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INNOVATION
IN THE CHEMICALS SECTOR
AND THE NEW EUROPEAN CHEMICALS REGULATION

A WWF CHEMICALS AND HEALTH CAMPAIGN REPORT SEPTEMBER 2003

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Innovation in the chemicals sector and the new European Chemicals Regulation

A report for WWF-UK by Frans Berkhout, Michiko Iizuka, Paul Nightingale and Georgina Voss at SPRU

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Executive Summary

In early 2001, the European Commission published proposals for a new policy on regulating chemicals, called REACH. This report analyses the potential impact of REACH on industrial innovation. Three studies of the business impact of REACH are critically reviewed. An alternative, qualitative assessment is made, drawing on previous research about the way in which health, safety and environmental regulations influence innovation.

Under the REACH system, a uniform procedure for registering existing and new substances produced in the EU, in volumes greater than one tonne per year, will be put in place over an 11-year period. By 2016, key health and environmental data on 30,000 chemicals traded in the EU will be centrally held, and partly accessible by producers and consumers. Substances produced in higher volume and substances more hazardous to human health and the environment will be subjected to more stringent testing and, where necessary, to an authorisation process. A range of provisions has been made under REACH to encourage innovation in chemical substances and formulations, and in alternative methods and techniques for testing and generating data on toxicity and ecotoxicity.

The report concludes that the negative impacts on innovation, competitiveness and employment have been overstated in industry-funded studies, and that insufficient account has been taken of broader social and environmental benefits. Other methodological problems with these studies are also highlighted, especially the absence of a sound treatment of innovation, and problems related to the changing nature of costs and benefits.

We find that many of the main provisions of REACH will 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. While there are some important uncertainties about the institutional framework and the degree of discretion available to regulators at the member state and Community levels, we would expect many of these to be resolved in practice as new roles come to be understood and worked through by industry and regulators alike. The expected positive impacts on industrial innovation may take some time to show through.

Specifically, we find the main positive attributes of REACH to be:

- the breadth of the "duty of care" provision, covering actors across chemical supply chains and downstream users, imports and substances in articles – this promotes uniform incentives to innovate and eliminates "free rider" problems;
- the clear separation of the role of industry (in the provision of data and assessment) and the regulator (in monitoring, evaluating and authorising) bringing greater predictability, enabling learning by industry, and imposing the costs of regulation on the producers and users of regulated chemicals;
- a clear (but challenging) timetable for implementation of the Regulation, covering all substances with a production volume over one tonne by 2016;
- the establishment of REACH on the basis of well-established testing protocols and procedures, many of which are becoming increasingly harmonised at a global level;
- new provisions for reducing the cost and time burden of the notification process;

- the enhanced coordination of registration, evaluation and authorisation by an independent Agency that advises the Commission – this should encourage greater legitimacy of decisions and ensure fair treatment of all parties in cases of dispute; and
- wide consultation with industry in developing the REACH proposals.
- Its potentially negative attributes are:
- uncertainties about the capacity of Competent Authorities (CAs) in member states, working with the new independent Agency to coordinate and advise on implementation, to handle the administrative and decision procedures relating to 30,000 substances;
- some uncertainties about the capacity of CAs, the Agency and the Commission to operate to consistent standards and procedures, and to resolve differences of opinion efficiently;
- uncertainties about how judgements will be made about "high concern" substances – those requiring authorisation, subject to restrictions, or submitted to "priority evaluation". These mechanisms appear to give regulatory authorities quite a wide degree of discretion in applying the REACH system.
- uncertainties about the precise costs and time associated with notifying and receiving authorisation for a substance; and
- the high costs of testing relative to average US and Japanese costs.

1 Introduction

In early 2001, the European Commission published proposals for a new policy on regulating chemicals, called REACH.[1] This report analyses the potential impact of REACH on industrial innovation. Three studies of the business impact of REACH are critically reviewed. The report focuses on the contention that REACH will impose large new costs on the European chemicals industry and have markedly negative impacts on innovative activity in the industry. An alternative, qualitative assessment is made, drawing on a short case study of the perceived impact of REACH on a subsection of the UK chemicals industry and previous research about the way in which health, safety and environmental regulations influence innovation.

[1] CEC, *Strategy for a Future Chemicals Policy*, COM (2001) 88 final, Brussels, 27 February 2001.

2 Background

The European Commission published proposals for a new policy on chemicals in early 2001. Following consultation and review, draft legislation was published in May 2003, with new regulations expected to come into force over the period 2005-2016/17.

Central to the White Paper was a new regulatory system, called REACH, for the "Registration, Evaluation and Authorisation of Chemicals" with three key components:

Registration: Chemical producers and importers will be obliged to provide basic safety data, by fixed deadlines, to authorities on all chemicals produced or imported in quantities above 1 tonne per year. Unlike existing requirements that apply only to new chemicals and cover a few thousand new substances, REACH will also apply to the approximately 30,000 existing substances currently traded in the EU that are produced in volumes exceeding 1 tonne.[2] It is estimated that about 80 per cent of chemical substances will require registration only. A tiered approach has been taken to registration, with the highest volume and most hazardous chemicals due to be registered earlier.[3]

Evaluation: The current proposals state that member state competent authorities, in association with a central coordinating body, will evaluate testing procedures for chemicals produced in volumes over 100 tonnes per year. Member states will also be able to evaluate the registration package for any chemical, and request more information if there is cause for concern.

Authorisation: The outcome of the evaluation will feed into the authorisation process. Chemicals considered to be of "very high concern" would be subject to specific authorisation. Such chemicals[4] will be phased out, unless industry can show that their use is adequately controlled or that it is acceptable, taking into account its socio-economic benefits, the lack of safer alternative chemicals and risk reduction measures. Approximately 1,400 substances are thought to fall in this category, the majority already identified.

The REACH concept seeks to bring greater regulatory pressure on industry to provide adequate hazard data on substances that have been on the market for some time. It also aims to shift the workload of proving the safety of chemical substances from member state authorities to industry, and require them to take more responsibility of downstream users of chemicals.

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[2] 'Existing chemicals' are chemicals that are on the European Inventory of Existing Commercial Chemical Substances (EINECS) list. EINECS was established in 1981 and contains about 100,000 substances (only about 30,000 are currently in commercial use). Any chemical not in EINECS is known as 'New' and requires notification as well as a 'Base set' of toxicological, environmental eco-toxicological data, and physico-chemical together with human and environmental risk assessments.

[3] The registration schedule for different categories of substances by volume is: substances exceeding production of 1,000 tonnes per year and mutagenic or substances toxic to reproduction to registered by end 2005; exceeding 100 tonnes by three years after the Regulation comes into force; and exceeding 1 tonne after 11 years.

[4] These classes of materials include carcinogenic, mutagenic and reprotoxic (CMR), persistent organic pollutants (POPs), Persistent, Bioaccumulative and Toxic (PBT) and Very Persistent and Very Bioaccumulative (VPVB) substances.

Inevitably, the new proposals have attracted widespread industry criticism. A number of claims have been made, principally that costs to EU industry will rise, leading to a general loss of competitiveness and a reduced rate of innovation. Estimates vary. A BDI (German industry association)-sponsored study conducted by Arthur D. Little (ADL) suggested that the REACH proposals would lead to a cumulative loss of between 0.4 per cent and 6.4 per cent of gross added value in the German economy, while a DG-Enterprise-funded study by Risk & Policy Analysts Ltd (RPA) suggested direct costs to the chemical industry of between €1.5 and 5.1 billion.[5] Fears have been expressed that these costs could lead to a relocation of the chemicals industry outside the EU (a "regulatory haven" hypothesis) and conversely that the new regulations represent a barrier to trade. It has also been argued that new, more stringent regulations tend to favour large companies, at the expense of smaller ones, and lead to processes of industrial concentration, so reducing competition (and possibly, in the long-run, competitiveness). Lastly, there has been concern about the impact of the legislation on innovation. This last topic is the focus of this study.

THE DEFINITION AND ANALYSIS OF INNOVATION

Innovation is defined as a process involving the creation of new or improved products, processes and forms of organisation or systems that can be sold in markets (Schumpeter, 1942). Innovation according to this definition is clearly different from the process of invention – the discovery of new ideas – and also diffusion – the dissemination of particular innovations into society. Innovation can be further differentiated in terms of its "rate" and its "direction" (Freeman and Soete, 1997). The "rate" of innovation is the *quantity* of innovations produced over a given period of time. The "direction" of innovation is related to the *quality* of innovation produced and its socially beneficial or damaging consequences. These differences must be clarified to evaluate the impact of regulation on innovation.

Rate of innovation

There are several ways to measure the "rate" of innovation. These involve indicators that serve as a "proxy" for the rate, such as "number of publications" (measure of the stock of knowledge), "R&D expenditure" (measure of capital invested in research), "number of research scientists" (measure of labour input), and "number of patents" (measure of invention). Each of these indicators demonstrates a different aspect of innovation. These indicators are more or less standardised as a measure of innovation at company, sector and country level; however, caution is required for the interpretation of these data.

Direction of innovation

Unlike the rate of innovation, there is no standardised indicator for the direction of innovation. Due to the inherently normative character of the quality of innovation objective measurement and comparison is difficult. Some forms of measurement have been suggested, such as physical or chemical criteria, the amount of residue permitted in foodstuffs (Marco et al, 1991), and the number of legal cases related to innovation or to a particular firm (Hoffman, 1999). However, all these measures need to be used with caution as they incorporate implicit normative value judgments.

[5] The White Paper estimated that the cost to industry of the new system for testing roughly 30,000 substances would be about €2.1 billion over 11 years until 2012 (COM (2001) 88 final: 15).

INNOVATION AND REGULATION

There is a well-established debate about the links between regulation and innovation in industry, with a range of opinions expressed on both sides.

Anti-regulation arguments

Some scholars argue that regulation stifles innovation. They claim that, in order to activate the innovation process, regulations should be relaxed or made less stringent. A number of arguments have been made.

The first argument is based on the allocation of R&D funding. This argues that, due to the presence of regulation, firms are obliged to allocate their R&D in complying with regulation, thereby reducing the amount of R&D that can be applied to more "productive" areas (Eads, 1980). This argument has been criticised because the future net earnings through innovation are not a simple function of R&D expenditure. The decrease or increase of innovative performance cannot be directly linked with a simple decrease or increase of R&D expenditure. A whole range of factors can influence the innovative performance of firms (Freeman and Soete, 1997).

