



A new chemicals policy in Europe – new opportunities for industry.

**A response to the claims made
regarding the business impact of
a new chemicals policy that is
designed to protect the
environment and human health**

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1 Executive Summary

- **The European Commission has proposed a new system for the regulation of the production, import and use of chemicals, the REACH system.** It aims to create a uniform system where both existing and new chemicals have to be registered and assessed. Chemicals of very high concern will need authorisation prior to any use. The system will place an increased responsibility upon industry to provide data on substances. The burden of proof will therefore lie with the industry, who are best placed to obtain usage data and who make a profit from producing the substance concerned.
- **In our view, this new system has the potential to ensure that the precautionary principle will be put in practice in a harmonised, simple, transparent, and predictable way.** However, the European chemical industry associations argue that the REACH system will damage the competitiveness of the industry, because of increased costs and other business impacts.
- **The costs estimated by industry, and by the Commission’s business impact study, ignore the potentially positive effects on innovation and competitiveness** presented by REACH, for example:
 - *New markets for safer and more environmentally friendly products;*
 - *Safer products will reduce the risk of future liability lawsuits, which can result in enormous costs (as has happened with asbestos);*
 - *Increased trust among consumers, employees, local communities and investors, leading to a more positive business environment;*
 - *Easier introduction of new chemicals onto the market will encourage development and innovation;*
 - *A more predictable regulatory system will aid future long-term planning by industry; and*
 - *Improved transparency and communication through the supply chain will lead to increased power and confidence for downstream users and SMEs.*
- **The biggest failure of the various business impact assessments has been an assumption that the market is inflexible and an associated focus on substances rather than services provide.** EU consumers will continue to purchase products – some products may leave the market due to problems with the chemicals they contain, but consumers will purchase other products that provide the same service. For example, if a manufacturer sells a chair which contains a chemical that is to be phased out, it will be up to that manufacturer – or another – to provide a chair which does not contain this chemical. The public will carry on buying chairs at the same rate, so the input of money into the retailing and manufacturing supply chain will remain constant.
- **REACH is in many ways a schoolbook example of innovation-friendly regulation,** since it does not tell business which chemicals to produce or which processes to use. Instead, it sets strict harmonised standards for all substances, it proposes a phase-in period, and it places the responsibility for the solutions on industry.
- **There are many contradictions in the concerns expressed by industry, with industry associations taking lowest common denominator positions.** Some players are also attempting to ‘scaremonger’ downstream industries with inaccurate and imaginative interpretations of the REACH system. This report examines some of the concerns of downstream users in detail.
- **Other players, notably the US Government, are also involved in scaremongering, using poorly researched and outdated figures.** For example, the US Government’s ‘non paper’ suggests that the EU may ban the import of US computers, based on a US chemical industry

association's misinterpretation of the White Paper. It also uses outdated figures from a UK study into animal testing and the new chemicals policy.

- **In discussing the costs of REACH it is equally important to identify the societal benefits of stricter chemical regulation in form of less environmental and health impacts.** Monetary values can be attributed to some benefits, but methodological and ethical problems prevent us from carrying out traditional cost-benefit analysis – e.g. what is the price of an uncontaminated foetus?
- **Industry has claimed that increased costs could lead to companies leaving Europe, however research does not support this claim.** Research has shown that compliance costs tend to be rather small compared to the direct and indirect costs of moving. Since the European chemical industry is a high technology sector with demand for skilled workers and research facilities, it is more likely that the labour, education and research policy will determine its future viability, not the environmental policy.
- **The evidence does not support claims that the US system is more innovation-friendly than the EU system,** nor does it show that it is more effective in protecting human health and the environment. It is also questionable if it is more cost-efficient for industry, since much of it relies on costly legal procedures, such as liability claims, instead of up-front corporate regulation.
- **Industry inside and outside Europe has argued that the requirements under REACH will lead to barriers of trade, yet this is unlikely to be the case.** We consider that it is important to avoid discrimination, and to achieve the environmental and health improvements envisaged, through ensuring that imported articles/goods are treated in the same way as domestically produced articles.
- **The chemical industry's voluntary "Responsible Care" programme is often referred to as a guarantee for safe management of chemicals, but this is not supported by the evidence.** A closer look at Responsible Care shows that it is impossible to identify what improvements Responsible Care has contributed, beyond the increasingly strict legal requirements.
- **The chemical industry's attempt to trial their 'thought starter' provides clear evidence than Responsible Care is not working.** The results suggest that industry cannot provide hazard data on substances, has little exposure information, is failing to communicate properly with downstream users, and will find it difficult to defend the use of substances of very high concern with socio-economic benefit analysis. This 'thought starter' trial demonstrates that Responsible Care needs REACH more than REACH needs Responsible Care.

Conclusions

REACH presents a huge business opportunity. It does have implementation costs, like any regulatory system, but these have to be weighed against the benefits that will flow from investment in safer and more efficient products and services – and in a reduction in the health and environmental costs of chemical use.

REACH will create a level playing field for all players in an EU market of 550 million consumers, large enough to set a new chemical safety standard that is competitive in the global market. This is a huge benefit to be weighed against any costs of implementing the legislation.

Many companies will experience considerable benefits from the REACH system. Such companies should be aware that they are not currently being properly represented by their trade associations.

2 Introduction

It is well known that the European public has little confidence in the chemical industry and its chemicals. For example, a Eurobarometer survey in 1999 found that “*Europeans establish an evident link between their health and the environment. Among a series of potential threats, it was the diffuse threat represented by chemicals which they feared most*” (EC 1999).

Similarly, opinion polls in the UK have concluded that only 22% of people are favourable to the chemical industry (Worcester 1999).

The lack of confidence is likely to make life more difficult for the chemical industry in many ways, from suspicion from investors to problems recruiting the best new employees. The increased focus by the EU on liability regulations, in combination with improving methods of linking exposure to harm, are also likely to make the chemical industry more vulnerable to liability claims in the future. The current asbestos litigations in the USA show such costs are already a reality for many European companies.

This public lack of confidence is founded on the reality that the chemical industry has been poorly regulated. For example, it has been allowed to continue selling chemicals for which there is no or very little safety data, and it continues to produce chemicals that accumulate in our bodies and those of wildlife, or which disrupt hormonal systems.

In response to the problems in the current regulatory system for chemicals, a debate on how to improve these regulations was initiated by Council in 1998, which resulted in the publication of a White Paper by the European Commission in February 2001. This White Paper has now been debated for around two years, and the Commission will shortly publish their legislative proposal based on it.

Parliament and Council have already expressed their broad support for the proposals in the Commission’s White Paper. However, industry – and the Commission’s own business impact study – have focused solely on costs of REACH and the claimed harm it could do to business. There are many flaws in these analyses, notably a general assumption that the market is inflexible and incapable of innovating. A number of industry studies predict huge losses in gross added value and jobs, based on very extreme and sometimes incorrect interpretations of issues that are not yet fully developed or are rather vague in the White Paper. Unfortunately, the potential benefits of the new system – the prevention of damage to human health and the environment (including related costs), as well the promotion of innovation and competitiveness, have been virtually ignored.

This discussion paper examines some of the claims that have been made by industry, and discusses the business advantages of a new, more precautionary and information based, regulatory approach. It argues that many of the industry’s arguments about loss of competitiveness and market shares because of increased compliance costs are not based on a realistic interpretation of either the proposed regulations or the market. It also outlines a wide range of business opportunities that a new system could create. In addition, this discussion paper examines the chemical industry’s Responsible Care programme, and shows that it cannot be used as a guarantee for product stewardship or effective environmental management. Voluntary initiatives in the chemicals sector are not a substitute for regulations.

