

Summary of REACH Phase I Regulatory Impact Assessment

Introduction

A Regulatory Impact Assessment is a tool to enable the Government to make informed policy decisions and inform the negotiating strategy. Attached is a Partial Regulatory Impact Assessment. It is an initial assessment of the impact of policy options in the UK in terms of the costs, benefits and risks of the European Commission's proposal.

The chemicals industry plays a very important economic role, stimulates innovation and contributes to economic development. It is therefore essential to correctly assess both the benefits of REACH and its effects on the competitiveness of industry, including SMEs.

On the 16 October the European Commission published an updated impact assessment which now estimates the maximum overall cost of the revised proposal to be €7.5bn – significantly lower than the €18bn-32bn previously estimated. They also estimate the health benefits to be as high as €50bn over 30 years as an illustration of the legislation's potential scale. A copy of the European Commission impact assessment can be found at: <http://europa.eu.int/comm/enterprise/chemicals/chempol/bia/eia.pdf>

The European Commission, in consultation with industry, has agreed that there are a number of areas where the impact of REACH has to be better clarified and understood. These areas include:

- **Impact on business throughout the supply chain:** Many down-stream users are worried that low-volume chemicals might be withdrawn from the market as a result of the requirement to register. The reasons for and mechanisms behind withdrawal of substances for commercial reasons require further study.
- **Impact on Innovation:** REACH is likely to have an influence on the rate of introduction of new products. On the one hand, it might stimulate innovation, because of an interest in substituting certain substances by more environment- or health-friendly alternatives, or because of the exemptions from registration for research and development. In addition, registrations will start at 1 tonne (as opposed to 10 kg under the current system for new substances). On the other hand, an increased procedural burden on industry might diminish the interest in developing new substances. There is a need to understand how the balance between these effects will influence the innovative capacity of the chemicals sector.

- **Impact on Accession Countries:** REACH will apply to the chemicals industry of the 10 new Member States in the same way as to the industry of the current Member States. More data on the effects in the Acceding Countries is needed to verify the impact of REACH on the entire (EU 25) internal market.

While the European Commission's work has helped in developing an understanding of the proposal and how it will impact on Europe in general, the Government needs an assessment of how REACH will impact on the UK, to take account of concerns specific to the UK industry. A contract was let to carry out a Regulatory Impact Assessment to assess the costs and benefits of the legislative proposal on the UK. Similar impact assessments are also being carried out by a number of other Member States.

As explained above, this partial Regulatory Impact Assessment is an initial attempt to estimate the potential costs and benefits to the UK of introducing the REACH legislation. As a partial Regulatory Impact Assessment it is, by its nature, incomplete and it is anticipated that the RIA will be updated and extended as the negotiations on REACH progress. In particular, the following should be noted:

- The cost estimation has focused initially on the direct costs to industry of implementing REACH. The Government recognises that the indirect costs passed down through the supply chain to downstream users are more difficult to assess but may be significant. A further study is expected to be undertaken to assess the impact of REACH at each stage of the supply chain in order to estimate the indirect costs and effects on downstream users.
- There are very significant difficulties in attempting to derive environmental or public health benefits for REACH and the limited information available to perform the calculations. In the light of these difficulties, an illustrative attempt has been made to use existing occupational health data to consider the issue further. However, any estimates derived in this partial Regulatory Impact Assessment must be considered in the context of the many assumptions made and uncertainties in the data used. The estimates are, therefore, subject to error and, even where uncertainties are explored through sensitivity analysis, these analyses are not exhaustive and do not necessarily represent the full range of the potential error.

In order to inform any further work in the Regulatory Impact Assessment we have posted specific questions in the assessment inviting stakeholders to provide comments. In addition, we would welcome any further information from stakeholders on the potential costs and benefits that REACH will generate.

Details of the Consultant's full report are available on the Defra Website.

Further information on Regulatory Impact Assessments and guidance on preparing such assessments is available on Cabinet Office website at: <http://www.cabinet-office.gov.uk/regulation/ria-guidance/>

1. Title of proposed legislation¹

COM(2003) 644 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}; and

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals.

2. Purpose and intended effect

2.1 Objective

The proposal adopted by the European Commission on 29 October 2003 (published on 28 November 2003), and which forms the basis of this consultation paper and partial RIA, seeks to establish the **REACH** system (**R**egistration, **E**valuation, **A**uthorisation and **R**estrictions of **C**hemicals), creates a European Chemicals Agency and amends current legislation in view of the proposed Regulation. This partial RIA has dealt with the costs of REACH generally, rather than look at the different categories subsumed under the term 'substance'.

The Regulation will be directly applicable in the UK. Once the Regulation has been adopted, the UK will need to introduce legislation to supplement it, including providing for new offences and penalties for non-compliance. Further, as the proposal would replace or amend a number of existing measures (e.g. Directive 67/548), the repeal or amendment of several UK legislative instruments will be necessary.

2.2. Background

The main focus of the proposal is the management of industrial chemicals in order to properly protect the environment and people such as the general public or consumers.

Around 100,000 different substances are on the EU's list of "existing" chemicals (EINECS), of which around 30,000 are thought to be manufactured or imported in quantities above 1 tonne in the EU (the exact figure is not known). Adequate data on the environmental and health effects are available

¹ 2003/0256(COD) and 2003/0257(COD) See <http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/consultation.htm> the Commission's proposals, adopted on 29 October 2003

for only a small proportion of these chemicals. By contrast, the regime for dealing with approximately 3,000 “new” chemicals has by and large ensured that appropriate information is available for these chemicals and that the potential risks are adequately controlled.

The proposal aims to address a number of short-comings found in the current systems relating to the supply and assessment of chemicals. These include: the lack of available information on risks to human health and the environment for many of the substances on the EU market; the slow and resource-intensive nature of the current system; the need for responsibility for the assessment of chemicals to shift from the regulatory authorities to industry; and the lack of information on uses of substances.

The proposal creates a single system to replace over 40 pieces of existing legislation (the main ones being Regulation 793/93 covering existing substances and aspects of Directive 67/548 covering new substances) for gathering information, assessing risks to human health and the environment, authorising and restricting the marketing and use of individual chemicals produced or supplied in the EU.

REACH consists of the following elements. **Registration** requires industry to obtain relevant information on chemical substances produced or supplied in quantities greater than 1 tonne per year and to use that data to manage the chemicals safely. **Evaluation** provides the opportunity for regulators to assess whether the information provided by industry is sufficient, allows the clarification of the risks posed by a chemical and seeks to prevent unnecessary testing.

Risks associated with uses of substances having hazardous properties of very high concern will be reviewed and, if they are adequately controlled, or if the socio-economic benefits outweigh the risks and there are no suitable alternative substitutes or technologies, then the uses will be granted an **Authorisation**. The **Restrictions** procedure provides a safety net to manage risks that have not been adequately addressed by another part of the REACH system.

In negotiating the resultant legislation, the Government will have three overarching objectives:

- Creating a fast, efficient and workable process of testing, screening and assessing chemical substances to provide the information necessary to control substances of concern, starting with the most harmful, because of their impacts on human health or the environment;
- Keeping animal testing to the minimum necessary to protect human health and the environment; and
- Maintaining or enhancing the competitiveness of the chemical industry and downstream users.

In addition, the Government will want to see a system that is transparent to all interested parties in its operation and that provides consumers, workers and users of substances with the level of information they require for the safe handling of substances with which they come into contact. The Government also fully supports the need for industry to assume responsibility for managing the risks from substances as far as possible.

2.3 Risk assessment

The key risks that the REACH proposal is designed to address concern the potential impacts of chemicals on human health and the environment.

Several high-profile cases of environmental damage from chemical contamination have emerged in the past. In the case of exposure to chemicals such as DDT, DDE and PCBs, hazardous substances have entered the environment and reached sufficiently high concentrations to induce adverse effects such as eggshell thinning, reproductive problems and skeletal malformations in birds, mammals and fish². In the case of human health, chemicals (although by no means the only cause) are associated with a number of human diseases including, for example, respiratory, bladder and other cancers, mesothelioma, skin disorders, respiratory diseases, eye disorders and asthma. These diseases affect a large share of the UK population.

Although it is not known how many of the substances currently supplied in the EU are hazardous and may result in a risk to human health or the environment, the output of the current regulatory system can be used as an indication of the potential impacts of chemicals. The risk assessment of existing substances under the current regulatory system in the EU has indicated that, of the 17 substances for which the results of the whole evaluation under Regulation 793/93 have been published, 12 needed further risk reduction. In other words, the risks to either human health and/or the environment from the use of these substances were not adequately controlled and additional risk management measures (sometimes through EU-wide restrictions) were needed. However, it is important to note that, in the majority of these evaluations, existing EU legislation was found to adequately address the risks identified to workers. In addition, of the 66 further substances for which scientific and technical discussions have been concluded and agreed at EU level, 53 are highlighted as requiring further risk reduction measures³. However, it has to be recognised that this is likely to over-estimate the potential need for risk management under REACH as the existing substances chosen were prioritised according to the perceived risk they posed.

REACH will provide basic information on the remainder of the estimated 30,000 chemicals supplied in the EU above 1 tonne allowing industry and the

² EEA and Swedish EPA sources quoted in Extended Impact Assessment, Commissions Staff Working paper, SEC (2003) 1171/3, COM(2003) 644 final.

³ European Chemicals Bureau Newsletter, Issue No. 4, 23 December 2003

authorities to assess the potential risks from the use of these substances and, if needed, introduce risk reduction measures.

Other risks that could impact on the UK include;

- creation of distortions to the European internal market if certain Member States take unilateral action on chemicals.
- unnecessary animal testing, if a harmonised, internationally acceptable chemicals safety regime with sharing of test results cannot be agreed.
- a lack of transparency and information on chemicals, which could adversely affect public confidence in the industry and, ultimately, the operations of companies engaged in the production, importation and use of chemicals.

3. Options

3.1 Option 1 – do nothing

The current system for assessing the risks from existing substances has been slow to produce results. This means that, in practice, there is limited information on the majority of chemicals supplied in the EU. Without a revision of the legislation there is a concern that risks from hazardous chemicals will not be adequately evaluated. As well as the impacts on health and environment a lack of effective regulation could adversely affect public confidence in the chemical industry. In addition, costs are currently being incurred by downstream users due to the lack of available information on chemicals. These costs would continue to be incurred should REACH not be implemented.

This option is the current, business-as-usual option, and hence is the baseline option against which the costs of implementing REACH have been assessed. Costs for the REACH implementation options that are considered in this partial RIA exclude costs that will already be incurred under business-as-usual.

3.2 Option 2 – adopt the Commission proposal

Under the Commission proposal, one registration dossier is required per manufacturer/importer per substance. Consortia-formation is encouraged (but not made mandatory), for example by financial incentives. A full description of the Commission's proposal is given in the consultation document.

