European Commission
Environment Directorate General

REACH

in brief

Why do we need REACH?

How does REACH work?

What are the benefits and costs?

What was the decision-making process?

How will REACH be implemented?

October 2007

Table of contents

1. WHY DID WE NEED A NEW EU CHEMICALS POLICY?

1.1 THE PROBLEMS OF THE FORMER CHEMICALS LEGISLATION

The former EC legislative framework for chemical substances was a patchwork of many different Directives and Regulations which has developed historically. There were different rules for “existing” and “new” chemicals. However, this system did not produce 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 possible hazards of a substance as well as exposure of humans and the environment to it – proved to be slow, as were the subsequent introduction of risk management measures. The former system hampered research and innovation, causing the EU chemicals industry to lag behind its counterparts in the US and Japan in this regard.

The distinction, introduced under regulation (EC) 793/93, between so-called "existing" and "new" chemicals was based on the cut-off date of 1981. All chemicals that were reported as being on the European Community market between 1 January 1971 and 18 September 1981 (listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)) were called "existing" chemicals. In 1981, they numbered more than 100.000 different substances. Chemicals introduced to the market after 1981 (more than 3800) were termed "new" chemicals.

While new chemicals have to be tested before they are placed on the market, there were 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 pre-REACH allocation of responsibilities was also not appropriate: Public authorities were responsible for undertaking risk assessments of substances rather than the enterprises that manufacture, import or use the substances; and these risk assessments were required to be comprehensive, rather than targeted and use-specific. Since 1993, only 141 high-volume chemicals were identified as priority substances for risk assessment. Recommendations for risk reduction were only available for a limited number of those chemicals for which the whole evaluation process under Regulation (EC) 793/93 has been completed.

Furthermore, the former legislation required the manufacturers and importers of chemicals to provide information, but did not impose similar obligations on downstream users (industrial users and formulators) unless the substance had to be classified and a safety data sheet had to be supplied with it further down the supply chain. Thus, information on uses of substances was difficult to obtain and information about the exposure arising from downstream uses was 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 pre-REACH process to restrict the marketing and use of substances has been very slow. It started in 1976 and restricted 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 (CMR substances).

1.2 THE OVERALL AIMS OF THE NEW CHEMICAL STRATEGY

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

In the Strategy for a Future Chemicals Policy, published in 2001 (COM (2001) 88), the Commission outlined the result of a review of the pre-REACH system and laid the basis for a new strategy for ensuring a high level of chemicals safety and a competitive chemicals industry through a system for the Registration, Evaluation and Authorisation of Chemicals – the REACH system.

The seven objectives that needed to be balanced within the overall framework of sustainable development were:

- 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.

2. HOW DOES REACH WORK?

REACH is based on the idea that industry itself is best placed to ensure that the chemicals it manufactures and puts on the market in the EU do not adversely affect human health or the environment. This requires that industry has certain knowledge of the properties of its substances and manages potential risks. Authorities should focus their resources on ensuring industry are meeting their obligations and taking action on substances of very high concern or where there is a need for Community action.

REACH creates a single system for both “existing” and “new” substances; substances are now described as non-phase-in substances (i.e. those not produced or marketed prior to the entry into force of REACH) and phase-in substances (those substances listed in the EINECS, or those that have been manufactured in the Community, but not placed on the Community market, in the last 15 years or the so-called “no longer polymers” of Directive 67/548).

Its basic elements are described below:

1. All substances are covered by the REACH Regulation unless they are explicitly exempted from its scope.

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

3. To reduce testing on vertebrate animals, data sharing is required for studies on such animals. For other tests, data sharing is required on request by other registrants.

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

5. Downstream users are brought into the system.

6. Evaluation is undertaken by the Agency for testing proposals made by industry or to check compliance with the registration requirements. The Agency co-ordinates substance evaluation by the authorities to investigate chemicals with perceived risks. This assessment may be used later to prepare proposals for restrictions or authorisation.

7. Substances with properties of very high concern will be made subject to authorisation; the Agency will publish a list containing such candidate substances. Applicants will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits of their use outweigh the risks. Applicants must also analyse whether there are safer suitable alternative substances or technologies. If there are, they must prepare substitution plans, if not, they should provide information on research and development activities, if appropriate. The Commission may amend or withdraw any authorisation on review if suitable substitutes become available.

8. 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.

9. The European Chemicals Agency (ECHA) will manage the technical, scientific and administrative aspects of the REACH system at Community level, aiming to ensure that the legislation can be properly implemented and has credibility with all stakeholders.

