

REACH impact assessments



ASSESSING EU ENVIRONMENTAL POLICY IMPACTS

A Critical Evaluation of Impact Assessments
carried out for Europe's chemical policy reform (REACH)

European Environmental Bureau

and the

WWF DetoX Campaign

June 2005

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1 Introduction and Executive Summary

REACH has been designed to establish a more uniform, more transparent and safer management of chemicals in the European Union. Unacceptable chemicals are to be identified and gradually substituted for safer alternatives, implementing the precautionary principle. At the same time REACH should enhance the functioning of Europe's internal market, creates a level playing field, fosters innovation and increases the competitiveness of businesses.

Limited costs and significant business benefits

REACH requires manufacturers and importers to register and provide safety information – within 11 years – on approximately 30,000 existing chemical substances which have been on the market for more than 25 years. Moreover, manufacturers and importers – acting together with downstream users – must analyse and communicate the use-related risks entailed by their substances. The Commission estimates that these requirements will cost companies a total of around 2.3 billion euros during the 11-year implementation period. Further expenses for industry caused by these costs are judged by the Commission to be "very limited", whereas REACH will contribute to significant business benefits such as enhanced innovation, improved worker safety and enhanced competitiveness of the chemical industry, as well as significant health cost savings.

Industry associations such as CEFIC and UNICE did not accept the above findings and conducted studies themselves (or urged some governments and EU institutions to do so). The industry studies are based on the assumption that the production of many chemicals would stop because of registration costs. This would – claimed the industry-sponsored studies – create massive additional costs for chemical users further down the value chain. While the Commission – and also the Nordic Council of Environment Ministers – anticipate these additional (indirect) costs to be roughly on the same scale of magnitude (factor 2 to 6) as the direct registration costs, the studies commissioned by industry reach the conclusion that the scale of magnitude would be up to 650 times the direct costs. These figures are then directly converted into figures for job losses that REACH is expected to cause. These industry-financed studies lack transparency, they have been dependent on unsubstantiated assumptions and the costs calculated are extremely high, leading to the accusation that the studies are biased.

Costs must be seen in their context

The EEB and WWF underlined that registration costs must be seen in their context. The 2.3 billion euros calculated by the Commission translates into 0.48 euros per EU inhabitant per year over the 11-year phase-in period for REACH, or into 0.04% of the turnover of the European chemical industry per year. Furthermore, the EEB and WWF highlighted a number of important business benefits: in particular, a clear safety responsibility on chemical producers and importers and the availability of chemical safety data for downstream users and retailers. Finally, they pointed to the weakness of the economic models used by industry, their lack of transparency and scientific evidence.

Additional impact assessment process: Case studies

As a result of massive industry lobbying, the Commission, CEFIC and UNICE endorsed the Memorandum of Understanding of 3 March 2004 in order to *“provide a framework for the efficient undertaking of further investigations on business impacts of REACH”*. Through case studies, factual evidence on how REACH affects businesses was to be collected, especially with regard to the mass disappearance of chemicals predicted by industry. Broad-based acceptance of the results was to be achieved through the involvement of key stakeholder groups.

The EEB and WWF worked intensively within the Commission working group that was subsequently established. For one year (May 2004 – April 2005), the working group supervised two studies – one analyzing the potential impacts of REACH on business and innovation (KPMG) and one addressing New Member States (IPTS). The results have now been published. Although KPMG started with worst-case cost assumptions, none of the case studies identified problems as predicted by previous industry studies: no loss (withdrawal) of important chemicals because of registration costs, registration costs will largely be passed on or absorbed by the supply chain and product reformulations are not likely. Furthermore, the New Member States’ industry will not face serious problems. Mr. Verheugen therefore stated: *“The argument that REACH, as it stands today, would ruin the industry, is now banished”*. (Environment Daily, 2005)

Verheugen (2005):
“The argument that REACH ... would ruin the industry is now banished.”

Interpretation by industry – and partly also by the Commission – of the case study results, stating possible problems for SMEs or low tonnage chemicals, cannot be inferred from the results of the case studies, due to the very low number of cases (2 cases) and inadequate validation. Due to a lack of transparency, neither representatives of environment or consumer associations nor the Commission’s verification experts received access to raw data so that industry interpretation cannot be verified in detail. Nevertheless, the EEB and WWF were able to reveal that the example of a European sales office with some 20 employees importing Chinese produced chemicals is used to illustrate a typical European SME problem.

Long (2005):
“No matter how hard it tries, industry cannot demonstrate that REACH is bad for business.”

Regarding innovation and business benefits, the KPMG study is a failure. Ignoring EEB’s and WWF’s suggestions for an improvement in methodology, the study does not offer valuable clues as to the structural impacts of REACH on the chemical industry. Considering their limited scope and methodological problems, the question arises as to whether these two studies were necessary at all. In summary, the additional two studies did not reveal new findings or unexpected impacts, but confirmed the need to better explain REACH and develop implementation guidance. But they provided strong arguments to convince industry of the necessity for a strong REACH. “No matter how hard it tries, industry cannot demonstrate that REACH is bad for business” (Tony Long, Director of WWF’s European Policy office). Meanwhile, more than 30 national and international studies have made further appraisals of the anticipated business impacts

of REACH. In October 2004 the Dutch presidency presented an overview study of 36 impact assessments. This compilation shows wide consensus on direct costs (some 50% above the Commission's calculations which might be reduced by arrangements that promote cooperation between companies and use of computer-based modelling techniques). Regarding macroeconomic effects, it highlights "*unrealistically high estimates*" in some studies due to "*unrealistic assumptions*". Benefits initially brought into play by environmental NGOs have been the subject of investigation in several studies: the Dutch report states benefits and positive effects in the long run concerning innovation, reputation and opportunities for export due to safer chemicals.

While it is not possible to estimate the overall impact of REACH on business with certainty, it is useful to explore which costs can be reduced and which benefits can be increased. Studies carried out by Member States, examining closely the mechanism of REACH upon selected industry sectors and companies (micro-economic approach), resulted in a number of useful proposals to improve and support REACH implementation, e.g. developing guidance for the application of the technical Annexes and other support measures by authorities. One important proposed change in legislation is the "one substance – one registration" principle in order to ease the burden for SMEs.

**Biased discussion in favour of
REACH losers**

The EEB and WWF support such improvements. It is regrettable that the debate should focus on the anticipated economic impacts, and not on ways to increase the benefits of REACH for business and the environment – as would occur if substitution of hazardous substances occurs and if information on dangerous substances in articles is communicated along the supply chain. Unfortunately, the discussion remains biased in favour of potential REACH losers and may well further weaken REACH instead of making it more successful.

2 REACH – a test case for impact assessments

Introduction

It is now 6 years since the debate on a new European chemicals policy began. For nearly as long, there has been concern about business impacts and the balancing of environmental, social and economic effects in general. There is no doubt that REACH *"represents a major policy reform in one or several sectors"* and that it *"will result in substantial economic, environmental and/or social impacts on a specific sector or several sectors and will have significant impact on major interested parties"* (European Commission, 2002). REACH was an auspicious candidate for the Commission's instrument of Extended Impact Assessment (EIA) adopted in 2002 to achieve *"better regulation"*. Although REACH was not on the 2003 candidate list for EIAs initially, DG Enterprise insisted on this and the Commission submitted an EIA in 2003 regarding the latest REACH proposal (Commission 2003a). The Commission's 2004 report (Impact Assessment: Next Steps) takes REACH as an example for some 50 impact-assessed regulation proposals. Regarding experiences, *"the Commission finds that the new Impact Assessment procedure is positively contributing to a new culture of transparency in regulatory design and management practice"*. (Commission, 2004, p.4)

A new culture of transparency in regulatory design and management practice

The purpose of the EIA is not only to study impacts but also to consult with interested parties and relevant experts with the objective of data and information gathering as well as validation (Commission, 2002). However, the Commission's work on the EIA for REACH started late in the process and stakeholders were not actively asked for input. On the other hand, it was one of the few Commission's EIAs which was developed in cooperation with different DGs and was presented to the public¹. Although the EIA process led to a substantial weakening of the reform, as can be seen with the deletion of three crucial test requirements for substances in the 1-10 tonne range, industry rejected the results. Instead of an open and transparent debate, massive lobbying happened with the result of re-opening the EIA and publishing a Memorandum of Understanding between industry and the Commission in order to start an additional impact study process (see chapter 3)².

