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COMMISSION STAFF WORKING PAPER

"REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} "

EXTENDED IMPACT ASSESSMENT

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EXTENDED IMPACT ASSESSMENT

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1 WHAT IS THE PROBLEM THE POLICY IS EXPECTED TO TACKLE?

On 27 February 2001 the Commission issued a White Paper (COM (2001) 88 Final) on a strategy for a future chemicals policy.

The need for a new strategy arose from wide acceptance that the existing legislation was not capable of responding adequately to public concern in Europe about the potential impact of chemicals on health and the environment, and would be increasingly unable to meet expectations in the future.

The existing legislation, while introducing a considerable number of risk reduction measures for certain dangerous substances, was seen as unsuited to the requirements of the new century. In particular, it did not make sufficient information available about the properties of "existing" chemicals (first marketed before 1981), which dominate the Community market, it was failing to deliver risk assessments within a reasonable timeframe, and it placed too much onus on public authorities to provide proof of risk. The fact that the requirements for putting new chemicals on the market were much stricter than those applied to "existing" chemicals was a further important argument in favour of modernising the system.

2 WHAT ARE THE MAIN OBJECTIVES?

The Commission's strategy for future chemicals policy is part of its wider sustainable development strategy. Its overriding goal is therefore to respect sustainable development by ensuring both a high level of protection of human health and the environment and the competitiveness of the chemicals industry, within the framework of the Single Market. The following specific objectives were identified:

– protection of human health and the environment;

– maintenance and enhancement of the competitiveness of the EU chemical industry;

– prevent fragmentation of the internal market;

– increased transparency;

– integration with international efforts;

– promotion of non-animal testing;

– conformity with EU international obligations under the WTO.

3 WHAT POLICY OPTIONS ARE AVAILABLE?

There was a wide measure of consensus on the need for reform. The Council of Ministers and the Parliament clearly favoured development of more effective mechanisms and procedures which would place a greater onus on industry to make available information on the hazards, risks, and risk reduction measures for chemicals currently in use, and would create greater confidence that dangerous substances were being used safely.

Chemicals is an area of Community activity that should be governed by full harmonisation because of the need to preserve the integrity of the internal market, to avoid trade distortions and conflicts and to guarantee a high level of protection of health and the environment. Accordingly, the question of whether to use alternative, more flexible, policy instruments such as co-regulation or self-regulation does not arise.

3.1. Subsidiarity

In considering the issue of subsidiarity in the sense of Article 5 EC, it should be taken into account that the present Community legislation on chemicals already provides for an extensive control over the classification, labelling, marketing and use of substances and preparations. The new legislation will to a large degree replace the existing one and will extend it in recognised areas of Community competence that have hitherto not been adequately dealt with. The subsidiarity issue therefore only arises with regard to this extension.

As chemicals are being traded across borders and if used improperly can lead to cross-border contamination, Member States cannot by themselves sufficiently achieve the objectives of the proposal. Community wide legislation therefore seems appropriate. There is a strong consensus among stakeholders including the institutions that comprehensive measures at EU level are required in order to achieve a high level of protection of health and the environment while at the same time ensuring a level playing field for all economic actors in the Internal Market.

The use of a Regulation (that replaces 40 existing Directives) is justified, as it will lead to the direct application of such legislation throughout the Community. In the area of technical legislation, this is a widely used technique that has already found the support of Member States in other areas of Community competence[1]. It is all the more justified in the perspective of an enlarged Community comprising 25 Member States and is essential to ensure homogenous and directly applicable rules throughout its territory.

3.2. Proportionality

An important feature of the new legislation in terms of proportionality (Article 5 subpara. 2 EC) is the fact that the responsibility for the safe management of the risks of chemical substances will be placed on the industry. This will encourage enterprises to apply risk reduction measures from an early point in the life cycle of the substance concerned and thereby to avoid any negative impact on downstream users and customers. It will also permit Member State competent authorities to re-orient their resources towards evaluating the quality of the information submitted by industry rather than doing risk assessments themselves.

While the new legislation is designed to cover all those chemical substances that can lead to exposure of citizens or the environment, great care has been taken to ensure that the new legislation is not excessive in terms of scope, costs and administrative burden. This is why the new legislation provides for a tiered approach for certain classes of chemical substances. This is in particular the case with regard to low tonnage substances or special uses (e.g. for R & D).

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[1] See the recent Regulation (EC) No. 178/2002 on Food Law, as well as the Commission's recent proposals for Regulations on Fertilisers (COM 2001/508), Detergents (COM 2002/485) and Drug Precursors (COM 2002/494).

At the same time this tiered approach leads to a lighter regime in terms of cost and administrative burden for low volume substances, from which SMEs in particular will stand to benefit, without diminishing the protection of health and the environment.

4 THE EU CHEMICALS INDUSTRY[2]

In assessing the potential impacts of the proposals, it is essential to assess the competitiveness of the chemicals industry and its role in, and importance to the EU economy as a whole.

4.1. The EU Chemicals industry – its performance and characteristics

The EU chemicals industry is one of the EU's most international, competitive and successful industries, embracing a wide field of processing and manufacturing activities.

The turnover of the EU chemicals industry (excluding pharmaceuticals) was € 417 billion per annum in 2000 making up roughly 8% of EU manufacturing production. The overall value-added of the EU chemicals industry (excluding pharmaceuticals) in 2001 was € 107 billion, contributing 1.3% of total economy GDP. The turnover of the chemicals industry in Candidate countries is estimated at some € 16 billion (roughly 4% of EU 15 production).

Chemicals output covers a wide range of chemicals products: basic chemicals, pesticides, paints and varnishes, soaps and detergents, and other chemicals. The industry is a key supplier of virtually all sectors of the economy. However, the significant share (30%) of chemical products is further processed within the industry itself through complex value chains.

The geographical location of the EU chemicals industry is mainly concentrated in four countries. Germany is the largest European producing country, accounting for over a quarter (26.2%) of the EU production in 2000, followed by France (17%), the United Kingdom (13.5%) and Italy (11.6%).

Its production pattern appears to be broadly similar to, if no less cyclical in recent quarters, than total manufacturing output. Over the ten–year period 1991–2000 output growth has averaged less than in the US. Only Denmark (largely due to the pharmaceuticals component) and Finland have experienced strong growth.

In the EU, the chemicals industry was made up of 22890 enterprises in 2000. It has a relatively high degree of concentration in comparison to the total manufacturing industry. However, it is also a very heterogeneous sector and the size of companies in the EU chemicals industry varies considerably. SMEs are often suppliers or customers of the larger companies and they play an important role in the chemicals industry network, providing a certain degree of flexibility. SMEs with less than 250 employees represent more than 95% of firms in the EU chemicals industry in 2000, accounting for 30% of the production value and 36% of employment.

4.2. Trade and competitiveness

The aggregate European chemicals industry remains competitive internationally, with the United States being the biggest international competitor.

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[2] Excluding the pharmaceuticals sector.

International trade data suggest that the European chemical industry has been strengthening its comparative advantage, especially in chemicals (less so in rubber and plastics). The chemicals industry's international trade position is markedly more favourable than that of total manufacturing, recording rising annual surpluses which in 2001 amounted to over € 50 billion. Excluding pharmaceuticals, the chemicals industry is also recording substantial surpluses in its international transactions and it appears to enjoy a strong comparative advantage. The surplus of the non-pharmaceuticals component of the industry has been rising over time and in 2001 it amounted to € 37 billion.

The industry has performed better than overall manufacturing in external trade during the period 1989–2001. In this period, the contribution of the chemicals industry to the trade balance of the EU has been higher than its share in manufacturing trade. This suggests that this industry (especially chemicals, chemical products and man–made fabrics) is crucial for Europe's manufacturing performance in international trade.

The industry is characterised by high levels of imports, which are indicative also of its global dimension.

4.3. Production, productivity and employment

During the period 1995–2002 the chemicals industry has displayed production growth rates that have been similar to or have exceeded the corresponding growth of manufacturing production; however, and with the exception of France, output growth in the large EU producers has been inferior to the US[3].

The available evidence for three countries – Germany, the UK and the US – suggests that, over the period 1989–1999, capital deepening per hour worked in Germany has taken place at a rate faster than in the UK or the US. However, capital spending per person employed[4] has been vigorous in some EU Member States (notably in Austria, Spain, Sweden and the UK) and for the EU as a whole at a rate comparable if not somewhat faster than in the US – a little over 2%.

