Improving REACH, the future European chemicals policy

Exposure to dangerous substances: a deeply disturbing situation

Thousands of chemicals have been developed and put on the market in the last fifty years. They are used in many consumer goods, and have been marketed with little regard for their potential impacts on human health or the environment.

There is also a steadily rising incidence of cancers, allergies, and hormonal system disorders, especially in children¹. While contact with dangerous substances can obviously not be blamed for all these multi-factorial diseases, increasingly close links between the development of some of these conditions and exposure to chemicals are now well established². Swedish research, for instance, has shown that compounds like PBDEs (polybrominated diphenyl ethers) can accumulate in the food chain, ending up in breast milk³. These compounds, which are used in the manufacture of textiles, electronic equipment and polyurethane foam for their fire-retardant properties, have a structure and toxicology akin to that of PCBs (polychlorobiphenyls) which were long used in electrical equipment before being banned in the late 1970s, after the discovery of their accumulation in the environment and toxicity to humans.

It is now clear that current chemicals legislation is not working, and unable to give proper protection to human and environmental health. The sad fact is that over 99% of the total volume of chemicals on the market has undergone no comprehensive human and environmental health risk assessment⁴, despite many being present in consumer goods (cleaning products, cosmetics, clothing, computers, etc.).

The situation is just as worrying for the millions of workers across Europe who are exposed to chemicals not just as consumers, but also because they are engaged in manufacturing them (chemical industry workers) or as users (workers in downstream sectors, like building, textiles, farming, motor manufacture, personal care, etc.).

A 1998 survey by the Finnish Institute for Occupational Health and Safety found that some 32 million workers in the European Union - nearly a quarter of the labour force - are exposed to carcinogens⁵, while in another study done by the Dublin-based European Foundation, 16% of workers in Europe reported handling dangerous substances, and 22% were exposed to fumes and vapours for at least a quarter of their working time⁶. From the Eurostat EODS⁷ survey findings for reference year 2001, the

TUTB estimates that between 18 and 30% of all cases of occupational diseases recognised in Europe are related to exposure to chemicals⁸. Dangerous substances are clearly therefore to blame for a very large proportion of the occupational diseases that affect some 7 million Europeans⁹.

Why is current chemicals legislation not working?

The first reason is that the current Community legislative system, dating back over 20 years, makes an arbitrary distinction between "existing" and "new" chemical substances. The 100,000-odd substances which were on the market pre-1981 - the "existing substances" - can be used with virtually no safety testing, while "new substances" (put on the market since 1981) have to undergo extensive testing before they can be marketed. This makes it easier (and cheaper) for industry to continue using untested or little-tested existing chemicals than to develop new ones. As a result, only about 3,700 new substances have undergone in-depth testing and been put on the market since 1981.

Another flaw in the current legislation is that the public authorities must prove an existing substance to be dangerous before they can impose marketing restrictions. This system is so cumbersome that only a few dozen existing substances or selected uses have so far been banned in Europe (PCBs, asbestos, phthalates in toys, mercury and lead in electronic appliances, etc.).

The European legislation on protecting workers from the risks of exposure to dangerous substances in the workplace doubles up with that on the marketing of chemical substances, and lays down specific obligations for employers. Two directives (one on carcinogens, the other on chemical substances) require them to perform a risk assessment and take the necessary prevention and protection measures (elimination, substitution with less dangerous substances, reduction of exposure levels, compliance with exposure limit values, etc.).

But there are still problems with implementing these laws in the workplace, and most of the time they are only partially enforced, especially in small and medium-sized firms.

One key reason for this must be the lack of information about chemical substances (risks that are unknown are unmanageable). Other reasons include: failings in conveying product safety information to

¹ Children's health and environment: a review of evidence, WHO/EEA, 2002. ² Strategy for a future Chemicals Policy, White Paper, COM(2001) 88 final, European Commission, 27 February 2001. ³ Norén, K., Mieronyté, D., Contaminants in Swedish human milk. Decreasing levels of organochlorine and increasing levels of organobromine compounds, Orga-

nohalogen Compounds, 35:1-4, 1998. ⁴ European Commission, White Paper,

⁵ Occupational exposure to carcinogens in the EU 1990-1993, Carex, international database on occupational

exposure to carcinogens.