10. A classification and labelling inventory of dangerous substances will help promote agreement within industry on the classification of a substance. For some substances of high concern there may be a Community wide harmonisation of classification by the authorities.

11. Rules on the access to information 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 SCOPE

REACH is very wide in its scope covering all substances whether manufactured, imported, used as intermediates or placed on the market, either on their own, in preparations or in articles, unless they are radioactive, subject to customs supervision, or are non-isolated intermediates. Waste is specifically exempted. Food that meets the definition of a substance, on its own or in a preparation, will be subject to REACH however, such substances are largely exempted from Registration, Evaluation and Authorisation. Member States may exempt substances used in the interests of defence. Other substances are exempted from parts of REACH, where other equivalent legislation applies. The Commission will review the scope of the Regulation five years after entry into force.

2.2 REGISTRATION

Registration means that a manufacturer or importer has provided a registration dossier to the Agency and not received any indication that it is incomplete. This does not by itself mean that the dossier is in compliance with the legislation nor does it mean all the properties of the registered substance have been identified.

2.2.1 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. If a company fails to register a substance it means that this company is no longer allowed to manufacture or import this substance.

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, oxygen, certain noble gases, and cellulose pulp. In other cases substances occurring in nature such as minerals, ores and ore concentrates, cement clinker, etc are not required to be registered as long as they are not chemically modified. Polymers are exempted as well 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.

Those exemptions are contained in Annexes IV and V of the REACH Regulation and will be reviewed by the Commission by June 2008.

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, for substances in quantities of 1 tonne or more, 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, information requirements are set out in the testing annexes that 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' has been chosen as it gives an indication of the potential for exposure. Tonnage for phase-in-substances is calculated as a three-year average as long as they have been manufactured or imported for 3 consecutive years.

General rules are also set out for the use of existing information, techniques such as (Q)SARs ((Quantitative) Structure Activity Relationship) and read across, and for waiving of tests (omitting them if they are not required because of their use or it is not technically possible to carry them out). New tests are only required when it is not possible to provide the information in any other permitted way. Where new tests are carried out there are general provisions on the generation of information to ensure the quality of the information. Application of Good Laboratory Practice (GLP) is required only for toxicological and eco-toxicological tests and analyses.

Substances in quantities of 1 to 10 tonnes, non-phase-in substances and phase-in substances meeting at least one of the two criteria set out in Annex III of the REACH Regulation: **either** substances that are potentially carcinogenic, mutagenic or toxic to reproduction (CMR category 1 or 2), persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances **or** substances that are potentially dangerous to health or the environment and are used in dispersive uses are prioritised. Registrants have to submit a defined set of information (set out in Annex VII) along with any other available information. Other substances at this tonnage level have to submit a set of physicochemical information and any available and relevant (eco)toxicological information.

For substances in quantities of 10 to 100 tonnes, information derived from the application of the relevant testing Annexes (VII and VIII) needs to be submitted with the registration as well as all available and relevant information the registrant has.

For substances in quantities of 100 tonnes or more, information derived from the application of Annexes VII and VIII, as well as all other available information the registrant has, needs to be submitted with the registration. In addition, if the manufacturer or importer does not already possess the required information required by Annex IX, and for substances at or above 1000 tonnes, Annex X, proposals for testing for the purpose of registration need to be submitted. As those tests might be costly or involve testing on vertebrate animals, the necessity for and the quality of the testing proposal will be checked by the Agency in the evaluation process to save animals' lives and unnecessary costs.

The chemical safety report (CSR) for substances manufactured or imported in quantities starting at 10 tonnes, documents the hazards and classification of a substance and the assessment as to whether the substance is PBT or vPvB. The CSR also describes exposure scenarios for specific uses of substances that are classified as dangerous or are PBT or 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 and operational conditions that, when properly implemented, ensure that the risks from the uses of the