The second argument concerns firms' perceptions of risks. This view considers that regulation may impose additional technical and commercial risks and therefore discourage future innovation (Mansfield et al 2002). Risk-averse firms would divert their investment into less risky areas and therefore the number of innovations would decrease. According to Eads (1980), however, this phenomenon is only temporary because firms learn that high returns for risky innovative investment are possible.

The third argument is related to the organisation of firms. It is considered that regulatory compliance requires large R&D investments. This means that smaller companies are relatively worse off since their R&D budgets are typically smaller. Consequently, smaller firms are taken over by larger firms and the number of firms in a given industry decreases. Any decrease in the number of firms within an industry would decrease the rate of innovation (Davis, 1983). The relationship between industrial concentration and innovation is complex, and this argument can be criticised as even though the number of firms goes down, their average size, and probably average R&D budget goes up. The actual impact of these changes will however depend on the relatively innovativeness of different sized firms and so the effect could be either positive or negative.

Anti-regulation arguments highlight additional "non-productive" R&D costs, the uncertainty caused by lack of clarity in the regulation, and the relatively higher costs of regulations for innovative small firms. It needs to be mentioned that all of these arguments focus on how regulation influences the *number* of innovations and little attention is paid to the *direction* of innovation. Finally, despite differences of opinion, it is generally argued that increased cost of compliance is the main factor decreasing industrial innovation (Milmo, 2000).

Pro-regulation arguments

Other scholars hold different views on the impact of regulation on innovation. While no-one supports regulation for its own sake, these scholars point out that it aims to achieve economically and socially desirable ends, and to the degree that it achieves these ends, it can be beneficial. The use of regulation is therefore justified to induce firms to conduct more socially beneficial innovation (Rothwell, 1980, 1992). Environmental and health regulation

produce quality of life benefits that are difficult to quantify in monetary terms and effectively police through the market. In such cases, regulation is a justifiable means of ensuring societal benefit and sustainable development.

Benefits also arise because new regulations can open up new market opportunities and help match industrial activity to public sentiment (Ashford and Heaton, 1983; Gerstenfeld, 1977; Marcus and Weber 1989; Howes, Skea and Whelan, 1997). However, critics argue that the majority of firms see regulation as a burden or barrier, rather than an opportunity (Grabowski and Vernon, 1979; Marcus, 1987).

Porter and van der Linde (1995) connect the regulation and innovation relationship with competitiveness. They argue that countries adopting stricter regulations can achieve competitive advantage by stimulating socially desirable innovations and gaining first-mover advantages for their firms, which can, in turn, be exploited in other markets. In other words, more stringent and forward-looking regulation enables firms to innovate in the right direction, thereby enhancing competitiveness. In this respect, Porter and van der Linde (1995) use the phrase "socially desirable innovation" as the result of regulation to indicate the desirable direction of innovation. Although this "win-win" hypothesis of environmental quality and economic gain has been influential, it has also been criticised as being difficult to test empirically and being too anecdotal (Jaffe and Palmer, 1997).

Rothwell (1981) discusses the indirect benefits from regulation on innovation. He states that regulation can change the direction of research by promoting new areas which otherwise would remain underdeveloped. By creating a stable climate of expectation ("clarity") on future regulation regimes, firms can better foresee the direction of technical change and are encouraged to make investments in R&D to adapt to or avoid new standards. In other words, regulation, if well planned, can reduce uncertainty for innovating companies and encourage technical convergence (Marcus and Weber, 1989).

The pro-regulation view on innovation therefore sees the benefit of regulation on innovation as generating overall social gain, the creation of new markets through clarity or reduced uncertainty over the future, and greater competitiveness through stringent and earlier introduction of regulation.

Regulation in the Pharmaceutical Industry

One industry where there has been a lot of academic research on the impact of regulation on innovation is pharmaceuticals, which is not only one of the most heavily regulated industries in the world, but also one of the most innovative. In a classic study, Thomas (1994) compared the regulatory environments of the UK pharmaceutical industry with that of the French. He found that the regulations of safety, pricing, basic research and foreign direct investment created an innovation-friendly and demanding local environment for UK firms. Companies responded to this demanding environment by developing a range of skills and capabilities that enabled them to compete successfully in world markets. In France, by contrast, there was an implicit industrial policy that focused on protecting industry and local markets from higher standards and international competition. As a result, the French pharmaceutical industry became "desynchronised" from the worldwide industry and was unable to compete (Thomas 1994).

There are four main differences between the UK and French regulations that are particularly relevant to discussions of the impact of REACH (Thomas 1994:461). First, the French system was initially designed to protect French firms, while the UK regulations were designed to prevent dangerous substances reaching the market. Second, decisions about drugs are taken by industry in France, while in the UK they are taken by committees of independent experts. Third, in the UK the safety regulations are much more stringent and require extensive, costly and time consuming clinical trials that focus on the more demanding standard of "efficacy", while in France the regulations are much more traditional and anecdotal and address the far less demanding standard of "safety". Fourth, the high costs of regulation and testing are paid for by industry in the UK.

The arguments of anti-regulation scholars can therefore be tested very simply by comparing the performance of the French and UK industries. If regulation is always harmful to firms, we would expect the French system to be superior; if on the other hand the role of regulation is more complex, then the UK might perform better. What the evidence clearly shows is that the UK pharmaceutical industry is a major international success story, while the French industry has performed very poorly. The experience of the pharmaceutical industry therefore provides a corrective to more simplistic views of the impact of regulation on innovation.

A wider analysis would seem to support Thomas' findings as a similar pattern emerges in the US. Despite rhetoric about government regulations destroying wealth, the US pharmaceutical industry is highly regulated (particularly following the Kefauver Amendments to the Food, Drug and Cosmetics Act (1962)) but the firms are internationally successful.[6] Like the UK, and unlike the French, the US Food and Drug Administration (FDA) enforces extremely strict safety regulations that significantly delay product introductions and rejects hundreds of drugs that are sold elsewhere in the world (Thomas 1994:452).

While it is true that the adoption of higher standards led to the significant reduction in the number of products produced in the short run, one also needs to pay attention to the direction of innovation, not just the rate. After higher standards were introduced in 1962, for example, the number of new drugs launched in the US fell from about 50 a year to 20 or fewer, yet the drugs that were produced were more globally successful (Thomas 1994:461). As in the UK, stricter regulations in the US produced a shakeout of inefficient firms. Stringent regulations forced the remaining firms to change the direction of innovation towards more effective and safe products that are much more likely to be competitive in international markets.

By contrast, the low levels of regulation in France meant French firms were able to produce large numbers of low-quality products in a weak competitive environment. The firms were therefore largely unable to compete in more demanding and lucrative international markets. While one must be careful not to over-extrapolate from one study (particularly a study of an industry with very particular features that are unlikely to be replicated elsewhere) Thomas' study clearly shows that the impact of regulations on innovation is complex. The simplistic view that regulations prevent innovation is not supported.

In summary, while there is no consensus in academic literature about whether regulation inhibits or stimulates innovation in industry, there are instances where regulations such as

[6] One could also point out that another very successful US industry is aerospace: that again is one of the most regulated industries in the world.

REACH have led to short-term reductions in the rate of innovation, but also longer term changes in the direction of innovation. As in pharmaceuticals, these can produce substantial positive impacts on long-run business competitiveness. However, the conditions under which regulation is more likely to stimulate innovation can be described. Criteria describing these conditions are used in section 5 of this report to assess the possible impacts of REACH on innovation in the European chemicals industry.

3 Business impact studies of the REACH system

A previous comprehensive study of the historical impact of environmental regulation on the behaviour of the chemicals sector, paying particular attention to its impact on innovation, concluded that even with good historical data, separating the effects of *previous* regulation from other effects was extremely difficult, and that almost all the studies reviewed had major flaws (Mahdi et al 2003). It should not come as a surprise to find that these methodological problems are even more extreme when trying to predict the impact of regulations *in the future* without the benefit of historical impact data. The studies analysed here – by ADL for the BDI and by RPA for the UK government and EU – are in part excellent attempts to assess the impact of REACH, but they have necessarily been undertaken in the context of major methodological constraints.

One of the main problems is that predicting the relative impact of different environmental regulation regimes is extremely sensitive to subtle changes in framing assumptions. The scale and distribution of costs and benefits of each regime, for example, are hard to identify, analyse, quantify and compare. Often by presenting the results as "objective" numbers, the underlying subjective assumptions behind the calculations are hidden. Comparing the costs of regulations with the benefits of an improved environment as a single scalar index, for example, is conflating "apples and oranges" and depends on an implicit social choice about their relative values. Similarly, the future is complex, continuous and often contested, so that predicting which, of a potentially huge range of outcomes is most likely, or assigning certain probabilities to an uncertain future again involves framing assumptions about relative likelihoods (Stirling 2000; Berkhout and Hertin, 2002). Adopting a static analysis may be a methodologically useful way of not having to deal with these issues, but it is of questionable appropriateness when addressing regulations that are intended to produce dynamic effects, and is inherently biased towards the *status quo* by not addressing exactly the positive dynamic effects that regulations are designed to achieve.

The costs, risks and benefits of different regimes have different social distributions, and part of the purpose of regulations is to change them (Moss 2001). This is particularly the case with environmental regulations, because the costs of pollution, as with many externalities, are highly uncertain and widely distributed across time and space. This makes them extremely difficult to quantify, cost and compare without resorting to simplifying assumptions and procedures. The benefits of lax environmental regulation, on the other hand, are concentrated on producers, who do not have to pay for environmentally friendly production, and are therefore easy to recognise and quantify.

The point of the REACH regulations is to change the social distribution of these costs through a "polluter pays" regime so that costs are concentrated to a greater extent at their source, where they can be more easily quantified. However, the effect of this is to make the benefits, particularly of an improved environment, much more widely distributed in Europe and internationally, and therefore more uncertain and harder to recognise and quantify. Some of the benefits of the new European system, for example, may fall outside the chemicals sector through reduced legal and insurance costs for firms using chemicals, innovations in other sectors and changes in the organisation of supply chains.

The design of the legislation is intended to reach a politically acceptable compromise that maximises the benefits, while keeping the costs reasonable. With the current system, most benefits accrue to industry, which doesn't have to pay for the safety analysis of existing chemicals. But even with this system, some costs are distributed back to industry "after the fact" through legal costs and uncertainties, poor public perception, higher insurance costs and a bias in the legislation away from innovative new products. The policy issue is therefore not just about shifting costs and benefits around, but a series of changes to their composition. This change in composition makes it almost impossible to quantify, aggregate or compare costs and benefits using a single scalar standard without running into major methodological problems (Stirling 2001).