Given the more than 30 additional business impact studies already produced, it makes sense to ask which gap in knowledge still has to be closed. The European Commission has already studied overall effects and reasoned: *"Taking account of the expected economic, social and environmental impact of its proposals, the Commission considers that a balanced approach has been achieved"* (p.32f). The Dutch presidency's compilation of the studies at hand (ECORYS, 2004) comes to a similar conclusion.

New studies because of unwanted results?

Instead of a thorough analysis of existing impact assessments with the aim of *"fine-tuning proposals ... (that) helps improve their cost-effectiveness"* (Commission, 2002, p.4), industry decided to launch a new impact assessment. At the same time, a coalition

¹ IEEP, 2004

² IEEP, 2004

of twelve EU business associations, calling themselves the Alliance for a Competitive European Industry, specifically set up to address REACH, demanded *"impact assessments to be made independently of the European Commission"*, adding: *"While welcoming the principle of impact assessments, EU industry is critical about how they have been implemented in practice"* (Environmental Daily, 2004). Regarding the Additional Impact Assessment process (chapter 3), it is doubtful whether industry participation really helps implementation in practice.

2.1 Main impact studies: methods and deficiencies

Already
36 studies completed

A detailed compilation of 36 different studies was made available by the Dutch Presidency in the run-up to a Member States' workshop in October 2004 (ECORYS, 2004). It aims *"to facilitate a comprehensive discussion on the impact of REACH"*. Meanwhile, further studies went on till the end of 2004. One of them is the British impact assessment made by DEFRA (2004), which tries to combine a case-study approach with an economic model to calculate indirect effects. The full results will not be available before 2005. The other studies are set within the additional impact study process led by KPMG and the JRC.

Impact studies generally have to choose between two possibilities to assess the business impacts of a new regulation:

- | Modelling the system within a **theoretical economic model** using econometric data. These models drastically have to simplify real life, e.g. the economies outside the EU are usually neglected. The results can be quantified statements about the expected costs or benefits. The study under the Commission's Extended Impact Assessment is an example of this (Canton/Allen, 2003). Another example is the Nordic Study (Ackermann and Massey, 2004). Regrettably, there is no overall calculation of the expected business benefits of REACH – with the exception of the calculations of occupational illness cost savings, which are also based on simplified assumptions.

Risk of strategic answers

- | **Looking into practice** (specific companies or branches) and focusing on specific mechanisms. In this case, the effects are examples, stories, suggestions and indications. Results cannot be generalized without taking into account the statistical evidence for doing so. And it is crucial not only to report the answers given but to validate and check them. *"The used method of interviews results in overestimation. If companies are to be asked whether or not they will withdraw a substance within the framework of an impact study, there is risk of strategic answers"*. (ECORYS 2004, p.93) Examples of microeconomic studies are the German Government Study (Ostertag e.a., 2004a), the REACH Pilot Testing in North-Rhine Westphalia (NRW, 2004), the opinion poll of Nordic concerns and benefits (Djerkyær, 2004) and the survey of companies in Baden-Württemberg (Baden-Württemberg, 2004) and Bavaria (Bavaria, 2004).

Both kinds of methodologies have advantages and disadvantages and both have different ends: when looking for an overall picture, it is necessary to use economic models; when trying to model the proposed legislation with regard to specific problems (e.g. SMEs, New Member States), it is necessary to look at specific companies, sectors or countries.

Some studies try to **combine both methods**: they use the results of case studies for validating theoretical models. From the scientific point of view, this is challenging because it requires highly sophisticated tools and in-depth verification and validation: checking the answers and performing a statistically sound extrapolation of results. If this is not done in a sound way, results may be arbitrary. An example is Arthur D. Little's study stating that the production loss due to disclosure (substance withdrawal) "*was estimated by industry experts*" (ADL, 2002, p.55). Asking industry about the number of substances to be withdrawn under REACH is akin to asking Marlboro about the consequences of higher tobacco taxes.

Looking at some industry studies, it seems that there is a formula for producing very high business costs:

A formula for producing very high business costs

- | assuming/calculating high direct costs as the driving force for withdrawal;
- | only focusing on economic-based withdrawal, avoiding investigation as to whether toxicological or other reasons could be involved;
- | asking the chemical industry about the probability of withdrawal and about time delays regarding the placing of new substances on the market;
- | not challenging answers that exaggerate what is actually required by REACH;
- | asking downstream users about the costs of substituting feedstock substances over night (ignoring the 11-year phase-in period);
- | adding direct and indirect costs – or not pointing out that they can't be added;
- | proceeding with the assumption that without REACH there would be no costs associated with chemical regulation;
- | neglecting all other future trends like exchange rates, oil prices, etc.;
- | avoiding transparency and a scientific review of the details of the study.

Transparency and scientific review as remedies

The last point seems to be the decisive remedy against partisan studies in any direction: transparency and scientific review of the chosen method. An example of what should not be done is the Mercer study (Mercer, 2003), which forecasts the loss of 360,000 jobs in France due to the latest REACH proposal. Only a PowerPoint presentation has ever been made publicly available and the slides which were presented on 22 June 2004 at the third meeting of the "Further work on impact assessment" Working Group showed grave inconsistencies in the basic assumptions concerning direct costs.

2.2 Direct costs of registration – the starting point of all impact assessments

REACH requires registration for chemicals produced in or imported into the EU in quantities exceeding one tonne per year per producer or importer. Where not available, the necessary information has to be gathered. For new substances, this has usually been already done – thus an estimated 30,000 "existing substances" are covered by REACH for the first time.

With increasing quantity (10, 100, 1,000 tonnes a year), the registration process demands more information. A manufacturer or importer that produces more than 10 tonnes of a substance classified as dangerous has to carry out a Chemical Safety Assessment (CSA) as part of the Chemical Safety Report. Moreover, manufacturers or importers – acting together with downstream users – must analyse and communicate the use-related risks entailed by their substances.

Higher one-off costs and lower costs after phase-in compared to current costs

Regarding direct costs linked to current legislation, REACH will lead to relatively higher one-off costs during phase-in. As a Dutch study shows, direct costs after phase-in will be even lower than current ones (KPMG/TNO/Sira consulting, 2004).

Direct costs for Dutch industry before, during and after REACH phase-in

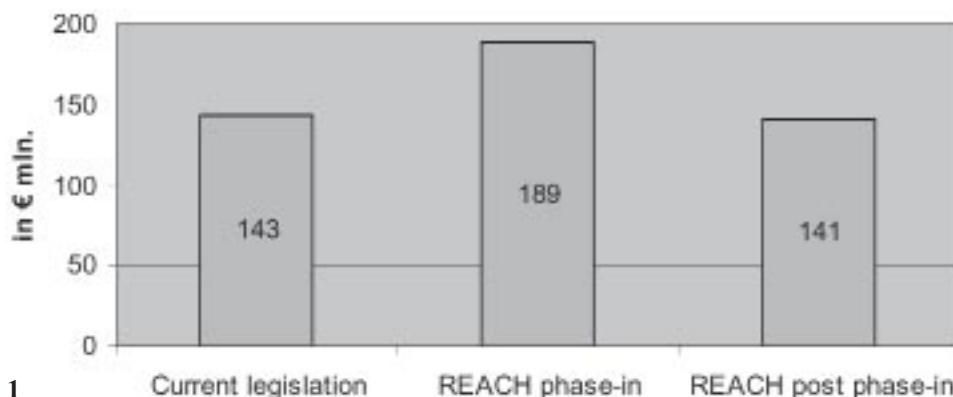


Illustration 1
(ECORYS, 2004, p. 64)

Future costs dependent on unknown future technology and techniques

As REACH is a largely procedural framework and practical application still needs to be developed, the exact measures necessary for gathering information are unknown at the moment. They can be lab tests, conclusions by analogy or group evaluations. It is also unclear how much data are already held by industry. In addition, the expected costs during the 11-year transposition period are assessed on the basis of today's methods and cost factors. With rising demand, there will be developments on the market. New and more favourable methods will be devised, for example (Q)SARs which are being developed as a possible substitute for expensive animal testing.