⁶ Third survey on European working conditions, Dublin, European Foundation for the Improvement of Living and Working Conditions, 2000.

⁷ Occupational Diseases in Europe in 2001, Statistics in Focus, No. 15, Euro-

⁸ Musu, Tony, REACHing the workplace. How workers stand to benefit from the new European policy on chemical agents, Brussels, TUTB, 2004, 36 p. ⁹ Eurostat data for 1998/1999.

the different users, lack of controls (insufficient labour inspection and market surveillance activities), but also the lack of collective representation of workers in small firms to uphold their interests.

REACH, the future European chemicals legislation

To address the failings of Community chemicals legislation, the European Commission adopted on 29 October 2003 a draft regulation which will abolish the distinction between new and existing substances, and will 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 (Registration, Evaluation and Authorization of Chemicals)¹⁰ has two main aims: one is to ensure a high level of protection for human health and the environment; the other is to ensure that the internal market operates efficiently and enhance the competitiveness of the European chemical industry.

The 30,000 substances concerned will have to be registered with a future European Chemicals Agency before being manufactured in or imported into the European Union. For this, a manufacturer or importer will have to supply information on their toxicological and ecotoxicological properties, describe their possible uses, and carry out a chemical safety assessment of the risks to human health and the environment¹¹.

The centrepiece of the reform therefore lies in shifting the "burden of proof" onto industry, which will now have to supply the information needed for its products to be used safely before they can be marketed. The other big change is that the use of the most dangerous products (e.g., carcinogens or PBTs¹²) will require authorization. The European Commission will also have the power to prohibit certain uses or substances if she deems the risks "unacceptable". A measure of transparency will also be introduced, in that non-confidential information on all registered substances will be available to the public.

A highly contentious reform

This proposed reform is important in many respects. Firstly, it will be a regulation (rather than a European directive), which will make it directly applicable in the 25 Member States as soon as it enters into force. REACH will replace forty-odd existing directives, and affect numerous branches of industry. The new system will create obligations not only for manufacturers (chemical industry) but also for the countless downstream users of chemicals (the building, woodworking, motor manufacturing, textile and computer sectors, etc.).

REACH has the potential to improve the legislation that protects workers exposed to dangerous substances in the different branches of industry by providing the missing information on their properties, making chemical safety data publicly available, requiring the effective circulation of information to users, and encouraging replacement of dangerous products through authorization and restriction procedures.

Since the publication of its draft (White Paper on Chemicals) in 2001, two opposing camps have been locked in a bitter battle for supremacy around this proposed reform. It has pitted industry against environmental NGOs, consumer groups and many trade unions who argue that economic considerations should not come before health and safety.

Industry clamours about the reform creating excessive cost burdens, raising the spectre of a backlash by undermining competitiveness in the many industries affected, the risks of industry relocations outside the EU, job losses and a collapse in GDP.

The latter argue that industry has responsibility for the safety of the products it markets, demand the right to know what risks people and the environment face, and call for dangerous substances to be banned or replaced. They also point to the major potential benefits of the reform, not just in health and environmental terms, but also in terms of innovation for industry.

Where does REACH stand today?

As a result of intense lobbying of the European Commission by industry and some Member State governments, the draft REACH regulation finally adopted by the Commission 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 revised drastically downwards (companies will now be required to supply chemical safety reports for only a third of the 30,000 substances initially foreseen) and the authorization procedures for the most dangerous substances have been eased.

The proposal for a regulation as adopted by the Commission has been sent to the European Parliament and Council, who must agree on the final version in a co-decision procedure.

As the result of a jurisdiction dispute in the European Parliament between the Environment Committee and the Industry Committee, each claiming substantive responsibility, the text had still not gone through its first reading at the end of the five-year legislature, despite the tabling of a preliminary report with proposed amendments in January 2004 by the Italian Socialist MEP Guido Sacconi, the Environment Committee's rapporteur on the matter.

¹⁰ Text available at http://www.europa. eu.int/comm/enterprise/chemicals/ index.htm.

¹¹ For substances manufactured or imported in quantities of more than ten tonnes/year per manufacturer or importer.

¹² Persistent, bioaccumulative and toxic substances, i.e., toxic substances which could accumulate irreversibly in the body and the environment.

