

The German Advisory Council on the Environment

# On the Economic Impact of the Planned Reform of European Chemicals Policy

# Statement



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## 1 Introduction

1. The German Advisory Council on the Environment (SRU) has on several occasions identified a need for far-reaching reforms in existing chemicals legislation (SRU, 2002, 2000, 1999, 1998). Current chemicals policy does not take account of unacceptable gaps in knowledge on the characteristics and uses of tens of thousands of chemical substances currently on the market. The present monitoring and control system is cumbersome and time-intensive, and only a small number of existing chemicals have been tested for their degree of harmfulness. We thus welcome the European Commission's efforts in attempting to correct these fundamental deficits with its *Consultation Document published in May 2003* (<u>http://europa.eu.int/comm/enterprise</u> /chemicals/chempol/whitepaper/reach.htm).

The new regulatory approach proposed under the REACH system (**R**egistration, **E**valuation and **A**uthorisation of **Ch**emicals) aims to combine existing knowledge on the properties, dangers and uses of substances and to close gaps in the knowledge base. An authorisation system has been devised for highly dangerous substances.

2. Even during its development, the Commission's reform proposals attracted a wide range of conflicting responses from the German government, the general public and from within the Commission itself. While many European countries support the reforms, the German chemicals industry, and its trade and industry associations, have expressed strong criticism of it being a barrier to trade and over-bureaucratic. Critics say the reforms weaken German industry's competitiveness and innovation and, in the worse case scenario, could lead to a reduction in Germany's gross value added by up to 6.4 per cent and a loss of up to 2.35 million jobs in Germany alone.

**3.** The German Advisory Council on the Environment reiterates the position expressed in its last Environmental Report that the costs of the reforms – spread across the REACH system's eleven-year implementation phase – are acceptable and that the system offers numerous opportunities for innovation (SRU, 2002, *Paragraph No.* 377). This is especially the case where it is recognised that comprehensive improvements to the present inadequate system for monitoring and controlling existing chemicals can no more be had for free than can a pioneer role in the global market, which would no doubt more than cover the costs incurred in the medium term. The German Advisory Council on the Environment thus welcomes the enhanced transparency aimed for in the systematisation and consolidation of complex and disparate European chemicals legislation. The Council also acknowledges the Consultation Document's functional deficits, whose correction appears both possible and necessary in the further legislative process.

4. Nevertheless, the German Advisory Council on the Environment sees a need to investigate the concerns of individual sectors and companies, not least those of small and medium-sized businesses. The investigation would look at whether their concerns are perhaps based on unrealistic or exaggerated requirements for disclosure and transparency, or whether they can be attributed to pessimistic interpretations of the wording of the Consultation Document. This type of case-by-case analysis is a vital prerequisite to the further development of the Consultation Document and to ensuring positive cooperation from the chemicals industry in times of economic downturn.

**5.** With this position paper, the Germany Advisory Council on the Environment provides a more detailed statement on the concerns of German chemicals trade and industry regarding the costs and the impacts of the planned reforms in terms of competitiveness and innovation. Based on assumptions made from a critical analysis of the premises underlying the industry cost 'projections', the Council aims to help place the costs debate on a more objective footing. Its most significant findings are:

- The existing cost estimates are systematically too high. The cost calculations take into account neither the opportunities for relatively cost-effective implementation provided for in the Consultation Document nor the savings made from using existing data.
- Given the small scale of the costs incurred by REACH compared to chemicals industry sales, the feared impacts on the industry as a whole are hardly plausible. The underlying models have fundamental methodological weaknesses in that they systematically over-estimate the economic impacts.
- Given its global impact, determined implementation of REACH system objectives could have positive outcomes in terms of competition and innovation. There is potential for worldwide replication and diffusion of the REACH system as a whole or of some of its key components (SRU, 2002, Paragraph No. 42).
- With all the uncertainties surrounding cost-benefit estimation, more recent analyses indicate that the benefits to human health outweigh the costs incurred. The harm caused to animals and plants – not yet evaluated in monetary terms – would also need to be considered.

## 2 Key Components of the REACH System

6. With REACH (Registration, Evaluation and Authorisation of Chemicals), the European Commission is aiming to implement systematic and integrated evaluation of all chemicals found on the market in significant volumes and of all chemicals about to be placed on the market. The Consultation Document combines existing regulations on new and existing chemicals, and directives on the banning and restricted use of hazardous substances, into one comprehensive regulatory instrument: it effectively consolidates some 39 directives and two very lengthy regulations.

- 7. The key components of the REACH system are:
- Systematic Obligation to Document: To comply with their general duty of care, manufacturers and users of chemical substances must produce Chemical Safety Reports to document in a standardised format available information on substance properties, the risks to human health and the environment, and adequate monitoring and control measures.
- Obligation to Register: Manufacturers and importers have an obligation to register substances produced in quantities greater than one tonne. Exceptions exist under specific conditions for polymers and intermediates. A prerequisite for registration is the provision of a technical dossier containing a chemical safety report which includes test data on substance properties, potential risks and information on major uses. The test requirements are phased according to production quantities. Responsibility will lie with manufacturers and importers to conduct the required tests or to have them performed, and to use the results of those tests to classify substances into a set of risk categories. Subject to phased interim arrangements, production and import of non-registered substances will no longer be permitted. The REACH system provides a range of opportunities that allow testing and disclosure requirements to be focused on substances of high concern and to avoid unnecessary duplication of effort.
- The evaluation of individual registrations is a state responsibility. The competent authorities within the Member States have an obligation to monitor the testing procedures involved in the registration of substances produced in large volume. They also have the option of conducting random checks on selected registrations. They may request additional information from manufacturers and users and conduct their own substance evaluation based on the information provided.
- An authorisation process will be implemented for substances whose properties give cause for high concern. Authorisation is required for carcinogens, mutagens and substances toxic to reproduction, persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances. The Member States are

afforded the opportunity to propose the addition of substances of similar concern to the authorisation process (e.g. endocrine disrupters). The Consultation Document exempts from the authorisation process all forms of substance use already covered by other directives. Other more general exceptions may be agreed by committee decisions. Authorisation takes place within specific periods upon application by manufacturers and users. A key authorisation requirement is that the risk posed by the substance be 'adequately controlled'. Authorisation may also be granted in cases where the socio-economic benefits outweigh the risks involved in using a specific substance.

- Authorisation is processed by two committees appointed by the Member States and the Commission, one for risk analysis and one for socio-economic analysis, and is granted by an Authorisation Committee comprising representatives from the Commission and the Member States
- The existing procedure for restricting use will be integrated into the REACH system in a simplified format. The Commission sees restrictions on use as a necessary back-up tool for substances that fall through the authorisation net but are still deemed in need of regulation.
- A European Chemicals Agency will be established to support the implementation and enforcement of the REACH system. The agency will be partly financed by registration fees.