3 A new Chemicals Policy in the EU - REACH

In February 2001, the European Commission published a White Paper entitled “*Strategy for a Future Chemicals Policy*” (EC 2001b). The White Paper presented a new regulatory system, called REACH, for the “Registration, Evaluation and Authorisation of CHEMicals”.

REACH includes three key components:

- **Registration:** Chemical producers or importers will be obliged to provide safety data by fixed deadlines to authorities on all chemicals produced or imported in quantities above one tonne per year.
- **Evaluation:** For higher volume chemicals, and for other chemicals of concern, this data will be *evaluated* by Member State experts in association with a central co-ordinating body. The evaluation may then lead to authorisation (in the case of chemicals of ‘very high concern’), risk reduction (where dangerous uses are restricted), or to no further regulatory action.
- **Authorisation:** Chemicals considered to be of ‘very high concern’¹ would be subject to authorisation. Such chemicals will be phased out, unless industry can show that a specific use presents negligible risk or that it is acceptable, taking into account its socio-economic benefits, the lack of safer chemicals and measures to minimise exposure.

REACH is intended to create a major change in the way chemical production and use is regulated in Europe.

This is likely to have a considerable impact on the chemical market. It should establish a uniform framework for all industrial chemicals produced and placed on the market in the EU, regardless whether they were marketed for the first time before 1981 (described as existing substances in the current system) or after that (new substances). The biggest changes are for existing substances, though there are also changes for new substances.

The key new features in the White Paper are:

- The burden to collect information, to produce a good quality risk characterisation and to disseminate it will be shifted from state authorities to industry. The REACH system will set up mechanisms to driving producers and users of chemicals to take their responsibility to prevent occurrence of relevant risks during the whole life cycle of the chemical;
- There will need to be improved communication up and down the supply chain in order to properly assess the risks of substances placed on the market, by linking hazard information (substance properties) to exposure information (types and conditions of use);
- All substances produced or imported at more than 1 tonne per annum (tpa) will have been registered and risk assessed by their producers and commercial users within around 10 years;
- Safety testing requirements will be triggered not only by volume but also by the expected type and extent of exposure;
- Registration dossiers for all substances > 100 tpa will be independently evaluated by the authorities, as will dossiers for substances < 100 t/a if there is a concern;
- An authorisation system will be introduced to control the use of substances with properties of very high concern. This will affect around 5% of industrial chemicals (about 1500 substances) currently marketed in volumes > 1t (about 30.000 substances). This system will forbid all uses that have not been specifically authorised, and the burden of proof will be on industry to prove the need for the product and/or to prove negligible exposure;

¹ Defined in the White Paper as Category 1 or 2 carcinogens, mutagens or reprotoxic substances (CMR), and particularly persistent, bioaccumulative and toxic substances, as defined in the Stockholm Convention on Persistent Organic Pollutants (POPs). This definition has been extended by the Council Conclusions of June 2001.

- More hazard and risk related information will become publicly available.
- The testing requirements for low volume new chemicals will be considerably reduced, with the threshold for registering safety information increased from 10 kg to 1 tpa, and reduced information requirements below 10 tpa (90% of all new substances).

4 Costs vs benefits

4.1 Cost – the estimates

Industry has reacted defensively to the REACH proposal, mainly because of the high costs it is claimed to entail. The first estimate by industry claimed costs in the range of € 20-30 billion. These high figures have now been modified, and CEFIC (the European Chemical Industry Council) now admits that they accept the upper range of the figures given in the Commission's business impact study (approximately €7 billion, below) (CEFIC 2002c).

The increased costs will, according to the chemical industry, lead to reduced innovation possibilities, since they will divert capital resources from profitable investments such as research into new substances. The German company BASF goes so far as to allude to emigration: *“Global companies like BASF compete directly with important industrial regions like America and Asia, which have different legal framework conditions. The same products can then be produced there without the precursor substances being subject to rigid European legislation”* (BASF 2002, p.1).

Below we outline a number of the most important cost estimates, and then discuss the deficiencies in these estimates, with an outline of industrial benefits that a precautionary new regulatory system could bring.

4.1.1 European Commission's Business Impact Assessment, May 2002

In May 2002, the European Commission published a business impact study which intended to examine what REACH would cost industry (RPA 2002b). This study concluded that the cost to industry would be between € 1.4 and € 7 billion, with a best approximation of € 3.6 billion. To put this into perspective, the € 7 billion can be divided by the number of years that it is expected that the existing chemicals will allowed to be phased into the system, say 11 years. This gives a cost of € 636 million a year, which should be compared with the annual sales revenue of the European chemicals industry of more than € 488 billion. So, even if we look at the worse case scenario, with costs at € 7 billion, this would only amount to costs in the range of 0.1% of the chemical industry's turnover per year.

It is also interesting to note that, based on industry's own estimates of available safety data, the impact study concluded that 88% of the costs to industry of implementing REACH would be due to the cost of safety testing for the existing chemicals that have already been on the market for more than 20 years. Other costs include submission of registration dossiers, pre-registration costs (for substances below 1,000 tonne/year), less-demanding registration costs when most of the data is available, authorisation, costs for downstream users (staff time etc) for providing information, and costs for downstream users producing risk assessments required for unintended uses (RPA 2002b). Depending on how well prepared a company is, and how much safety data it already has on a substance, the costs for individual companies will vary greatly. Those companies which already have safety data for the chemicals they sell will be rewarded with lower costs, those that don't will have to pay more.

There are many important aspects omitted by the Commission's May 2002 business impact study, for example:

- It ignores the potentially positive impacts of a new chemicals policy on competitiveness, such as new market opportunities, first-mover advantage and stimulation of innovation.
- It ignores the savings that are likely to accrue to companies through the reduction in liability risks (which should include, if the insurance market is given confidence by REACH, a reduction of premiums).

- It makes no attempt to quantify the positive impacts of the use of safer chemicals on human health and the environment.
- It assumes that testing and assessment costs will remain constant throughout the decade or more of testing, whilst in reality there will be innovations in testing methods (e.g. improved computer-based predictions of chemical properties and development of cheaper and more rapid non-animal techniques using expression profiling) and the cost of assessment and associated bureaucracy will reduce as the new system becomes routine.

4.1.2 German employers organisation (BDI) study

At the beginning of November 2002 the German employers' organisation BDI released the executive summary of study on the impacts of the new EU chemicals policy on German industry, performed by consultants Arthur D. Little (ADL). This study claimed that "*The implementation of the ideas of the White Paper will cause a cumulated loss of gross added value between 0.4% and 6.4% for the national German economy according to the available model calculations.*" ADL translates this to job losses of 150.000 to 2.35 Million (BDI 2002). Furthermore, ADL predicts that a loss of production will be connected with loss of innovation due to the geographic proximity of research and development activity to production.

The results of the study were initially released only as an executive summary, without any documentation on how the figures were generated, with the full text of the report only emerging 2 months later. This lack of transparency is not acceptable when such bold claims are made.

The basic approach of the study could have generated interesting insight on how downstream users may react to REACH and what problems they may face. The applied model could also have been used to learn more about critical drivers in REACH. However, the figures predicted by the model are only valid in a static economy, where no active and innovative response to changing conditions is expected. This is a completely unrealistic assumption, as outlined in the following sections. In dynamic markets companies are highly flexible, and new regulatory frameworks create new business and/or adaptation of current business. An 11 year time frame, as foreseen in the White Paper (i.e. from the year after publication of the White Paper, 2002, to the registration deadline for >1 tpa of 2012, given that it should be obvious to industry from the publication of the White paper that the regulatory system was going to change) leaves enough room for adaptation to avoid losses. Nevertheless, the BDI used the results to claim that the model was a prediction of real market developments.

Arthur D. Little are well known for another cost-benefit study they performed, in which they argued that smoking was good for the Czech government as it reduced the number of old people (BBC 2001).