Once a new Parliament including MEPs from the 10 new Member States had been formed after the June 2004 European elections, the Environment Committee was given leadership of the dossier and the re-elected MEP Guido Sacconi was confirmed 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 - Employment and Social Affairs, Economic and Monetary Affairs, Legal Affairs, Budgets, Women's Rights and International Trade - are less directly involved, but will still be able to express an opinion. The first reading is scheduled for autumn 2005.

Within the Council, the Heads of State assigned responsibility for REACH to the Competitiveness Council composed of the national trade and industry ministers, 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 set up in November 2003 under the Italian presidency to assist the Council in working out a common position.

At the various meetings of this working group held under the Irish presidency in the first half of 2004, a number of amendments were put forward 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 strengthening of the substitution principle, etc.

The working group has taken its discussions forward since July 2004 under the Dutch Presidency, which has set itself the task of scrutinising the first three chapters of the regulation - on registration and data sharing - with a view to putting forward specific proposed amendments by year-end. The Dutch Presidency also held a workshop in late October 2004 to analyse, and draw conclusions from, the findings of the various impact studies available on REACH¹³.

In 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, getting strategic partnerships going 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

Figures that put the claims in perspective

According to the Commission's own economic impact assessment of REACH a:

- The direct costs to the European chemical industry, arising mainly out of 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, due chiefly to the fact that 4,500 lives will be saved every year, corresponding to the number of fatal work-related cancers that will be avoided by improved knowledge of the properties and effects of chemical substances.
- Environmental benefits are also anticipated but have not yet been quantified by the Commission.

The chemical industry has done its own impact studies, which predict overall costs 30 to 100 times higher, and foresee the loss of hundreds of thousands of jobs and a sharp fall in GDP in Germany and France ^{b-c}.

In the opinion of the Commission ^d and independent economic experts ^e, these unrealistic estimates of the macroeconomic effects of REACH should be given little credence. The methodologies used in them are judged 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 approximate direct and indirect costs estimated by the European Commission $^{\rm f}$.

Finally, it is interesting to note that the amount 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.
- $^{\rm d}$ DG ENTR, presentation at the workshop "Impacts of Chemicals Policy How to measure it?", Laulasmaa, Estonia, 11-12 November 2004.
- 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.

Council), has also set up a working group to oversee three further studies to assess the impacts of REACH. The first two studies, financed and carried out by industry, assess the impacts of REACH on trade throughout the supply chain, and on innovation. The third study, financed and carried out by the Commission's Joint Research Centre (JRC), addresses the impacts 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 for early 2005. Other impact studies, begun in 2004, are likewise expected to present their findings in 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's reckoning is that the Parliament-Council co-decision procedure could be concluded in 2006, with the REACH system entering into force in 2007.

¹³ 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.

Conclusions

While the need for the REACH system is now beyond question, the battle to shape the final content of the reform, and hence the cost-benefit balance, continues unabated. Looking at the different versions of the regulation as it has gone through the drafting process, there is no denying that the requirements made of manufacturers, importers and users of chemical substances have been revised downwards, reflecting an unrelenting attempt to slash the cost to industry. This trend, if continued, will inevitably affect whatever benefits REACH may bring.

It might have been thought after the joint letter sent in late September 2003 by President Jacques Chirac of France, Chancellor Gerhard Schröder of Germany, and Britain's Prime Minister Tony Blair asking Commission President Romano Prodi "not to undermine the international competitiveness of European industry", that little improvement was to be expected from the Council. But if the German delegation's statements to the ad hoc working group on REACH¹⁴ are anything to go by, a better costbenefit balance could be achieved by requiring more data on chemicals in the 1 to 10 tonnes a year bracket (including reintroduction of the chemical safety report), and a minimum level of information on intermediate substances.

MEPs could also insist on putting deleted provisions back in order to stop the dilution, and raise back the sights of this REACH legislation which, provided it is not emasculated, could materially improve the protection of environmental and human health (including that of workers) from dangerous substances. All hope of improving REACH is not yet lost.

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¹⁴ Council of the European Union, document 8396/04 of 15/04/04.

TUTB Publication

REACHing the workplace

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

Tony Musu

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 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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