Over the ten years or so ending around 1999/2000 labour productivity growth in the chemicals industry has ranged from a minimum of around 1% to a high of 7% and it has been particularly pronounced in the chemicals sector. In the US, however, vigorous labour productivity growth has taken place at rates (in excess of 4%) comparable to the whole of the chemicals industry. Total factor productivity growth in Germany (2.6%), France (1.8%) and the UK (2%) has been faster than in the US (1.3%).

In the 1990s, unit labour costs and producer prices grew at diverse rates across the industry. Unit labour cost declined in Austria, Denmark, Finland, France and Germany at rates greater than in the US. However, high unit labour cost growth in Italy and the UK suggests that industry competitiveness in these countries may have entered a period of fragility.

The EU chemicals industry employs about 1.2 million people in 2000, or 4.2% of the overall workforce in the manufacturing industry. Over the last ten years, as the industry has been modernised and restructured and production processes have become automated, its employment levels have fallen in most EU countries; this occurred at a faster pace than in the

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[3] Output growth averaged around 1.3% in Germany and a little over 2% in Italy and the UK; in the US, the corresponding data show average growth of chemicals of 4.1% and rubber and plastics of 6.1%.

[4] Another measure of capital deepening; the data refer to the period 1990–2001.

US. Only in Denmark, in the case of pharmaceuticals, and in Finland, Italy and the UK in the case of rubber and plastics has there been some employment growth.

It is important to recognise that it is not only the chemicals industry that is concerned by the proposals. In reality the widespread use of chemicals throughout Europe's entire manufacturing sector requires consideration of the likely effect of the new proposals across the entire spectrum of industry.

The Environmental Performance of the EU Chemicals Industry

Environmental expenditure in the EU chemicals, rubber and plastics industries[5] amounts to € 7.7 billion per annum, or 3.5% of value-added, and account for 23% of total EU environmental protection expenditure in all industries.

The environmental performance of the EU chemicals industry from 1990 –2000 has improved very significantly with relation to emissions of greenhouse gases, acidifying gases, and ozone precursors by the chemicals industry falling strongly and faster than those of EU manufacturing as a whole.

The 50% fall in greenhouse gas[6] emissions from chemical processes was mainly due to high reductions in nitrous oxide emissions, which decreased by 56%. This decrease can be largely attributed to specific emission reduction measures at adipic acid production plants in the UK, Germany and France. The contribution of chemical processes to the overall EU-wide emissions change of greenhouse gases between 1990 and 2000 was 48%. The production of ozone depleting substances has almost stopped.

Most striking is the case of the acidifying gases[7], where although the chemical production rose with 33% in the period 1990-2001, the emissions of these gases dropped by 48%. Amongst individual gases, the nitrogen oxides emissions decreased by 57% and sulphur dioxide emissions decreased by 43%.

Overall ozone precursor emissions[8] from chemical processes decreased by some 38% between 1990 and 2000. Amongst the individual gases, the non-methane volatile organic compounds decreased by 26%, partly through anticipation of the solvents directive.

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5 It is not possible to disaggregate the chemicals component of this data.

6 Greenhouse gases are carbon dioxide, methane, nitrous oxide and an aggregation of three halocarbons. Data are derived from the CRF Tables for the European Community 1990-2000 (submission to the UNFCCC Secretariat)

7 Acidifying gases consist in sulphur dioxide, the nitrogen oxides and ammonia. Data on ammonia emissions are not available, but are not so important, less than 2% of total EU15 emissions in 1999.

8 Ozone precursor gases consist in non-methane volatile organic compounds, nitrogen oxides, carbon monoxide and methane.

Table 1. Change in emissions over the period 1990 – 2001

	EU chemicals industry emissions	EU manufacturing emissions	Total EU economy emissions
Greenhouse gases	**- 50%**	**-17%**	**-2%**
Acidifying gases	**-48%**	**-44%**	**-50%**
Ozone precursors	**-38%**	**-17%**	**-29%**

As far as emissions to water are concerned, emissions of nitrogen compounds were reduced by 25% in 2000 compared to 1996. Chemical oxygen demand and heavy metal emissions were reduced by 17% and 43% respectively (CEFIC Responsible Care data, matched samples).

Finally, the chemical industry has also performed remarkably in reducing its energy intensity, which improved by 32% between 1990 and 2000, due to structural changes in the chemical industry and to the strenuous efforts of the sector. Eurostat estimates the CO_2 emissions from energy combustion in the chemicals industry to have decreased by 23 %. The share of the chemicals industry in the overall emissions of CO_2 has dropped from 3.2% to 2.2%.

These improvements have come at a cost. Spending on environmental protection is proportionally significantly higher in the chemical industry than in other manufacturing sectors. Total environmental protection expenditure spent in 1999 by chemicals, rubber and plastics industries amounts to € 7.7 billion, which represents about 3.5% of value added in those industries.

The chemical industry's expenditure is equal to 23 % of total environmental protection expenditures by industry.

Table 2. Environmental protection expenditure (EPE) by Chemicals, rubber and plastics industry in the EU in 1999 (NACE 24-25), billion Euro and % of total industry (Eurostat estimate)

	Chemical etc. EPE (€ billion)	Chemical etc. EPE % of total	Total Industry EPE (€ billion)	Chemical etc. EPE % total Industry EPE
Air	**1.6**	**20%**	**7.8**	**20%**
Wastewater	**2.7**	**36%**	**9.7**	**28%**
Waste	**2.3**	**30%**	**9.5**	**24%**
Other	**1.1**	**14%**	**6.3**	**18%**
Total	**7.7**	**100%**	**33.4**	**23%**

5. THE ECONOMIC IMPACTS OF THE NEW CHEMICALS REGULATION

5.1 Objectives of REACH and general considerations

REACH aims to:

– get enterprises that manufacture and import chemicals to generate information about their intrinsic properties and the potential risks which they may pose for health and the environment, and to develop strategies to manage these risks;

– ensure that the resulting information is made available to downstream industries, the authorities, civil society and to the general public;

– encourage industry to develop and use substances less dangerous to health and to the environment (where, for socio-economic reasons, authorisations for use are given for the use of substances of high concern);

– permit the authorities to take more speedy action in cases where risk reduction measures are needed.

It is useful to distinguish two different categories of costs and benefits when estimating the impacts of this new chemicals policy.

In a first phase, information will be gathered on the chemical, health and environmental properties of individual chemical substances. This information gathering is of benefit to all those in charge of designing risk management measures in public authorities and enterprises. It will give rise to testing and registration costs, and to costs of running the chemical agency. They mainly fall on the chemicals industry, either producers or importers[9], and may be passed on to downstream users in whole or in part depending on competitive pressures. Costs falling on downstream users result either from increases in prices of chemical substances or substitution costs in case downstream users have to engage in substitution activities as a result of some suppliers of chemical substances withdrawing substances because testing and registration costs make their production unprofitable. Additional costs to downstream users may be passed on to their customers in whole or in part depending on the competitive pressures on their markets. There may also be other costs incurred in consequence of adaptation in the industry supply chain as a result of the new requirements. And, while in normal circumstances it can be expected that adaptation will be smooth, it cannot be excluded that, in contrast to the normal expectation, the efficiency of chemical substances and their reformulation to meet the needs of the market may be reduced.

In a second phase, risk management measures may be taken in relation to certain substances in the light of the information gathered in the first phase. Most of the benefits to public health and the environment stem from these measures aiming at reducing risk of exposure to hazardous chemicals. The resulting measures will give rise to a cost to industry. The proposed legislation provides that each risk management decision will be accompanied by a socio-economic assessment of its costs and benefits.

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[9] The downstream users industry may also, under particular circumstances or for specific substances, decide to carry out themselves the tests. In such a case, they will directly bear the testing and related costs.

Recognising the need for a cost-effective system the Commission has made all reasonable efforts to

- reduce costs of testing by allowing waivers where information can be provided by other means, or is unnecessary because the profile of a substance's use does not require it.

- prescribe lower test requirements for quantities between 1 - 10 t. This accounts for the greatest number of substances produced and used by tens of thousands of downstream users.

- develop lighter registration requirements for intermediates.

- excluding polymers from registration and evaluation pending the establishment of a practical and cost efficient way of selecting polymers for registration on the basis of sound, technical and valid scientific criteria.

- lay the basis for even lower costs in future by encouraging the development, regulatory acceptance, and use of non-animal testing methods, including the use of quantitative or qualitative structure activity relationships ((Q)SARs). It is expected that (Q)SARs will come on stream prior to the introduction of the test requirements for lower volume substances (which will be subject to review 6 years after adoption of REACH).

