European Commission

Enterprise Directorate General

Environment Directorate General

Why do we need REACH?

REACH

in brief

How will REACH work?

What are the costs and benefits?

What is the state of play?

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1. WHY IS A NEW EU CHEMICALS POLICY NEEDED?

1.1 THE PROBLEMS OF THE CURRENT SYSTEM

The current EU legislative framework for chemical substances is a patchwork of many different Directives and Regulations which has developed historically. There are different rules for “existing” and “new” chemicals. However, this system has not produced sufficient information about the effects of the majority of existing chemicals on human health and the environment. The identification and assessment of risks - covering the hazard of a substance as well as exposure of humans and the environment to it – have proved to be slow, as have been the subsequent introduction of risk management measures. The current system has hampered research and innovation, causing the EU chemicals industry to lag behind its counterparts in the US and Japan in this regard.

The current distinction between so-called "existing" and "new" chemicals is based on the cut-off date of 1981. All chemicals that were put on the market before 1981 are called "existing" chemicals. In 1981, they numbered 100,106 different substances. Chemicals introduced to the market after 1981 (about 3000) are termed "new" chemicals.

While new chemicals have to be tested before they are placed on the market, there are no such provisions for "existing" chemicals. Thus, although some information exists on the properties and uses of existing substances, there is generally a lack of sufficient information publicly available in order to assess and control these substances effectively.

The current allocation of responsibilities is also not appropriate: Public authorities are responsible for undertaking risk assessments of substances rather than the enterprises that manufacture, import or use the substances; and these risk assessments are required to be comprehensive, rather than targeted and use-specific. Since 1993, only 141 high-volume chemicals have been identified for risk assessment and possible recommendations for risk reduction, of which only a limited number (27) have completed the process.

Furthermore, current legislation requires the manufacturers and importers of chemicals to provide information, but does not impose similar obligations on downstream users (industrial users and formulators) unless the substance has to be classified and a safety data sheet has to be supplied with it further down the supply chain. Thus, information on uses of substances is difficult to obtain and information about the exposure arising from downstream uses is generally scarce.

On the other hand, new chemicals have to be notified and tested starting from volumes as low as 10 kg per year. This has been a barrier to innovation within the EU chemicals industry by discouraging research and invention of new substances and favouring the development and use of existing substances over new ones.

If an EU wide control is necessary, the current process to restrict the marketing and use of substances has been very slow. It started in 1976 and restricts the marketing or use of only about 100 substances, including the use of some of them in articles, as well as the marketing to the general public of about 900 substances classified as carcinogenic, mutagenic or toxic to reproduction.

1.2 THE OVERALL AIMS OF THE NEW CHEMICAL STRATEGY

The two most important aims are to enhance the competitiveness of the EU chemicals industry and to improve protection of human health and the environment from the risks of chemicals.

In the White Paper on the Strategy for a Future Chemicals Policy, published in February 2001 (COM (2001) 88), the Commission outlined the result of a review of the current system and its new strategy for ensuring a high level of chemicals safety and a competitive chemicals industry through a system for the **R**egistration, **E**valuation and **A**uthorisation of **Ch**emicals – the REACH system.

The White Paper identified seven objectives that need to be balanced within the overall framework of sustainable development:

- Protection of human health and the environment
- Maintenance and enhancement of the competitiveness of the EU chemical industry
- Prevention of fragmentation of the internal market
- Increased transparency
- Integration with international efforts
- Promotion of non-animal testing
- Conformity with EU international obligations under the WTO.

The Council gave its opinion on the White Paper in its Conclusions of 7/8 June 2001 and the Parliament adopted a report on the White Paper on 15 November 2001. Both Council and Parliament endorsed the objectives.

Following the principles of Better Regulation, the Commission consulted widely in preparing its proposal. It convened a series of Technical Working Groups to seek advice from stakeholders and put a draft version of the proposal on the internet for public consultation in the Summer of 2003. More than 6000 distinct comments were received and taken into account by the Commission in preparing its final proposal, together with the views of the other Institutions.

