Comments of the Stakeholders

to the research project

„Analysis of the Costs and Benefits of the new EU chemicals Policy“

commissioned by the
Federal Environmental Agency

to
Fraunhofer Institute for Systems and Innovation Research (ISI)
Oekopol GmbH, Institute for Environmental Strategies

BUND

and

joint comment of the

Federation of German Industries (BDI)
German Association of Chemical Distributors (VCH)
German Chemical Industry Association (VCI)

Evaluation of the Study "Analysis of the costs and benefits of the new EU chemicals Policy"

Research Project of the
German Federal Environmental Agency
conducted by
Fraunhofer ISI (Karlsruhe) and Oekopol (Hamburg)

Berlin, 17 October 2004

Foreword

The debate around the new EU chemicals regulation is often focused on short-term costs that companies will incur on account of REACH. Above all the reservations of industry associations—given the stagnation of European economy over the last several years—have led to a significant weakening of the earlier Commission draft. Despite this fact, the controversies surrounding the chemicals policy have not declined. Instead they continue to be fed by industry studies using dubious methodologies which depict REACH as anti-business and overly bureaucratic.

BUND (Friends of the Earth Germany) welcomes the cost-benefit study of REACH commissioned by the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) and the Federal Environmental Agency (UBA) as a serious and scientifically-founded analysis: The economic benefits for companies are examined for the first time within the research project. In contrast to previous studies, the adaption and innovation capacity of the sector is also examined. The findings show that REACH is a flexible system which closes information gaps with respect to existing substances in a cost-efficient and harmonised manner. The success and costs of REACH will ultimately depend on the development of workable implementation instruments and comprehensible guidelines. The study also makes clear that the current REACH draft is insufficient to effectively protect humans and the environment from harmful chemicals. In the following, the most important findings of the research project will be summarised and evaluated from the standpoint of BUND.

Benefits of REACH

The potential risk to humans and environment from chemicals and their degradation products has been a continuous problem for decades. Regularly new substances and effects become the subject of public debate whether it is allergy-causing fragrances in cosmetics, hormone-disrupting softeners in plastics, or reproduction-damaging flame retardants in electrical devices. Above all consumers, employees and the environment will benefit from a sustainable management of chemicals. The study prepared by Oekopol (Institute for Environmental Strategies) and Frauenhofer ISI (Institute for Systems and Innovation Research) on the cost-benefit potential shows however: even companies can benefit from REACH. E.g. better knowledge of the health and environmental properties of chemicals will be available. In addition REACH creates a stronger incentive for firms to think about the safe use of their substances. The communication between manufacturers and users of chemicals will be improved and responsibility interfaces will be unambiguously defined. This will contribute the following advantages:

- Lower liability risk
- Less image loss
- No competitive advantage for substances whose risk cannot be assessed
- Reduced costs for chemical-related occupational health problems
- Cost savings in the healthcare sector and environmental protection. The damage costs documented in the study lie between EUR 0.5 and EUR 5 per inhabitant per year.

These findings confirm BUND in its position that REACH is an investment in safer chemicals and products that will pay. Even if the exact quantification of the benefit is not possible, due to methodological difficulties, the study strengthens the assumption that already the savings in the healthcare sector will significantly exceed the medium-term costs. We see further economic advantages of an effective chemicals control in higher industry credibility among consumers. According to a survey by the EU Commission, 93% of Europeans believe that chemicals are harmful to their health (Soufflot de Magny, 2004).

Costs of REACH

In the opinion of Oekopol and Fraunhofer ISI, REACH is a flexible system, leaving a wide scope for implementation. How much REACH costs will depend primarily on how successful the instruments of REACH are and how much companies already know about the properties of their substances. Since according to the VCI self-commitment (German Association of Chemical Industry) minimum information exists for all substances in quantities of one tonne per year, the scientists assume that a large amount of the required data is already available. They also point out that there is still a lot of time before the registration phase begins, to accelerate development of cost-effective techniques to determine substance properties. In addition, the willingness of market actors to cooperate, e.g. through formation of consortia, will have an impact on costs. Monopolies law and know-how rights do not constitute any fundamental obstacles.

BUND welcomes the study's approach to keep the burden on companies as low as possible. However, when discussing cost minimisation, it must not be forgotten that the foremost purpose of REACH is to better protect humans and the environment from hazardous chemicals. What does it cost when new-borns are already contaminated with chemicals or if hormone-disrupting substances threaten the existence of a sea snail? Is an environment free of pollutants only "valuable" if we can save costs thereby?