3.3 Option 3 – “one substance, one registration”

REACH has the potential to increase the number of animals used in tests and thus increase the cost for manufacturing industry, particularly in the chemicals

sector. In addition, producers of any one substance may hold existing data. In order to ensure that maximum benefit can be gained from the generation of new data, as well as that already produced, an option is to ensure that all organisations who wish to register for REACH should share data on an equitable basis. One way of achieving that would be to require companies to jointly submit aspects of the registration dossier with the aim of achieving **one registration per substance**.

The main advantages of “one substance, one registration” would be:

- Reducing the workload and simplifying the system for industry and authorities;
- Reducing the cost of REACH to the economy by sharing costs of testing;
- Maximising the sharing of existing data and creating one data package per substance;
- Minimising animal testing through sharing of data in consortia;
- Aiding rapid decision making through the use of one registered data package;
- Creating a level playing field for all registrants, including late entrants to the EU-market.

Details of the Government’s current thinking are given in the consultation document.

4. Costs

4.1 Business sectors affected

There are approximately 3,500 chemicals companies in the UK, which vary enormously in size. The Chemical Industries Association (CIA)⁴ and the Chemicals Innovation and Growth Team (IGT)⁵ have published headline data for the sector:

- The CIA reports Gross Output (broadly equivalent to company turnover which includes sales of all products including merchandising) is £49 billion. This is 10 percent of UK manufacturing and two percent of Gross Domestic Product. The IGT, using its narrower definition of the sector, reports sales of £26 billion.
- Exports were £28.7 billion and imports £23.2 billion in 2001, giving a trade surplus of £4.6 billion. The sector is extremely open to trade, with 75 percent of UK output being exported and 75 percent of domestic demand being satisfied by imports. Sixty percent of the UK industry is in the higher value added speciality sector. This compares with 40 percent of the German chemicals industry and 44 percent of the US

⁴ Source: http://www.cia.org.uk/newsite/industry_glance/facts.htm. Data are for 2001.

⁵ Report by the Chemicals Innovation and Growth Team, "Enhancing the Competitiveness of the UK Chemicals Industry", December 2002. Available at <http://www.dti.gov.uk/cigt/reports.htm>

industry. The UK has a higher proportion of speciality chemicals, a similar proportion of consumer chemicals and a lower and declining proportion of bulk chemicals when compared with its major competitors. Whilst the commodity, speciality and consumer chemicals have all generated trade surpluses consistently in recent years, the trade balance in speciality chemicals has been declining due to rapidly growing imports of fine organic chemicals from countries such as Ireland, China and India.

The main business sectors affected will be:

- **Manufacturers and importers** of chemical substances will need to register their substances with the European Central Agency if manufactured/imported in quantities of over 1 tonne. Failure to register a substance means that a manufacturer/importer can no longer manufacture or import that substance.
- **Downstream users** of a substance will have a duty to ensure the substance is handled according to the manufacturers/importers recommended risk management measures passed down to them via a safety data sheet. If their use is not covered by the manufacturers risk assessment they will have to notify the Central Agency and prepare a chemical safety report if necessary.
- **Importers and retailers** of finished products will need to ensure that the products they sell meet the requirements of the REACH regime.
- REACH will have the greatest **direct impact** on the chemical industry and importers of chemicals as they will be responsible for registering substances they manufacture or import in quantities of greater than 1 tonne.

Direct costs will be incurred primarily for:

- Pre-registration – where companies will have to gather available data and make themselves known to the authorities.
- Registration – which involves data gathering and, where necessary, testing to obtain additional data if it is not already available from industry, as well as risk assessment related to use/exposure.
- Evaluation – where further information may be requested by authorities relating to the possible risks posed by a substance.
- Authorisation – which, for substances of very high concern, will require industry to justify continued use.

Estimates of the direct costs of REACH vary primarily because of uncertainties about how much data industry holds, whether it is recent and of acceptable quality, the scope for flexibility in testing requirements depending, for example, on exposure and the extent to which alternatives to testing such as computer modelling techniques can be used. The estimates presented in the partial RIA are, therefore, subject to these uncertainties and, although a

range of potential costs is presented, this is not intended to represent the full extent of the uncertainty.

Cost estimates can also be separated into policy and implementation costs. Policy costs are those that are directly attributable to the policy goal while implementation costs are those that are not and as such represent the 'red-tape burden' of the policy. Testing costs, considered as policy costs, have been calculated based on the Commission's proposed testing requirements. Costs of forming consortia are based on US experience. As an initial calculation, they have been included solely as policy costs. The main reason being that the Commission's proposal provides for companies forming consortia and encourages them to do so. We recognise that aspects of consortia-formation may be considered as implementation costs, however we have not attempted at this stage to split the costs of consortia-formation into the two categories.

Reporting costs are those associated with preparing testing proposals, reporting test data and preparing accompanying information. These have been included as implementation costs although, again, aspects of these may be considered as policy costs. In terms of the different stages of REACH, we have attempted to divide the costs as shown in the following table.

Table 1 Implementation and policy costs

Stage of REACH	Policy cost	Implementation cost
Pre-registration	Information gathering	-
Registration	Testing costs and consortia-formation	Reporting
Evaluation	Fulfilling the requirements of the authorities	-
Authorisation	Testing costs relating to authorisation and consortia-formation	Reporting

Unlike direct costs based on prescriptive data requirements, indirect costs passed down through the supply chain to downstream users are more difficult to assess. These will be based on different scenarios, consequential to the decisions made by those further up the supply chain with responsibility for registering substances.

A further study is expected to be undertaken to assess the impact of REACH at each stage of the supply chain in order to estimate the indirect costs and effects on downstream users.

4.2 Administrative costs for the authorities

The Government recognises that there will be costs to the UK authorities associated with the regulatory requirements of REACH.

In the Commission's proposal, Member States shall each appoint a Competent Authority with the expertise and resources available to carry out the tasks assigned to it. The main functions of the Competent Authority will be: to carry out the evaluation of dossiers submitted under REACH and to produce a draft decision on whether more information (including testing) is required; to undertake substance evaluations and propose restrictions for those that show immediate concern; and to submit proposals on which substances should be subject to authorisation. Once substances have been identified as requiring authorisation, industry will submit proposals requesting authorisations for a particular use.

The appointment of a Competent Authority or Authorities in the UK is a practical issue relating to the introduction of REACH and will need further consideration. The Government has not included estimates of costs to the authorities in this partial RIA as this issue will be the subject of a separate consultation exercise planned later.

4.3 Cost of option 1

If we do nothing there will be no additional direct cost to the chemical industry. However, the main risk arising from this option is that, should substances on the market subsequently be found to be of concern, the chemical industry could face liability costs and loss of reputation for any harm caused to human health (workers or consumers) or the environment.

Indeed the current chemical management system imposes costs which will be absent under REACH. For instance, new substances supplied in quantities of 10 kg to 1 tonne per year currently require a reduced set of information to be supplied to the authorities prior to marketing. This will not be the case under REACH where only substances supplied in quantities greater than 1 tonne will come under the scope of REACH.

Additionally, costs are currently incurred by downstream users as a direct consequence of the lack of available information on chemicals. We have not, at this stage, attempted a full calculation of these costs to the UK but these should be considered as potential savings resulting from REACH.

As an example, a UK retailer has estimated that, due to the current lack of a trusted system of chemical management, costs are being incurred as a consequence of: assembling available information on chemical safety; identifying potential problem chemicals and phasing-out in the absence of information and regulatory action; stakeholder engagement; collection of information on chemical safety; and time spent managing chemicals in their products through product development. Costs associated with these activities vary but, for example, phasing-out of one chemical in all product lines cost in excess of £1 million. In addition, there are two significant areas where calculation of costs is difficult: loss of research and development options and a reluctance to innovate due to uncertainty on chemical safety; and the risk of a significant consumer scare about the presence of chemicals of concern in

consumer products. The last item was given as potentially the most important risk that REACH would reduce.

4.4 Cost of option 2

This option reflects the Commissions proposal as published on 29 October 2003. Under this proposal, companies may form consortia should they choose to do so. There is encouragement to do so, and experience in the United States and elsewhere suggests that this is almost certain to occur extensively. However, it has to be noted that the US experience is based mainly on high production volume chemicals supplied mainly by large companies. The main risk from this option is that consortium-uptake is low. This may result in: an increased burden on industry and the regulators in preparing and assessing different data packages for the same substance; a potential for duplication of animal testing; a potential for confusion in the supply chain resulting from different information being supplied for the same substance; and the possibility of anti-competitive practices resulting from selective membership of voluntary consortia.

It is difficult, at this stage, to assess the likely take-up of consortia under REACH. However, based on the US experience, the assumption used as the basis of the calculations is that 85 percent of substances will be tested through consortia (Option 2a). However, two other variants have been used to illustrate the effect of a lower rate of consortia formation: 50 percent and 25 percent. The options considered are, therefore:

- Option 2a – voluntary consortia with 85 percent participation (best estimate);
- Option 2b – voluntary consortia with 50 percent participation; and
- Option 2c – voluntary consortia with 25 percent participation.

The following basic steps were used to estimate total EU costs:

- a representative sample of chemicals (all of which are produced in the UK) was selected from the 30,000 chemicals estimated to be affected by REACH;
- for each of these chemicals, the requirements of REACH, such as requirements for information on chemical properties, were estimated;
- the extent to which testing requirements were already met (e.g. through existing available test data generated through other testing programmes, such as the US High Production Volume Programme) was assessed with reference to existing databases and also committed future activities;
- the extent to which testing could be further reduced by use of techniques such as (Quantitative) Structure-Activity Relationships ((Q)SARs) was also assessed with reference to experience of existing test programmes.

This process therefore gave estimates for the total EU-wide cost for each major aspect of REACH (i.e. pre-registration, registration, evaluation and authorisation).

In order to calculate the proportion of total EU costs likely to fall on the UK, two principle indicators have been used – the UK chemical industry’s output as a proportion of EU output and the proportion of notifications under the current Notification of New Substances regulations (NONS) by UK firms.

We recognise that neither value is likely to accurately represent the proportion of costs that will be borne by UK industry and this leads to a further uncertainty in the cost estimations. However, these are the best indications we have been able to identify and we would welcome comments from stakeholders on alternative approaches to estimate the potential cost to UK industry.

According to Eurostat data, the UK accounts for approximately 15 percent of the output of the EU chemicals industry. As a worst-case, we have assumed that this is likely to underestimate the UK’s share of future REACH costs, because of our relative concentration on speciality chemicals – these are more likely to require testing and are less likely to be tested through consortia.

One way of identifying impacts on the speciality chemicals sector is to use the proportion of notifications under NONS. UK notifications account for 28 percent of notifications under NONS. However, not all UK notifications are from UK-based firms. Many importers and sole representatives choose the UK as the country of notification.

The UK proportion of total REACH costs is therefore likely to be between 15 and 28 percent. There is no accurate way of estimating where in this range the actual proportion will be, but for the purposes of this RIA we have adopted the mid-point (21.5 percent of total costs).