While addressing the benefits of the regulations was outside the scope of each of the studies, quantifying the costs alone has clear rhetorical value, especially if it can be presented as a comprehensive study. It changes the nature of the debate and in doing so biases it against the implementation of REACH. The ADL study, for example, claims to be a study of the "economic effects of the EU substance policy", but it is nothing of the kind. It is a study of the costs of the regulations along a few industrial supply chains, which are then extrapolated through a series of methodologically weak steps to the industry and then the economy. A comprehensive economic analysis would need to address benefits as well, and be sensitive to the fact that they will be more widely distributed, often taking the form of counter-factuals about what didn't happen. These are, by their nature, much harder to quantify.

Since chemicals regulations address externalities which are widely spread and difficult to quantify or manage, we should be sceptical about the ability of methodologies designed to address well-defined costs and benefits to do them justice. It is precisely because the costs and benefits of these changes are highly uncertain, difficult to measure and dependent on social choices concerning their relative value that the policy question exists at all. If the costs and benefits were well defined and socially robust, then cost benefit analysis would work unambiguously and the policy problem generated by externalities wouldn't exist. Unfortunately, the uncertainties involved mean that these types of questions involve political judgements and while policy decisions can be informed by high-quality analysis, they cannot be "scientifically" decided by it (Sarewtiz 1996).

The chemical industry itself has published figures indicating that the costs of REACH will be between €1bn and €30bn, which gives an indication of the uncertainties involved in calculating fairly well-defined and constrained costs. The poorly-defined and socially distributed benefits are substantially harder to analyse. The BDI study did not include these benefits in its analysis, while the first RPA study only looked at a very limited range of industrial chemical exposure data when doing a cost benefit analysis. Moreover, the BDI study took the removal of some chemicals as a cost, but failed to point out that this is exactly the objective of regulation – it is intended to remove and reduce exposure to dangerous chemicals.

RISK& POLICY ANALYSTS (RPA) STUDIES

RPA conducted two similar studies on the impact of REACH, one for the UK government (2001) and one for the EU (2002) with Statistics Sweden. A third study was published in the summer of 2003, too late to be included in this review.[7] The aim of the RPA studies was to develop implementation scenarios, provide some estimates of their impact on business, explore how these costs were distributed on different-sized business and investigate some of the wider impacts of REACH on innovation, competitiveness and intellectual property rights (IPR).

RPA (2001) Cost-Benefit Analysis

The first RPA study attempted a crude cost benefit analysis of the introduction of REACH. Potential benefits accrue from reductions in the risk of chemicals, particularly chemicals of high concern, and reductions in the costs of bringing new chemicals to market (RPA, 2001:22). The study noted that these benefits were difficult to quantify and analyse, so it relied on data from the Health and Safety Executive (HSE). The HSE estimates that there are 5-10 fatal accidents, 1,000 major injuries and 4,000 incidents that require at least three days absence from work each year, as a result of exposure to chemicals (RPA, 2001, 22). This method will over-estimate benefits as not all the costs will be caused by chemicals, or be reduced by legislation that bans or restricts their use. However, it is also a potentially large under-estimation of the benefits because it ignores the benefits to health, the environment, innovation and society that are not identified and quantified by the HSE. As the study notes, these benefits from reductions in industrial injuries could amount to between £64 million and £129 million over 10 years, based on willingness to pay to reduce the costs (RPA, 2001:22). Similarly, savings could be made by reducing the £580 million to £1.2 billion costs for occupational asthma and dermatitis over 10 years, based on medical and related costs of illness, and the unknown benefits from reduced work-related cancers, which are estimated to generate between 200 and 9,000 cases a year.

Further benefits include reductions to the level at which testing takes place which will reduce the initial costs to industry of introducing new compounds (estimated to be about £34 million a year at 6 per cent over 20 years). The proposals will also encourage more innovation as only new products require registration at present, encouraging industry to use older and potentially less safe or less efficient alternatives. These benefits were not quantified in the studies, but are acknowledged to be potentially substantial. Similarly, second-order effects on the behaviour of the industry were not analysed or quantified. There was no quantification of the benefits to the insurance industry, the potential reduction in legal costs, the potential improvements in products from innovation, the potential benefits of firms providing more value added services, the potential value of "EU" quality products for global sales, the potential benefits of a simplified regulatory environment, the potential innovation benefits of not discriminating against new products, or the potential for regulation induced innovation outside the chemicals sector (the list could be extended).

The analysis of the costs in RPA (2001) involved three UK scenarios and included a base scenario to allow comparisons: these were £107 million for the base legislation, £197 million

[7] Preliminary analysis of the 2003 study suggests that it is a similarly high-quality study that suffers from the same difficulties as the previous studies. The conclusions of the 2003 study are based on slightly more up to date legislation, but the overall picture it presents is consistent with the studies analysed here.

for the UK chemicals strategy, and £620 million for the EU White Paper (RPA 2001, 32). These costs were highly uncertain (RPA, 2001: 27), will potentially be subject to bias, and do not take into account declining marginal costs of testing or economies of scale in testing that could substantially reduce the costs of regulation.

The cost benefit analysis concluded that the UK chemicals strategy would be justified by a 15 per cent reduction in occupational asthma, while the EU legislation would require a 70 per cent reduction. As we have argued, cost benefit analysis of this kind is substantially biased towards a *status quo* that keeps benefits clearly defined within industry and spreads externalities widely. A more realistic approach would be to say that there are a number of costs, many of which are either unknown, unknowable or uncertain, and a number of benefits, many of which are similarly unknown, unknowable or uncertain, and we can only provide limited and contentious quantification of some of them. Using deterministic modelling and false precision hides the reality of policy uncertainty, and privileges a sub-set of costs over a sub-set of benefits.

Given the difficultly of the subject matter, and the time and funding constraints, the RPA study was professionally undertaken. The study was well conducted, and provided interesting information on costs and sensitivities; however its analysis did not claim to be comprehensive, nor could it have been in the time provided. The study used a static analytical framework that could not address the dynamic impact of innovation on the behaviour of the sector, and therefore under-estimated the benefits.

RPA (2002)

The second RPA study relied on a series of questionnaires sent to companies (n = 260), associations (n = 51) and competent authorities (n = 7) that revealed that there are 30,000 or fewer substances placed on the market a year and about 100,000 intermediates (though with approximately 23 per cent on the market, there is clearly double counting going on as all traded intermediates should be either listed as existing chemicals list or should have been treated as a new chemical). The questionnaire methodology and overall study was of high quality and produced interesting findings about the data companies hold, the number of unintended uses of chemicals and the variation in perceptions of the number of intermediates (ranging from 50,000 to 120,000, with most believing it would be below 100,000). Given that this questionnaire was addressed to experts, this variation reveals once more a high degree of uncertainty about the data.

Based on the data collected in the questionnaire, and data on the costs of tests supplied by a major EU chemical company and supported by OECD figures (RPA, 2003:viii), RPA conducted a series of scenarios based on variations in regulatory enforcement. The total present value costs of the four scenarios are (RPA, 2002:76):

Scenario 1: €1,911 million
Scenario 2: €2,940 million
Scenario 3: €3,101 million
Scenario 4: €5,099 million

More detailed variation in the scenarios produced Present Value costs over 10 years ranging from €1.4 billion, to € 7 billion, with the medium test conditions and mid range assumptions of numbers producing a cost of €3.6 billion (RPA, 2002:xiv). The vast majority of the costs

are for testing and registration (~98 per cent, with testing comprising about 88 per cent). As these figures stand, the study has shown some useful variations in costs that would be helpful for policy-makers fine-tuning the regulations.

Again, these costs are potentially over-estimates as they don't take into account potential economies of scale and demand-induced innovation in toxicology testing. The potential for economies of scale can be seen in the pharmaceutical industry where High Throughput Screening methods have produced radical improvements in testing, particularly *in vivo,* and increasingly *in vitro* (Nightingale 2000). As markets expand, the potential application of these improved capital goods increases, with resulting productivity improvements and reductions in unit costs, so we would expect substantial reductions in costs as the number of tests increased, suggesting that the larger numbers are over-estimates.

Similarly, the questionnaire results are subject to bias and misinformation – questionnaire methodologies provide data on what people are prepared to tell you about, which can be different from what they know – which in turn can be different from what actually is. The problem with methodology in this case is complicated because data is not being gathered on what actually is, but on what may be in the future. The final report highlights some of these potential difficulties, particularly the lack of understanding of the regulation by respondents, and treats them in a sensitive manner.

Given these methodological difficulties, it is interesting that even if we take the highest of the RPA values for the costs of REACH of €7 bn over 11 years, this comes to about €636 m/year, which is small compared with the sales and profits of the industry (i.e. €484 bn sales in 2000) (WWF & EEB 2003:8). Compared with features such as changes in the price of oil or fluctuations in currency exchange rates, these costs, while large in themselves, are likely to have a small effect on the bottom line. However, the RPA study correctly points out that the distribution of these costs within the chemical sector will differ between small and large firms, and between firms with and without existing safety data. The RPA study suggests that some costs will fall disproportionately on certain SMEs, while other SMEs will substantially benefit from the reductions in the testing requirements of small production volume chemicals.

Innovation

The RPA study highlights some of the impacts of the regulations on innovation and competition. Because the testing threshold is increased from 10kg/year to 1 t/y, testing is more substance-tailored and the time permitted for processing R&D is extended, the costs of complying with regulations may decrease for many firms. SMEs notify 51 per cent of their new substances at less than 1 t/y and therefore would see substantial decreases in costs for these substances (for large firms the figure is 16 per cent) (RPA, 2002: xv, 77). Moreover, the regulations remove the bias against innovation in current regulations, which impose testing costs only on new products.

However, the RPA study addresses innovation in a static context and does not explore the potential dynamic impact of regulations on the nature of innovation in the industry. There is substantial academic literature on innovation which highlights how it is improved by:

- close contacts with customers;
- accessing external sources of knowledge;
- having effective internal communication; and

- being able to recruit educated people who are linked into wider knowledge networks (cf Freeman and Soete 1999, Tidd et al 1997).

The REACH regulations are innovation friendly – encouraging closer contact with users, improving external linkages, improving the image of the industry etc – but these changes are very difficult to quantify and are therefore under-represented in cost benefit analyses.

