

ANALYSIS OF STUDIES DISCUSSING BENEFITS OF REACH

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1. Aims and work process

Various studies have been carried out to determine the impacts of REACH on businesses and the European economy at large. Much less work has been carried out to determine its potential benefits for human health, the environment and for businesses.

The aim of this study was to:

- identify which types of benefits have been qualitatively described in studies on REACH
- identify how the described benefits have been linked to actual REACH mechanisms or policy outcomes of REACH and
- extract how the benefits have been assessed and quantified

It was not the aim of this report to provide an in-depth critique of each of the analysed studies or to develop a method for benefit analysis. However, the approaches and methods applied, questionable assumptions and procedures are described in the detailed analyses.

In order to focus the study analysis, a description of expected benefits was developed listing the types of benefits and linking these to specific mechanisms of REACH and its policy outcomes. This was based on own experience and assumptions about the impacts of REACH. It is provided as Annex to this report.

Most of the studies assessed have been produced in an early phase of the discussion on REACH. Some of them are based on the White Paper of 2001 and some on the Commission proposal of October 2003. Only the most recent study, namely the one on the impacts of REACH on developing countries, was based on the Council Common Position of December 2005. The studies are of varying scope, quality, level of uncertainty and depth of assessment. It was therefore not attempted to compare the studies.

There are significant differences in these three 'REACH versions' with regard to the main benefit triggers of REACH: the type of substance property information to be submitted in a registration dossier, the conditions under which a chemical safety assessment is required, the conditions of the authorisation procedure (candidate list, requirements of an application). The main principles of REACH, namely the shift of responsibilities from competent authorities towards industry, the shared responsibility in the supply chain and the same requirements for new and existing substances remained unchanged.

Not all available studies on the impacts of REACH were analysed in this review, but a selection has been made. It is the main aim of this overview to identify the various types of benefits described in existing studies, rather than to compare which stakeholders find which benefits relevant or how these benefits are quantified, studies were selected that focus on benefit assessment. Furthermore, the perspective of the various stakeholder groups were aimed to be covered as authors of these reports.

We acknowledge that we may have overlooked benefit descriptions by excluding some studies, which may be of relevance.

General REACH impact assessments are covered by the inclusion of the Commission impact assessment as well as by evaluating the summary of impact assessments carried out as preparation for a Commission workshop. Benefit assessments/descriptions were looked at as commissioned by DG Environment, Member States, industry and NGOs. The following studies have been analysed:

Table 1: List of studies analysed with regard to benefits

Title of study	Context
DHI: <i>The impact of REACH on the environment and human health</i> , September 2005	For DG Environment, based on October 2003 proposal
Global Development and Environmental Institute, Tufts University, Boston, USA: <i>The impact of REACH on developing countries</i> , March 2006	For EP, based on October 2003 proposal
David Pearce and Phoebe Koundouri: <i>The social cost of chemicals – The Cost and benefits of the future chemicals policy in the European Union</i> , May 2003.	For WWF, Based on White Paper of 2001
EU Commission: <i>Extended Impact Assessment</i> , October 2003.	Staff working paper, based on October 2003 version
Berkhout et. al.: <i>Innovation in the chemicals sector and the new European chemicals regulation</i> , September 2003.	For WWF, based on Consultation version of May 2003
RPA: <i>Assessment of the Impact of the New Chemicals Policy on Occupational Health</i> , March 2003	For DG Environment, based on White Paper of 2001
School of Health and Related Research University of Sheffield, UK: <i>The impact of REACH on occupational health – with a focus on skin and respiratory diseases</i> , September 2005.	For ETUC, based on October 2003 proposal
RPA/BRE: <i>The impact of the New Chemicals Policy on Health and the Environment</i> , June 2003.	For DG Environment, based on White paper of 2001
KPMG: <i>REACH – further work on impact assessment</i> , July 2005.	For UNICE/CEFIC, based on October 2003 proposal
Massey of GDEI, Tufts University: <i>Surviving REACH – A guide for Companies that Use Chemicals</i> , March 2005.	For ChemSec, based on October 2003 proposal
Danish Eco-council: <i>REACH – a leap forward for industry</i> , 2004.	For Nordic Council of Ministers, based on October 2003 proposal
Fraunhofer ISI, Ökopol: <i>Analysis of the costs and benefits of the new EU chemicals Policy – An examination based on selected sectors taking into account effects on competitiveness, innovation, environment, and health</i> , October 2004	For UBA, based on October 2003 proposal
ECORYS & Opdenkamp Adviesgroep: <i>REACH – The Impact of REACH - overview of 36 studies on the impact of the new EU chemicals policy (REACH) on society and business</i> , October 2004.	For The Netherlands presidency of the EU, various studies

2. Overview of potential benefits identified

In the description of benefits (c.f. Annex 1), three areas have been distinguished: Business benefits, benefits for human health and benefits for the environment. Most of the analysed studies focus on benefits for occupational health and the environment, whereas benefits for public health and benefits that directly relate to business performance are only briefly discussed, if at all.

The benefits are mostly described qualitatively in the studies analysed and quantification is attempted in a few cases. Many REACH impact assessments exercises have focussed on quantifying compliance costs for manufacturers and importers and benefits of REACH are seldom given the same attention. The benefits to public health have been calculated in two studies, however, without specifying the type of damage expected to be reduced and the mechanisms achieving these.

2.1. Basic REACH mechanisms that may cause benefits

The REACH system responds to a number of widely acknowledged shortcomings of the current system of chemicals control in Europe. This includes:

- Lack of information on substance intrinsic properties relevant to establish appropriate measures to control risks at user's level,
- Lack of information on substance properties to establish cause-effect links for chemical effects on human health and the environment
- Quality of safety sheets often insufficient to provide the user of a dangerous chemical with the information needed for efficient risk management with regard to workers, consumers and the environment
- Lack of legal responsibility on manufacturers and importers of existing substances to establish and document the condition of safe use for their products,
- Lack of mechanisms to avoid gaps in responsibility to identify risks and to take the appropriate measures throughout the lifecycle of a substance,
- Lack of information on the conditions of use available to the substance manufacturers preventing the development of appropriate product safety strategies at this level.
- Lack of harmonised concept to make best use of existing information before investing in the generation of new information and animal testing.

REACH is designed to overcome these shortcomings in the current system, and it is expected that this also contributes to i) a decrease of exposure of man and environment to dangerous substances (and hence adverse effects), ii) to more transparency on hazards, risks and exposure and iii) prevention of unnecessary testing of vertebrates

Assessing the benefits of REACH is hampered by various difficulties:

- Lack of data a) to characterise the baseline situation of current chemical exposures of humans and the environment and related risks or actual effects / damage and b) to characterise individual cause effect links c) to characterise gaps in the implementation of existing legislation
- Linking a measurable or predictable adverse effect related to chemicals to one or more of the shortcomings addressed above would need a case by case assessment on the reasons why a particular case or a series of cases occurred.
- The possibilities of current legislation have not yet been fully exhausted. Thus, when assuming that REACH would improve the situation it is important to distinguish whether it better facilitates the implementation of requirements within existing legislation or whether the new requirements of REACH are expected to address the shortcomings in the current legislation.
- Benefits of REACH depend on the type of behaviour of the different actors, as many mechanisms realise through the generation of information. If and in particular to which extent this information is actually used to reduce the risks related to chemicals and to produce safer products is difficult to predict.

- Extrapolating effects from case examples involving one particular substance and exposure in a well-defined region to larger domains with wider or different exposure patterns, or to more chemicals is not a straightforward matter but is rather complex.

2.2. Business benefits

Benefits enterprises can have from REACH can be differentiated into cost savings and non-monetary advantages on the market. Cost savings could be realised by using the more comprehensive and new REACH-information to make better choices for raw materials, to manage more efficiently the risks on the own site and those along the supply chain or to prevent unnecessarily frequent changes in process or product design due to emerging chemical issues etc.¹ Direct benefits could stem from the alleviated requirements for new substances and R&D as well as the harmonisation of chemicals legislation (less costs to comply with different provisions). Market advantages could result from the availability of better information, but also from the prevention of unfair competition (level playing field) or improved cooperation along the supply chain as well as improved corporate reputation. The following table lists which potential benefits are discussed in the studies and which REACH triggers² were linked to them. Consequences of the implementation of REACH that can lead to improvements in business performance because they are an immediate requirement of REACH or they could cause immediate effects are called direct effects. REACH mechanisms that enhance existing procedures or company policies as well as the implementation of existing requirements are specified as indirect effects.

Table 2: Potential business benefits discussed in the analysed studies

Benefit	REACH effect	Studies discussing benefit	Remarks
Enhancing more efficient and effective RMM at enterprise level	Direct: RMM information in exposure scenario to be implemented, information on substance properties Indirect: proof of better chemicals risk management may lead to reduced legal insurance costs	COM: extended impact assessment – qualitative Chemsec: Surviving REACH – qualitative Danish Eco-Council: Leap forward – qualitative KPMG: further work on impact assessment UBA: benefits in selected chains - qualitative WWF: innovation in chemicals - qualitative	Savings / improved efficiency in risk management have not been described in detail or quantified. Differences between improved RM for workers, consumers or environment have not been made.
Reducing costs from health damage of workers Improving well-being of workers	Indirect: better information on substance properties	Chemsec: Surviving REACH – qualitative ECORYS: summary IA's – quantitative ETUC: impacts occupational health – quantitative RPA: occupational health – quantitative, but savings for business (lost output) not singled out UBA: benefits in selected chains - qualitative	Authorisation only mentioned by RPA as driver for workers health protection (enhances implementation of existing legislation for SVHC), role of ES not discussed either
Better conditions and positive incentives for innovation	Direct: reduced requirements for 'new' substances Indirect: better / comparable information on substance properties; better information on substance uses at M/I aids R&D; enhancing fairer competitive situation for safe products	Chemsec: Surviving REACH – qualitative COM: extended IA – qualitative Danish Eco-Council: Leap forward - qualitative ECORYS – Summary IA's - qualitative UBA: benefits in selected chains - qualitative WWF: Innovation in chemicals – qualitative	Also negative impacts on innovation predicted, innovative advantages will only realise for some companies.

¹ It has to be noted that e.g. due to the phase in scheme in the first years of REACH information is provided 'step-by-step' potentially increasing the need to reformulated.

² For more details on the benefits, c.f. initial description of REACH-benefits

Benefit	REACH effect	Studies discussing benefit	Remarks
Prevention of business risks, better corporate reputation	Indirect: more / better information on substance properties and uses, information in the supply chain; improved corporate reputation	Chemsec: REACH in developing countries – qualitative Chemsec: surviving REACH – qualitative ECORYS: summary IA's – qualitative UBA: benefits in selected chains - qualitative	No information on the baseline was found in the studies related to the prevention of liability claims.
Safer substitutes have better market chances	Indirect: more / comparable information on substance properties Indirect: identification of SVHC	Chemsec: Surviving REACH - qualitative COM: extended IA - qualitative Danish Eco-Council: Leap forward - qualitative UBA: benefits in selected chains - qualitative	Authorisation was not explicitly mentioned as trigger for developing new substances, however; the provision of the candidate list was introduced only after the studies were finished. Negative effects through substance withdrawal predicted
More efficient chemicals risk communication	Indirect: standardised communication on risk through RIPs and ES; shared responsibility triggers supply chain to develop common strategy	COM: extended IA - qualitative UBA: benefits in selected chains - qualitative WWF: Innovation in chemicals – qualitative	Only vaguely described in all studies
One regulation for all	Direct: replacement of other directives, harmonised implementation in MS	Chemsec: Surviving REACH - qualitative Danish Eco-Council: Leap forward – qualitative	
Market is more predictable	Direct: time schedule of REACH and defined procedures	Danish Eco-Council: Leap forward - qualitative WWF: Innovation in chemicals – qualitative	

2.3. Benefits for the environment

The benefits of REACH related to the environment are detailed at three levels in the benefit description: less actual damage to the environment, lower spending to remediate or compensate for environmental damage and lower risks of damage to the environment; inevitably, these levels overlap. All three levels were found in the analysed studies. The prevention and remediation of environmental damage were quantified and monetised in some studies.