The Regulation proposed by the Commission on 29 October 2003 achieves all the objectives identified in the White Paper and thus represents a model of sustainable development by pursuing objectives of the three pillars: economic (industrial competitiveness), social (health protection and jobs) and environmental.

2. HOW WILL REACH WORK?

REACH will create a single system for both “existing” and “new” chemicals. Its basic elements are:

1. **Registration** requires manufacturers and importers of chemicals to obtain relevant information on their substances and to use that data to manage them safely.

2. To reduce testing on vertebrate animals, **data sharing** is required for studies on such animals.

3. Better **information** on hazards and risks and how to manage them will be passed down and up the supply chain.

4. Downstream users are brought into the system.

5. The aim of **Evaluation** is to prevent unnecessary testing, by having authorities evaluate the proposals for testing made by industry and to check compliance with the registration requirements, and if not, ask industry for further information. Evaluation also enables authorities to investigate chemicals with potential risks by asking industry for further information. This information may be used later to prepare proposals under Restrictions or Authorisation.

6. Substances with properties of very high concern will be made subject to **authorisation**: Applicants will have to demonstrate that risks associated with uses of these substances are adequately controlled. In this case the Commission will grant an authorisation. Otherwise an authorisation may be granted for uses of these substances if the socio-economic benefits outweigh the risks and there are no suitable alternative substitute substances or technologies.

7. The **Restrictions** provide a procedure to regulate that the manufacture, placing on the market or use of certain dangerous substances shall be either subject to conditions or prohibited. Thus, restrictions act as a safety net to manage Community wide risks that are otherwise not adequately controlled.

8. A **European Chemicals Agency** will manage the technical, scientific and administrative aspects of the REACH system at Community level, aiming to ensure that REACH functions well and has credibility with all stakeholders.

9. A **Classification and labelling inventory** will help promote harmonisation of different classifications of a substance. For substances with carcinogenic, mutagenic properties and those toxic for reproduction (CMRs) as well as respiratory sensitisers there may be a Community wide agreement on the classification by the authorities.

10. **Access to information** rules combine a system of publicly available information over the internet, the current system of requests for access to information and REACH specific rules on the protection of confidential business information.

2.1 REGISTRATION

2.1.1 Substances on their own or in preparations

There is a general obligation for manufacturers and importers of substances to submit a registration to the Agency for each substance manufactured or imported in quantities of 1 tonne or above per year. Failure to register means that the substance is not allowed be manufacturing or importing.

However, the Regulation exempts certain substances that are adequately regulated under other legislation, like medicinal products, or that generally present such low risks as not to require registration, like water. Polymers are also exempted from the requirement to register, since they usually are not very hazardous, but in certain circumstances monomers in polymers, have to be registered. However, the registration of polymers may be reviewed later.

Manufacturers and importers of substances will need to obtain information on the substances they manufacture or import and use this information to assess the risks arising from the uses and to ensure that the risks which the substances may present are properly managed.

Registration documents the performance of this duty and requires manufacturers and importers to submit

- a technical dossier and
- a chemical safety report, for substances in quantities of 10 tonnes or more.

The **technical dossier** contains information on the properties, uses and on the classification of a substance as well as guidance on safe use.

To find out the properties of the substances, the information requirements in the testing annexes vary according to the tonnage in which the substance is manufactured or imported, and to the needs of the chemical safety assessment. The tonnage 'trigger' is chosen as it gives an indication of the potential for exposure.

General rules are set out for the use of existing information, techniques such as (Q)SARs and read across, and for waiving of tests. New tests are only required when it is not possible to provide the information in any other permitted way. For substances in quantities of 1 to 100 tonnes, information derived from the application of the relevant testing annexes needs to be submitted with the registration as well as all available information the registrant has. For substances in quantities of 100 tonnes or more (i.e. cases where more expensive tests, many on vertebrate animals, may be necessary) the manufacturer or importer who does not already possess the required information, only needs to submit proposals for testing for the purpose of registration for the tests required by Annexes VII and VIII. The necessity for and the quality of the testing proposal will be checked by the authorities in the evaluation process before the tests are performed, this is to save animals' lives and unnecessary costs. General provisions on the generation of information also ensure the quality of the information.