BUND is of the opinion that the costs of REACH for companies are entirely reasonable. Based on the estimates of the EU Commission, the costs lie at around EUR 200 million per year for eleven years. That is equivalent to just 0.05% of the annual turnover of the European chemical industry. In comparison, the US chemical group DuPont faces a USD 250 million fine because it concealed knowledge of the dangers of Perfluorooctanoic Acid (PFOA) for decades. In comparison to other factors such as wages, oil price and exchange rate fluctuations, the costs of REACH are of relatively little significance (SRU, 2004). The long phase-in time also favours learning and adaptation processes as well as product and process innovation that can lead to further cost savings.

REACH and innovation

Innovation behaviour of companies is dependent on a variety of factors and is therefore difficult to predict. Oekopol and ISI assume that with REACH manufacturers will be better informed how customers use their substances. This knowledge can be used for innovation. It is the opinion of the scientists that the loss of know-how feared by many companies can be avoided in the context of REACH. In addition, REACH can lead to product and process innovation: where dangerous substances are absolutely necessary for certain functions, the user can adapt his products and processes so that the conditions for safe use are fulfilled. REACH therefore opens innovation potential toward holistic assessment of chemical products.

BUND is of the opinion that a chemicals policy which sets clear targets for companies and gives them enough time to implement it, increases the competitiveness and innovative strength of the chemical industry. Empirical studies show that companies often react to strict regulation with product and process innovation. Sometimes just the announcement of regulatory measures or the beginning of research programmes on particular substances or substance properties can cause innovation. Under the current system, poorly tested existing substances have an advantage over well-documented new substances. REACH will put an end to this and ease the registration of new substances. There will also be exceptions for substances under development. BUND assumes that in future new substances will play a greater role and that an innovation in the direction of safer products will occur.

Despite this fact, REACH is no paradigm of innovative environmental policy, especially since authorisation provides too weak an incentive to substitution: if a company can prove "adequate control" of dangerous chemicals, then the substance may be further marketed even if there is a safer alternative. The opinion of BUND is that REACH does not offer sufficient certainty for innovators and suppliers of substitute solutions. In terms of innovation and protection of humans and the environment, the use of safer alternatives must be preferred to "adequate control" of substances.

REACH and competitiveness

The fear has often been expressed, especially by industry, that REACH would cause many companies to leave Europe. The present study concludes that REACH will not be a determining factor in the relocation of production. At the most, it will only reinforce existing relocation trends. A complete relocation of manufacturing abroad is unlikely, especially in innovative sectors with often expensive and complex facilities – the costs of chemicals are negligiblein comparison. Moreover, large corporations already supply non-European companies from locations outside Europe. For smaller firms, markets outside Europe play an altogether subordinate role.

The scientists also point out that REACH can have a positive impact on competitiveness:

- Imported sbstances also fall under REACH. European manufacturers of substances who already have much data about their chemicals have a competitive advantage over imports.
- "First Mover" advantage: According to the 2002 Johannesburg Summit health and environmentally harmful effects of chemicals ought to be minimised by 2020. That means there is a medium-term necessity for better chemicals control.

BUND points out that the EU was by far the greatest importer and exporter of chemicals in 2001 with global exports of 53.9% and global imports of 44.6%. It is unlikely that non-European companies will not adapt to the requirements of the European internal market and thus be not present in the world's largest economy. Finally, it is interesting to observe that since the beginning of the discussion of the EU chemicals reform, a broad debate about REACH has emerged even in the USA, Japan and Australia.

In the view of BUND, the advantages for foreign trade also result from better testing of chemicals for environmental and health hazards in comparison to competitive products. "REACH tested" can motivate manufacturers and users in non-European countries to import more in future. By using safer products, the importer can reduce the risks of use, improve workplace safety and productivity and increase planning and legal certainty. Especially in the USA, companies would be less vulnerable to litigation. BUND is of the opinion that REACH offers companies the opportunity to introduce new safety standards for managing chemicals and thereby retain long-term competitiveness. Often it is erroneously assumed that less control means more competitiveness. Compared internationally, the highly regulated countries such as Finland, Sweden, Denmark and Norway are the ones distinguished by economic success.