Table 3: Environmental benefits discussed in the analysed studies

Benefit	REACH effect	Studies discussing benefit	Remarks
Less environmental damage	Indirect: better information on substance properties and safe conditions of use	COM: extended IA - qualitative RPA & BRE: env. and hh benefits – qualitative + examples	Quantification in 'damage units'. No monetisation of this benefit type
Less spending for environmental damage	Direct: safety assessment before marketing; (quicker) implementation of risk management measures; control of uses through authorisation	Chemsec: Developing countries – qualitative Chemsec: Surviving REACH – qualitative DHI: impact env and hh - quantitative ECORYS: summary IA's – qualitative + example PCB clean-up RPA & BRE: env. and hh benefits – qualitative + examples	Quantified examples were not extrapolated in the studies.
Reducing risk to the environment from SVHC	Direct: through implementation of RMMs; through the implementation of (conditions of the authorisation)	COM: extended IA - qualitative ECORYS: summary IA's – qualitative DHI: impact env and hh - quantitative	Both, information from registration and the authorisation scheme are mentioned

2.4. Benefits for occupational health

Benefits related to occupational health are described as the prevention of occurrence of occupational diseases and respective costs (curative, disabled life years and costs for employers) through the generation and communication of more and better information on substance properties and risks. The role of the exposure scenario in exposure reduction and damage prevention was not further described

in the studies. When the studies make reference to the benefit trigger 'registration', it may be that also the safety assessment, respective reformulation of products and/or recommendation of safe conditions of use are addressed; however this is not made explicit. As workers protection legislation exists, REACH is seen as making the implementation of that legislation more efficient, mainly through the provision of better hazard information.

Table 4: Occupational health benefits discussed in the analysed studies

Benefit	REACH mechanism	Studies discussing benefit	Remarks
Less public spending to compensate damage	Indirect: better information through registration, authorisation and restrictions procedure	Chemsec: Developing countries – qualitative ETUC: occupational health - quantitative RPA: occupational health – quantitative UBA: benefits in selected chains - qualitative	This benefit relates to the medical care costs for curing workers' diseases borne by society as a whole (through the public health system).
Less incidence of occupational diseases	Indirect: better information through registration	ETUC: occupational health - quantitative RPA: occupational health – quantitative	This benefit relates to the quality of life of the worker, whereas related savings to employers are discussed in Section 5

2.5. Benefits for public health

Benefits related to public health are only roughly described in the studies and neither related to specific types of health damage from chemicals nor to specific sources of exposure.

Table 5: Public health benefits discussed in the analysed studies

Benefit	REACH mechanism	Studies discussing benefit	Remarks
Less public spending for public health damage	Direct: control of uses through authorisation Indirect: better information through registration (substance properties and RMMs)	RPA & BRE: env. and hh benefits– quantitative examples	Food chain effects and purification costs of drinking water addressed
Less incidence of public diseases	Direct: control of SVHC in consumer products through authorisation Indirect: better information through registration	UBA: benefits in selected chains – qualitative and examples WWF: social costs of chemicals - qualitative	Discussion of allergies and skin cancer incidents. Baseline: Use of SVHC in consumer preparation forbidden under current legislation (except PBTs)
Reducing risks/exposures of the general public	Direct: control of SVHC in consumer products through authorisation Indirect: better information through registration (properties and safe use)	COM: extended IA - qualitative DHI: impact env and hh - quantitative ECORYS: summary IA's – qualitative UBA: benefits in selected chains – qualitative and example	General reference to REACH triggers, however little argumentation

3. Results of the assessment of business benefit descriptions

3.1. Prevention of business risks related to liability claims

Several studies³ mention the prevention of business risks related to liability claims as benefit for enterprises, which would be realised through the generation of new information on substance properties enabling the development and improved control of chemical products through the chemical safety assessment as well as enforcing the general duty of care. This effect appears logical but is not supported by evidence or examples in the studies. A result of the chemical safety assessment will be that M/I cannot market their substances for which used are shown to pose risks. This signifies a reduction of business risks for M/I, as downstream users applying a substances in a use not supported by their M/I will be responsible for that and cannot make their suppliers liable. The extent to which uses currently posing risks will be identified and not supported any more can not be derived from the information in the studies, due to lack of data on the current situation and predictions of the situation under REACH. Shared responsibility in the supply chain and generation and communication of risk information is seen as the REACH-trigger of these types of benefits.

The improvement of corporate reputation is another perspective on prevention of business risks detailed in one study⁴. It is stated that a good company reputation improves the financial performance, decreases crisis recovery times and encourages supportive behaviour of other stakeholders, all of which could reduce business risks in general. It is neither specified how reputation related to chemicals could be measured nor how the improvement of reputation could be achieved by the implementation of REACH. The benefits have not been quantified.

No information⁵ on a potential baseline scenario could be provided in the studies in terms of how many liability claims are currently incurred and how high the related expenses are⁶. It is not specified whether liability claims are expected from consumers or from enterprises, nor is it considered that new information may also lead to higher risks of liability claims.

³ Chemsec: REACH in developing countries, Chemsec: surviving REACH, ECORYS: summary IA's, UBA: benefits in selected chains

⁴ ERM: New European Chemicals Strategy, UK partial regulatory impact assessment. The study was referenced in the overview of impact assessments and assessed for this benefit, as it was described only by ERM. The study was not fully analysed as the main studies analysed.

⁵ The study '*Surviving REACH*' quotes liability claims related to the use of asbestos in the United States and gives further, unquantified, examples. However, the liability system in the United States differs considerably from that implemented in the EU and can thus not be regarded as reference scenario.

⁶ This concurs with a fast track review of RPA carried out in the context of their REACH Technical Assistance work for DG ENTR in 2006. This review did not reveal clear examples of chemical related liability cases resembling the potential cases under REACH. Neither have such liabilities had an impact on Mergers & Acquisitions. RPA argues that therefore any reduced risk for public liabilities seem to benefit insurance companies more than chemicals companies.

3.2. More predictable market conditions

One business benefit of REACH is seen in a more predictable chemicals market⁷. The underlying assumption is that the current chemicals market is insufficiently safeguarded from unpredictable events (e.g. sudden identification and scandalisation of a substance of high concern) as it lacks a systematic screening of eco-toxicological consequences of chemicals. This unpredictability is stated to impair business performance.

REACH aims to systematise chemicals regulation based on information, which would provide long-term perspectives to enterprises and thus a better basis for planning and decision making⁸. The higher predictability of the chemicals markets also implies that the frequency of and the costs for re-formulation of preparations and/or re-design of articles could be avoided. This consequence of a better predictable market has been qualitatively described in the UBA study, including some data on reformulation costs. However, the extent to which REACH would prevent such costs is not given.

An overall baseline description on current market conditions was not found in the assessed studies. The UBA study provides some data regarding legally required substitution versus market dynamics.

3.3. Reduced company costs related to occupational health

Several studies⁹ describe business benefits in terms of savings related to occupational health; the benefits for employers are however, usually not separated from the overall saved costs¹⁰.

The REACH mechanism triggering potential benefits is seen primarily in the identification of dangerous properties of substances in the registration. The chemical safety assessment and the resulting identification and recommendation of safe conditions of use¹¹ as well as the authorisation procedure of SVHCs are mentioned less frequently and with less impacts on improving workers' health.

Due to different data management systems in the Member States and insufficient level of detail in the available data, an overall baseline situation could not be described. Information on workers health costs at company level have not been quoted in the studies. Whereas some studies assume that REACH will have an effect on exposures to all chemicals, others only look at chemicals where little or no information is available or cause – effect links are not established at present. A clear illustration of how the information generated through REACH would impact on the frequency of diseases was not identified.

⁷ Danish Eco-Council: Leap forward; WWF: Innovation in chemicals

⁸ However, non –standard or new effects may even be missed under REACH.

⁹ Chemsec: Surviving REACH, ECORYS: summary IA's; ETUC: impacts occupational health, RPA: occupational health

¹⁰ There are considerable differences between MS in who pays and how. This might be one reason for the lack of information on the distribution of benefits

¹¹ It may be that the chemical safety assessment and related communication of conditions of safe use are included in the mechanism 'registration' and the authors have not distinguished between hazard and exposure information made available through REACH.

Nevertheless, cost savings for employers were quantified by assuming the number and types of occupational diseases that could be prevented by REACH. The resulting benefits have been quantified by summing up employers' costs for lost, less effective or disabled workers¹².

3.4. More efficient and effective risk management at enterprise level

Five studies¹³ state that chemicals risk management at company level could benefit from REACH resulting in lower expenses. The REACH mechanism through which this would be realised is the improved chemicals information, in particular on safe handling and risk management measures. Concrete examples illustrating this mechanism were not found in the studies. Some studies provide some details of the nature of benefits, which could be e.g. reduced legal and insurance costs for chemicals users, less effort needed to answer customer requests etc and less efforts to optimise risk management measures.

Current expenses for risk management and improvement possibilities have not been detailed in the studies. Thus, no baseline is described against which benefits from REACH could be measured. Potential benefits are qualitatively described but not quantified.

3.5. Reduced communication efforts through the introduction of standard procedures to facilitate communication on chemical safety along the supply chain

In the Commission Impact Assessment as well as in the UBA study discuss the potential of REACH to enhance strategic and systematic risk management in the supply chain as potential indirect benefit from REACH. The REACH mechanism facilitating this type of benefit is the shared responsibility along the supply chain made concrete via the exposure scenario and the communication needs as well as the agreed rules on how to do this (REACH requirements plus guidance on interpretation and implementation).

Related to the baseline situation of supply chain management it is described that improvements with regard to communicating on and managing of chemical risks are possible. It is not specified which types of problems or inefficiencies faced today could be addressed. The benefit descriptions are qualitative.

¹² Societal and individual costs are also part of these assessments. Since in this chapter only the benefits for businesses are addressed, these are not further discussed here. For more details on the quantification method, c.f. Section 5

¹³ COM: extended impact assessment, Chemsec: Surviving REACH; Danis Eco-Council: Leap forward; KPMG: further work on impact assessment; UBA: benefits in selected chains; WWF: innovation in chemicals

3.6. Better conditions for innovation

Several studies¹⁴ state that the overall conditions for innovation will be improved by REACH. This relates to the development of new substances as well as new uses of existing substances and/or product and process optimisations. REACH mechanisms triggering the benefit:

- a) all substances have to be registered → regulatory differences between “new” and “existing” substances (i.e introduced on the EU market before or after 1981 respectively) are eliminated; equal requirements apply
- b) the requirement to register applies from a higher tonnage (1 tonne instead of 10 kg) and is less strict compared to the Dangerous Substances Directive → substance development becomes less risky
- c) all market actors have better hazard, risk and use information → the decision basis for R&D is more complete, long term planning becomes easier. Information exchange on substances may lead to coordinated decisions on substance uses by all concerned actors
- d) REACH will foster competition in the field of product safety and information on safe handling and use → R&D for safer products will be rewarded on the market

The listed mechanisms have also been considered in the benefit description prepared before the analysis. In addition, the provisions for product and process oriented research and development (PPORD) exemptions have been listed but were not mentioned in the studies.

Related to the baseline situation, in the studies it is assumed that current market conditions don't optimally support innovative activities. However, this has not been detailed at company level nor have concrete indicators for measuring innovative activity been described¹⁵. As usually the case on prospective innovation appraisals, the extent to which REACH would support innovation is not quantified¹⁶.

3.7. Level playing field: one regulation only

Two studies¹⁷ mention the fact that enterprises may save costs and resources as they have to comply only with one harmonised chemicals regulation on Community level in the future. Here, REACH as such triggers the benefits as it replaces and integrates existing legislation on Community level, also preventing fragmentation on the Internal Market through some Member States setting up their own registration system.