A summary of the estimated direct costs is presented in the following tables (labelled as “central” costs). Minimum and maximum values are also given as an indication of the potential uncertainties in the calculations. However, estimates of the direct costs of REACH vary as described earlier. The estimates presented in the partial RIA are, therefore, subject to these uncertainties and, although a range of potential costs is presented, this is not intended to represent the full extent of the uncertainty.

4.4.1 Option 2a – Voluntary consortia with 85% participation

Table 2 shows the total estimated costs to EU industry of the REACH proposal over the 11-year phase-in period.

Table 2 Costs of REACH to EU industry

	Costs in £		
	Minimum	Central	Maximum

Pre-registration	30,000,000	60,000,000	100,000,000
Registration	1,051,235,000	1,496,400,000	3,009,117,914
Evaluation	150,000,000	240,000,000	661,128,000
Authorisation	9,500,000	600,500,000	873,500,000
Total	1,240,735,000	2,396,900,000	4,643,745,914

Assuming 21.5 percent of costs to EU industry are incurred by the UK, the estimated costs for the UK are presented in Table 3.

Table 3 Costs of REACH to UK industry

	Costs in £		
	Minimum	Central	Maximum
Pre-registration	6,450,000	12,900,000	21,500,000
Registration	226,015,525	321,726,000	646,960,352
Evaluation	32,250,000	51,600,000	142,142,520
Authorisation	2,042,500	129,107,500	187,802,500
Total	266,758,025	515,333,500	998,405,372

Further separation of the central costs to UK industry (given in the table above) into policy and implementation costs are given in Table 4.

Table 4 UK costs separated into policy and implementation costs

	Policy Costs	Implementation Costs
Pre-registration	12,900,000	-
Registration	310,782,500	10,943,500
Evaluation	51,600,000	-
Authorisation	126,312,500	2,795,000
Total	501,595,000	13,738,500

The regional impact of REACH will not be even. In order to estimate costs by devolved administration and English region, we have used data from the Office for National Statistics' (ONS) Annual Business Enquiry. This is not available for sub-sectors of the chemical industry, and hence the geographic allocation of REACH costs has been calculated with reference to the proportion of turnover in each devolved administration/region. The following table illustrates the anticipated costs, broken down by devolved administration and English region.

Table 5 UK cost estimates according to English region and Devolved Administration

Devolved Administration / Region	Turnover of Manufacture of Chemicals, Chemical Products and Man-made Fibres		Cost of REACH by Region / Country
	£ million	Percent of Total	
United Kingdom	43,270	100%	515,333,500
England	37,898	88%	451,354,495
- North East	3,681	9%	43,839,672
- North West	9,096	21%	108,330,795
- Yorks and Humber	3,695	9%	44,006,408
- East Midlands	2,458	6%	29,274,087
- West Midlands	1,489	3%	17,733,570
- East of England	3,344	8%	39,826,097
- London	3,336	8%	39,730,819
- South East	9,461	22%	112,677,842
- South West	1,338	3%	15,935,203
Wales	1,852	4%	22,056,798
Scotland	3,028	7%	36,062,626
Northern Ireland	492	1%	5,859,581

Source: ONS analysis of Annual Business Enquiry, September 2003 (survey data are from 2001)

4.4.2 Option 2b – voluntary consortia with 50% participation

Sensitivity tests have also been undertaken to assess the impacts of lower rates of consortium formation. The impact of just 50 percent of chemicals being tested through consortia, is illustrated in Table 6.

Table 6 UK costs of REACH with 50% consortia participation

	Costs in £		
	Minimum	Central	Maximum
Pre-registration	6,450,000	12,900,000	21,500,000
Registration	475,920,023	757,343,413	1,332,762,705
Evaluation	32,250,000	51,600,000	142,142,520
Authorisation	2,042,500	129,107,500	187,802,500
Total	516,662,523	950,950,913	1,684,207,725

As can be seen, under this option the costs of the registration phase increase substantially. For these calculations, it has been assumed that about 15 percent of chemicals are produced or imported by a single company. Otherwise, it is assumed that as the percentage participation in consortia decreases, increasing numbers of tests (many duplicative) will be performed and that multiple reports will be submitted covering the same tests for the same chemicals. It was also assumed that there could be up to eight producers of a single substance. The costs related to percentage participation are not a straight line increase because companies participating in consortia will have to review the test reports and submissions, and individual companies may have test results to contribute that they have conducted (but not through the consortium).

4.4.3 Option 2c – voluntary consortia with 25% participation

The impact of just 25 percent of chemicals being tested through consortia is illustrated in Table 7.

Table 7 UK costs of REACH with 25% consortia participation

	Costs in £		
	Minimum	Central	Maximum
Pre-registration	6,450,000	12,900,000	21,500,000
Registration	868,097,760	1,414,405,450	2,461,247,461
Evaluation	32,250,000	51,600,000	142,142,520
Authorisation	2,042,500	129,107,500	187,802,500
Total	908,840,260	1,608,012,950	2,812,692,481

It should be stressed that this is well below the level of participation that is expected. However, the option has been included to illustrate the effect of any changes to REACH that would actively discourage firms from participating in consortia.

4.5 Cost of option 3 – “one substance, one registration”

Table 8 shows the costs assuming that only one registration is accepted per substance.

Table 8 UK costs with mandatory consortia

	Costs in £		
	Minimum	Central	Maximum
Pre-registration	6,450,000	12,900,000	21,500,000
Registration	290,184,358	311,296,350	521,304,120
Evaluation	32,250,000	51,600,000	142,142,520
Authorisation	2,042,500	129,107,500	187,802,500
Total	249,926,858	504,903,850	872,749,140

As well as providing benefits to industry, a single registration package should reduce the administrative burden to the regulators by reducing the number of registration packages submitted, transferring many of the responsibilities of ensuring one coherent package for each substance to industry and simplifying the enforcement of REACH.

4.6 Benefits for industry

As well as direct and indirect costs for industry, it is worth briefly highlighting potential benefits for industry which may need to be considered in balance to the costs. We have not, at this stage, attempted to off-set our cost calculations to take into account these factors.

The reputation of the industry was one of the three major issues identified by the Chemicals IGT. Recent research suggests that enhanced reputation can impact positively on bottom-line performance via three mechanisms⁶.

4.6.1 Financial performance

A comparison of book values with market valuations indicates that more than half of company market value derives from intangible assets, including the company's reputation. Separating the value of reputation from other intangibles is not clear-cut, but research suggests that corporate reputation is built from six components, each related to stakeholder perceptions i.e. emotional appeal, vision leadership, financial performance, workplace environment, social responsibility, products and services.

Of these components, it seems most likely that compliance with legislation under the proposed REACH system could enhance the social responsibility and product/service-related perceptions of Europe-based chemical companies. However, it should be noted that whilst there is no universally accepted definition of "social responsibility", it is often viewed as the extent to which companies go beyond compliance in meeting their environmental and social commitments and is often closely tied in to differentiation between companies. Hence "raising the bar" through implementation of a new legislative regime may have limited impact on the sector's reputation (or the relative reputation of individual players in the sector) in the eyes of some stakeholders.

4.6.2 Crisis recovery time

After crisis events, some companies recover lost value more quickly than others. Research suggests that a good reputation acts as insurance against the more prolonged adverse impacts of crises, particularly by bolstering investor perceptions of the impacts of future clean-up, legal and compensation costs.

⁶ Fombrun C (2000) Value to be found in Corporate Reputations, Financial Times Mastering Management Series; New York; Dec 4, 2000.

4.6.3 Supportive behaviours

The market valuation of companies derives from analysts' perceptions of the company's future prospects, with more attractive valuations promoting growth. A strong reputation can encourage supportive behaviour from company stakeholders (e.g. customers, employees, media), in turn improving perceived prospects (from analysts) and increasing the financial value of the company. Examples of supportive behaviour include growth in revenues, growth in employment and increased visibility.

4.7 Concluding remarks on the cost estimation

Using the central estimate from Table 3, REACH is expected to impose direct costs on UK industry of about £515 million. The estimated total costs for the EU are £2.4 bn. This estimate should be viewed as indicative, and it is important to note that some uncertainty will inevitably remain about final out-turn costs until well beyond the implementation of REACH. For example:

- test cost estimates are based on current testing prices. It is possible that the considerable extra testing that REACH will require may drive up prices during the phase-in period. Alternatively, the increase in volume of many tests may yield economies of scale.
- scientific innovation, for example better QSAR techniques and software, may lead to lower requirements for REACH testing than is currently anticipated.
- other countries may also strengthen their chemical testing regimes, which could mean that more of the existing stock of chemicals is tested under overseas testing programmes and in a manner that complies with REACH requirements, leading to lower additional costs for implementing REACH.

It is worth noting that the Commission published an extended impact assessment together with the legislative proposal on 29 October 2003⁷. In this, the estimated direct costs to the EU (at 3% discount) was €2.3 bn (£1.5 bn). Assuming that the proportion of costs incurred by UK industry is 21.5% (as calculated in section 0), this would result in estimated UK costs of €490 million (£322 million).

Q.RIA 1 We would welcome views on the methodology used to derive cost estimates including the assumptions made.

⁷ Extended Impact Assessment, Commissions Staff Working paper, SEC (2003) 1171/3, COM(2003) 644 final.

5. Benefits

5.1 Overview

The benefits of REACH are expected to accrue mainly in terms of reduced risks to human health, reduced risks of damages to the natural environment and benefits to the chemical industry in terms of improved reputation and competitive advantages.

The benefits can be categorised as follows:

1. Reduction of environmental risks:
 - a. from the production process; and
 - b. the use and disposal of chemical substances.
2. Reduction of risks to human health:
 - a. through occupational exposure;
 - b. through exposure via the environment; and
 - c. risks from use of consumer products.
3. Benefits for industry (a brief discussion is included in the previous section):
 - a. improvement of the chemicals industry's reputation and improvement of the public's attitudes (and attached values) about chemicals and the chemicals industry (linked to a perceived higher degree of safety);
 - b. savings associated with a lightening of the regulatory burden for low production volume chemicals;
 - c. innovation associated with R&D to create substitutes and reformulated products; and
 - d. savings to downstream users associated with increased knowledge on chemicals.

5.2 Reduction of environmental risks

In terms of environmental pollution, better information about the properties of chemicals (and subsequent risk management if required) may result in subsequent benefits. This in turn should lead to better use and disposal of chemicals, enabled by better-informed producers and users, and improved, evidence-based chemicals regulation. The types of benefit that could be expected include:

- lower accumulations of pollutants in freshwater and marine environments;
- consequent reduction of impacts on the health of flora and fauna;
- fewer impacts on biodiversity;
- reduced land contamination; and
- safer management of accidental releases.