- reduce the cost of passing information to downstream users by using Safety Data Sheets rather than the previously proposed parallel system of Chemical Safety Reports.

Owing to limited available information, the cost estimates presented in this chapter are based on estimations for the EU 15 countries. They therefore do not include potential costs in candidate countries (constituting an additional 4% of EU 15 chemicals turnover). However, there is no indication that impacts in candidate countries would be other than broadly proportional to those in the existing countries of the EU[10].

5.2. Testing and Registration Costs

It is possible, on the basis of intensive work carried out by an independent consultant and, taking into account also some internal investigation by the Commission services, to establish the costs of testing and registration with reasonable certainty. The principal variable, which may influence future costs relates to the validation, application, and acceptance of (Q)SARs[11].

This leads to an estimated testing and registration cost of REACH (including € 0.3 billion Agency fees) of € 2.3 billion in present value terms. On the one hand this may increase by € 0.9 billion if progress with validated (Q)SARs is slower than currently expected. On the other hand, the lower limit of the range might be reduced by a further € 0.4 billion if progress on (Q)SARs is faster than currently anticipated. These estimates assume a high level of sharing of information and co-operative actions between stakeholders.

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[10] Support is already given to the candidate countries to align their chemical legislation to that of the EU in several areas, e.g. through seminars on the approximation of chemical legislation in the candidate countries, the screening exercise and through the Phare Business Support Programme. The Programmes provide for assistance to business organisations in the CEECs aimed to support companies to adjust to the requirements of the EU acquis.

[11] QSARs (Quantitative Structure-Activity Relationships) are computer-based methods that permit the prediction of physiochemical, environmental, or health effects based upon the molecular structure of a chemical, without the need for further animal testing.

Details of the relevant calculations and principal assumptions determining the different estimates are presented in the following sections.

A business impact study carried out by independent consultants was finalised in September 2003[12]. The cost estimate (excluding Agency fees) of the draft legislation put on the Internet for consultation, based on historical prices for testing chemicals and the most likely testing assumptions, was € 12.6 billion[13] over the 11 year period.

Meanwhile, and as a result of the Internet consultation, the draft legislation has been amended with a view to reducing costs as far as possible without diminishing the protection of health and the environment. Table 3 describes the main measures taken to reduce costs and their impact in terms of cost savings.

Table 3: Measures to improve the cost-effectiveness of REACH

Net present value (€ millions, 3% discount factor)

Measure	**Cost Saving**
Major reduction in requirements for Chemical Safety Reports	- € 6,450 million
Exclude Polymers, pending selection criteria	- € 1,900 million
Increased use of QSARs*	- € 950 million
Reduced requirements for 1 to 10 tonnes	- € 500 million
Lighter requirements for transported intermediates	- € 600 million
Other factors	- € 200 million
Cost savings	**€ 10,600 million**

* assuming validation and acceptance of (Q)SARs can be applied within the timeframe envisaged

[12] For details, see RPA and Statistics Sweden (2003) "Assessment of the Business Impact of New Regulations in The Chemicals Sector" available at http://www.europa.eu.int/comm/enterprise/chemicals/bia/index.htm

[13] This cost estimate assumes a low number of polymers to be registered and that the labour costs associated with the different activities involved in preparing a registration dossier are € 875 a day

Table 4: Testing and registration costs of REACH

Net present value costs of REACH (€ millions, 3% discount factor)

	>1t/y	>10t/y	>100t/y	>1000t/y	**Total**
Registration costs	€ 100 mn	€ 100 mn	€ 100 mn	€ 200 mn	**€ 500 million**
Testing costs	€ 150 mn	€ 300 mn	€ 350 mn	€ 450 mn	**€ 1250 million***
Safety data sheet costs					**€ 250 million**
Authorisation procedures					**€ 100 million**
Reduced costs for new substances below 1t etc.					**(benefit of € 100 million)**
Total testing and registration costs					**€ 2, 000 million**
Agency fees (paid by chemicals sector)					**€ 300 million**
Total costs (including Agency fees)					**€ 2, 300 million**

* assuming validation and acceptance of (Q)SARs can be applied within the timeframe envisaged leading to a cost reduction of € 0.949 million.

A further analysis of the testing needs arising from REACH[14] concluded, inter alia, that use of (Q)SARs should allow industry to significantly reduce testing costs. The reduction in testing costs arising from the availability and use of (Q)SARs is, however, conditional on the validation, the acceptance and use of such techniques on a large scale and their practical application for regulatory purposes. Given the incentives for public authorities and industry to achieve the necessary breakthroughs, such a development appears feasible.

Concerns have been raised that capacity constraints in chemicals testing may occur and result in testing costs which are higher than the figures in table 4. One estimate is that EU chemicals testing capacity is capable of undertaking only 25 - 30% of the required testing[15]. However, this estimate was made prior to the drafting of any legislation and so was based on an interpretation of the White Paper. It therefore did not take account of the provisions in the current draft for reduced testing requirements or the use of (Q)SARs. Furthermore, EU capacity may be supplemented by capacity from elsewhere in the world but with some additional costs. Non-EU manufacturers are likely to use domestic testing capacity to meet any testing needs for the substances they export to the EU. It may also be supplemented by investment in additional testing capacity. The risk of testing capacity constraints therefore seems manageable.

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14 JRC, Institute for Health and Consumer Protection (2003) "Assessment of additional testing needs under REACH: Effects of (Q)SARs, risk based testing and voluntary industry initiatives"

15 See Institute for Environment and Health, "Testing Requirements for Proposals under the EC White Paper – Strategy for a Future Chemicals Policy" IEH Web report W6, Leicester, July 2001.

In addition to testing and registration costs, the chemicals industry is estimated to pay some € 0.3 billion in fees to the new chemicals agency[16].

Costs of running the chemical agency

The costs of running the REACH system are estimated at some € 0.4 billion as a one-off cost over 11 years (cost of establishing and running the chemical agency). This cost will be met from the fees paid by industry (€ 0.3 billion) and the remainder from the Community budget.

Direct Benefits

The direct benefits coming from testing and registration requirements will be the information gathered on the chemical, health and environmental properties of chemical substances and uses covered by the proposed legislation. The information gathered will be of benefit for all those in charge of designing appropriate risk management measures, for industries and enterprise producing and/or handling and using these substances, and for end-users exposed to these substances and products containing them.

Authorities will benefit from the information gathered as it should eventually lead to a better management of the risks associated with individual substances and uses, potentially yielding added benefits for the workforce exposed to these chemicals and for society at large, including an improved status of the environment. It will assist authorities to ensure more effective implementation of the precautionary principle through being alerted at an earlier stage to potential risks and acting more rapidly to address the problem.

Enterprises will benefit from the increased responsibility devolved to them under REACH, and will be better able to appreciate the potential health and environmental risks associated with the substances they produce or use. The process may also create an incentive for the development of new and safer substances, and should encourage innovation.

The public at large will benefit from the information gathered because of REACH as they will be better informed about potential risks from specific substances. Confidence of end-users in the safety of their purchases may rise.

The most important benefits expected from REACH will be benefits to health and the environment due to the expected improvement of the risk management. These are discussed in chapter 6, below.

[16] The estimated cost for the Community budget could be around € 76 million, as detailed in the financial statement.

5.3. Costs for Downstream Users

The potential withdrawal of chemical substances

Considerable attention has been focussed on the implications of the REACH system for downstream users of chemicals and the estimates of likely costs of the REACH system to the downstream users have differed widely.

On one side, it has been argued (see the A.D. Little study for BDI and the Mercer study for UIC) on the basis of the White Paper and the internet text that the measures envisaged would lead to a significant withdrawal of substances from the market. This would lead to a loss of production and a cascading effect on downstream users, were substitute substances not available or not to emerge through innovation. Other concerns expressed include fears of a loss of confidentiality induced by REACH, increased time to market, delays in getting access to substances because of authorisation procedures and possible refusal to give authorisations in the case of dangerous substances which are essential to existing manufacturing processes. The cumulation of these claimed effects is described as bringing about an important reduction in the efficiency of industry along the entire value-chain, thereby giving rise to a serious impact on GDP and employment. The Commission has carefully considered these arguments, organising two workshops at which these issues were discussed in depth.

On the other side, it has also been argued that, as a general rule, the costs of REACH to downstream users should not be higher than the costs initially imposed on the chemical industry. The chemical industry would either pass through its additional costs to its users, or the users would engage in substitution activities which come at a lower price than paying for additional testing and registration of the original substance. Hence, the withdrawal of substances for economic reasons should not lead to significantly higher costs to downstream users.