¹⁴ Chemsec: Surviving REACH; COM: extended IA; Danish Eco-Council: Leap forward; ECORYS – Summary las; UBA: benefits in selected chains; WWF: Innovation in chemicals

¹⁵ This issue is addressed in some of the studies on costs of REACH. These studies were not analysed and therefore, respective considerations or assessments are not included here.

¹⁶ Some studies also mention some negative incentives from REACH on innovation on short and medium term, such as the registration costs and the enhanced regulatory requirements on “existing” substances.

¹⁷ Chemsec: Surviving REACH; Danish Eco-Council: Leap forward

Regarding the baseline it is assumed that significant expenses stem from assessing and implementing compliance with different chemicals legislation in different EU Member States¹⁸. It has not been specified how many resources are spent by companies nowadays for complying with different legislation. The potential benefit has not been quantified or valued.

3.8. Better market chances for safer substitutes

Several studies¹⁹ state that REACH motivates manufacturers to develop safer alternatives once substances of very high concern are identified or applications become known, where the risks from the use of a substance cannot be adequately controlled²⁰. Information on problematic chemicals would be made available in the classification and labelling inventory and the REACH data base, which could be an incentive for searching for and developing of alternatives. Substance withdrawal would be followed by substitution efforts of the market actors stimulating the demand for less dangerous alternatives.

The benefit was described as being triggered by the same mechanisms as assumed in the original listing before the study analysis, also. In addition, the availability of a comparable data set for all substances was given as another factor enhancing substitution rather at formulators than at manufacturer's level.

The difficulties and barriers to the development and use of safer alternatives for substances of very high concern faced by manufacturers, formulators and end-users of chemicals are described qualitatively in the studies. This does not include a specification of numbers of actors involved, current substitution activities or costs for substitution²¹. The benefits for developing or using safer substitutes have not been quantified.

3.9. Benefits not discussed in any of the studies

Several potential benefits were identified and described in the benefit description before the analysis (c.f. Annex) but haven't been described or assessed in the analysed studies. The reasons for this could be that few studies focussed on business benefits and did so at a rather general level as their purpose was more to illustrate benefits in other areas. Another reason may lie in an insufficient understanding of the studies' authors on how REACH will affect companies at a detailed level and/or the REACH version on the basis of which the study was conducted. Finally it may be a result of the level of detail provided in the benefit description paper compared to that in the studies analysed.

It is acknowledge that due to the nature of REACH and the fact that benefits may be created indirectly through the use of (new and better) information, establishing 1:1 links between a particular REACH mechanism and a benefit may principally be difficult. The following potential benefits were not found in the analysed studies.

¹⁸ This aspect relates to chemicals legislation only. Requirements from environmental, occupational health and other existing legislation remain in place an their implementation may differ across the EU.

¹⁹ Chemsec: Surviving REACH; COM: extended IA; Danish Eco-Council: Leap forward; UBA: benefits in selected chains

²⁰ As has been shown in the company survey on authorisation undertaken by RPA under their Technical Assistance work for DG ENTR and the case study on the announcement effect of the candidate list by Ökopol, substitution incentives are most likely to come from the formulators and end-users of chemicals rather than the manufacturers.

²¹ Case studies on substitution are available however in other publications.

3.9.1. Limiting testing costs due to accepted rules for use of non-test data and an information exchange platform for substance information

The use of (Quantitative) Structure Activity Relationships (QSARs) and other non-test data is seen as an option to decrease costs in the testing of substances by the Commission Impact Assessment. However, this is not seen as a benefit against the current situation, as testing would not be required without REACH and indeed it is unclear to which extent enterprises are currently using QSARs. The indirect benefit of REACH could nevertheless be seen in an enhanced development of QSARs and other non-test methods, the development of guidance on how to use these and increasing of acceptance of this information in the long term.

The establishment of a platform for facilitating cooperation in particular in the area of data exchange (c.f. Substance Information Exchange Fora (SIEFs)) and substance assessment is not identified as a benefit to the current situation in the studies, either. Thus, it is also assumed that enterprises do not (want to) voluntarily test their substances²² in order to fulfil their obligations under the General Product Safety Directive or the general duty of care. Currently information is exchanged within industry, and cooperation projects such as HERA exist, but are mostly run by the larger companies and are initiated by associations. Thus, whether or not enterprises will experience the need to cooperation in SIEFs as benefit or not remains to be shown.

3.9.2. Less costs from penalties related to environmental emissions

Whereas reduced costs related to occupational diseases seem to be well accepted as potential business benefit from REACH, savings related to current costs for environmental emissions or waste have not been mentioned in the studies. The reason for that could lie in the fact that such costs are not relevant for enterprises. It is unclear if environmental emissions from unknown sources – and only these would be newly detectable and reducible by REACH information – are causing problems in compliance or not. If a general emission reduction of environmentally hazardous substances is assumed, it seems not logical to assume that no benefits from saving penalties or fees for environmental emissions would occur. Since no indication of this benefit being recognised by any of the authors was found, it can be questioned if this benefit would actually occur.

3.9.3. Risk managements is internalised in product development allowing for quality differentiation in the market

This potential benefit was formulated stressing that the safety information communicated with a substance or preparation will have significant effects on their uses. The benefit for enterprises would be to already assess product safety (according to common and agreed rules) during the development of the products. This has not been discussed explicitly in the analysed studies. However, discussion of substitution and market effects of safety information as well as prevention of liability claims may relate to this potential benefit as well.

²² This would be the baseline for measuring saved costs due to the introduction and higher acceptance of non-test data.

3.10. Discussion of business benefits

3.10.1. Baseline issues

A baseline description of the situation at industry or company level was not found in the studies for the potential business benefits. The current level of 'chemicals risk management' and associated inefficiencies or costs are not assessed and no information is provided on e.g. costs or efforts to prevent liability claims or uphold a good company reputation. This may be due to the fact that corporate data keeping is usually not structured and/or detailed in the respective categories, and within the normal business routines this data is not used for controlling or other purposes and is thus not extracted and available. Furthermore, the information may be regarded as confidential and therefore not normally provided to outsiders. Such information is not reported to statistical services and can hardly be deduced from other information on business performance. As no respective case studies have been carried out in the frame of the analysed studies, the authors could only describe their assumptions qualitatively or what they know from own experience but were not able to underpin this with actual data.

The baseline related to market effects of REACH and gains in competitiveness or better abilities to innovate has also not been described in a quantitative or exemplary manner in the studies analysed. However, respective data may be available in e.g. studies on substitution. A mere statistical exercise is not likely to help in such analysis, as the specific situation companies would have to be looked at in relation to other actors and the market flow of chemicals.

3.10.2. Links between benefits and REACH

Various REACH mechanisms triggering benefits at company level are given in the studies. Direct benefits are said to be triggered by the implementation of REACH as such (harmonized legislation) and the requirement for importers to register substances (competitiveness of manufacturers and formulators). Furthermore, the less stringent requirements for new substances were named. Indirect benefit mechanisms are the generation of new information supporting more efficient risk management at company level (including workers protection) and preventing liability claims. Communication and shared responsibility were said to be leading to more efficient supply chain management.

Whether or not business benefits will be realised to a large extent depends on the way enterprises make use of new information from REACH and how the supply of and demand for safer products develops under REACH. Thus, the attitudes and behaviour of the individual enterprises as well as the interaction within the supply chain will determine the extent of benefits that can be realised at enterprise level. This makes it particularly difficult to establish precise links between REACH and the benefits expected at enterprise level.

Most of the links between benefits and REACH mechanisms that were formulated in the benefit description were found in the studies as well, but at a less detailed level. However, the information provided in the studies frequently doesn't substantiate the links with data or examples. Thus, whether or not and to which extent the benefits will actually realize remains a hypothesis.

3.10.3. Assessment methods

All studies described benefits at a qualitative level. Examples of companies having faced benefits or expecting these from the implementation of REACH are given in some of these. Benefits at enterprise level have not been quantified, thus no methods are discussed here.

3.10.4. Conclusions

A lot of potential business benefits have been identified and described that could be triggered by REACH. These benefits remain abstract with regard to the actual cost and resource savings that could be realised at individual and also at macro-economic level. Due to the lack and difficulties of obtaining general baseline data, business benefits could best be explored based on a case study approach. A more concrete description of business benefits from REACH may be helpful in creating a better overall acceptance of the new regulation, enhancing the efficient use of new information, and promoting to explore cooperation possibilities with regard to the development of safer products.

4. Environmental benefits identified in the studies

In the benefit description paper, expected benefits for the environment are listed as: less environmental damage; less public spending for compensation of environmental damage and reduction of risk expressed as less exposure to SVCHs. Whereas the first was meant to provide for quantification of the (avoided) damage, the second aimed at quantifying remediation costs. The last benefit type was included, as it could be a potential indicator to monitor policy success. Whereas the last was only identified indirectly in the studies, environmental damage and related costs have been directly described²³.

4.1. Discussion

4.1.1. Baseline issues

In all studies²⁴ discussing environmental benefits triggered by REACH, it was stated that the characterisation of the baseline is very difficult to almost impossible at a broader scale due to a lack of knowledge and information. The main reasons stated were the lack of information on:

- Cause-effect links of dangerous substances
- Volumes, types of uses, amounts of emissions and their pathways as well as exposures
- Geographical distribution of emissions
- Extent of damage caused to the environment by exposures to chemicals at present
- Monitoring data

It is unlikely that the data base on the state of the environment (pressure, state and response indicators) will significantly improve in the future. However, information on cause effect links, volumes, uses and amounts of emissions and levels of modelled exposure should improve under REACH. This increased information on the properties and use of chemicals is a benefit of REACH as such, as it enables better chemicals control and targeting of regulatory measures by authorities. New monitoring data may be generated for substances that are subject to authorisation²⁵. In order to monitor the impacts of REACH on the state of the environment, a careful selection of indicators could help in making a targeted assessment of reduced exposures of the environment.

²³ Chemsec: Developing countries; Chemsec: Surviving REACH; COM: extended IA; DHI: impact env and hh; ECORYS: summary IA's; RPA & BRE: env. and hh benefits

²⁴ Environmental benefits were qualitatively described in several studies. Quantification at EU level was done only in the study on impacts of REACH on human health and the environment by DHI.

²⁵ Monitoring obligations could be part of the conditions of the authorisation.

4.1.2. Links between benefits and REACH

The mechanism through which REACH would trigger benefits for the environment such as reduced damage and/or reduced remediation costs are stated to be the generation of new information on substance properties and the chemical safety assessment with related recommendation and implementation of risk management measures. Due to new information, environmentally dangerous substances would be:

- a) withdrawn from the market (Manufacturer (M) / Importer (I) does not register or demand decreases driven by Downstream Users (DU)
- b) included in other environmental legislation (due to new classification) and thus more strictly regulated
- c) recommended for use under safe conditions as specified in an Safety Data Sheets (SDS) / Exposure Scenarios (ES) with the respective implementation of measures at DU level or
- d) subject to the authorisation or restrictions procedure, with related more stringent conditions of use as currently applicable.

4.1.3. Assessment methods

The quantification and monetisation of potential benefits relates to the prevention or remediation of damage while the reduction of risk as such is not quantified in the studies. Three methods of quantification were used:

- case studies analysing (clean-up) costs for remediation of substance-triggered environmental damage in the past and assumption of REACH impact in preventing such damage
- assessment of current costs incurred for preventing substance-related environmental damage, extrapolation and assumption of REACH impact on the extent of measures needed to prevent that damage and
- assessment of willingness to pay for a certain environmental good and assumption of REACH contribution to the undamaged existence of that environmental good.

The RPA / BRE study quantifies environmental costs in form of case studies and makes an assessment on whether or not the data requirements and risk management conclusions under REACH would resemble those being imposed were the substances regulated under the existing substances regulation. An overall result of that assessment is that the speed of implementation of risk management measures will be higher under REACH and that the risk assessment and risk management conclusions would be similar to those of a procedure under the Existing Substances Regulation (ESR)²⁶, with the exception that break-down products of a substance would be detected to a lesser extent.