The study highlights how the costs of the regulations may be disproportionately high for certain types of SMEs that are unable to join testing consortia or pass on costs to customers compared to larger firms. Some low-value product lines may be rationalised, and this may have an impact on R&D. At present this is uncertain and the regulations allow for easier registration for the small quantities of chemicals usually used for R&D purposes. While there is likely to be some product substitution if costs rise, customers within the EU will not have the option to move to untested products and it is therefore unlikely that European customers will be able to avoid sharing some of the costs. The RPA study is perceptive in its analysis of innovation, and highlights the fact that European chemical firms already under-invest in R&D compared with their competitors in the US and Japan, and that this has little, if anything, to do with regulation (RPA 2002:106). We have shown elsewhere that the supposed superiority of the US chemical sector in notifying new products is based on a misunderstanding of the distinction between pre-manufacture and pre-market notification (cf Mahdi 2002).

Competitiveness

The RPA study also briefly analysed the impact of REACH on competitiveness and employment potential of the chemicals sector. The whole concept of international "competitiveness" is problematic (Krugman 1994) because while firms compete with one another, countries don't. This makes the relationship between productivity, employment and wealth generation complex. Compared with changes in exchange rates or feedstock prices, even the most extreme and unlikely outcome of REACH (€7bn) is insignificant for trade at the European level. Discussion about European competitiveness is therefore a bit of a red herring and involves two rhetorically useful but analytically problematic moves. First, a mercantilist assumption that equates what is good for industry as being what is good for the nation; and second, some dubious assumptions about what is good for industry. The first issue was addressed by Adam Smith: increases in productivity in a sector can lead to a reduction in its share of employment. If productivity goes up, employment goes down because fewer people are needed to produce the same level of output. This can be seen in the increases in productivity and decreases in employment in agriculture over the 20th century.

The second problem is that competitiveness rhetoric implies that industrial and societal goals coincide, so that because environmental regulation or enforcement of liabilities impose costs on industry they should be avoided. Competitiveness, if such a concept makes analytical sense, is only one of a range of issues that policy-makers have to address. Nor is it true that regulations are always bad for industry. Historically industry has often encouraged regulations to create barriers to entry and typically the most competitive "nations" in given sectors also have some of the highest levels of regulation. There is a considerable academic literature on this subject (Porter 1999, Thomas 1996).

When the study attempts to link competitiveness to output by linking the costs of regulation to the loss of low-value products, the analysis falls below the generally high standard in the rest of the report. In discussing the costs of product rationalisation (RPA, 2002:104), the study assumes that 20 per cent by value of the €485 billion EU chemicals turnover comes from low-

value products, which approximates to €97 billion in turnover. However, the study then suggests that 51 per cent of these will stop production and comes to the conclusion that this will produce about a 10 per cent reduction in overall production. This is not a surprising outcome because approximately half of 20 per cent is approximately 10 per cent – so if we assume that 10 per cent of chemicals by value will disappear, then we should not be surprised to find this. As the study notes, this is likely to be an over-estimate, as the distribution of value will not be evenly distributed across all the chemicals.

The study also notes that the questionnaire data on low-value products and their potential losses was poorly defined and a large number of responders left the answer blank (RPA, 2002: 41). The responders generated significant variation in their answers: for example, the percentage of turnover from (undefined) low-value products varied from 0.1 per cent to 100 per cent! The questionnaire responders also highlighted some of the complexities of the issues – such as having to have an appropriate product mix of high- and low-value products – and how this would influence rationalisation. Given the poor quality of the data and the problem with definitions, this part of the report should be treated with some scepticism.

Unsurprisingly, using a second method, the RPA study found that only 1 per cent of EU turnover would be lost. While this is not an insignificant amount, it is substantially below 10 per cent and RPA suggests it be used as a lower bound.

Table 1: Costs of lost production based on RPA (2002) Tables 4.3 and 4.4

	Scenario 3		Scenario 1		Scenario 2		Scenario 4	
Value	**Numbers Withdrawn**	**Costs € m**	**Numbers Withdrawn**	**Costs € m**	**Numbers Withdrawn**	**Costs € m**	**Numbers Withdrawn**	**Costs € m**
>1000 t/y	0	0	0	0	0	0	0	0
>100 t/y	461	2,305	111	555	111 + 250	1,805	0	0
>10 t/y	2,140	1,605	795	596	795 + 1,725	1,890	265 + 1,150	2,565
>1 t/y	4,995	999	4,000	800	4,000 + 1,900	1,180	2,000 + 1,900	780
Total		**4,909**		**1,951**		**4,875**		**3,345**

However, according to its own figures on tables 4.3 and 4.4, this 1 per cent (€4.9bn) is not the lower bound (see Table 1). With scenario 1 the cost is only 40 per cent of the "lower bound". Similarly, RPA assumed when constructing the lower bound that production of each chemical was at the maximum allowed volume. If we assume a normal distribution of production within each boundary and average out at about 50 per cent of the maximum permitted level, then the lost production costs halve. As a result, by assuming that average production values were all at a maximum permitted level, the RPA study over-estimated the lower bounds. It does, however, note that should production of one chemical stop, firms are likely to attempt to move into new markets and expand production there, indicating that even their lower bounds may be over-estimated (RPA, 2002:105).

The two RPA studies are carefully-done and provide useful policy insights into the distribution of costs. They suffer, as all studies would, from the inherent difficulties of trying to analyse a complex and uncertain future. The studies provide useful information about the *relative* distribution of costs, but because they use a static methodology they are likely to over-estimate the *actual* costs as they do not take into account technical change, economies of scale in testing, innovative benefits to the industry or reductions in costs and risks in other sectors (insurance, legal, worker safety).

FEDERATION OF GERMAN INDUSTRIES (BDI) STUDY

The Federation of German Industries (BDI) study (ADL, 2002) undertaken by Arthur D. Little has generated a large amount of concern because it estimates that the implementation of REACH will cause a cumulated loss of gross added value between 0.4 per cent and 6.4 per cent of the German economy, and potentially cause up to 2.35 million lost jobs. Clearly, a variation between scenarios that covers 6 per cent of German gross added value indicates substantial uncertainty. There are problems with analysing the study as it currently only exists in German, and is written in "consultancy-speak", so it is difficult to understand exactly what procedures were followed. As noted earlier, the study claims to be an economic impact study, but is not, as it only analysed costs in a selection of "value chains", and only with a static methodology.

The BDI study used a "bottom up" approach that worked in three steps. The first step involved analysis of industrial value chains based on interviews and workshops. This step formulated how the legislation would influence key success factors for the industries in question. This was used to produce a semi-empirical model that could be used to illustrate how changes in legislation influenced costs.

The second step involved extrapolating from the cases to the entire industry. The model highlighted the importance of a range of parameters, particularly costs, time delays, the extent of restrictions on substances of particular concern, and transparency. The third step extrapolated from the industry to the entire nation. Depending on how the parameters varied, three scenarios were formulated – "clouds", "storm" and "hurricane" with losses of 0.4 per cent, 2.4 per cent and 6.4 per cent of German gross added value and 150,000, 900,000 and 2.35 million job losses expected. The job losses were based on a identical percentage loss calculation that is methodologically extremely weak to the point of being untenable. The report further argues that there will be substantial loss of chemicals to the market, with corresponding impacts on R&D, innovation, investment and competitiveness.

The BDI study is analytically ambitious in seeking to isolate and measure the economic impact of regulation, and in trying to predict the impact of a policy that is not fully formulated on an uncertain future. Part of the analytical problem is that it is extremely difficult to provide a counter-factual scenario that can be used to explore what would have changed without legislation. This would be required if one were to isolate their impacts. The BDI study got around this conceptual problem by not having a reference scenario. This leads to a substantial over-estimate of the impact of regulation. For example, even if the methodology accurately approximated the number of products that would be taken off the market over the implementation period, this would over-count the substantial number of products that would be removed anyway as part of the normal product life-cycle, irrespective of any regulations.

Similarly, if we wanted to understand how many people were killed by smoking, it is not enough to count the number of smokers who die of lung cancer or heart disease: we also want to have a matched sample of non-smokers whose deaths by cancer and heart disease can be contrasted with the smokers. If we don't have a matched sample of non-smokers, we substantially over-estimate the health impact of smoking by counting the people who would have died anyway. As a result, by assuming that testing is only required because of the REACH legislation, and ignoring initiatives such as the 1997 VCI voluntary commitments of the German chemicals sector to test a large number of chemicals, the costs of REACH are over-estimated. This is only one of a number of problems with the study.

The early parts of the study are well done and reveal interesting insights into the impacts of the EU legislation on three sectors. The study did not attempt to verify what the interviewees said and this may introduce a substantial bias. Experts at a conference held by the German Federal Environmental Agency (FEA 2003) questioned many of the underlying assumptions, and suggested that they substantially over-estimated the negative effects. They noted, for example, that the study incorrectly assumed that expensive animal testing would be required for substances produced in quantities between 1 and 10 t/y, that the study incorrectly assumed that new tests would be required for every workplace, and that many of the interviewees seemed to be misinformed about the proposed legislation (FEA 2003:6). Since the inputs to the analysis were largely unquestioned and unverified, there is a danger of reproducing errors – what software engineers call "garbage in, garbage out". Again, as with the RPA studies, the costs are static and do not take into account economies of scale or improvements in testing that would be expected to substantially reduce some of the costs of testing.

The Model

The study identified a number of parameters that influence the costs of the legislation and paid particular attention to "costs, time, authorisation and transparency". The study differed from the RPA studies in addressing second order costs in downstream industries outside the chemical sector. The testing costs were €13.3/tonne, €6.0/tonne and €1.4/tonne for 1-100, 100-1,000 and >1,000 t.p.a. These figures differ from those used in the RPA study, which were derived from a study by Morris for KPMG management consultants, which are less than half the BDI estimates. As with the RPA study, there is no attempt to address the likely reductions in costs that would be generated by economies of scale and technical change over the implementation of the legislation. The figures for costs are compared to an 8 per cent profit margin in a normalisation procedure which allows analysis of relative differences between the two scenarios, but complicates the production of absolute figures.