The **chemical safety report** (CSR) for substances manufactured or imported in quantities starting at 10 tonnes documents the hazard classification of a substance and the assessment as to whether the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioacccumulative (vPvB). The CSR also describes exposure scenarios for specific uses of substances classified as dangerous and for PBT and vPvB substances. Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends to control exposures of humans and the environment. The exposure scenarios must include the appropriate risk management measures that, when properly implemented, ensure that the risks from the uses of the substance are adequately controlled. Exposure scenarios need to be developed to cover all "identified uses" which are the manufacturers' or importers' own uses, and uses which are made known to the manufacturer or importer by his downstream users and which the manufacturer or importer includes in his assessment. Relevant exposure scenarios will need to be annexed to the safety data sheets that will be supplied to downstream users and distributors (see 2.3 and 2.4).

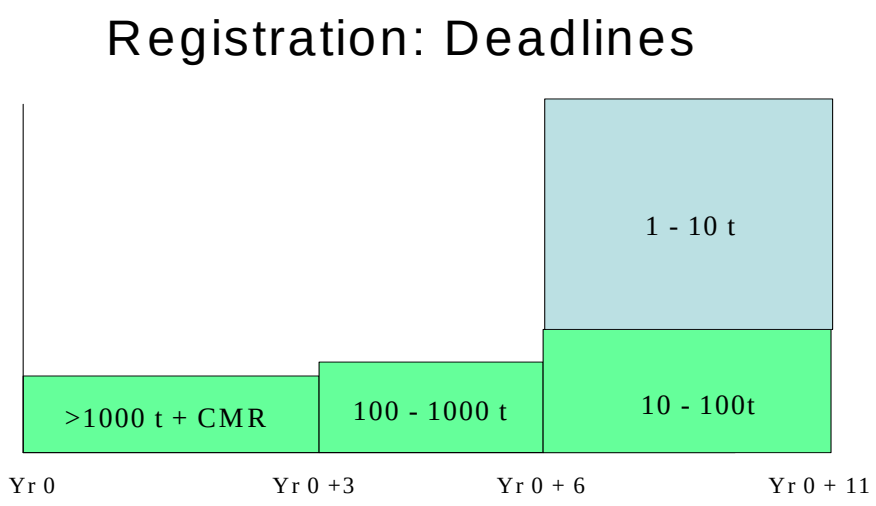
To reduce costs for industry and authorities, it is possible for registrants to form **consortia** in which case information on the properties of the substance and its classification is submitted by one member of the consortium on behalf of the others. The consortium can choose to submit the chemical safety report jointly or separately. Commercially confidential information will always have to be submitted separately. Consortia are encouraged but remain voluntary.

A "light" registration is required for certain **isolated intermediates**. These are substances that are used in the manufacturing process but are consumed or transformed into another substance and therefore are not present in the final manufactured substance. For those intermediates that do not leave the site on which they are used, and those that are transported between sites under controlled conditions, only the hazard classification and any information on the properties of the substance that is already available to the registrants need to be submitted to the Agency. If more than 1 000 tonnes of an intermediate are transported under controlled conditions, as the risk of exposure is potentially higher, information which is required for substances between 1 and 10 tonnes needs to be included in the registration dossier and submitted to the Agency.

To facilitate the transition to the REACH system, the registration provisions will be applied in a step-wise fashion to most "existing substances". For substances that have already been manufactured or that already have been on the Community market for the last 15 years, the so-called "phase-in" substances, a series of registration deadlines are established. Notifications under Directive 67/548/EEC are considered as registrations. They may need to be updated when a higher tonnage range is reached.