## 3 Preliminary Evaluation of the Proposed System

**8.** The German Advisory Council on the Environment has repeatedly indicated that the exposure of humans and of nature to harmful substances remains an unresolved and ongoing environmental issue (SRU, 2003, 2002, 1999, 1979). The problem areas include:

- The ubiquitous distribution of persistent and bioaccumulative substances across great distances from their sites of production and use, and also their long retention time in ecosystems.
- The impact of numerous substances on human health: the range of effects that give cause for concern has increased in recent years. Apart from those that are toxic, carcinogenic, mutagenic and toxic to reproduction, there are also intensely debated hormonal and allergy-inducing effects.
- The considerable effects of substances on marine ecosystems a priority issue in ocean protection.

A prerequisite for preventive and responsible substance management is knowledge on substance properties and uses and their potential risk to human health and the environment.

Substances whose properties and uses give cause for concern must be monitored and controlled using this knowledge base. The existing monitoring and control system, which involves a multi-phase process that keeps risk analysis and risk management separate from one another, and which only allows use restrictions or bans following comprehensive risk analysis, is too cumbersome to ensure an adequate level of safety for existing chemicals within a foreseeable timeframe (see SRU, 2002, Paragraph No. 338).

**9.** Against this background, the German Advisory Council on the Environment welcomes the Commission's approach to the reforms. The Council's evaluation is as follows:

(1) Although the REACH proposal would have direct application as a regulation, it also has numerous characteristics that lend themselves to a framework directive. Its registration requirements and authorisation process contain many relatively uncertain legal terms that need to be clarified to allow implementation at the respective administrative levels. In further finalisation phases, any review of the Consultation Document should lay store in problem-focused disclosure requirements and a prevention-oriented authorisation system.

Clarification is especially needed on the amount of detail required in chemical safety reports and information on substance uses. In the case of complex production systems (for example, use of a substance in multiple applications or the use of multiple substances by one user or in a multi-phase onward processing chain), without an even more standardised and problem-focused reporting system it cannot be ruled out that the research, testing and documentation obligations would be too much for at least small and medium-sized businesses.

(2) The new Consultation Document provides a range of options for minimising the costs of registration. Manufacturers and users may form consortia to reduce the costs of testing and registration. They also have the option to waive the prescribed standardised tests under certain conditions. Equivalent processes, analogies derived from the properties of structurally related substances and grouping may be officially recognised and authorised. Testing to ascertain the degree of risk to specific environmental media and providing that information by means of chemical safety reports can be avoided if it can be shown that those media are not burdened by the substances in question.

The German Advisory Council on the Environment welcomes such problem-focused relief for the chemicals industry. Nevertheless, it has repeatedly indicated that substance-related risk is not solely dependent on production quantities and that, on the one hand, quantity-dependent test requirements lead to considerable protection deficits while, on the other, they may require unnecessary testing (SRU, 2002, Paragraph No. 360). It is thus worth considering the option of reducing reporting requirements for registration and chemical safety reports and to link them to the level of concern caused by substance properties like persistence and bioaccumulation (see RCEP, 2003). The implementation of a criteria-based 'selection phase' would need to be investigated, which would allow focus on comprehensive reporting and data collection obligations for potentially harmful substances and uses.

(3) Under the REACH system, disclosure requirements for substance registration assume a sense of self-responsibility on the part of manufacturers, importers and users. No provision has been made for system-wide external quality assurance in the evaluation, disclosure and classification of low-volume substances. This only occurs by means of the obligations for transparency and disclosure and these in turn may be restricted by business secrecy provisions. Looked at realistically, it is unlikely that public agencies will exercise the option for random testing during the system's decade-long implementation phase: they will be busy complying with their evaluation obligations, which will take several years at minimum. Because the operability of the entire system and that of other statutory environmental requirements based on classification of chemical substances depends on the quality of the data provided, the

principle of self-responsibility poses considerable risk. Thus, wherever public agency evaluation does not occur the German Advisory Council on the Environment deems external quality assurance indispensable during registration.

(4) The registration obligations for substances contained in imported products are inadequate. These are considerably less stringent than those for substances produced within the EU. This may place European manufacturers at a competitive disadvantage.

(5) While the authorisation system has a pleasingly broad area of application as regards substance properties that give cause for concern, its implementation contains some serious functional deficits. The original aim of adopting a preventive approach by providing for the banning of the use of substances whose properties give cause for concern has been abandoned in favour of a traditional risk-focused case-by-case regulatory approach. In future, a negative authorisation decision will still require proof of a pollutant concentration above an acceptable threshold for a specific environmental medium. This type of risk analysis has long been considered too cumbersome for effective and timely monitoring and control of the vast majority of high-concern substances.

The key authorisation requirement, namely 'adequate risk control', is inadequately defined in the Consultation Document. The operability of the authorisation system is thus endangered. Authorisation decisions are made by a committee that is not provided with clear evaluation criteria. Technical committees are thus overburdened with highly political decisions. A poorly designed authorisation system provides only limited incentive for substance substitution and depends, as has long been the case, on after-the-fact management in response to scandalisation of the impact of harmful substances and their uses. The German Advisory Council on the Environment sees considerable need for further review to establish a sophisticated and prevention-focused reference system for authorisation decisions made by the various committees and for effective incentives for substance substitution.

## 4 Potential Costs of the REACH System

#### 4.1 Methodological Aspects of Cost Estimation

**10.** With the REACH system, the chemicals industry and down-stream sectors of trade and industry that use, process or dispose of chemicals incur direct costs that are spread across testing and registration, administration, authorisation and accelerated risk management. For the most part, these costs involve substance testing when substance-specific data is not readily available. Other indirect costs may be incurred across all sectors of trade and industry if, for example, registration and authorisation make substances or preparations more expensive or if authorisation is not granted. In extreme cases, products may lose out to those of competitors because they are too expensive or their market launch is delayed. This can also impact on business innovation.

These costs must in turn be set against direct cost reductions and benefits. Compared with the existing process, direct cost savings are made, among other things, in the abolishment of testing requirements for new chemicals produced in volumes less than one tonne per year, by the exception provisions for research and development and by the simplified registration process for low-volume production of less than 10 tonnes per year. New chemicals innovation is easier. Despite regulatory systems that differ in detail, there is a global market for substitutes that are more compatible in terms of the environment and human health, and for safer, environmentally compatible products overall. Competitive advantages can thus be assumed. Increased demand for such products coupled with enhanced knowledge of the properties of harmful chemicals signal potential savings in preventive healthcare and environmental protection.

**11.** The Commission has responded to wide-ranging criticism of its White Paper from the chemicals industry and from other industry associations and has softened specific requirements in the text of the draft regulation (the obligation to register intermediates, for example). This can lead to considerable cost reductions. It has explicitly opened up the proposed system to cost-minimising registration approaches. Particularly noteworthy are the option to form consortia, recognition of alternative testing procedures, analogous findings from data on structurally-related substances (Annex IX, 1.3) and other grouping methods (Annex IX, 1.4) and data requirements that focus on substance use. Costs should thus be significantly lower than those calculated in available studies that are based on the White Paper's out-dated requirements.