Especially sensitive with regard to business costs is the question of whether each company has to gather and submit necessary data on its own, or whether manufacturers and importers of the same substance should establish consortia. REACH forces companies to share animal test data and encourages consortium formation.

Notwithstanding these unknown factors, there is a wide consensus about the range of expected direct costs. After considering seven different impact studies, the Dutch review (ECORYS, 2004) concludes that the direct costs for the registration process – including tests, registration fees, drawing up Chemicals Safety Assessments and Safety Data Sheets – for companies in the EU will add up to 4 billion euros over an 11-year period, a result which is 65% higher than the Commission's assessment. These figures are supported by the latest impact studies from the Nordic Council of Ministers (Ackermann/Massey, 2004) and from the German Government (Ostertag e. a., 2004a). Differences in estimation arise from different assumptions like use of QSAR's (the Dutch study doesn't take them into account because of uncertainty while the Commission takes them into account, which reduces testing costs by nearly 1 billion euros), consideration of existing or synchronously generated data (e. g. the ICCA initiative on high production volume chemicals considered by the Dutch Study) and assumptions about the establishment of consortia.

Results determined by assumptions
(e. g. consortia, QSAR³)

2.3 Indirect business impacts: threats and opportunities

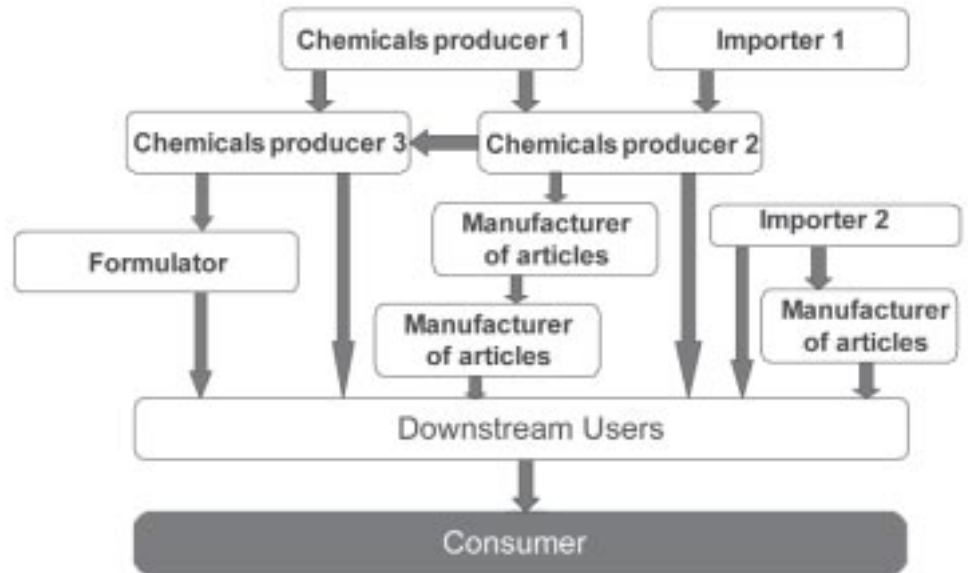
One-off costs for testing and registration mainly arise for chemical suppliers and importers. Depending on what they do to cope with these direct costs, indirect impacts evolve along the value chain for downstream users. Identifying these impacts is a difficult task: most trends and future developments have several reasons and influential factors, REACH being one of them. REACH-related impacts have to be stringently separated from the impacts resulting from other future developments which might be much stronger than the responsibilities required by REACH: wages, raw material prices, exchange rates, trade relations etc. Furthermore, the impacts attributed to REACH have to be compared with the impacts of today's chemicals regulation in order to measure the difference.

In the face of this major task, it is helpful to chart the value chain of chemicals in a simplified manner with three components: the producers and importers of chemicals (chemical industry), the downstream user (e. g. manufacturer of articles but also building industries and service sector) and the consumer. In practice, it is a lot more complex. Downstream users usually purchase preparations mixed by formulators. And there are usually several downstream users connected in series and in parallel (see illustration 2).

Indirect impacts are based on huge uncertainties

³ *Quantitative Structure Activity Relationship - a computer based modelling of chemical properties*

Illustration 2
(following KPMG, 2004b)



Simplified scheme of interactions in the supply chain*

**The figure above is meant to give an example and will most likely not reflect the actual situation in all sectors.*

Results often slanted towards related fears or hopes

Due to necessary assumptions and methodological pitfalls, most studies on indirect effects are controversial, with potential business impacts – benefits and disadvantages – being assumptions, often slanted towards related fears or hopes. Surveys that interview business staff are a good way of assessing internal knowledge but can be disqualified as “opinion polls”. Theoretical considerations may allow for a broader approach – and are criticized as being too academic and not in touch with realities.

2.3.1 Benefits

In January 2003 WWF and EEB discussed **benefits** for industry. Meanwhile, a number of these benefits have been supported by independent investigations showing decisive business benefits, especially for the users of chemicals.

Specific business benefits (WWF and EEB, 2003)

Evidence to support the benefits listed in other investigations

REACH is designed to create a **level playing field**, ensuring that all new or existing chemicals are shown to be safe. How industry reaches that target and what substances they substitute for unsafe chemicals is not defined in the regulation, but is open to competition and innovation.

Cost reduction for those companies which are active in more EU countries (level playing field) (Commission, 2003a)

Scandinavian industry sees a level playing field: REACH will create a new large market with homogenous rules and legislation on chemicals. This will make it easier for companies that operate in more than one country. Today many international companies use much administrative time in sorting out national legislation in all those countries in which they operate in order to be able to operate legally everywhere. In addition, a level playing field for all players in a common market of 25 Member States will set new chemicals safety standards that are competitive on the global market (Dyerkjær, 2004, p.32).

REACH will especially result in cost reduction for those companies which are active in more EU countries (ECORYS, 2004, p.46).

At the same time, the competitive advantage for manufacturers of substances not classified as dangerous due to lack of data will also diminish. Companies aiming to improve the safety of products and processes will be able to choose among substances which can be accurately compared with regard to their properties (Ostertag e. a., 2004a, p. 7)

New, green products can increase consumer appeal and **open up new business opportunities**. Companies that are proactive can gain a competitive edge over those struggling behind.

In the long term, there are opportunities for companies to make new products. REACH will result in an increase of opportunities for new substances in the European market. There are also opportunities for SMEs, because they are flexible and able to find niches in the market (ECORYS, p. 54).

Complying with stricter rules can **minimise future risks and liabilities**.

Massive savings in health care costs, lost output and "human" costs at downstream user level (different studies cited in ECORYS, 2004).

Prevention of damage costs esp. regarding skin diseases (Ostertag, e. a., 2004a).
Less work for downstream users and retailers to provide information about safety of substances; easier compliance with other legal acts (e. g. workers health provisions) (Ackermann/Massey, 2004; Dyekjaer, 2004)