4.2 Costs - are the assessments accurate?

The cost estimates above can, in some cases, be justified according to traditional micro-economics, but only if we also assume that:

- the regulation and its impacts on individual chemicals are seen as independent singular events, without context;
- industry is not flexible;
- industry is not innovative;
- industrial innovation is not spurred by market forces.

In reality, industry has proven over and over again that these assumptions do not correspond to reality. As John Hontelez, Secretary General of the European Environment Bureau (EEB), put it:

"Industry is usually afraid of change, but once change happens, then industry is perfectly able to turn this to its own advantage. We want this ability to be promoted and rewarded with the new system." (EEB 2002, p.8)

4.3 Benefits – for industry

It is often claimed (as in this case) that regulations will always lead to increased costs – the reality is somewhat different. Research has shown that “*external pressures* [such as regulations] *can enhance resource productivity and innovation.*” (Porter 1998, p.120). By responding to new regulations, a number of positive effects for companies have been identified (Elkins et al, 1998, p.38):

- New, green products can increase consumer appeal and open up new business opportunities;
- Companies that are proactive can gain a competitive edge over those struggling behind;
- Complying with stricter rules can minimise future risks and liabilities;
- An environmentally progressive reputation can improve recruitment, employee morale, investor support, acceptance by host community and management’s self-respect.

These positive effects of regulations are particularly likely to materialise if the regulations are well designed. Features of innovation-friendly regulations include (Porter 1995):

- focus on outcome, not technology;
- enact strict rather than lax regulations;
- employ phase-in periods;
- harmonise regulations, and;
- require industry participation.

REACH is in many ways a schoolbook example of innovation-friendly regulation, since it does not tell business which chemicals to produce or which processes to use. Instead, it sets strict harmonised standards for all substances, it proposes a phase-in period, and it places the responsibility for the solutions on industry. The REACH system even gives a direct incentive to innovation of new substances by raising the threshold for chemicals produced in small quantities from the present 10 kg/year to 1 tonne/year. This benefit has been estimated at € 69 million over ten years, and is believed to be particularly important for SMEs (RPA 2002b).

REACH is designed to create a level playing field, ensuring that all chemicals, whether new or existing, have been shown to be safe. How industry reaches that target, and what substances they substitute the non-safe chemicals with, is not defined in the regulation, but is open to competition and innovation.

It must be remembered that REACH will not diminish the market’s demand for products, because the demands from consumers will still be there and will be met. Put at its simplest, EU consumers will continue to purchase products – some products may leave the market due to problems with the chemicals they contain, but consumers will purchase other products that provide the same service.

For example, if a manufacturer sells a chair which contains a chemical that is to be phased out, it will be up to that manufacturer – or another – to provide a chair which does not contain this chemical. The public will carry on buying chairs at the same rate, so the input of money

into the retailing and manufacturing supply chain will remain constant. This key factor is ignored in many business impact studies.

It must also be remembered that complying with the requirements of the new REACH system will provide industry with access to a market of more than half a billion consumers in the enlarged EU.

4.3.1 Some specific business benefits of REACH

There are many specific business benefits that should flow from implementation of the REACH system, as long as it is well designed, open, and precautionary, including:

- **Reduced business risks related to liability and reputation.** The information generated in the REACH System will contribute to the development of safer products and processes with regard to both health and environment. This will make companies less vulnerable to both liability claims and loss of reputation (with the general public or with the stock market). Chemicals “*assessed according to EU standard*” could become an interesting alternative to domestic products for industrial users of chemicals in the US and other countries.
- **REACH increases the predictability of substance regulation.** The current system of regulatory risk prevention and risk management related to chemicals is costly and highly unpredictable. A wide range of legislation impacts on chemical use, including substitution requirements based on IPPC, VOC and Chemical Agents Directives, bans on substances imposed by waste legislation and direct or indirect marketing and use restrictions based on the current chemicals legislation. Industry has frequently asked for a more predictable system, and the REACH approach should create this.
- **REACH reduces the cost of bringing new substances onto the market.** For 50% to 90% of currently notified new substances the requirements for registration under REACH will be lower than in the current system.
- **REACH assists in the creation of new markets.** REACH will trigger more intensive communication up and down the supply chain, which will enable the companies within the supply chain to better understand the needs of the other players. This will aid innovation of both products and services, opening up potential new markets. REACH is likely to promote a situation where the chemical industry and traders will tend to sell solutions to their customers rather than chemicals. It will also encourage many traders to re-define their role to providing integrated consultancy and risk assessment services for their SME customers.
- **REACH will create markets for safer products that substitute hazardous substances.** Currently, innovative and pro-active companies who have developed alternatives to hazardous chemicals often face the problem that potential customers are not sufficiently motivated to buy “the better” product. The authorisation regime will give a clear and convincing signal to, and pressure on, the market to look for better alternatives. Of course, chemical producers who do not react to such signal in time will lose their market – but this is an incentive for innovation and gives the first mover a competitive advantage.
- **REACH will create new markets for innovative safety testing and risk assessment tools.** The information demands of REACH, combined with the phased introduction of existing chemicals into the system, will provide a powerful incentive to develop and market innovative new testing methods, for example those based on computer prediction and expression profiling – this should also reduce testing costs over time. There will also be a demand for companies that can provide risk assessment services.
- **REACH should promote improved public trust in chemicals and the chemical industry.** In recent decades the public (and many professional users) have lost confidence in chemicals and chemical industry, due to the regular emergence of new problem chemicals, lack of safety information and secrecy. The REACH system must increase the public availability of good

quality safety data, and must provide a rapid method of controlling the use of problem chemicals.

- **REACH should make ‘product stewardship’ a reality.** The chemical industry’s responsible care program (see page 22) claims to implement ‘product stewardship’ down the supply chain. In reality, responsible care, as a voluntary, industry controlled, programme has not proved capable of implementing this supply chain responsibility. REACH should ensure that there is transfer of information up and down the supply chain, and that chemicals are used safely throughout the chain.

4.3.2 Previous examples of regulation leading to innovation in the chemicals sector

There are many examples of regulations leading to innovation. For example, the World Business Council for Sustainable Development (WBCSD) has published a number of examples of how companies and industries have benefited financially from being environmentally proactive (DeSimone 2000), including many case studies from the chemical industry.

Examples of the positive impact of regulations on innovation include:

- In Sweden in the 1970’s and early 1980’s, strict emission rules, in combination with increased consumer awareness, forced producers to phase out chlorine gas in pulp bleaching. This stimulated the Swedish paper industry to develop new, more environmentally friendly processes. This technology is now successfully exported all over the world, since an increasing number of countries are introducing stricter regulations. (Porter 1998)
- Volatile organic compounds (VOCs) in paint create environmental and health problems, and have recently been subject to stricter regulations. A proactive company, ICI Autocolor, developed water-based products for metallic car paints that reduce VOC emissions substantially, and they also turned out to be more energy efficient for the company. This led to important savings for the company, as well as for the environment (DeSimone, 2000).
- In 1982, Sweden banned cadmium from being used as pigment, stabiliser or coating. Before the ban, companies dealing with cadmium additives claimed that the regulations would have serious consequences for them. An evaluation carried out in 1997 showed that because of the short phase-out time, the companies had in fact encountered short-term technological and economic difficulties. However, in the longer term, the companies judged that the ban had not made them lose market shares or reduced their profits. (Kemi 1999)
- One of the most commonly stated examples of a “success story” is how the company DuPont gained competitive advantage by phasing out CFCs in advance and investing in developing the substitute, HCFCs (Howes 1997). However, from an environmental point of view this is also an example of how to substitute the wrong chemicals, since HCFCs were already known to be greenhouse gases, and are to be phased out – and less damaging alternatives based on simple hydrocarbons and ammonia were already available (ENDS Report 2002b), though less profitable for the chemical industry. This is one of the problems with the existing, ad hoc, chemical by chemical, problem by problem, approaches to chemicals regulation – a problem that will be largely solved by a precautionary implementation of REACH.