Accurate quantification of both the total costs and the benefits of the reform of European chemicals policy is, however, impossible given the existing status of the Consultation Document and the various methodological difficulties. A key factor is that, in its fundamental structure, the proposed regulatory text has the characteristics of a

framework directive which is to be further defined in its implementation and enforcement.

## 4.2 Estimating Direct Costs

## 4.2.1 Available Studies on Direct Costs

12. In May 2002, the Commission published a study on estimating the direct costs and potential economic impacts of the REACH system (RPA and Statistics Sweden, 2002). Depending on the structure of the individual regulations, the RPA study projected costs of between EUR 1.4 and EUR 7 billion by 2012, with costs in the region of EUR 3.7 billion seen as most likely. 88 per cent of the costs involve testing required for the registration of existing chemicals (RPA and Statistics Sweden, 2002). In its White Paper, the Commission assumed testing costs in the amount of EUR 2.1 billion by 2012 (European Commission, 2001). The calculations in the RPA study are based on significantly higher cost assumptions than those used in the White Paper. This results in average costs of EUR 154,972 for a basic description involving volumes of between 10 and 100 tonnes per year, while the costs of testing required for substances in volumes of 100 and 1000 tonnes per year (Phase 1 of the EU New Chemicals Directive contains additional tests for the evaluation of long-term undesired effects) would be EUR 419,800, and EUR 638,400 for substances in volumes exceeding 1000 tonnes per year (Phase 2 of the EU New Chemicals Directive contains further tests: for example, for chronic toxicity of a substance) (see SRU 202, Paragraph No. 334 et seq for the requirements of each phase). However, calculations have also been made to take account of the possibility of minimised data requirements. The estimates in the White Paper are based on assumed testing costs of EUR 85,000 per basic description, EUR 250,000 per Phase 1 test and EUR 325,000 per Phase 2 test. The White Paper's calculations do not include additional costs incurred in things like exposure studies, administration, documentation or charges levied by public authorities.

**13.** The RPA study supports the reform's general compatibility with industry and its innovation-fostering approach. It nevertheless projects high costs and impacts on the competitiveness of small and medium-sized businesses in the producer sector and in certain down-stream user sectors. It is estimated that around half of all small and medium-sized businesses produce or use their new chemicals in volumes less than 1 tonne per year and thus benefit from the exemption from the obligation to register. Then again, cost savings are estimated at only around EUR 68 million over the next ten years and are more than off-set by testing costs. Cost reductions of between EUR 400 and 600 million are however projected if intermediates that remain at the site of production were to be exempt from the obligation to register. The exemption provisions for intermediates contained in the Commission's Consultation Document go even

further. As regards small and medium-sized specialist suppliers who either produce or use substances in small quantities, it is feared that production will be halted, that products will become too expensive or that business closures and relocations will result. Simplified testing procedures and the formation of consortia are deemed vital to the economic compatibility of the REACH system (RPA and Statistics Sweden, 2002, pp. 121 et seq). The Commission has integrated these calls into its Consultation Document.

14. The chemicals industry estimates the direct costs to be considerably higher. With 30,000 substances to be tested, the European Chemical Industry Council puts initial estimates at between EUR 7 and 10 billion by 2012, and with the possibility of some 70,000 substances to be tested at around EUR 15 to 20 billion by 2012 (CEFIC, 2002a). The German Chemical Industry Association (VCI) has not produced its own estimates, pointing instead to those of the Commission. According to both CEFIC and VCI, the costs mainly lie in the fine and speciality chemicals sectors. 80 per cent of the overall costs of the REACH system are thus said to be borne by only 20 per cent of businesses, so that an even and moderate cost burden for businesses in the chemicals industry over eleven years can not be assumed. Businesses in these sectors are largely small and medium-sized businesses who often operate in market segments with low profit margins and whose existence would be endangered by the additional burden (CEFIC, 2002a; VCI, 2003a). According to a survey conducted by the VCI, the 13 top chemicals producers in Germany estimate their total costs as regards their obligation to register at between EUR 2 to 2.2 billion (VCI, 2002a). Added to these are the costs of the required chemical safety reports. The VCI estimates these at between EUR 1,000 and EUR 40,000 per substance depending on production quantities (VCI, 2003b).

**15.** A study commissioned by Britain's Department of the Environment and Transport estimates testing costs at EUR 8.68 billion. This is based on significantly higher cost assumptions than in the Commission's study (IHE, 2001). The study expressed general concern about the practicability of the prescribed timeframes. It says that current testing capacities are not sufficient to test some 30,000 chemicals: by 2012 only about 7,040 of the aimed-for 30,000 chemicals could be included in basic testing. Testing 30,000 chemicals would require an additional 12.8 million animal tests (IHE, 2001). Industry argues that the reforms must be rejected on the grounds of animal protection. A closer look reveals, however, that the study is based on unrealistic assumptions: for example, that for each substance a full testing procedure must be carried out using new animal tests. This is not the intention: the issue is to enhance and complete existing data. This figure is no longer mentioned following criticism from environmental associations (Friends of the Earth, 2002).

#### 4.2.2 Cost Estimates: Evaluation

**16.** It is difficult to arrive at an accurate estimate of the direct costs of the REACH system due to the diverse influencing factors, which in some cases are uncertain or unknown. For example, it is not known what substance-specific data businesses already possess. Nor can anyone predict what registration practices businesses will prefer. Nevertheless, the estimates arrived at by the Commission and by trade and industry can be seen as too high. The reasons are as follows:

(1) For low-volume (Phase-In/Existing) chemicals, the obligation to register applies for eleven years from the date the regulation enters into force. Until then, both registering authorities and businesses involved in the registration and authorisation of high-volume substances will have the opportunity to gather experience in the practicable design and implementation of the new procedures, particularly when it comes to cost-minimising alternatives to the standard testing procedures. An adequate period of time has been allocated to preparation for the introduction of REACH system requirements. In each of the studies, however, costs are kept high across the entire period. It is more than likely that the learning curve will result in cost reductions due to product and process innovation, especially in the use of alternative methods. There is potential for structure-response analyses, grouping and limiting to actual exposure paths.

(2) One unknown cost factor is the amount of substance-specific information held by businesses. The high costs pointed to by the chemicals industry as regards risk analysis in substance use and substance characterisation are not plausible. The REACH system is aimed at enhancing and consolidating an existing informational base, not at establishing a completely new one. It can be assumed that for reasons of liability, industry possesses more substance-specific data than is generally made public, particularly regarding health and safety in the workplace and accident prevention (RPA and Statistics Sweden, 2002). Existing data can be used in many cases. IT-based models also play a key role (UBA, 2003). According to the VCI's declaration of self-responsibility in 1997, the German chemicals industry possesses only a minimum of data and emphasises its success in the self-monitoring of chemicals under the EU's Responsible Care Programme. The Existing Substances Regulation also provides for basic data on high-volume substances. There should, then, be an existing set of basic data. If this turns out not to be the case, it would support rather than negate the necessity of the REACH system.