The Agency is responsible for managing all registrations. About 30000 phase-in substances are expected to be registered over the first 11 years after the entry into force of REACH, plus the "non-phase-in" substances. Given the number of registrations expected, only a simple completeness check will be performed by the Agency at this stage. The quality of the submitted dossiers may be checked in the evaluation process. If the registration is not rejected within a set deadline, then the registrant may begin (for non-phase-in substances) or continue (for phase-in substances) to manufacture or import the substance. However, this does not imply any form of approval by the Agency of the assessment or use of the substance.

Registration deadlines for phase-in substances in different tonnage ranges are illustrated below (Yr 0= entry into force):



2.1.2 Substances in articles

For the registration of substances in articles (e.g. manufactured goods such as cars, textiles, electronic chips), a special regime applies. The rules for substances in articles have been developed bearing in mind the need to adopt a proportionate approach to the millions of articles placed on the market in the EU, and the potential some of them may have to cause harm to human health and the environment due to the chemical substances contained in them. REACH requires certain substances that have been incorporated into articles to be registered according to the normal rules if those substances meet criteria for classification as dangerous and are intended to be released from the article during normal and reasonably foreseeable conditions of use. For substances that are not intended to be released, but may be released incidentally to the use of the article, a simple notification is required, on the basis of which the Agency may request a registration. The volume thresholds are as for any substance manufactured in, or imported into, the EU and apply per article type. The registration deadline is 11 years plus 3 months after the entry into force of the Regulation.

2.2 DATA SHARING

Rules on data sharing are set out to reduce testing on vertebrate animals and to reduce costs to industry. Data gained by animal testing are to be shared, in exchange for payment. Communication mechanisms are set up to enable and encourage manufacturers and importers to reach agreements on the sharing of studies on vertebrate animals.

For phase-in substances, a system is established to help registrants to find other registrants with whom they can share data and to get an overview about which studies are available (pre-registration). Pre-registrants of the same phase-in substance are then required to share existing animal test data and agree on the generation of new animal test data in a substance information exchange forum (SIEF).

The communication mechanisms set out may also be used for tests which do not involve vertebrate animals, since this will reduce costs.

2.3 INFORMATION IN THE SUPPLY CHAIN

The communication requirements of REACH ensure that not only manufacturers and importers but also their customers, i.e. downstream users and distributors, have the information they need to use chemicals safely. Information relating to health, safety and environmental properties, risks and risk management measures is required to be passed both down and up the supply chain, and between all actors in that supply chain. Commercially sensitive information is not required to be exchanged.

The primary tool for information transfer is the well-established and familiar safety data sheet (SDS) for all dangerous substances. The provisions of the current Safety Data Sheets Directive (91/155/EEC) are carried over into the REACH Regulation. As more information will be available as a result of registrations the quality of safety data sheets will improve. Where chemical safety assessments are performed according to the registration requirements, relevant exposure scenarios shall be annexed to the safety data sheet and shall thus be passed down the supply chain.

New information on hazardous properties and information that challenges the quality of risk management measures in the safety data sheets shall be passed up the supply chain.

2.4 DOWNSTREAM USERS

Downstream users may be any industrial user of chemicals, whether formulators of preparations (e.g. paint producers) or users of chemicals such as oils and lubricants in other industrial processes. They are required to consider the safety of their uses of substances, based primarily on information from their suppliers, and to apply appropriate risk management measures. Downstream users will need to communicate effectively with their manufacturers or importers, to get the information they need in the safety data sheet supplied to them. In particular they will have to check that their use(s) are “covered” by the safety data sheets, i.e. that they use a substance within the conditions described in the exposure scenarios in the Annex to the SDS, and apply these conditions.

To get the right information, downstream users have the right to make their uses known to their manufacturers or importers so that the manufacturers or importers can include these uses in their chemical safety assessments as "identified" uses. The relevant exposure scenarios developed for these uses will need to be annexed to the safety data sheets.