It is important that regulations assist in creating a level playing field instead of supporting outdated technologies. REACH should be an instrument to promote innovation and safer products, by no longer favouring older substances, by applying the substitution principle, and by phasing out hazardous substances through the authorisation process.

4.4 Benefits – for human health and the environment

At the time of writing, there has been no substantial attempt to assess the environmental and health benefits that REACH should achieve – a major deficiency. In a related problem, much of the debate on innovation has ignored the importance of regulation defining the direction of

innovation to ensure that there are health and environmental benefits flowing from the innovation:

“An assessment of innovation productivity which [...] simply rates each substance on the market as marking innovative progress misses the central point of chemicals regulation and the attempts to make it more effective.” (Nordbeck 2002, p.23)

The central point we risk missing is that chemical regulations are put in place because of a political and societal wish to protect human health and the environment.

There is no doubt that there will be clear benefits to human health and environmental resources if there are less hazardous substances in products, air, soil, water, buildings, etc. The challenge is how to measure these impacts in monetary terms to enable them to be directly compared with implementation costs. Despite the great methodological problems in doing so, some attempts have been made in putting monetary values on the expected benefits of REACH:

- Costs of occupational injuries and fatalities could be reduced by £64-129 million over ten years (RPA 2001);
- Costs of occupational asthma and dermatitis could be reduced by £580 million to £1.2 billion over ten years (RPA 2001);
- The socio-economic costs of allergies in Europe have been estimated to €29 billion per year and are believed to be reduced by a few percent with stricter chemicals regulation (EC 2001b).

These figures show, though they are raw estimates, that there are large savings for society to be made by applying a more precautionary chemicals policy. Chemicals may also be partly responsible for some cancers, both in the work force and in the general population. However, most benefits to health and the environment have not been given a monetary value, mainly because this is methodologically and ethically difficult. Many open questions remain, such as: How do we value fewer chemicals in breast milk or foetal blood? Or immune system dysfunction in polar bears or seals?

Just because health and environmental benefits are difficult to quantify, it does not mean that they are unimportant – in reality they are the driving force behind the regulation of chemicals, so ignoring them is not acceptable.

5 Responses to industry claims and concerns

The chemical industry and other industries have been making a wide range of claims, many hugely exaggerated, about the impacts of the REACH system. The most important claims are discussed below.

5.1 “The chemical industry will be forced to leave the EU”

The chemical industry has claimed that if there are increased costs for environmental and health regulations, parts of the industry could be forced to move to the USA or to developing countries, where the costs would be lower (BASF 2002). This would then have serious implications for employment in Europe, since ca. 1.7 million people are directly employed by the chemical industry (VCI 2002).

It is clearly important that the European chemical industry remains competitive, and stays based in Europe. As discussed above, REACH will provide many economic benefits to the chemical and other industries. In addition, the costs imposed by REACH or other environmental regulations are not likely to be the deciding factor in moving production out of Europe. Research examining the impact of high environmental standards on competitiveness has tended to find no evidence that high environmental standards reduce competitiveness (see for example Jaffe 1995). The reasons are for example:

- The compliance costs are generally relatively low. Industry’s total costs for environmental regulations are ca. 2%, both in the EU and the USA (Pearce 2000). As we have seen, the cost of REACH would be ca. 0.1% of the industry’s turnover. The costs for an industry to migrate would be substantially higher;
- The chemical industry is dependent on skilled employees and research facilities, with which it is well supplied with in Europe;
- It is important for the industry to be able to rely on a functioning infrastructure and political stability to avoid unpredictable costs;
- It is possible that other countries will follow EU’s stricter chemicals legislation, which would make a move out of Europe more costly in the long run, and make companies lose the opportunity of a first mover advantage in new technology and substances.
- Companies outside the EU, but exporting to the EU, will still have to comply with REACH.

The compliance costs for environmental regulations are many times outweighed by the benefits the industry enjoys from a common European market. The current EU population is 375.3 million, with a further 4.77 million in the EEA, and up to another 169.2 million people in the 13 applicant countries. That makes a total of 549.3 million consumers, which is nearly double the US population. (2000 figures, EFTA 2002, EC 2001a)

It is worth noting though that regardless of environmental regulations, there is a trend in the chemical industry to concentrate some production to developing countries. In a study by the OECD (OECD 2001) it is noted that there is a growth of production of basic, high volume chemicals in developing countries, while the OECD countries tend to focus on specialty chemicals (life science, agriculture, industrial chemicals etc). The study also concludes that: *“The trend towards fewer and larger multinational producers is expected to continue, with companies becoming increasingly knowledge-based rather than asset based”* (OECD 2001, p.39). For the EU to keep its chemical industry health it is clear that education, research and labour policy will be the major determining factors in the future, not environmental policy. In addition, a benefit of REACH should be that the industry’s image improves, enabling it to recruit more easily.

5.2 “The regulatory system is better in the USA”

The chemical industry often claims that innovation is better stimulated in the USA than in Europe. It argues that the bureaucratic and expensive registration system in the EU does not favour innovation (Chemie 2000). It bases this judgement mainly on comparing the amount of new substances that are being registered yearly. The chemical industry points out that more than ten times as many substances were registered in the USA than in Europe during the past 20 years, which could indicate that the EU system is not innovation friendly (Chemie 2000).

Researchers who have been looking at the trends of new substance registrations over time have drawn other conclusions (Nordbeck et al 2002). When the EU started registering chemicals in 1983, it had a base of more than 100,000 existing chemicals. The US inventory started four years earlier, but contained only 62,000 chemicals. The number of newly registered chemicals increased rapidly in the US until 1988, but then it started to decline. In 1999, the number of chemicals registered in the US converged with the European. Hence, in recent years, these data do not support the claim that there is higher innovation productivity in the US. The larger inventory of existing chemicals in Europe might be an explanation to why the total numbers of newly registered substances have been higher in the US in the last decades.

It is also interesting to note that in the US it is mandatory to register a substance before it has been manufactured, through a premanufacture notice. Most of these chemicals are never brought to the market (only 10% are estimated to result in substances sold on the market). The US EPA receives 1,500-3,000 premanufacture notices per year. In the EU, the law requires review prior to market rather than prior to manufacture, and thus results in 200-300 applications per year (Goldman 2002). It seems as if the figures from these two rather different procedures have been mixed up in some reports, and they might both have been assumed to stand for finalised registered substances sold on the market. The aim of premanufacture registration in the US is to give a company feedback on the likely hazard properties of a chemical (using quantitative structure activity relationship computer software), enabling them to realise, early in development, if a chemical is likely to have hazard properties which will cause regulatory problems.

No one denies that the present EU system is slow and inefficient in many ways and that it needs to be reformed through implementation of the REACH system. Despite this unfavourable situation, researchers who compared 50 chemical companies with the highest numbers of innovations in a given period, found that 23 were from Europe (46%), 21 from the USA (42%) and 6 from Japan (12%). Europe and the USA were in absolute terms approximately on the same level (Fleicher 2000).

From this information one can conclude that the US system is not necessarily more innovation-friendly than the EU system. Neither does it seem to be more effective when it comes to protecting health and the environment. Just as the present EU system, the US chemical regulation differs between existing and new substances, where existing substances are exempt from risk assessments. Even for the approximately 2,800 high production volume chemicals (for which a special voluntary initiative with industry exists) only 7% have got adequate safety data publicly available (Goldman 2002). Old chemicals are “innocent until proven guilty”, and the burden of proof lies exclusively with the public authorities, who’s work can be particularly hampered due to the strict rules on confidential business information. For new chemicals testing requirements exist, but they are less stringent than the EU’s, since they do not require a screening toxicity dataset but rely mainly on structure/function data (Goldman 2002).

