In order to better understand in what way the REACH reform represents a real opportunity to reduce the number of occupational diseases related to exposure to dangerous substances, this publication begins by examining the reasons why a reform is needed; it then describes the content of the REACH reform and the changes it will make to the existing legislation. It concludes by explaining the state of play in the legislative process underway at the European Parliament and the Council, which should result in the adoption of the REACH Regulation.

The debate about REACH has been highly contentious ever since an initial draft was adopted in 2001 in the White Paper on a future EU chemicals policy. Even though - as is clear from some international acts (e.g. the Johannesburg Summit) - there is a broad consensus on the need for better surveillance of the safety of chemical substances circulating on the European and international markets, certain companies, echoed by certain governments, maintain that enforcement of this new legislation will provoke a marked increase in the cost of chemical products in Europe; consequently, a large number of substances will be withdrawn from the Community market and massive job losses caused in the sectors concerned.

We believe on the contrary, based on national experiences, that legislative changes designed to protect the environment and health can stimulate technological innovation, a key element of competitiveness, and that REACH constitutes a common system for more than 25 countries to minimise and manage the risks associated with chemical substances and preparations placed on the market.

The purpose of this brochure is to feed into the REACH debate so as to provide convincing evidence of the urgent need for such a reform. A European conference is to be held by the European Trade Union Confederation on 11 and 12 March 2005, at which the trade unions have every intention of making a constructive contribution to the process of drawing up this reform.

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Director of the TUTB

December 2004

## Summary

Chemicals are an integral part of our daily lives. They are present in most everyday consumer articles, and there is no doubt that they afford a number of benefits which our developed societies could not do without. Unfortunately, it must also be acknowledged that a large number of them also pose problems in terms of health and the environment. It is partly due to flaws in the existing European legislation that numerous chemical substances can be marketed even though we do not really know what effects they may have on human health and the environment.

The proposed reform of the European legislation on trade in chemical substances, known as REACH (**R**egistration, **E**valuation and **A**uthorisation of **C**hemicals), aims to tackle this problem by pursuing two main aims : ensuring a high level of protection for human health and the environment; and strengthening the competitiveness of the European chemical industry.

European workers stand to benefit enormously from this reform, since at present the manufacture and use of chemicals in the workplace takes a heavy toll on them. Indeed, approximately one out of every three occupational diseases recognised annually in Europe can be ascribed to exposure to hazardous chemicals.

Alongside the European legislation governing trade in chemicals, there is legislation to protect the health and safety of workers from the risks related to exposure to chemicals at work. Implementation of this legislation still remains problematical, however, and most of the time it is scarcely or only partially enforced, especially in small and medium-sized enterprises.

One of the main reasons for this state of affairs is no doubt the lack of data about the intrinsic properties and the safety of chemical substances. Without such data, it is not possible to carry out a proper risk assessment or to put in place the control and prevention measures set out in the legislation on worker protection.

REACH should therefore significantly boost the effectiveness of the existing legislation on the protection of workers exposed to dangerous substances in various branches of industry and should help to combat the risk of occupational diseases :

- by supplying missing information on the properties of chemical substances and ways of minimising risk during their use;

- by improving the communication of this information along the entire production chain;
- by encouraging the replacement of the most harmful substances by less hazardous ones, through authorisation and restriction procedures.

The European Commission adopted the proposal for a REACH Regulation in October 2003, and it is currently being examined by the European Parliament and the Council in a co-decision procedure. The REACH Regulation should enter into force in the 25 EU countries sometime in 2007.

# 1. Chemicals : two sides to the story

## A major contribution to the economy

The production of chemical substances worldwide has risen from one million tonnes in 1930 to more than 400 million tonnes today. There are almost 100,000 different substances listed on the Community market, 30,000 of them placed on the market in quantities of more than 1 tonne/year<sup>1</sup>. The European Union's chemical industry, producing approximately one third of total international output, is the largest chemical industry in the world. Its turnover in 2003 was estimated to be € 556 billion for the EU-25<sup>2</sup>. It is also Europe's third largest manufacturing industry, employing 1.7 million workers directly and several million more indirectly. The vast majority of chemical firms in Europe (96%) are SMEs, yet a few influential multinationals account for over 70% of total production.

While there is no denying that chemicals yield benefits which our developed societies could not do without (e.g. for food production, the manufacture of medicines, the textiles industry, etc.), and that they also contribute to economic prosperity in terms of trade and jobs, there is another side to the story that must be given serious attention.

## Workers exposed to chemicals

Millions of European workers are exposed to chemical substances on a daily basis, not only in the sectors manufacturing them (the chemical industry) but also in the downstream sectors where these substances are used : the building trade, woodworking industry, automotive sector, textiles, agriculture, the provision of services in the environmental and health sectors, the computer sector, etc.

Whereas many chemical products used in the workplace are entirely harmless, others may have damaging effects on workers' health. Several hundred different chemicals have been found to cause recognised occupational skin diseases or respiratory diseases<sup>3</sup>. Under the systems for recognition of occupational diseases, most of these chemicals have been defined according to their industrial use (paint, varnish, cosmetics, insulation, etc.) and not by their chemical structure. The health problems they cause derive both from their intrinsic hazardous properties and from workers' levels of exposure to these products, reflecting the way in which they are used in the workplace and in different branches of industry. Nevertheless, the fact still remains that

<sup>1</sup> All the annual production or import volumes referred to in the text are per manufacturer or importer.

<sup>2</sup> *Facts and Figures, The European chemical industry in a worldwide perspective*, Cefic, June 2004. See : [www.cefic.org/factsandfigures](http://www.cefic.org/factsandfigures).

<sup>3</sup> *Work and health in the EU, a statistical portrait. Data 1994-2002*, Luxembourg, Eurostat, 2004. See : <http://europa.eu.int/comm/eurostat> > Publications.

many chemicals are used in the workplace even though we do not know precisely (or only too late) what effects they might have on the health of workers exposed to them. The case of glycol ethers – solvents that are extremely widely used in a whole series of industrial processes and to which millions of workers are exposed – is without doubt a clear illustration of this state of affairs (see Box below).

It can be estimated on the basis of the Eurostat EODS survey, for which the reference year is 2001, that between 18 and 30% of the cases of occupational diseases recognised in Europe are related to exposure to chemical products (see Box, p. 8).

### Glycol ethers : an asbestos-like health disaster?

Glycol ethers are a family of solvents consisting of over 80 derivatives. They have been known since the 1930s but their use increased markedly from the 1960s onwards. The upsurge in industrial use of glycol ethers is attributable to their solubility both in water and in organic solvents, making substances soluble with one another that otherwise would not be. Glycol ethers are present in all so-called “water-based” products.

Although employees in certain branches of industry (manufacture of printed circuits, manufacture of paints and varnishes, paintwork in the automobile, aeronautical, building and screen-printing industries, etc.) are particularly exposed to these solvents, they are also present in many everyday consumer goods (glues, inks, cosmetics, cleaning products, etc.).

The toxicity of glycol ethers varies. Most of those belonging to the P series (propylene glycol derivatives) are deemed harmless, whereas by contrast members of the E series (ethylene glycol derivatives) may be highly toxic : carcinogenic, causing sterility and birth defects. The first warning was issued by the State of California back in 1982. Sweden banned certain glycol ethers in 1990. Since 1993 the European Union has classified a dozen derivatives of this family as toxic for reproduction and has banned four of them from sale to the public. Their industrial use, however, is still permitted but with a label stating “may impair fertility” and “possible risk of harm to the unborn child”.

In a medical report published in September 2003, the French courts recognised for the first time the

“direct and undoubted” responsibility of glycol ethers in the infertility of a worker exposed to these solvents over a period of several years. Such lawsuits are still few and far between in Europe, but over 200 similar cases are currently underway in the United States. Since the disorders connected with glycol ethers have delayed effects and more and more studies are being carried out into the links between occupational exposure to these substances and the onset of certain diseases, it is highly likely that the number of complaints of this type will grow in the years ahead.

The European market in glycol ethers amounts to some 400,000 tonnes per year and worldwide demand is rising by more than 5% per year. In France alone the number of workers exposed to glycol ethers (P and E series) is thought to be almost one million. EGBE (Ethylene Glycol n-Butyl Ether), for instance, is still extensively used by industry and in staple consumer products even though it is classified as carcinogenic for mice.