A downstream user can also choose to keep his use confidential or decide to use a substance outside the conditions described in an exposure scenario communicated to him. In these cases he will have to perform a chemical safety assessment himself: the downstream user chemical safety assessment consists of developing the exposure scenarios for his intended uses and, if necessary, a refinement of the supplier's hazard assessment.

If a downstream user is using a substance in quantities starting at 1 tonne per year outside the conditions described in the exposure scenario communicated to him in the safety data sheet he will need to report his use in a brief general description to the Agency. The chemical safety assessment itself does not have to be submitted with the report. These reports enable authorities to evaluate substances if reported uses give rise to concern and to take appropriate measures. In rare cases, the downstream user may propose additional testing if he considers this necessary to complete his chemical safety assessment.

2.5 EVALUATION

Evaluation under REACH is a structured means by which Member State authorities may examine registration dossiers. It may result in a request for further information on substances. There are two types of evaluation with different aims:

- Dossier evaluation: this is a quality check of the registration dossiers:
    - Checking of testing proposals: the aim here is to prevent unnecessary animal testing, i.e. the repetition of existing tests, and poor quality tests. Therefore, the authorities will check the testing proposals submitted as part of the registrations before such tests are performed;
    - Compliance check: Authorities may check the compliance of registration dossiers with the requirements laid down for registration in the Regulation;
- Substance evaluation: Authorities may clarify suspicions of risks to human health or the environment by requesting further information from industry.

  To promote a consistent approach, the Agency will develop guidance on prioritisation of substances for evaluation. Member States then prepare rolling plans of the substances that they wish to evaluate. A procedure is foreseen to resolve disagreements over which Member State evaluates which substance.

Any draft decision prepared by a competent authority of a Member State requesting further information on a substance must either be accepted by all other Member States' competent authorities in which case the Agency takes the decision or if an agreement cannot be reached the Commission takes the decision. The Agency is also given responsibility for assuring the consistency of such decisions at the draft stage.

Evaluation may lead authorities to the conclusion that action needs to be taken under the restrictions or authorisation procedures in REACH, or that information needs to be passed on to other authorities responsible for relevant legislation. The evaluation process will ensure that reliable and useful data is provided and made available to the relevant bodies by the Agency.

2.6 AUTHORISATION

For substances of very high concern, an authorisation is required for their use and their placing on the market.

The substances required to be authorised are substances which are:

– carcinogenic, mutagenic or toxic for reproduction (CMRs) category 1 and 2,

– persistent, bioaccumulative and toxic or very persistent and very bioaccumulative (PBTs/vPvBs), and

– identified as causing serious and irreversible effects to humans or the environment equivalent to those above on a case-by-case basis, such as endocrine disrupters.

These substances have hazardous properties of such high concern that it is essential to regulate them centrally through a mechanism that ensures that the risks related to their actual uses are assessed, considered and then decided upon by the Community. This is justified because the effects on humans and the environment of these substances are very serious and normally irreversible. Substances that fall into these categories will be fed into the authorisation system as resources allow. Their uses will not be banned by default.

The authorisation procedure consists of two steps: in a first step, a decision is taken via comitology as to which substances will be included in the system, which uses of the included substances will be exempted from the authorisation requirement (e.g. because sufficient controls established by other legislation are already in place) and which deadlines will have to be met. This step is necessary to prioritise substances and to focus resources. The Agency will prepare such decisions and recommend substances for inclusion, and interested parties will have an opportunity to comment on such recommendations.

Once a substance is included in the system, in the second step of the procedure, those using or making available such a substance will need to apply for an authorisation for each use of the substance within the deadlines set. The burden of proof is placed on the applicant to demonstrate that the risk from the use of the substance is adequately controlled or that the socio-economic benefits outweigh the risks, taking account of available information on alternative substances or processes. The Agency will provide expert opinions on the application and the applicant has an opportunity to comment on draft opinions. The Commission will grant an authorisation for each use for which the applicant's demonstration is successful. In case of authorisations that are granted for socio-economic reasons, the authorisations will normally be time-limited.