The general US approach to regulation has often been portrayed as more cost-efficient than the European, since it in general involves less up-front legislation. However, the US system complements the generally weaker regulation with an active liability regime, which is estimated to cost US industry 1.9% of GDP (\$180 billion), in contrast to the UK, where liability costs are less than 0.5% of GDP (IHT 2002).

The ever-rising asbestos claims provide a salutary example, with US claims having substantial impacts on European companies such as ABB, who have proposed a \$1.1 billion settlement to cases against them, and PricewaterhouseCoopers estimates the costs for the European insurance industry at up to \$80 billion (IHT 2002). In addition, 60,000 jobs are believed to have been lost in the US through asbestos-related bankruptcies (FT 2002).

It could be argued that the predictability of the REACH system is more business-friendly than the unpredictability of a system predominantly based on liability, particularly as scientific advances are now making it easier to prove causality (Warhurst 2002). Of course, the EU still needs an effective liability system as one of its elements, but the REACH system will reduce the risks of companies running into liability problems.

The US (and other countries) have the same ‘existing chemicals’ problem as the EU. The EU looks like it will be the first to address this backlog, through the REACH system. It is likely that other countries will have to do the same eventually – but when this happens companies in the EU will already have had the ‘first mover advantage’.

5.3 “REACH will create barriers to trade”

Industry positions stress the fact that the new chemicals policy must be compatible with WTO regulations, to avoid trade conflicts (CIA 2002, VCI 2002, CEFIC 2002b). While this is important, WTO rules are more complex than is often portrayed, and are open to interpretation in many areas. Crucially, the WTO allows countries to set their own level of safety protection; in the preamble to the “Agreement on Technical Barriers to Trade” it states:

“Recognizing that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade.”

The key feature of WTO rules is the concept of equality of treatment, which is reflected in the above statement. Therefore, to put it simply, if the EU requires its domestic producers to follow the standards set in the regulations, without biased exemptions, it can require the same from external producers.

The current regulatory system already covers imported chemicals and preparations, which leaves the issue of chemicals in imported articles as the main point of debate in the new REACH system. Interestingly, business is split on the issue of incorporation of chemicals in imported articles, with downstream users in the EU stating that substances in imported articles should be covered by REACH (CEFIC, 2002e), whilst the American Chamber of Commerce (2002) and the Japan Business Council in Europe (2002) are among those who call on the Commission not to include imported articles in the regulations. Some of the American lobbying on this issue is extremely misleading; see below.

In the view of the environmental NGOs, chemicals in imported articles must be covered by the system, for example by importers having to provide a declaration of conformity with

REACH, stating that the chemicals present in the article have been registered in REACH and they are being used in accordance with any restrictions imposed.

Lack of control of substances in imported articles will lead to:

- Relocation of the production of threatened articles to countries outside the EU.
 - Discouraging innovation of new products
 - Damaging EU jobs
 - Promoting damaging industries outside the EU
- Continued import of articles containing hazardous substances, leading to continuing human and environmental exposure.

Control of substances within all articles will lead to:

- Promotion of innovation within and outside the EU
- Cleaner industries outside the EU exporting to the EU
- Protection of EU jobs against poor quality imports
- A level playing field

As part of its responsibility towards global chemical safety the EU would also need to make a maximum effort to tell the rest of the world about REACH, including the new, freely available, chemical safety database.

5.3.1 Extreme scaremongering from the American Government & Chemical Industry

In spring/summer 2002, a US Government ‘non paper’ starting circulating in the EU, which included some strong criticisms of the Commission’s White Paper. One of the most striking was the claim:

“Examination of just four commercially important chemicals on the authorization list shows that \$8.8 billion worth of downstream products are at risk for bans or severe restrictions under the new system.” (US Government, 2002)

On further investigation, it was confirmed that this figure came from a paper by the American Chemical Industry Association (the “American Chemistry Council”, ACC), which concludes that:

“If the proposed EU policy addresses chemical constituents in finished products, the impact on U.S. exports would be wide in scope. Examination of just four commercially important chemicals on the EU authorization list shows that \$8.8 billion worth of U.S. exports are at risk.” (ACC 2002)

The chemical that makes up the bulk of these ‘at risk’ exports is acrylonitrile, which is widely used to make polymers, for example ABS plastic (acrylonitrile-butadiene-styrene), used in many electronics items such as computer housings. The bulk of the \$8.8 billion figure is made up of US exports of business machines, at \$7.485 billion, in which acrylonitrile is involved in their production in some way. So, to put it simple, when ACC say that \$8.8 billion of US exports are ‘at risk’ they are assuming that there is a reasonable risk that the EU will ban the import of US business machines, such as computers (and by implication, would also ban their import from other countries and their production in the EU, if they contain the same plastics).

Is the White Paper proposing to ban the production and import of most computers?

The source of this misunderstanding is the assumption that a chemical subject to authorisation – such as a reactive intermediate like acrylonitrile – will be banned from all uses, and use in the production of all articles. There are two key misunderstandings here

- The Authorisation system is mainly designed to target substances of very high concern used outside rigorous containment. Producers and users of acrylonitrile will need to demonstrate this containment, and will then be subject to either a general exemption from authorisation (as the White Paper states, “*Uses which do not give rise to concern - such as well controlled industrial uses or uses in research laboratories - may be subject to general exemptions from the authorisation procedure.*”) or a specific authorisation for this type of use of the specific chemical.
- Regulations regarding the presence of chemicals in final articles (whether imported or made within the EU) will not cover the monomers used to make polymers in the final article, e.g. the acrylonitrile used to make ABS, unless the monomer is present in the final product, which is unlikely given the reactivity of acrylonitrile. The import of ABS-containing business machines from the US would therefore be unaffected by REACH.

It is unfortunate that the US Government did not do more research itself before repeating these exaggerated chemical industry figures in their “non paper”. It’s worth noting that other figures in the “non paper” are also flawed – see page 20.

5.4 Concerns of downstream companies

Downstream users of chemicals are a crucial part of the REACH system, and their voice needs to be heard in the debate, independent of the voice of the chemical industry, with whom they will not always share common interests.

CEFIC, who represent primarily chemical producers, have been producing information which is very worrying for downstream users, for example their claim that 20-40% of chemicals might be removed from the market (Barometer of Competitiveness 2002).

A number of specific concerns expressed by downstream users are discussed below.

5.4.1 “Delays in time to market”

The electronic industry, in particular, has expressed concerns that delays in the chemical regulatory system can have major impacts on them, as the innovation cycle in this particular market is extremely short and that delays of some months in the availability of a chemical are of high concern.

In principal this concern is valid, however the current debate lacks more detailed information on the extent of the problem, where exactly it would occur and how the current and new systems would compare.

Three scenarios could be described where an electronics manufacturer wants to import a processing aid to Europe, and this processing aid contains substances:

- **Not registered at all in Europe.** This is already an issue under the current regulatory system, which would require such substances to be registered under the new substances process (similar requirements exist in the US and Japan). REACH will simplify this process by increasing tonnage thresholds for testing of new substances. Industry sources suggest that new substances registration can be a quick process, if documents are well prepared.
- **Not registered under REACH.** If a substance is an existing substance, but has not been registered by any company under REACH, and is to be imported at a tonnage which requires registration at the date under discussion, then the importer will need to provide a risk assessment which includes the intended use. Once the REACH risk assessment process is widely understood – it is not likely to be hugely different from current methodology, and is

likely to be simpler – this should not be an overly time consuming process. In addition, there will also be guidance available to make clear if waiving of testing can be claimed.

- **Not registered for this particular use.** Under REACH the importer must risk assess any new intended use. In most cases such a risk assessment is likely to be very straightforward.