Specific business benefits (WWF and EEB, 2003)	Evidence to support the benefits listed in independent investigations
Reduced business risks relating to liability and reputation	<p>Less danger of scandals because of predictability of substances' properties (Dyerkaer, 2003)</p> <p>REACH may prevent damage costs through standard information requirements. Definition and communication of exposure scenarios by the manufacturer may prevent substances from being used in an unsafe manner. (Ostertag e.a., 2004, p.9)</p>
Increased predictability of substance regulation	Lesser complexity of chemical regulation (Dyerkaer, 2004)
<p>Cost reduction for bringing new substances onto the market</p> <p>Assisting in the creation of new markets</p>	<p>We find that many of the main provisions of REACH tend to promote innovation both within the EU chemicals sector and more widely – especially by encouraging the replacement of older, more risky and less sustainable chemicals with newer alternatives and by changing the direction of innovation towards safer and less damaging chemicals (Berkhout e.a., 2003, p.3)</p> <p>The claim that REACH tends to block innovation is rejected for lack of conclusive evidence. In contrast, the paper reinforces the view that the White paper strategy is an important step forward towards sustainability in the chemicals sector. (Nordbeck/Faust, 2002, p.1)</p> <p>Innovation involving new chemical substances will not be delayed. Since regulatory requirements will be eased on small-volume new substances, REACH should if anything, accelerate their introduction, boosting innovation and improving the competitive position of European producers (Ackermann/Massey, 2004, p.10)</p>
Creation of markets for safer products that are substituted for hazardous substances	A number of studies also indicate that there will be better market opportunities for the chemical industry by manufacturing ecological products and by improving the image of the chemical industry (ECORYS, 2004, p.46)
<p>Making "product stewardship" reality.</p> <p>Improved transparency and communication through the supply chain will lead to increased power and confidence for downstream users and SMEs.</p>	<p>Exposure assessment and the definition of conditions for safe use throughout all the relevant life cycle steps will be a pre-requisite for registration and hence for the continued marketing and use of a substance. This sets a strong incentive for substance manufacturers and importers to improve the exposure related parts of their safety data sheets and thereby support small and medium-sized users, in particular. At the same time, this mechanism will provide an incentive for downstream users to make information on use and exposure available to suppliers. (Ostertag e.a., 2004a, p.7-8)</p>

Out of this list, the downstream users' benefits seem to be most important. "Downstream users currently bear the burden of the on-going 'everyday' costs of worker protection, pollution control, risk management and waste management. By increasing the incentives for the development of safer products and processes, REACH would decrease this burden" (Ackermann/Massey, 2004). This will have two consequences:

- | **Reduction of uncertainty:** saving time, image and costs because of better information about possible (toxic, legal and market) risks;

Need for effective regulation and clear communication

The Retailers' Story

The most vulnerable companies are those which are at the end of the supply chain, closest to the ordinary and professional consumers, such as retailers and consumer goods manufacturers. This is why these companies tend to be most supportive of REACH, particularly if they have been running a proactive chemicals policy and have found how difficult it is to do this under the current regulatory system, e.g. companies such as Marks and Spencer's, Ikea and H&M: "We believe it is far more efficient and effective to regulate a single chemical in a consistent way rather than expect hundreds of different

retailers to take their own potentially conflicting views of the many thousands of different uses a particular chemical could be put to" (ChemSec, 2005, p. 12). At the EEB 2002 Copenhagen Conference, Mr. Mike Barrey, of Marks and Spencer's UK, made a point on communication to consumers regarding complexity: "It is too complex a message for my consumers to say this isomer is safe, this one is unsafe. For them, it is just a brominated flame retardant". (EEB, 2002, p. 22)

- | **Reduction of occupational illness:** saving money in terms of expenses for health care costs, lost output and "human costs", including occupational invalidity and disability.

The German "Berufsgenossenschafts" Story

One of the best sources of data on current health costs relating to occupational exposure to chemicals are the German industrial employers' liability insurance associations (Gewerbliche Berufsgenossenschaften), which are responsible for paying out pensions to industrial workers who have been shown to be ill as a result

of workplace exposure, for example to isocyanates or certain hairdressing products. Since 1988, thousands of hairdressers in Germany have been sensitised by one ingredient in acidic perm lotions, glyceryl monoethioglycolate. This sensitisation meant that many could no longer work in the industry.

The German "Berufsgenossenschafts" Story

A detailed analysis of the German health data has been performed (Rühl/Wriedt, 2004). It concluded, by adjusting figures from Germany to a 15-state EU:

- | Epoxy resin-related worker compensation would cost 18.5 million per year
- | Isocyanate-related worker compensation would cost 21.5 million per year

If worker compensation costs for skin diseases and asthma (excluding isocyanate) are calculated, the cost would be 275 million per year in Germany alone, including an estimated 10% contribution from public sector workers. Therefore, in EU-15: 1.38 billion per year – "For days lost, you would have to reckon about the same sum again".

Significant savings in health care costs, lost output and "human" costs

Several studies have calculated considerable future savings in health care costs, lost output and "human" costs. Estimates range from 18 to 54 billion euros (RPA 2003). Miliøstyrelsen (2004) estimates environmental benefits in Denmark to amount to a total of 450 million euros, which only relates to a selection of effects. An investigation commissioned by WWF puts the cumulative benefits of REACH for European societal health expenses at between 57 and 283 billion euros (Pearce e. a., 2003).

2.3.2 Indirect costs

Due to registration, industry has to bear additional costs for a limited timeframe of 11 years. Different investigations show a huge range in results. While the Commission – and also the Nordic Council – anticipate indirect costs on roughly the same scale of magnitude (factor 2 to 6) as the direct registration costs, the studies commissioned by industry reach the conclusion that the scale of magnitude would be up to 650 times the direct costs (storm scenario, ADL, 2002). These figures convert directly into figures for the job losses that REACH is expected to cause.

With regard to testing and registration costs, chemical suppliers and importers have three possible responses:

1. **Higher costs will be passed on to customers** (like costing supplements for kerosene in aviation)

This is likely to occur if a market has a high price elasticity. This means that higher prices do not significantly change the demand. Customers are not very price-sensitive or they do not have big choices because all relevant manufacturers and importers raise prices.

2. **Higher costs will reduce profit and will be adjusted at some other level**

Low price elasticity means that customers are able and willing to sidestep – higher prices lead to lower demand. Manufacturers and importers cannot pass on registration costs. In this case, they will think about offsetting the costs internally.

Price elasticity determines reactions

3. The substance in question will be sorted out of the portfolio (withdrawal)

Should manufacturers know or fear that the safety assessment of a substance is not favourable to safe use, or should they realize that registration costs will be higher than expected profits for the substance in question and the price increase cannot be passed on, they will think about ceasing production.

Passing on registration costs will confront **downstream users** with the problem of their market's price elasticity. They have the same three possible choices as manufacturers, one level higher: (i) passing on costs to consumers, (ii) internal adjustment and (iii) change of portfolio. There is a fourth option, however: users can relocate their production outside the EU. In all four cases, the highest possible costs for them will be the registration costs that they get passed on, because reactions only make sense if passed-on registration costs are higher than costs for portfolio change or relocation. The upper limit for costs is therefore the registration costs.

The dramatic costs calculated in some studies come from the fact that substances that downstream users are dependent on are no longer available.

Dramatic costs in some studies come from disappearance of critical substances from the market

In a functioning market downstream users which are faced with a substance withdrawal have the following alternatives:

- | Maybe they already use an alternative feedstock substance anyhow. Or they are working with several substances in parallel. Within the phase-in period of REACH, it seems realistic to assume normal turnover of input chemicals (e.g. 1.7 to 5.6% per year in the case of manufacturers of preparations of cleaning agents and detergents (Ostertag e. a., 2004b, p. 1176). They can then react quickly.
- | Or they are thinking anyhow of relocating production outside the EU. Then withdrawal will be an additional argument.
- | Or they will reorganize their production/service, the feedstock or the process, or perhaps both. The involved costs can be huge.
- | To avoid high costs, it can make sense to speak with the manufacturer at an early stage – perhaps to agree on a strategic division of registration costs. In this case too, registration costs will be the upper limit. A problem might be insufficient communication. But REACH is precisely aiming to provide this communicative interface.

This discussion shows that indirect costs should be in the same range as direct costs. They will probably exceed direct costs by an amount corresponding to interaction costs. But these interaction costs can be reduced by rational behaviour and enough time to react.

In a functioning market indirect costs will be in the same range as direct costs

Parallels are sometimes drawn with the biocides and pesticides regimes, which have resulted in a considerable reduction in availability of active ingredients. However, the data requirements for such substances are much higher than those of REACH, and many of the withdrawn substances do have hazardous properties and are estimated to be unsafe in their use, so this comparison is not useful.