Quantification of these benefits in monetary terms would be extremely difficult, if not impossible. There are two primary reasons:

- although better information (and hence REACH) will help secure these benefits, the extent to which existing problems will be ameliorated is as yet unclear as is, in many cases, the existing baseline; and
- it will be very hard to value such benefits. There are economic valuation techniques (such as stated preference methods) that are increasingly used to elicit values of non market benefits including environmental benefits. However, it is a complex issue to present the environmental impacts in a way that can be properly understood and hence valued by the general public.

Although, it is thus not possible to attempt the valuation of potential environmental benefits of the REACH regulation, it can be assumed that increased information on chemical substances could lead to enhanced risk management, specifically of those substances which are considered to present an unacceptable risk to the environment. The precautionary principle is thus of acute relevance here.

5.3 Reduction of risks to human health

The effects on human health, and thus the potential benefits of REACH, can be divided into occupational impacts and public health impacts. The latter includes the effects on children, the elderly and even embryos, all of which may be more vulnerable to exposure to certain substances. It is very difficult to estimate how many of these illnesses and even deaths, can be associated directly with certain chemicals, i.e. to establish clear causation. This is partly because of problems of cocktail and multi-causal effects and the difficulty in obtaining robust dose-response functions to quantify the health impacts.

As is the case for the environmental benefits, it is very difficult to value potential human health benefits of REACH. The difficulties associated with attempting such a valuation include:

- the uncertainty over actual damage (i.e. how many of the illnesses and deaths can be linked to chemicals). For most chemicals it is not known how they pass through the environment (accumulated, dispersed or transformed), and how they affect living organisms at different concentrations (dose-response relationships – the relationship between a change in concentration level of a chemical substance and the health impacts).
- the lack of good statistical information on the total number of people affected by a certain disease.
- the absence of behavioural models showing how Government, other public bodies, industry and consumers would respond to the information provided by REACH, and how industry and users would then respond to the true costs of compliance. This means that there is also uncertainty about the effect REACH will have on reducing

exposure to chemicals found to have damaging effects on human health, meaning that quantifying the risk reduction is impossible.

For these reasons we have not attempted the estimation of the benefits of REACH from reduced damages to human health. Instead we have adopted a 'break even' approach focusing on occupational health impact, as shown in the following section.

It is worth noting that the Commission has given an illustration of the potential long-term health benefits of risk reduction measures in their Extended Impact Assessment⁸. The Commission based the calculations on various assumptions:

- the proportion of all disease (based on World Health organisation figures and measured in Disability Adjusted Life Years – DALYs) due to agro-industrial chemicals and chemical pollution from diffuse sources is between 0.6% and 2.5% in developed market economies. A conservative figure of 1.0% is therefore taken from this range.
- the proportion of this disease that will be identified and tackled by REACH is 10%.
- 10 DALYs are equivalent to 1 life saved.
- in line with an experts' workshop on valuing health impacts, a value per statistical life estimate of € 1 million was adopted.
- the positive effects on public health would start to occur 10 years after REACH starts to be implemented, and persist for another 20 years.

The total health benefits would be in the order of magnitude of €50 bn over the next 30 years. In other words, a 0.1% reduction in the burden of disease due to REACH would yield health benefits of €50 bn. The Commission stressed that this was not an estimate of the benefits of REACH, but rather an illustration of their potential scale.

5.4 'Break even' estimations of required benefits in terms of occupational health impacts

The previous sections highlighted the very significant difficulties in attempting to derive environmental or public health benefits for REACH and the limited information available to perform the calculations. In the light of these difficulties, an illustrative attempt has been made to use existing occupational health data to consider the issue further.

Any estimates derived in this partial RIA must be considered in the context of the many assumptions made and uncertainties in the data used (for instance the uncertainty in the cost of REACH, the number of cancer deaths, the cost of cancer deaths etc.). The estimates are, therefore, subject to error and, even where uncertainties are explored through sensitivity analysis, these

⁸ Extended Impact Assessment, Commissions Staff Working paper, SEC (2003) 1171/3, COM(2003) 644 final.

analyses are not exhaustive and are not intended to represent the full range of the potential error.

Attempting to quantify occupational health benefits in monetary terms faces the same difficulties as highlighted in the previous section. In absence of information on dose-response relationships and the reduction in exposure to harmful chemicals from implementing REACH, a 'break even' approach has been adopted. This considers what risk reduction is required to compensate for the estimated costs of the implementation of REACH. However, this approach has to be examined in the context of existing workplace legislation (and the impact this legislation already has in reducing cancer deaths).

Occupational health is already the subject of a large amount of EU⁹ legislation. Workplace legislation and controls have been progressively tightened over a long period of time, suggesting that the number of cancer cases that will occur in the future as a result of current exposure will actually be considerably smaller. For these reasons, the estimates provided are only illustrative.

The 'break even' approach requires:

- an estimation of the total costs of the implementation of REACH in the UK (approximately £45 million per year based on the central costs in Table 3 over a period of 11 years);
- an estimation of the current total external cost of the use of chemical substances in the UK, including costs to human health and the natural environment (these cost categories are the reverse of the maximum potential expected benefits of REACH);
- the calculation of a percentage risk-reduction required for the regulation to provide benefits to the value of the expected costs ('break even' point); and
- an informed opinion on the likelihood of achieving the required risk-reduction.

The 'break even' approach adopted assumes that the total potential cost to occupational human health of exposure to chemicals is considered as the maximum benefit that could be achieved from implementing REACH. Comparing this total cost to society of occupational health impacts to the total cost for implementing REACH allows us to calculate what proportion of total costs to occupational human health would have to be prevented for the benefits of REACH to at least balance the costs. Due to the assumptions and uncertainties discussed elsewhere in this section, we recognise that there are difficulties in adopting this approach. However, this is the best method we have been able to identify and we would welcome comments from stakeholders on alternative approaches.

⁹ For example, Protection of Workers Health and Safety from Chemical Agents at Work (98/24/EC) and the Protection of Workers from Occupational Exposure to Carcinogens (90/394/EEC as amended by 97/42/EC). Implemented in the UK by, for example, the Control of Substances Hazardous to Health Regulations (COSHH).

The limitations of the data and their potential interpretations have made it necessary to make a range of assumptions. We have therefore estimated the 'break even' point in several different ways providing a range for the percentage reduction required in occupational health costs (and one in terms of required reduction of the number of cancer deaths) for the benefits to at least match the estimated costs.

5.4.1 Costs per disease

Unfortunately, there is no single source of information available for occupational disease in the UK and it is the Health and Safety Executive's policy to use a range of sources in deriving estimates of the extent of work-related disease¹⁰. Table 10 provides statistics for a range of disease end points associated with exposure to chemicals. In theory, an estimate of the total external cost of occupational health due to chemical exposure could be calculated by multiplying cost per disease estimates for the number of occupational health diseases in the UK by unit values for each health end-point.

However, an important issue with the use of this data is that the categories (such as skin diseases and respiratory illnesses) include a wide range of diseases of varying severity and length of illness. For example, skin disease can include everything from dermatitis to skin cancer and it is clear that the cost implications to the individual and to society will be very different for these types of skin diseases. Therefore it becomes difficult to attach a cost value to the end point category as a whole, e.g. respiratory, skin etc¹¹. The only aggregate estimate available is the average social cost to Britain of work-related accidents and work related ill health, estimated between £11,315 and £11,725 per case¹² (2003 prices) – for each person in the working population with work-related illness. However this estimate is not felt to be appropriate for use in these calculations.

This has meant that the focus of the subsequent 'break even' analysis has concentrated on cancer fatalities where it has been possible to apply a value for a cancer death. The cost of a fatality is estimated at £1.229 million¹³ (2003 prices). This includes the WTP (willingness to pay), gross loss output, medical and ambulance costs. Following HSE guidance, for cancer deaths, double the value of the above prevented fatality figures will be used. This is to account for the so-called 'dread factor' society has for cancer deaths.

¹⁰ HSE considers the Self-reported Work-related Illness (SWI) surveys to provide the most inclusive estimates of the scale of occupational disease. A comparison of incidence rates between SWI and other sources, such as the DWP Industrial Injuries Scheme (IIS), and The Health and Occupation Reporting network (THOR), suggests that the latter sources tend to underestimate incidence for many diseases. Other sources include the Reporting of Injuries Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) and the Office for National Statistics which provides statistics on cancer registration and death.

¹¹ The current cost of an asthma case is estimated at £43,000 (2003 prices) and the case of dermatitis is £2,000 (2003 prices) but as explained it would not be appropriate to simply apply these values to all disease end points within these categories.

¹² Source: HSE, CHIP 99(2): Regulatory Impact Assessment (Post-Consultation), Health and Safety Executive, available from Her Majesty's Stationery Office, London, United Kingdom, 1999).

¹³ Source: HM Treasury Green book, as derived by the Department for Transport.

It is important to realise that the decision to omit other end points in fact over-estimates the required percentage reduction of occupational cancer deaths for the benefits to match the estimated costs of REACH. However, to the extent that cancer mortality makes a significant contribution to the total external costs of occupational health, these 'break even' calculations can still be useful in illustrative terms.

5.4.2 Assumptions and further issues

Even when limiting ourselves to occupational cancer deaths because of a lack of other reliable data, the data still inherently hold uncertainties. Asbestos related cancer deaths are excluded from the data. The potential reduction of asbestos related cancer would not be as a result of REACH. In addition, it is uncertain what proportion of the non-asbestos related cancer deaths REACH could have an impact on.

Even excluding asbestos related cancer deaths, the current data on occupational cancer deaths still partly reflects the risks from chemicals exposure in the past rather than the current position. Hence, the current data on occupational cancer deaths may not provide a good indication of the 'maximum' benefits that REACH could act on. This needs to be taken account of in sensitivity analysis by looking at how the 'break even' estimates change if the baseline for non-asbestos related cancer deaths is reduced.

Costs of REACH are expected to be incurred over a 11 year period; however, benefits are expected to be on going. Comparison of 'break even' calculations on an annual basis can thus be misleading. On this factor, the annual 'break even' calculations would seem to be an over-estimate as benefits occurring after the eleventh year (when cost cease to be taken into account) are in fact ignored for the 'break even' calculations.

However, other factors may tend to raise the 'break even' estimates. For reductions in occupational cancer deaths, there is a very long latency period; any benefits of REACH in prevention of cancer deaths might not be realised for at least 10 years (and potentially much longer) due to the latency associated with the disease (for instance, all solid tumours are likely to have a latency period of between 15 – 30 years). The annual 'break even' calculations imply the benefits would be immediate rather than future benefits. However, the present value of benefits a long way in the future would be lower because of discounting; hence annual 'break even' calculations would be an under estimate.

The yearly costs estimated in this partial RIA consider only the test costs. For REACH to have an impact, additional down-stream costs will be incurred in terms of the behavioural response by industry or Governments. The costs could thus be considered an under-estimate of the total costs so that the 'break even' calculation would also be an under-estimate. In addition, the cost estimates themselves are subject to uncertainties and assumptions.