The DHI study estimates benefits at European scale based on extrapolation of case studies. The impact of REACH has been assumed at '10% reduction' of exposures / damage by DHI (in line with

²⁶ Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances.

similar assumptions in previous appraisals) and is stated to mainly stem from reduced releases of substances (and to a lesser extent to market withdrawal).

Table 6 gives an overview of the attempts to quantify the environmental impact of REACH. As illustrated in the table with the range estimates and the column with assumed REACH shares, the quantitative appraisals are uncertain and dependent on assumptions. However, the table also makes clear that the potential environmental benefits are substantial.

Table 6: Overview of assessment methods in studies on environmental benefits

Study	Method	Assumed share of REACH in the overall appraised impact	Result [Euro]
			The quantified results are not additive as they refer to overlapping effects or different appraisals of the same effect
Cost of late action – the case of PCB ²⁷	Costs for repair of environmental damage, control of PCBs and other societal costs related to the use of PCBs in Sweden were summed up and extrapolated to the EU (based on inhabitants). Adjustment to consumer price index and discounting of 4% over 23.5 years	50% of that misstep or 5 missteps 10% the size could be prevented	PCB clean-up 7 -25 billion€ savings between 2005 and 2028 in the EU
'Costs for contaminated sites in Finland' ²⁸	Sum of clean-up costs calculated, no statement on how much REACH would reduce the costs.	Impact not specified	Not calculated
UBA Study	Sum up of costs from historical damage and normalisation as per capita cost. No extrapolation to EU-level. No time scaling	Impact analysed qualitatively for each case	PCB clean – up 25 €/ resident Cleaning of drinking water 0.78 – 2.75 €/ resident
REACH impact on environment & human health ²⁹	Willingness to pay for clean drinking water and to avoid morbidity and mortality were extrapolated to EU based on inhabitant numbers. No baseline assumptions except. Assumption that WTP-values can be transferred between study contexts and over EU citizens This approach was stated to be the second robust one applied in the study	10% improvement of drinking water quality.	Clean drinking water By 2017: 1,730 mil €; 2017 – 2041: 34,000 mil €
REACH impact on environment & human health(29)	Historical damage costs from 4 substances were summed. No baseline description Substances with similar risk profiles as the example substances identified through a ranking system and potential cost savings extrapolated using the number of substances that are as or more risky. The approach is stated to be the weakest one of the study.	10 % reduction in damage	Improved reuse of sludge: 2017: 16 – 133 mil € 2017 – 2041: 300 – 2,600 mil €
REACH impact on environment & human health(29)	Current expenditures to mitigate damage caused by chemicals was assessed for different areas and extrapolated to the EU No baseline description	10 % reduction in damage	Building of STPs: 2017: 7.1 – 24 mil €; 2017 – 2041: 131 – 440 mil € Drinking water purification: 2017: 49 – 302 mil €; 2017 – 2041: 896 – 5,564 mil € Disposal of dredged sediment: 2017: 13.1 – 78 mil €; 2017 – 2041: 241 – 1,540 mil € Sewage sludge: 2017: 38 b mil €; 2017 – 2041 1,520 mil €

²⁷ Jenny von Bahr and Johanna Janson; the study was quoted in the ECORYS overview study of REACH impact assessments and partially evaluated for this study.

²⁸ Kimmo Järvinen and Sakari Salonen; the study was quoted in the ECORYS overview study of the REACH impact assessments and partially evaluated for this study.

²⁹ DHI Water & Environment

5. Benefits related to occupational health

Positive impacts of REACH on occupational health are usually seen as reduced costs to cure workers' ill-being by the general public (medical care), improved quality of life for the individual worker and reduced costs for the employer (work days, Risk Management Measures (RMMs)). The saved costs for employers are part of the occupational health benefits; they have already been discussed as business benefits in Section 3.3 of the report.

Benefits related to occupational health – the avoidance or reduction of diseases caused by occupational exposure to chemicals - are discussed in almost all of the analysed studies. A quantification of saved costs at EU-level was done by RPA and in the ETUC study. Rühl/Wriedt³⁰ sum up costs related to occupational exposures to two groups of chemicals in Germany and extrapolate these to the EU level. In the UBA study costs of occupational diseases in Germany are listed.

In the benefit description before the study analysis, benefits related to occupational health were named as reduced ill-being of workers and saved costs due to reduced illness at work. The main mechanisms triggering these benefits were listed as the generation of new information on substance properties in the frame of registration, the derivation of safe conditions of use and the communication of these along the supply chain via the exposure scenario.

In the studies, qualitatively discussing benefits for workers, the same structure of benefits and related REACH-triggers were found. Studies, which have quantified the benefits, were more detailed with regard to the type of damage that could be prevented. In these studies, the REACH trigger 'Exposure Scenario' was found to be much less important than the generation of new property data, as workers protection legislation requires a risk assessment at workplaces, already.

5.1. Discussion on benefits for occupational health

5.1.1. Baseline issues

Difficulties about determining the baseline scenario were reported, but appear to be less fundamental than for the environment. The main factors that make the description of the base line difficult are stated as:

- Establishing cause-effect links between the use of dangerous substances and the occurrence of occupational health damage³¹
- Lack of data on use volumes, types of uses and available risk management measures at work places and on the occurrence of occupational diseases at present
- Differences in statistical systems and rules across the EU

Some statistical data on occupational diseases could be retrieved from EUROSTAT, national data bases and other information sources.

³⁰ Reinhold Rühl und Henning Wriedt, "An assessment of the Benefits with REACH", 2004

³¹ This is also reflected in the fact that 'acknowledged' occupational diseases are different in different Member States. Furthermore, there is a high range of 'suspected' but not proven links.

Difficulties connected to characterising the baseline scenario against which REACH – benefits would have to be seen relate to the interlinks between REACH and existing legislation:

- existing workers protection legislation is/was not fully complied with by the time the studies were written. Thus, the level of protection / exposure of workers with 100% legal compliance cannot be determined.
- REACH information, in particular on substance properties but also on risk management measures is expected to contribute to the implementation and compliance of occupational health legislation. It is usually not distinguished between an additional level of protection triggered by REACH and the contribution to compliance with existing standards.
- As it could be expected that substance properties may be determined under existing chemicals legislation also, but most likely later than under REACH, the benefit could be seen in an enhanced identification of dangerous properties. For this, trends in the implementation of existing legislation would have to be extrapolated.

5.1.2. Links between benefits and REACH

The most prominent link between REACH and benefits for workers' health was identified as the generation and communication of new information on substances properties, enhancing the implementation of existing workers' protection legislation. RPA assumed that this information would lead to reduced occupational exposure to unknown or unspecified chemicals, for which new dangerous properties are detected. In contrast, in the ETUC study it is assumed that REACH would affect exposure levels regardless of the current knowledge base; however different 'impact efficiencies' are specified for different end-points. This means that a general enhancement of workers legislation is assumed rather than a specific impact on areas of little knowledge. Rühl/Wriedt, by extrapolating current costs to the EU level implicitly assume that all costs could be prevented by REACH. The UBA study quotes a German information source that states 7% of occupational unfitness being due to chemicals exposures and 30% of these being unnecessary and preventable.

5.1.3. Assessment methods

The study of Rühl/Wriedt³⁰ sums up current costs related to health damage from occupational exposure to isocyanates and epoxy resins in Germany and extrapolates to the EU-level. It is not assessed, which of these costs could actually be prevented by REACH and no specific mechanism how REACH could impact on the occurrence of occupational health is specified.

The assessment method of RPA and ETUC are similar. In general the quantification and monetisation is done by assessing current occupational diseases for different endpoints (baseline), assuming the percentage of cases REACH could prevent and multiplying these by a set of costs associated with the type of endpoint including the value of disabled life years. Data from national sources were extrapolated to the EU level based on the number of employees.

Differences between the two studies exist in the primary data sources used to determine current levels of occupational diseases, the type and number of endpoints assessed, the types and extent of costs associated with the different endpoints, the valuation of disabled life years and the assumptions on the extent to which REACH would lead to a reduction in number of cases. Furthermore, RPA assumed that REACH would have an impact only in those cases, where workers health is damaged

from unknown and/or unspecified sources, whereas in the ETUC study, effects were assumed for all substances handled at the workplace. Whereas the effectiveness of REACH in reducing occupational damage was assumed at 10% by RPA, in the ETUC study different percentages were used for different endpoints, ranging between 10 and 50 %.

The selection of valuation parameters and ‘damage end-points’ for a certain type of benefit - e.g. the choice to assess dermatitis, Chronic Obstructive Pulmonary Disease (COPD) and asthma cases due to occupational exposures to chemicals by the University of Sheffield (the ETUC study) - seem to be based on considerations of data availability rather than on the significance of current damage or the influence of REACH thereupon.

Table 7 gives an overview of the quantitative estimates of the REACH impact on occupational health. Similarly to the estimates on the environmental impacts in Table 6, the quantitative appraisals are uncertain and dependent on assumptions. However, the table also makes clear that the potential benefits are substantial.

Table 7: Overview of assessment methods in studies on occupational benefits

Study	Method	Assumed share of REACH in the overall appraised impact	Result [Euro]
An assessment of the benefit of REACH ³⁰	Statistical data on acknowledged occupational diseases related to chemicals exposure in Germany Baseline = current costs for occupational disease Extrapolation to EU by number of workers.	Not specified, but as all costs are extrapolated, 100% reduction is factually assumed	The quantified results below are not additive as they refer to overlapping effects or different appraisals of the same effect 18.5 mil € per year (epoxy resins) born by industrial economy 21.5 mil € per year (isocyanates) Total 40 mil € per year
UBA: benefits of REACH in selected supply chains ³²	Compilation of German statistical data on costs from occupational diseases and relating it to the German population Quotation of a BAuA report on chemicals related occupational diseases	Discussed qualitatively	1.3 €/ capita compensation payments + 4.7 €/ capita for diseases not related to one specific substance → 6 Euro / capita 21 Euro per capita overall and total costs related to chemicals induced occupational diseases
Impacts of REACH on Occupational Health ³³	Derivation of current health impacts related to occupational exposure to unknown or unspecified chemicals by comparison of various data. Baseline = estimated level of occupational disease related to exposure to chemicals Determination of costs per endpoint from existing data and hypothetical values (WTP) Extrapolation to EU level by number of workers	10% reduction of effects related to occupational exposure conditions	Skin: 11.6-102.9 mil € Respiratory: 4.0 – 53.5 mil € Eye: 0.4 – 0.4 mil € CNS: 7.1 – 68.8 mil € Cancer: 17,591.6 – 54,166.8 mil € Total: Between 17.6 and 54.4 billion € over 30 years
The impact of REACH on occupational health with a focus on skin and respiratory diseases ³⁴	Current occupational skin and respiratory diseases determined and the cases attributable to exposure to chemicals estimated (88% for skin and 36% for respiratory diseases). Baseline = current occurrence of endpoints assessed The number of prevented cases is multiplied with the costs (comprise health service costs; productivity costs; and value of lost health-related quality of life) Extrapolation based on numbers of workers	All chemicals regarded as being affected by REACH. Different percentages applied to the effectiveness of REACH in reducing exposure: Asthma - 50%, COPD – 10 %, Dermatitis – 50%	Asthma: 10 years: 1,115 mil €; 30 years: 44,966 mil € COPD 10 years: 255 mil €; 30 years: 10,116 mil € Dermatitis 10 years: 2,063 mil €; 30 years: 35,868 mil € Total 10 years: 3,433 mil €; 30 years: 90,951 mil €

³² UBA: Analysis of the costs and benefits of the new EU chemicals Policy – an examination based on selected An examination based on selected sectors taking into account effects on competitiveness, innovation, environment, and health, October 2004

³³ RPA and Statistics Sweden

³⁴ School of Health and Related Research University of Sheffield, UK (ETUC study)

6. Benefits related to public health

Benefits for public health are not described in greater detail in the studies other than ‘the overall exposure to dangerous substances would be reduced’. This seems mainly due to the large uncertainties and knowledge gaps on cause-effect links; types, amounts, durations and pathways of consumer exposures; combination effects with other chemicals but also with other factors triggering ill-being. Also in the first benefit description no higher level of detail was attempted.