(3) While it cannot be denied that in some cases, and especially in that of small and medium-sized businesses, considerable costs can ensue if multiple combinations of substances are produced or if substance are used other than as intended by the manufacturer. This is where the cost minimisation strategies contained in the Consultation Document should be systematically exploited. What should also be

considered is that to some extent, future public availability of substance-specific data can assist these businesses, most of them being users and not manufacturers. A practicable and informative system of use categories, as already discussed, could keep registration costs within an acceptable framework. In designing the REACH system, attention should be paid to excluding multiple registrations wherever possible and to protecting the property rights of businesses who disclose substance-specific data. Free access to substance databases like that offered by the state of North Rhine-Westphalia can certainly help small and medium-sized businesses to reduce their costs. There is, however, no way that the REACH system will be implemented without any costs to industry.

**17.** One important indicator of the burden imposed by the REACH system is the scale of the costs relative to annual sales in the chemicals industry. Given that the available estimates are based solely on the costs for the European chemicals industry as a whole, the following direct additional costs relative to annual sales are presented for the European chemicals industry only (see Table 1). In 2001, the proportion of the German chemicals industry in Europe's overall sales was 25.7 per cent, which at least indicates its share in the costs (CEFIC, 2002b).

#### Estimated Costs of the REACH System Relative to

	Estimated Total Costs Over Eleven Years (€ billion)	Estimated Annual Costs (€ billion)	Annual Sales 2001 (€ billion)	Relationship Between Annual Addition Costs and Annual Sales (per cent)
CEFIC Estimate				
Total Chemicals Industry	approx. 7	approx. 0.63	519.0	0.12
Manufacturers of Fine and Speciality Chemicals*	approx. 5.6	approx. 0.50	126.6	0.39
European Commission Estimate (Average)				
Total Chemical Industry	approx. 3.7	0.33	519.0	0.06
Manufacturers of Fine and Speciality Chemicals *	approx. 2.96	approx. 0.27	126.6	0.2

#### Annual Sales in the European Chemicals Industry

\* The calculations are based on the assumption that manufacturers of fine and speciality chemicals will bear approximately 80 per cent of the costs. Sales were calculated using the proportion of fine and speciality chemicals in total sales accrued by the European chemicals industry (24.4 per cent in 2001) because that was the only figure available.

Source: In-house collation; after CEFIC, 2002b.

**18.** Independent of whether one takes the rather pessimistic estimate arrived at by CEFIC or the more optimistic one from the European Commission, the overall outlook for the European chemicals industry is one of low direct costs ranging from 0.06 to 0.12 per cent of total annual sales for 2001. The direct additional costs to the fine and speciality chemicals sector, which according to VCI and CEFIC figures would bear around 80 per cent of the costs, lie somewhere in a moderate range of between 0.2 to 0.39 per cent of total annual sales for 2001. These figures should be interpreted with care. To gain a better overview of the costs involved, the table shows the annual costs as an average of the estimated total cost over eleven years. Then again, those costs will not be evenly spread across the eleven year period. Individual businesses may incur higher costs in some cases. Taken overall, the costs identified retain their accuracy as a point of reference.

## 4.3 Estimating the Potential Costs to the Economy Overall

## 4.3.1 Estimates by the Chemicals Industry and the Federation of German Industries

**19.** Because the studies outlined in Section 4.1.2 are solely based on direct costs, the Federation of German Industries (BDI) commissioned management consultants Arthur D. Little to conduct a study on the overall economic impact on German industry (Arthur D. Little, 2002). Using three different scenarios, the study calculates the potential outcomes for German industry. Its *hurricane* scenario is based on experience with substance analysis and the costs and level of effort involved in registration under the existing system. The *storm* scenario adopts the same assumptions the White Paper applies to the cost of testing. Both scenarios assume an obligation to disclose operational and business secrets. The *clouds* scenario is based on the most practicable implementation of the White Paper's requirements, in which costs and level of effort are reduced to a minimum and provision is made for the protection of operational and business secrets. Serious losses are incurred in the storm scenario, while the hurricane scenario results in dramatic losses (see Table 2).

Table 2:

	Production Loss in Production Sector	Gross Value Added Losses All Sectors	Jobs Losses in All Sectors
Clouds Scenario	1.4%	0.4%	150,000
Storm Scenario	7.7%	2.4%	900,000
Hurricane Scenario	20.2%	6.4%	2,350,000

Arthur D. Little Study: Scenario Results

Source: Arthur D. Little, 2002

**20.** A similarly negative estimate was arrived at in a much-quoted study – so far only available in picture and presentation form – conducted by French management consultants Mercer Management Consulting and jointly commissioned by the French Chemical Industry Association and the French government. The study shows that, depending on the design of the regulatory text, over a period of ten years losses to French industry could amount to between EUR 29 and 54 billion or between 1.7 and 3.2 per cent of gross national product per year. A reduction in investment in the region of between EUR 47 and 88 billion is also expected over the same period (Mercer Management Consulting, 2003).

**21.** The studies cite a range of causes for these serious economic impacts. A key influencing factor is production stoppage for chemicals rendered unprofitable due to testing and registration costs. This is considered most likely for production of low-volume substances and special preparations. According to supplementary information from the VCI and CEFIC, depending on the design of the regulatory instrument, this could involve between 20% and 40% of substances produced in volumes of less than 100 tonnes per year (VCI, 2002b; CEFIC, 2002b). It is projected that up to two-thirds of the products manufactured by the German chemicals industry's 1,750 medium-sized businesses who manufacturer these substances will be taken from the market (Ahrens, 2002). Losses in profits and sales are expected for down-stream users: the study conducted by Mercer Management Consulting estimates that approximately 80 per cent of small and medium-sized businesses in France will suffer a 10 per cent decline in production (Mercer Management Consulting, 2003).

According to the studies, the high costs are a result of the obligation for down-stream users to register substance uses that deviate from those intended and registered by the manufacturer. Concerns have been expressed regarding over-burdening of capacities within public agencies and businesses. Most down-stream users use chemical preparations that contain multiple substances, many of which are imported. The obligation to register any substance use that deviates from the manufacturer's instructions and to register all imports places an excessive burden on small and medium-sized businesses (Mercer Management Consulting, 2003; Erbslöh, 2003; Arthur D. Little, 2002). When dealing with imported products, it is impossible to request the manufacturer's instructions directly from the manufacturer. The difficulties involved in disseminating information between manufacturers and users is shown in a study conducted by Öko-Institut, which describes clear, transparent requirements as the key to success (Öko-Institut, 2002).