Having carefully considered both of these arguments, the Commission considers that whilst some substances may be withdrawn from the market, their number is likely to be limited and, in any case, considerably less than some have estimated. Nevertheless, there will be economic consequences of the withdrawal of substances, notably in a situation in which the adjustment of industry to the new requirements does not proceed smoothly.

The REACH system in effect will require every chemical producer to make an investment decision either to continue to market each substance by incurring the required testing and registration costs or whether instead to withdraw it from the market. Producer options to fund the testing and registration costs to keep a substance on the market include increasing its sales price or temporarily reducing their profit margins. Alternatively, the firm may stop production of the substance and remove it from the EU market[17].

It is possible that in some cases chemical producers will withdraw substances even though their value to downstream users is higher than the testing and registration costs that are being avoided. This may occur when there are a large number of downstream users, long and complex value-chains, and/or when the information flow between producers and clients is limited (possibly for confidentiality reasons). All of these factors are characteristic of the chemicals industry. Product withdrawal is also more likely to occur if firms, such as SMEs,

[17] The firm may also relocate their production of the substance outside the EU, e.g. if they only sell the substance outside the EU market.

are capital constrained or if there is limited information about the value of a product along the supply chain owing to confidentiality considerations. In such cases, there will be gradually increasing economic consequences through the value chain.

For producers of low-volume substances (under 100 tonnes), the testing and registration costs will be higher per tonne than in the case of high-volume substances. For them, the testing and registration costs could be unaffordable even if spread over several years. This risk of such withdrawal would have been especially high in the sensitive 1-10 tonne range. As a result, in the proposals considerable relief is being provided in terms of reduced obligations in the case of Chemical Safety Reports and testing requirements. Overall, the total costs per tonne of registration and testing for this range are now of the same order as those for substances in the 10-100 tonne range. The reduced testing requirements will also be carried through to the obligations for registration of new substances which, with an increasing registration threshold, should be capable of being generated on a wider scale than previously, thereby providing an important incentive to the generation of substitute substances.

In relation to imports, it is to be noted that importers of substances will be subject to the same testing and registration requirements as EU producers. Moreover, in a dynamic industry, the removal of substances from the market will lead to the development of alternative and more profitable, products.

The consequences of the withdrawal of chemical substances will be seen in the reduced availability - and possibly performance - of the chemical preparations available to downstream users. The chemicals industry rarely directly sells substances themselves. Instead, the industry sells chemical preparations, which are ready-prepared mixtures of basic substances. The typical chemical preparation sold by the industry may contain between 5 – 500 mixtures of basic substances, sourced from numerous suppliers. It is therefore likely that the withdrawal of particular substances will lead to the need to reformulate or replace a wider variety of preparations. As well as entailing the costs of reformulation, the actual performance of the reformulated preparations may in some cases be poorer. The existence of such cases has been documented in particular instances; it is uncertain however how widespread such occurrences would be in practice.

Additional costs to downstream users will therefore arise from (i) a higher price of chemicals because testing costs initially paid for by the chemical industry will be passed through in whole or part depending on the degree of competition; (ii) the need to find substitutes for those chemicals substances and preparations that have been withdrawn from the market; and (iii) some increase in market power that remaining suppliers might temporarily exploit. Substitution costs will occur from the need for downstream users to find potentially higher cost or less-effective replacements for those substances removed from the market. In some cases, downstream users may be able to find available substitutes relatively easily or be able to reformulate the required preparations themselves. In other cases, production techniques may needed to be modified, resulting in additional investment or longer production times. Finally, in some cases, the non-availability of chemical preparations may lead to a deterioration in product quality and some loss of product competitiveness.

Examples of key downstream sectors that could be affected by the policy are the textile industry, the pharmaceuticals industry, the electronics industry, the motor car industry, users of advanced materials, and producers of sensory products. Detailed sectoral surveys of

downstream users[18] based upon an earlier draft of the REACH proposals indicated that problems from the withdrawal of products were expected by businesses to be particularly acute for users of pigments and dyes, adhesives, surfactants, inks, plastic additives, silicones, and leather treatments. Serious and very specific impacts were also expected by businesses on specialised chemicals used in particular industries such as semi-conductors, photographic chemicals and non-woven and absorbent hygiene products.

The indications are that these industries would be the most sensitive to changes in the availability of chemical products as many of them use a wide range of speciality chemicals. Withdrawal of chemical products on a significant scale could result in potentially expensive reformulation costs and some loss of efficiency in production and quality standards[19]. However, having regard to the significant reduction in the testing requirements for low tonnage and the substantial reduction in administrative burdens and costs introduced in the proposed legislation, the Commission considers that the potential adverse consequences for downstream users will be substantially reduced.

Moreover, it is possible for downstream users to avoid substitution costs by engaging in the testing and chemical safety assessment themselves[20]. This would ensure that substances of high value to them will not be withdrawn. It is therefore in the interests of downstream users to communicate with producers if they feel that their products are at risk. The draft legislation strongly encourages this by allowing a downstream user to require that his producer's registration covers all of the downstream uses and by requiring pre-registration of low volume substances well in advance of the registration deadline. The latter point was a particular concern for downstream users during the Internet consultation. However the high number of substances and the complexity of the value chain will result in a limited number of cases in which substances are withdrawn with high costs of substitution for downstream users.

REACH and the Textiles Industry

As part of the impact assessment process, Commission services held a Workshop on the Impacts of REACH on the textile industry on 22 September 2003 to which industry experts and stakeholders were invited. The EU textile industry has a turnover of € 115 billion and directly employs some 1,100,000 persons. It contributed a net € 8 billion to the EU balance of payments in 2002. The industry has restructured successfully towards higher-value and niche products, but now faces the challenges of EU enlargement in 2004 and of the removal of all import quotas on 1st January 2005.

The textiles industry is among the most chemical-intensive industries in the EU, with chemical inputs making up some 5.6% of its overall turnover. Whilst the textile industry uses basic chemicals for lubrication, sizing, mercerising, and bleaching etc., the industry's most important chemical inputs are textile auxiliaries and dyestuffs. These are typically produced with relatively low margins and in small volumes between 1-100 tonnes. These preparations

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18 See RPA (2003) "Availability of Low Value Products and Product Rationalisation", Working Paper 2, CEFIC (2002) Business Impact Study, Sectoral Fact Sheets, Mercer Consultants (2003) "Study of Impact of European Chemicals Policy" March 2003.

19 See especially Mercer Consultants (2003) "Study of Impact of European Chemicals Policy" March 2003.

20 The legislation allows only manufacturers or importers themselves to register a substance. A downstream user may however decide to carry out tests and chemical safety assessment to address additional uses of an already registered substance.

should therefore benefit considerably from the proposals to reduce testing requirements and the obligations for Chemical Safety Reports.

Potential impacts from REACH on the textiles industry itself could have come about both through the rationalisation of the range of available chemical preparations and as a result of the expected increase in the price of chemical products. Effects from the possible withdrawal of chemical substances could have been most harmful and might have occurred along the entire textile value-chain: from spinning to weaving and knitting, through dyeing and printing to textile finishing. The potential withdrawal from the market of some chemical preparations, such as dyestuffs and basic auxiliaries, could have been dealt with through substitution with other products or by reformulation done within the textiles industry itself. The loss of these preparations might have resulted in lower production speeds and product characteristics and might have imposed re-engineering and reformulation costs and some time delays. Further impacts might have occurred were some of the technological textile auxiliaries used in the finishing industry to be withdrawn: these preparations are used for example to obtain soil-resistant and easy-care properties. Re-formulation by the textiles industry itself would not have been possible to replace such products.

However, the analysis presented at the Workshop and the subsequent discussion showed that the REACH proposal should not lead to the high costs suggested, for example, by the analysis of Mercer. The Commission considers that the threat of withdrawal of substances and significant increase in prices of chemical substances have been considerably alleviated following the changes made to reduce testing and registration costs, especially for low tonnages. In particular, several of the dyestuffs and auxiliaries that the industry fears the withdrawal of most are actually produced in quantities below ten tonnes, and therefore will benefit from the lower testing and registration requirements for these substances under REACH. Where dyestuffs and auxiliaries are affected, participants noted that their withdrawal will only occur when continued production would not be profitable (for example, because a close substitute is available). A number of participants indicated the need for communication along the chemical supply chain so as to ensure that products are not withdrawn where there is demand for them.