Deselection of substances

The purpose of REACH is to recognise chemicals with the worst environmentally and health damaging properties and replace them with safer alternatives. If *dangerous* substances are withdrawn from the market for cost reasons, then REACH will already have met one major goal during the registration phase. However, a part of the registration costs is independent of the substance's risk. In the case of substances with low margins REACH may therefore make it unprofitable for a company to register the chemical. The scientists point out however, that this does not necessarily mean that the substance is withdrawn from the market since other firms could also manufacture and register the chemical. The decrease in functionality is also lower since there are alternatives for many substances. The study finds that to a certain extent the withdrawal of substances is normal and companies have practice in re-formulating. The development of efficient implementation instruments for REACH will minimize the impact.

An interesting finding of the study is that companies could also profit from a reduced substance portfolio, e.g. simplifying warehousing or requiring less safety management. In the past, substances also had to be substituted frequently since the alternative turned out to be environmentally harmful. Since REACH increases the knowledge about alternatives, the number of repeated re-formulations would be reduced in future.

Optimise REACH ...

A central finding of the research project is that the development of implementation instruments and guidelines is essential for the success of the chemicals reform. The scientists make specific proposals to minimise risks and optimise the opportunities, which are to be evaluated below.

... through better information for companies

The study makes clear that many companies have only a vague idea what the new legislation requires them to do. The lack of knowledge means that the companies often overestimate the burden. In addition there is a high degree of uncertainty as to how the legislative process continues, what significance the RIP process (REACH Implementation Project) has and how they may prepare themselves for REACH.

BUND demands that industry associations end their campaign of deficient information, which has been a primary cause of the unclarity among companies. The companies do not need horror scenarios about the de-industrialisation of Europe. Rather they require information about REACH that is appropriate to the actors, correct and supports them in preparation.

... through exposure categories

Oekopol and ISI come to the conclusion that it is not feasible for a chemical manufacturer to make a detailed evaluation of every conceivable use of a substance. Therefore, the scientists recommend that the various uses should be combined to use and exposure categories. In Annex I, REACH offers the possibility for such a grouping. In order to facilitate communication between the actors, a standardised system should be developed by the time REACH enters into force.
BUND expresses the reservation that a standardised exposure assessment on one hand must contribute to an easy implementation. On the other hand, the categories must not be so broad that a meaningful risk assessment is no longer possible.

BUND rejects the proposal by industry and others to make test requirements for registration solely dependent on the exposure of a substance. We consider this proposal problematic and impracticable for the following reasons:

- To date models for prediction of exposure are significantly less standardised than test regulations. The use of exposure models for regulatory purposes therefore presents substantially more difficulties.
- At present, many firms do not know how their substances are used. Current chemicals management has failed among other reasons because there is tool little information about the use of substances.
- The use of a substance can change rapidly (according to the VCI, innovation is often application innovation). The test requirements would have to be updated with every new application.
- The exposure of a substance can only be estimated on the basis of a solid data set. Without an adequate minimum data set it remains unclear how a substance behaves in the environment or whether it is harmful. It is not possible to derive the risks arising from it.
- The procedure is virtually uncontrolable by the authorities.

... through higher data requirements

Oekopol and ISI come to the conclusion that REACH must be strengthened so that the benefits for the environment and health can actually be realised. In particular, the reduction of the test requirement and the reduction of the risk assessment to hazardous substances only has significantly diminished the potential benefit of REACH. The current proposal only calls for an exposure assessment of hazardous substances. However, whether or not a substance is hazardous can only be decided if appropriate tests have been performed. The scientists are of the opinion that the following improvements are possible without unreasonable increase in costs:

- More data for substances under ten tonnes per year (especially acute toxicity, biodegradability). The minimum data set is insufficient to identify risks and derive measures.
- Simple exposure assessments for substances less than 10 tonnes per year.
- Obligatory use of quality assurance systems. Completeness check and dossier evaluation by the authorities are insufficient for quality assurance.

BUND supports these demands but points out that improvements in public access to data and in the authorisation procedure must also be made:

- More transparency: the restrictive interpretation of company secrets makes it difficult for users and consumers to decide for safer products. That means an essential control and innovation mechanism of the REACH system fails.
- Strengthen authorisation: especially dangerous chemicals must not be allowed if safer alternatives are available, unless their use is not absolutely essential for society. The substitution principle should be obligatory.
- Include imported products: The present REACH propsal allows companies outside the EU to import products with chemicals that have not been registered under REACH. That is of no benefit to the consumer and leads to distortion of competition.