Taking this argument further, it is suggested that products containing harmful substances or speciality chemicals will no longer be manufactured within the EU or no longer be imported into the EU. Consequently, a reduction in both imports and exports and in investment is shown. Relocation of entire production chains or parts thereof to foreign sites are not ruled out. The study by Mercer Management Consulting concludes that between 10 and 15 per cent of production sites will be relocated in the fine chemicals sector alone (Mercer Management Consulting, 2003; Arthur D. Little, 2002). Concerns are also expressed by the US chemicals industry. The American Chemistry Council estimates that American exports of some US\$ 8.8 billion are at risk and puts registration costs for US exports at up to US\$ 400 million (American Chemistry Council, 2002). The US government has taken note of these figures and has since called for a softening of requirements (US State Department, 2003).

**22.** Critics of the REACH system see their concerns confirmed by scientific evidence in studies like those of Arthur D. Little and Mercer Management Consulting. They emphasise that concerns about serious economic damage have since been confirmed by two independent and unrelated studies. Consequently, they are calling for fundamental corrections to be made to the system by which the level of effort and costs are to be kept to a minimum (see CEFIC, 2003; VCI 2003; BDI 2002).

## 4.3.2 Methodological Critique of the Studies Conducted by Arthur D. Little and Mercer Management Consulting

**23.** An evaluation of the studies gives rise to considerable doubt regarding justification of the extent of the concerns expressed by the chemicals industry and the Federation of German Industries (BDI). The studies indicate considerable weaknesses in the methodology used, which has attracted much criticism from experts (see UBA, 2003). Problematic is also that the full versions of the studies were only published long after the summaries were presented and that primarily the results of the worst-case scenarios were brought into public debate with no reference being made to the REACH system's eleven-year implementation phase. Although it has been the source of regular citations for some time now (see VCI, 2003b), the Mercer Management Consulting study remains unavailable to the public at the time of publication of this statement (July 2003). This lends weight to the assumption that the studies were used to generate politically meaningful results and not as part of conscientious scientific discourse.

24. In estimating the costs to industry under the REACH system, Arthur D. Little devised a calculation model that is based on a three-phased bottom-up approach. Using expert interviews on the influence of key business success factors, the first phase analyses the impacts of the REACH system (costs, time, authorisation obligations, data transparency) on almost all sectors of the processing industry and takes an even closer look at the impacts on value chains in the automotive, textiles and electrical and electronics industries. The second phase extrapolates the results for the value chains and industrial sectors involved in the study by analogy to the entire processing industry. The additional costs identified are weighted with a so-called 'industry factor' comprising the factors 'competitive intensity', 'ability to relocate production' and 'need for market proximity'. The result of such weighting is the relative change in production and the change in gross value added in processing industry. This is then used to extrapolate the results for all industry sectors. It was assumed that upstream input from other industrial sectors into processing industry will change in proportion to production within processing industry. This statistical input-output analysis results in a change in gross value added in German industry as a whole. The resulting jobs losses are identified as percentages of the production losses.

**25.** Apart from diverse issues of detail, the unreliability of this study is highlighted by a number of fundamental concerns regarding its methodology, as outlined below:

- The data that provided the basis for the study on the costs to the sectors in question is not based on data from independent institutions but rather is almost entirely derived from information from the industries involved, which cannot be verified without special expertise. Given that industry representatives had for obvious reasons considerable incentive to adopt strategic response behaviour, considerable doubt exists as to the reliability of the information involved. After evaluation by an expert panel at the Federal Environment Agency it would appear that the costs of risk analysis, and substance characterisation in particular, are significantly overestimated (UBA, 2003).
- The costs to processing industry as a whole are arrived at by extrapolating the results of selected value chains and sectors. It is assumed that the textile, automotive and electronics industries are representative of the sectoral structure within processing industry. This assumption is just as questionable as the assumed overall costs to these sectors.
- The study uses no reference scenario along 'business as usual' lines, so that it is not clear to what extent the calculated impacts can be solely attributed to the implementation of the REACH system or whether they would occur without its implementation. That substances will be removed from the market and be replaced by new ones is a normal process in any market facing the pressures of global competition. These processes are influenced by numerous factors, not just the costs of chemicals registration and authorisation.
- The so-called 'industry factor' which determines the relationship between overall increase in costs and productivity losses, that is, it describes to what extent increased costs can be passed to the customer and the degree of production loss they would lead to, is based on ordinal survey results which are then interpreted on a cardinal scale albeit a rather arbitrary one of 0-12. The actual value of the amounts in millions of euros, which might only make up a fraction of sales and profits, is distorted by the use of a non-transparent classification along a cardinal scale of none to significant impact. In methodological terms, the definition of the industry factor itself appears questionable. The price-elasticity of demand is not taken into account which, among other things, leads to the methodologically false conclusion that where a monopoly exists, additional costs can be completely passed on and thus production losses avoided. But this leads to over-estimation of the costs to users. As regards passing on additional costs, market structure and the price-elasticity of demand must be considered simultaneously.

- The extrapolation of production losses from processing industry to industry as a whole is done by means of input-output analysis. This approach is methodologically outdated and unsuited to calculations over such long periods because a completely static world is assumed in which no natural adaptation processes and no technological advancement take place. The assumption that companies do not adapt to new market conditions and that product or process innovation does not take place is unrealistic. The use of an empirical equilibrium model would have been methodologically superior or 'state-of-the-art'.
- To assume proportional changes at the level of up-stream services is just as inappropriate as linear conversion of reduced production into jobs losses. In the first case, relative price differences for different material inputs are not considered. In the second, sectoral differences as regards labour intensity and associated substitution effects are not accounted for.
- The calculation model takes no account of any benefits that the implementation of the REACH system may bring to German industry. Such benefits may occur from increased work safety and an associated increase in productivity due to lower absences. Also, in the case of changing demand for environmentally compatible products (see Eder, 2003; Eder and Sotoudeh, 2000) the implementation of the REACH system may also have a positive impact on international competitiveness in both German and European industry. The German Advisory Council on the Environment takes a closer look at these issues in assessing the REACH system's impact on innovation.

Overall, the Arthur D. Little study shows an inherent trend towards over-estimation of the costs involved with REACH and towards under-estimation of the benefits. The study does little service to the debate on the economic impacts of REACH.

**26.** The German Advisory Council on the Environment was unable to obtain a copy of the Mercer Management Consulting study. In addition to the less than substantive summary, the only other information available was a slide presentation of the study on the Federation of French Chemical Industries web site, which gives some indication as to the methodology used in the study. This is again based on a bottom-up approach: for 14 segments of the chemicals industry and specific down-stream user sectors, the additional costs are quantified and responses from market players analysed. Five different scenarios are simulated. The results are then extrapolated for French industry as a whole using a macro-economic model. This comprises various sub-modules: costs, market shares, demand for capital and labour, production, and development of the earning population. A detailed evaluation of the study was not possible due to the absence of the full version. For the following reasons, however, the study shows similar fundamental and methodological irregularities to those in the Arthur D. Little study.