One of the main aims of the reform is to provide simple, transparent and less bureaucratic chemicals management, which should therefore result in fewer time delays and more clarity of process. The risk assessments performed for REACH will also be useful in the industry's own health, safety and environmental systems. Much of the concerns expressed by industry are based on the current cumbersome process of comprehensive risk assessment for multi-purpose substances. Compared to that, a well documented one-use registration should be far more straightforward and rapid.

5.4.2 “A rationalisation of chemicals will occur”

Many sectors have expressed concerns about a possible rationalisation of the chemicals available to them, with RPA's business impact study predicting that 20% of the substances on the market, those of particularly low value, could be withdrawn (RPA 2002b). Though this could be valid in exceptional cases, there are a number of factors that will considerably limit its impact:

- The market is flexible, and the chemical supply chain can pass on increased costs of individual components, which will generally make up a tiny percentage of the cost of a final product.
- Registration requirements will be tiered, with low volume chemicals being registered substantially later than those at high volume. This will both delay any registration costs and is likely to reduce the scale of these costs, as innovation in testing methods may reduce testing costs and a well established regulatory system reduces administrative costs.
- In addition, a low value usually indicates that i) either the users does not fully depend on this substance or ii) there is more supply than demand in the market. Hence the low value may indicate that the demand side is flexible giving room for adapting to any rationalisation effects.
- There may be a few chemicals which of such a low value to the producer that they are not prepared to register them. In such cases it should be possible for the user register them, if there is no alternative available.

5.4.3 High costs for producing low volume speciality chemicals

Companies using and producing low volume speciality chemicals have expressed concerns over how to recover their costs for testing and risk assessment whilst competing in the global market. There are three key responses to this concern:

- As described in the previous section, registration of low volume chemicals will occur considerably later than those of high volume, which will give time for innovation and experience to reduce testing and registration costs.
- A properly-functioning enforcement system should ensure that competitors from outside the EU still have to conform to EU requirements if they export to the EU (which many will, due to the half a billion consumers), including sharing of testing and assessment costs.
- Companies outside the EU are likely to become increasingly interested in the assurance that a company is selling them a chemical with a high quality safety assessments, completed to European standards.

5.4.4 A large number of substances needing to be registered

Some sectors, such as textile processing suppliers, are concerned about the great variety of substances that they use when producing their articles. Such companies are particularly concerned about four issues:

- (i) The producers of the substances may have a low interest in registering the textile application of a multi-purpose substance if the market share is low (e.g. < 5%). In such case the formulator is responsible for the risk assessment for this use.
 - As mentioned above, the risk assessment of an additional use should, in most circumstances, be reasonably straightforward, so be of low cost.
- (ii) The producer may be willing to cover the textile application in his risk assessment, however the downstream user is reluctant to disclose details on the conditions of use, aiming to protect his business secrets.
 - The new system will require improved co-operation up and downstream. Such co-operation will cut costs for all parties, so is likely in most situations.
- (iii) The European manufacturer of textile processing chemicals imports components from outside the EU. His supplier is not willing to disclose information relevant for registration in Europe and the European customer is of minor importance for his business.
 - Most suppliers of chemicals outside the EU will adapt to the new rules in the EU, as it is a major market that they cannot afford to ignore. A refusal to disclose safety information is not acceptable.
- (iv) The customers (textile finishers) have to compete with the textile manufacturers in Asia and hence will be reluctant to contribute to recovery of assessment costs occurring in the European chemicals supply chain.
 - Competition with textile manufacturers outside the EU is a serious issue, but can partly be dealt with through ensuring that the new regulations state that substances contained in articles imported into the EU must be registered under, and used in accordance with, the REACH system. In addition, there is increased public focus on textile safety, which is likely to increase as public knowledge of some of the chemicals involved improves. Many producers outside the EU will realise the advantages of being able to claim that their products are produced according to EU standards (e.g. the CE mark), particularly if the problems of less safe products are exposed (including impacts on worker health outside the EU).
 - Some retailers already have well-developed chemicals policies which they apply to their suppliers throughout the world. For example, Marks and Spencer's has had a dyeing and finishing code of practice since 1995, which bans the use of many chemicals (M&S, 2001). Otto in Germany established a qualification programme for its textile suppliers in 1996, including test data requirements and substance bans. More recently, Otto has been qualifying and certifying its Turkish textile suppliers under the "Pure Wear" programme (Otto, 2002).

5.5 Testing costs: "Re-testing on 12.8 million animals"

There has been much debate on the potential costs of additional safety testing for those chemicals that have little or no safety data available – which appears to be the majority of chemicals, according to studies done by the public authorities. Nevertheless, there is great uncertainty about the availability of safety data within the industry. Industry is constantly claiming that their products are safe, implying that they must have the safety data. But at the same time industry assumes that nearly all existing chemicals need will require a full safety data set to be generated.

Friends of the Earth published a detailed report (freely available on the web) on this issue in May 2002 (FOE 2002), so we will only cover the issue briefly here. The Friends of the Earth report discusses the inaccuracies that are incorporated in many of the calculations that have been done, and also goes on to suggest methods of developing and implementing alternative non-animal tests. Environmental NGOs have also been working closely with animal welfare and animal rights groups to promote the importance of data sharing and the development of alternatives (EEB et al 2002, EEB et al 2001).

It is, however, worth pointing out in this paper that many players in the debate persist in giving inaccurate information. The most common source of inaccurate information is a paper that the UK Institute for Environment and Health (IEH) produced for the UK Government in 2001 (IEH 2001). This report had a large number of questionable assumptions, including:

- all 30,000 existing chemicals produced or imported at greater than 1 tonne per annum would have to have animal test data - whilst the White Paper specifically stated that the 20,000 chemicals produced/imported at <10tpa would generally not require animal testing.
- no chemicals will be withdrawn from the market because of concerns about their safety profile.
- no chemicals will be grouped, or use data from similar chemicals.

These concerns, and others, were pointed out numerous times by environmental NGOs, for example in a joint paper in August 2001 (EEB et al 2001). Eventually, IEH re-did their calculations, as a result of pressure from the environmental representatives on the UK Government's stakeholder forum on chemicals. This revised paper, with considerably reduced predictions, was presented at the March 2002 UK Stakeholder forum meeting (IEH 2002), and is further discussed in the Friends of the Earth paper.

The revised IEH report – which accepts that the first paper was a 'worst case' analysis - examines a range of scenarios, with scenario 2 the closest to the White Paper proposals – this scenario gave a total of 2.8 million mammals for all testing, substantially lower than the 8.4 million mammals (plus 4.4 million fish) in the original study. However, as the Friends of the Earth paper points out, there is a considerable potential to reduce this figure, for example through grouping of chemicals and innovation in alternative testing methods (neither of which is incorporated at all in the IEH's Scenario 2).

In spite of the fact that the original IEH study was heavily criticised, and has been superseded, it is still being referred to by some players, including the chemical industry and the US Government:

- The Director of the UK Chemical Industries Association, Judith Hackett, stated in November 2002 that "*According to a UK study, up to 12.8 million laboratory animals would be needed to carry out the full scale of tests required of at least 30,000 chemicals*". These figures are from the original IEH study, and are particularly surprising given that Judith Hackett is a member of the UK Government's stakeholder forum (EDIE, 2002).
- Figures from the outdated UK IEH study were also quoted in the US Government's 'Non paper' in April 2002
"Testing costs will total Euro 9 billion, according to a UK Institute for Environment and Health study...The UK study estimates that the EU would need to extend its time line by 36 years, to 2048, to accomplish the minimum level of testing...The same UK study estimates that nearly 13 million animals will be required for testing under the proposed system." (US Government 2002)

This is not the only doubtful information in this paper - see p17 for more.

