REACH, the new European chemicals policy: what for?

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Abstract

In October 2003 the European Commission adopted a proposal for a regulation aimed at radically recasting the Community policy on chemical substances. This proposed reform, known as REACH, sets up an overall system for the registration, evaluation, authorisation and restriction of chemicals. The objectives of REACH are to ensure a high level of protection for human health and the environment while strengthening the competitive position of the European chemical industry. How to strike that delicate balance remains riven with controversy. While intense lobbying by industry has substantially reduced the REACH requirements on the producers of chemicals, big changes in the management of chemical risks in Europe are still in the making. The reform which has yet to be approved by the Council and Parliament in a co-decision procedure represents a real opportunity to reduce the number of chemical-related occupational diseases.

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.

At the same time, we are seeing a steadily rising incidence of cancers, allergies, and hormonal system disorders, especially in children [1]. 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 established [2]. Swedish research, for instance, has shown that compounds like PBDEs (polybrominated diphenyl ethers) can accumulate in the food chain, and end up in breast milk [3]. These compounds, used to add fire-retardant properties to textiles, electronic equipment and polyurethane foam, have a structure and toxicology akin to PCBs (polychlorobiphenyls) which were long used in electrical equipment before being banned in the late 1970s, after their accumulation in the environment and toxicity to humans were discovered.

It is now clear that current chemicals legislation is not working, and unable to give proper protection to human and environmental health. The appalling fact is that over 99% of the total volume of chemicals on the market has undergone no comprehensive human and environmental health risk assessment [2], despite many being present in consumer goods (cleaning products, cosmetics, clothing, computers, etc.).

The situation is equally alarming for the millions of workers across Europe who are exposed to chemicals not just as consumers, but also in their workplaces. Research done by the Dublin-based European Foundation found that 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 time [4]. From the Eurostat EODS [5] survey findings for reference year 2001, our research institute estimates that between 18 and 30% of all recognised occupational disease cases in Europe are related to exposure to hazardous chemicals [6].

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 that will apply to the 30,000 chemicals produced or imported into the EU in quantities of more than one tonne per year. This draft legislation, known as REACH (**R**egistration, **E**valuation and **A**uthorization of **Ch**emicals)[1] 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 they can be manufactured in or imported into the European Union. This will require manufacturers or importers 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 environment.

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

The centrepiece of the reform therefore lies in shifting the "burden of proof" from the public authorities onto manufacturers. As things stand, the public authorities have to prove that an existing substance is dangerous in order to impose restrictions on it. Under REACH, industry will have to supply the information needed for its products to be used safely before they can be marketed. Another big change is that the use of the most dangerous products (e.g., carcinogens or PBTs[2]) will require authorization. The European Commission will also have the power to prohibit certain uses or substances if it deems the risks "unacceptable".
A degree of transparency will also be introduced, in that non-confidential information on all registered substances will be available to the public.

REACH, a highly contentious reform

This proposed reform is important in many respects. Firstly, it will be a regulation (rather than a European directive), which means it will be 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, because the new system will create obligations not only for manufacturers (chemical industry) but also for the countless downstream users of chemicals (in the building, woodworking, motor manufacturing, textile, computing and other industries).

REACH can potentially make the legislation that protects workers exposed to dangerous substances in all branches of industry more effective by providing the missing information on their properties, making chemical safety data publicly

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

available, requiring information to be effectively circulated to users, and encouraging replacement of dangerous products through authorization and restriction procedures.

Since it was published in draft form (the White Paper on Chemicals) in 2001, two opposing camps have been locked in a fierce struggle to influence this proposed reform, pitting industry against environmental NGOs, consumer groups and many trade unions who argue that health and safety should not take a back seat to economic considerations.

Industry has complained that the reform will cost too much, and has run a scare campaign playing up the backlash effects: lost competitiveness in the many industries affected, the risks of offshoring to non-EU countries, job losses and a collapse in GDP.

The latter argue that industry has a responsibility for the safety of the products it markets, claim the right to know what risks people and the environment face, and demand that dangerous substances should be banned or replaced if a safer alternative is available. 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.

Urged on by the US chemical industry, the Bush Administration also joined in the fight, with strenuous efforts to scupper the draft regulation. A US House of

Representatives report prompted by Los Angeles Democrat Congressman Henry A. Waxman, published in April 2004, lifts some of the veil on the Bush Administration's tactics, including a divide-and-rule strategy towards European Union countries, instructions from Secretary of State Colin Powell to US embassies to coordinate lobbying towards EU countries, etc.

The Bush Administration and the US chemical industry are obviously fearful about the increased difficulty that US-manufactured chemicals will have getting onto the European market by having to meet the REACH standards; but what most frightens them is the spectre of US consumers ultimately demanding protection against chemical risks like that under European rules, and hence legislation similar to REACH.

Counting the real costs and benefits of REACH

According to the Commission's own economic impact assessment of REACH[3]:

- *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 deaths that will be avoided by improved knowledge of the properties and effects of chemical substances.

[3] http://www.europa.eu.int/comm/enterprise/reach/eia.htm.

• *Environmental benefits are also anticipated* but have not yet been costed out 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 [7-8].

In the opinion of the Commission[4] and independent economic experts [9], little credence should be placed in these unrealistic estimates of the macroeconomic effects of REACH. The methodologies they use 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 [10].

It is also interesting to note that the figure of *€ 2.3 billion represents approximately 0.04% of the European chemical industry's annual turnover* (€ 586 billion for the EU-25 in 2004).