2.3.3 Appreciation/Weighing

<p>REACH can give a direction to innovation</p>	<p><u>Innovation:</u> REACH will fundamentally foster the development of new and safer substances. Exempting product- and process-oriented research from registration for a five-year period (which can be renewed for another five years) would help prevent negative impacts on innovation. Grievances that <i>"the implementation of testing requires highly skilled personnel, which may limit the personnel available for Research and Development activities"</i> (Commission, 2003a, p 20) can be changed into: sustainable development means that researchers have to consider innovation process not only under technical and economical but also under HSE aspects.</p>
<p>REACH can change the direction of problematic trade processes</p>	<p><u>Changed competition between Europe and the USA or Asia:</u> Cheap and potentially impure chemicals from outside the EU will lose their competitive advantage. On the other hand, downstream users outside the EU may use cheaper feedstock substances without registration costs. But cautious retailer companies (e.g. IKEA, Marks and Spencer's) will be encouraged to buy in the EU, because it is guaranteed that chemicals are REACH-registered. Finally, this depends on how REACH will deal with chemicals in imported articles, which at the moment is not resolved. Industry claims that the time required for placing new substances on the market will be longer in Europe than elsewhere. But compared to current legislation, REACH does reduce that time.</p>
<p>Funding problems but innovation benefits for SMEs</p>	<p><u>SMEs</u> 99% of companies in Europe are SMEs (19.27 out of 19.31 million in Europe⁴). Within the manufacturing industry (2.25 million companies), SMEs are the dominant category (Commission, 2003b). In comparison, the proportion of SMEs in the chemical industry falls to 95% (Eurostat 2004). While manufacturing SMEs in particular, as part of downstream users, should expect a lot of benefits (see chart above), industry claims possible disadvantages for SME chemical manufacturers. Published examples mainly apply to importing SMEs (VCH, 2005, KPMG, 2005; IPTS 2005b), showing a possible shift in use from imported to "home-grown" chemicals. Regarding European-based SME chemical manufacturers, there will mainly be the problem of funding one-off costs (KPMG, 2005), a common problem for most investments at SME level, which is not specific to REACH. On the other hand, SMEs are often at the forefront of innovation and could therefore benefit from the reduced regulatory burdens REACH would introduce.</p>

⁴ EU-15 plus the three other countries of the European Economic Area (Norway, Liechtenstein, Iceland) together with Switzerland (Commission, 2003b).

REACH can strengthen structural change in the NMS**New Member States**

The average size of companies in the new Member States is smaller than in the EU-15 and their competitive position is often fragile. *"Compared with the volume of the chemical industry in the EU-15 (96%), the total chemical production in the new member states is limited to 4%"* (ECORYS, p.24).

The chemical industry in the New Member States is still dependent on petrochemical raw materials coming from Russia and the Ukraine, and the chemical industry in some countries still reflect historical trade relations with the former Soviet Union (e. g. Estonia). REACH will strengthen structural change in the direction of integration in the European market (IPTS, 2005a). Additionally, the already realized full compliance of the Chemical Acquis in the NMS can become an advantage, *"as the full body of chemicals legislation has yet to be fully implemented in the EU-15"* (IPTS, 2005a, p. 8).

3 Two additional impact studies – no new results

3.1 Background

A Memory of Understanding between industry and commission

After rejecting the results of the Commission's extended impact assessment accompanying its REACH proposal and massive political pressure using studies to predict massive job losses, UNICE and CEFIC convinced former Industry Commissioner Liikanen to further investigate REACH business impacts. Eventually industry and the Commission endorsed a Memorandum of Understanding on 3 March 2004 with the objective of *"providing a framework for the efficient undertaking of further investigations on business impacts of REACH"* (MoU, 2004). They agreed upon *"further investigations (that) take the form of specific detailed studies additional to the Commission staff working paper on Extended Impact Assessment of the REACH Proposals"*. The results of this work should *"form an essential input to inform the legislative process of the REACH regulation"*.

The Memorandum mentions that through case studies, *"factual evidence on how REACH is expected to affect enterprises and material streams in practice shall be collected"*.

The focus on **availability of substances to downstream users** and **withdrawal of substances** shows the high priority given to the disappearance of chemicals as predicted by industry.

Following the Memorandum, three issues were to be analysed by additional studies commissioned by industry and the European Commission: the potential impacts of REACH on **business throughout the supply chain**, on **innovation** and on **New Member States**. A Working Group was to monitor these studies and report the results of its work to a High-Level Group. Broad-based acceptance of the results was to be achieved through the involvement of key stakeholder groups.

Commissioners assure a fully transparent process

Although they did not participate in negotiations on the Memorandum of Understanding, the EEB and WWF were invited by the Commission to take part in the working group that was subsequently established. After being assured by Commissioners Liikanen and Wallström (Commission, 2004g) that minority views in the working group would be duly recorded and the process would be fully transparent, both organisations decided to participate and from April 2004 to April 2005 intensively contributed to that working group. Here the opportunity for a **joint learning process** presented itself. The European Commission, industry, trade unions as well as consumer and environmental NGOs together with their respective consultants discussed scientific approaches, listened to experiences gained from other studies (Dyckjaer, 2004, Mercer, 2003) and particularly monitored progress of the two studies initiated by the Memorandum of Understanding:

- | Joint Research Centre/Institute for Prospective Technological Studies, financed by the Commission: **The Impact of REACH in the New European Union Member States**
- | KPMG, Netherlands, commissioned by UNICE and CEFIC: **Analysis of the potential impacts of REACH on business and innovation throughout the supply chain.**

Good intentions

Major disputes have arisen about the KPMG study. The Working Group's main struggle was the paradox of dialogue: starting a dialogue and offering participation means that you have to be open to developments that lead you to another point than what you initially aimed for. In its first proposal, KPMG stresses: *"There is limited acceptance of most of those (impact) studies; ... The additional impact study to be undertaken is intended to gain a wider acceptance. This requires some kind of cooperation at two levels: with industry ... and between the European Commission, industry and NGOs. ... On contents, broad acceptance of the approach of the study is highly recommendable. ... A proper process requires transparency ..."* (KPMG 2004a).

... without compliance

In spite of these assurances, the study was conducted without the changes that were suggested by NGOs. At the start of the process, it became apparent that KPMG was not paid for an upfront dialogue about its planned procedure – in fact, KPMG had no contract at all until July 2004. The EEB and WWF submitted comments on the KPMG proposal (EEB/WWF, 2004a; EEB/WWF, 2004b). At the 14 July meeting, there was no resolution of the points of divergence, no fixed methodology and no information on the selection of companies for the case studies – and without having reached any consensus, industry and KPMG went ahead and officially launched the investigation in July (Commission, 2004b). Until the end of the process, there was no *"clear and well-documented protocol on the methodology of the KPMG exercise, with references to the methods approved by the scientific community"*, which the Commission adviser Prof. Leo Sleuwaegen characterised as important to enable internal verification at the 1 March meeting of the working group (Commission, 2004f, p. 9).

EEB and WWF withdrew their support to the KPMG work

As the study proceeded, it became obvious that the mistakes of previous industry-led studies would be repeated. After constructive but unsuccessful input and attempts to overcome some of those shortcomings, the EEB and WWF withdrew their support to the KPMG work. EEB and WWF could show that the KPMG study was merely an opinion survey without safeguarded statistical representativeness (Commission, 2004c, d, Commission, 2005a). The confusion between soft facts (opinions of company staff) and so-called hard facts (calculation of economical relevance within the companies' financial frame) and the methodological bias towards potential losers was not only mentioned by the environmental groups but also addressed by trade union representatives (Commission, 2004d). Even the Chair pointed out: *"However, a residual point of concern was the order of material in the questionnaire and data processing sheets which bears the risk of mixing hard facts with data based on the opinion of the interviewee"* (Commission, 2004d, p 8).

Validation of an industry paid study by unknown industry representatives

The struggle regarding the participant lists of validation workshops (see Commission, 2005b, p. 6) seems to be characteristic of the Working Group's atmosphere. Validation with broader industry participants should make up for the empirical deficiency (very small case numbers) of the study. But the names of the companies participating in two of the four workshops (electronics and automotive) were not circulated. So the Working Group members had to accept the validation of an industry-paid study by unknown industry representatives if a common view was to be reached.