The example of glycol ethers clearly illustrates the flaws in the current legislation, which allows chemicals whose hazards are unknown or have for too long been underestimated (as in the case of asbestos) to be widely used in the workplace and in general consumer goods.

The REACH system should rectify this situation by generating the missing information and promoting the substitution of the most hazardous E series derivatives by P series ones which are safer and equally effective.

### Chemical hazards : a major cause of mortality among European workers

Exposure to dangerous substances also leads to a large number of deaths. According to a survey conducted in 1998 by the Finnish Institute for Occupational Health and Safety, approximately 32 million workers within the European Union - or almost a quarter of the working population - are exposed to occupational carcinogens at doses that can be considered beyond safety<sup>4</sup>, and there are between 35,000 and 45,000 work-related cancer deaths a year<sup>5</sup>.

Chemical hazards currently represent a major cause of mortality related to working conditions in the European Union countries, far ahead of deaths caused by accidents at work.

<sup>4</sup> *Occupational exposure to carcinogens in the EU 1990-1993*, Carex, international database on occupational exposure to carcinogens.

<sup>5</sup> KOGEVINAS *et al.*, *Estimation of the burden of occupational cancer in Europe* - Study financed by Europe Against Cancer (contract SOC 96-200742 05F02), 1998.

### Under-reporting of occupational diseases

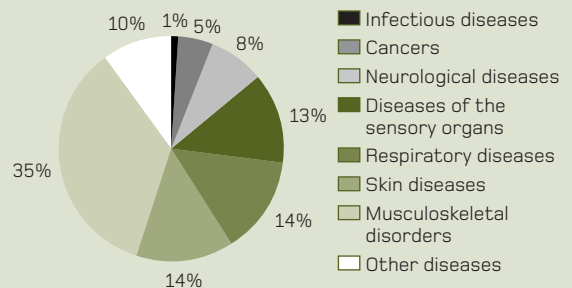
We should also remember that, throughout Europe, numerous cases of work-related disorders are not registered as such by the relevant insurance bodies. The main explanation for this state of affairs is the fact that the victims are uninformed about the presence of dangerous substances in the work-

### Occupational diseases recognised in Europe in 2001

As far as occupational diseases are concerned, recognition procedures and social security systems differ from one Member State to another. As part of the EODS (European Occupational Diseases Statistics) project, Eurostat gathered a series of European statistics on recognised cases of occupational diseases for the reference year 2001. What is interesting about this project is that it makes available for the first time harmonised, comparable and reliable data on instances of occupational diseases recognised in 12 Member States (Belgium, Denmark, Spain, Ireland, Italy, Luxembourg, the Netherlands, Austria, Portugal, Finland, Sweden and the United Kingdom). 31,945 new cases were recognised for all the diseases covered by all the national systems in 2001. By extrapolating these figures according to the working population ratio, the number of cases in the EU-15 can be estimated at 52,884. The incidence rate per 100,000 workers is higher among men (48) than women (22).

The three most common occupational diseases are musculoskeletal disorders (35%), skin diseases (14%) and respiratory diseases (14%). Next come diseases of the sensory organs, the main ones being noise-induced hearing loss (13%), neurological diseases (8%), cancers (5%), infectious diseases (1%) and other diseases (10%).

We also learn from the EODS study that up to 90% of cancers recognised as being work-related are due



to exposure to hazardous chemicals. The main one is asbestos (86%), but other chemical substances (4%) such as aromatic amines, chromium, hydrocarbons, dyestuffs, etc. are also involved.

Similarly on the basis of the EODS study data, we have estimated for the other categories of recognised occupational diseases with a possible link to chemicals the proportion of them which may indeed be related to exposure to chemical substances. As concerns disorders of the nervous system, we are dealing with toxic encephalopathies (2%) due mainly to solvents. For work-related disorders of the respiratory tract, we saw fit to distinguish (as can be done for cancers) between those related to exposure to chemical dust (asbestos, silica, etc. - 53%) and those related to other chemical agents (isocyanates, solvents, paints, etc. - 36%). Lastly, for skin diseases, we have used the 88% estimate made in a study commissioned by the



place and their potential effects, and fail to lodge a report<sup>6</sup>. The scale of the problem becomes manifest when the number of cases of occupational skin diseases and respiratory disorders recognised by the competent authorities is compared with the number of cases reported by workers when surveyed via a self-administered questionnaire (Table 2, p. 10).

According to the most recent Eurostat data, 200,000 Europeans consider that over the past 12 months they have suffered from a work-related skin disease and 600,000 from a work-related respiratory disease, whilst the numbers of cases recognised by insurance bodies are respectively 25 and 60 times lower. Therefore the real number of instances of occupational diseases in Europe related to exposure to hazardous chemical agents is undoubtedly underestimated.

<sup>6</sup> Survey on under-reporting of occupational diseases in Europe, Eurogip, December 2002.

**Table 1** Estimated percentage of occupational diseases related to exposure to chemical substances (%)

Type of occupational disease	Estimated % of cases related to exposure to chemicals	Proportion of all recognised occupational diseases	Estimated % of recognised occupational diseases related to exposure to chemicals
Cancers	4 - 90* %	5 %	0.2 - 4.5* %
Neurological disorders	2 %	8 %	0.2 %
Respiratory diseases	36 - 89* %	14 %	5 - 12.5* %
Skin diseases	88 %	14 %	12.3 %
<b>Total</b>			<b>~18 to 30* %</b>

\* including chemical dust

Source : Extrapolated from Eurostat EODS data, 2004

European Commission on the impact of REACH on occupational health (RPA).

By combining these data with those in the chart on page 8, we can estimate that approximately 30% of all the occupational diseases recognised every year in Europe are related to exposure to chemical substances (around 18% if chemical dust is excluded).

Even though they are not directly comparable, we would also recall the findings of the third survey on working conditions in Europe by the European Foundation in Dublin, which indicates that 23% of European workers claim to inhale fumes and vapour at work and 15% claim to handle dangerous substances for at least a quarter of their working time.

Sources :

- Occupational Diseases in Europe in 2001, *Statistics in Focus, Population and social conditions*, No. 15, Eurostat, 2004. See : <http://europa.eu.int/comm.eurostat> > Publications.
- *The impact of the new chemicals policy on health and the environment, Final Report*, RPA and BRE Environment, June 2003, prepared for the European Commission Environment Directorate-General. See : <http://www.rpaltd.co.uk/tools/tools-fullreports.htm>.
- PAOLI, P., MERLLIÉ, D., *Third survey on European working conditions 2000*, Dublin, European Foundation for the Improvement of Living and Working Conditions, 2001. See : <http://www.eurofound.eu.int/publications/files/EF0121EN.pdf>.

**Table 2** Comparison of the annual number of cases of occupational diseases recognised and reported by self-administered questionnaire in the Europe of 15

Type of occupational disease	Number of cases self-reported by questionnaire	Number of cases recognised *
Skin diseases	200,000	8,000
Respiratory tract disorders *	600,000	10,000

\* including cancers  
Source : *Work and health in the EU. A statistical portrait*, Eurostat, 2004

**A very worrying situation for consumers and the environment too**

Over the past few decades the thousands of chemicals used to manufacture numerous everyday consumer products have been marketed without much attention being paid to their potential impact on human health or the environment.

Many scientific publications have also shown that the incidence of certain cancers, allergies and disorders of the hormonal system is rising steadily, especially in children<sup>7</sup>. Of course, not all of these multi-factor diseases can be ascribed solely to contact with dangerous substances, but ever closer links between the development of some of these conditions and exposure to chemicals are now becoming well established<sup>8</sup>.

Some Swedish researchers have for example demonstrated that synthetic molecules such as PBDEs (pentabromodiphenylethers) can accumulate in the food chain, ending up in mothers' milk<sup>9</sup>. These molecules, which are still used in the manufacture of textiles, electronic appliances and polyurethane foam due to their fire-retardant properties, possess a structure and a toxicology similar to that of PCBs (polychlorobiphenyls) which were for a long time used in electrical equipment before being banned in the late 1970s, when it was discovered that they accumulated in the environment and were toxic for humans.