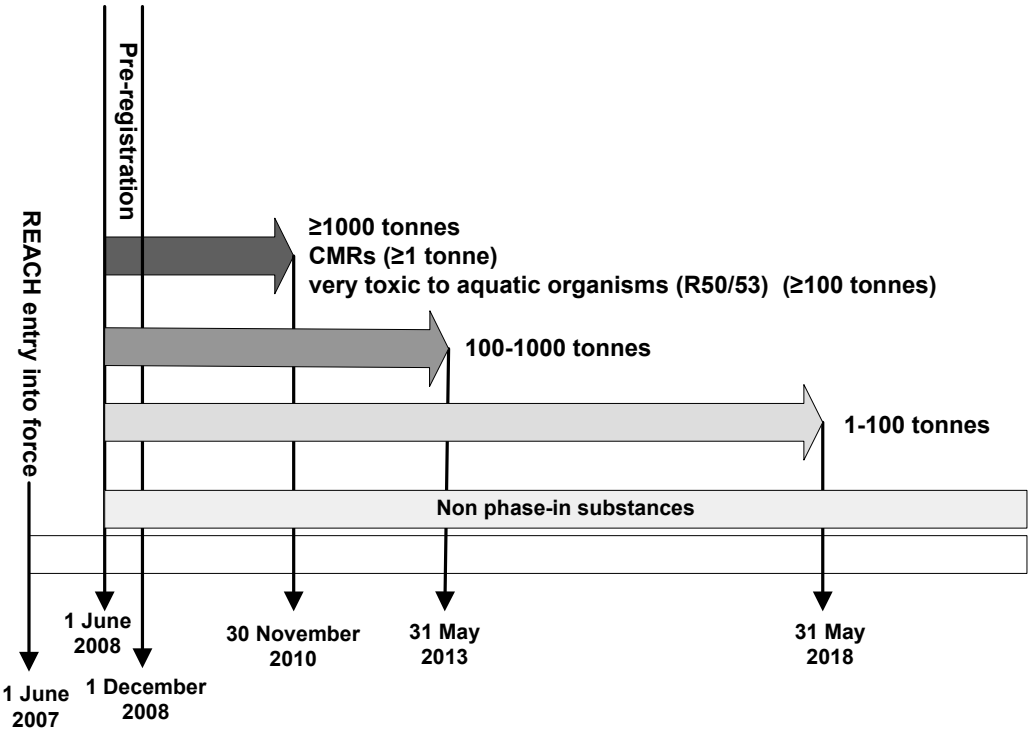
substance are adequately controlled. Exposure scenarios need to be developed to cover all "identified uses" which are the manufacturers' or importers' own uses, and uses which are made known to the manufacturer or importer by his downstream users and which the manufacturer or importer includes in his 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, the Agency and Competent Authorities, registrants are required to jointly submit information on the hazardous properties of the substance and its classification, and can, if they agree, also jointly submit the chemical safety report. The intention is that registrants will save money by co-operating on the preparation of the dossier. (This is in addition to the provisions of sharing of costs for generating information as described under section 2.3.) The information is submitted by one lead registrant on behalf of the others; the other joint registrants have to submit other information individually, such as their company details and their production volume. However, manufacturers and importers are allowed to opt out of the joint submission of registration dossiers if this would result in excessive cost, if they disagree with the lead registrant on the interpretation of information or if disclosure of confidential information would cause substantial commercial damage.

A "light" registration is required for certain isolated intermediates as long as they are being manufactured under strictly controlled conditions. Intermediates 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, any information on the properties of the substance that is already available to the registrants and information on the risk management measures applied, or recommended, 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 in Annex VII 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 phase-in substances manufactured/imported at and over one tonne per year. For these substances, a series of registration deadlines are established for the different tonnage ranges. In addition certain substances of high concern (CMRs and potential PBT/vPvBs (classified with N: R50-53)) will also need to be registered early. This is illustrated below (Yr 0= entry into force= 1 June 2007):

Registration: Deadlines



Notifications under Directive 67/548/EEC of 'new substances' are considered as registrations. They will need to be updated when a higher tonnage range is reached.

The Agency is responsible for managing all registrations. About 30,000 phase-in substances (excluding intermediates) are expected to be registered over the first 11 years after the entry into force of REACH, plus a number of “non-phase-in” substances. Given the number of registrations expected, only a simple electronic 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.

2.2.2 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 all substances that are intended to be released from articles during normal and reasonably foreseeable conditions of use to be registered according to the normal rules, including tonnage deadlines and information requirements, if those substances are present in the articles above 1 tonne per year.

In addition, all substances of very high concern (on a list of candidate substances for authorisation that will be published on the Agency-website) present in articles above a concentration limit of 0.1% weight by weight and present above 1 tonne per year must be notified to the Agency except where exposure to humans and environment can be excluded during normal conditions of use including disposal. In such case safety instructions should be provided. Information will also be made available to consumers on request.

As a safety net, the Agency can require the registration of a substance in an article at any time when it considers that its release poses a risk to human health or the environment.