The mechanism triggering reduced exposure of consumers established in the initial benefit description is that on the one hand SVHC would be identified, safety assessed and adequately controlled with respective consequences for their use in consumer products. This was also reflected in the studies that mentioned reduced exposure of the general public. Overall cost savings and human health benefits have been quantified by the WWF and DHI. Case studies have been carried out in the UBA study.

Table 8 presents the quantitative estimates of the REACH impact on public health. Similarly to the estimates in Table 6 and 7, the quantitative appraisals are uncertain and dependent on assumptions, but the potential benefits seem to be substantial.

Table 8: Overview of studies discussing benefits to public health

Study	Method	Assumed share of REACH in the overall appraised impact	Result [Euro]
			The quantified results below are not additive as they refer to overlapping effects or different appraisals of the same effect
Summary impact assessment, quotation of the World Bank	Not described, not further researched	Not specified	Pollution from industrial and agro-industrial chemicals causes between 0.6 and 2.5% of the total burden of disease
UBA: benefits of REACH in selected supply chains ³⁵	Based on literature: 7% of general public in Germany quoted to be affected by contact allergies, treatment of which costed at 840 Euros per case. Costs for additional skin cancer cases	Between 1 and 10 % reduction of cases 0% for ozone depletion as effect unknown by that time	Prevention of costs from allergic skin eczema 0.5 – 5.2 €/capita Treatment costs of skin cancer due to ozone depletion 0.5 €/capita
The impact of REACH on the environment and human health ³⁶	Willingness to pay for clean drinking water and to avoid morbidity and mortality were extrapolated to EU	10% reduction in environmental damage	By 2017: 1,730 mil €; 2017 – 2041: 34,000 mil €
The impact of REACH on the environment and human health ³⁶	Historical damage from 4 substances was summed. Substances with similar risk profiles were identified and potential cost savings extrapolated.	10 % reduction in damage	Avoidance of severe health effects: 2017: 210 – 2,500 mil €; 2017 – 2041: 4,000 – 50,000 mil €
The impact of REACH on the environment and human health ³⁶	Current expenditures to mitigate damage caused by chemicals was assessed for different areas and extrapolated to the EU	10 % reduction in damage	Cleaning of fish meal: 2017: 0.9 mil €; 2017 – 2041: 16 mil €
The social costs of chemicals ³⁷	World Bank estimates for the fraction of DALYs ³⁸ from exposure to chemicals. Three models were used: a) based on health expenditure in UK and EU; b) adds additional value to the DALY including WTPs and c) derives DALYs from medical costs and forgone productivity from specific diseases	10% of reduction of DALYs caused by chemical exposure	Model 1: -3.5 – 18.8 billion € Model 2: -1.2 – 27.7 billion € Model 3: 33.1 – 259.5 billion €

³⁵ UBA: Analysis of the costs and benefits of the new EU chemicals Policy – an examination based on selected An examination based on selected sectors taking into account effects on competitiveness, innovation, environment, and health, October 2004

³⁶ DHI Water & Environment

³⁷ WWF

³⁸ Disability Adjusted Life Year

7. Summary and discussion

Whereas benefits for human health and the environment expected from REACH have been described in the studies, business benefits elaborated in the benefit description paper were found to a much lesser extent in the studies. Benefits for the environment and human health are expressed as prevented damage and saved costs, whereas business benefits are seen in competitive advantages - through the elimination of unfair competition due to different applicable regulations, saving costs or resources, improving product quality or enhancing innovation. A table summarising benefits is presented as Annex to this report.

The lack of knowledge, information and data for carrying out quantified estimates of benefits from REACH was compensated by making assumptions or extrapolating case study data to higher levels. These assumptions are mostly made transparent in the studies. Improved assessments and quantification of REACH benefits would need:

- Better data on the current state of the environment and human health as well as information on dose-response relationships and the populations at risk to make better / more thorough descriptions of baseline scenarios
- Better information on trends of behavioural responses to the REACH mechanisms in order to refine the assumptions on the effectiveness of REACH
- More and wider distribution of data sources on specific cases in order to have less uncertainties in extrapolations from small samples to high scales
- Clearer understanding of how REACH affects substances, the exposure to which is unknown (don't have to be identified in preparations) and substances which are not classified although they are dangerous chemicals (no data available, yet) in order to not under- or overestimate the effectiveness of REACH.
- Better understanding how chemicals' effects and related costs may be double counted, as the implementation of risk management measures for one substance also influences emissions / exposures from another
- Better understanding of the amount of classified substances that have not been tested for all end-points, yet and thus may be classified stricter or for additional end-points under REACH
- Trend information on the effect of communication on the general awareness on chemicals risks.

The effectiveness of REACH may be underestimated because synergistic effects and currently not known adverse effects are not accounted for. Overestimations may occur due to double counting of benefits and too high assumptions on the REACH contribution in the efforts for better health and environment protection.

7.1. Benefit descriptions and links to REACH

Business benefits of the REACH regulation are qualitatively described but not monetised in the studies. The most frequently mentioned REACH mechanism leading to further benefits in various areas at downstream users' is seen in the registration and related generation of new information on chemicals risks. From the perspective of substance manufacturers some direct benefits are expected through the reduced registration requirements for 'new substances' or the (further) harmonisation of legislation. Importers are not mentioned as group of actors having benefits from REACH.

Although benefits for enterprises not only stem from the policy outcome 'new information', explicit links to other REACH mechanism are hardly made in the studies. This applies also to the descriptive and more general publications by NGOs. In consequence, concrete indications on how enterprises could integrate other REACH mechanisms in their business strategy in a way that benefits would be generated are missing.

The description of benefits for the environment are quite concrete in those studies discussing (potentially saved) clean-up costs of historical or current damage and are vague when the consequences of an overall reduced exposure of the environment is predicted. The link between REACH and potential benefits for the environment is established mostly through the registration of substances and the related generation of new information. Less explicit emphasis is put on the communication of risk information and the actual implementation of risk management measures as well as the authorisation procedure.

The quantification of environmental benefits suffers from the lack of information on the current impacts of chemicals on the environment related to chemical pressures, state and responses. Furthermore, clear cause-effect links and use and exposure information is missing. Hence, a comprehensive baseline can hardly be described and the specific effects of currently unregulated chemicals on the environment are neither 'measured' nor can they be properly modelled. In the light of this, the studies describing and quantifying benefits for the environment are believed to make their best estimates on the current and future situation with regard to environmental benefits of REACH.

The type and extent of current damage to workers' health is described at a relatively high level of detail in those studies particularly addressing occupational health benefits. As occupational exposures and related diseases are quite concrete, the consequences of reduced exposures are obvious. The most important, and frequently the only, respective benefit trigger of REACH is seen in the registration and respective generation and communication of new information on substance properties. Thus, particularly in the field of labour protection, REACH is seen as enhancing the implementation of existing legislation rather than creating benefits in itself.

Across all benefits assessed or described in the various studies, the data base on workers health can be seen as best³⁹. Furthermore, information on costs associated with a particular chemicals-related occupational disease could be better structured and explored than e.g. those related to an environmental damage. In consequence, a baseline could be described. Nevertheless, the impact of REACH on occupational exposures to chemicals is difficult to estimate and related costs may vary across the EU.

³⁹ All studies made clear that the data is insufficient to make precise estimates and assumptions are needed to fill information gaps.

Benefits to public health are the least explored in the studies analysed. The main reasons are probably that cause-effect links between chemicals and diseases are the most complex because a) even if a scientific link has been established, information on actual exposures are usually lacking and b) the influence of other factors on the development of a disease are more important than for workers, as consumer exposure to one single substance is comparably low.

7.2. Methodological difficulties in quantitative estimates⁴⁰

Quantified benefits of REACH in terms of saved costs and or valuation of good health / a functioning environment were found in some of the studies assessed. The principle steps of quantification are similar in these studies:

- estimation of the extent of chemicals-related damage to a subject of protection either as a whole (overall estimates, e.g. by WWF) or in part (case studies, e.g. DHI or UBA)
- assumption of the impact of REACH in preventing that damage - in most studies a 10% effectiveness is assumed
- compilation of information on costs related to that damage, either as
 - 'real' figures - costs already incurred are summed up or costs for curing a certain disease are compiled,
 - assumed average figures – for example monetisation of productivity losses from disabled workforce or
 - virtual values – the willingness to pay as well as the concept of DALYs were used, in particular to value individual health damage and damage to the environment.
- multiplication of damage prevented with damage costs
- extrapolations to the EU level from a single case/substance to 'all chemicals on the market' or 'all damage to a subject of protection'.

In all studies discussing benefits to human health or the environment, major difficulties in defining a baseline scenario were reported. These difficulties are related to the lack of data on the current state of ill-health or damage and the current chemical pressure in terms of information on uses, emissions and exposures to particular currently regulated and yet unregulated chemicals. The lack of data on uses, emissions and exposures will be partially⁴¹ closed by REACH and more information will become available on cause-effect links as well. Whereas in the area of labour protection it may be possible to get an idea on the extent of the knowledge gap that REACH will decrease, this will be possible to a much lesser extent for the environment and consumer protection, as here exposures are more complex. Studies assessing benefits to workers health described the baseline as 'current occurrence of occupational diseases' whereas studies on the environment and public health mostly evaded that difficulty by assessing historical or current damage and extrapolating the related (clean-up / curative) costs.

⁴⁰ This section only relates to the studies that have made quantified assessments.

⁴¹ The lack of information on e.g. the geographical distributions of emissions may only be closed for substance subject to authorisation.

The baseline scenario for the current state of chemicals risk management at enterprise level and related costs could not be described in the studies. Respective data is not available in statistics and can hardly be estimated due to the high diversity of actors affected by REACH and their various uses of chemicals. Studies carried out in other contexts, e.g. research on substitution or on the implementation of environmental or workers protection legislation may contain respective information but is scattered and has not been consolidated in the studies. It is unlikely that enterprises would be able to easily retrieve that information from their data bases, also, as the normal information structure relevant for controlling in companies is not compatible to these information needs.

Another difficulty of all studies was the derivation of 'a value' for the effectiveness of REACH. This is mostly due to the nature of REACH and the most prominent policy outcome triggering benefits – new information. The benefits that REACH could create are mostly indirect and depend on the behaviour of the economic actors, their willingness and capacity to take their responsibility and use that (new) information. Hence, even if it was possible to precisely determine the nature and amount of information that would be newly⁴² available under REACH, the actual effect on risk management could hardly be derived.

Also for areas, where REACH would have a direct effect, like the reduced requirements for placing new substances on the market or the harmonisation of chemicals legislation, the quantification of an effectiveness appears difficult due to the lack of information on how much current regulatory burdens hamper respective activities of enterprises. So also here, the derivation of an effectiveness of REACH is hampered by the ignorance of the extent and reasons for the existence of the problem.

The effectiveness of REACH is given as '10%' in most studies. This value addresses the reduction in occurrence of damage and thus integrates assumptions on the reduction of exposures and cause-effect links. These '10%' effectiveness was assumed by expert judgement and has been used by most of the authors of studies discussing benefits. This value may be a realistic assumption and may relate to a reduced exposure to substances (due to market withdrawal, improved controls and limitation to applications which are safe).

The valuation of costs that could be saved due to REACH is done differently for human health and the environment. In the field of workers protection, actual values for curative costs and estimates on the average employers' costs per incident of disabled worker (lost output) are researched from data bases or other studies and summed up. The individual suffering of workers is quantified using DALYs. The valuation of public health benefits is based mainly on DALYs. The quantification of costs related to environmental damage that could be saved under REACH is derived mainly from current expenses to mitigate negative impacts of chemicals on environmental goods for human use (e.g. purification of drinking water, use of sewage sludge) or costs for clean-up of historical damage.