It would seem that everyone living in an industrialised country is contaminated by a variable cocktail of persistent and bioaccumulative chemicals (see Box, p. 11). Workers are consumers too, and those who are in contact with chemicals in their workplace combine occupational exposure with exposure to everyday consumer goods. Among the many other well-known examples of widely used chemical substances which can impair human health and the environment, we must mention asbestos, notoriously responsible for lung cancer and mesothelioma, benzene from fuel and cigarette smoke, which causes leukaemia, nickel in jewellery, which is the most common contact allergen, and lastly the insecticide DDT (dichlorodiphenyltrichloroethane), intensive use of which has led to reproductive disorders in birds. Even though such substances have either been totally banned or subjected to other restrictions, these measures were taken only once the damage had been done, since the harmful effects of these substances remained unknown until they had been used in large quantities.

Civil society and the authorities are concerned about this state of affairs. At the Johannesburg world summit in 2002, governments undertook to ensure that by 2020 chemical substances would be used and produced

<sup>7</sup> *Children's health and environment : a review of evidence*, WHO/EEA, 2002.

<sup>8</sup> *Strategy for a future Chemicals Policy*, White Paper, COM[2001] 88 final, European Commission, 27 February 2001.

<sup>9</sup> NORÉN, K., MIERONYTÉ, D., Contaminants in Swedish human milk. Decreasing levels of organochlorine and increasing levels of organobromine compounds, *Organohalogen Compounds*, 35 : 1-4, 1998.

### A cocktail of industrial chemicals in blood

Fourteen EU Ministers for the Environment and Health recently gave a blood sample at the request of the World Wide Fund for Nature (WWF). Analysis of the blood samples found traces of 103 chemical substances in their bodies. The findings revealed the presence of 55 chemical agents in total, i.e. an average of 37 substances per individual. The substances found in the Ministers' blood are used in fire-proofed sofas, non-stick frying pans, fat-resistant pizza boxes, plasticised PVC, perfumes and insecticides. Some have been banned for decades (DDT, PCBs), but others are still in use today (phthalates, flame retardants). Since the effects of these substances are largely unknown, the WWF acknowledges that it is extremely difficult to determine the potential health hazards of exposure to a cocktail of industrial chemicals in the concentrations detected by their study. They nevertheless believe that, as a precaution, the manufacture and use of chemical substances capable of accumulating in blood or mothers' milk should not be permitted.

See : WWF, Detox Campaign, *Bad Blood? A survey of chemicals in the blood of European Ministers*, October 2004. <http://www.panda.org/downloads/toxics/badbloodoctober2004.pdf>.

in ways that lead to the minimisation of significant adverse effects on human health and the environment<sup>10</sup>. In Europe, in addition to the reform of the legislation on chemicals (REACH), the Commission has proposed an integrated strategy (the SCALE initiative)<sup>11</sup> in respect of the environment and health, devoting particular attention to children and other vulnerable population groups. In May 2004, at the end of an international symposium held by UNESCO, the Paris Appeal<sup>12</sup> was issued : its aim is to alert society to the health hazards of chemical contamination.

<sup>10</sup> <http://www.johannesburg-summit.org>.

<sup>11</sup> A *European Environment and Health Strategy*, COM(2003) 338 final, Communication from the Commission, 11 June 2003.

<sup>12</sup> <http://appel.artac.info/appel.htm>.

## 2. Why is a reform needed ?

It has become abundantly clear that the current Community legislation on chemicals is not operating properly and is incapable of effectively safeguarding the health of workers, consumers and the environment. It is a regrettable and appalling fact that over 99% of the total volume of substances found on the market have not undergone any in-depth assessment of their risks to human health and the environment<sup>13</sup>, even though many of these chemicals are present in the workplace and in staple consumer goods (cleaning products, cosmetics, clothing, computers, etc.).

The first reason for this is that the current legislative system consisting of directives and regulations is a complex one, dating back over 20 years. It makes an arbitrary distinction between “existing” chemical substances<sup>14</sup> and “new” chemical substances<sup>15</sup>. The 100,000 or so substances which were on the market before 1981, known as “existing substances” may be used with virtually no safety testing whatsoever, while “new substances” (placed on the market since 1981) produced in quantities of at least 10 kg per year are subject to a battery of tests before they can be placed on the market. It is therefore easier (and cheaper) for industry to continue using untested or little-tested existing substances than to develop new ones. Thus the number of new substances placed on the market since 1981 and having undergone in-depth testing comes to just 3,700 or so.

What is more, under the current legislation, only manufacturers and importers are obliged to supply information about the chemicals they place on the market. No such obligation exists for other users situated downstream of them (formulators, for instance). Hence it is very difficult to obtain information about the use made of these substances and exposure levels downstream.

Another flaw in the current legislation is that responsibilities are allocated inappropriately. Indeed, for existing substances produced in very large volumes, it is up to the public authorities and not the companies manufacturing, importing or using them to carry out a risk assessment and, where necessary, to propose measures for reducing these risks. Even though the competent authorities in the various Member States share out this work, since 1993 only 141 chemicals in this category have been identified for risk assessment and possible recommendations for risk reduction.

<sup>13</sup> European Commission, White Paper, *op. cit.*

<sup>14</sup> Covered by Regulation (EEC) 793/93 of the Council on the evaluation and control of the risks of existing substances.

<sup>15</sup> Covered by Directive 67/548/EEC of the Council (and its amendments) on the classification, packaging and labelling of dangerous substances.

In the case of the most dangerous substances, the Member States may also agree to restrict the use or marketing of these chemicals. This system, initiated in 1976 by a Council directive<sup>16</sup>, is likewise very slow-acting and only a few dozen substances - or some of their uses - have so far been banned in Europe. It is in this context that the marketing and use of articles containing asbestos have been totally prohibited in Europe as from 2005. Other well-known restrictions are the total ban on the marketing of PCBs and the ban on phthalates in toys, mercury and lead in electronic appliances, etc.

<sup>16</sup> Directive 76/769/EEC of the Council on restrictions on the marketing and use of certain dangerous substances and preparations.

### 3. Content of the REACH proposal

#### A reform demanded by the chemical industry

Growing concern about the ineffectiveness of the current legislation in safeguarding health is not the only reason why the authorities were prompted to envisage a reform. Industry itself, greatly dissatisfied with the way in which the existing legislative system governing trade in chemical products is operating, called for it to be overhauled. The legislation in force is regarded by industry as too bureaucratic, too slow-acting and above all not conducive to innovation, which is crucial in such a highly competitive field as that of chemistry<sup>17</sup>.

In order to meet these demands, and following on from the White Paper on the Strategy for a Future Chemicals Policy published in 2001, the European Commission adopted on 29 October 2003 a draft regulation which would apply to the 30,000 chemicals produced or imported into the territory of the EU in quantities of more than one tonne per year. This draft legislation, known as REACH (**R**egistration, **E**valuation and **A**uthorisation of **C**hemicals)<sup>18</sup>, pursues two main aims :

- to ensure a high level of protection for human health and the environment;
- to guarantee that the internal market operates efficiently and enhance the competitiveness of the European chemical industry.

#### Registration

It will be mandatory for the 30,000 substances concerned to be registered with a future European Chemicals Agency if they are to be manufactured in, or imported into, the European Union. Registration will be in accordance with an 11 year timetable, beginning with volumes of more than 1,000 tonnes per year and CMR (carcinogenic, mutagenic, toxic for reproduction) substances (see Table 3). To this end, the manufacturer or importer of a chemical will be obliged to supply a registration dossier containing information about the identity, toxicological and ecotoxicological properties of the substance, to describe its possible uses, to supply a safety data sheet for all dangerous substances and, in certain cases, to carry out a chemical safety assessment<sup>19</sup>, and also to implement and recommend risk reduction measures.

<sup>17</sup> <http://www.chemicalspolicyreview.org/frameglobal.asp?redirecturl=whydo.html>.

<sup>18</sup> Text available at <http://www.europa.eu.int/comm/enterprise/chemicals/index.htm>.

<sup>19</sup> Only for substances manufactured or imported in quantities of more than 10 tonnes/year. The chemical safety assessment of a substance includes (*inter alia*) an assessment of its risks to human health and the environment.