2.3 DATA SHARING

Potential registrants of phase-in substances are required to pre-register their substances between 1 June 2008 and 1 December 2008. This is to facilitate data sharing and so reduce testing on vertebrate animals and to reduce costs to industry. For both phase-in and non-phase-in substances, data gained by vertebrate animal testing are to be shared, in exchange for payment. Communication mechanisms are set up to enable manufacturers and importers to reach agreements on the sharing of studies on vertebrate animals. Information not involving tests on vertebrate animals (e.g. in vitro studies and QSARs) must be shared on the request of a potential registrant.

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, gathering in a 'Substance Information Exchange Forum' (SIEFs), are then required to share existing vertebrate animal test data as well as other information and agree on the generation of new test data. Other holders of appropriate information (e.g. downstream users) are encouraged to join the SIEF to prevent the unnecessary duplication of existing data.

Downstream users of a substance that has not been pre-registered may ask the Agency to extend the pre-registration period by six months to give them more time to find a supplier or pre-register the substance themselves.

2.4 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. 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) were carried over into the REACH Regulation and in addition added the requirement for SDS to be provided for PBT or vPvB substances and preparations containing them. 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 need to be annexed to the safety data sheet and have thus to 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 will be passed up the supply chain.

2.5 DOWNSTREAM USERS

Downstream users (DU) 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 or producers of manufactured articles such as electronic components. 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. DU will need to communicate effectively with their suppliers, to get the information they need in the SDS supplied to them. In particular they will have to check that their use(s) are "covered" by the SDS, 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 relevant information, downstream users have the right to make their uses known to their suppliers so that the suppliers can include these uses in their chemical safety assessments as "identified" uses or pass the request on up the supply chain. Downstream users can apply a system of brief general descriptions of uses that can be used as a minimum to identify such uses to the supplier. The relevant exposure scenarios developed for these uses will need to be annexed to the SDS.

A DU can also choose to keep his use confidential or decide to use a substance outside the conditions described in the exposure scenario(s) communicated to him. In these cases he will have to perform a chemical safety assessment (CSA) developing the exposure scenarios for his intended uses and, if necessary, a refinement of the supplier's hazard assessment. This obligation does not apply if the DU uses less than 1 tonne of the substance per year. However, a DU relying on the 1 tonne exemption still needs to consider the use(s) of the substance and identify, apply and recommend appropriate risk management measures.

In rare cases, the DU may propose additional testing if he considers this necessary to complete his chemical safety assessment.

2.6 EVALUATION

There are two types of evaluation with different aims:

- **Dossier evaluation**: the Agency will do a quality check of the registration dossiers:
    - Compliance check: the Agency may check the compliance of registration dossiers with the requirements laid down for registration in the Regulation. At least 5% of dossiers should be checked;

- 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 Agency will check the testing proposals submitted as part of the registrations before such tests are performed. The Agency will also invite third parties to submit information that would avoid the need for vertebrate testing;

- **Substance evaluation**: The Agency in co-ordination with the Competent Authorities of Member States 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, in co-operation with the Member States, develop guidance on the prioritisation of substances for further evaluation. The Agency will publish a Community rolling action plan on its website identifying the Member State who shall carry out the evaluation of those priority substances.

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.

2.7 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:

– CMR category 1 and 2,

– PBT, vPvBs, and

– Identified from scientific evidence as causing probable serious effects to humans or the environment equivalent to those above on a case-by-case basis, such as endocrine disrupters. The European Commission will develop guidance to clarify the criteria for such a case-by case detection in close co-operation with in industry, Member States and other relevant stakeholders.

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 Agency will publish a list of substances meeting the criteria above and reflecting its multi-annual work plan, taking into consideration comments from interested parties.

The authorisation procedure consists of two steps: in a first step, a decision is taken via comitology as to which substances on the candidate list will be included in the system (Annex XIV), 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.

In the second step, , those using or making available a substance included in Annex XIV will need to apply for an authorisation for each use of the substance within the deadlines set, including an analysis of possible substitutes and including information on relevant research and development activities, if appropriate. If this analysis shows that suitable alternatives are available then the application must also include a substitution plan. An authorisation will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. If not, then it may also be granted if the socio-economic benefits outweigh the risks and there are no suitable alternative substances or processes. PBTs, vPvBs and those CMR substances for which a safe level cannot be defined, cannot be authorised based on adequate control of risk. Six years after the entry into force of the Regulation, the Commission will review whether endocrine disrupters should also be excluded from the adequate control route. 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 meeting the above conditions. All authorisations will be reviewed after a certain time which will be set on a case-by-case basis. In setting the length of this review period the Commission will take into account relevant information, including the risks of the substance and of alternatives, socio-economic benefits, analysis of alternatives and any substitution plan. If suitable substitutes have become available by the time of the review, the Commission may amend or withdraw the authorisation, even one given for adequate control. Downstream users may apply for their own authorisations or 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.