Also for the quantification of costs related to the mitigation or prevention of certain incidents or negative impacts is connected to assumptions and the use of hypothetical values. The quantification of human health costs is dominated by the value of a statistical life or the adjustment to a lower quality of life, which is a hypothetical value. The compilation of costs related to environmental damage is commented in the studies as being incomplete as either no data are available and/or costs that are indirectly related cannot be singled out (e.g. research activities). In consequence, also the valuation of costs per incident or per type of damage contains assumptions and could therefore be questioned.

⁴² As it is not clear what information on chemicals risks is currently available and as the available information is not structured according to respective needs, it is not even possible to determine the respective knowledge gap that will be closed by REACH.

The saved costs / benefits are extrapolated to the EU level only by RPA and in the ETUC study (workers' health) and in the study by DHI (environment). Estimates on benefits for consumers are already based on the number of EU inhabitants. The extrapolation of occupational benefits appears to be valid. However; the workplace situation could differ across the EU – baseline data are mostly derived from Northern Member State data bases – as well as the costs related to occupational diseases. DHI extrapolates benefits for the environment using a 'risk ranking' of substances which is based on available information on substance properties and produced tonnages. This extrapolation can be questioned because of the data on which the ranking system is based on (IUCLID data has hardly been updated, QSARs are not fully reliable for all end-points or don't apply to a number of substances) and because of potential double counting or missing out on REACH impacts.

In the following table, information on benefit assessments in the studies quantifying the effects is summarised.

Table 9: Summary of quantifications of potential benefits

Study	Benefit	Method	Assumed share of REACH in the overall appraised impact	Result [Euro]
Summary of impact assessment, quotation of the study: cost of late action – the case of PCB ⁴³	Savings from avoiding health damages and irreversible effects on biodiversity and ecosystems	Costs for repair of environmental damage, control of PCBs and other societal costs related to the use of PCBs in Sweden were summed up and extrapolated to the EU. Adjustment to consumer price index and discounting of 4% over 23.5 years	Assumption that one misstep half the size or 5 missteps 10% the size of PCBs could be prevented by REACH	The quantified results below are not additive as they refer to overlapping effects or different appraisals of the same effect 7 -25 billion € savings between 2005 and 2028 in the EU
Summary impact assessment, quotation: Costs for the remediation of chemically contaminated sites in Finland ⁴⁴	Clean-up costs for contaminated soil could be partially prevented by REACH	Sum of clean-up costs calculated	The impact of REACH on preventing soil contamination is not specified	Not calculated
Summary impact assessment, quotation of the World bank	Damage to public health could be prevented, if exposure to chemicals was reduced	Not described, not further researched	Not specified	Pollution from industrial and agro-industrial chemicals causes between 0.6 and 2.5% of the total burden of disease
Evaluation of environmental and health benefits of REACH ⁴⁵	Benefits in the field of occupational health	Same method as used by RPA (occupational health), calculations for Denmark only	10% reduction of effects related to occupational diseases	Not calculated
Assessment of the impact of the New Chemicals Policy on Occupational Health ⁴⁶	Less health damage related to occupational exposures	Derivation of current health impacts related to occupational exposure to unknown or unspecified chemicals, assumption of REACH effect, extrapolation to EU level and multiplication with costs associated with the respective health endpoint	10% reduction of effects related to occupational diseases	Between 17.6 and 54.4 billion € over 30 years Skin: 11.6-102.9 mil € Respiratory: 4.0 – 53.5 mil € Eye: 0.4 – 0.4 mil € CNS: 7.1 – 68.8 mil € Cancer: 17,591.6 – 54,166.8 mil €
New European Chemicals Strategy, UK Partial regulatory impact assessment	Less cancer cases due to occupational exposure to chemicals	Break-even of costs and benefits calculated only for the end-point cancer	If 18 cancer deaths were reduced per year, costs and benefits would break even	Not calculated.

⁴³ Jenny von Bahr and Johanna Janson

⁴⁴ Kimmo Järvinen and Sakari Salonen

⁴⁵ Miljøstyrelsen

⁴⁶ RPA and Statistics Sweden

Study	Benefit	Method	Assumed share of REACH in the overall appraised impact	Result [Euro]
The impact of REACH on the environment and human health ⁴⁷	Less environmental damage and less ill-health / deaths due to reduced exposures to chemicals	Willingness to pay for clean drinking water and to avoid morbidity and mortality were extrapolated to EU	10% reduction in environmental damage	The quantified results below are not additive as they refer to overlapping effects or different appraisals of the same effect By 2017: 1,730 mil €; 2017 – 2041: 34,000 mil €
The impact of REACH on the environment and human health(47)	Less environmental damage and less ill-health / deaths due to reduced exposures to chemicals	Historical damage from 4 substances was summed. Substances with similar risk profiles were identified and potential cost savings extrapolated.	10 % reduction in damage	Avoidance of severe health effects: 2017: 210 – 2,500 mil €; 2017 – 2041: 4,000 – 50,000 mil € Improved reuse of sludge: 2017: 16 – 133 mil € 2017 – 2041: 300 – 2,600 mil € Total potential benefits: 2017: 226 – 2,633 mil Euro 2017 – 2041: 4,300 – 52,600 mil €
The impact of REACH on the environment and human health(47)	Less environmental damage and less ill-health / deaths due to reduced exposures to chemicals	Current expenditures to mitigate damage caused by chemicals was assessed for different areas and extrapolated to the EU	10 % reduction in damage	Building of STPs: 2017: 7.1 – 24 mil €; 2017 – 2041: 131 – 440 mil € Drinking water purification: 2017: 49 – 302 mil €; 2017 – 2041: 896 – 5,564 mil € Disposal of dredged sediment: 2017: 13.1 – 78 mil €; 2017 – 2041: 241 – 1,540 mil € Sewage sludge: 2017: 38 b mil €; 2017 – 2041 1,520 mil € Cleaning of fish meal: 2017: 0.9 mil €; 2017 – 2041: 16 mil € Total: 2017: 153 – 488 mil €; 2017 – 2041: 2,804 – 8,990 mil €
The impact of REACH on selected supply chains ⁴⁸	Prevention of clean-up costs of environmental damage Prevention of costs for occupational diseases Prevention of costs to cure public health damage	Summing up of historical costs for the clean-up of PCBs in Germany and relating it to the number of residents. Summing up current costs for drinking water purification and relating it to the number of residents Compilation of German statistical data on compensation costs for occupational diseases, relation to number of residents Quotation of study on costs of chemicals related occupational diseases	By the time PCB caused damage, P&B were no 'dangerous properties' → 0% Qualitative discussion Qualitative discussion Not specified	PCB clean-up 25 €/ resident Drinking water purification 0.78 – 2.75 €/ resident Prevention of compensation for occupational diseases 6 €/ resident Prevention of costs for occupational diseases 21 €/ resident

⁴⁷ DHI Water & Environment

⁴⁸ UBA

Study	Benefit	Method	Assumed share of REACH in the overall appraised impact	Result [Euro]
		Summing up costs for cure of skin eczema from contact allergies, costing per case Summing up costs to cure additional skin cancers (compared to before ozone depletion)	1 – 10% 0% as ozone depletion was an unknown effect	The quantified results below are not additive as they refer to overlapping effects or different appraisals of the same effect Prevention of skin eczema in the public 0.5 – 5.2 €/ resident Prevention of skin cancer 0.5 €/ resident
The social costs of chemicals ⁴⁹	Less health damage to the general public due to reduced exposures	World Bank estimates for the fraction of DALYs from exposure to chemicals. Three models were used: a) based on health expenditure in UK and EU; b) adds additional value to the DALY including WTPs and c) derives DALYs from medical costs and forgone productivity from specific diseases	10% of reduction of DALYs caused by chemical exposure	Model 1: -3.5 - - 18.8 billion € Model 2: -1.2 – 27.7 billion € Model 3: 33.1 – 259.5 billion €
An assessment of the benefit of REACH ⁵⁰	Cost savings from less occupational diseases due to reduced occupational exposure to chemicals	Assessment of statistical data on acknowledged occupational diseases related to chemicals exposure in Germany and extrapolation to EU. Summing up of costs born by industry for compensation.	Not specified, only costs of current occupational diseases related to exposures to isocyanates and epoxy resins calculated	18.5 million € per year (epoxy resins) born by industrial economy 21.5 million € per year (isocyanates) Total 40 million € per year
The impact of REACH on occupational health with a focus on skin and respiratory diseases ⁵¹	Cost savings from less occupational diseases due to reduced occupational exposure to chemicals	The current burden of occupational skin and respiratory diseases was determined and the cases attributable to exposure to chemicals estimated (88% for skin and 36% for respiratory diseases). The reduction of these cases under REACH was estimated. The number of prevented cases is multiplied with the costs (comprise health service costs; productivity costs; and value of lost health-related quality of life)	All chemicals regarded as being affected by REACH. Different percentages applied to the effectiveness of REACH in reducing exposure: Asthma - 50%, COPD – 10 %, Dermatitis – 50%	Asthma: 10 years: 1,115 mil €; 30 years: 44,966 mil € COPD 10 years: 255 mil €; 30 years: 10,116 mil € Dermatitis 10 years: 2,063 mil €; 30 years: 35,868 mil € Total 10 years: 3,433 mil €; 30 years: 90,951mil €

⁴⁹ WWF

⁵⁰ Reinhold rühl, Niddatal and Henning Wriedt, Hamburg

⁵¹ School of Health and Related Research University of Sheffield, UK

8. Conclusions and recommendations

Studies and assessments of REACH impacts have focussed on the determination of costs for industry, whereas the description and quantification of benefits has been addressed to a much lesser degree. Due to the lower emphasis on benefit assessment as such and the various difficulties connected to benefit estimation - such as the dependency of impacts on the behaviour of industry actors, the lack of data on cause-effect links, current chemicals related damage or baseline information at enterprise level – well funded information on benefits of REACH are scarce. However, the fact that benefits are created is substantiated at qualitative and quantitative level by the studies analysed. Since the realisation of benefits largely depends on the behaviour of industry actors and how they will respond to the new requirements as well as chances under REACH, more effort may be put on illustrating business benefits from REACH in more detail.

REACH aims at generating information on properties of and exposures to substances in order to enable the actors in the market to better describe and communicate the conditions of use leading to adequate control of risk. Quantification of costs and benefits would largely need the information which is only to be generated under REACH. Thus, it is a 'mission impossible' to determine "pure benefits" like i) reduction of true risk or ii) prevention of "true" current damage, independent of the improvement in the knowledge basis. To this end, it will be very difficult to differentiate between "true" benefits, and "virtual benefits" (related to better information on risks). Thus any benefit study in future will have to cope with the fact that only changes in the perceived risk can be measured since there is no baseline available on "true risks". Also, in generating risk related information, REACH interacts with current legislation in various fields and with ongoing developments in the chemicals world market. A "pure" REACH triggered impact (advantage or drawback) is therefore unlikely.

REACH shifts the responsibility to document safe use to the manufacturers and importers of substances and provides at the same time for mechanisms to share this responsibility with downstream users. REACH also establishes the duty to make use of the generated information and establishes mechanisms supporting feedback on the quality of risk management information from customers to suppliers. In theory this should lead to an improvement of quality of the current key information instrument, the safety data sheet.

It is unlikely that a consolidated benefit assessment methodology (prospective appraisal) related to human health or the environment can be developed. There are numerous different types of methodologies that could be (and are) applied, as evidenced by the findings of this study. It is more promising to adopt and adapt a methodology, so as to ensure that it is most suitable to the issues at hand and the data available.⁵²

However, in order to create a basis to monitor and assess success and failure of the REACH regulation (ex-post analysis) and thus being able to make informed and transparent choices when reviewing the legislation after a period of time, a number of arrangements should be made now.

⁵² The range of potential methodologies was covered in RIP 3.9-1 ("Preliminary study for a guidance document on carrying out a SEA or Input for one" prepared by RPA in association with SYKE for the European Commission.) which concluded that it was not possible to eliminate the variety of the possible approaches, as there were often examples where a particular type of information may be of value.