... through one substance, one registration (OSOR)

According to REACH every manufacturer or importer must submit a registration to the Agency for every substance. From the scientists' standpoint, there are strong arguments for registration of each substance one time only.
BUND also welcomes this approach since multiple tests and unnecessary animal experiments can thus be prevented. Also SMEs can profit if only the respective market leader registers the substance. It is to be expected that large companies already have more data than SMEs and therefore enjoy an initial advantage. Because of the temporary monopoly, these companies have little incentive to share their data with others. With OSOR (one substance, one registration), the common use of existing data will be mandatory. Moreover, OSOR can contribute to simplification and acceleration of REACH.

Further information:

Patricia Cameron, patricia.cameron@bund.net
Ulrike Kallee, ulrike.kallee@bund.net

18 October 2004

~~Joint Commentary~~[1] ~~by~~

~~Federation of German Industries, BDI~~

~~German Association of Chemical Distributors, VCH~~

~~German Chemical Industry Association, VCI~~*

On the study commissioned by the Federal Environmental Agency of Germany

"Analysis of the Costs and Benefits of the New EU Chemicals Policy"

A Prefatory Note

This study commissioned by the Federal Environmental Agency (UBA) was assisted by an advisory group. The latter's role was to introduce technical aspects and discuss them. However, the aim was not to achieve a consensus on all issues. Far from it: certain points, particularly relating to methods and hypotheses relied on, aroused vehement controversy within the advisory group itself and remained unresolved. A so-called "final" draft of the study was submitted on 30 September 2004. It contained a lengthy chapter listing conclusions drawn, but there was no summary of the study's findings. Members of the advisory group were afforded the opportunity to submit their own commentaries on this draft, on the understanding that the commentaries would appear in a separate volume appended to the study. This opportunity was used as follows.

B General remarks on the study's findings

The study makes a series of notable statements, to which we here deliberately give prominence by isolating them from their original context within extensive detailed argument. They are reproduced below, mainly in the form of word-for-word quotation from the Conclusions (Chapter VIII unless otherwise stated)

[1] The quotations are translated from the original German version.

- The interface between legislation relating to chemical law on the one hand and substance-related health and environmental protection on the other has already reached a degree of complexity that is often insurmountable for small and medium-sized enterprises. If, in the course of the implementation of REACH, the complexity of the information and evaluation processes is not reduced, the deficit in implementation which already exists will increase.
- The exact amount of the direct registration costs depends on the detailed structure and final form of the REACH regulations. The relevant factors here include the recognition of existing data (e.g. VCI self-commitment); exemption from tests if there is no relevant exposure and the use of validated, non-testbased methods for substance evaluation.
- A portion of the registration costs is not affected by the behaviour of the company with registration duty, and can therefore not be influenced by risk-reducing product design or risk-reducing distribution strategies. Especially for substances < 100 t/a this cost factor can contribute to substances being withdrawn from the market for cost reasons.

  Example (quote from Chapter V.5.2 of the study): In the course of its preparations for REACH, the manufacturer of tensides (Company a) surveyed has already drawn up a fairly extensive portfolio analysis. The implications of this for the investment decision of the registration was presented in Chapter V.2.2., which reveal that on the basis of cost estimates of the company, adverse cost-price ratios prevail in the whole range up to 1000 t/a constellations. This is the case for tensides because of their relatively low market price level and the rather low margins of the industry. For the substance manufacturer (Company a) in question, somewhat over 40 % of tensides related to washing and cleaning detergents are in the sensitive tonnage band under 1000 t/a, while this figure is around 75 % in the company's entire total substance portfolio. This makes the company's statement that it is not planning to register around 40 % of its substances, seem plausible. The anticipated resulting reduction of sales lies between 5 – 10 %, and the anticipated cut in earnings between 10 – 25 %. The substance manufacturer surveyed makes the decision to register according to the same criteria as for other investment projects, i.e. it has to earn an internal return rate of 25 %. The possibility of forming consortiums has already been taken into account in the estimate of the quota of substances to be withdrawn.
- If the deselection of substances is essentially purely cost-driven and brought about by risk-independent data requirements then REACH will have failed one of its major objectives and, in addition, will have weakened the innovation basis of formulators. The relation of risk-driven substance rationalisation to risk-independent substance rationalisation depends on the structure of the system.
- Even under the current cost assumptions of the EU Commission, the risk-independent information requirements in Annex V and VI (even using non-testbased information) already lead to relatively high specific registration costs in the small-volume category. To prevent a large-scale risk-independent withdrawal of substances, further options for a closer relation of the information requirements to risk on the one hand, and options for further reducing testing costs on the other should be investigated.
- For example, in view of the large number of raw materials and formulations especially in the paint chain, a REACH-induced substance withdrawal, which clearly exceeds the current base level, could lead to substantial consequential costs for the manufacturers of preparations.