2.8 RESTRICTIONS

The Restrictions procedure enables to regulate Community wide, yet in a focused way, conditions for the manufacture, placing on the market or use of certain substances where there is an unacceptable risk to health or the environment or the prohibition of any of these activities, if necessary.

All activities with a substance which are not restricted are allowed under REACH 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 need to be addressed on a Community wide basis. 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.

2.9 EUROPEAN CHEMICALS AGENCY (ECHA)

The ECHA manages the registration process, carries out dossier evaluations and co-ordinates the substance evaluation process and generally takes decisions resulting from evaluations, except in cases of disagreement among Member States representatives when the Commission would decide. It provides expert opinions to the Commission in the authorisation and restriction procedures and has duties with regard to confidentiality and access to information. 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 enabling the formation of the Substance Information Exchange Forums (SIEFs).

The ECHA comprises 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 provides technical, scientific and administrative support for the Committees. It will also undertake a number of other tasks including pre-registration, registration, evaluation and information provision.
- a Board of Appeal that considers any appeals against the decisions of the Agency.

The ECHA is located in Helsinki and is required to be operational on 1 June 2008..

2.10 CLASSICATION 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 EC's chemicals legislation. REACH builds on 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 promoting agreement on the classifications. Industry will be

required to submit all its classifications to the Agency, to be included in the inventory by 1 December 2010.. Most 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, respiratory sensitisers, and other substances if justified on a case-by-case basis.

To complement REACH, the Commission adopted on 27 June 2007 a new proposal for a Regulation on classification, labelling and packaging of substances and mixtures (COM(2007) 355 final). The new proposal incorporates the classification criteria and labelling rules agreed at UN level, the so-called Globally Harmonised System of classification and labelling of chemicals (GHS). If agreement with the European Parliament and Council can be reached at first reading, the phasing-in of the new provisions could be made consistent with the relevant provisions of REACH, in particular the classification and labelling inventory.

2.11 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 web site, 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 an incentive for the use and development of safer substances which will direct and stimulate innovation while REACH gives more flexibility for chemicals used for the purposes of research and development.

3.1. 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.

The public health benefits of the Extended Impact Assessment of the Commission proposal were based on World Bank estimates and a number of prudent assumptions. Diseases caused by chemicals were 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 due to cancer being avoided every year. On the basis of a € 1 million value of life, the

potential health benefits of REACH were then estimated to be roughly € 50 billion over a 30 year period.

A study commissioned by DG Environment looked into the benefits of REACH derived from the fact that current chemicals releases to the environment and exposure of humans via the environment can be reduced. Through a number of cases using different appraisal methods, the study further illustrated that the long-term benefits of REACH would be significant. However, due to the limited number of cases and a general lack of data it was not possible to provide a comprehensive quantitative assessment of the overall impacts on the environment. Much of the information needed will only become available after the chemicals on the market today have been registered.

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.

3.2 COSTS

3.2.1 Direct Costs

In the Extended Impact Assessment the direct costs of REACH to the chemicals industry were estimated at a total of € 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 was thoroughly revised to cut costs and minimise bureaucracy whilst safeguarding human health and the environment. The reduction was 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.

The cost efficiency of the Commission's proposal has been further improved, in particular with the prioritisation scheme for the registration of substances with annual volumes between 1 and 10 tonnes; stronger incentives for registration consortia through the requirements on joint submission of data, SME fee reduction and wider exemption of substances used for R&D purposes. These changes have further reduced the overall direct cost.

3.2.2 Costs to Downstream Users

Assuming that the market behaves as expected with only 1-2 per cent of substances withdrawn because their continued production would not be profitable, the additional costs to downstream users of chemicals were estimated at €0.5 – 1.3 billion in a "normal expectation" case and €1.7 – 2.9 billion in a scenario with higher substitution costs assumed. The estimated total costs therefore ranged between €2.8 and 5.2 billion; how much of the total costs will be borne by the downstream users depends on the amount of the cost pass-through of the direct costs from the chemicals suppliers downstream.

The introduction of a tonnage threshold for downstream user obligations is intended to help

downstream user SMEs.