*Manufacture  
and import prohibited  
without  
registration*

Downstream users will likewise be obliged to meet certain requirements concerning the chemical safety assessment, depending on whether or not they choose to keep confidential the use which they intend to make of the substance supplied to them. If they decide to inform the manufacturer of that use, the latter will have to carry out the chemical safety assessment; otherwise it will be the responsibility of downstream users.

The larger the annual volume of substances manufactured, the greater will be the amount of data to be supplied and the number of tests to be performed for registration purposes. New substances notified under Directive 67/548/EEC will be deemed to be already registered. Polymers, certain intermediates and products intended for research and development will be exempted from the requirement to register but these provisions may be reviewed once the reform has entered into force. Manufacturers will also be encouraged to form consortia and share the data they hold, so as to avoid unnecessary testing and reduce registration costs.

**Table 3**

Tonnage / year	1 - 10 t	10 - 100 t	100 - 1,000 t	> 1,000 t
Estimate of the number of chemical products	20,000	4,600	2,800	2,600
Registration deadline after entry into force of REACH	11 years	11 years	6 years	3 years*
Chemical safety assessment	No	Yes	Yes	Yes

\* Substances classified as CMRs manufactured or imported in quantities starting at one tonne per year will likewise have to be registered within the first three years.

### Evaluation

The evaluation procedure will enable the competent authorities in the Member State where the manufacturer or importer is established to examine some of their registration dossiers. This procedure will also enable them to demand additional information where necessary.

Provision is made for two types of evaluation : dossier evaluation and substance evaluation. The former will serve to check the compliance of registration dossiers and to prevent unnecessary animal testing. The latter will enable an authority to require the manufacturer or importer to obtain and submit more information in case of suspicion of a risk to human health or the environment. The evaluation procedure may lead authorities to the conclusion that action needs to be taken under the restriction or authorisation procedures in respect of certain substances.

In order to promote a consistent approach, the future Agency will develop guidance on prioritisation of substances for evaluation. It will be risk-based and will take into account the information available about hazards, production volumes and potential exposure. There is also a procedure for resolving any disagreements over which Member State evaluates which substance.

### Authorisation

The use of substances of very high concern (CMRs, PBTs, vPvBs<sup>20</sup>) will be subjected to authorisation on a case-by-case basis. In order to obtain an authorisation, the applicant will have to demonstrate that the risks related to the

<sup>20</sup> CMRs : carcinogenic, mutagenic, toxic for reproduction; PBTs : persistent, bioaccumulative and toxic; vPvBs : very persistent and very bioaccumulative, i.e. toxic substances which could accumulate irreversibly in the body and the environment.

*Evaluation serves to  
verify the information  
submitted by  
manufacturers or  
importers*

*An authorisation will be required for every use of substances of very high concern*

use of the substance concerned are “adequately controlled”. If that is not the case, authorisation may nonetheless be granted if it can be demonstrated that the risks are outweighed by socio-economic benefits and that the substances cannot be replaced by any suitable alternative substances or technologies. Authorisations will be time-limited and may affect roughly 1,400 substances.

Provision is also made for a system of restrictions, whereby the manufacture, use(s) and/or placing on the market of a dangerous substance may be prohibited or subjected to certain conditions if the European Commission deems the risks to human health or the environment to be “unacceptable”.



## 4. How REACH will alter the existing legislation

The European legislation on dangerous substances can be divided into two categories : one dealing with trade in these substances and the other concerning the protection of workers exposed to these substances.

The European directives laying down rules for the marketing of dangerous substances establish total harmonisation of national legislations (Article 95 EC Treaty), while those on the protection of workers' health and safety aim for minimum harmonisation of the different Member States' legislative provisions (Article 137 EC Treaty).

Consequently, in the former case, the Member States cannot in principle impose any further restrictions at national level, whereas in the latter they are fully entitled to impose national rules that are more stringent than the European rules if they see fit to do so<sup>21</sup>.

The entry into force of REACH will have significant effects on all these legislative provisions : on the first group because they will be amended or repealed for the purposes of adaptation to the REACH Regulation. As for the second group, which will continue to coexist with the first, the information resulting from implementation of the REACH system will improve the effectiveness of legislation governing the protection of workers.

- **Shifting the burden of proof**

The principal aspect of the reform lies in a transfer of the "burden of proof". Under the present system, the authorities are responsible for proving that an existing substance is dangerous before they can impose any restrictions. With REACH, industry itself will have to provide the necessary information about its products, prior to placing them on the market, in order that appropriate risk management measures can be taken.

- **A single legislative system for the marketing of chemicals**

REACH will abolish the distinction between "existing" and "new" substances and will establish a single legislative system for the marketing of chemical substances in Europe. The REACH Regulation will replace Regulation 793/93 on the evaluation and control of the risks of existing substances as well as Directive 76/769 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

<sup>21</sup> See for example the ban on the use of trichlorethylene imposed by Sweden on the company Toolex Alpha AB because of its inability to present a plan for the replacement of this substance by another one less hazardous to its workforce.

in an annex to the REACH regulation.

Other directives currently in force will coexist with REACH but will need to be amended to incorporate the provisions of the reform. All in all, forty or so directives will have to be repealed or amended in this way.

## Regulation 793/93

### Evaluation and control of the risks of existing substances

This legal text, generally known as the “Existing Substances Regulation”, was adopted by the Council in 1993 to complement the measures taken for “new substances” in Directive 67/548/EEC. “Existing substances” are defined as substances introduced onto the European market prior to September 1981. The number of “existing” substances is 100,195 : they are listed in the EINECS inventory (European INventory of Existing commercial Chemical Substances).

Regulation 793/93 initially covered only existing substances produced or imported in quantities starting at 1000 t/year (High Production Volume Chemicals, HPVCs) and subsequently those produced or imported at between 10 and 1000 t/year (Low Production Volume Chemicals, LPVCs). Risk evaluation and control is carried out in 3 major steps once the Commission has gathered the data supplied by manufacturers or importers :

1. **Establishment of priority lists** : the Commission, in conjunction with the Member States, draws up lists of priority substances requiring immediate attention because of their potential effects on humans or the environment.
2. **Risk assessment** : the Member States share out the priority substances and, for each substance for which they are the designated “rapporteur”, undertake an assessment of the risks to workers, consumers and the environment. The final risk assessment report arrives at one of the following three conclusions :
  - Further information is needed
  - No cause for concern
  - Cause for concern – risk reduction is required
3. **Risk reduction** : If the 3rd conclusion is reached, the Member States must agree on a risk reduction strategy which may go so far as to restrict the use or marketing of the worrying substance (see Directive 76/769/EEC).

Between 1993 and 2004, just 141 substances were given “priority” status and risk assessments have been completed for only twenty-seven of these.

→ Regulation 793/93 is to be repealed when REACH enters into force.

## **Directive 67/548/EEC**

### **Classification and labelling of dangerous substances**

The two main elements of the directive are :

1. Classification and labelling of dangerous chemical substances according to their intrinsic properties. Fifteen risk categories have been defined : “explosive”, “highly toxic”, “carcinogenic”, “hazardous to the environment”, etc.
2. Notification of “new” chemicals before they are placed on the market. Since September 1981, importers and manufacturers of chemicals have been obliged to test the substances they wish to place on the market (starting at 10 kg/year) and to supply the results to the competent authorities of the Member States in which they run their business. Only 3,700 or so “new” substances have been notified in 23 years (three quarters of them for volumes of less than 10 t/year). These appear on the cumulative ELINCS list (European List of Notified Chemical Substances).

Annex 1 of this directive also contains a list of substances classified as dangerous, currently comprising around 7,000 substances (existing and new). This directive is regularly updated to take account of scientific and technical progress in the field of dangerous substances. It has so far been amended 9 times and adapted to technical progress on 29 occasions.

→ The next amendment will probably serve to adapt this directive to the future REACH Regulation.

## **Directive 1999/45/EC**

### **Classification and labelling of dangerous preparations**

This directive is a recast of Directive 88/379/EEC. It lays down harmonised rules for the classification, packaging and labelling of dangerous preparations (mixtures of substances at least one of which is classified as dangerous). It uses the same risk categories, the same classification criteria, the same labelling symbols, the same testing methods and the same packaging rules as Directive 67/548/EEC but there is no requirement to notify new preparations.

→ This directive will also be amended to align it with the REACH legislation.