  Where REACH induces a withdrawal of a substance or functionality that exceeds adaptive capacity, especially companies with a wide range of special products will be among the "losers".
- Concerning the development of new substances, it becomes apparent by adding up past notifications to the value chains under investigation that the number of new substances in the chains has to date been very low. These would therefore not balance out the possible withdrawal of old substances.
- If substance prices are increased, the formulators and the users of preparations will have to adjust to this change. All the companies surveyed considered it unlikely that the registration costs would be passed on via the prices to the manufacturers of preparations and from them to the users of

preparations. In the opinion of the manufacturers, the experience gained from price negotiations with large customer industries (paint chain) or retailers (washing and cleaning detergent chain) and given the general "relocation option", for example of the automobile and electronics industry in the course of globalisation, speaks against optimistic assumptions about costs being passed on.

- Seen as a whole, in the opinion of the research institutions, every cost increase of production in the EU that does not lead directly or indirectly to innovation, sales and/or earnings increases, has the potential to reinforce the relocation trend which is taking place in any case.
- Substance manufacturers are not able to carry out detailed individual evaluations for all conceivable conditions of use. This would also not be desirable for the following reasons: A too detailed description of the safe conditions of use restricts the necessary flexibility of substance use and relies on the extensive transfer of (possibly sensitive) application related know-how to the substance manufacturer.

  In the joint assessment of the Federal Government, VCI and IG BCE (Mining, Chemical and Energy Industrial Union) from 21 August 2003, the suggestion is made that an exposure assessment should be made on the basis of use and exposure categories in the context of a tiered approach.
- The chemical import trade is subject to different market conditions than the manufacturers of substances and preparations. In comparison to the manufacturers of chemicals, their distribution volumes of a substance fluctuate much more and their product range is usually much more extensive. REACH therefore presents special challenges for these importers and their registration decision should be examined separately. (Chapter II. 4.2)
- At the same time, the registration mechanisms of the draft regulation and the level of registration costs in the medium scenario of the Commission presents the importers of chemicals with a relevant technical and economic hurdle. Firstly, registration of all components of the imported preparations by the importers themselves is only limitedly feasible both technically and in relation to the know-how of the formulation. Secondly, in the case of one-off or irregular imports, the importers must achieve significantly shorter pay-back times than the manufacturers of chemical products. This means that registration by the importers themselves may well not be worthwhile.

These statements are intended to focus attention from the perspective of industry on the difficulties which the Conclusions identify as arising from the current regulation proposal and from the instruments currently under discussion for its implementation. It should also be borne in mind that the text of the commentaries has been finalized at a time when no official summary of the study's findings has been published and much uncertainty therefore remains as to which points will be given most emphasis.

C Evaluation of the study / Points of criticism

The statements quoted above from the study are essentially comparable with the results reached by numerous other studies and projects – e.g. Arthur D. Little, Mercer, DIHK, Bavaria, Baden-Württemberg or the pilot project in North Rhine Westphalia. Some of these expressed considerable anxiety concerning, for example, such features of the REACH regulation proposal as its lack of compatibility with economic imperatives and innovation, the very low cost-efficiency of the procedures, the significant burdens imposed on small and medium-sized enterprises, and its general impracticability.

The studies published hitherto, which differ in focus and in their specific objectives as well as in methods and models, have increased the flow of knowledge relating to the potential economic impact of REACH on a range of different companies, industries

and national economies. The study now to hand, commissioned by the Federal Environmental Agency (UBA) and entitled "Analysis of the Costs and Benefits of the new EU Policy on Chemicals", shows once again, like its predecessors, how extensively and how severely a new regulation may damage the innovative vigour and competitiveness of private enterprise.

The UBA study also shows clearly how difficult it is to work out meaningful findings as to the costs and benefits of REACH on the basis of an objective, scientifically valid methodology. In this respect it is of particular importance to note that the study has only limited information value for all sectors concerned.

As a consequence of the methodological problems and of the project's limited scope as commissioned, those undertaking the study only partly achieved their original objective of identifying indicators on the basis of which the potential value of REACH could be realised and its costs kept down.