Working Group failed in its task to submit consensual results

Consequently, the EEB and WWF repeatedly distanced themselves from the KPMG study. (Commission, 2005a, p.3: *"He (the EEB representative) stated that the NGOs had not seen new facts which would induce them now to accept the methodology chosen by KPMG".*)

In the end, the Commission chair of the Working Group did not make any effort to find a common position on the final studies of KPMG (2005a) and IPTS (2005a, b). So the Working Group failed in its task to submit the result of its monitoring of the studies to the High-Level Group. Although both studies suffered from the limited number of cases, industry managed to delay the submission of the IPTS study to the High-Level Group – allegedly because of lacking validation but presumably because of unwanted results. This unequal treatment seems to be unreasonable compared to the inadequate validation of the KPMG study and taking into account that contrary to KPMG, IPTS embedded their case study results into a macroeconomic analysis of the chemical industry.

Both studies show: No withdrawal of critical substances

3.2 Overall results

Even though the studies' methodology was biased towards potential losers, there are some overlapping results from both studies which are valid for the companies considered:

- | There is no indication of withdrawal of critical substances and there will be no significant withdrawal of other chemicals because of REACH.
- | Costs of registration will have limited impact on competitiveness and profitability of companies. They will be diluted down the value chain.
- | Significant problems for single companies might arise in the context of REACH – but mostly as windfall wastages. Case studies showed that the planned rationalisation of the portfolio of suppliers and formulators might be encouraged anyway – but only after discussion with their clients (KPMG, 2005, p.20).
- | Whilst companies acknowledge the benefit of better data and management, there are concerns within the industry that the economic impact of REACH will be greater than has been identified on the basis of the financial data of the companies visited.
- | Importers of non-EU chemicals might face problems because the competitive edge over EU chemicals given in the past will disappear.

When comparing both studies, one must say that both have some pros and a lot of cons. Neither brings really new results.

Nonetheless, the industry and Commission highlighted in their respective conclusions the problems that SMEs and low-volume chemicals would face and the fact that confidentiality issues and lack of supply chain communication are matters of concern.

Although some of those points could be based on common sense and practical experience, for example the fact that SMEs generally find it more difficult to implement legislation than larger companies, there is no basis for drawing such conclusions from the KPMG and JRC studies.

3.3 KPMG study on business impacts and innovation

3.3.1 Approach

The study is limited to case studies. Validation and verification of the results are restricted to the chosen methodology (inherent). No certification regarding macroeconomic effects in value chains (price elasticity) was made.

KPMG conducted interviews with staff of representative companies out of four downstream industry sectors: automotive industry, electronic/electrical goods, packaging industry and inorganics industry. The companies were chosen in cooperation with industry sector associations.

tonnage band	Total test costs	Registration costs	Total costs
1-10 t/a	8.7	5.9	14.6
	7.7	5.4	13.1
10-100 t/a	151.6	11.1	162.7
	73.1	7.9	81.0
100-1,000 t/a	243.5	38.6	282.1
	163	28.7	191.7
> 1,000 t/a	278.2	45.0	323.2
	208	28.7	236.7

Table 01:

Standardised individual testing and registration costs applied in the KPMG study for non-dangerous substances in 1000 EURO; *as a comparison with the costs chosen in the IPTS study.*

Direct costs at the upper limit

Testing and registration costs were chosen by using the ECB/RPA Maximum Scenario (low regulatory acceptance of QSARs; RPA, 2003a). For its part, IPTS used the average scenario. Moreover, KPMG only presumed the establishment of consortia with two companies, while IPTS regarded consortia formation with more than three firms. These costs seem to be unrealistically high. Compared with the Commission's Impact Assessment (Commission 2003), KPMG uses exaggerated testing cost scenarios which are up to two times higher. Additionally, the potential for consortia formation is underestimated.

Regarding the 10 downstream user companies⁴ chosen for the KPMG study, KPMG selected substances of critical importance for products/processes and traced them back via formulators to suppliers. At supplier level, the economic vulnerability of these substances was checked out by confronting the substance specific profits with the expense

⁵ *It is not clear whether 12 downstream users (p.12) or 10 downstream users (p.6) participated in the study. It should be noted that out of the 10 users, there were two companies from the electronics sector, which is "not covered in this summary" (p.5).*

of necessary testing requirements (NPV method: net present value). It was assumed that vulnerable substances (discounted testing requirements were higher than expected profits) faced the possibility of being withdrawn. Formulators and downstream users were confronted with passing on costs or having their feedstocks withdrawn, depending on the suppliers' and formulators' response. At each stage, impacts were assessed (KPMG, 2004b). Overall, the study looked at a total of 152 substances, from which 46 critical substances were NPV-assessed. In addition, 28 non-critical substances were NPV-assessed.

Level	A	I	F	E+	Approach to impact assessment
Chemical supplier	3	5	4*	(1+?)	Define reaction Assess vulnerability Assess impact
Formulator	4	**	4	(2)	Define supplier Select substances Define reaction Assess impacts
Downstream user	2	4	2	(2)	Define supplier Select critical preparation Define reaction Assess impact

START RESULT

Table 02: (KPMG 2005b and KPMG, 2005c). Numbers of participating companies for the Automotive (A), Inorganics (I), Flexible Packaging (F) and Electronics (E) Sectors
*: plus 5 for extra check; **: category was not used; +: The electronics case has not been finished yet, the results are not part of the final report (KPMG, 2005a, p 5).

”what if” assumptions instead of real findings

Due to the very low impacts found and unsatisfactory results (no vulnerability found, substance-specific reactions could not be recorded, uncertainty about interpretation of REACH), KPMG used methodological dodges: scenarios, assumptions and simulations were made to presume ”what if” situations: what if natural materials (like zinc ores) had to be registered, what if significant parts of the downstream users’ input materials had to be withdrawn, etc.

Until now no consistent methodology available

The main points of criticism which have been made by the EEB and WWF from the beginning lay in the fields of **methodology and transparency**. Globally, it should be mentioned that even the executive summary from April 2005 (KPMG 2005a) does not contain a consistent and scientifically sound description of the methodology used. KPMG quotes one single publication out of business management literature, but not

one single scientific proof. Basic questions regarding scientific soundness have never been answered.

| **Why did the study only focus on possible losers? REACH will bring change and there will be winners and losers. Who has talked to the winners?**

The concept of critical and vulnerable substances means that KPMG only looked for losers. A balanced approach would also require looking for companies and sectors with high occupational illness costs and high uncertainty regarding the hazardous properties of chemicals, or for companies closer to consumers interested in high safety levels and reputation, or for insurance companies. In the study, negative results are predetermined. Asking the potential losers questions about benefits appears to be a poor compromise. And when looking only at possibly withdrawn substances and not their replacement, we cannot see the companies that will benefit if substitution occurs.

| **Why have the results never been embedded into macroeconomic and technical know-how about the sectors?**

Price elasticity as the decisive parameter for reactions along the value chain does not seem to have been considered at all by the authors of the study. Instead they rely on company staff opinion. In addition, the study barely looks at technical processes and developments, substitution potentials and process innovations. Microeconomic considerations stayed in the foreground.

| **How is it ensured that the interviews follow the quality criteria of "good opinion poll practice"?**

KPMG's papers stated again and again that they collected factual information, in fact the whole study was based on the individual views of company staff. Due to repeated interventions through the EEB and WWF, KPMG provided assurances that they would instruct the interviewers about the details of the REACH proposal and that they would inform companies prior to the interviews about how REACH would affect them. But in addition to knowledge about REACH, interviewers should have some knowledge about empirical social research: how to interpret answers, how to phrase questions, how to disclose tactical answers. However, there was no way for any stakeholder to verify that interviewers had been trained.

| **How can single case study results (2 downstream users per sector) achieve broader validity?**

Which persons and companies have to be present in the validation workshops for this aim? Where is the scientific evidence for this kind of validation? Since May 2004 (see Commission, 2004f, p. 2+3), the issue of generalizing the insights gained in single cases has been discussed. Consensus was reached in the working group about the fact that the study could and should only provide insights into the mecha-

nisms of how REACH can affect particular companies and that there could not be any extrapolation to a macroeconomic level. But in the end, results were formulated as if it was possible to draw general conclusions (e.g.: *"Taking these measures into account, it will be difficult for SMEs to fund the direct costs"* p.20, or: *"Passing on costs may be more difficult for SME companies"* p.23).