Overall, the Workshop provided reassurance that the measures proposed by the Commission should address the key problems identified by the textiles sector. The proceedings of the workshop provided an input to the cost estimates indicated in relation to downstream users in the text below.

Quantification of the costs to downstream users

There is no fully reliable methodology to assess the costs to downstream users associated with REACH. However, prediction of costs to downstream users, albeit with certain margins of uncertainty, can be made on the basis of normal business behaviour in response to changes in the market, and expert knowledge of the competitive situation of the many sectors and sub-sectors involved.

An internal calibrated microeconomic model[21] has been developed and used to assess how the chemicals industry would react to the testing and registration costs. The model simulates the reaction of chemical producers and downstream users to an increase in the cost of producing

[21] For details see the DG Enterprise note "A Microeconomic Model to Assess the Economic Impacts of the New Chemicals Policy"

chemicals due to the need to undertake testing and registration. The model aims to measure the cost to downstream users of higher prices for chemical substances, as well as the cost of substituting withdrawn substances with others. The cost of substitution is quantified through an elasticity of substitution (higher is the elasticity of substitution, easier and less costly are the possibilities of substituting withdrawn substances by others).

Two scenarios for the costs of REACH to downstream users have been investigated: a "normal expectations" scenario, which is what in normal circumstances the Commission expects should happen and a "higher substitution costs" scenario, which cannot be excluded. Both scenarios are based upon estimated testing and registration costs of € 2.3 billion, i.e. including both testing and registration costs and Agency fees paid by industry as contribution to the running of the agency. In each case a lower and upper estimate of the costs are derived for two time periods: 11 years (the time to register all substances currently on the EU market) and 15 years (to allow for a longer adjustment period).

The "normal expectation" case examines the impact of the introduction of REACH, where the implications for downstream users come solely from the pass-through of testing and registration costs and the effects of the withdrawal of chemical substances on individual downstream users.

A "higher substitution costs" scenario illustrates the effects where the withdrawal of substances further increases the costs of substitution, through the cumulative effects of the withdrawal of substances in terms of adaptation to the whole of the chemicals supply chain. In this case, it has been assumed that the efficiency of the chemicals industry is reduced marginally in proportion with the withdrawal of chemical substances. It also results in some increase in the market power of the suppliers of substitution substances. In this case, higher downstream user costs would be expected.

Table 5: Summary of estimated costs to chemical industry and downstream users*

Net present value costs (€ billions at 3% discount factor)

	Lower estimate	Upper estimate
Normal expectation	€ 2.8 billion	€ 3.6 billion
Higher substitution cost	€ 4.0 billion	€ 5.2 billion

* These estimates include costs passed on from the chemicals sector to downstream users.

Table 5 presents the results of the two scenarios. In either case, the use of the microeconomic model suggests that only some 1-2% of chemical substances (0.5% of the overall value of chemical substances) will be withdrawn from the market as a result of REACH.

In the "normal expectation" case, the costs to downstream users of the introduction of REACH is assessed to be in the range € 2.8 – 3.6 billion. These costs will occur in the form of higher chemical prices resulting from the passing through of testing and registration costs and as a result of the additional substitution costs for downstream users of chemicals in finding potentially higher cost or less-effective replacements for those substances removed from the

market. In the "higher substitution cost" scenario, the costs to downstream users of the introduction of REACH is assessed to be in the range € 4.0 – 5.2 billion.

From a macroeconomic perspective, the overall impact in terms of the reduction in GDP is likely to be very limited.

5.4. Effects on Innovation

The proposal includes a series of measures and requirements that will influence the pace and the direction of industrial innovation both at product and process development level as well as at organisational level. Specific measures include increasing the testing threshold from 10 kg/y to 1 t/y, and exempting product and process oriented research from registration for a period of five years (renewable for an additional five years). In addition, there will now be a level-playing field introduced for new and existing products, rather than existing substances being favoured.

In the short-term, much will depend on the impact of the requirements of REACH on the resources available for R&D. The implementation of testing requires highly skilled personnel, which may limit the personnel available for R&D activities, especially for SMEs. Reduced profits could restrict the finance available for reinvestment in R&D spending, which is an input to innovation. The direct costs of REACH are equivalent to around 3% of current expenditure on R&D. If chemical companies were prepared to recruit additional staff or to contract out testing (as is the norm today) then no negative impact on R&D should be expected. However, if companies decided to leave their R&D budget unchanged, there would be then opportunity costs in form of reduced traditional R&D, because resources can only be used once: either from traditional R&D or for testing resulting from, REACH requirements. In case companies were to sacrifice their R&D budget, however, direct costs would only occur in terms of opportunity costs in form of less R&D and innovation. Double counting of these effects should be avoided.

The modifications made to the chemical R&D regime by the introduction of the REACH system will facilitate R&D, especially in the longer-term. The new system may also lead to induced innovation in the chemicals industry towards the development of new and safer products and processes. Additionally, the greater certainties given by the current proposal in terms of implementation timetable may promote uniform incentives to innovate

The collection of information at the first phase of implementation of REACH as well as the sharing of information across the supply chain may have considerable influence over the way the chemical industry works and how strategic decision are taken. Closer contacts between users and suppliers, better external linkages and access to external source of knowledge, and the ability of European industry to project a more attractive image for its products vis-à-vis international competitors should improve the direction and pace of innovation as well the development of newer and safer products.[22].

Enterprises should particularly benefit from the lighter requirements for new substances produced or imported below 10 tonnes a year. This is especially the case for production or imports under 1 tonne, which will no longer have to undergo registration. This is expected to have a significant impact, given the fact that more than half of their notified new substances are below this threshold.

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[22] Berkout, F., et all, "Innovation in the chemicals sector and the new European Chemicals Regulation", a report for WWF-UK by the University of Sussex, SPRU, September 2003

The substantially lighter registration requirements for new substances should significantly reduce the concern that REACH could increase the average time-to-market of chemical substances not in continuous production[23]. Under the present proposals, substances on the former existing substances list can still be produced in quantities less than one tonne on an immediate basis. Moreover, provided that such a substance had been marketed, manufactured, or imported in the EU sometime in the 10 years prior to the entry into force of REACH, it would be treated as a phase-in substance and therefore benefit from not requiring any registration before the relevant registration date.

Concerns have been expressed that the introduction of the REACH system might seriously affect innovation, through compromising the confidentiality of business information in the chemicals industry[24]. The Commission has addressed these concerns by tightening up the protection of confidential business information. The most sensitive types of information (exact production tonnage, customer information etc) will always be treated as confidential, and it will be possible for companies to request more extensive confidentiality upon application, when specific reasons are given and approved.

A number of reports and case studies[25] have looked into the impact of the current legislation (Directive 67/548/EEC) on innovation. DG JRC-IPTS[26] has collected the main recommendations stemming out from these investigations and compared them with the REACH provisions. The results are summarised in Table 6 below.

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23 See A.D. Little (2002) "Economic effects of EU Substance Policy", December 2002 and Mercer Consultants (2003) "Study of Impact of European Chemicals Policy" March 2003.

24 e.g. A.D. Little (2002) "Economic effects of EU Substance Policy", December 2002.

25 Fleischer, M., Kelm S., Palm D. (2000) "Regulation and innovation in the chemical industry", DG JRC-IPTS Technical Report, EUR1973EN. Fleischer, M. (2001) "Regulierungswettbewerb und Innovation in der chemischen Industrie", WZB Discussion papers FS IV 01-09. Fleischer M. (2002) „Regulation and Innovation: chemical policies in the EU, Japan and USA", IPTS Report, Vol.64, pp.4-17.

26 Wolf O., Delgado L., "The impact of REACH on innovation in the chemical industry", DG JRC-IPTS, September 2003.

Table 6: Overview of recommendations and REACH provisions relating to innovation

Recommendations	REACH	Expected impact on innovation
A risk-oriented notification system might reduce costs and time-to-market	Prioritisation of testing for high production volume substances, reduced requirements for intermediates, and the exemption for polymers all implement risk elements, but REACH is no real risk-contingent system.	+/-
EINECS and ELINCS should be unified to move innovation to new substances	REACH comprises all substances and replaces the existing split system. Incentive to use new substances for R&D, makes old substances costly.	+/-
R&D exemption too narrow defined (max 2 years, with volume thresholds)	R&D exemption can be extended up to 10 years, no volume thresholds. Promises trigger for innovation.	++
Polymers exemption too rigid	Polymers are exempted. Strong push for innovation	++
Intermediate exemptions	Slightly extended exemptions foreseen. Impact on innovation may be positive but low.	+
Volume thresholds too low	Volume thresholds have been increased 100 times. Creates more space for R&D.	++
Phase-in time	Reduces burden caused by adaptation to new regulation and keeps resources in R&D.	+

+ = positive/ - = negative/ +/-= unclear

Overall, the attempt to foster innovation can clearly be seen in the current REACH proposal. However, it has not been possible to place a monetary estimate on the resulting benefits, which should be understood to offset at least part of the financial impact on the chemicals industry over time.