The study has the following major weaknesses:

- The comparison with the voluminous and complex regulatory machinery currently in place in the EU and Member States, undertaken to demonstrate a supposed additional benefit for consumer protection, jobs protection and environmental protection, is inadequate. Many of the benefits allegedly accruing from REACH are in fact provided for by legislation already in force.
- Historical examples selected with a view to demonstrating an alleged merit of REACH in fact bear no direct relation to REACH and are therefore inappropriate.
- What the study says about the indirect costs of REACH – an issue of fundamental importance – is inadequate.
- The findings cannot be considered representative and generalizable, as only two industries were studied and only a few companies surveyed.
- The procedure used is often hard to follow, as the transition from the hypotheses to the study itself and the conclusions drawn are for the most part lacking in both methodological and logical transparency.

Fully argued criticisms of specific points are contained in the Appendix.

The study under discussion also clearly illustrates yet a further major problem, one which regrettably receives no explicit mention in the Conclusions. It is simply not meaningful to compare the costs of the future REACH system with its potential benefits – whatever their nature might be – let alone offset them. The reason is that potential for benefit cannot possibly develop unless regulations introduced in the future are both practical and cost-effective to implement.

Overall, we wholeheartedly support the calls made in the UBA study for *"intensive discussion and development"* with particular reference to the following areas:

- the legislative process, e.g. involving changes to the actual draft regulation itself
- the implementation of REACH, e.g. involving development of practicable implementation instruments
- the need for further research, e.g. into the implications for international competitiveness and for reduction of the complexity of the existing legislation

The BDI, VCH and VCI* organizations have already developed and initiated a number of constructive proposals serving these ends.

* **The following organizations worked with the VCI in the advisory group:**

- Industrieverband Hygiene und Oberflächenschutz für industrielle und institutionelle Anwendungen e.V. (IHO)
- Industrieverband Körperpflege- und Waschmittel e.V. (IKW)
- Verband der deutschen Lackindustrie e.V. (VdL)
- Verband der Mineralfarbenindustrie e.V. (VdMi)
- Verband TEGEWA e.V.

Appendix

Detailed criticisms

1. Comparison with existing legal regulations

Any benefit to be obtained from REACH can only be realistically estimated if it can be demonstrated convincingly just what improvements in product safety and/or consumer and environmental protection are attainable over and above the level afforded by existing regulations. It is not sufficient simply to draw a comparison, as the study does, with the *TRGS 220* "Sicherheitsdatenblatt" (Safety data sheet) (which is virtually a German "guideline" to implementation of the EU Safety Data Sheet Directive), a comparison almost entirely restricted to worker protection, and then use it to infer the existence of a deficit in environmental and consumer protection.

It follows that demonstration of additional benefit to be gained through REACH must start from a much more thorough analysis of existing legislation and of the duties it imposes – at least for the value chains investigated by the study.

This would include e.g. the following regulations: Product Safety Directive 2001/95/EC and numerous special directives including those for toys, personal protective equipment, cosmetics; Product Liability Directive 85/374/EEC; Environmental Liability Directive 2004/35/EC; Draft of the Service Liability Directive; Substances Directive 67/548/EEC; Preparations Directive 1999/45/EC; Restrictions Directive 76/769/EEC; Chemical Agents Directive 98/24/EC; Plant Protection Products Directive 91/414/EEC; Biocidal Products Directive 98/8/EC; Washing and Cleaning Agents Regulation and the future Detergents Regulation; The Food and Commodity Act and many more – especially also separate national provisions and other instruments and measures (e.g. standards, environmental labels, voluntary self-commitments).

It is regrettable that the study has undertaken this analysis only incompletely and patchily. Thus there is not nearly enough evidence to make the alleged additional benefits from REACH plausible. It is true that the long-term need for further research is recognized, but to see this is not to tackle the problem. The REACH regulations will need to have been harmonized with existing law by the time they come into force. This is also in line with the study's conclusions, quoted above, the study having found that the interface between legislation relating to chemicals on the one hand and substance-specific health and environmental protection on the other is already reaching a level of complexity which many SMEs are unable to handle.

In its "*Resolution on the Commission White Paper, Strategy for future EU policy on chemicals*" (Resolution 84/2002) the European Parliament has already called on the Commission to "*submit, not later than mid-2002, a wide-ranging analysis and study of all substance and product-specific regulations together with proposals as to which regulations need to be modified, simplified or even abolished in the light of the new policy on chemicals.*" To date, unfortunately, no such analysis has taken place. The REACH regulation proposal now under consideration in fact complicate the existing law on substances considerably, rather than simplifying and de-bureaucratising it.

Conclusion: In the absence of comparison with existing regulations no additional benefit from REACH can be plausibly demonstrated

2. Potentials for benefit

The commissioned researchers evidently scrutinized existing benefit studies by third parties less critically than available cost studies. The source most relied on in their argument is the report by the German Council of Environmental Advisors (Sachverständigenrats für Umweltfragen - SRU) report, which gives a one-sided view. The findings of benefit studies to date, in particular, are at the very least suggestive and merit discussion.