These include the absence of a business-as-usual scenario, the extrapolation of production losses via input-output calculations, and the neglect of positive benefit outcomes.

**27.** It is questionable whether, as the studies outlined above indicate, production relocation will occur on a large scale. This is an argument long used by industry in criticising regulation of the environmental sector and, as shown in numerous studies, there is no empirical evidence to back it up (see SRU, 2002, Paragraph No. 61 et seq.). Many sectors find themselves in competition as regards quality and technology. This is especially true of those sectors that use speciality chemicals. A breakdown of the value chain (i.e. the process from the supply of raw materials through to delivery of a product) appears unlikely given the dependence of these businesses on market proximity, qualified employees and infrastructure. It is not expected that competition, in the automotive industry for example, will be purely price-based (see UBA, 2003).

Equally questionable is an assumed significant decline in exports and imports and in investment – particularly foreign investment – in the chemicals sector. For the most part, the German chemicals industry exports to other EU Member States that are all affected by the reforms in chemicals legislation. According to the VCI, the German chemicals industry sold three-quarters of its products within the European Single Market in 2001. The European chemicals industry as a whole sold 71 per cent of its products within the EU (VCI, 2002c; CEFIC, 2002b, 2002c). The share of exports outside the EU in sales by the European chemicals industry was 29 per cent in 2001. In the same vein, the vast proportion of imports come from other EU Member States. In 2001, 19 per cent of imports came from outside the EU (CEFIC, 2002b).

It should be noted that there are also foreign trade benefits to be had. Implementation of the REACH system could motivate or create incentives for both manufacturers and users of chemicals in non-EU countries to import substances and preparations from the EU because these will have the advantage of being declared safe compared with competing products. Businesses will thus face less risk when using a substance or a preparation, which in turn will enhance work safety and productivity. Literature on the impact of stringent product standards on the European Single Market contains comprehensive evidence that (exporting) countries with less stringent regulations tend to adopt the more stringent standards in the medium term (among others Scharpf, 1999, with further references; Eliste and Frederickson, 1999).

As regards complaints that importers will be over-burdened by the obligation to register, it is clear that under the existing system for new chemicals, importers must register every chemical that they import. If substance-specific costs for new chemicals have not been a burden to date, there is no reason why the alignment of substance-specific costs for existing and new chemicals should pose an excessive burden.

#### 4.3.3 The Commission's Total Cost Estimate

**28.** The Commission has also estimated the overall costs to the economy of the REACH system. It estimates overall costs of between EUR 14 and 26 billion over the period up to 2020. The Commission thus places the direct and indirect costs of REACH in the region of EUR 18 to 32 billion (Liikanen and Wallström, 2003) over the period up to 2020.

### 4.4 Estimated Potential Economic Benefits

29. One-sided focus on the costs to and impacts on innovation in business and on competitiveness neglects the diverse benefits that arise from enhanced knowledge of the properties of harmful substances and from a market for products containing lessharmful substances. But reliable cost estimates are hardly possible given the diverse and conflicting influencing factors. Overall, it can be assumed that enhanced knowledge of substance properties in harmful chemicals will lead to not inconsiderable savings in preventive healthcare and environmental protection in both the medium and longer term. Given the considerable methodological problems involved, such quantification of the benefits of the REACH system must however be considered with caution. At best, they can serve as a rough indication. What must be remembered is that in many cases, the past system of chemicals monitoring and control only kicked in when harm or damage could be proven. It was sometimes a matter of decades between a harmful substance property being detected and effective action being taken. The long retention time of persistent substances in the natural environment means that even after such substances have been banned, there is potential for considerable delayed effects. The damage caused by neglected preventive measures have thus been considerable at times (see RCEP, 2003; EEA, 2001). Examples from the past include asbestos and ozone-depleting substances, while more recent examples include hormone-influencing substances like brominated flame retardants used with electrical devices, which often make their way into mothers' milk, or the recently banned tributyl tin (EEA, 2003, p. 143; RCEP, 2003, p. 2). While it is possible to produce figures on the health costs from exposure to harmful substances, it is hardly possible to put a price on the loss of biodiversity

**30.** The Commission recently published a study that placed the potential savings in health-related work safety at somewhere between EUR 18 and EUR 54 billion over a period of 30 years (RPA, 2003). Based on statistics from Eurostat and extrapolation of data from EU Member States on skin disease, respiratory infections, eye disease, disease of the central nervous system and sixteen different types of cancer, estimates were made as to how many incidents of illness could be prevented with enhanced information on substance characteristics.

In the case of cancer, and depending on scenario-specific assumptions, the study arrives at a reduction in the incidence of illness somewhere in the region of 2,167 to 4,333 cases. To calculate the economic benefits of reducing illness, these figures were linked to the costs of medical care, the costs incurred from workers' absence and the costs of individual preventive measures (RPA, 2003). The broad-ranging estimate emphasises the considerable difficulties in quantifying the benefits of the REACH system. These methodological difficulties and uncertainties are also taken up in the study commissioned by the European Commission.

**31.** Due to methodological difficulties, a similar study commissioned by Britain's Department of Environment waives quantification of cost savings from things like lower incidence of cancer. In the case of workplace-related asthma and dermatitis, it arrives at a cautious estimate of cost savings in the amount of EUR 1.2 billion over ten years (RPA, 2001, p. 23).

32. A new study conducted by the London University College (Pearce and Koundouri, 2003) and commissioned by WWF UK arrives at a cautious conclusion that the benefits of the REACH system will outweigh the costs. The study uses a variety of calculation models to calculate how effective chemicals monitoring and control can lead to savings in welfare costs related to illness and shorter life-expectancy. The figures show that the so-called 'disability adjusted life year (Daly)' approach used by the World Bank combines as a monetary value the losses caused by increased incidence of illness and shorter life-expectancy. The first model only calculates healthcare costs involved in aggregate loss of life-expectancy (Daly). The second model also takes account of analyses of willingness to pay to avoid Daly. The third model calculates the direct costs to health, loss of production from associated illness and shortened lifeexpectancy, and production and productivity losses. Depending on the model and model-specific assumptions, the study arrives at a broad –range of potential savings to be made up to 2020 somewhere in the region of EUR 4.8 and 283.5 billion. The lowest figures are limited to monetary savings in healthcare, while the highest figures are based on losses in production and productivity that can occur from chemical-related illnesses and which could be prevented by the REACH system. A price has not been applied to avoidable damage to the natural environment. Given this broad range, the study explicitly states that any estimation of the costs and benefits of the REACH system is surrounded by great uncertainty, but that it is safe to assume positive overall benefits.