3.2.3 Total Costs

Combining the estimates of the direct and indirect costs, the Extended Impact Assessment of the Commission's proposal of October 2003 has estimated the overall costs to fall in the range of €2.8 - 5.2 billion. These costs will be incurred over a period of 11 to 15 years. Therefore, 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.

The Extended Impact Assessment and several background documents can be found at: http://europa.eu.int/comm/environment/chemicals/background/impact_assessment_intro.htm.

3.2.4 Further work on impact assessment

The Commission also carried out further work on the REACH Impact Assessment under a Memorandum of Understanding (MoU) between the Commission Services (DG Enterprise and Industry and DG Environment) and industry (UNICE/CEFIC) to further investigate the issues of the potential withdrawal of substances for commercial reasons, innovation and the potential impact on New Member States.

The results of this work led to modifications in the registration system for substances below 10 tonnes and on the requirements for substances below 100 tonnes. The average registration costs for this group were substantially reduced, for a large part through reducing the number of substances requiring any toxicology testing. A fee reduction for SMEs and a help desk arrangement focused on this type of companies has also been introduced.

4. HISTORY OF THE DECISION MAKING PROCESS

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 have discussed the proposal in great detail for about three years.

The Proposal was communicated to the European Parliament and the Council in November 2003. During the first reading, work in the Parliament was led by the Committee on the Environment, Public Health & Food Safety, which co-operated for this purpose with the Committee for Internal Market and Consumer Protection and the Committee for Industry, Research and Energy. Apart from these 3 committees, seven other parliamentary committees tabled amendments. The European Parliament adopted its first reading opinion in its plenary session on 17 November 2005.

Following the Parliament's opinion, the Council reached a political agreement on a Common Position in the Competitiveness Council of 13 December 2005 under the UK Presidency. The formal Common Position of the Council was approved under the Austrian Presidency on 27 June 2006.

The European Parliament adopted its second reading opinion (which reflected an agreement reached with Council) on 13 December 2006. The Council adopted **Regulation (EC) N° 1907/2006** on 18 December 2006.

5. HOW WILL REACH BE IMPLEMENTED?

5.1 INTERIM STRATEGY

The Commission's 'interim strategy' covers all the practical activities 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 formats and software to enable technical dossier development by industry and Member States and the submission of these dossiers to the Agency under REACH, as well as the development of a work flow IT system for dossier handling by the Agency, the Member States Competent Authorities.

- The preparation of technical guidance to provide advice to industry, Member States and the Agency on the detailed requirements of the new system. Experts from Member States, industry and NGOs are working closely together with Commission staff to manage the detailed technical work.

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

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

5.2 TRANSITIONAL AND IMPLEMENTING MEASURES

REACH aims to ensure a smooth changeover from the current legislation. It does this by setting appropriate deadlines for the repeal of various aspects of the current legislation and by setting corresponding deadlines for the phasing in of various provisions of REACH. It further aims to ensure that work undertaken under the current legislation is not wasted under REACH, in particular as regards the preparation of proposals for restrictions.

By 1 June 2008 the Commission will review Annex I (rules for chemical safety reports), Annex IV (substances exempted from registration where sufficient information is known showing that they cause minimal risk because of their intrinsic properties) and Annex V (substances exempted from registration under the pre-REACH legislation) of the REACH Regulation.

By 1 December 2008 the Commission will review Annex XIII (criteria for identification of persistent, bio-accumulative and toxic or very persistent and very bio-accumulative substances (PBTs and vPvBs).

By 1 June 2012, the Commission will review the scope of the REACH Regulation. This is to avoid

overlaps with other relevant Community provisions and the rules concerning the European Chemicals Agency.

By 1 June 2013, the Commission will review whether or not substances that have endocrine disrupting properties should still be authorised if a suitable safer alternative exists.

By 1 June 2019, the Commission will review whether or not to extend the obligation to submit a Chemical Safety Report (CSR) to CMR substances below 10 tonnes and after twelve years a similar review will consider all substances below 10 tonnes.

Furthermore, by 1 June 2019, the Commission will also carry out a review on whether or not to extend the duty to inform consumers about substances in articles to other substances which are not of very high concern but which could still be dangerous or unpleasant (e.g. allergens). The requirement for a reproductive toxicity test for volumes between 10 and 100 t per year (laid down in Annex VIII) will be also reviewed by the same date.

6. MORE INFORMATION

http://ec.europa.eu/echa/

http://europa.eu.int/comm/environment/chemicals/reach/reach_intro.htm

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

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

Environment Directorate General, European Commission, October 2007