As stated above, a careful selection of indicators could help in monitoring policy success and determining reduction of exposures to dangerous chemicals. So far, a study has been launched by the Commission that aims at defining policy success indicators for REACH and the respective baseline. A “quality and risk” indicator has been defined and will be applied to a random sample of 125 out of 10.000 substances. Based on available information on substance properties, use and exposure, the baseline risk connected with each of the substances is established. For this, 125 fast track tier 1 risk assessments are carried out. At the same time the quality of the available data is scored. In 6 and 12 years time the same collective of 125 substances will be re-assessed and changes in risk and quality established. For substances disappearing from the market substances from a reserve list will be added to the sample. Each change will be analysed to which extent it is directly driven by REACH and/or by other co-factors, The core-indicator of risk and quality will be supplemented by indicators simply monitoring progress in substance registration, data availability with regard to registered substances, use of QSARS and other non-animal testing, The core-benefit indicator in this concept is “decrease of perceived risk” and “increase of information quality”. The improvement of data quality is not a value in itself however it enables more rational allocation of resources for risk management.

It may be also possible to launch a study on monitoring policy success with regard to competitiveness and innovation effects in the same way. This should be based on a representative sample of companies, for which impacts over 12 years can be monitored. An indicator concept around “product safety”, “innovation” and “efficiency of risk management” would still need to be developed. A long term case study approach may be needed to enable identification of REACH related impacts in the overall development of these companies. It is unlikely that such impacts would be traceable with a more general approach.

As REACH builds on enterprises taking their responsibility for safe products, more efforts could be made to motivate enterprises by quantifying expected benefits at company level based on case studies. Furthermore, an illustration of how enterprises could integrate REACH mechanism in their business strategies in a way that benefits would be generated, might encourage enterprises to be proactive, foster quality differentiation in the market and thus promote the implementation of REACH in the own supply chain.

Annex 1: Summary of benefits

Table 10 to Table 12 summarise in a qualitative way the various potential benefits described and / or assessed in the reviewed studies.

Table 10: Summary of business benefit assessment⁵³

Study	More efficient and effective RM at enterprise level	Better conditions for innovation	Reduced costs related to damage of workers health	Prevention of business risks related to liability claims	Safer substitutes have better chances on the market	Improved well-being of workers	More efficient communication on chemical risks	One regulation for all	Market more predictable (prevention of product re-design)
Chemsec: Implications of REACH for the developing countries				More information on the own products and alternatives through registration and public data access --> safer products in general					
Chemsec: Surviving REACH - a guidance for companies that use chemicals	Improved information basis enables more efficient risk management at enterprise level	Difference between existing and new substances is offset by REACH. Registration applies to all substances alike, provisions for 'new' substances less strict as currently, M/I have better info on uses --> R&D enhanced, more assistance to innovating formulators.	Less occupational health damage under REACH due to new information on substance properties (and quicker risk management) resulting in lower costs for employers and better implementation of occupational health legislation.	Better information on own products as information on safe use will be generated and forwarded along the supply chain (SDS/ES).	REACH motivates manufacturers to develop safer alternatives to avoid costs, once dangerous chemicals are identified. Information on problematic chemicals becomes available (registration, info in the supply chain), which may be an incentive for searching and developing alternatives			Enterprises will have to comply only with one regulation.	
RPA: occupational health			Less occupational health damage under REACH due to new information on substance properties (and quicker risk management) resulting in lower costs for employers through better implementation of occupational health legislation.			Workers will suffer less from occupational diseases or workplace related health damage, as exposure will be reduced/eliminated more efficiently under occupational health legislation.			

⁵³ Yellow shaded cells indicate that a quantitative assessment of benefits was done in the study. However, the costs/benefits were not extrapolated.

Annex 1: Summary of REACH benefits described in the analysed studies

Study	More efficient and effective RM at enterprise level	Better conditions for innovation	Reduced costs related to damage of workers health	Prevention of business risks related to liability claims	Safer substitutes have better chances on the market	Improved well-being of workers	More efficient communication on chemical risks	One regulation for all	Market more predictable (prevention of product re-design)
Danish eco-council: a leap forward for industry	Cost savings as risk management can be based on improved information base (registration and information in the supply chain)	REACH will reward good performance and front-runners in terms of safe products as it is expected that knowledge and safe handling become a competitive advantage. European companies are seen at the lead of safe product marketing.			Both, the development of new substances and the use of less dangerous substitutes will be promoted by REACH, as information on problematic substances becomes available.			Legislation will be more transparent and simple as REACH replaces legislation.	Under REACH, chemicals regulation will be less influenced by unpredictable events, public campaigns or new classification, as safety considerations are to be made systematically during the phase in scheme.
COM: extended impact assessment, staff working paper	Information from registration on properties, exposures and risk can contribute to better risk management in industry.	Having the full responsibility for safe products and less requirements for new substances may encourage industry to innovate.			Substances may be withdrawn from the market, opening opportunities for alternatives.	REACH will reduce damage to workers health as occupational health legislation will be implemented in a more effective manner.	Shared responsibility and communication along the supply chain will lead to more strategic and systematic risk management in the supply chain.		
WWF: innovation in the chemicals sector	Reduced legal and insurance costs for chemicals users.	Innovation through quality differentiation is enhanced also in the non-chemicals sector.					Changes in the organisation of supply chains. No further explanation		Industry has a more predictable business environment, REACH enables to learn.
ECORYS and Opednkamp Adviesgroep: summary of impact assessments		Businesses will benefit from reduced requirements for marketing new substances (lower tonnage threshold, less strict requirements, PPORD).	Less occupational health damage under REACH due to better/more information on properties (and safe handling), thus reduced costs for employers and more efficient implementation of occupational health legislation.	Improved corporate reputation related to chemicals by compliance with REACH resulting in improved financial performance, decreases crisis recovery time and supportive behaviour of other stakeholders.					

Annex 1: Summary of REACH benefits described in the analysed studies

Study	More efficient and effective RM at enterprise level	Better conditions for innovation	Reduced costs related to damage of workers health	Prevention of business risks related to liability claims	Safer substitutes have better chances on the market	Improved well-being of workers	More efficient communication on chemical risks	One regulation for all	Market more predictable (prevention of product re-design)
ETUC: impact on occupational health			Better workers protection under existing legislation due to more/better information on substances properties and exposure controls. Saving costs related to lost productivity, compensation etc			Less lost health-related quality of life due to less cases of dermatitis, asthma and chronic obstructive pulmonary diseases			
KPMG: further work on impact assessment	Controlling risks becomes easier for enterprises based on better/new information from registration and improved SDS.								
UBA: Benefits of REACH in selected supply chains	Improved info on health and environmental properties of substances not previously considered dangerous enables formulators and downstream users better to assess their raw materials and document their safety.	Little evidence for benefits from PPORD, as few new substances used in the selected chains	Due to better information, employers can better fulfil workers' health legislation	Improved info on health and environmental properties of substances not previously considered dangerous enables formulators and downstream users better to assess their raw materials and document their safety.	Due to better information and a comparable data set for all substances, safer substitutes have better opportunities on the market (actors have a basis to compare)	Due to better information, employers can better fulfil workers' health legislation	M/I's exposure estimation & description of safe use provide basic support to DU in assessing risks & product safety. Demarcation of responsibility through checking compliance and taking responsibility for exposure and risk assessment; standard for communications on product safety and responsibility across product chains.		

Table 11: Summary table of potential benefits related to the environment⁵⁴

Study	Less environmental damage	Less public spending for compensation of environmental damage	Reduction of risk expressed as lower exposures to substances which are persistent, bioaccumulative and toxic (PBTs), very persistent and very bioaccumulative (vPvBs) or having endocrine disrupting properties (EDCs).
Chemsec: Implications of REACH for the developing countries		Cost savings by preventing damage based on new knowledge on hazards.	
Chemsec: Surviving REACH - a guidance for companies that use chemicals		Costs for repairing environmental damage can be avoided, as risks from substances are identified in registration and risk management measures are recommended.	
RPA & BRE: impacts on health and environment	Risks will be identified and respective measures recommended before damage occurs. Systematic data provision enables rigorous risk assessment and management. Action will be taken quicker	Damage avoided if REACH had been implemented much earlier are described for four example substances. Exemplary and qualitative demonstration.	
ECORYS and Opednkamp Adviesgroep: summary of impact assessments		REACH will avoid costs for compensating environmental damage (occurrence of damage as such and speed of implementing risk reduction measures). Example given for clean-up costs related to the use of PCBs (Swedish study).	REACH will result in reduced exposures of the environment, as registration will deliver information on chemical risks and risk management measures are recommended. Lower exposure are expected also due to substitution
COM: extended impact assessment, staff working paper	Damage to the environment will be reduced under REACH as more information on substances and environmental risks will be provided and respective RMMs implemented.		Exposure to dangerous chemicals will be reduced as RMMs will be implemented based on safety assessment. More targeted control based on knowledge of uses.
DHI: impact on environment and human health		Benefits resulting from reduced/prevented environmental damage due to substitution or implementation of risk management measures (quantified with a use of three methods)	REACH will result in reduced overall exposure to chemicals.

⁵⁴ Yellow shaded cells indicate that a quantitative assessment of benefits was done in the study. However, the costs/benefits were not extrapolated.

Table 12: Summary table of potential benefits related to the public and occupational health⁵⁵

Study	less public ill-being	Less public spending related to (preventing) health damage	Reduction of risk expressed as lower exposures to CMRs or EDCs	Less public spending to cure health damage of workers
Chemsec: Implications of REACH for the developing countries				Workers exposure is reduced due to new and well available information in some growing industries in ACP, like textile, use many chemicals.
RPA: occupational health				Less incidents of occupational health damage will occur under REACH, resulting in less public spending through the generation of new information on substance hazards.
RPA & BRE: impacts on health and environment		No explicit reference to the public at large, however, secondary poisoning and drinking water treatment mentioned. Due to earlier implementation of REACH, costs could have been saved.		
ECORYS and Opednkamp Adviesgroep: summary of impact assessments			REACH will result in reduced exposures of the public at large as registration will deliver information on chemical risks and how to control these including substitution	
COM: extended impact assessment, staff working paper	REACH reduces public ill-health due to information.		Exposure reduced as risk management measures will be improved based on chemical safety assessment.	
DHI: impact on environment and human health		Avoidance of severe health damage. Remediation costs to provide unpolluted natural resources such as clean drinking water.	REACH will result in reduced overall exposure to chemicals due to better information and the implementation of improved risk management.	
WWF: the social costs of chemicals		REACH will reduce damage to human health related to chemical exposure due to better/more information		
UBA: Benefits of REACH in selected supply chains	Reduced public ill-being due to reduced exposures (allergies and skin cancer)	Less public spending (curative costs) for chemicals-related ill-being	Reduction of risk, shown at the example of PCB remediation of public buildings and drinking water cleaning	Less spending on workers' health damage from chemicals-related exposures
ETUC: impact on occupational health				Less health care costs due to less cases of dermatitis, asthma and chronic obstructive pulmonary diseases. Prevention of cases through generation of information on hazards and risks.

⁵⁵ Yellow shaded cells indicate that a quantitative assessment of benefits was done in the study.

The benefits listed in this table were observed in the analysis of studies but not further worked on due to limitations in scope and resources of this study.

Table 13: Summary table of other potential benefits

Study	Less efforts for RM by authorities	Community measures more targeted	Standardised assessment, management and communication on chemical safety	Re-establishing trust in chemicals and ensuring a stable business environment for innovation	Incentive for others to implement CRMS
Chemsec: Implications of REACH for the developing countries	Authorities in Least Developed Countries and the developing countries can use knowledge & infrastructure of industrialised countries to improve national chemical risk management systems.				Least Developed Countries and the developing countries could imitate REACH and develop a chemicals risk management system as well.
Chemsec: Surviving REACH - a guidance for companies that use chemicals				Trust in chemicals is needed to create a good business environment for innovation. Due to clear rules on safety assessment and testing of substances under REACH, consumer confidence will be strengthened.	Higher safety standards could spread around the world. This would also create a front-runner advantage for European companies. 'Produced in Europe according to REACH' will be a quality label acknowledged by the consumers
Danish eco-council: a leap forward for industry				Trust in chemicals as such and in general is good for enterprises. Under REACH more information will be generated, less substances should end-up in unsafe uses, thus trust may be re-established.	
COM: extended impact assessment, staff working paper	Authorities can obtain better information for chemicals risk management as information on (safe handling of) chemicals will be available through substance registration and data bases.	Appropriate risk management can be identified (quicker) and implemented due to better information and before damage occurs as information is provided by industry. Authorities have more resources to evaluate, target assessment efforts and introduce substances into authorisation and/or restrictions			
WWF: innovation in the chemicals sector		Authorities' resources are allocated more efficiently on targeted risk reduction needs.	Standardisation helps innovation due to long-term perspective and prevention of unfair competition.		