The impact on production of time delays is substantial in the analysis, producing 90 per cent of the costs of the "clouds" scenario. However, the analysis confuses "innovation life cycles" with "product life cycles", and as a result substantially over-estimates the costs involved. Innovation life cycles are the consecutive steps that are undertaken during R&D before a product is launched onto the market. The product life-cycle is the period from R&D to a product's removal from the market. The study assumes that production losses over a product life cycle are proportional to the extra time taken for registration divided by the total innovation life cycle. This is a very dubious metric, as it is rarely possible to clearly define the start of an innovation process, especially when there are generations of products within a product family. Moreover, it is highly unlikely that such a relationship exists – if a product is on the market for 20 years, and has to undergo a six-month registration period during an 18-month innovation life cycle, it is unlikely that production will decline by a third. This also

fails to address the fact that new products *already* have to register (unlike old products) even before REACH is implemented. Since REACH is intended to *reduce* rather than increase the time taken for registration for some classes of products the implication of the model should be that there will be substantial and proportional production gains.

The impact of these costs is analysed using a scaled "industry factor". This describes the particular market conditions of the sector under analysis and is derived from interview data. It indicates how much of the added costs can be passed on to customers and involves three factors – extent of competition, the relatively fixed nature of production and the need to be near the market. These are derived from ordinal-scaled interview data gathered on a high-low scale measured between 0 and 4 (ADL 2003: 54) that are then simply added together (FEA 2003). This introduces a substantial over-estimate of the costs, as the three factors are very different, which creates difficulties in understanding what adding "apples and oranges" together means for the data. And because the factors interrelate substantially, their combined effect will be less than their addition suggests. The next step of assuming that they will be proportional to production losses (ADL 2003, 191) is very questionable. There is no reason to assume that this can be directly related to percentage production losses, or to assume that it has a linear relationship to production losses. To do so without comment or verification seriously compromises the study. As Dr Andreas Ahrens from Ökopol pointed out, verification could be done easily by using data about changes in exchange rates or the price of feed-stocks (Ahrens 2003). Given that changes in exchange rates or feedstock prices generate costs that are likely to be substantially higher than the costs of REACH, we may expect the BDI methodology to predict larger production losses and even more extensive unemployment than the 2.3 million job losses of the "hurricane" scenario. Since we do not observe these effects in practice, it may be assumed that the linear relationship between changing costs and losses of production is untenable and introduces a substantial bias to over-estimate the losses to industry and the economy.

The reason that we would not expect to see a directly proportional relationship between costs and production losses over the implementation period of the legislation is because of technical change, adaptation by industry, and the ability of customers to find alternative production inputs. If the price of inputs goes up, as they do all the time in industry, and the costs cannot be passed on to customers, then firms tend not only to stop production, but instead search for lower-cost alternative methods.

When these production losses are extrapolated to the entire industry and then on to the entire German economy, the methodology is simplistic and is likely to substantially over-estimate the impact. The people interviewed and engaged in the workshops are unlikely to be representative of the entire economy – and indeed are likely to be those who are particularly concerned about the impact of REACH within their sectors. Similarly, the sectors are not representative (or are at least not shown to be representative) of German industry, let alone the German economy, which includes a large service sector. It is unlikely that bank tellers and teachers will be influenced by REACH to the same extent as textile manufacturers. Extrapolating from this data set is therefore unlikely to lead to robust results. Moreover, the model is static and fails to address how changes in relative prices will influence either the static supply and demand characteristics of the sector, or dynamic effects due to innovation and the opening up of new markets and opportunities.

The additional direct jump from production losses of the German economy to job losses is extremely weak. It is likely to over-estimate the job losses involved by not taking into account the relative capital intensity of sectors influenced by REACH. Furthermore, it fails to take into account the fact that firms may move into new markets or new product lines if options are closed. Exit will be only one of several options open to a company. A more likely effect would be that German chemical firms search for alternative chemicals and improve their production processes. It may even be the case that chemical firms have far better information about the use of their products along value chains that enables them to offer additional value added services.

Overall, the study can be criticised on a number of issues that will cause it to inflate the costs of regulations. The initial industry studies, while themselves of high quality, are unlikely to be representative of the total German economy because they focus on sectors that are more likely to be more negatively effected by regulations that is typical. Similarly, the small number of interviewees, and lack of collaboration or triangulation of their responses and the potential biases involved in their selection, would suggest that the costs may be over-estimated and should not be repeatedly aggregated as representative mean values of the industry or economy.

The study is presented as an "economic study" but only concerns itself with costs. The detailed case studies of value chains are very useful and are well conducted. However, the lack of a baseline scenario, the use of a linear model, the very static nature of the analysis and the failure to pay adequate attention to the positive features of the REACH legislation limit its usefulness as a policy evaluation tool.

4 Analysing the potential impacts on innovation of the REACH system

This section sets out a qualitative assessment of the REACH proposals against a number of factors influencing innovation. First, the main factors for assessing regulations are set out. Second, the factors influencing innovation are described. Third, European chemicals regulation is compared with regulation in the US and Japan. Fourth, the characteristics of "innovation-friendly" regulation are described and the main characteristics of REACH outlined.

FACTORS FOR ASSESSING REGULATION

As we have seen, regulatory impact analysis is complex, especially when dealing with the prospective impacts of future legislation. A first step is to establish the nature of the new regulations. The factors that are compared are the stringency of regulation and its positive/negative impact on industrial performance (Lyon and Huang, 1995), and the cost and time that it may take for industries to comply with regulation (Rothwell, 1992).

Kahn (1989), based on these factors, states that regulations can be compared according to their relative effectiveness and efficiency. Effectiveness is related to the degree to which regulation achieves its primary objective, while efficiency is related to the time or the cost associated with regulatory compliance, compared with alternative policy instruments. Other authors (for example, Oates, 1996) compare regulations in terms of their relative "stringency" and "flexibility". Stringency is associated with the relative degree to which the level of compliance is enforced, while flexibility is associated with the degree to which exemptions may apply within a regulatory regime. In principle, it is possible to have stringent but flexible regulations.

Other factors that need to be considered in comparing regulations include goal, content, process for compliance, and scope (Oates, 1996). The goal of regulation describes its main purpose. The content explains the requirements for compliance and the process describes the procedure necessary for compliance (including cost and time). Finally, the scope of regulation describes the different groups targeted by the regulation and can be used to compare the flexibility of regulations.

FACTORS INFLUENCING THE INNOVATION PROCESS

The literature on how regulation influences innovation (Rothwell et al, 1974; Van de Ven et al, 1989) as well as literature reviews by Saren (1984) and Brown and Eisenhardt (1995), suggest that innovation is produced by processes of varying complexity, and agent actions within this process are partly motivated by their perception of rewards, which are structured by Intellectual Property Rights (IPR) regimes.

There are many innovation models in the chemical industry and a multitude of factors that cross-cut regulation and innovation activities by firms. A typical model of innovation for the chemical sector is a complex division of labour involving highly specialised human, technical and financial capital. The innovation process is influenced by the availability of these resources. In this context, regulations influencing labour and finance (Tylecote, 1994)

become an important factor in influencing the innovation process of the chemical industry (Arora et al, 1998).

Decisions on innovative activities are closely related to perceived future benefits. Innovation is likely to occur when future earnings are larger than the costs of R&D, marketing and licensing. Earnings are dependent on market demand, which is influenced by factors such as technology, competition and social and political factors (Horstmeyer, 1998; Schwartzman, 1976). Regulations such as those on pricing and competition can also influence the industrial innovation process (Grabowski and Vernon, 1979). In the chemicals industry, the costs of testing and approval of products play an important role in determining the profit, and thereby the decision on innovation-related activities (Eads, 1980). A new innovative product is extremely costly to develop and commercialise, and it is crucial for firms to secure their profit in the form of intellectual property rights, such as patents (Hartnell, 1996).

Current chemical notification procedures of the EU, US and Japan are compared in Mahdi et al (2002). Drawing on earlier work by Fleischer et al (2002), they find that although regulatory regimes in all three countries have a similar purpose – "to protect man and environment from contamination produced by chemicals" – there are substantial differences between them. The product notification regulations between the three regions show substantial differences in the structure of their testing requirements, cost of notification, level of exemption and government intervention. In this area of chemical notification, European regulation is considered more stringent than that in the US on the volume level for initial notification (the initial volume level for chemicals that require notification in Europe is 10kg and will be 1 tonne in the new system, while Japan is 1 tonne per year and the US 10 tonnes). Current European regulations appear less flexible in comparison with the US and Japan since EU regulations require fixed text compared with a contingent (risk-based) approach by the US and Japan. Even though the basic exemption criteria (such as for exports and R&D) are similar across the three regions, American and Japanese regulations have exemptions for low release and exposure to substances. As a result, costs of compliance in Europe have been substantially higher than in the US and Japan (averaging $117,000 per substance in the EU, compared with $40,000 in the US and $80,000 in Japan). This may suggest that current EU policy is less efficient in comparison (Fleischer et al, 2000; Milmo, 2000).

5 Impact of the REACH system on innovation in the chemical industry

REACH aims to integrate the two systems of notification for existing and new chemicals. Under the new proposed system, the responsibility for the new testing system will be shifted from government agencies to chemical firms, with the creation of a single coherent system for both existing and new chemicals by 2016-17. This will involve more downstream user involvement in testing, and increased public openness and transparency about information on chemicals.

Here, REACH is examined for its impact on innovation (and by implication on competitiveness), using Michael Porter's argument that competitiveness can be gained from the "productive innovation" that is caused by stricter regulation. Based on the literature, a number of assessment criteria are set out, and REACH is evaluated qualitatively against these, taking into account the *status quo ante* and the situation in North America and Japan. Furthermore, the impact of REACH is examined in terms of the different scope of effects: sector-specific and macro. Sector-specific effects concern only the EU chemicals industry, while macro effects are translate to wider contexts.