5.5. International competitiveness

Insofar as competition within the European market is concerned, the fact that importers will have to fulfil the same obligations as EU producers should mean that there would be no unfair competition. Problems could arise in case importers were to import in quantities below certain thresholds that would allow them to benefit from lighter testing and registration procedures for these smaller volumes as compared to their European competitors. However, by definition, this should not enable them to gain significantly higher market shares as in such a case they would no longer be able to benefit from these lighter procedures. Problems might also arise because importers will not be subject to testing and registration costs for all the chemical substances used upstream in their processes of production or along the value chain.

However, given the limited scale of cost increases triggered by REACH, namely when one compares this with other elements determining international competitiveness such as wage developments or exchange rate fluctuations, potential distortion of competition on the European market as a consequence of REACH should on average remain negligible. Indeed, no convincing evidence has been made available to the Commission that the potential distortion of competition on the European market could turn into a real issue of concern.

As far as exports are concerned, there will be a potential risk of some loss of market share if prices of domestically produced chemicals are forced up due to REACH. This namely holds for cases where competitors exist on third markets that totally neglect the important European market.[27] Indeed, it would be only these companies that would completely escape the REACH legislation and its testing and registration requirements and costs associated to this. No statistical information is available that would allow to identify the companies that are on the one hand in direct competition with European producers on third markets without being competitors when it comes to also serving the EU market itself.

In the longer run, the balance of impacts on competitiveness on these third markets as well as on the European market will also depend on the extent to which the REACH regime is successful in establishing itself as a new international standard. This would give the EU chemicals industry a substantial boost in terms of international competitiveness. In this context one might want to recall the recommendations adopted by the World summit on sustainable Development in Johannesburg in September 2002 where chemicals were specifically mentioned as a key area where sustainable production and use must be achieved by 2020.

5.6. Competition and effectiveness

The EU chemicals industry has been experiencing a trend towards concentration as shown by a number of significant mergers and acquisitions over the last business cycle. Nevertheless, it remains a very fragmented industry with thousands of SMEs, often only producing tiny quantities of substances. The imposition through REACH of additional fixed costs for the producers and importers namely of existing chemicals might trigger two changes: further consolidation and further concentration.

Indeed, REACH might serve as an occasion for producers of existing substances to screen their production portfolio and to consolidate the number of substances they produce. This might then lead to an accelerated withdrawal of substances, namely of those for which close or perfect substitutes for downstream users are produced by the same company, and where therefore the willingness of downstream users to pay for testing and registration costs might be rather limited. Indeed, as the production process of the chemical industry is often characterised by important economies of scale, such a consolidation might be welcomed by downstream users as they might reap the benefits of lower production costs.

On the other hand and as a result of the problem mainly to be faced by the producers of low volume substances, the above consolidation might also trigger a consolidation not only of the number of substances but also of the number of companies. This could namely affect some specialised SMEs that produce substances in small quantities. While this effect might lead to a crowding out of these producers it should not have a measurable impact on competition in this sector.

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[27] The EU market accounts for 27.5 percent of the global market.

Impacts of the chemicals policy on SMEs.

As well as the major players, the EU chemicals industry is currently characterised by many SMEs, often producing low-volume chemicals.

The REACH system has been designed to vary data requirements according to the tonnage produced, in order to reduce costs to SMEs. Substances produced in lower tonnages can be registered with less data and will be phased into the system later. These measures are necessary to ensure that the effects of the system on SMEs will not be detrimental to their capacity for innovation and the creation of jobs.

Animal testing

The need for animal testing has been minimised by a number of measures. For example, information requirements have been trimmed to enable smart and targeted testing without compromising the safety for human health or the environment. Also, registrants will not necessarily need to do new testing to register. They can make use of other information available such as studies from other countries, previous animal testing, available in vitro data, epidemiological studies etc.

For low volume chemicals, as far as possible no animal testing will be required. In particular, REACH promotes the use of (Q)SARs as a cheap alternative that does not involve animal testing.

For higher volumes, animal testing may be necessary if existing information and validated alternative methods are not sufficient. In these cases, testing programmes needs to be agreed with the competent authorities before the experiments start, to ensure that the endpoints studied are relevant, that the scientific validity of the research is sufficiently high, and finally to ensure that the testing programme is not duplicating other studies. Finally, to avoid minimise duplicate testing, data sharing between enterprises will be required.

6 POTENTIAL HEALTH AND ENVIRONMENTAL BENEFITS

The production, use and disposal of chemicals and of products containing hazardous chemicals has been linked to a wide range of environmental and health impacts. However, due to a lack of data a comprehensive quantitative assessment of the impacts of chemicals on the environment and human health is not possible. Indeed, much of this information will only be available after the chemicals on the market today have been tested and registered in line with the requirements of REACH Accordingly, the benefits of REACH will occur over a longer time frame. This chapter provides a qualitative description of the possible impacts and some illustrative quantitative figures.

6.1. Human health impacts of chemical releases

Chemicals are linked with a considerable number of diseases including respiratory and bladder cancers, leukaemia, mesothelioma, skin disorders, respiratory diseases, eye disorders, asthma and others. The link with chemicals varies from well-known causal relationships such as benzene and leukaemia, to suggestive associations, such as chemical sensitivity. Most harmful effects are the result of many causes acting together, such as genetics, lifestyle, radiation, diet, pharmaceuticals, chemicals (manufactured and natural), smoking and air pollution, including indoor and outdoor exposures. Sensitive groups, such as the elderly,

children, the embryo, the sick, and pregnant women, may be affected at much lower doses than others.

However, there is frequently not enough information to be clear about the epidemiology, which makes it very difficult to link diseases to particular chemicals and estimate the aggregate health impacts. For example, to estimate the number of cancer cases requires information on the dose received, the potency of the carcinogen, the presence of other exposures (notably tobacco smoking), and the susceptibility of the group at risk. REACH is a response to a gap in knowledge regarding the intrinsic properties of substances already on the market and exposure to them.

As well as lacking basic information about the effect of existing chemicals on health and the environment, epidemiology is complicated by cocktail effects, non-linear dose-response functions etc. In addition, aggregate data can be poor and underreporting can be rife: one review of the data for asthma suggested that the incidence of diagnosed occupational asthma was underestimated by at least a third; aggravation of existing cases are often not included.

The European Environment Agency's report "Europe's environment: the third assessment"[28], stresses this lack of robust epidemiological evidence on the link between chemicals and public health, "the health consequences of … chemicals in the environment, are a result of complex interactions between the environment and humans that are far less understood. For some chemicals, such as endocrine-disrupting substances, the effects on humans are particularly difficult to unravel but the impacts on wildlife have been substantial, with implications for human health."

Notwithstanding all the uncertainties, however, the evidence available supports the assessment that the health burden related to chemicals is considerable.

6.1.1. Occupational Health Impacts

Occupational health is already the subject of a large amount of Community legislation. This includes the recent directives on the 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). The increased information obtained through the REACH system will make the application of this legislation more effective.

The REACH system may be expected to result in health benefits for workers, some of whom may face the highest exposure to hazardous chemicals such as carcinogens. However, it is impossible to identify accurately the benefits that will arise from REACH. The reduced occupational exposure is not limited to workers in the chemicals sector. Indeed, most occupational health benefits will probably be for workers in downstream sectors who use chemicals or substances that contain them[29].

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[28] The "Kiev Report", available at http://reports.eea.eu.int/environmental_assessment_report_2003_10/en/kiev_chapt_12.pdf

[29] RPA, "Assessment of the Impact of the New Chemicals Policy on Occupational Health", 2003 provides a description of the methodological issues and the potential benefits relating to occupational health.

6.1.2. Public health impacts

The health impact of chemicals is not limited to occupational exposures. A World Bank study[30] estimates that in established market economies pollution from agro-industrial chemicals and chemical pollution from diffuse sources cause between 0.6% and 2.5% of the total burden of disease (that is, deaths and general ill health) with a central estimate of 1.5%. These estimates were based on conservative (5% of the total burden) and liberal (20% of the total burden) percentages of the amount of disease related to around 15 diseases (that is, not all health end-points were included). The degree of imprecision in these assumptions, which still represent expert estimates, by itself indicates that we do not have a robust feel for the impact of chemicals on the general health of the population. For example, another estimate[31] suggests that the World Bank may have underestimated the burden of disease that is environmentally attributable by around 150%.