5.4.3 Standard range estimations

In this base approach we compare the annual estimated costs to the annual estimated benefits to derive a required percentage reduction of occupational cancer deaths. We have used an uncertainty range for the number of cancer deaths, resulting in a required percentage reduction of (non-asbestos) occupational cancer deaths ranging from 0.4 percent to 1.5 percent. The uncertainty range is derived from the information in Table 10 and is based on the uncertainty in the numbers of non-occupational cancer deaths per annum. There are, of course, other areas of uncertainty which will affect the calculations (for instance the uncertainty in the estimates of the costs of REACH and the costs of cancer deaths). Some sensitivity analysis is presented to illustrate the possible uncertainties associated with this calculation although this analysis is not intended to be exhaustive.

Table 9 Base range of required 'break even' percentage reduction

	Low	Medium	High
Number of occupational non-asbestos cancer deaths per annum ¹⁴	1,250	2,500	5,000
Value of a cancer death	£2.457 million	£2.457 million	£2.457 million
Total value of occupational non-asbestos cancer deaths p.a.	£3.0 billion	£6.1 billion	£ 12.3 billion
Estimated annual cost of REACH	£45 million	£45 million	£45 million
Estimated required 'break even' percentage reduction	1.5%	0.7%	0.4%

Source: ERM calculations

¹⁴ See Table 10

Table 10 Annual incidence of occupational diseases in Great Britain associated with exposure to chemicals

Disease	SWI ⁽²⁾ – Annual incidence ⁽³⁾ (95 percent confidence interval)	THOR ⁽⁴⁾ (95 percent confidence interval)	RIDDOR ⁽⁵⁾	IIS ⁽⁶⁾	Deaths
Skin	14,000 (9,000 to 19,000)	3145 (excl. skin cancer & infective skin disease)	301 (Dermatitis)	168 (Dermatitis)	
Respiratory	36,000 (27,000 to 34,000)	1971 (allergic alveolitis, asthma, bronchitis, emphysema, benign pleural disease, pneumoconiosis)	80 (pneumoconiosis, byssinosis, asbestosis, alveolitis, asthma)	2828 (all respiratory excluding mesothelioma and lung cancer)	315 (underlying cause of pneumoconiosis, asbestosis, byssinosis, or allergic alveolitis)
Cancer ⁽⁷⁾	Not Available	0	13	28	2,500 ⁽⁸⁾ (Uncertainty range 1,250, 5,000)
Accidental injury due to hazardous substance	Not Available	126	1600	Not Available	
Poisoning	Not Available	Not Available	2	13	

Source: HSE, 2003.

1. SWI prevalence and incidence estimates for 2001/02; THOR/IIS estimated incidence in 2002; RIDDOR reports during 2001/02; Deaths in 2001 - all figures were provided by HSE.
4. SWI = Self-reported Work-related Ill Health survey.
5. Incidence is used here to mean number of new cases a year.
6. THOR = The Health and Occupational Reporting Network.
7. RIDDOR = Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985
8. ISS = Industrial Injuries Scheme.
9. Note that this excludes asbestos related cancer. The potential reduction of asbestos related cancer would not be a result of REACH.
10. Estimate derived by subtracting the estimated number of asbestos related cancers from Doll and Peto's attributable fraction estimate of cancers (considered individual cancer types and the likely proportion of each due to occupation). Including asbestos cancers the uncertainty range was 3000/6000/12,000. From the base-point of 6,000 we have subtracted the estimated asbestos related cancers, which were 3,500. The mid-point is thus 2,500. We then used proportionate reductions in both the lower and higher parts of the range to estimate the 1,250/2,500/5,000 range

5.4.4 Sensitivities

We discussed in the previous section how the current data on occupational cancer deaths may not provide a good indication of the ‘maximum’ benefits that REACH could act on and that this needs to be taken account of in sensitivity analysis.

The sensitivity analysis that follows looks at this by considering the effect on the ‘break even’ estimates if the current data on cancer deaths (excluding asbestos) over-estimated the baseline that REACH could have an impact by 20 percent, 50 percent or 80 percent. This sensitivity results in a wide range of the required ‘break even’ percentage reduction in occupational cancer costs between 0.5 percent and 7.3 percent.

Table 11 Required ‘break even’ percentage reductions with sensitivity for different assumptions on cancer deaths baseline

	Low	Medium	High
Value of a cancer death	£2.46 million	£2.46 million	£2.46 million
Estimated annual cost of REACH	£45 million	£45 million	£45 million
Number of cancer deaths pa – 20%	1,000	2,000	4,000
Total value of occupational non-asbestos cancer deaths p.a.	£2.5 billion	£4.9 billion	£9.8 billion
Estimated required ‘break even’ percentage reduction	1.8%	0.9%	0.5%
Number of cancer deaths pa – 50%	625	1,250	2,500
Total value of occupational non-asbestos cancer deaths p.a.	£1.5 billion	£3.1 billion	£ 6.1 billion
Estimated required ‘break even’ percentage reduction	2.9%	1.5%	0.7%
Number of cancer deaths pa – 80%	250	500	1,000
Total value of occupational non-asbestos cancer deaths p.a.	£0.6 billion	£1.2 billion	£ 2.4 billion
Estimated required ‘break even’ percentage reduction	7.3%	3.7%	1.8%

Source: ERM calculations

For any of the above calculations, if a lower value were put on a cancer death (e.g. such as not doubling the value for a fatality to take into account the ‘dread factor’), then all of the ‘break even’ calculations would be effectively doubled.

As there is some concern about the different time horizons for costs and benefits and the latency effects for occupational cancer, an additional sensitivity to apply an NPV (net present value) approach to the ‘break even’ analysis has been explored. The ‘break even’ calculations were made in NPV terms and costs and benefits were discounted over a 30-year time horizon. This resulted in lower ‘break even’ points, confirming that the annual calculation is, on this factor, an overestimate. However, accounting for the potential latency effects with cancer (for example using a 20-year latency

period) can offset this effect and can raise the breakeven point back to the range found using annual costs and benefits. Hence these two effects can be seen as offsetting to some extent, although will of course depend on different assumptions made in terms of the time period and latency.

5.4.5 'Break even' reduction in number of occupational cancer deaths

An alternative method to the estimation of percentage reductions is to consider what reduction in the number of occupational cancer deaths would be required for the benefits to at least match the costs.

Using this methodology – which simply divides the annual costs by the valuation for a cancer death to derive the number of cancer deaths that would need to be reduced annually for REACH to 'break even' – 18 cancer deaths would have to be reduced a year (based on a cancer death valuation of £2.46 million). As a sensitivity, 37 cancer deaths would have to be reduced a year, based on a cancer death valuation of £1.228 million (without the societal 'dread factor'). Clearly, this only covers one parameter (the cancer death valuation which itself is subject to uncertainty) and therefore is not intended to represent a full examination of all the factors leading to uncertainty.

This seemingly much simpler approach is however fraught to the same uncertainties as the percentage estimations including problems of latency, under-estimation of costs, omission of other benefits etc. It is, therefore, an indicative figure which must be considered along with these uncertainties.

5.5 Concluding remarks on the benefit estimation

There is considerable uncertainty involved in estimating the benefits of REACH. As an illustration, this section has provided estimates for the required reduction in the external costs associated with occupational cancer for REACH to 'break even'. Asbestos related cancer deaths were not included. The reduction of asbestos related cancer would not be as a result of REACH.

Using an uncertainty range for the number of cancer deaths, we found a required percentage reduction of (non-asbestos) occupational cancer deaths ranging from 0.4 percent to 1.5 percent in order to compensate for the direct costs of REACH. However, current data on occupational cancer deaths (excluding asbestos) is still partly a reflection of past rather than current exposure and it is possible that as a result of tightening controls in UK and EU legislation that the baseline for cancer deaths related to current exposure (and hence what REACH would work on) is considerably lower. This was investigated through different assumptions of percentage reductions in cancer deaths, up to a reduction of 80%. For example, assuming the baseline for cancer deaths was better represented by a 80% reduction on the current data would increase the 'break even' range to between 1.8 to 7.3 per cent¹⁵. It

¹⁵ While this analysis made use of HSE guidance on the value for a cancer fatality, for any of the above calculations, if a lower value were put on a cancer death (such as not doubling the value for a fatality to account for the 'dread factor'), then all of the break even calculations would be effectively doubled.

must be noted that, even though some sensitivity analysis was applied, this does not cover all possible uncertainties.

All of these 'break even' calculations have been presented in terms of annual costs and benefits. However, the annual calculations do not take account of the fact that costs will be spread over a limited period (e.g. 11 years) but potential benefits would be on-going; this would reduce the 'break even' estimates. In contrast, taking account of latency – benefits in terms of reductions in cancer deaths would not arise until perhaps well into the future – would raise the required 'break even' rate. Initial analysis shows these two effects are offsetting, although this will of course depend on different assumptions made in terms of the time period and latency.

The analyses above presents just some of the sensitivities and it is important to recognize this point. For example, no sensitivity analysis is presented in terms of the costs of REACH. The uncertainty ranges, where presented, are not intended to cover all uncertainties.

A final point with respect to the 'break even' calculations is that these figures should be seen as over-estimates, because it is accepted that, although not valued, there will also be benefits to society in terms of environmental benefits, benefits to industry, non-occupational health benefits, and occupational illnesses besides cancer deaths.

Q. RIA 2 We would welcome views on approaches for considering REACH benefits including the method used in this RIA.

6. Issues of equity and fairness

Option 1 will result in downstream users, consumers and the general public – as well as manufacturers and importers – having limited access to information on the majority of chemicals currently supplied in the UK and EU thereby restricting their ability to make informed choices regarding the chemicals they use. In addition, protection of human health and the environment could be jeopardised by the lack of basic information on chemicals.

Option 2 – where each manufacturer and importer has to prepare a separate registration package – may result in an unnecessary burden on industry if data- and cost-sharing is not maximised. This potential extra cost may be passed down the supply chain. In addition, the proposal may affect the coherency of the information provided to downstream users, consumers and the general public thereby impacting on their ability to make informed decisions on chemical usage. The proposal may also result in an unnecessary burden on the regulatory authorities.

Having "one substance, one registration" (as under Option 3) will ensure maximum cost- and data-sharing by using all available information and spreading the costs of information gathering and registration across the

members of the consortia. This should not result in an additional, unnecessary burden on industry. In addition, the burden on the regulatory authorities should be minimised by ensuring that no duplicate registration packages for the same substance are submitted.

In general, the proposal will have an indirect impact on downstream users of chemicals. In some cases the cost of chemicals may increase which could result in the cost being passed down the supply chain and ultimately on to the consumer. It could also result in substances being withdrawn from the market. If a manufacturer withdraws a chemical from the market, the downstream user may have to source an alternative which could involve a costly process of reformulation.

We intend to commission further work to explore the indirect costs of REACH on downstream users.