Despite the uncertainties, the results of the University College study deserve particular mention because the study explicitly focuses on the methodological weaknesses and uncertainties, makes the methodological process transparent and thus verifiable, and

conducts its model calculations based on appropriate methodologies in a scientifically rigorous manner. The scope of the results confirms the German Advisory Council on the Environment in its estimation that reliable results on the cost-benefit relationships of the reforms are difficult to achieve. Nevertheless, the study in question confirms the plausibility of the assumption that the REACH system has potential and that the benefits will outweigh the costs over time and will thus enhance social well-being.

## 4.5 Cost-Benefit: An Overview

**33.** The *German Council of Environmental Advisors* points to the considerable uncertainties that must surely ensue regarding cost-benefit. In both cases, it is necessary (in part) to work with arbitrary assumptions. Serious estimates that are less broad-based cannot be arrived at.

There are plausible arguments to show that existing cost estimates are too high. Existing information, growing experience with more cost-effective alternatives to the standard testing programme and supportive measures for small and medium-sized businesses (information infrastructure, development of use categories) will allow actual costs to fall below those projected.

Given the small scale of REACH-related costs compared with total sales by the chemicals industry, the German Advisory Council on the Environment believes the economic distortions indicated in the Arthur D. Little and Mercer Management Consulting studies are not plausible. With their methodological weaknesses, these studies hardly serve well-founded debate on the economic impacts of the REACH system.

The German Advisory Council on the Environment wishes to emphasise the potential positive impacts of the REACH system on foreign trade. Implementation of the REACH system could motivate manufacturers and users of chemicals in non-EU countries to import substances and preparations from the EU because they will have the advantage of having been declared safe compared with competing products. The German Advisory Council on the Environment points to the considerable benefits the new system may bring. The enhanced transparency of the REACH system enables private and public actors to respond early to substance risk. Available benefit studies show that the benefits will outweigh the costs.

The costs of the REACH system thus appear acceptable, particularly if further development of the Commission's Consultation Document makes use of the Council's strategies for cost-minimisation recommended in Section 3 above.

## 5 Potential Impacts on Innovation

## 5.1 Critique and Concerns

**34.** The chemicals industry has long complained that the European system of chemicals monitoring and control hinders innovation in business and is an obstacle to international competitiveness. Such criticism is based in particular on a comparative study (Fleischer et al, 2000) of the innovation profiles and rates of the chemicals industries in the European Union, the USA and Japan, which identifies a deficit in the marketing new chemicals by European businesses, particularly in the second half of the 1990s. This is said to be the result of the cumbersome and inflexible requirements for authorisation of new chemicals within the European Union (see Fleischer, 2003; Fleischer et al 2000; see Milmo, 2001; SRU, 2002. Paragraph No. 376).

The introduction of the REACH system is coupled with concerns that this deficit in innovation will continue. It is recognised that simplification of the registration process for new chemicals fosters innovation in the new chemicals sector. The impact is, however, seen as negligible compared with the serious impacts on business innovation from the new regulation of existing chemicals. Substance innovation and thus flexibility for innovation are reduced, and businesses must utilise a not inconsiderable proportion of their resources for substance testing and registration which means they are longer available for R&D (Ahrens, 2002).

Critics say that the scope of regulation on environmental protection and health and safety in the workplace already places considerable burdens on the chemicals industry. The intended registration and authorisation procedure is not aimed at harmonisation and simplification of the complex requirements of EU chemicals policy, it actually makes it more complicated. It has not enhanced transparency in the operating conditions for businesses – these play a role in innovation. There is also criticism that the length of time involved in registration and authorisation is an obstacle to competition and innovation for businesses in industrial sectors with extremely short innovation cycles, like electrical engineering. The German Federation of Electrical and Electronics Industries has warned that a delay of months in placing new products on the market, say photolithographic resins for semi-conductor production, would set businesses back somewhere in the region of an entire product generation compared with foreign suppliers (ZVEI, 2003). Overall, the competitiveness of European industry in the entire value chain – from substance manufacturers to processors and users – is believed to be at risk (VCI, 2001).

## 5.2 Evaluation

**35.** The claim regarding a general deficit in innovation among European businesses compared with their US or Japanese competitors in questionable. The following presents a brief outline of the Fleischer study (Fleischer et al, 2000) and sets out the key points of criticism:

The study is based on a comparison of the following four factors:

- Productivity in R&D
- Productivity in patents
- The rate of innovation
- The rate of registration.

For all indicators, the study conducted by Fleischer et al (2000) puts the EU behind compared with the USA and Japan. It shows only minor differences for the first three indicators, while considerable differences are evident in the rate of registration and this applies to all sub-sectors of the chemicals industry. The study has attracted wide criticism. For example, that the results are not based on the number of absolute innovations in the new chemicals sector. If absolute numbers are used, better results are arrived at for both the EU and the USA (Mahdi et al, 2002). It should be noted, however, that methodological difficulties do not allow simple comparison. Another criticism is that European businesses whose R&D expenditure is lower than that of their competitors actually market a similar number of innovations so that rather than being lower, their R&D productivity must in fact be higher. The study calculates the rate of innovation based, among other things, on content analysis of company reports and thus relies on subjective information. What is presented in a company report depends on a number of factors, perhaps making this indicator less than convincing. Additionally, the analysis of registrations in the USA, Japan and the EU does not show whether they involve domestic or foreign companies (Mahdi et al. 2002, with other references).

Fleischer et al (2000) have also been criticised for using the average number of product registrations rather than the trend curve. This is rising for the EU and falling for the USA, whereas the USA actually registered fewer patents than the EU in 1999. A general consideration to be made when comparing the EU and the USA is that the EU introduced registration of new chemicals in 1983 with a base of 100,000 marketed substances, while registration in the USA began four years earlier with a base of only 62,000 substances. Given their later start, European businesses had a larger stock of existing chemicals which is why they then had a lesser need for new chemicals compared with their US competitors, who had fewer existing chemicals available and thus had to register a greater number of new ones (Nordbeckand Faust, 2002). Also, in

the USA there is an obligation to register while a substance is still in its trial phase. Many chemicals registered under these conditions never reach the market (WWF and EEB, 2003).

36. Innovation in business is driven by a range of conflicting factors like company size, R&D activities, in-house resources, market demand, market structure, available technologies, the learning environment and policy requirements (see SRU, 2002, Paragraph No. 50). Isolated consideration of individual factors like a delay in the registration process would thus appear less appropriate. The German Advisory Council on the Environment notes that in the case of existing chemicals, the REACH system gives businesses up to 11 years to register – this should be sufficient time to collect the necessary information. It is wrong, therefore, to talk of considerable uncertainty and delays. The REACH system means deregulation and acceleration of the process for new chemicals with a production volume less than 10 tonnes per year. The Commission's proposal provides for exemption from REACH system obligations for a period of up to 10 years for chemicals research and development. Registration can be prepared for during this time. However, for products with a short life-cycle the costs of testing and registration per business are higher. Less realistic is the process of making innovation and product life-cycles independent from the conditions of market launch and competition – as used in the Arthur D. Little study (UBA, 2003).