6.2. Environmental impacts of chemical releases

The problems that prevent a comprehensive quantitative picture of the health impacts of chemicals being identified are generally the same for the environmental impacts. Again, although there are important knowledge gaps, it seems that the impacts of chemicals on the environment are potentially large.

6.2.1. Knowledge Gap

Managing chemical substances safely requires a thorough understanding of the inherent properties of a substance and the dose-response-relationship, that is, the concentrations at which desired and undesired effects on the environment might occur. Unfortunately, this information is not available for a significant percentage of the chemical substances on the European market.

The availability of qualified monitoring data on environmental concentrations of chemicals is limited, and restricted to persistent organic pollutants (POPs), heavy metals and some pesticides. A joint EEA/European Science Foundation study on European monitoring of chemicals[32] concluded that: 'Monitoring is partial, uncoordinated, sometimes out of date, and, on many occasions, irrelevant to current policy needs; centralised knowledge about chemical monitoring activities that are conducted for different purposes is incomplete; there is a lack of integrated exposure assessments that consider all relevant exposure routes; there are huge data gaps in information on chemical exposures and impacts, especially concerning vulnerable groups and ecosystems; …'

6.2.2. Chemical releases

Chemical substances get into the environment in a number of different ways. For example, chemical substances in water can degrade and accumulate in biota or sediment but they can also subsequently enter the air or migrate to soil and groundwaters.

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30 K. Lvovsky et al, "Health and Environment Strategy Papers", No1, 2001, World Bank Working Paper 24096, 2001, World Bank

31 "How Much Global Ill Health Is Attributable to Environmental Factors?" by Kirk R. Smith, 1 Carlos F. Corvalán, and Tord Kjellström, 1999

32 "Europe's environment: the third assessment", EEA, 2003

Emission patterns vary widely from well-defined point sources (single or multiple) to diffuse emissions from articles during their service life. For substances used in long-life articles the latter may be a major source of emissions both during use and as waste remaining in the environment.

Emissions related to the waste life stage can take place several decades after production and processing of a substance. For example, waste disposal can lead to widespread diffusion of substances into the environment. Furthermore, a compound can degrade to substances of lower or higher toxicity; it might be absorbed from plants or terrestrial organisms or accumulate in soil or organisms or there may be leakage to groundwater or volatilisation to air. The total amount of hazardous waste from the chemicals industry is reported by CEFIC to be 3.2 million tonnes for the EU 15 (excluding Luxembourg and Greece) in 2000, although this figure does not allow any conclusions on the amount of emissions entering from landfills into the open environment.

There are around two million sites with contaminated soil in the European Union, with considerable associated costs of clean up. For instance, in 1990 the costs associated with polluted industrial sites in the Netherlands were estimated at about €23 billion. However, such environmental impacts, whilst necessitating considerable clean up expenditure, should not be seen as benefits estimates for REACH as much of the pollution is either historical or does not relate to chemicals that will be tackled under the REACH regime. It gives however an idea of the potential costs which could be avoided as a better knowledge of the environmental effects of chemical substances will allow for more cost-effective policies through preventive action. Another example of the financial cost of chemical pollution is where aquatic sediments prevents the use of dredged sediment as fertiliser, instead requiring it to be isolated and stored at higher net cost.

6.2.3. Environmental impacts

Lack of data means that it is not possible to provide a comprehensive assessment of the environmental impacts arising from the exposure of the environment to hazardous chemicals. Any assessment limited to chemicals currently known to be dangerous for the environment and to those currently monitored may underestimate potential effects.

In particular, not enough information is available on how many of the approximately 30,000 substances currently estimated to be covered by the REACH proposals have dangerous properties. Indeed, one of the aims of REACH will be to provide further information on these substances. However, of the new substances assessed under existing EU legislation around 70% have been shown to have one or more dangerous properties. An unknown but potentially significant proportion of all chemical substances will enter the environment and reach sufficiently high concentrations to induce adverse effects. For example, various reproductive disorders observed in a considerable number of bird and animal species have been associated with exposure to dangerous chemicals (see table 5).

Table 7: Examples of types of environmental impacts

Observation/impact	Species	Substance	Association
Large-scale effects			
Eggshell thinning	Guillemot, eagle, osprey, peregrine falcon	DDT/DDE	5
Reproduction	Seal, otter	PCB	4
Skeletal malformation	Grey seal	DDT, PCB	4
Pathological changes	Seal	PCB, DDT, metabolites	3
Reproduction	Mink	PCB	5
Reproductive disturbances	Osprey	DDT, PCB	5
Reproductive disturbances	Eagle	DDT, PCB	2–3
Reproduction (M74 syndrome)	Salmon	Chlorinated substances	2
Imposex	Molluscs e.g. dogwhelk	TBT	5
Impairments in wildlife in relation to endocrine disrupting chemicals (EDCs)			
Sperm quality, cryptorchidism	Panther		2–3 (effects observed in inbred population)
Population decrease	Mink, otter		2–3
Female reproductive disorders,	Seal		4–5
adrenocortical hyperplasia			4–5
Eggshell thinning	Birds		4–5
Embryotoxicity and malformations			4–5
Malformation of reproductive tract			2–3
Reproductive behaviour			2–3
Microphalli and lowered testosterone levels	Alligators		3–4 (effects seen in connection with accidental contamination)
Vitellogenin	Fish		4–5
Masculinisation			3–4
Lowered testosterone levels			2–3
Reduced testis size			2–3
M74 and early mortality syndromes			1–2
Imposex	Molluscs		5

Notes: The strength of the association is assessed on the scale: 1 = no observed association, 2 = suspected association, 3 = weak association, 4 = clear association, 5 = significant association.

Sources: EEA, 1998 (large-scale effects); Swedish EPA, 1998b (impairments in wildlife in relation to EDCs)

As well as the impact on the environment, human exposure to chemicals can take place via the environment. There can be direct uptake from air and drinking water, or contaminated soil can lead to direct exposures by skin contact, or by inhaling and swallowing dust. Environmental concentrations can also cause high levels of contaminants in crops, vegetables and wild and/or farm animals consumed by humans.

6.3. The potential benefits of REACH

Ideally, any impact assessment of REACH would separate human health and environmental impacts due to historical emissions from those caused by ongoing chemical releases. REACH is unable to deal retrospectively with historical releases, and only has the scope to reduce emissions of, or exposures to, future releases of chemicals. Not surprisingly, the inability to provide a comprehensive quantitative assessment of current impacts means it is also impossible to apportion environmental impacts between historical and ongoing emissions. In particular, the fact that monitoring concentrates on known problem chemicals means that the unknown problem chemicals that REACH will identify cannot be systematically included in any assessment.

On the positive side, for some of those chemicals already known to be hazardous, trends in environmental concentrations and health impacts do seem to be declining. For example, over the period 1990-2001 levels of pollution by heavy metals demonstrate a stable declining trend. Also, a recently conducted evaluation report[33] on levels and trends of hazardous substances in mussels and fish in coastal areas, based on assessments for the six substances for which data were available, showed a declining trend for five of them.

In summary, the data available indicate that there are significant health and environmental impacts associated with certain chemicals. Better knowledge of the properties of chemicals acquired through REACH can be expected to result in better safety and control measures, reducing exposure and hence, the impacts on human health and the environment. As it is currently unknown how many substances may be found to have dangerous properties that are not known today, an accurate quantitative assessment is not possible.

6.3.1. Impacts arising through risk reduction measures

If testing and registration identify that the intrinsic properties of a substance combined with its exposure creates a danger to human health or the environment then appropriate risk management measures or restrictions are to be put into place. Such measures could, for example, include restricting use of dangerous substances, users substituting safer substances, enclosing processes, better ventilation, and so on.

A number of the risk management measures taken will be voluntary, with firms acting to improve the control of substances based on new information or because they are better able to digest existing information. In addition, REACH's restriction process will be used in cases where it is considered that a substance poses an unacceptable risk to human health or the environment that is not adequately controlled. The cumulative result of these risk management measures will be to reduce the risks to the environment or to workers and the general public.