'INNOVATION-FRIENDLY' REGULATION

As we have seen, regulation may both inhibit and stimulate innovation in industry and several authors have sought to define the conditions under which regulation may be deemed "innovation-friendly". Rothwell and Zegveld (1981) argued that performance standards are more likely than technology standards to provide dynamic incentives to innovate because they allow for "…greater latitude in determining how to achieve the regulatory goal" (p143). Porter and van der Linde (1995) developed a number of principles for the design of social regulation to promote innovation, resource productivity and competitiveness. These were:

1 *Focus on outcomes* (not technologies): give greater freedom to industry to make choices about the best means of achieving performance standards, while achieving social and environmental goals;

2 *Distance from end-user*: regulate as close to the end user as practical, while encouraging upstream solutions: companies operating closer to the final consumer are more likely to be able to appropriate market advantage based in non-price-driven innovations through a strategy of differentiation;

3 *Definition of implementation timetable*: employ well-defined and appropriate phase-in periods: greater certainty about when innovations are likely to generate market rents and reduces the risks faced by innovators;

4 *Procedural stability and predictability*: make the regulatory *process* more stable, clear and predictable: greater predictability about procedures to be followed and criteria to be applied reduces the risks faced by innovators;

5 *Time and cost of regulatory process*: minimise the time and resources consumed in the regulatory process itself: regulatory procedures can impose rigidities and costs on industry that militate against innovativeness. Regulatory processes should be set up in such a ways as to encourage innovation and change, where justified;

6 *Level of stringency*: enact strict regulation to stimulate innovation (rather than lax regulation): greater stringency gives more innovative companies an advantage since they are more likely to be able to adapt efficiently to new regulations;

7 *International context*: develop regulations *in sync* with other countries (or slightly ahead of them): There may also be a "first mover advantage" for companies in a more tightly regulated jurisdiction, assuming other jurisdictions eventually adopt similar standards;

8 *Harmonisation with other policies*: harmonise regulations in associated fields - companies face an increasing number of demands from regulators. Harmonisation (or policy integration) is a way of achieving regulatory goals more effectively (by avoiding split incentives that may arise in complex regulatory contexts), while reducing the burden on industry;

9 *Industry participation*: require industry participation in setting standards from the beginning: efficient and effective regulation is more likely if industry understands it fully and has a stake in its development. Industry has more knowledge than the regulator about the practicality and cost of new technologies;[8]

10 *Regulatory capabilities*: develop strong technical capabilities among regulators: more knowledgeable regulators are likely to apply regulatory procedures and judgement in an effectively and fairly; and

11 *Incentive-based regulation*: use market incentives: the argument that monetary inducements, either as subsidies or as penalties, are the most efficient way of changing market behaviour.

One additional issue has been raised in relation to the REACH proposals, which envisage access to technical information on substances, their properties, authorised uses and risk management measures:[9]

12 *Transparency*: encourage greater transparency: greater transparency about the risks and benefits of chemicals substances should enable consumers to make more informed choices and hence encourage innovation. The White Paper states that only "non-confidential" information will be made generally available in summaries. Some companies believe that too great a level of transparency will put at risk their intellectual property, so reducing the incentive to invest in innovation.

ASSESSING REGULATORY IMPACTS OF REACH

Our approach to the assessment of the impacts on innovative activity of REACH is to compare its provisions against each of the 12 factors listed above. This analysis is set out in Table 2 below and draws on publicly available literature about REACH and the results of a mini-case study that examined industrial perceptions of the legislation in two sectors. This mini-case study is outlined in appendix 1. Against each of the criteria we have set out both positive (according to the Porter framework) and negative aspects of REACH. In many cases we find both positive and negative attributes of the system when judged against these criteria. Where appropriate we give a commentary to further explain our evaluation. Finally, we indicate the extent of the impacts that are likely: whether limited to the sector, or broader. We find that many impacts will be limited to one sector, with a few important exceptions.

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[8] Industry participation may be complicated because there are inevitably 'winners' and 'losers' as a result of new regulations. In the case of REACH, smaller and less innovative companies are likely to be the main losers.

[9] COM (2001) 88 final: 27.

To summarise this analysis, we find that the positive attributes with regard to innovation are:

- the breadth of the "duty of care" provision, covering actors across chemical supply chains and downstream users, imports and substances in articles – this promotes uniform incentives to innovate and eliminates "free rider" problems;
- the clear separation of the role of industry (in the provision of data and assessment) and the regulator (in monitoring, evaluating and authorising) bringing greater predictability, enabling learning by industry, and imposing the costs of regulation on the producers and users of regulated chemicals;
- a clear but challenging timetable for implementation of the Regulation, covering all substances with a production volume over one tonne by 2016;
- the establishment of REACH on the basis of well-established testing protocols and procedures, many of which are becoming increasingly harmonised at a global level;
- new provisions for reducing the cost and time burden of the notification process;
- the enhanced coordination of registration, evaluation and authorisation by an independent Agency that advises the Commission – this should encourage greater legitimacy of decisions and ensure fair treatment of all parties in cases of dispute; and
- wide consultation with industry in developing the REACH proposals.

As to the negative attributes, these are:

- uncertainties about the capacity of Competent Authorities (CAs) in member states, working with the new independent Agency that will coordinate and advise on implementation, to handle rapidly administrative and decision procedures relating to 30,000 substances;
- some uncertainties about the capacity of CAs, the Agency and the Commission to operate to consistent standards and procedures, and to resolve differences of opinion efficiently;
- uncertainties about how judgements will be made about "high concern" substances – those requiring authorisation, subject to restrictions, or submitted to "priority evaluation". These mechanisms appear to give regulatory authorities quite a wide degree of discretion in applying the REACH system.
- uncertainties about the precise costs and time associated with notifying and receiving authorisation for a substance; and
- the high costs of testing relative to average US and Japanese costs.

Some of the uncertainties are likely to be resolved through "learning by doing" as the REACH system comes into force. In particular, the extent of discretion and processes of referral and dispute resolution will be clarified only after precedents have been set. Questions about how long it takes, and how much a simple registration will cost, will become clearer once the whole institutional architecture for the new system has been put in place. The largest cost in the system – testing – is likely to decline as economies of scale emerge as a greater amount of testing is carried out, and firms develop cooperative strategies.

Table 2: Assessment of REACH

Assessment criteria	REACH Proposal		Comments	Scope of impact
	Positive	Negative		
1. Focus on outcomes	Key objective of REACH - to develop an evidence base about the health and environmental effects of traded chemical substances – makes no prescriptions about uses of substances.	Restrictions and bans will be imposed on substances of high concern (a technology-focused rather than outcome-focused provision) this is inevitable given the nature of the regulatory task.	REACH has a wide variety of stated objectives – reconciling these will be challenging.	Sectoral
2. Distance from end-user	The REACH system imposes a duty of care on all companies that produce, import and use chemicals, and for the transfer of information through the supply chain. Downstream user involvement may force producers to eliminate certain chemicals and to develop alternatives.	Registration of the majority of chemicals will be by upstream producers far from the end-user.	REACH applies across the chemicals supply- and value-chain, and should have impacts within the EU and more broadly (since the EU is a major net exporter of chemical products). 90% of 'intended uses' for chemicals should be covered in notification.	Cross-sectoral (includes downstream users of chemicals) and macro
3. Definition of implementation timetable	Clear timetable for implementation of REACH system is set out, providing industry with a clear picture of information and risk assessment requirements	Capacity of CAs[10] to carry out evaluations and to pronounce on authorisations and restrictions on substances and specific uses (especially where there is disagreement and/or a decision needs to be made at community level) has not yet been tested at the volume expected under REACH.[11] However, only an automated completeness check is required for registration, so for many chemicals there will be no further overview by authorities.	Norbeck and Faust (2000) argue that the EC has imposed 'an ambitious timetable'.	

[10] Competent Authorities in member states, who will carry out evaluations.

[11] Under the present system just 2,700 'new' substances (those brought on to the market after September 1981) have been tested and assessed. This compares with 30,000 chemicals which need to be registered under REACH in 11 years. The authorisation timetable is dependent on the competent authorities, priority evaluation is entirely voluntary for the competent authorities, while standard evaluation only affects chemicals produced or imported in amounts larger than 100 tpa.

Assessment criteria	REACH Proposal		Comments	Scope of impact
	Positive	Negative		
4. Procedural stability and predictability	Building on previous legislation and established test procedures, REACH sets out a clear, unified process for registration, evaluation and authorisation of chemicals, using established testing proposals, and on the basis of well-defined production volume thresholds. A central task of the new Agency will be to ensure consistency of decision-making and enforcement across member states. A proactive role for industry in the provision of information and the doing of risk assessments will facilitate learning, and should increase predictability about regulatory outcomes.	The criteria for making judgements about 'high concern' cases – substances, their uses and their justification[12] – remain uncertain (i.e., whether rule-based, norm-based, or at the discretion of CAs, the Agency, or the Commission), and will be handled on a case-by-case basis.[13] The division of labour between CAs and between the CAs and the new, independent Agency are not fully worked-out.	As the responsibility of risk assessment shifts to industry, industries are better able to plan ahead in terms of marketing since they no longer need to wait until authority is given to conduct the risk assessment.	Sectoral

[12] The need to show that the risk for the use of a substance can be adequately controlled, or that the socio-economic benefits outweigh the risk.

[13] 'Priority evaluation' of a substance by a CA may require additional information to be made available. Likewise, authorisations for 'high concern' substances will be given only if it can be demonstrated that the risk of the substance can be controlled, or that socio-economic benefits outweigh the risk.

Assessment criteria	REACH Proposal		Comments	Scope of impact
	Positive	Negative		
5. Time and cost of process	By setting a tight deadline for initial registration and authorisation of substances, the Commission has put regulatory authorities under pressure to work quickly. A wide range of new provisions has been included to reduce costs and speed procedures (exemptions, a higher volume threshold[14] with tiered information requirements, accelerated risk assessments, use of existing information, use of in vitro data, reading across from other substances, sharing test results in 'consortia'[15], grouping of substances, etc.). Existing exemptions for substances used in research have been extended.	The costs of initial registration and follow-on administration are currently unspecified – industry estimates range from €0.03-13.3/kg of substance (BDI, 2002: 49) Testing costs are likely to remain high by international standards, even on the Commission's own figures (€85-325,000 per substance under REACH, compared to $40-80,000 in Japan and the US).	The main cost burden of the registration and testing procedure seems likely to apply to smaller volume chemicals where regulatory costs cannot easily be passed on. The RCEP (2003: 158) suggests that smaller 'service based' companies may play a larger role in the future. However, lower volume chemicals require less safety information and have longer deadlines. Cost estimates vary depending on the calculation. If calculated as sector-specific and short-run, costs include: a reduction in investment in new equipment; slowing in the diffusion of new process innovation; and diversion of R&D resources away from commercially-oriented innovation to compliance-related R&D. Including costs incurred by the downstream users and retailers produces a larger number.	Sectoral

[14] Production (or import) volume threshold at which registration required is raised to 1,000kg (from 10kg under previous legislation for new chemicals).

[15] Manufacturers and importers that have pre-registered the same substance will be able to form a 'substance information exchange forum' (SIEF) to exchange test information involving vertebrates.