Damage costs avoided through REACH? The UBA study declares it has no intention of "*quantifying ... the damage avoidance potential of REACH*". Instead, one reads, *"certain selected cases of damage caused by chemicals ... will be quantified in terms of order of magnitude and characterized with regard to their causation. By applying the REACH effect mechanisms it will then be possible to determine whether the causes could have been eliminated by means of REACH, or could be so eliminated in future"* (Chapter IV.5.1). This approach is problematic for at least three reasons:

1. Application of REACH methodology to substances which were new introductions in the past does not yield findings permitting inferences about effects linked to current established substances for which user experience has been built up over decades.
2. Even if the attempts made at quantification are intended only to serve "comparability of damage costs between different cases", they remain a further temptation to the reader to regard such costs as "reducible through REACH".
3. It assumes that the scenarios discussed and the specific measures adopted in individual cases were correct and appropriate.

The last-named point is illustrated in Chapter IV.5.2, e.g. "*PCB clean-up in public buildings"* or the *"purification of untreated water for use as drinking-water".* Here – very much contrary to the intention of the study's authors – there are exemplary demonstrations of how it is possible, as a result of an at least disputed risk statement (e.g. a non-riskbased, partly arbitrary determination of so-called "precautionary levels") for a false perception of health risk to arise, leading to unnecessary expenditure. Here lies, without doubt, one of the greatest dangers inherent in the exaggerated argumentation on health grounds in connection with REACH.

In Chapter IV.5.4, the discussion of work-related disorders with chemical involvement begins by listing the costs that arise from recognized substance-generated occupational diseases such as skin diseases and asthma. All these aetiologies have of course been familiar for years. They either stem from hazard exposure in the past, or they are disorders that occur in spite of the known hazards of the substances concerned. There are not the slightest grounds for assuming that their incidence could be reduced as a result of REACH (as opposed to systematically implemented worker protection measures based on the existing legislation). Moreover, for established substances that

have been in use for decades, the chemical industry has a wealth of experience already available in work practice and industrial medicine, so that there is no prospect of significant gains either in information or in safety being achieved through REACH.

A further statement appearing in the study reads: "*The specific contribution made by industrial chemicals to the incidence of contact allergies in the general public is not quantifiable. Nonetheless, the list of the most frequently occurring allergens shows clearly that industrial chemicals contribute in significant measure".* This statement is neither scientifically well-founded nor accurate. In fact by far the greatest number of known allergens are natural substances. The UBA study asks: Can REACH help us recognize the allergenic potential in substances? And it gives its answer: YES – registration is to involve testing for skin allergenic effect. But the question asked is the wrong one. What needs to be asked is: Can REACH help us to recognize, for the first time, the allergenic potential in established substances which have been marketed for at least 20 years? The answer then would be: NO, because allergies come about very quickly following the exposure; in other words, the allergizing properties of established substances have either been noted long ago or are irrelevant in practice, for instance because there has been no relevant contact with the substance tested.

The study's discussion of individual cases from the past is a further demonstration that REACH could not in any of the cases have contributed to a reduction of damage to the environment or to health.

Conclusion: The contention that REACH will be of benefit cannot be made plausible by the examples used in the study. Moreover, the authors themselves emphasize that the benefit is not quantifiable.

3. Representativeness and scientific argumentation

Neither the value chains of the chemical industry selected nor the spot test of the selected companies are representative. The washing and cleaning agents industry and the paint industry together account for less than one tenth of the German chemical industry. The value chains connected to these industries were only represented selectively. It is not evenly remotely possible to derive overall statements for the selected industries, let alone for entire value chains, from the spot test of 13 or 15 companies.

Conclusion: The results of the study give, at best, indications of possible effects of REACH on the value chains, but these can definitely not be generalised.

4. Direct and indirect cost estimates

In deviation to the task set out in the study, the direct costs were not verified by the authors of the study themselves. The authors make extensive use of the JRC data. Other sources, e.g. the VCI estimates with higher costs were documented but the plausibility of the different values were not discussed. Cost-saving potentials (e.g.

QSAR) are in our opinion overestimated, while burdening factors (e.g. insufficient testing capacities) are underestimated.