Q. RIA 3 We welcome comments on how best to target further work to estimate the indirect costs of REACH.

7. Small firms impact test

Two case studies are presented to illustrate the potential impact of the legislation on small businesses (case studies 1 and 2). In addition, five other case studies are presented which cover other sectors where REACH may have an impact.

These case studies reflect the views of the businesses contacted and were not peer-reviewed. They are designed to be illustrative of possible problems rather than representative of all outcomes. In addition, there is a possibility that these case studies were based on previous drafts of the REACH proposal and not the one adopted by the Commission on 29 October 2003.

In order to protect information that could potentially be commercially sensitive, the case studies have been presented in a way that protects their anonymity.

7.1 Case study 1 – small producer of speciality chemicals

The first case study relates to a speciality chemical produced by a small producer in the UK. Most of the product is used as a process ingredient in a key automotive product. The product is beneficial because it reduces the level of energy required to produce the product to the required high standards. The company understands that there is only one other supplier of the product in the EU – one of the leading European chemicals firms with a multi-billion pound turnover. However, this manufacturer produces the chemical in the USA and imports it into the EU.

Total production and importation into the EU is about 630 tonnes per annum, and the market is evenly split between the two suppliers. It is not anticipated that the product would require authorisation. The total value of the EU market is about £3.25 million.

The UK producer estimates that registration and evaluation costs amount to approximately £300 to 350k. This is ten percent of one year's value of sales. However, the manufacturer also expects the costs of raw materials to rise by five to ten percent because of REACH requirements on these substances. There is a real concern that the increased costs will lead customers to choose high-energy techniques instead of the chemical process. If this were the case, the 25 jobs related to production of the chemical would be lost.

More broadly, the manufacturer believes there is a more important potential consequence. The product is one of 10 – 12 different process chemicals used to make the end product. The cumulative effect of price increases in all of these chemicals may well be to encourage the multinational manufacturers to relocate their production outside of the EU, where these cost increases will not be felt. If this occurs, many industrial jobs will be lost in the EU, with production being shifted to locations that will almost certainly have lower environment and health standards than existing EU factories.

Finally, the producer believes that similar arguments can be made for many of its other products. However, in addition, some of their small volume, niche speciality products rely on raw materials that are themselves produced in only small quantities. So, these products will, effectively, take an unsustainable "double hit" in terms of cost increases and will lose their markets. Also, some of the company's products are competing against other products (chemically different, but with similar performance characteristics) that are manufactured in large volumes by multinationals. Thus the effect on costs will be wholly disproportionate.

7.2 Case study 2 – small producer of speciality chemicals

The second case study also relates to a manufacturer of speciality chemicals. The producer manufactures pigments and dyes, and provided details for one of its products, which illustrates the problems it believes will be caused by REACH. The company is one of two main producers in Europe, although it is aware that there may be some other production within the EU and also imports from non-EU countries.

About 250 tonnes of the product is used in the EU per annum and the company has a 20 percent market share. A large proportion of EU production is also exported. It is not anticipated that the product would require authorisation. The value of the EU market is estimated at about £1.25 million per annum (£5,000 per tonne), with a similar value being sold outside the EU. The company's output is worth about £500,000, about half of which is exported.

The company reports several major concerns with REACH:

- Firstly, it believes the larger producer may refuse to share test data and the costs of providing new data. This would mean that it could not produce the product at a competitive price.
- Secondly, whilst the company supplies to a range of downstream users, the issues raised by this product are very typical of the 12 others that it makes, and hence the overall effect of REACH could be disastrous for the firm.
- Thirdly, many of the company's customers demand rapid product development in response to changing demand. The requirements of REACH may lengthen its product development cycle to such an extent that it would not be able to compete with non-EU suppliers. This would also have an implication for downstream users within the UK that make use of the firm's products, which could push production offshore (particularly amongst textiles sector customers).

Overall, the managing director of the company believes that it would have to close, with the loss of about 35 jobs in the UK and 20 elsewhere in the EU.

7.3 Case study 3 – large producer of a bulk chemical

The bulk chemical in question is a high production volume substance with extensive and varied use pattern extending to industrial uses as an intermediate, and as a component of professional and consumer products.

In 2000 estimated world production was 500,000 tonnes, and in the EU output is estimated at 227,000 tonnes per annum, about 28,000 of which was produced in the UK.

The substance already has considerable information available, and is considered to be low hazard. There is a European industry consortium that would be able to share any testing requirements, and the financial cost is not expected to be great. However, given the multiple uses the administrative burden is expected to be significant.

The overall view of the producer is that whilst REACH will not jeopardise production, the administrative burden will be very large, which is not justified by the extensive information that is already held on this substance.

7.4 Case study 4 – paper mill (downstream user)

The Paper Federation of Great Britain has produced estimated costs for a typical UK paper mill. Paper mills consume a large number of chemicals. Key elements of the Paper Federation's work include:

- an assumption that about 20 percent of chemicals that they currently use will be withdrawn, and that investments will need to be made to find substitutes;
- that considerable additional administrative, scientific and IT staff will be required to manage the information burden; and
- the costs of chemicals purchased will rise.

Overall, the Federation forecasts an average cost per paper mill over a five year period of £3.372 million, which is equivalent to 1.6 percent of the turnover of a typical paper mill. In reality, some of these costs will be incurred over an eleven year period because of the phase-in dates proposed for REACH. However, even on this basis a typical mill would be experiencing costs of about one percent of turnover. Whilst one percent may seem small, paper manufacture is a capital intensive, relatively low margin business – at present UK mill profitability is estimated at two to ten percent of turnover, meaning that REACH costs could equal 10 to 50 percent of profits.

Clearly, all other European producers will face similar cost pressures, and hence there will be scope for passing on some of this increase to customers. However, there are numerous paper producers that, by producing outside the EU, will not be subject REACH. Therefore, there will clearly be adverse financial implications that financially weaker paper mills will find difficult to bear.

7.5 Case study 5 – car producer (downstream user)

This case study relates to one of the UK's major car producers. The company's operations and UK supply chain encompass a wide range of activities associated with vehicle manufacture. The company has a UK turnover in excess of £1 billion and directly employs many thousands of workers. The great majority of its output in the UK is exported.

The company reports that at present estimating its REACH costs is extremely difficult because of the complexity of chemicals use within the automotive industry (including the extended supply chain). A key area of uncertainty relates to substances in articles.

Direct chemicals purchasing represents about 0.8 percent of the company's turnover in the UK and 1.1 percent of all procurement, which itself accounts for 70 to 80 percent of turnover.

The company is assuming a maximal withdrawal of about 10 to 15 percent of chemicals that it currently uses, and it is this that is anticipated to cause the greatest difficulties. The recent experience of complying with a number of European Directives has convinced the company that these withdrawals will be problematic.

The company stresses that although substitutes are often available, the process of introducing them into capital-intensive products that are heavily

regulated due to environmental, safety and other factors is complex and resource intensive. Also, many components are inter-dependent, and a change to one component thus often requires changes to other components.

If new processes or techniques need to be introduced to products before the end of their natural cycle, this has a major effect on profitability, because of the considerable up-front investment costs associated with even relatively minor product revisions.

In addition to the costs and technical difficulties of changes brought about by REACH, the company has major concerns that the timescales may be inadequate to deal with the withdrawal of some substances. Under REACH, the company estimates that for a typical substance subject to restriction, it would have about 33 months to cease use, and re-engineer in alternatives. Key problems relate to:

- the need to cascade awareness of the proposed restriction through the supply chain, and in particular to SMEs;
- the time required to identify all uses of the substance;
- the time needed for investment and research into substitute substances or processes; and
- the limited time (three months) it will have to comment on Commission proposals for future restrictions.

As an indication of how complex this process could be, the average vehicle is comprised of up to 10,000 substances, and the producer estimates that about 15 percent will be classified as hazardous though beyond this, the majority of (non-polymer) substances would be impacted in some way under REACH.

The company agrees with impact assessments made by the Commission and other organisations that the single greatest economic impact for downstream users will be the aggregate indirect costs. These will arise due to cascaded registration and testing costs from suppliers; substance loss due to economic withdrawal or regulatory withdrawal; re-engineering of products; increased more complex material tracking etc.

Finally, the company has grave concerns about its continued international competitiveness:

- It is believed that non-EU competitors will gain a cost and technology advantage, because: (a) they will not be affected by increases in the cost of substances due to the costs of REACH Registration – both in terms of sourced product materials, and also for manufacturing support materials not incorporated into product; (b) these competitors will potentially have access to substances no longer registered in the EU which could provide greater product innovation and economic opportunities. As a result, and particularly in the case of article purchasing, this is expected to force the company into increased sourcing of finished articles from outside the EU.

- The risks from certain higher hazard substances can be adequately controlled within some applications, e.g. their non-dispersive use in articles. However, for EU producers it is probable that numerous substances within the scope of REACH Authorisation will be adversely impacted in applications relevant to their use in articles. There will be a contrasting situation for non-EU producers/importers of articles, whereby even potentially high risk CMR's, ecotoxicants, and substances of equivalent concern, will be subject to minimal control provided their use in imported articles is not dispersive (via intentional or incidental release).

Overall, the company is convinced that the current proposal will have a marked impact on the company's UK (and European) cost base, that the administrative burden will be great, and that it may not actually have time to comply with any restrictions without entailing excessive cost. It therefore believes that it will be at a significant disadvantage in terms of cost and ability to innovate when compared with non-EU competitors, and that to help compensate for this it will have to increase non-EU sourcing.

7.6 Case study 6 – automotive component manufacturers (downstream user)

This case study, provided by the Society of Motor Manufacturers and Traders (SMMT), relates to a consortium of automotive component manufacturers. Seven companies, all of whom are members of the EDIT (Eco Design Interactive Tools) network, estimated costs arising out of REACH arising from:

- staff time;
- training;
- new IT systems and licenses; and
- associated overheads.

However, process re-engineering costs were not included. The conclusion of a working group of all seven companies was that REACH would have a cost equivalent to 0.2 percent of annual sales for the period of its implementation. Because this excludes any re-engineering costs, it is likely that this will prove to be an underestimate.

7.7 Case study 7 – car producer (downstream user)

This case study relates to a foreign volume car producer with a well-established manufacturing presence in the UK. An internal review of the implications of REACH has found:

- initial investments related to meeting REACH costs will be € 12 million;
- on-going costs relating to substitution of chemicals will be equal to £46 per vehicle produced; and

- the costs of vehicles to customers will need to rise modestly over and above what they would otherwise be, and this would be expected to have a modest impact on export success and, potentially, long-term investment plans.

One area of particular uncertainty that the manufacturer wasn't able to quantify related to the costs of REACH to the company's suppliers, and the knock-on effect that it could have on the company itself.

Q. RIA 4 We welcome further case-studies from stakeholders highlighting the potential impacts – both negative and positive – of REACH.

8. Competition assessment

8.1 Introduction

The competition assessment reflects the early stage at which the RIA currently is. It is anticipated that information from stakeholders will inform later drafts. The case studies (discussed in the previous section) provide some illustrative examples of the impact REACH will have on different chemical markets. We have drawn from these illustrative examples to try and stimulate debate of the impact REACH may have on competition and they are not necessarily typical of every market.