**Directive 76/769/EEC****Restrictions on the marketing and use of certain dangerous substances and preparations**

This directive is known as the "Restrictions" directive. The substances concerned are set out in its Annex 1. The restrictions generally take the form of regulated use, i.e. confining the use of the substance to certain applications. In a minority of cases, they take the form of a ban with an exemption (e.g. asbestos) or even a total ban on placing on the market, as in the case of PCBs.

The directive is regularly updated to add new substances to the annex. It has so far been amended 26 times and adapted to technical progress 13 times. It lays down restrictions for 47 substances or groups of substances, representing more than 900 individual substances in total, the majority of them carcinogens.

- This directive will be repealed when the REACH Regulation, along with its authorisations and restrictions, enters into force. The existing restrictions will remain in force and will be included in Annex XVI of the REACH Regulation.

**Directive 91/155/EEC****Safety Data Sheets for dangerous substances and preparations**

This directive was amended for the second time by Directive 2001/58/EC. It defines and lays down the detailed arrangements for the system of specific information relating to dangerous substances and preparations. The person responsible for placing a dangerous substance or preparation on the market, whether the manufacturer, importer or distributor, must supply the recipient who is an industrial user of it with a safety data sheet.

These standard-format data sheets (16 headings) provide details of the information on the label (properties of the substance, health and environmental hazards, risks related to its physical and chemical properties) and add information concerning handling, storage, disposal and transport. Safety data sheets also give advice on worker protection, fire-fighting measures, accidental release measures and first-aid measures where appropriate. They are therefore supposed to enable industrial users to take the necessary measures in respect of health and safety protection in the workplace and environmental protection.

- The provisions of Directive 2001/58/EC will be incorporated into the REACH Regulation. Safety data sheets will therefore continue to play the same role as today, but their quality will be improved thanks to the additional information deriving from the registration requirements. Indeed, when a Chemical Safety Assessment is required (see footnote 19), relevant information about ways of minimising human and environmental exposure must be annexed to the safety data sheet for all identified uses.

- Gradually bridging the knowledge gap according to a set timetable

The widespread ignorance about the toxicological and ecotoxicological properties of the 100,000 or so substances currently on the European market ought to be reduced thanks to the information which will be required for the registration of the 30,000 substances manufactured or imported every year in quantities of at least 1 tonne per year. This information will be gathered in accordance with a set timetable spanning 11 years and beginning with substances produced in large volumes and CMRs.

- Downstream users are included in the system

REACH will affect numerous branches of industry. This system will in fact generate obligations not only for manufacturers (chemical industry) but also for the many downstream users of chemical substances (the building, woodworking, automobile, textile and computer sectors, etc.). These sectors will need to communicate effectively with their suppliers so as to receive all necessary information for their “safe” use, in the form of the safety data sheets which must accompany dangerous products placed on the market.

- Transparency

REACH will introduce a degree of transparency, since all non-confidential information about registered substances will be publicly available. This will inevitably enhance the image of the chemical industry.

- Choice of legal instrument

The draft REACH reform is a regulation and not a European directive, meaning that it will be directly applicable in all 25 Member States as soon as it enters into force.

## 5. How workers stand to benefit from REACH

### Ineffectiveness of the existing legislation in protecting workers exposed to dangerous substances

Alongside the legislation establishing the rules on the marketing of chemical substances, there is European legislation designed to protect workers exposed to hazardous chemicals in the workplace. This legislation mainly consists of two directives : one dating from 1990 on carcinogens, the other dating from 1998 on chemical agents. These directives compel employers to carry out a risk assessment and take the necessary prevention and protection measures. A hierarchical set of obligations is clearly set out : elimination of the hazardous substances, substitution with less dangerous substances, reduction of exposure levels, compliance with exposure limit values, etc. (see Boxes, p. 25-26).

However, implementation of these legal texts in the workplace remains problematical and most of the time they are scarcely or only partially enforced, especially in small and medium-sized enterprises<sup>22</sup>.

### Importance of market rules for health and safety at work

One of the main factors explaining this situation is that the effectiveness of legislation on the protection of workers exposed to chemicals is heavily dependent on the legislation governing their trade and, more specifically, the data which this legislation is supposed to generate on the intrinsic properties and hazards of chemical substances.

*By providing missing information about the properties of chemical products, REACH should improve the labelling of dangerous substances*

- A lack of information about chemical hazards

The packaging of all dangerous chemical products placed on the EU market must bear a label, harmonised at European level, giving information about the risks inherent in the substance. A standard set of pictograms is used to indicate the principal risks recognised by the directives (toxic, harmful, corrosive, irritant, etc.); “R” risk phrases indicate the risks (e.g. R45 means “may cause cancer”) and “S” phrases give advice on safe use (e.g. S24 means “avoid contact with skin”). These labels are often the only source of information available in the workplace to alert users to the risks they run. As has already been mentioned, the current state of knowledge about the properties of chemical substances and in particular their long-term effects on health is very limited. A recent study has moreover demonstrated that the labelling of

<sup>22</sup> VOGEL, L., *The potential of REACH for improving enforcement of the rules on chemical risk prevention at the workplace*, TUTB, 2004. See : [http://tutb.etuc.org/uk/dossiers/files/Reach-LV\\_EN.pdf](http://tutb.etuc.org/uk/dossiers/files/Reach-LV_EN.pdf).

one third of the preparations currently on the market does not comply with the regulations<sup>23</sup>.

The direct consequence of this lack of data is that many hazardous chemicals are not classified as such and are therefore marketed without appropriate labels.

<sup>23</sup> ECLIPS Project (European Classification and Labelling Inspections of Preparations, including Safety Data Sheets), final report, June 2004.

### **The Ardystil affair : an illustration of the tragic consequences of inadequate safety data sheets**

Six workers (five women and one man) at the Spanish company Ardystil, specialising in fabric printing and dyeing, contracted a mysterious, devastating lung disease and died between February and November 1992. More than 80 other workers employed by Ardystil or by other firms in the aerographic textile printing sector likewise succumbed to serious pulmonary disease. The labour inspectorate then decided to close down all the companies in this sector and, at the close of a meeting of Spanish and foreign experts, the health department issued a press release declaring “Ardystil syndrome” to be a new occupational disease, unknown in the specialist literature. Following a lengthy inquiry and a lawsuit, it finally became clear what had happened.

Ardystil was one of the companies competing for design printing work subcontracted by the textile industry : pieces of plain fabric were taken in, designs were printed on them, and the fabrics were then returned to the manufacturing companies for placing on the market.

The product used for the fabric printing was Acramin F, created and marketed by Bayer for roller application. The inquiry revealed that the health disorders began to appear when the Acramin F supplied by Bayer in powder form was replaced by Acramin F in liquid form, which enabled Ardystil to use it by means of spray-printing and caused the workforce to be exposed and poisoned through inhalation. The safety data sheet supplied by Bayer indicates that Acramin F is considered as a non-irritant for skin and eyes; it says nothing about respiratory toxicity or about the associated risks.

When the case subsequently came to court, Bayer repeatedly declared that its product was designed

for roller application and not for spraying. In June 2003, more than eleven years after the events, the managing director of Ardystil as well as the directors of six other SMEs and one labour inspector were finally sentenced to a variety of prison terms on grounds of negligence. Whilst it is true that the working conditions in these firms were particularly insalubrious, the documentation supplied by the product manufacturer did not allude to the possibility of aerographic use. Neither did it state that such usage – which could surely have been thought likely – was especially hazardous.

This raises an important question of principle. Can tests, commercial documentation and safety data sheets be produced on the basis of what the manufacturer describes as the normal conditions for use of a product, or must they cover all reasonably foreseeable uses?

The REACH system ought to clarify this point, since downstream users must check that the safety data sheet accompanying the substance supplied really does cover the use they intend to make of it. If that is not the case, the supplier can be informed of this use so as to make it an “identified use” : the supplier is then obliged to take it into account when drawing up the safety data sheet, which must contain exposure scenarios corresponding to this use.

A downstream user will also be able to opt to keep his intended use confidential. In this case he himself will have to carry out a chemical safety assessment and devise exposure scenarios for his own use.

By requiring better communication between users and suppliers, the REACH system should in future help to avoid tragedies such as the Ardystil affair.