There are procedural deficiencies beneath the scientific data:

| **Who are the companies, which substances were involved and who did the validation?**

Because of confidentiality issues, KPMG didn't want to disclose the names of participating companies. In May 2004 Commission services noted during the second meeting of the Working Group: *"This would be fine, provided that the reasons for choosing each supply-chain and companies were transparent and justified"* (Commission, 2004f, p 2+3). KPMG disclosed the selection criteria (KPMG, 2005a, p.5) but without knowing which companies had been interviewed, which substances were tested for vulnerability and even which persons and institutions (in the automotive sector) validated the results – this is nothing more than a hide-and-seek exercise. Nobody from outside could prove whether the selection was justified. In view of the many unclear methodological issues and the poor past experience with industry-financed business impact studies, consumer and environmental associations demanded access to raw data and to intermediate steps of the study from the beginning. This is the only way to monitor the generation of results. Suspicions accordingly arose when industry refused access. There was no possibility for environmental and consumer associations to ensure that the experts they trust did take part in the interviews or inspect the interview minutes, nor could they even take part in the validation workshops.

| **Innovation and business benefits: checklists instead of curiosity**

At the last Working Group meeting of 13 April 2005 (no minutes available), representatives from environmental groups and from trade unions expressed their disappointment about the innovation case. Instead of innovation dynamics, KPMG only detected burdens again because of REACH: because R&D departments are also involved in registration activities, they might be distracted from their original task. The same went with benefits: checklists instead of curiosity characterized the interviewers.

3.3.2 Results

Following the original approach, virtually no vulnerability was observed. Out of 22 critical substances in the flexible packaging industry, only one was vulnerable. And out of 24 critical substances in the automotive industry, one substance was vulnerable – a component of a multi-substance package, which as a whole is not vulnerable (KPMG, 2005a, p. 17).

More vulnerability was found when KPMG expanded the focus to non-critical substances. But most of the 8 additional vulnerable substances are part of the portfolio of a sale office with some 20 employees for oil additives imported from China. This single and specific case is then used to conclude that *"almost all vulnerable substances found are in < 100 tonnage band"* (KPMG, 2005b, p.4) and that *"vulnerability is found at SMEs"* (KPMG, 2005a, p. 18). So in this biased result, the description of the problems of one Chinese importer's European office is used to mention possible typical SME problems and hypothetical considerations ("what if") lead to the emergence of real problems. Regarding larger chemical suppliers, KPMG states that there are *"indications of low vulnerability, but difficult to quantify"* (p. 18). Chemical suppliers and formulators try to maintain their portfolio in order to keep their customers satisfied (continuity of supply, trust quality, customer communication, p. 19). *"Chemical suppliers prefer to register such a substance" (which is part of a functional package) "to prevent reformulations of many packages"* (p. 18).

In fact, KPMG could have stopped its work at this point: no vulnerability of critical substances means that profits at supplier level are higher than registration costs. Suppliers may have a problem with funding one-off registration costs, but forming consortia and rationalising the non-critical part of the portfolio will help (p.20). Only SMEs might have a problem with funding – with the sales office of Chinese chemicals being one of two SMEs at the root of this statement.

KPMG also tries to focus on the magnitude of direct costs. KPMG finds a 6-20% one-off cost increase of a selected product in one SME case and a cost increase amounting to 20% of annual turnover in another SME. The figures are then used to claim i) competitiveness and ii) SME-funding problems:

- i. This seems to be the SME in the flexible packaging case study where the production cost of a selected pigment/dye may increase by 20% over one year (assumption: no consortia and high testing costs scenario). If the whole portfolio is taken into account and consortia formation is assumed, it will be 6% (p.22). In the automotive case, the highest figure is 17% (with consortia); it most likely refers to the SME importer of Chinese oil additives and is due to the fact that for substances with a relative low turnover, the organization of consortia does not pay off. Hence such an importer may choose to do it on its own (6% cost increase). In the end, in the cases in point, it may come down to a maximum cost increase of around 6% for one year at portfolio level with the most efficient consortia choice. This can still represent a lot of money for a company, but this is mainly a funding problem.

One Importer's problems used to claim typical SME problems?

**Maximum one-off costs:
6% for one year**

**Price increase of paints
well below 0.2%**

- ii. This seems to be the specific case of the EU sales office of Chinese chemicals, 17% of its portfolio being potentially vulnerable. One-off registration costs amount to 20% of its annual turnover.

A potential one-off product cost increase of a single pigment/additive product (used in paints) of up to 20% was calculated. This high figure is wrongly used to demonstrate funding or competitiveness problems at SME level. It is a worst-case cost scenario which is not put into perspective. Considering a more appropriate registration-cost scenario assuming increasing availability of alternative testing and data sharing, this on-off product cost increase could be around 6%. This can be more easily spread over e.g. 3 years, reducing the price increase to 2%. According to KPMG, pigments/additives make up 10% of costs of the final paint. This means that the price increase due to REACH for paints will be well below 0.2%.

Despite these not very impressive findings on the impact of direct costs on business, the idea of indirect costs seemed to be refractory in the study. KPMG continued to assume that theoretically, substance loss could still take place. All the more so since the formulators interviewed expressed *"uncertainty and concern about the availability of critical substances and the timing and likelihood of withdrawal"* (p.21), leading to the conclusion: *"If withdrawal of critical substances took place, the impact downstream will be significant in a relevant amount of situations"* (p.21).

On the other hand, KPMG puts this statement in relation to the value chain where (direct) costs will be either absorbed by the suppliers or get diluted down the chain, *"as additives make up 10% (paint) to 30% (engine oil) in the value of a preparation" and "major other components" are "exempt (resins) or less vulnerable (solvents)"* (p.22).

**Absurd daily testing rates for
recovered paper or zinc ore**

A special case in the study is the inorganics sector. The participating companies from this sector felt *"strong uncertainty ... as how (if at all) to apply REACH"* (p.24). To cope with this uncertainty, scenarios with different interpretations of REACH were used which partly diverged from the attitude that the Commission expressed in the Working Group (e.g. waste material to be registered). The assumptions that *"raw material (primary and secondary and alternative fuels) are not exempt from the scope of REACH"* (p.24) and that non-homogeneous material like recovered paper in huge quantities has to be tested every day leads to absurd daily testing rates and accordingly to a high impact on profitability and competitiveness.

Overall, the KPMG study gives an insight into very specific single cases where even in the assumption of worst-case cost scenarios and no business benefits, only very limited negative impacts can be detected.

3.4 IPTS study on New Member States (NMSs)

3.4.1 Approach

The study provides "a general analysis of potential impacts of REACH in the New Member States, illustrated by techno-economic case studies ..." (IPTS, 2005b, p. 11).

Study embedded in macroeconomic context

Starting with a general overview of the chemical sector in all New Member States, IPTS collected key macroeconomic data like sector development, trade patterns (with EU and non-EU) and described subsectors. The macroeconomic view was refined by examining the impact on the chemical industry through the implementation of the Chemical Acquis and EU Accession. Results were subsequently compared with other impact studies.

Average cost scenario

The case studies were selected in Poland, Czech Republic and Estonia. Difficulties in access to companies led to changing the countries studied (Estonia instead of Slovenia). Due to the scope of the study – the specialty chemicals – IPTS started with formulators, unlike the KPMG study. And instead of substances, IPTS looked for potentially vulnerable preparations. The approaches are then comparable: tracing back to suppliers, calculating the NPV and asking them about possible reactions. Differences exist within the testing cost assumptions (look at table 03): IPTS used average QSAR-scenarios and presumed consortia of more than three companies.

Level	Cz	P	E
Chemical supplier	2	3	3
Formulator	2	1	3
Downstream user	--	--	--

Table 03:

Number of participating companies (IPTS, 2005b)

Very small number of participating companies

The originally planned interviews with downstream users could not take place as the interviewed companies were reluctant to name their customers. So reactions were assessed by macroeconomic data (price elasticity).

There was no SME within the group of interviewed companies.