The REACH proposal will impact on a wide variety of markets within the chemicals industry. We recognise therefore that a consideration of the potential impacts on competition should take into account the implications for different types of chemical manufacturer, upstream producers of raw materials and downstream customers. We also acknowledge that the extent of any impact will also vary according to the characteristics of each market (e.g. degree of concentration, technology in use, geographic market).

The competition filter test has been employed to consider the scale of the impact of the REACH proposal on competition. In undertaking the test, we have sought to broadly:

- define and describe the UK chemicals industry and its market structure (questions 1, 2 and 3);
- to discuss differential effects by type and size of company, and whether there are likely to be structural impacts on the market (questions 4 and 5);
- assess whether the regulation is likely to create barriers to entry (questions 6 and 7); and
- consider impacts on innovation and product availability (questions 8 and 9).

Since the proposal will impact on a wide variety of markets, it is not possible to apply the competition filter test to all of these. The competition filter has therefore initially been applied to three broad sub-sectors. Given the complexity and diversity of the industry, the assessment is at an inevitably fairly high level and further analysis will be needed as awareness of the potential impact of the proposal increases.

These three sub-sectors are derived from the classifications used by the Chemicals IGT and comprise of:

- bulk/commodity (those sold to specification and price);
- speciality chemicals (those sold on performance); and
- consumer products (performance products sold on the basis of brand).

Table 12 Competition assessment summary

Question	Sub Sectors		
	Commodity	Speciality	Consumer
Q1: In the market(s) affected by the new regulations, does any firm have more than 10% market share? ⁽¹⁾	Most markets	Some markets	Some markets
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share? ⁽¹⁾	Some markets	Few markets	Few markets
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share? ⁽¹⁾	Some Markets	Some markets	Some markets
Q4: Would the costs of the regulation affect some firms substantially more than others?	No	Yes	Yes
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No	Yes	No
Q6: Would the regulation lead to higher set-up costs for new or potential firms that existing firms do not have to meet?	No	No	No
Q7: Would the regulation lead to higher ongoing costs for new or potential firms that existing firms do not have to meet?	No	No	No
Q8: Is the sector characterised by rapid technological change?	No	Yes	Yes
Q9: Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products?	No	To a small extent	To a small extent

(1) Answers relate to product markets within sub sectors

8.2 Market structure

If one considers the more general level of the sub-sectors identified, it is unlikely that one company has more than a ten percent market share or any three companies have more than 50 percent. However, if the industry is assessed at the product level, market shares are often highly concentrated.

8.2.1 Commodity chemicals sub-sector

Commodity chemicals can be specified entirely by their chemical composition: apart from possible differences in purity, products supplied by different manufacturers are interchangeable¹⁶. The commodity chemicals sub-sector is dominated by a small number of companies that operate on a global scale, seeking the least cost location for production. Location choice is in part restricted by transport costs. However, the need to produce large volumes, often on low profit margins, means that there are only a small number of manufacturers supplying particular chemicals in any given national market.

An illustrative example of the impact REACH may have on a commodity chemical producer is provided in case study 3.

8.2.2 Speciality chemicals sub-sector

Speciality chemicals have very different market structures to those in the bulk or commodity sub-sector. Speciality chemicals are higher value added chemicals sold on the basis of the product's capacity to fulfil a specific function in use. Manufacturers seek to differentiate their products buyers are looking for specific "effect". Speciality chemicals are often designed for a particular customer's application, on a fast running production line. They are characterised by lower volumes, higher unit values, proprietary formulations and often a high service content. A large number of chemicals are produced in batches or made to order, some of which are often close substitutes for each other. Market shares are, therefore, largely dependent on how markets are defined. A narrow definition based on chemical formulae would result in most product markets being highly concentrated. However, a more meaningful definition of markets is to consider the function that a speciality chemical performs. On this basis some markets will have firms with shares greater than 10 percent and 20 percent, and some firms will quite often have market shares in excess of 50 percent.

Two illustrative examples of the impact REACH may have on specialist chemical producers are provided in case studies 1 and 2.

¹⁶ Report by the Chemicals Innovation and Growth Team, pages 77-78 "Enhancing the Competitiveness of the UK Chemicals Industry, "Background on chemical industry and standard industrial classification" Annex 2, December 2002. Available at: <http://www.dti.gov.uk/cigt/pdf/annex2.pdf>

8.2.3 Consumer chemicals

Consumer products are higher value added chemicals sold on the basis of brand image. Examples include personal care items, decorative paint and photographic goods. Sales and marketing skills are as important as manufacturing; sellers use advertising and branding to differentiate their products and maintain margins. Consumer chemicals by definition have a much larger customer base, and hence the market share of any particular company or group of companies is unlikely to exceed the thresholds set out in the competition assessment. There are exceptions to this general rule of which detergents would be a good example. Consumer chemical markets are also subject to greater change as brand and marketing play a more significant role in competition between companies.

8.2.4 Upstream producers of chemicals/raw materials

It is recognised that the REACH proposal may have implications for upstream suppliers of chemicals and/or raw materials. As in the case of the manufacture of chemicals under the three sub-sectors identified, it is expected that there may be significant variation in the structure of the markets and intensity of competition according to the chemical and material concerned.

8.2.5 Downstream

It is anticipated that the REACH proposal will similarly have implications for downstream users – for example, if manufacturers of chemicals withdraw production lines, switch supply to alternatives or pass on test costs. The downstream sector consists of a variety of businesses and the characteristics of these markets will vary.

Two illustrative examples of the impact REACH may have on downstream users are provided in case studies 4 and 5.

8.3 Test costs in the UK – high-level estimates

It is not possible to accurately allocate the proportion of European test costs that will be incurred by UK industry. However, in this RIA, we have assumed a value of 21.5 per cent. This gives a range of between approximately £265 million and £1,000 million with a central estimate of £515 million direct costs to UK industry over 11 years (based on 85% consortia uptake, Table 3).

Allocation on a sub-sector basis in line with value of sales (from the IGT report) would suggest the following estimates:

- commodity – approximately £245 million out of a turnover of about £12.5 billion;
- speciality – approximately £125 million out of a turnover of about £6.2 billion; and

- consumer – approximately £145 million out of a turnover of about £7.3 billion.

However, this is likely to grossly underestimate the impacts on speciality chemicals, because of the much greater number of chemicals that are produced by the sector. Actual experience in the US is that speciality chemical producers manufacturing products under the US HPVC programme face costs of five to ten times of those faced by bulk chemical producers for each chemical produced. This is partly because speciality chemicals are much less likely to benefit from the use of consortia, and partly because of the relative lack of existing data. We have been unable to identify data that would help allocate test costs by sector on a more robust basis, but if speciality chemicals were responsible for 50 percent of costs, consumer 40 percent and bulk just ten percent, then sectoral allocations would be:

- commodity – approximately £50 million;
- speciality – approximately £260 million; and
- consumer – approximately £205 million.

This level of cost would have a major impact on the speciality sector's ability to compete with non-EU competitors, generate profits and raise funds for investment, research and development.

8.4 Test costs in the UK – product level estimates

At a product market level, it is difficult to predict with any great accuracy, the scale of the likely costs (or benefits) arising from REACH.

The case studies presented in the previous section provide some illustrative examples of the impact REACH may have on different chemical markets. We have drawn from these illustrative examples to try and stimulate debate of the impact REACH may have on competition and they are not necessarily typical of every market.

8.4.1 Commodity

In the case of the high volume substance with extensive and varied use patterns, the existence of a European industry consortium would be expected to reduce the scale of testing costs. However, a multiple risk assessment for each use will be likely to be required. Whilst the businesses in this market will face potentially high costs these are not expected to be of sufficient size to have implications for competition in either resulting in a significant number of businesses exiting the market or creating significant additional barriers to entry.

Q. RIA 5 We would welcome views from stakeholders on whether such an impact would be likely to be typical for this sub-sector.

8.4.2 Speciality

In case study 1, concerning a process ingredient in a key automotive product, the view from that stakeholder was that registration and evaluation costs are estimated to be equal to 10% of its value of sales which if spread over 5 years amounted to 2% of annual costs. It was suggested that the costs implications are greater when the potential resultant rise in raw material costs are taken into account.

In case study 2, concerning a dye/pigment, the stakeholder anticipates that the larger producers in the market will not share test data. Whilst the refusal to share test data is not anticipated to arise in many cases, it is recognised that this might be a difficulty particularly in markets where there are few players and where the refusal might be a strategic measure adopted to increase costs of competitors.

Q. RIA 6 We would welcome views from stakeholders on whether such impacts would be likely to be typical for this sub-sector.

8.4.3 Consumer

Q. RIA 7 We do not have an illustrative case study from the consumer chemicals sub-sector and therefore welcome views from stakeholders on what the impacts would be for this sub-sector.

8.4.4 Upstream

In case study 1, concerning a speciality small producer of speciality chemicals, it was suggested that some of their smaller volume, niche speciality products which rely on raw materials themselves produced in only small quantities might take a double 'hit' in terms of unsustainable costs increases and thereby lose their markets. At this stage, it is unclear whether this would be likely to occur and if so, the extent to which this might be a problem prevalent in other markets.

Q. RIA 8 We would welcome views from stakeholders on whether such an impact would be likely to be typical for this sub-sector.

8.4.5 Downstream

In case study 4, concerning a paper mill, it was indicated that the Paper Federation anticipated that about 20 per cent of chemicals they currently use will be withdrawn and that investments will be needed to find substitutes. They also anticipate that the costs of chemicals purchased will rise and that additional staff will be required for handling the additional information burden. The federation anticipated that these would amount to an average cost per paper mill over a 5 year period of around 1 per cent of annual turnover, allowing for the phase-in dates proposed. Given the low profit margin, where

at present UK mill profitability is estimated at two to ten percent of turnover, this could equal 10 to 50% of profits.

In cases study 5, it was suggested that direct chemicals purchasing represents about 0.8 percent of the company turnover in the UK and 1.1 percent of all procurement, which itself accounts for 70 to 80 percent of turnover. The business was assuming a maximal withdrawal of about 10-15 percent of chemicals that it currently uses. It suggested that although substitutes are often available, the process of introducing them into capital-intensive products that are heavily regulated due to environmental, safety and other factors is complex and resource intensive. It also stressed the interdependency of many components, that innovations are often cascaded through the product range.

Q. RIA 9 We would welcome views from stakeholders on whether such impacts would be likely to be typical for this sub-sector.

8.5 Structural impacts

The distribution of costs and impact on market structures will vary by sub-sector.

8.5.1 Commodity

In the commodity chemicals sector, costs will be shared amongst a small number of large firms. Whilst these costs will be small relative to total sales, the sub-sector operates on tight margins. However, the level of costs is unlikely to have a significant impact on market structure, particularly as the majority of test data required by REACH already exist for most of these substances (for example because of the US High Production Volume Challenge and ICCA test programmes).