Another frequent problem is the use of the term ‘retesting’, as if the EU proposals are aimed at repeating safety tests that have already been done. As is well known, the aim of the REACH proposals is to ensure that there is adequate safety information on chemicals – not to ‘retest’ any chemicals. One example of this problem was in a speech by the US Ambassador to the European Union, Rockwell Schnabel, on 3/12/2002:

*“New regulations being drafted by the European Commission will require **retesting** of some 30,000 chemicals”* (Schnabel, 2002, our emphasis)

5.6 An uneven distribution of implementation costs will put a particular burden on SMEs

In many industry statements it is claimed that small and medium sized enterprises (SMEs, defined as having <250 staff) will have to bear higher implementation costs, in relative terms, than bigger companies and will be wiped out by the new system. It is clear that SMEs in some sectors will face problems in adapting to higher standards, but this cannot be used as an argument for weakening regulations, as chemicals from SMEs are no different from those from multinationals. We would therefore propose that Governments should provide assistance to SMEs, not only to enable them to implement the new legislation, but also to help them move to greener chemistry. Numerous studies of waste minimisation in SMEs have shown that many are wasting large amounts of money because of poor management and selection of chemicals. Government-funded projects to advise SMEs have been very effective in saving large amounts of money, and should be expanded.

In addition, SMEs are likely to gain from a number of the market changes that are likely to occur as a result of the new legislation, for example:

- **Improved transparency and communication through the supply chain** will lead to increased power and confidence for downstream users and SMEs, for example allowing them to make more informed choices between competing suppliers.
- **The new legislation is likely to promote a move from chemical products to services, which will provide an opportunity for innovative SMEs.** Chemical ‘service’ companies focus on providing a function for their customers rather than a product, and they have more opportunities to reduce risks at the production, use and waste disposal stage. SMEs are perfectly placed to develop such services.
- **Being smaller in size means that some SMEs are able to be more flexible and innovative than larger companies.** Some SMEs will therefore be well placed to capitalise on the development of safer alternatives.
- **Multinational companies will have more responsibility to provide information to downstream users,** assisting SME customers in implementing pollution prevention, resource efficiency and safety policies.

Nevertheless, it has to be acknowledged that the main challenge to the chemical industry as a whole, and not just SMEs, is coming from global competition, not environmental or health legislation. According to the OECD's study (OECD 2001) on the environmental outlook for the chemical industry, the trend of companies consolidating into ever-larger multinationals is likely to continue.

5.7 “The chemical industry is taking responsibility through ‘Responsible Care’”

In its response to the Commission’s White Paper, the chemical industry often comes back to Responsible Care. It has repeatedly stated that its activities are safe and constantly improving, with references to the results of Responsible Care (BASF 2002, CEFIC 2002b). Responsible Care is proclaimed as a guarantee for responsible chemicals management. BASF states that: *“We act in a responsible manner and support Responsible Care initiatives. Economic*

considerations do not take priority over safety and health issues or environmental protection” (BASF 2002).

To respond to these claims adequately, we must examine what responsible care is, and does it mean that the chemical industry has the safety data on its substances and can guarantee their safe use?

5.7.1 What is Responsible Care?

Responsible Care is the chemical industry’s unilateral voluntary initiative, which it claims “improves environmental, safety and/or health performance”. It was developed in Canada in the 1980’s as a reaction to the public’s lack of trust in the industry and to the increased regulatory burdens governments put on the chemical industry in order to improve public safety (ICCA 2002). By introducing voluntary measures, industry wanted to show that it was taking responsibility and that mandatory regulations would be superfluous (Chemical Industry Archives 2002).

Responsible Care can now be found in 47 different countries, with each national chemical industry association deciding how ambitious Responsible Care should be. Many associations require, as a condition of membership, that the member companies subscribe to Responsible Care. However, so far there has been no example of any actions taken against companies not signing up to the programme, or not complying with it (Chemical Industry Archives 2002).

One of the catch phrases created when launching Responsible Care was: “*We don’t expect the public to trust us, we ask them to track us*” (CMA 1990, in Chemical Industry Association 2002). The question then remains: Is it possible to track changes in the chemical industry by looking at Responsible Care?

Most Responsible Care programmes only contain a set of guiding principles, which do not provide a useful framework for judging the level of progress attained by a company. To be measurable and meaningful, these principles would have to be put into practice through a set of clear targets and indicators. In addition, these measurable targets would have to be independently verified. However, most Responsible Care programmes stop at the guiding principles, without developing any codes or practise with indicators that can be quantified or measured.

An International Labour Organisation (ILO) study published in 1999 carried out an international evaluation of a large number of Responsible Care programmes (ILO 1999). Looking at the European countries that figure in the study (UK, France and Sweden), one can see that none of them has sufficiently developed codes of practise to enable measurements of progress on product stewardship, employee health and safety, pollution prevention and community awareness. France, for example, had no code of practise addressing any of the main topics that Responsible Care is supposed to control (ILO 1999).

In 2002, CEFIC published a status report of the performance of Responsible Care in Europe 1996-2000 (CEFIC 2002a). Twelve indicators were reported on, mainly focusing on emissions to water and air caused by production. CEFIC announced drastic reductions of emissions of e.g. phosphorous, nitrogen, heavy metals, SO₂, NO_x and VOCs. But were these reductions a result of the voluntary responsible care programme? Unfortunately CEFIC fails to answer this question, as it does not consider the vital fact that its member companies were subject to regulatory and other changes during this period, after all, Responsible Care, being a voluntary initiative, should by definition report on what is being done in addition to mandatory regulations, rather than what companies are forced to do anyway. For example:

- This period coincided with continued tightening of emission limits in existing regulatory regimes, development of new regulatory regimes, and radical changes in the markets for some hazardous substances due to new restrictions, including:
 - Pollution control regulations at national level which regulate multiple emissions from industrial processes (e.g. Integrated Pollution Control in the UK), which are now being harmonised through the implementation of the Integrated Pollution Prevention and Control Directive, which demands the use of Best Available Technology;
 - The Air Quality Framework Directive (1996/62/EC), and Daughter Directives (1999/30/EC), regulate a number of air pollutants including SO₂, NO₂, NO_x, benzene, heavy metals (e.g. cadmium, arsenic, nickel, mercury, lead, etc.);
 - National Emission Ceilings (not in force yet at EU level, but many Member States have already regulations in place) regulating emissions of NO_x, SO₂, VOCs and ammonia;
 - Dangerous Substances Directive (76/464/EEC) restricting the uses of a number of problematic chemicals.
 - Constantly developing Health & Safety legislation which can have a major impact on the economics of producing and using more hazardous substances.
- This period also included economic changes which are likely to have changed emissions of these chemicals – for example more polluting industries closing in the former East Germany.

Because of the weak targets and indicators, and the failure to disaggregate regulatory and economic changes, it is impossible to measure any clear improvements triggered specifically by Responsible Care that go beyond legal requirements.

Just like any management system, RC could, if well designed, assist in a company in finding the weaknesses of its management of environmental and health issues. However, in comparison with externally verified management systems such as ISO14001 and EMAS, Responsible Care is always going to be weak, as it does not require external verification and, unlike in EMAS, there is no obligation to make documents public and involve stakeholders.

It is also worth noting that even complex, externally certified environmental management systems such as EMAS and ISO14001 have yet to be shown to have a substantial impact on environmental performance. A detailed analysis of Operator Performance and Risk Assessment (OPRA) by the Environment Agency in the UK found that 15% of processes with either EMAS or ISO14001 received poor scores for pollution incidents and complaints. For companies without a certified environmental management system, 14% of processes had a poor compliance score (ENDS Report 2002a). The figures suggest that it is by no means certain that any environmental management system, not even when certified, will result in better environmental performance.