*REACH should improve data transmission and communication between manufacturers and users*

- Poor transmission of data

The legislation (Directive 91/155/EEC) also stipulates that safety data sheets must accompany all dangerous substances or preparations and complement the information provided by industrial users (see Box, p. 20). These data sheets elaborate on the information given on the label (properties of the substance, hazards to health and the environment, risks linked to its physical and chemical properties) and add extra information concerning handling, storage, transport and disposal. They also contain advice on worker protection, fire-fighting measures, measures to be taken in the case of accidental release and first-aid measures where appropriate.

Safety data sheets are a vital means of enabling employers to meet their obligations in terms of protecting workers exposed to dangerous substances, yet the information provided is not always reliable or exhaustive. A survey conducted across various European countries on the usefulness of safety data sheets to SMEs concluded that their content is lacking in respect of product composition and protection measures during use. These shortcomings can lead to disastrous situations such as the deaths of 6 workers in the Spanish textile industry (see Box : the Ardystil affair, p. 23). Furthermore, the survey revealed that many SMEs are not even aware that these data sheets exist. More recently, these conclusions were confirmed by the ECLIPS project which demonstrated that over 40% of safety data sheets are incorrectly filled in<sup>24</sup>. Thus not only are the data themselves defective but so is their transmission along the production chain.

Without these data, however, employers are unable to conduct a proper risk assessment or to implement the control and prevention measures laid down in the legislation on worker protection.

- Insufficient enforcement of the substitution principle

*REACH should help to enforce the substitution principle*

The 1990 directive on carcinogens stipulates that employers must replace these substances in the workplace with less dangerous products. This obligation exists whenever it is technically possible to do so. The existing legislation does little to promote the search for an alternative solution. By encouraging the replacement of dangerous substances thanks to authorisation and restriction procedures, REACH should help to enforce the substitution principle.

<sup>24</sup> ECLIPS Project, *op. cit.*



### Directive 2004/37/EC

#### Protection of workers from the risks related to exposure to carcinogens or mutagens at work

This directive is the codified version of Directive 90/394/EEC (the “carcinogens” directive), which has now been repealed along with all its successive amendments. A hierarchical set of obligations is laid down for employers as concerns the reduction and substitution of category 1 and 2 carcinogens and mutagens as well as the obligation to inform and train the workforce.

The first of these measures is the obligation to replace the carcinogen or mutagen with a substance which is not dangerous or is less so. Should such substitution prove technically impossible, the employer must ensure that the production or use of the carcinogen or mutagen takes place in a closed system. If this precaution cannot be taken, the employer must ensure that the workers’ level of exposure is reduced to a level as low as is technically possible.

The directive on carcinogens or mutagens also makes provision for the introduction, wherever possible, of Occupational Exposure Limit Values (OELVs). Whereas OELVs exist for a number of carcinogens in several countries’ national legislation, the process currently used to establish them at European level is so slow that limit values have been set for only 3 substances in this context (benzene, vinyl chloride monomer and hardwood dust).

→ This directive will coexist with the REACH Regulation. There is talk of extending its provisions on carcinogens and mutagens in the near future to substances which are toxic for human reproduction.

#### Other measures are also needed to make the legislation on worker protection more effective

Although REACH has the potential to make a positive and lasting contribution to the health and safety of workers exposed to chemicals, other measures will be needed to improve and complete the implementation of the legislation to protect workers in various branches of industry.

- Improving worker representation

The study carried out by the ETUC and TUTB on a sustainable system for worker participation and representation in SMEs<sup>25</sup> shows how necessary it is to enhance collective representation in such firms. Worker representatives have an essential role to play in bringing about a change of practice and culture in small businesses in order to better safeguard the health and safety of workers exposed to dangerous substances.

- Intensifying the social dialogue

A constructive, ongoing social dialogue between the social partners at European and national levels is one of the key prerequisites for improving the implementation of the existing legislation on worker protection.

This dialogue must however be conducted in such a way as to guarantee broad-based participation by all relevant social groups and satisfactory democratic supervision.

<sup>25</sup> WALTERS, D., *Working safely in small enterprises in Europe. Towards a sustainable system for worker participation and representation*, European Trade Union Confederation, Brussels, 2002.

### Directive 98/24/EC

#### Protection of workers from the risks related to chemical agents at work

Better known as the “chemical agents” directive, this directive covers all chemical substances and preparations manufactured or used in the workplace, whatever their volume or their classification. It lays down various obligations for employers :

1. Ascertaining whether or not hazardous chemical agents\* are present in the workplace.
2. If so, assessing the associated risks.
3. If risks do exist, taking measures to prevent and reduce these risks. Such measures include, in order of priority :
  - Replacing the hazardous chemical agent
  - Avoiding or minimising the release of the hazardous chemical agent
  - Applying collective protection measures at the source of the risk (e.g. ventilation)
  - Applying individual protection measures (e.g. masks, gloves, goggles)
4. Monitoring the workers’ health.
5. Complying with the existing occupational exposure limit values.
6. Regularly assessing the effectiveness of the risk reduction measures taken so as to keep them up to date.

In addition to the above points, the employer is also obliged to provide information and training for the workforce.

The production, manufacture or use at work of certain chemical agents may be prohibited if they represent a health hazard to workers. This is currently the case for four substances listed in Annex 3 of the directive.

→ Directive 98/24 will coexist with the REACH Regulation, which should make it considerably more effective. Indeed, the information generated by the REACH system should help employers to detect the presence of hazardous chemical agents in the workplace - a crucial first step without which all the other obligations simply could not be met.

NB : the European legislation on the protection of workers does not apply to domestic staff or the self-employed.

\* The definition of a hazardous chemical agent is not confined to substances or preparations classified as dangerous in accordance with the criteria of Directives 67/548/EEC and 1999/45/EC but also includes any chemical agent which may represent a risk to the safety and health of workers because of its physico-chemical, chemical or toxicological properties.

- Encouraging initiatives that are complementary to the legislation on worker protection

Voluntary initiatives such as the “responsible care” programme, which seek to improve the performance of the chemical industry in the fields of safety at work and the environment, should be encouraged. By identifying and disseminating sound management practice through the publication of codes and guidance, as well as by compelling industry to comply

with and enforce them, such initiatives can undoubtedly contribute to safeguarding human health and the environment.

The latest report on the implementation of this programme in the European countries<sup>26</sup> shows that some progress has been made in respect of the environment (a substantial reduction in pollutant emissions in air and water over a 5-year period).

Nevertheless, the meagre results achieved in terms of accidents at work and occupational diseases demonstrate that these systems and initiatives are not in themselves enough to guarantee a sufficient degree of safety on the shop-floor. Such voluntary initiatives and agreements must, therefore, be regarded as a complement and not an alternative to legislation.

<sup>26</sup> *Responsible Care 2002, Status Report : Europe*, CEFIC, June 2003. See : <http://www.cefic.be/Files/Publications/RCreport2003.pdf>.

## 6. What is the current state of play on REACH?

Following intense lobbying of the European Commission by industry, the draft REACH regulation finally adopted by the Commissioners in late October 2003 is a very watered-down version of the initial text published for the public consultation procedure in May 2003 : polymers have been excluded from the scope of the reform, the amount of information to be supplied has been drastically revised downwards (companies will now be required to supply Chemical Safety Reports for only a third of the 30,000 substances initially foreseen) and the authorisation procedures for the most dangerous substances have been made less rigorous.

The proposal for a regulation was forwarded to the European Parliament and the Council, which must agree on the final version in a co-decision procedure.

A power struggle took place within the European Parliament between the Environment Committee and the Industry Committee, each of which wanted responsibility for examining this dossier. As a result, the first reading of the text was not completed before the end of the previous legislature despite the tabling of a report and proposed amendments in December 2003 by the Italian Socialist MEP Guido Sacconi who was appointed rapporteur by the Environment Committee.

Once a new Parliament incorporating MEPs from the 10 new Member States was formed in the wake of the June 2004 European elections, the Environment Committee was put in charge of this dossier and Guido Sacconi MEP, having been re-elected, was endorsed as principal rapporteur for the Parliament. He will have to work in close cooperation with Ms Lena Ek (Sweden, ALDE) for the Industry Committee and Mr Hartmut Nassauer (Germany, EPP-DE) for the Internal Market Committee. Six other Parliamentary committees, less directly involved, will nevertheless be able to express an opinion : Employment and Social Affairs, Economic and Monetary Affairs, Legal Affairs, Budgets, Women's Rights and International Trade. The first reading is scheduled for autumn 2005.