For chemicals for which test data are not available and consortia are not formed (either because there is only one business in the market or where businesses are not willing to enter into consortia with one another), then the impact on individual companies could well be significant given the low margins and high test costs. If this led to the withdrawal of particular chemicals or to an increase in market concentration then this might have implications for competition.

At this stage, we believe that this is likely to be the exception rather than the rule: however, we are keen to identify any product markets where a greater affect might be anticipated, in order to undertake further analysis.

Q. RIA 10 To this end, we would be particularly grateful for views from stakeholders on this aspect.

8.5.2 Speciality

Speciality chemicals are produced by firms that vary enormously in terms of size and product range. Hence the impact of test costs will be unevenly distributed in both absolute and proportionate terms. The sector is characterised by small variations to achieve performance advantages for customers and often very little test data exist other than for basic properties.

In most markets test costs will be relatively small and hence impacts will be limited. However, for some products there are either very few or indeed only one supplier, and hence the opportunity to form consortia and spread test costs will not be available. In these sub-sectors companies may be forced to reduce output to come within lower thresholds, withdraw products or face test costs that are high in relation to the total value of the chemical being sold. This problem would be exacerbated if companies were required to undertake multiple risk assessments

It has been suggested (e.g. case study 1), that some firms may seek to locate outside the EU. Impacts have also been identified on small businesses which suggest that there may be some rationalisation of the number of companies.

Q. RIA 11 We would welcome comments from stakeholders on any of the points raised concerning this sub-sector.

8.5.3 Consumer

The consumer chemical sub-sector has some of the same characteristics as speciality chemicals in terms of market structure, and hence test costs will be unevenly distributed. The effect, however, is likely to be on product range rather than on the number and market share of companies, as consumer products companies are generally characterised by production of multiple products with common basic ingredients (for example shampoos and soaps). Whilst we do not anticipate a significant affect on competition arising from the REACH proposal for the consumer chemical sub-sector generally or individual product markets, we are keen to identify any potential exceptions where a greater affect might be experienced and assess the potential implications for competition.

Q. RIA 12 We would welcome input from stakeholders on this aspect.

8.5.4 Upstream

It is recognised that a more significant affect may arise for those businesses which produce raw materials for a sub-sector, such as that for speciality chemicals, where potentially some products may be withdrawn as a result. As such, it is difficult to identify any likely general affects.

Q. RIA 13 We are keen to receive views from stakeholders on how the REACH proposal might affect upstream producers.

8.5.5 Downstream

As with upstream producers, downstream manufacturers and customers may be significantly affected. For example, by the removal of a chemical used in a downstream process where no substitute or a costly substitute is needed, or if test costs generated upstream are passed to downstream users. The extent to which this might have implications for competition would be dependent on how vital a particular chemical is for a downstream process, the extent to which such an impact would be proportionate (disproportionate) on all businesses and whether it could create additional costs and thus act as a potential barrier to entry for new entrants.

Q. RIA 14 We would welcome views from stakeholders on this aspect.

8.6 Barriers to entry

There are already high barriers to entry in most parts of the industry due to high capital costs and REACH compliance costs will seldom constitute a significant item for new entrants. Moreover, the nature of the regulation is such that existing firms, rather than new or potential entrants, will incur most costs. Indeed, potentially for new chemicals produced in low volumes, REACH may lead to a significant lightening of the existing regulatory burden under the Notification Of New Substances regulation). In this sense, the new regulations may reduce barriers to entry rather than increase them, although the impact is unlikely to be significant.

Q. RIA 15 Against this we are uncertain as to the extent to which REACH compliance costs may create additional barriers to entry in specific product markets. We would welcome comments from stakeholders on the above.

8.7 Innovation and product availability

Structurally, the UK would be expected to spend above the international average given that speciality and consumer products form a proportionately larger part of the UK industry. Historically, the UK Chemicals industry has a long tradition of innovation. However, this has changed in recent years, with only incremental changes and research and development (R&D) spending below the international average. The recent DTI R&D scoreboard points to under-investment in R&D by the UK Chemicals industry, as did the sector's Innovation and Growth Team report. In 2001 the UK average R&D spend as just 2.2 percent of sales, against an international average of 4.2 percent of sales.

While R&D spending is only a proxy for innovation (because innovation covers much more than R&D), this under-investment has been a persistent finding over a number of years. There is a major challenge in raising the innovation ambitions of all UK chemicals companies. A major criticism within

industry is that the knowledge transfer schemes, which operate at national and regional levels, are both too many and too varied and consequently resources are spread too thinly. It is also perceived that there is a high administrative burden attached to such schemes. Overall this leads to confusion and limits impact. There is a pressing need for simplification and focus.

Within the context described above, it is recognised that the new testing regime will make what is already a major challenge for the UK chemicals industry in relation to innovation more difficult, and could limit future product availability in some sub-sectors.

For example, the stakeholder in case study 2 suggested that the requirements of REACH may lengthen its product development cycle to such an extent that it would not be able to compete with non-EU suppliers (a potential competition concern if a fall in competitiveness resulted in increases in concentration of product markets). Similarly, the downstream car producer in case study 5 anticipated difficulties where changes to products were required before the end of their natural cycle because of the considerable up-front investment costs associated with even relatively minor product revisions.

We also acknowledge that the desire to protect new developments and related concerns on confidentiality might deter some businesses from joining or forming consortia.

Against this, the impact is likely to be limited in relation to the scale of the existing challenges and pressures in the industry.

Q. RIA 16 We would welcome views from stakeholders on this aspect.

8.8 Concluding remarks on the competition assessment

The UK chemicals industry is large, diverse and already faces major challenges in competing in domestic and international markets. Whilst at an industry and sub-sector level markets are highly competitive, there are often only a few suppliers of any specific product. Test costs are unlikely to alter the structure in commodity chemicals sub-sectors, but could affect the number of companies producing speciality chemicals and the range of consumer chemical products. Barriers to entry are already a significant feature of the industry. The new regulations could favour new entrants as costs fall largely on existing producers. Finally, the regulations may have some negative effects on the rate innovation and pace of technological advances. However, the structure of the industry is such that innovation will remain a major factor in competition between firms. We intend to continue developing our analysis on the initial findings in this assessment.

9. Enforcement and sanctions

The European Commission proposes the creation of a European Chemicals Agency which will provide services to the REACH system. The Agency will manage the technical, scientific and administrative aspects of the system at Community level, aiming to ensure that it functions well, and ensures consistency in decision-making.

Member States shall each appoint a competent authority with the expertise and resources available to carry out the enforcement tasks assigned to it. It will be down to Member States to lay down provisions to deal with non-compliance. Penalties must be effective, proportionate and dissuasive. Fines should be set at a level which ensures it has a deterrent effect. Member states are required to submit a report to the Agency by 1 July each year on the results of checks, fines etc.

The appointment of a Competent Authority or Authorities in the UK is a practical issue relating to the introduction of REACH and will need further consideration. The Government intends to carry out further work to assess the practical implications of REACH to the UK authorities and this will be the subject of a separate consultation exercise planned later.

10. Monitoring and review

The Commission proposes that every ten years (the first report will be ready within five years of entry into force of the legislation) Member States and the Agency will submit a report to the Commission on the operation of the Regulation.

11. Summary and recommendations

This partial RIA has estimated direct costs from REACH to the UK chemical industry of approximately £515 million over the eleven-year phase-in period (£2.4 bn for the EU). This equates to approximately £45 million per annum for the UK. This estimate should be viewed as indicative, and it is important to note that some uncertainty will inevitably remain about final out-turn costs until well beyond the implementation of REACH. In addition, estimates of the direct costs of REACH vary primarily because of uncertainties about how much data industry holds, whether it is recent and of acceptable quality, the scope for flexibility in testing requirements depending, for example, on exposure and the extent to which alternatives to testing such as computer modelling techniques can be used. The estimates presented in the partial RIA are, therefore, subject to these uncertainties and, although a range of potential costs is presented, this is not intended to represent the full extent of the uncertainty.

The cost estimation has focused initially on the direct costs to industry of implementing REACH. The Government recognises that the indirect costs

passed down through the supply chain to downstream users are more difficult to assess but may be significant. A further study is expected to be undertaken to assess the impact of REACH at each stage of the supply chain in order to estimate the indirect costs and effects on downstream users.

There is considerable uncertainty involved in estimating the benefits of REACH. We have described the significant difficulties in attempting to derive environmental or public health benefits. However, as an illustration, we have provided estimates for the required reduction in the external costs associated with occupational cancer for REACH to 'break even'. Asbestos related cancer deaths were not included since these deaths relate to past rather than current exposure and hence REACH would have no effect.

Using an uncertainty range for the number of cancer deaths, we found a required percentage reduction of (non-asbestos) occupational cancer deaths ranging from 0.4 percent to 1.5 percent in order to compensate for the direct costs of REACH. However, current data on occupational cancer deaths (excluding asbestos) is still partly a reflection of past rather than current exposure and it is possible that as a result of tightening controls in UK and EU legislation that the baseline for cancer deaths related to current exposure (and hence what REACH would work on) is considerably lower. This was investigated through different assumptions of percentage reductions in cancer deaths, up to a reduction of 80%. For example, assuming the baseline for cancer deaths was better represented by a 80% reduction on the current data would increase the 'break even' range to between 1.8 to 7.3 per cent.

An alternative method to the estimation of percentage reductions is to consider what reduction in the number of occupational cancer deaths would be required for the benefits to at least match the costs. Using this methodology – which simply divides the annual costs by the valuation for a cancer death to derive the number of cancer deaths that would need to be reduced annually for REACH to 'break even' - 18 cancer deaths would have to be reduced a year (based on a cancer death valuation of £2.46 million). As a sensitivity, 37 cancer deaths would have to be reduced a year, based on a cancer death valuation of £1.228 million (without the societal 'dread factor').

All of these 'break even' calculations have been presented in terms of annual costs and benefits. However, the annual calculations do not take account of the fact that costs will be spread over a limited period (e.g. 11 years) but potential benefits would be on-going; this would reduce the 'break even' estimates. In contrast, taking account of latency – benefits in terms of reductions in cancer deaths would not arise until perhaps well into the future – would raise the required 'break even' rate. Initial analysis shows these two effects are offsetting, although this will of course depend on different assumptions made in terms of the time period and latency.

The analyses above presents just some of the sensitivities and it is important to recognize this point. For example, no sensitivity analysis is presented in terms of the costs of REACH.

However, a final point with respect to the 'break even' calculations is that these figures should be seen as over-estimates, because it is accepted that, although not valued, there will also be benefits to society in terms of environmental benefits, benefits to industry, non-occupational health benefits, and occupational illnesses besides cancer deaths.

The Government intends to carry out further work to build upon this partial RIA and we will use the views of stakeholders in response to this document when considering what further work is required.