Assessment criteria	REACH Proposal		Comments	Scope of impact
	Positive	Negative		
6. Level of stringency	REACH will impose new scrutiny to many existing chemicals and create a 'level playing field' relative to new substances, tending to give the latter an advantage. Imported substances and substances in articles will also be treated equally to some extent, producing uniform incentives and eliminating 'free rider' effects.	Generation of data for registration, evaluation and authorisation, and application of standard risk assessment methods and norms does not materially change the level of stringency, but universalises it.	Norbeck and Faust (2002) suggest that, due to an expected overall decline in the rate of innovation, there will be some delays in the market launch of new products. This phenomenon is considered as an 'innovation shock' caused by the introduction of new regulation (Achilladelis et al., 1990; Macinnes et al., 1994; Granderson, 1999). It is not known how long this innovation shock would last.	Macro
7. International context	By routinising the evaluation/notification of high volume and priority existing substances, the EU is falling into line with US practice. US test results, and some test results from other OECD countries, will be accepted under REACH			Sectoral/International
8. Harmonisation with other policies	Single system established for the regulation of existing and new chemicals.	No explicit harmonisation with other health, safety and environment legislation.		Macro

Assessment criteria	REACH Proposal		Comments	Scope of impact
	Positive	Negative		
9. Industry participation	Industry has been consulted from the beginning of the legislative process, participated in two major workshops and has had ample time to respond to proposals.			Sectoral
10. Regulatory capabilities	Specialisation by authorities in monitoring, assessing and judging data. Harmonisation of capabilities among CAs across the EU and creation of a central chemicals agency	Possibility of considerable differences in capabilities and opinions of CAs across member states, leading to Community-level decision-making.	Under REACH the regulatory function will shift the burden of carrying out and deciding upon risk assessments from authorities to industry. Regulators under REACH will have a clearer role in monitoring and evaluating data generated by industry.	Macro

Assessment criteria	REACH Proposal		Comments	Scope of impact
	Positive	Negative		
11. Incentive-based regulation	All costs of registration, testing and evaluation will fall on industry – fully internalising costs of social and environmental risk management. Companies will have property rights to test data which can be traded with other companies.[16] REACH aims to stimulate innovation in specialised instruments and equipment by giving industry the role (and the costs) of generating data and conducting risk assessments.	REACH is an information instrument with 'command and control' features (imposing restrictions and bans on higher risk substances)		Sectoral
12. Transparency	Greater data transparency and data transfer empowers downstream customers and final consumers to make better-informed choices (thus stimulating innovation across the supply chain).	There may be a greater potential for commercially-sensitive information to be transferred to competitors.	The trend to transparency assigns a smaller role to 'experts' and 'authorities', and encourages more participative and democratic ways of decision-making. REACH not only shifts responsibility to industry, but also to the general public through disclosure.	Sectoral

[16] Copyright may be held singly or jointly (in the case of data being produced in a SIEF) by companies.

6 Conclusions

Assessing the impacts of regulation on innovative activity within companies is fraught with difficulties. Evidence is hard to find and lines of causation difficult to establish. Producing an assessment of prospective legislation, which will not be fully implemented for another decade or longer, is even more problematic. Nevertheless, in the framing and design of new policy, it is vital to seek to understand what its impacts may be, not just in terms of achieving its principal objectives (the protection of human health and the environment in the case of REACH), but also in terms of indirect and unintended impacts.

In this report we have evaluated three business impact studies of REACH, and proposed an alternative, more qualitative analysis that aims to match a number of principles that describe "innovation-friendly" regulation with the attributes of the proposed REACH system. We find that previous impacts studies have a range of methodological problems, and generally make simplifying assumptions about regulations and how business responds to them. In particular, industry-sponsored impact studies are likely to be pessimistic about impacts because they are concerned with costs to industry, and not with the wider societal benefits of a new regulation. They are cost studies, rather than cost-benefit studies. Many of their more dire predictions of impacts on competitiveness and employment appear to substantially overstate the sensitivity, and understate the adaptive capacity of industry. Generally, a static approach is taken which takes no account of innovation and processes of adjustment.

Moreover, such static methodologies are particularly poorly suited to analysing the costs and benefits of legislation such as REACH as it is specifically designed to change the nature of the costs and benefits. Previously, the costs were widely distributed throughout society, uncertain and impossible to quantify, while the benefits were concentrated within the chemicals sector. Under the new system, the costs change and are more concentrated (towards chemical producers and importers) and are easier to quantify, while the benefits become more widely distributed and difficult to measure. As a result, cost benefit analyses that address only well-defined costs and benefits will incorporate a major bias against REACH and should be treated with caution.

In our qualitative assessment of the REACH system, we find that many of its main provisions will tend to promote new innovation – 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. While there are some important uncertainties about the institutional framework and the degree of discretion available to regulators at the member state and Community levels, we would expect many of these to be resolved in practice as new roles come to be understood and worked through.

Based on historical experience, we would expect the *rate* of innovation initially to fall following implementation of new regulations. How serious and how persistent this dip will be in the case of REACH depends very much on whether the measures put in place to encourage, rather than stifle, innovation are successful. Over the longer term the wide societal benefits of removing chemicals dangerous to humans and environmental health, and changes to the *direction* of innovation, should greatly outweigh this short-term fall in the *rate* of innovation in the chemicals industry. It will be important to continue to monitor both the health and environmental benefits of REACH, as well as its impacts on innovation.

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Appendix 1

RESPONSES TO THE NEW EUROPEAN CHEMICALS STRATEGY IN THE UK CHEMICALS INDUSTRY – BY GEORGINA VOSS

Introduction

This mini-case study explores the opinions of industrialists about REACH, first to see if the predictions of industry-sponsored regulatory impact studies are accepted by industry, and second to understand what different sub-sectors of the UK chemicals industry feel will be the major impacts. Four main factors were evaluated:

- the clarity of the legislation;
- the potential changes that the legislation would have on the time and costs of innovation;
- perceptions of the stringency of the regulation; and
- perceptions of the transparency of the regulations.

The case study involved two sub-sectors of the UK chemicals industry. We interviewed eight firms (four in each sector) and gathered their opinions about REACH. With such a small sample, the case study is not intended to be representative of the entire UK industry.

A central point of this report is that REACH is radically changing the social distribution of risks and benefits of chemical externalities. The risks are shifting from people and the environment – where they are difficult to recognise and quantify – to their source in the chemical sector that is better able to deal with them. This case study is intended to inform the qualitative analysis of REACH within the report by highlighting how the firms most likely to shoulder the short-term costs perceive the legislation. It is therefore heavily biased towards the negative impacts of the regulation.

Even when concentrating on costs in sub-sectors that will have to change after the introduction of REACH, the opinion of the companies we interviewed contrasts significantly with the more extreme view expressed in the BDI report. None of the firms saw REACH as having implications for the sector. Many of the large firms and industry bodies generally supported the need to rationalise the regulation process. This was true even though we went out of our way to find a sub-sector that might be particularly hard-hit by REACH – for example, colorants and pigments, which is dominated by small production, small firms and complex multi-substance products. Clearly, as the responses outlined below show, firms recognised that there would be extra short-term costs, but as REACH is shifting the costs of dealing with externalities to producers and importers, this is to be expected.

We were also struck by the general lack of up-to-date understanding of the legislation in some of the firms sampled. The case study also shows that firms focus on short-term costs and rarely consider the longer-term dynamic impact of the regulations (i.e., removing the bias against innovative, newer chemicals). Even the costs that are highlighted are likely to reduce significantly over time as they distribute along the supply chain in the form of higher prices to other sectors and the consumer, or as technical change allows improved safer products to be introduced. Again, we point out that this is a very unrepresentative sample and care should be taken before generalising.

The Chemical Industry and Sample

The British chemicals industry is one of the UK's largest manufacturing industries and the number one export earner. It employs 235,000 people and spends on average £3.5 billion a year in research and development. In 2001 it created an annual trade surplus of more than £5.5 billion and made capital investments worth £2.7 billion. In the same year the total gross output was £49 billion, with £28.7 billion being exports, a large proportion of which were to the EU. While REACH will influence many different sectors and industries, the chemicals sector will be particularly affected. It is important to gather information on how this will happen.

The two sectors analysed are the agrochemicals industry and the colorants and pigments industry. The two differ in structure: the agrochemical sector is dominated by a small number of multinational firms, while colorants and pigments primarily comprises small to medium size firms. Information on the viewpoint of the chemical industry's various collective non-government organisations (NGOs) was also gathered to provide an overview of the entire sector.

Industry organisations

The main industry body for the UK chemicals industry is the Chemical Industries Association (CIA), whose initial position about REACH was generally positive. It recognised the need for appropriate levels of regulation that balance macro-economic costs with the benefits of improved health and the environment. The CIA proposed that government should assess the business impacts before the EU, and emphasised the importance of looking at the broader economic implications of REACH.

Over time, the CIA position has modified. In December 2002, it still fully supported the basic aims of REACH, recognising the need for comprehensive system that demonstrably ensures safe use of chemicals. It highlighted the fact that it was already involved in the voluntary group, Confidence in Chemicals, but held that the proposal, as it stood at the time, would be "overly ambitious", administratively demanding and could damage EU attractiveness as a location. The proposals have been modified to take some of these concerns into account.

At the European level, CEFIC developed its own "thought starter" which set out practical approaches for implementing REACH, the results of which were presented to the EU in April 2002. These results posited that the regime proposed in REACH could damage competitiveness of the EU chemical and customer industries. Adoption of a more stringent system than other countries could lead to an overseas shift of chemical and downstream product manufacture. Potentially, finished goods, possibly containing hazardous materials, would be imported. Conversely, however, concerns were voiced about the delay in bringing forward the regulations, as any delays could lead to investor uncertainty and potentially reduce investment in the EU. With regard to risk assessment procedures, CEFIC argued that information gathering should serve a purpose, rather than being an end in itself. Authorisation should be restricted to high priority substances, and risk assessment should be science-based if it is to be workable, as set out in the 2002 World Summit on Sustainable Development.

Agrochemicals Sector

At the sub-sector level, opinion about the potential impact of REACH was gathered from a number of large multinational and small UK-based firms. Opinions varied between the large and small firms, with large firms largely positive about the need to rationalise the regulation

process (but wary about the potential costs), while small firms were more confused about the legislation, more focused on short-term costs and less likely to address longer-term changes.

When asked about the clarity of the proposed policy, the general consensus was that REACH would increase ambiguity in registration. One company stated that, given that registration was occurring through a centralised system of member states, ambiguity in registration would increase due to difficulties in reaching a consensus between member states. Some large firms were also unsure of the structure, process and workings of REACH, so were uncertain about how it would be implemented.