As far as the Council is concerned, the Heads of State and Government allocated responsibility for REACH to the Competitiveness Council comprising the national ministers of industry and trade, rather than to their colleagues in the Environment Council. An ad hoc working group on REACH, consisting of representatives from the different ministries

(industry/trade and environment) was nonetheless established in November 2003 under the Italian presidency to assist the Council in drawing up a common position on the REACH proposal.

At the various meetings of this working group held under the Irish presidency during the first six months of 2004, a certain number of textual amendments were proposed by the Member States : the OSOR (one substance, one registration) system, the reintroduction of the “duty of care”, additional powers for the Chemicals Agency, a reinforcement of the substitution principle, etc.

Discussion has continued in this working group since July 2004 under the Netherlands presidency, which has set itself the task of scrutinising the first three chapters of the regulation - devoted to registration and data sharing - with a view to putting forward specific proposed amendments by the end of the year. The Netherlands presidency also held a workshop in late October 2004 to analyse, and draw conclusions from, the findings of the various impact studies available on REACH<sup>27</sup>.

Turning to the Commission, DG Environment and DG Enterprise are handling the dossier jointly and are currently working on the practical implementation of REACH (based on the October 2003 text). The main elements of this interim strategy are developing new software to manage the REACH system, drawing up guidelines to help Member States and industry meet their obligations under REACH, launching strategic partnerships to test certain aspects of the reform and establishing the European Chemicals Agency in Helsinki.

The Commission, by agreement with UNICE (Union of Industrial and Employers' Confederations of Europe) and CEFIC (European Chemical Industry Council), has also created a working group to supervise three additional studies to assess the impact of REACH. The two first studies, financed and carried out by industry, assess the impact of REACH on trade along the entire length of the supply chain, and on innovation. The third study, financed and carried out by the Commission Joint Research Centre (JRC), concerns the impact in the new Member States. The ETUC and some environmental NGOs are members of this working group. The results of these microeconomic studies are awaited in early 2005. Other impact studies, begun in 2004, are likewise expected to present their findings during the course of 2005 : an additional Commission study on the environmental benefits of REACH and one by the ETUC on the benefits of REACH for workers' health.

The Commission estimates that the co-decision procedure between Parliament and Council may be concluded during 2006 and the REACH system may enter into force in 2007.

<sup>27</sup> Overview of 36 studies on the impact of the new EU chemicals policy (REACH) on society and business. See : <http://tutb.etuc.org/uk/dossiers/files/EU2004REACH.pdf>.

## Costs and benefits of REACH : what is at stake

According to an economic impact assessment conducted by the European Commission<sup>a</sup> :

- The direct costs to the European chemical industry, related mainly to the registration and testing of substances, are estimated at € 2.3 billion over a period of 11 years (between € 2.8 and 5.2 billion in total over 15 years including the indirect costs borne by downstream sectors).
- The health benefits are estimated at € 50 billion over a 30 year period, above all due to the fact that 4,500 lives will be saved every year. This figure corresponds to the number of lethal work-related cancers that will be obviated thanks to a better knowledge of the properties and effects of chemical substances.
- Environmental benefits are also anticipated but have not yet been calculated by the Commission.

The chemical industry, which has carried out its own impact studies, predicts overall costs which are between 30 and 100 times higher and foresees the loss of hundreds of thousands of jobs as well as a substantial fall in GDP in Germany and France<sup>b-c</sup>.

In the opinion of the Commission<sup>d</sup> and independent economic experts<sup>e</sup>, these unrealistic estimates as to the macroeconomic effects of REACH should be given little credence. The methodologies used in these

assessments are believed to lack transparency and the extrapolations made are based on errors and exaggerations.

Another study assessing the economic impact of REACH, commissioned by the Nordic Council of Ministers, confirms the order of magnitude of the direct and indirect costs estimated by the European Commission<sup>f</sup>.

Finally, it is interesting to note that the sum of € 2.3 billion represents approximately 0.04% of the annual turnover of the European chemical industry ( € 556 billion for the EU-25 in 2003).

a. <http://www.europa.eu.int/comm/enterprise/reach/eia.htm>.

b. ARTHUR, D., *Little GmBH, Economic effects of the EU Substances Policy*, 2003.

c. *Study of the impact of the Future Chemicals Policy*, Mercer Management Consulting, 2003.

d. DG ENTR presentation at the workshop "Impacts of Chemicals Policy – How to measure it?", Laulasmaa, Estonia, 11-12 November 2004.

e. *Methodological Problems of assessing the Economic Impacts of EU Chemicals Policy*, UBA, 2003.

f. ACKERMAN, F., MASSEY, R., *The true costs of REACH*, TemaNord 2004:557, Nordic Council of Ministers, Copenhagen, 2004. See : <http://www.norden.org/pub/miljo/miljo/sk/TN2004557.pdf>.

## 7. Conclusions

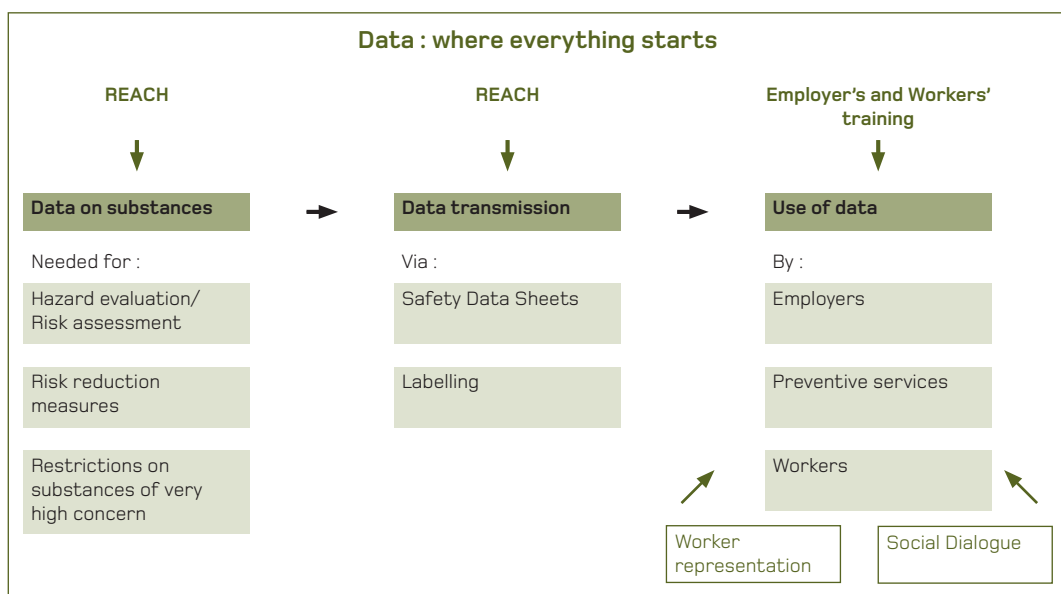
REACH is an opportunity to improve the effectiveness of the existing European legislation for the protection of workers exposed to chemicals and, consequently, to reduce the risk of occupational diseases related to dangerous substances in future.

The data generated by REACH should in fact foster a better knowledge of the properties of chemical substances, their effects on human health and ways of reducing and minimising risk during their use.

REACH should also greatly improve the transmission of such data along the entire length of the production chain, thanks to better quality labelling and safety data sheets.

In addition, the authorisation and restriction procedures provided for in REACH should promote the substitution of the most harmful substances by less hazardous ones.

REACH will therefore enhance the European directives on worker protection in various ways, and will promote their implementation by employers in the workplace.



Of course, the REACH reform will not be sufficient in itself to solve all the problems of occupational diseases related to exposure to chemicals. Even when data exist and are properly communicated, they still have to be put to effective use by recipients in the workplace.

For this reason, other measures will likewise be required in order to improve the effectiveness of the legislation on worker protection : stepping up their representation in the various branches of industry, intensifying the social dialogue at national and European level, providing training for workers and employers about chemical risks, and redoubling checks on compliance with the legislation in the workplace, etc.