Furthermore, neither the indirect costs nor the overall economic consequences of the REACH system were calculated by those commissioned to do the study. In the introduction, it is primarily only the one-sided report of the German Council of Environmental Advisors (SRU) that is quoted in this respect. Other studies with deviating opinions - of which there are many by now - are hardly taken into consideration. There is no comprehensive explanation or an own assessment of the estimate of indirect costs. The summary of the studies on the economic consequences is one-sided: the methodical weaknesses of the studies with higher cost estimates are pointed out, while the methodical weaknesses of the studies with lower cost estimates are ignored.

Conclusion: The UBA study does not provide any new insights on the direct and indirect costs of REACH. Many cost potentials are blanked out.

5. Adaptive capacity

High R&D expenditures do not necessarily signify a high adaptive capacity of the companies to the introduction of the REACH system. Companies carry out R&D so that they can survive in competition. REACH definitely entails an additional burden for companies. If they have to perform research on substitutes there will be fewer resources available for research which is aligned to specific customer wishes – this results in a loss of competitiveness. In most cases it will not be possible to stock up R&D budgets.

The authors of the UBA study argue that the manufacturers of preparations with short product life cycles (Chapter V.4.6) and a high raw material exchange (each over 30% in 10 years) can cope with the withdrawal of substances up to a certain limit (Chapter VIII.2.8). Both phenomena are however the consequence of specific competitive processes within the industries. They have nothing to do with the adaptive capacity to REACH. REACH simply means additional adaptive pressure for companies, as the authors themselves point out.

Even if the proportion of the chemical costs in the production costs of the user can be very low, the production conversion process following the withdrawal of raw materials will be significantly costly, and in extreme cases will threaten the very existence of some companies.

One finding of the study is that already in the current system, the protection of know-how is not absolute. This is commented on with the following words: “This shows that the market players can handle a certain degree of know-how spill-over.” The competitiveness of European industry is however not enhanced by maintaining or even aggravating current deficiencies and undesirable situations. Rather, it is important for weak points in the current regulations to be eliminated via REACH.

A discussion of the unsatisfactory profit levels of companies, which does not allow for any additional burdens through REACH, is not included even though profit is an important indicator of adaptive capacity.

Concerning the possibility of switching to countries outside the EU because of REACH, the report says *"that the two large companies surveyed, a substance manufacturer and a manufacturer of preparations, already serve non-European markets for which they use their production locations outside the European Union. If REACH leads to an increase in the growth of these markets, because the downstream chain relocates to outside Europe, then the expansion of the production locations there is seen as an easy option for adaptation"* (Chapter V). What is harmlessly described here as an "easy option of adaptation" ultimately means the reduction or termination of production here and therewith a loss of jobs in Germany.

In our view, the results of the UBA study on adaptive capacity clarify one aspect more than any other: If companies – the study here explicitly names formulators – do not have sufficient adaptive capacities (R&D, management) (Chapter VIII.2.8), the negative effects of REACH will be even higher than has been estimated in all investigations on indirect costs to date. Because in this case, not only test and registration costs, but also problems in the conversion to the new system and in its implementation, will lead to a reduction of product diversity.

Conclusion: The analysis of adaptive capacity has weaknesses, but at least it does point out some important restricting factors. Low adaptive capacity means higher costs through REACH. A simplification of REACH will facilitate the adaptation process of companies to REACH and reduce the ensuing economic costs.

6. Import trade

As these regulations will also apply to them, importers are challenged by REACH to the same extent as manufacturers in Europe. Nonetheless, there is no in-depth analysis as to the effects of REACH on them, something also missing in the Business Impact Assessment of the EU Commission. At least - and for the first time in a study of this kind - the study establishes that:

"At the same time, the registration mechanisms of the draft regulation and the level of registration costs in the medium scenario of the Commission presents the importers of chemicals with a relevant technical and economic hurdle. Firstly, registration of all components of the imported preparations by the importers themselves is only limitedly feasible both technically and in relation to the know-how of the formulation. Secondly, in the case of one-off or irregular imports, the importers must achieve significantly shorter pay-back times than the manufacturers of chemical products. This means that registration by the importers themselves may well not be worthwhile." (Chapter VIII. 2.7).

And it goes on to say:

"The chemical import trade is subject to different market conditions than the manufacturers of substances and preparations. In comparison to the manufacturers of chemicals, their distribution volumes of a substance fluctuate much more and their product range is usually much more extensive. REACH therefore presents special

challenges for these importers and their registration decision should be examined separately." (Chapter II. 4.2).

We would certainly recommend investigating these statements in further depth. But acknowledgment is due in that the study has at least addressed this topic.