There was wide agreement that the regulations would increase the time and costs of procedures, despite REACH being intended to reduce the registration times for some classes of products. Large firms believed that, politically, a move to a centralised system was a good idea. However, they warned that it should be beneficial to both the industry and the regulators, so must be both time- and cost-efficient. While concerns were raised about the potential impacts of perceived direct costs, little comment was given to the widespread benefits that the system could achieve through industry insurance, innovations in other sectors and better public relations.

By contrast, the small firms interviewed suggested that the *current* regulation system is cumbersome for them, due to the many changes already being enforced, and they believed it would be difficult and costly to change it again. And as the system required member states to coordinate their variable opinions, the companies believed that the time taken to bring each state "into line" would be extremely costly. However, one large company stated that the UK was "very good" in terms of efficiency of procedure, and that the problem mainly lay in other countries.

There was general agreement that the regulations would be stringent, as intended by REACH. Other companies believed that if the evaluation procedure were conducted on purely scientific terms, stringency would not increase; however, if politics became involved (as many firms believed would happen), the evaluation procedure would become more stringent. Overly politicising the debate could lead to an inappropriate policy response – or as one respondent put it, "taking a sledgehammer to crack a nut".

Frustration was expressed about changes in availability of various chemicals as a result of changing regulation, and the effects on industrial innovation. Examples were given of how the reclassification of one chemical (which had been used in industry for 30 years) from non-polymer to polymer reduced its availability within the EU. Firms also thought that this would be more widespread as a result of REACH.[17]

When asked about the transparency of the legislation, interviewees were uncertain about what data would have to be provided, and how it would be used. Many small firms (and this may also hold true for the colorants and pigments sector) are involved in developing unique *mixtures* of chemicals, rather than specific molecules. However, one small firm said it would be happy simply to register the active ingredient of a formula, but warned that if it were

[17] Another unnamed chemical, used in fertiliser production, is widely available in the US and Australia, but will need to be re-evaluated before it can be authorised for use again in the EU.

required to register specific formulations, it might give away technical knowledge and intellectual property.

Colorants and Pigments Sector

Interviews were also conducted with small and large firms in the colorants and pigments sector. Some firms were members of the Ecological and Toxicological Association of Dyes and Organic Pigments (ETAD), an international association representing those industries on matters relating to health and environment. ETAD's position statement on the potential impacts of REACH was supported by the member firms. ETAD supports the stated objectives of REACH, but is concerned that neglect of competitiveness would hinder speciality chemical sectors and small firms. Ink makers, in particular, were of the opinion that the EU was too focused on chemical producers, especially large companies, and had not paid enough attention to their customers and to how chemical products were used in manufacturing.

Most firms were confident about their knowledge of the structure, process and implementation of REACH. However, they felt that REACH would lead to increased ambiguity in registration, primarily because of the number of member states involved in reaching a consensus.

Many companies believed that the cost burden for testing would fall on firms producing small-volume specialty products. Some products would not be cost effective to register, so much so that up to 30 per cent could be withdrawn from the market for this reason alone.

One of the aims of REACH is to increase the involvement of downstream users in testing. Implementing REACH could be costly in this regard for sectors such as inks and coatings, and particularly for small firms that may have to test their own formulations to ensure that they can market them.[18] These costs could also stop some chemical producers providing raw materials, particularly for low-volume products.[19] To overcome this problem, the inks and coatings industry as a whole might have to develop its own means for testing and evaluating substances.

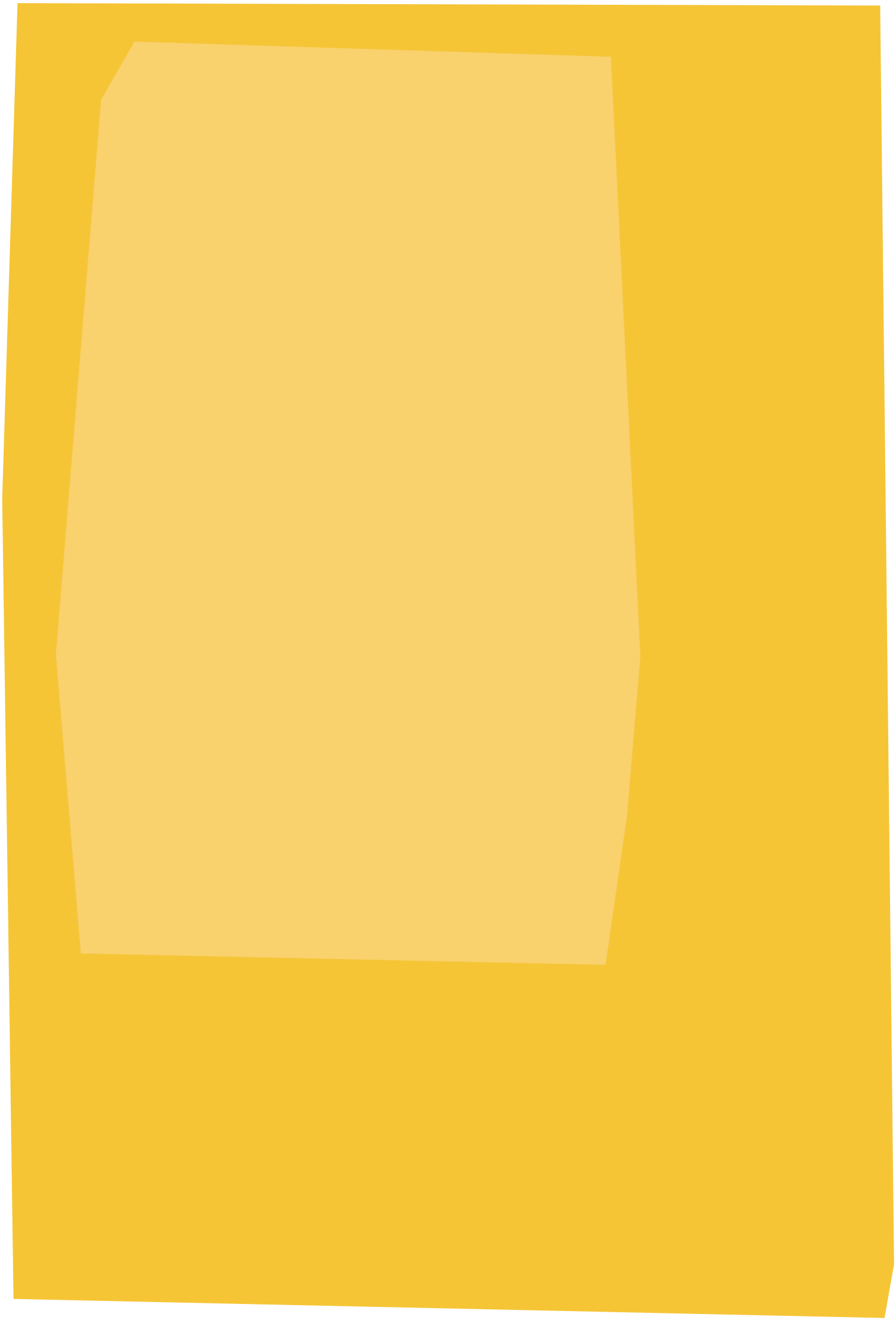
Most colorants are manufactured in a multi-stage process. If required to register intermediates, EU manufacturers might be at a disadvantage compared with importers who only need to register the colorant itself. Some interviewees felt that the complexity of the chemicals industry, and the interdependency between products, was not appreciated, specifically the niche applications of colorants outside dyes and pigments. Any reduced choice or uncertainty about availability of essential raw materials within the EU may discourage investment in EU as manufacturing base, reducing competitiveness.

[18] Many companies produce a large variety of different and specialised products, often in small volumes: a typical printing-ink company could use 6,000 raw materials to formulate up to 30,000 individual products, each designed to meet a specific customer requirement.

[19] Some firms had heard warnings from large chemical companies that they would have to cut back on their portfolios of products when REACH came into operation.

Conclusion

Interviewees expressed a wide range of opinions about REACH and differed substantially in their understanding of the legislation and in their concerns about its impact. Unsurprisingly, a number were concerned that certain chemicals would be taken out of circulation. Since the aim of REACH is to remove dangerous chemicals, these negative perceptions should be qualified. However, there was widespread concern about the short-term costs of the legislation and the potential costs of finding alternative substances – particularly in complex, low-volume production processes such as pigments. Larger firms generally had a more positive attitude towards REACH and recognised the need to rationalise the control of hazardous substances. The findings of these interviews were used to inform the analysis of REACH according to criteria outlined earlier in the report.



TAKE ACTION: IF YOU WOULD LIKE TO SUPPORT WWF'S CHEMICALS AND HEALTH CAMPAIGN AND TAKE ACTION FOR A SAFER FUTURE FOR WILDLIFE AND PEOPLE, PLEASE CALL 01483 860869 FOR A CAMPAIGN LEAFLET, OR VISIT WWW.WWF.ORG.UK/CHEMICALS

WWF'S CHEMICALS AND HEALTH CAMPAIGN

Along with wildlife around the world, we are being subjected to an uncontrolled and dangerous global experiment. Exposure to hazardous man-made chemicals is putting us all at risk. Our children and wildlife are especially vulnerable. WWF's Chemicals and Health campaign is seizing a once in a lifetime opportunity to put an end to this threat, by asking people to help us ensure forthcoming European chemicals legislation brings chemicals under control.

WWF is calling for hazardous man-made chemicals to be properly regulated – replaced where safer alternatives exist, or banned where necessary.

CAMPAIGNING TOGETHER

WWF has joined forces with two campaign partners, the National Federation of Women's Institutes and The Co-operative Bank.

Women's Institute

As the largest women's organisation in England and Wales, the National Federation of Women's Institute is working for a safer future for our children and grandchildren.

www.womens-institute.co.uk

The CO-OPERATIVE BANK
Customer led, ethically guided

Through its Customers Who Care campaign, The Co-operative bank is calling for the phase out of persistent and bioaccumulative chemicals.

www.co-operativebank.co.uk/cwc

WWF

The mission of WWF – the global environment network – is to stop the degradation of the planet's natural environment and to build a future in which humans live in harmony with nature, by:

- conserving the world's biological diversity
- ensuring that the use of renewable resources is sustainable
- promoting the reduction of pollution and wasteful consumption

Taking action for a living planet

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