Downstream users may use a substance for an authorised use provided they obtain the substance from a company to whom an authorisation has been granted and that they keep within the conditions of that authorisation. Such downstream users will need to notify the Agency that they are using an authorised substance.

2.7 RESTRICTIONS

The Restrictions procedure enables to regulate Community wide in a focussed way conditions for the manufacture, placing on the market or use of certain dangerous substances or the prohibition of any of these activities, if necessary.

Note that all activities with a regulated substance which are not restricted are allowed unless the substance is included in the authorisation system.

Any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions if it is demonstrated that risks are not adequately controlled. Thus, the restrictions provisions act as a safety net.

Proposals for restrictions will be prepared by Member States or by the Agency on behalf of the Commission in the form of a structured Dossier. This Dossier is required to demonstrate that there is a risk to human health or the environment that needs to be addressed at Community level and to identify the most appropriate set of risk reduction measures. Deadlines for the procedure to prepare a Commission decision are set out in the Regulation. Interested parties will have an opportunity to comment and the Agency will provide opinions on any proposed restriction.

The existing restrictions set out in Directive 76/769/EEC (such as the ban on asbestos and restrictions on the uses of certain azo-dyes) are carried over in a consolidated version into the REACH Regulation. Also the ban of persistent organic pollutants (POPs) is carried forward.

2.8 EUROPEAN CHEMICALS AGENCY

A European Chemicals Agency is created to manage the technical, scientific and administrative aspects of the REACH system, and to ensure consistency of decision making at Community level.

The Agency manages the registration process. It plays a key role in ensuring a harmonised approach is taken to evaluation, by providing criteria to guide Member States' selection of substances for evaluation and by resolving disputes about requests for further information on substances arising from evaluation and takes such decisions. It provides expert opinions and recommendations to the Commission in the authorisation and restriction procedures and has duties with regard to confidentiality. It also handles requests for exemptions from the registration requirement for product and process oriented research and development, and facilitates the sharing of animal test data at the pre-registration stage by putting registrants of non-phase-in substances in touch with each other, and provides a database listing what studies are available to members of each SIEF.

In designing the structure of the European Chemicals Agency, the Commission considered its experience with existing agencies in other fields, in particular those in the field of medicinal products and food safety. The Commission also followed the principles set out in its recent Communication on the operating framework for European Regulatory Agencies. A number of new elements have also been developed to address the specific nature of the chemicals sector.

The Agency will comprise the following elements:

- a Management Board,
- an Executive Director, reporting to the Management Board,
- a Committee on risk assessment and a Committee on socio-economic analysis
- a Member State Committee,
- a Forum for exchange of information on enforcement activities. This Forum integrates the current informal network of Member States authorities into the Agency.
- a Secretariat that will provide technical, scientific and administrative support for the Committees and will undertake a number of other tasks.
- a Board of Appeal that will consider any appeals against the decisions of the Agency.

Following the decision taken by the Heads of State in December 2003, the Commission is working on the basis that the European Chemicals Agency will be located in Helsinki.

2.9 CLASSIFICATION AND LABELLING INVENTORY

A requirement for industry to classify and label dangerous substances and preparations according to standard criteria has long been a feature of the EU's chemicals legislation. REACH builds on the existing legislation. The classification and labelling inventory ensures that hazard classifications (and consequent labelling) of all dangerous substances manufactured in, or imported into, the EU are available to all with the aim of harmonising the classifications. Industry will be required to submit all its classifications to the Agency, to be included in the inventory, 3 years after the entry into force of the REACH Regulation. Any divergences between classifications of the same substance should be removed over time either through co-operation between notifiers and registrants or by EU harmonised classifications for substances that are category 1, 2, and 3 CMRs, or respiratory sensitisers.