As an example of the lack of evidence that Responsible Care works, one of the sites with the worse OPRA rating in 2002 was the Great Lakes Chemicals site in Newton Aycliffe, UK. This plant has a long record of bad environmental performance and has recently been prosecuted in the UK for a major pollution incident of brominated compounds in the North Sea, yet Great Lakes is committed to Responsible Care and claims to have translated it “*into a course of action and a way of life*” (ENDS Report 2002c).

In the USA in the 1990’s, more than 10 million dollars were spent on advertisement and public relations about the programme (Chemical Industry Archives 2002).

5.7.2 Responsible Care and the new REACH system

One component of Responsible Care is supposed to be the principle of Product Stewardship:

“We will assess the risks associated with our products, and seek to ensure these risks are properly managed throughout the supply chain through stewardship programmes involving our customers, suppliers and distributors.” (ICA 2002)

It’s already well known that in reality the chemical industry has little safety data on many of its chemicals. However, CEFIC themselves provided further evidence of the inadequacies of product stewardship, in their pilot trial of their “Thought Starter”.

In 2001, CEFIC published its view of what REACH should consist of, in its ‘Thought Starter’ (CEFIC 2001). In the view of the environmental NGOs (and others) this document was not, in reality, an implementation of REACH, but was instead a completely different proposal, which would continue to put the burden of evidence on the authorities.

CEFIC then set up a pilot trial of this "Thought Starter", performed by the consultants RPA. The final report was published in March 2002 (RPA 2002a). It involved 11 companies that had volunteered to participate in the study, and each company could chose which substance it wanted to submit for registration. All participating companies had Responsible Care programmes in place. Considering these favourable conditions for the trial, the results were surprising:

- *“In four cases (out of eleven), the **data provided** on physico-chemical properties, toxicity and ecotoxicity was **significantly below that required** and thus did not result in a suitable basis for a risk assessment of the substance” (RPA 2002a, p.10);*
- The companies failed to provide enough data for the reviewer to understand how a substance is used throughout the product life. *“In general, the companies held some exposure data, with this often having been developed owing to Responsible Care audits” (RPA 2002a, p.22)* However, the problem was that there was very limited data on **downstream** use and exposure. Even where downstream users gave information there were still important data gaps in e.g. working handling scenarios, environmental releases and residuals in end-products. *“Often this is because such data is not regarded as a priority” (RPA 2002a, p.22);*
- *“Many of the companies were not able to provide data on EU or global **production volumes**” (RPA 2002a, p.8);*
- Some companies could not provide a quantitative risk assessment with PEC/PNEC ratios (predicted environmental concentration to predicted no effects concentrations). *“In reviewing the submissions, we did not always find the more qualitative assessments to be convincing. [...] some of the more qualitative assessments provided **insufficient information** to give us confidence in the conclusions drawn.” (RPA 2002a, p. 24);*
- For the substances requiring authorisation (substances of very high concern), data could only be provided for the use and safety measures taken on the production site, not at the user installations. Companies could also not provide a **socio-economic** justification for why the substance is used in preference to any alternatives. (ibid, p.29).

This trial clearly demonstrates that Responsible Care and Product Stewardship are not working, even in companies that volunteer to participate in such trials. There is an obvious lack of hazard data on substances, lack of exposure information, missing communication with downstream users and no clear analysis on why a hazardous substance is used instead of an alternative. According to the guiding principles of Responsible Care, this information should be part of responsible chemical management.

Despite these obvious shortcomings of the Thought Starter and Responsible Care, CEFIC describes both as success stories and models to be build on (CEFIC 2002a, 2002b). Another interpretation would be that Responsible Care needs REACH rather more than REACH needs Responsible Care!

6 Conclusions

The issue of chemicals regulation and its impact on innovation is much more complex than industry and the Commission's business impact study have led us to believe. The picture will not be balanced if only costs and no benefits are accounted for. It is important to realise that stricter chemicals legislation can actually lead to new market opportunities for safer and greener products, with positive spin-off effects in form of better reputation, consumer appeal, improved recruitment potential and acceptance by host community.

Thorough risk assessments and a phase out of the most hazardous chemicals can also minimise future liability claims, which, as we have seen in the asbestos case, can amount to enormous costs for companies. Liability claims are likely to become more common in the future, as new methods make it easier to link exposure and harm.

It is also important to acknowledge that REACH is designed in an innovation-friendly manner, with the setting of a standard (safe chemicals) without prescribing which chemicals or which processes industry must use; with harmonised and strict rules; and with industry involvement. The market for products and services will remain, because consumers will continue to demand them, with the only difference that they must be safe. This will spur innovation of greener and safer products.

When looking at costs and benefits, it is important to keep in mind that chemical regulations are put in place because of a political and societal wish to protect human health and the environment. Therefore, the benefits to health and environment have to be accounted for in an impact assessment. It is difficult to put a monetary value on intangibles such as fewer chemicals in foetuses or breast milk, but it does not make them less important or valuable. Many people would no doubt consider such options to be priceless, and it certainly could be speculated that many women would be willing to pay substantial amounts to ensure their baby was uncontaminated.

The chemical industry talks about its commitments to Responsible Care and Product Stewardship, but there is currently little evidence that they have an impact, with the chemical industry's effort to trial its alternative "Thought Starter" demonstrating the huge lack in safety data and up and downstream communication. In many ways the results of this trial demonstrate the need for REACH.

6.1 The need for positive engagement from industry

REACH provides several mechanisms to promote innovation and sustainable business, but most industry comment has been focussed on extreme claims that the new system will destroy the European economy. We consider that many statements of trade associations and individual companies seem to be in conflict with the long term interests of European industry, promoting a weak regulatory system which would allow the continued use of problem chemicals.

We see an urgent need for more positive, forward-looking, companies to raise their voice on the advantages to be gained from a system that better manages the risks related to chemicals. Many such companies have an interest in supporting a new system which assists them in:

- marketing, buying and using safe chemicals;
- getting good quality information from their suppliers;
- regaining public trust in chemicals used as components in textiles, furniture, toys, electronic goods, cars;

- preventing of economic losses due to: i) a loss of public confidence in particular products; or ii) liability claims; or iii), marketing and use restrictions imposed by authorities as a result of new safety data emerging;
- finding markets for innovative, safe and environmentally sound products.

6.2 A new market in safer chemicals and products

REACH will create a level playing field for all players in an EU market of 550 million consumers, large enough to set a new chemical safety standard that is competitive in the global market. This is a huge benefit to be weighed against any costs of implementing the legislation.

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WWF's European Toxics Programme

WWF's European Toxics Programme is particularly focussing on the new EU chemicals policy.

A general introduction to this policy review is given in the following briefing:

“A new regulatory system for chemicals in Europe: A step towards a cleaner, safer world?”

This publication and others are available from the 'toxics' section of the WWF European Policy Office web site:

<http://www.panda.org/epo/>

WWF's Global Toxics Programme

Recognising the far-reaching effects of pollution on wildlife throughout the world, WWF's Toxics Programme:

- investigates toxic chemicals and their relationship to biodiversity and human health;
- works to phase out and ban chemicals that threaten life on Earth;
- seeks to identify and promote safe, effective, and affordable alternatives.

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The European Environmental Bureau (EEB)

The EEB is a federation of 133 environmental citizens' organisations based in all EU Member States and most Accession Countries, as well as in a few neighbouring countries. These organisations range from local and national, to European and international. The aim of the EEB is to protect and improve the environment of Europe and to enable the citizens of Europe to play their part in achieving that goal.

The EEB office in Brussels was established in 1974 to provide a focal point for its Members to monitor and respond to the emerging EU environmental policy. It has an information service, runs 11 working groups of EEB Members, produces position papers on topics that are, or should be, on the EU agenda, and it represents the Membership in discussions with the Commission, the European Parliament and the Council. It closely co-ordinates EU-oriented activities with its Members at the national levels, and also closely follows the EU enlargement process and some pan-European issues.

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