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[33] EEA, 2003 "Technical Report n° 86", volume 3

These risk management measures will often involve costs to enterprises or users of the substances in question. These costs will be in addition to the costs of REACH that were identified in Chapter 5. An estimation of these costs is not possible without knowing the substances affected and the risk management measures needed. This is why a separate socio-economic analysis (effectively a cost-benefit analysis) will be undertaken before the authorities make any decisions on such risk management measures, which will ensure that benefits will outweigh costs. Of course, it is through these risk management measures that the health and environmental benefits of REACH will be delivered.

It is not possible to predict the total costs and benefits of risk management measures taken as a consequence of REACH until information is available for each substance on its intrinsic properties, its exposure and the availability of substitutes. This information will only become available after the testing and registration phase has been completed when, as described below, a socio-economic assessment will ensure that each measure proposed takes account of its costs and benefits.

The authorisation process contains provision for an authorisation to be granted if the risk to human health and/or the environment is adequately controlled or if it is deemed that the socio-economic benefits would outweigh the risk to human health and the environment arising from the use of the substance and there are no suitable alternative substances or technologies. Thus, an assessment of the relative costs and benefits of such measures and an analysis of the alternatives will inform any decision to restrict substances. This socio-economic assessment will act as an essential guarantee that every decision to restrict the use of a substance takes account of the resulting costs and benefits.

6.3.2. Potential long term health benefits of risk reduction measures - an illustration

The following illustrative scenario gives a feel for the potential magnitude of the health impacts, though it does not include the environmental impacts.

Estimating the benefits of REACH requires assumptions about the amount of disease that is due to chemicals, the proportion of this unknown amount of disease that will be identified by REACH, what proportion will be tackled through risk management measures after socio-economic assessments have been carried out, the number of lives subsequently saved and other health improvements, and the monetary value attached to these.

A starting point for the amount of disease attributable to chemicals is the World Bank estimate referred to in 6.1.4[34], that the proportion of all disease (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 for use in this scenario.

The next assumption necessary is the proportion of this disease that will be identified and tackled by REACH. Here, a figure of 10% is used, implying that 90% of the health impacts associated with chemicals are either related to historical exposures, will not be identified by REACH or cannot be tackled[35].

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[34] The World Bank estimate uses the analysis by Murray and Lopez, 1996, "The Global Burden of Disease"

[35] Support for this figure comes from RPA, ""Assessment of the Impact of the New Chemicals Policy on Occupational Health"," 2003

The figures above suggest that 45,000 DALYs will be avoided every year due to REACH. The translation of DALYs into mortalities depends on the precise nature of the health impact. For example, for occupational cancers in developed countries between 8 and 9 DALYs are equivalent to one mortality[36]. Assuming that on average 10 DALYs are equivalent to 1 life saved, then 45,000 DALYs would be equivalent to 4,500 lives saved per year due to REACH.

In line with an experts' workshop on valuing health impacts, a value per statistical life estimate of € 1 million is adopted[37]. Again, this is a conservative value, and does not include an adjustment for any pain and suffering related to cancer cases.

It is assumed that the positive effects on public health would start to occur 10 years after REACH starts to be implemented, and persist for another 20 years.

Using the prudent assumptions above, the total health benefits would be in the order of magnitude of €50 billion 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 billion. This is not an estimate of the benefits of REACH, but rather an illustration of their potential scale.

7 HOW TO MONITOR AND EVALUATE THE RESULTS AND IMPACTS OF THE PROPOSAL AFTER IMPLEMENTATION?

It will be necessary to keep all the different impacts set out earlier under close review in order to make sure that the implementation of the new legislation will result in a balanced outcome as required by the sustainable development approach. It will be important to monitor how the chemicals industry and their clients fulfil the new requirements and it should be ensured that SMEs understand the implications of REACH. In particular, the Commission will closely observe the industry's competitiveness, its environmental performance and any variations in employment over time.

Similarly, it will be necessary also to maintain close consultation with other stakeholders, such as environmental NGOs and consumer representatives, which will require the Commission to ensure that industry lives up to its obligations to produce safer chemicals.

The Commission will publish a first report reviewing the operation of the REACH legislation after six years and thereafter every 10 years.

8 STAKEHOLDER CONSULTATION

Stakeholders have been consulted continuously from the early stages of the development of the legislation.

Even before the White Paper was adopted, an initial brainstorming meeting was held in February 1999 with more than 150 stakeholders - regulators, scientists, industry, environmental and consumer NGOs as well as representatives from applicant countries. –This helped to provide the Commission with an overall view of the problems with the current system and potential solutions.

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[36] World Health Organisation, "World Health Report", 2002

[37] See http://europa.eu.int/comm/environment/enveco/others/value_of_life.htm for the papers of this workshop, a summary of the discussion and recommended interim values.

Subsequent to the publication of the White Paper, there followed a period of considerable public discussion, including hundreds of written comments from stakeholders on a range of issues linked to the proposed new system. This exchange of views took place in the course of conferences, stakeholder working groups and bilateral contacts between the services and stakeholders. Specific studies, notably in relation to the likely impact of the system proposed, were also initiated.

Both the Council of Ministers and the Parliament adopted conclusions on the White Paper and, in addition, several Member States and certain third countries, such as the United States, made known their views separately.

In May 2003, the Commission decided to launch an Internet consultation to consider the workability of the draft legislation, including the technical requirements. The consultation took place between 15 May and 10 July 2003.

More than 6000 contributions were received. Almost half of these were sent by industry – firms or associations. 142 NGOs, including trade unions, responded. From the Member States, six governments (DE, A, IRL, F, NL, UK) have sent comments, as well as a number of public authorities (A, B, D, DK, FIN, GR, I, NL, S, UK). Public authorities from three Accession countries (LAT, LIT, PL) gave their input as well as authorities and governments from third countries (Australia, Canada, Chile, China, Israel, Japan, Malaysia, Mexico, Norway, Singapore, Switzerland, Thailand, USA). The international organisations APEC and OECD also sent comments[38].

Approximately half of the contributions came from individuals. Many raised issues in relation to animal testing, others voiced fears of job-losses or demanded increased protection of the environment and human health and better information for consumers. In addition, two petitions were submitted, supported by 34000 individuals and organisations.

The overall thrust of the comments, including those made earlier by the Council and the Parliament, is supportive both of the aims, especially the sustainability dimension, and of the essential features of REACH. The reaction of stakeholders has been more questioning. In all cases, the issue of workability, (i.e. availability of resources, knowledge and technical capacity to operate the new system), is seen to be a key factor.

The comments received through the internet consultation have provided valuable information on ways of improving the workability of REACH. While retaining the main features of the system set out in the White Paper, the following adjustments have been made to the system in order to respond to the main issues raised:

– **Substantial simplification** of the requirements to be met by manufacturers and importers in relation to Chemical Safety Assessments and Chemical Safety Reports, and a much reduced burden for downstream users;

– **No registration or evaluation for polymers;**

– **Lighter registration for substances produced between 1 – 10 tonnes,** with reduced testing requirements and no need to complete Chemical Safety Assessments or Chemical Safety Reports;

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[38] Further details can be found at http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/contributions.htm

– **A reinforced authorisation system,** introducing a specific requirement for applicants to present a substitution plan in cases in which authorisations are being granted on socio-economic grounds;

– **Streamlined administration of REACH**, giving the proposed chemicals agency more responsibility in the areas of registration, evaluation and data-sharing;

– **Greater legal certainty** is provided through clarification of the requirements for the duty of care, the treatment of confidential data, exemptions for research and development and sanctions while still protecting health and the environment; and

– a more practical formula has been introduced for determining when substances in articles need to be registered or notified to the authorities.

9 CONCLUSION

The Commission's legislative proposals represent a balanced approach which will contribute to improved health for the citizens of the EU and greater protection of the environment; will bring added benefits to worker safety; will improve the conditions for innovation, by making it easier and cheaper to develop new and safer substances; and, also by limiting cost, will help to maintain the competitiveness of the chemicals industry.

The choice of a Regulation as the legal instrument, based on Article 95 of the Treaty, will ensure the integrity of the Single Market for chemicals.

The assessment of the economic, social and environmental impact of the proposals is a difficult exercise arising from a variety of factors such as the complexity of the value chain, the response of manufacturers of chemicals and downstream users notably as regards the development of co-operative structures, the results of waiving of tests and the prospects for the development, validation and application of non-animal test methods, and the impact of risk management measures, which may have to be taken on a voluntary basis or as a result of the authorisation and restrictions processes.

Taking account of the expected economic, social and environmental impact of its proposals, the Commission considers that the balance required by the sustainable development strategy has been achieved.