REACH is therefore just one step towards improving the health of workers exposed to chemicals, but it is undoubtedly a crucial step and definitely one not to be missed.



## European trade unions call for a more ambitious European policy on chemicals

### **ETUC DECLARATION on REACH, the proposed reform of EU policy on chemicals, 17–18 March 2004**

The draft Regulation on REACH (Registration, Evaluation and Authorisation of Chemicals) applies to the 30,000 chemical substances produced or imported into the European Union in quantities exceeding 1 tonne per annum. By adopting it on 29 October 2003, the European Commission pursued two main objectives, the first being to achieve a high level of protection for human health and the environment, the second being to promote the efficient functioning of the single market and enhance the competitiveness of the European chemical industry.

The European Trade Union Confederation is of the opinion that the REACH proposal constitutes a significant contribution to sustainable development in keeping with the commitments made by the EU and its Member States in Lisbon and Gothenburg.

The planned reform is important for several reasons. Firstly, concerning a Regulation rather than a Directive, it will apply directly in the 25 Member States as soon as it enters into force. REACH will replace around 40 existing directives and affect a very large number of different sectors. The system adopted will not only impose obligations on manufacturers (in the chemical industry), but also on numerous users of chemicals (e.g. in the building trade, woodworking industry, automotive sector, textiles, agriculture, the provision of services in the environmental and health sectors, the computer sector...)

REACH should also have considerable impact on the existing legislation designed to protect workers exposed to hazardous substances in the various sectors concerned, namely by :

- providing missing information on their properties;
- making chemical safety data publicly available on a right-to-know basis;
- enforcing the efficient distribution of information to downstream users and their personnel in a bid to counteract the risks of occupational diseases;
- encouraging the substitution of the most harmful substances by less hazardous substances, via restrictive and authorisation procedures, with a view to minimising risks.

With a view to genuinely improving the health protection of workers exposed to chemical products, the ETUC demands that particular attention should be paid to ensuring that the obligations laid down in the REACH system are consistent with those of the occupational safety and health directives.

REACH fits in with the approach set out in the Single European Act aimed at expressly linking the development of the internal market with respect for workers' rights and their protection in health and safety terms. ETUC believes that downstream users, like manufacturers and importers of chemical substances, must be responsible for all safety-related aspects of their products for that part of the life cycle in which they are involved, including recycling and disposal.

The 30,000 substances concerned will have to be registered with a future European Chemicals Agency. In this framework, the producers will henceforth have to supply the appropriate information required to ensure the safe use of their products before those products can be marketed within the European Union. ETUC welcomes this adoption of the principle of shifting the burden of proof, and strongly supports it.

ETUC calls upon all the economic actors to recognise the principles of registration and duty of care as general principles. ETUC also believes that the inclusion of other worrying substances should be facilitated in the authorisation procedure.

ETUC demands that workers' representatives be made members of the future European Chemicals Agency on a tripartite basis because it believes that the involvement and initiatives of employers and unions in the bid to securing better health and safety standards is a key precondition for the success of the Lisbon Strategy. Greater familiarity with good practices is essential in this connection. ETUC stresses that ongoing, constructive social dialogue between the social partners at both European and national level is an essential prerequisite for improving the implementation of existing legislation on workers' protection and training.

ETUC also notes that REACH should foster innovation. This is vital for the European economy as a whole and for the chemical industry in particular. It must enhance its capacity to come up with modern solutions for its future by developing criteria that embody respect for the environment and social responsibility.

To meet the requirements set out in Johannesburg in 2002, the European Union must take steps to ensure that the principles of REACH are recognised worldwide, thereby ensuring fair conditions of global competition.

There is a pressing need at European level to diagnose the requirements that this imposes in terms of defining and financing public and private sector R&D. Equally, smaller and medium-sized companies (SMEs) in particular need to gain a finer appreciation of the specific impact on employment of the implementation of the REACH Regulation, failing their adoption of appropriate preventive or stopgap measures. These measures ought to go hand in hand with a sharing of the costs, risks and financing schemes between producers and users, and especially between the major chemical groups and SMEs and SMIs. This can be done

in particular by facilitating the application by SMEs and SMIs of the rules set out by the REACH system via the use of clear and simple procedures which enable them to cut their costs.

The ETUC wishes to make a full contribution to the debate on REACH and has set up an internal working group whose purpose is to reflect in depth on certain aspects of the proposed draft reform with a view to improving its content. The following elements have been singled out :

### **1. Duty of care**

Manufacturers and importers must be made responsible for documenting and communicating all relevant information about the safety of their products to downstream users and consumers by whatever means are appropriate.

A general principle of this type defining the responsibility of manufacturers and importers should be reintroduced into the REACH system for all chemical substances manufactured or imported.

### **2. Registration**

A Chemical Safety Report must be required in order for substances subject to registration and preparations to be handled safely while being manufactured, imported or used along the entire production chain.

This is particularly important for substances classified as hazardous since their safety data sheet will be complemented by relevant information about ways of controlling human and environmental exposure for all identified uses.

For substances produced in quantities of between 1 and 10 tonnes per annum, more basic information should be required, such as acute toxicity and biodegradability tests, in order to improve on the classification and risk assessment contained in the current legislation.

### **3. Evaluation**

Steps should be taken to discourage the submission of poor quality registration dossiers so as to safeguard the quality of information supplied by manufacturers or importers. The Member States' authorities should be required to check the compliance of a minimum number of dossiers selected at random.

### **4. Authorisation**

The aim of the authorisation procedure should be to encourage the substitution of the most hazardous chemical substances, as provided for in the European legislation on carcinogens (Directive 2004/37/EC).

An authorisation should therefore be granted only if it can be demonstrated that no suitable alternative substances exist, the socio-economic advantages outweigh the risks to human health and the environment, and the risks from the use of the substance are adequately controlled. Authorisations should be time-limited so as to encourage substitution plans.

The authorisation procedure should also be extended to other extremely hazardous chemicals which have serious or irreversible effects.

### **5. Links between REACH and legislation governing worker protection**

Particular attention should be paid to the compatibility of the obligations envisaged under the REACH system with those laid down in the directives on health and safety at work.

The social partners should engage dialogue on this subject. It could take place in the context of the Luxembourg-based Tripartite Committee on health and safety at work. The outcome of the London seminar<sup>a</sup> would be a good point of departure. The social sectoral dialogue should likewise address this issue.

In order to avoid contradictions and to increase the synergy between these two sets of legislation, workers' representatives should be consulted about the drawing up of guidelines aimed at helping industry to comply with the REACH legislation<sup>b</sup>.

### **6. Downstream users and SMEs**

Downstream users and SMEs should be assisted by their representatives in existing national industry associations or European federations.

### **7. Impact on employment, health and the environment**

The costs and benefits of REACH should be looked at from three perspectives - social, environmental

and economic - so as to assess the effectiveness of the new system and its impact on employment and health.

There is clearly a need for a better understanding of the potential effects (positive and negative) that REACH could have on employment in the various sectors concerned throughout the period of its implementation.

This has led the ETUC to take the following initiatives :

- Stepping up cooperation with its European industry federations, especially in terms of assessing the impact of REACH.
- The ETUC is actively involved in the working group formed by the Commission and UNICE/CEFIC which is carrying out a study assessing the impact of REACH on trade along the entire length of the supply chain, on innovation and in the new Member States.
- The ETUC has also launched a first study aimed at assessing the impact of REACH on occupational diseases of the skin and respiratory system.

- The ETUC has also launched a second study whose aims are :

1. to identify and suggest action which could facilitate implementation of REACH, particularly in SMEs and for downstream users;
2. to analyse other European policies which could affect the attainment of the goals of the REACH reform (e.g. research, training, etc.) and to propose long- or medium-term reorientations of these policies so as to help REACH achieve its goals.

The results of these studies and their analysis by the internal ETUC working group will be presented at the **REACH Conference to be held by the ETUC on 11 and 12 March 2005**, at which the European trade unions expect to make a constructive contribution to the debate.

- a. Final report of the seminar "Relation between Chemicals Legislation and Worker Protection Legislation" organised by the UK, German, Netherlands and Swedish governments on 14-15 June 2004. See : <http://tutb.etuc.org> > Main topics > Chemicals.
- b. REACH Implementation Project RIP 3.2.