3.4.2 Results

IPTS embedded the case studies in the following macroeconomic findings.

Case study results embedded in macroeconomic findings

- | Trade deficit of the chemical industry in all New Member States taken together in relation to the EU-15 amounted to nearly 10 billion euros (2003). These trade deficits of chemicals represent 88% of the total trade deficit of the NMS in relation to the EU-15. One possible explanation is that the chemical industry in the NMS is growing slower than the average industry and that other manufacturing sectors are dependent on EU-15 chemicals (IPTS, 2005a, p.3).

- | Many of the NMS and their chemical industry are largely dependent on Russia and the Ukraine for oil, gas and petrochemical raw products as a basis for specialty chemicals. The price for these products coming from outside the EU is still relatively low and it can be assumed that quality of imported bulk chemicals is comparably low too. Implementation of REACH will therefore raise prices and lead to problems for importers because their competitive advantage will decrease (depending on consortia building).

- | *"Progress is made in implementing the Chemicals Acquis in the NMS, public infrastructure (authorities with clear responsibilities) is in place, staff has been trained in instruments of EU chemicals legislation, although understaffing remains a problem in most NMS and might lead to a bottleneck when REACH will be implemented"* (p.8). Together with the fact that R&D budgets are lower than in the EU-15, this may also become a problem for innovation in the NMS chemical industry. On the other hand, full compliance in the NMS can become an advantage, *"as the full body of chemicals legislation has yet to be fully implemented in the EU-15"* (p.8).

Very little impacts on business

- | In the interviews, company staff expressed concerns about possible withdrawal, increasing costs and the administrative efforts required by REACH. But *"the quantitative analysis on the selected cases showed very limited impacts on the competitiveness of the chemical manufacturing companies due to REACH testing and registration costs"* (p.5). The same is true for formulators. Impacts on the product portfolio were not expected because *"only a small number of the analyzed substances have been identified to be vulnerable"* (p.6).

- | *"Cost impact for chemicals was in most cases manageable with one case going up to 7% under a worst-case scenario assumption"* (p.6).

No downstream users participated

Because of the lack of participating downstream users, the reaction down the value chain was assessed on the basis of passed-on costs and the price elasticity of demand showing that no significant price increases for the downstream user was to be expected. The high price elasticity has its reason in manufacturing companies, increasing demand for input materials.

Possible drawbacks for implementation of REACH in NMS

Generally speaking, *"the starting point for REACH implementation seems to be at a common level between EU-15 and NMS companies. However, lack of experience, low innovation capacity, a general competitive disadvantage, combined with increasing competitive pressure from the EU-15 ... might be drawbacks for the implementation of REACH in the New Member States"* (p. 10).

The study gives a lot of very helpful insights into the situation of the chemical industry in the New Member States. Regarding downstream users, it is limited to theoretical estimations, which, on the one hand, is a real weakness. On the other hand, macroeconomic estimations are much more solid than more or less randomly chosen case studies. The selection of case studies was done without any scientific criteria but on the basis of the willingness of industry to participate and the proposals made by governmental institutions (Estonia) and industry associations from NMS as well as from the European level.

Regarding formulator and supplier level, the empirical basis is as thin as in the KPMG study. So the same criticism as for the KPMG study applies as regards sweeping statements. But contrary to KPMG, IPTS provides a lot of statements with introductory phrases or restrictions like *"The interviews confirmed ..."* or *"... for the assessed examples"*.

Also commendable in the IPTS study is the Annex explaining exactly how many substances were assessed and which share of them was vulnerable, the size of the portfolios and the price increases (p. 11).

General methodological flaws – like in KPMG study

The main problem is the methodology in common with KPMG: looking for vulnerable substances means searching for potential losers and asking them afterwards with regard to benefits. The results: with their HSE staff and related management system, companies are in a relatively good position. Communication along the value chain could be better. *"The establishment and maintenance of such cooperation, which is not driven by the operational business, is one of the new experiences coming up with REACH"*. (p. 8)

Regarding this conclusion, it seems clear that it would have been a challenging experience to assess the benefits for business and society connected with better cooperation along the value chain.

4 Outlook

The pivotal points of REACH are the producers' overall safety responsibility, including information, transparency and communication on the basis of well-established risk assessment methods – not only for new chemicals but also for existing chemicals, the current legislation's most significant weak point. Downstream users have the right to make a specific use known in writing to the producer, which has to account for this specific use in its Chemical Safety Assessment. The producer must identify and take the appropriate measures to adequately control the identified risks. If downstream users do not make use of their "right to tell", they are obliged to disclose their use patterns to the European Chemicals Agency and make a safety assessment on their own accord.

"Right to tell" and "duty to account for"

The downstream user's "right to tell" connected with the manufacturers' "duty to account for" is nothing less than a revolution. Until now, most importers and chemical producers were not at all obliged to take care of the safety of their products along the value chain. Conflicts with NGOs, consumers, retail or courts are downstream users' problems. This situation will change, bringing significant benefits, especially to SMEs. REACH will lead to a more responsible and more transparent handling of chemicals.

Real costs will not be as high as industry studies imply

The studies suggest that these testing and registration requirements will lead to costs – costs which are negligible for the big chemical companies but present a bigger challenge for SMEs that produce certain chemicals and an even greater one for those which import them. But this has to be seen in the context of general very low application and enforcement of chemicals safety rules at SME level in general. But industry and industry-commissioned studies far exaggerate these costs. With the help of (i) QSAR usage, (ii) mandatory data sharing and (iii) facilitating supply chain communication and SME assistance, foreseeable direct costs will be further reduced and so will the induced indirect costs.

On the other hand, the studies suggest that REACH will help reduce damage in the field of occupational health, consumer health and the environment. Savings will far exceed costs.

Neither new findings nor consensus amongst stakeholders

The additional studies carried out after the Commission's proposals under the Memorandum of Understanding between Commission and industry did not result in any significant new findings or in a consensus among the different stakeholders. It can be argued that the exercise has nonetheless had an important training and learning effect and may have increased the acceptability of REACH to industry or made it easier for industry to move towards a more constructive role.

**No further impact assessment –
but implementation and
assistance**

On the other hand, it can be argued that all the manpower and money spent in this exercise could have been better and more efficiently invested in developing guidance for the implementation of REACH, which will define in the end whether REACH will be a success or a failure. REACH means changing interactions in a complex system composed of manufacturers, importers, formulators, downstream users and consumers within and outside the EU. The system reacts and aligns in a new way. There will be winners and losers. Viewing the aligned system from today's viewpoint means ignoring the dynamics of the system. We do not have any other vantage point but we should be aware of the possible distortions linked to this ignorance. And, as a final point, we know that market forces will find the most efficient way of coping with these new regulations as they provide only general guidance, remain non-descriptive about technologies and built on industry's responsibility.

In conclusion, the EEB and WWF believe that no further impact assessments are now necessary at this stage. EU legislators should build instead on the Commission proposal to achieve robust and transparent industry responsibility for the safe management of chemicals, taking special account of the need for increased capacity within public authorities and for the rapid development of an implementation guide.

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EEB

The European Environmental Bureau (EEB)

The EEB is a federation of more than 140 environmental citizens' organisations based in all EU Member States and most Accession Countries, as well as in a few neighbouring countries. These organisations range from local and national, to European and international. The aim of the EEB is to protect and improve the environment of Europe and to enable the citizens of Europe to play their part in achieving that goal. The EEB office in Brussels was established in 1974 to provide a focal point for its Members to monitor and respond to the emerging EU environmental policy. It has an information service, runs 11 working groups of EEB Members, produces position papers on topics that are, or should be, on the EU agenda, and it represents the Membership in discussions with the Commission, the European Parliament and the Council. It closely co-ordinates EU-oriented activities with its Members at the national levels, and also closely follows the EU enlargement process and some pan-European issues.

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WWF's European Toxics Programme

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

A general introduction to this policy review is given in the following briefing: *"A new regulatory system for chemicals in Europe: A step towards a cleaner, safer world?"*

This publication and others are available from the 'toxics' section of the WWF European Policy Office web site: <http://www.panda.org/epo/>

WWF's Global Toxics Programme

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

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

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