2.10 ACCESS TO INFORMATION

Non-confidential information on chemicals, for example to allow those exposed to chemicals to make decisions on the acceptability of the related risks, will be made available. This is done in such a way that the interests of the public's 'right to know' is balanced with the need to keep certain information confidential. Some information will be published on the Agency's webpage, some information will generally be always kept confidential, and some may be made available on request in accordance with the Commission's normal rules on access to information.

3. WHAT ARE THE COSTS AND BENEFITS?

REACH creates a level playing field for "existing" and "new" substances. It simplifies EU level regulation in replacing 40 existing pieces of legislation and in creating a single system for all chemicals. By closing the knowledge gap for more than 30 000 existing substances it will provide information on both their acute and long-term effects. For industry, there will be higher demand for safer substances which will boost innovation while REACH gives more flexibility for chemicals undergoing research and development. The total costs to the chemical industry and its downstream users are between €2.8 and 5.2 billion.

3.1 DIRECT COSTS

In the REACH Impact Assessment the direct costs of REACH to the chemicals industry are estimated at a total of some € 2.3 billion over the first 11 years after the entry into force of the Regulation. This is a reduction of over € 10 billion compared to the earlier draft of the proposal that was published on the internet for consultation in May 2003. The draft proposal which was posted for Internet consultation has been thoroughly revised to cut costs and minimise bureaucracy whilst safeguarding human health and the environment. This reduction is due to changes such as reduced testing and reporting requirements and simplified registration procedures for low volume chemicals, exclusion of polymers from registration, and a major reduction in downstream user requirements.

3.2 COSTS TO DOWNSTREAM USERS

The costs to downstream users of chemicals are estimated at €2.8–3.6 billion if the market behaves as expected with 1–2 per cent of substances withdrawn because continued production would not be profitable. Costs could rise to €4.0–5.2 billion if industry faces higher supply chain adaptation costs. These estimates include the direct costs passed on from the chemicals sector to downstream users.

3.3 TOTAL COSTS

The overall costs to the chemicals industry and its downstream users would then be €2.8–5.2 billion. From a macroeconomic perspective, the overall impact in terms of the reduction in the EU's Gross Domestic Product (GDP) is expected to be very limited.

3.4 BENEFITS

With regard to the benefits, positive occupational impact and public health impact of REACH is expected as chemicals are linked to respiratory and bladder cancers, mesothelioma, skin disorders, respiratory diseases, eye disorders, asthma etc. Increased information on hazards and controls will help better implementation of existing legislation. Authorisation of substances of very high concern and speedier restrictions will also assist positive occupational and public health and positive environmental impact of REACH.

Public health benefits are based on World Bank estimates. This illustrative scenario is based on a number of prudent assumptions. Diseases caused by chemicals are assumed to account for some 1% of the overall burden of all types of disease in the EU. Assuming a 10% reduction in these diseases as a result of REACH would result in a 0.1% reduction in the overall burden of disease in the EU. This would be equivalent to around 4.500 deaths being avoided every year. On the basis of a € 1 million value of life, the potential health benefits of REACH could then be evaluated at approximately €50 billion over a 30 year period.

Due to lack of data it is not possible to provide a comprehensive quantitative assessment of the impacts on the environment. Much of the information needed will only be available after the chemicals on the market today have been tested and registered in line with the requirements of REACH. All in all, REACH will contribute to reduced pollution of air, water and soil as well as to reduced pressure on biodiversity. Improved control of persistent bio-accumulative and toxic substances is needed to ensure these substances are prevented from polluting the environment as once there they are very difficult to remove. In addition REACH will help to reduce the effects from endocrine disrupting chemicals.

4. WHAT IS THE STATE OF PLAY?

4.1 LEGISLATIVE PROCEDURE IN COUNCIL AND PARLIAMENT

Within the Council, Heads of State gave the Competitiveness Council the responsibility for REACH. An ad hoc working group (AHWG) of representatives of the Competitiveness and Environment Ministries is assisting in developing a Council Common position. The Italian Presidency held one and the Irish Presidency a number of meetings of the AHWG. The approach was to have a first, high level reading of the proposals to improve understanding. In this first stage, the Commission explained the proposal article by article and answered questions raised by the Member States. This first stage was completed by mid March 2004.