In its last report, the German Advisory Council on the Environment took a detailed look at innovation-focused approaches in environmental policy and showed that strict environmental policy can foster both innovation and pioneer effects. It showed in particular that in a plausible scenario, businesses in polluting industries in a pioneering country could experience a competitive disadvantage due to the additional costs incurred as a result of more stringent environmental regulation. These costs are however reduced by innovation induced over time. In the longer term, other countries will follow suit and competitive disadvantage will turn around to become competitive advantage (SRU, 2002, Paragraph No. 46).

**37.** The German Advisory Council on the Environment cannot rule out that implementation of the REACH system could place a considerable burden on some sectors of industry because businesses must initially use more resources for substance testing and, in the interim, may have fewer chemicals available (Granderson, 1999; Achilladelis et al, 1990). Disadvantages could also arise from unsatisfactory regulation of product imports. There is no doubt that for small and medium-sized businesses, the level of effort involved in data generation, drawing up chemical safety reports and their consolidation is not inconsiderable. For this reason, the data requirements in the Consultation Document that focus on problematic exposure paths, the use of quality assured but cost-effective alternatives to the standard testing programme, the

establishment of standardised and informative use categories, and the implementation of cost-reducing cooperative approaches must be systematically further developed and made possible when finalising the system. The German Advisory Council on the Environment believes this type of problem-focused concentration of data requirements is possible under the REACH system. Additionally, an information and advisory structure for small and medium-sized businesses must be established to minimise their level of effort in obtaining information.

**38.** In both the medium and longer term, we can in all probability assume an increase in innovation and enhanced competitive advantage in markets for substitute and environmentally and health compatible products.

This assumption is based on a number of factors. Empirical evidence shows that businesses respond to stringent requirements with product and process innovations (Driesen, 2003; Blazejczak et al, 1999). Empirical studies show that, with adequate adjustment deadlines, the mere announcement of regulatory measures in the chemicals sector triggers innovation (Jacob, 1999). The OECD has on many occasions emphasised the positive impact on innovation of authorisation procedures and product bans (Stevens, 2000; OECD, 1999). A wide range of case studies exist that show the positive impacts of regulation on innovation in the chemicals industry (deSimone, 2000; Porter and van der Linde, 1995; see Bongaerts and Kraemer, 1989; Hartje, 1985, Ashford and Heaton, 1983). A survey of experts commissioned by the European Commission highlighted the fact that the scope for environmentally compatible innovation has yet to be fully exploited (Eder, 2003).

A further point in favour of greater innovation is the fact that existing legislation has made innovation in the new chemicals sector more difficult and largely favours use of existing (poorly tested) chemicals. The increase in volume thresholds for registration of new chemicals, and particularly putting them on an equal footing with existing chemicals, will foster innovation. It is thus surprising that trade and industry claim the impact on innovation will be negligible. No convincing evidence has been provided to support this assumption. It is obviously based on current innovation, which largely involves existing chemicals. Given the unpredictability of market dynamics, to conclude that the new chemicals sector will continue to play a subordinate role because businesses cling to their existing chemicals is more than questionable. Nor can it be ruled out that the expected enhancement of knowledge on substance properties will lead to increased public scandalisation of substances that were previously not known to be harmful to human health and to the environment. This in turn can motivate businesses to engage in greater innovation in the new chemicals sector.

**39.** It must be remembered, however, that the REACH system does not provide a best-practice model for innovation-focused environmental policy. Here, we would

highlight the weaknesses of the authorisation process which is not aimed at implementing preventive substance monitoring and control based on substance properties and use categories, and which provides only weak incentives for substitution. The management impact of the Consultation Document is largely limited to the informational nature of the REACH system. The proposed system thus fails to create the desired level of safety and the incentives for innovators and suppliers of substitute solutions. But consideration must also be given to the fact that reliable, catch-all planning security cannot be provided for because it is impossible to predict the substance-specific problems that might be detected by the REACH system, thus effecting a ban during the authorisation process. Even with a stricter authorisation process, innovators face risks, albeit of a lesser degree.

**40.** The debate on competitiveness in the chemicals industry is too one-sided to take in any potential restrictive impact of the REACH system. Its global impact receives little acknowledgement. On the one hand, this involves the potential impacts of tension between more stringent registration and authorisation processes within the EU and strict liability law in the USA. On the other hand, global replication and diffusion of the REACH system as a model for regulation and control of existing chemicals appears plausible against the backdrop of agreement reached at the Johannesburg Summit to minimise harmful effects on human health and the environment by 2020. The REACH system can serve as a best-practice model for the diffusion of environmental policy and position the EU as a lead market for risk-free substances.

**41.** Much of the heavy criticism from the USA stems from the concerns expressed by its domestic businesses that petitions brought by consumer protection associations could force them to withdraw chemicals from the market if they are labelled as harmful under the EU's REACH system. Consideration should also be given to the influence of the European Single Market on market structures in that its requirements also impact on non-EU competitors' innovation. In 2001, the EU was by far the biggest importer and exporter of chemicals. Its share of global exports was 53.9 per cent, while its share of global imports amounted to 44.6 per cent (CEFIC, 2002b). It is unlikely that non-EU businesses will fail to adjust to the requirements of the European Single Market and pass up the opportunity to become a market player in the world's biggest economic area.

## 6 Literature and Other Sources

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Während der Vorbereitung der Stellungnahme führte der SRU folgende Fachgespräche durch bzw. nahm an folgenden Veranstaltungen teil:

- Teilnahme einer Vertreterin des SRU an den Neunten Osnabrücker Gesprächen zum deutschen und europäischen Umweltrecht: Umgestaltung des deutschen Chemikalienrechts durch die europäische Chemikalienpolitik am 27. und 28. Februar 2003
- Fachgespräch eines Vertreters des SRU mit Ökopol am 7. Mai
- Fachgespräch mit Vertretern des UBA und des SRU am 16. Januar 2003 und am 14. Mai 2003
- Beteiligung eines Vertreters des SRU an der Tagung der Landesregierung Nordrhein-Westfalen: Neue Chemikalienpolitik – Chancen und Risiken für Nordrhein-Westfalen, am 16. Mai
- Teilnahme eines Vertreters des SRU an der Diskussion in der "Strukturpolitischen Gesellschaft" u.a. mit Herrn Dr. Romanowski (VCI) zur Chemikalienpolitik am 21. Mai 2003
- Gespräch des SRU mit Vertretern des BMWA am 6. Juni 2003
- Gespräch des SRU mit BDI und den Umweltverbänden am 7. Juni 2003

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