The European Trade Union Confederation's research institute recently unveiled the findings of research into the potential benefits of REACH to European

[4] DG ENV, presentation at the workshop "Impacts of Chemicals Policy - How to measure it?", Laulasmaa, Estonia, 11-12 November 2004.

workers' health[5]. The study done by the University of Sheffield shows that REACH would help avoid 90,000 cases of occupational diseases from workers' exposure to dangerous chemicals in Europe every year.

That would add up to total average savings of 3.5 billion euros over 10 years and more than 90 billion over 30 years for the EU-25. The savings would benefit social security systems and workers, but also employers in all industries, by avoiding sickness absence-related lost productivity.

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 heavily watered-down from the initial version put out for public consultation in May 2003: polymers are now outside the scope, the amount of information to be supplied has been cut drastically (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.

[5] See: www.etuc.org > publications or http://hesa.etui-rehs.org.

In the Council, the Heads of State have 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, including compulsory information-sharing to cut registration costs – the OSOR (one substance, one registration) system – and additional powers for the Chemicals Agency.

The Dutch Presidency hosted a workshop in October 2004 to review the 36 impact assessment studies done on REACH[6]. It found that the Commission's estimates of the general range of the direct costs of implementation were about right, and concluded that the human health and environmental benefits of REACH are undisputed but hard to cost out.

In May 2005, the Luxembourg Presidency presented the findings of the further impact studies done by industry, overseen by a working group of representatives of the Commission, various industrial sectors, trade unions and NGOs. The results of these microeconomic studies show that the costs of REACH will be

[6] Overview of 36 studies on the impact of the new EU chemicals policy (REACH) on society and business. See: http://hesa.etui-rehs.org/uk/dossiers/files/EU2004REACH.pdf.

manageable for industry and scotch the nightmare scenarios painted by industry, although concerns remain for chemical manufacturing SMEs.

The current UK Presidency is hoping to broker a political compromise in Council by the end of 2005, around proposals that include narrowing-down the scope of the reform (by excluding waste and ores), introducing an OSOR system, further watering-down the information requirements for substances in the 1-10 tpa range, and making all authorisations fixed-term.

As the result of a jurisdiction dispute in the European Parliament, in which the Environment Committee and Industry Committee each claimed lead responsibility, the text had still not passed 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.

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 handed lead responsibility, and the re-elected MEP Guido Sacconi was confirmed as principal rapporteur for the Parliament. He has since been working 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 – although less directly involved, have still given opinions.

The Environment Committee approved its final report on the draft rules by a resounding majority (40 for, 19 against, 2 abstentions) on 4 October 2005. The amendments voted through to some extent offset those that diluted the reform, adopted in mid-September by MEPs in the Industry and Internal Market committees.

A duty of care was restored for all chemicals, whether or not covered by REACH, application of the substitution principle was beefed up in the authorisation phase, and the requirement for a chemical safety report was reintroduced for the 30,000 substances covered by the reform.

The burden of proof was shifted firmly onto industry, and the OSOR system was added to simplify the registration phase. On the downside, the information requirements were reduced overall for the 20,000 substances between 1 and 10 tonnes, which rolls back some of the gain made by the reintroduction of a chemical safety report in this range.

REACH passed a major milestone on 17 November 2005 when MEPs voted through a substantially amended text in first reading by a majority of 407 for, 154 against with 41 abstentions. This was achieved through a political compromise engineered a few days ahead of the vote between the European Parliament's 3

main political groups (conservatives, liberals and socialists). The compromise safeguards some big gains won by the Environment Committee - like the principle of compulsory substitution of the most dangerous chemicals, and the duty of care - but at the price of a further reduction in the information that industry will have to supply for almost all the 30,000 chemicals covered by REACH.

The ball now lies with the 25 EU Member State governments, who have to adopt their own common position on the text. The British Presidency is poised to broker a political agreement in Council on changes akin to those adopted by Parliament. There is little prospect, therefore, of the Member States reaching a more ambitious final position than the MEPs, particularly given the return to government in Germany of conservatives with close links to the chemical industry.

The Commission believes that the co-decision procedure between the European Parliament and Council could be concluded in 2006, with the REACH system coming into effect in 2007. The regulation would then be fully implemented 11 years later, when the 30,000 substances covered by the reform are registered with the European Chemicals Agency.

Conclusions

Comparing the successive versions of the text as it has been “nipped and tucked” throughout the legislative process between being first floated in the 2001 White

Paper and the European Parliament and Council's recent policy positions, there is no denying that the requirements on the manufacturers, importers and users of chemicals have been watered down. This has been achieved through hardball lobbying aimed mainly at cutting the cost burden on industry. It is bound to have consequences on the benefits that REACH can deliver. Every step back makes it harder to give credence to the lawmakers' claims that costs have been successfully brought down without detracting from the expected benefits for human health and the environment.

While economic interests may have substantially curbed the initial aims of the reform, therefore, big changes in the management of chemical risks in Europe are still in the making. Shifting the burden of proof onto industry is a mini-revolution in itself. This change in roles and responsibilities cannot but bring about a mindset change in the chemical industry and among downstream user industries.

REACH stands at the interface of more growth in the chemicals market and a greater respect for the rights and protection of workers, consumers and the environment, and can be seen as a decisive step towards a sustainable chemical industry - in Europe first, and perhaps the rest of the world thereafter?

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