In the second part of the Irish Presidency, the Council ad-hoc working group focussed on identifying issues for policy debates in the Competitiveness and Environment Councils. A number of major cross-cutting proposals have been tabled by the Member States: a key issue is the UK/Hungary proposal for "one substance, one registration" (OSOR); but other proposals – for a duty of care; for more prioritisation; for more powers for the Agency; if the proposal encourage substitutions enough, and how to ensure the quality of information submitted – have also been discussed. The Netherlands Presidency has proposed to build on the work done so far by a detailed examination of the first three titles of REACH resulting in an annotated text with amendments, at least of the Titles dealing with registration and data-sharing, by the end of the year 2004.

In the European Parliament the committees giving an opinion on REACH will be: Environment Committee (probable Lead), Industry Committee and Internal Market and Consumer Affairs Committee (operating in close co-operation with the Environment Committee). Other Committees expected to provide opinions: Economic and Monetary Affairs, Employment and Social Affairs, Budgets, Women's rights and International Trade.

The Economic and Social Committee adopted an opinion on REACH in April 2004 (http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/c_112/c_11220040430en00920099.pdf).

4.2 FOLLOW-UP WITH STAKEHOLDERS WITH REGARD TO IMPACT ASSESSMENT

The Commission completed an extended impact assessment which accompanied the REACH proposal that covered the overall cost to chemical industry and its downstream users as well as its benefits. However the Commission has agreed a Memorandum of Understanding with UNICE and CEFIC to undertake a number of further focussed studies (business case studies) to analyse the potential impacts of REACH on:

- the availability of substances of critical importance to downstream users, specifically the issues of product withdrawal for commercial reasons and the time-to-market of substances;
- innovation;
- new Member States.

The assessments of business benefits have been also integrated into the analyses. The first 2 studies are being carried out together by KPMG on behalf of UNICE and CEFIC, whilst the 3rd by the Institute for Prospective Technological Studies of the European Commission Joint Research Centre (JRC-IPTS). This further work on impact assessment is being discussed in a working group with representatives from the Commission, from industry, from consumer and environmental NGOs and from Trade Unions. The results from these case studies are foreseen around the end of 2004. A number of impact assessment studies are also under development at Member State level. Recently, the Dutch presidency has called upon the Member States to send in impact studies for a workshop that will be held in October in the Netherlands.

In parallel the Commission has launched a study to assess the impact of REACH on the environment and human health that will complement the appraisal of benefits already included in the Extended Impact Assessment.

4.3 INTERIM STRATEGY

The Commission's 'interim strategy' covers all the practical activities that are underway to prepare the implementation of REACH. There are a number of elements to the interim strategy, the main ones being:

- The preparation of the new IT system to replace the existing system at the European Chemicals Bureau and to enable it to cope with the much heavier and more elaborate requirements of REACH. Good progress is being made in the design of the new system.

- The preparation of technical guidance to provide advice to industry, Member States and the Agency on the detailed requirements of the new system. Member States and NGOs will join industry and Commission staff in small sub-groups to manage the detailed technical work.

- Testing of elements of the REACH system in strategic partnerships.

- The practical arrangements for the establishment of the Agency in Helsinki.

5. MORE INFORMATION

http://europa.eu.int/comm/enterprise/reach/index.htm

http://europa.eu.int/comm/environment/chemicals/index.htm

http://ecb.jrc.it/REACH/

On the Commission websites you will find

- The text of the proposed Regulation
- Flowcharts on the functioning of REACH
- Questions and answers on REACH
- Process descriptions of REACH (REACH Implementation Project 1 (RIP 1))
- The Memorandum of Understanding on further work on impact assessment and an outline of further work
- Material on the Internet consultation
- Latest news
- Contact information
- Further details of the interim strategy