Annex 2: Summary of REACH mechanisms triggering benefits

1. New information on substance properties – classification - availability of a standard set of property information – identification of SVHC

The most prominent and highlighted policy output through which benefits are expected is additional information on (dangerous) properties of existing substances. It is expected that a relevant share of existing substances will prove to have dangerous properties and thus be (re-)classified under REACH. This is stated to trigger benefits that partially would realize due to REACH and partially due to other legislation or market forces:

- a) The (re-)classification may result in a substance falling under other regulatory regimes and being controlled there under, e.g. workers' protection legislation. This would result in benefits by the implementation of exposure reducing measures triggered by that other legislation. Thus, REACH is regarded as enhancing the efficient implementation of other legislation through additional data. Nevertheless, benefits can be attributed to REACH, as under current legislation, the new/additional dangerous properties would not be identified or only identified after a longer period of time.

This argumentation was followed mainly in the field of occupational benefits. It was assumed that REACH affects damages attributable to 'unknown or unspecified chemicals and hence, substances already identified as dangerous⁵⁶ were usually not considered⁵⁷. In another approach all substances were assumed to be affected by REACH, however to a different degree⁵⁸

- b) Another reasoning in the studies is that (re-)classification may initiate substitution efforts by formulators and article producers who wish to avoid classification of their products (preparations) or the use of dangerous substances in general (articles), thus market forces would lead to further impacts following a classification. The substitution of substances by formulators and/or article producers may cause costs for them but would reduce the exposures of humans and/or the environment to that substance. This was not explicitly assessed or quantified, but stated at qualitative level or included in the overall benefit of having more/better information on substance properties.

⁵⁶ Substances which are currently classified can have a harmonised classification under Directive 67/548/EEC, be classified under the New Substances Directive or be self-classified. Under none of these regimes it is standing practice to classify all endpoints. Thus, also substances which are classified as dangerous could prove to have further dangerous properties which have not been identified yet. Therefore, assuming all classified chemicals would not be affected by REACH may lead to an underestimation of positive impacts.

⁵⁷ C.f. in particular the RPA: The impact of REACH on occupational health.

⁵⁸ C.f. in particular the Study for ETUC by the University of Sheffield

- c) Another effect of the availability of more information on substances discussed in the studies is that substances of very high concern (SVHC) will be identified and may be placed on the candidate list of substances subject to authorisation or be subject to the authorisation procedure. Benefits that could relate to their identification and listing as SVHC were not mentioned in any of the studies⁵⁹. However, in which way and to which extent the use of SVHC and the control of their emissions would be influenced by their having to be authorised was not described and not separately quantified.

The ways through which new information would influence the market and the overall use (and control) of substances was not provided in detail. In most studies, the effect of REACH was assumed to be “10% reduction of exposures”. These “10%” reflect an assumption that between 8 and 12% of dangerous substances would be withdrawn from the market due to REACH and it seems that most authors have referred to that.

2. Availability of information on safe conditions of use through chemical safety assessment and communication in the supply chain

The duty of M/I to assess chemical safety for substances produced or imported in amounts exceeding 10 tonnes per year and actor, by which risks are identified and respective risk reduction measures are communicated along the supply chain is seen as second most important policy output of REACH triggering benefits for human health and the environment. The chain through which benefits would realise is described as follows:

- a) The safe conditions of use are defined in principle and are communicated and implemented along the supply chain resulting in an exposure reduction. The precautionary principle is seen implemented here, as damage is aimed to be prevented rather than compensated. None of the studies elaborated on the factors influencing the degree of implementation of the exposure scenario and respective risk reduction measures.
- b) The process of identifying and implementing risk management measures by industry is regarded as much quicker than under the Existing Substances Regulation (ESR). Therefore, a shorter time period between the identification of risks and their actual control is stated as benefit leading to earlier exposure reduction and thus less damage⁶⁰.
- c) Substances identified as posing high risks (in certain applications) may be withdrawn from the market and potentially substituted with less dangerous alternatives. This benefit relates to situations where M/I decide not to register a substance (for a specific use) based on a safety assessment showing that risks cannot be adequately controlled. This is related to the discussion about substance withdrawal based on economic considerations, which is perceived as a negative impact of REACH (innovation).

⁵⁹ None of the studies used the newer REACH versions as basis of their assessment, thus this list did not exist for them. A case study on the announcement effect under this contract may provide further information on this specific issue.

⁶⁰ This type of benefit has been described mainly in the RPA study on benefits to human health and the environment. In four case studies the results of a REACH – dossier was compared to the result of an EU risk assessment and respective risk reduction strategies or other measures.

3. Other REACH mechanisms expected to generate benefits

Apart from the above mentioned policy outputs, few other REACH mechanisms have been addressed in more detail. Among these were:

- harmonisation and simplification of chemicals legislation as a whole (business benefit from less differences and lower complexity as well as better predictability of the market)
- publication of data and methods for simplified risk assessments may lead to the 'copying' of procedures and use of information on chemicals in lesser developed countries to improve their national chemicals risk management systems
- mechanism for communicating chemical safety information (exposure scenario – facilitates standardised communication) and demarcation of responsibilities in the supply chain (= driving force to comply).

Apart from the higher predictability of the chemicals market, the policy outputs related to the evaluation and the authorisation procedure were only implicitly taken into account as 'accelerated action taking' after risks are identified. The inclusion of articles is also not discussed as potential benefit generating provision of REACH.

Annex 3: Benefit descriptions

1. Introduction

1.1. Work process

As a starting point for the in-depth report on the existing REACH benefit studies, this paper details a number of hypotheses on benefits likely to be generated by the REACH system. The potential benefits, the corresponding REACH-mechanisms as well as the interpretation of the current situation of chemicals control in Europe will in the first step be communicated and discussed between Ökopol and DG Environment.

In the second step, studies discussing REACH benefits will be analysed with the aim of critically reviewing these and summarising which of the potential benefits have been assessed, which underlying assumptions were made, which REACH-mechanisms were accounted for and which methodology was used. Furthermore, quantified estimates in terms of monetary values will be extracted from existing studies⁶¹. Where the time scale of benefit realisation was considered, this will be extracted as well. Benefits identified in the study analysis which have not identified in the list of potential benefits in step 1 will be added.

In a third step, it will be assessed which changes related to the nature and extend of benefits have been brought about by the agreement reached in the Competitiveness Council of December 2005.

1.2. Structure of benefit descriptions

Figure 1 shows that in discussing REACH related benefits three elements will be considered:

- an assumption about the current regulatory situation including trends from legislation already in place (characteristics of baseline situation = no policy change scenario),
- a description of the REACH mechanism(s) potentially triggering a benefit (changing the baseline situation/trend)
- and the definition of the benefit itself.

⁶¹ It is possible that not all benefits identified in the initial description of benefits are outlined in the studies to be analyzed. Nevertheless, all hypotheses will be reflected when assessing the gains and losses of the political agreement and the proposals of the parliament.

The difficulty encountered in all benefit studies so far is to characterise the baseline. This is due to the lack of ‘hard’ data characterising the state of “chemicals control” (= process and product safety with regard to chemicals) in Europe and the different interpretations of the current situation from the perspective of the stakeholders⁶². Statements on the baseline situation are characterised by large uncertainties on the actual risks and the adverse impacts connected to the current production and use of chemicals. In addition, various pieces of legislation are not yet fully implemented, like worker’s protection legislation or the biocides directive, but are likely to have an impact in the future. REACH will replace a number of chemicals related legislation (e.g. notification of new substances, existing substances regulation). Some of the expected REACH benefits would have been achieved also with the existing legislation, though perhaps not as early or in the same amount as under REACH. This has to be taken into account when attributing benefits as well.

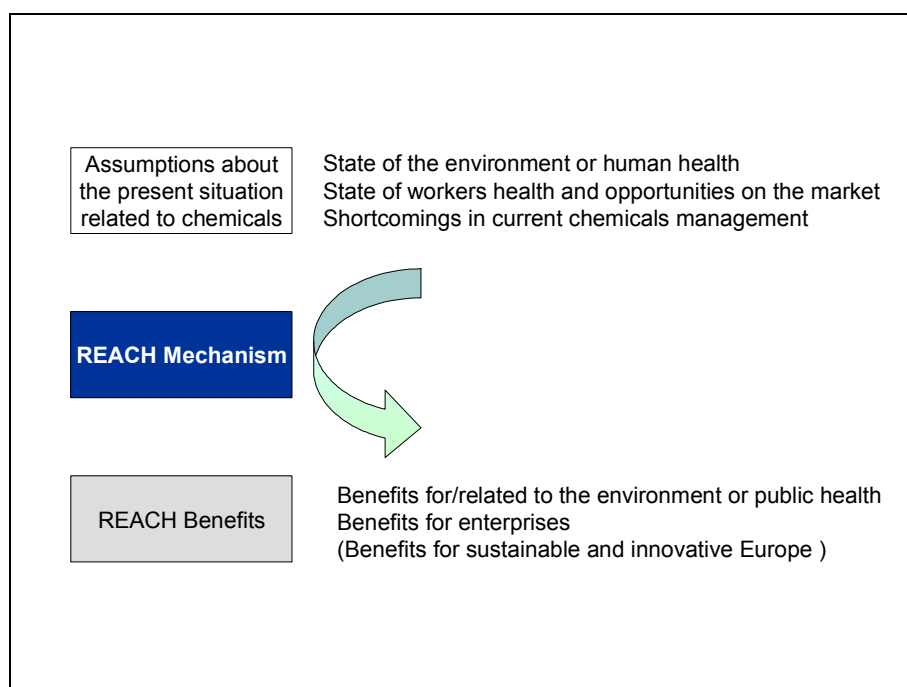


Figure 1: Elements of REACH-benefit descriptions

In the following, it is elaborated which benefits could be triggered by REACH. The description differentiates between benefits at company level (business benefits), benefits for public health and the environment and ‘other’ benefits. The latter one is not detailed out further in the work but was included for reasons of completeness.

⁶² The difficulty to define a baseline situation and the related lack of data indicate one potential benefit of REACH already. If REACH leads to a better information basis (existence of data, methodologies to generate information, accessibility of data and information, methodologies to draw conclusions on measures) to identify action needs this would be an important benefit with regard sustainability: The possibility to take informed, transparent and broadly accepted decisions on chemicals safety.

1.3. The role of enforcement

When describing the benefits of REACH, the baseline against which these will be measured is influenced by the degree of implementation of existing legislation:

- Existing legislation may not be fully implemented (e.g. worker's protection legislation), among other because it is insufficiently enforced. Here, REACH can enhance implementation either by generating additional information or by "doubling" requirements. In assessing and discussing potential benefits 100 % implementation will be assumed.
- REACH may not be sufficiently enforced, e.g. related to the quality of registration dossiers or the implementation of exposure scenarios. The degree of enforcement by authorities may influence the amount and quality of information generated by REACH as well as the actual risk reduction achieved. In assessing and discussing potential benefits 100% enforcement of REACH will be assumed.
- REACH does not rely on the traditional enforcement approach, but expects responsible behaviour of industry actors. Supply chain mechanisms and communication between industry actors will be complex making predictions about the power of the REACH-inherent mechanisms difficult.

Information on the assumptions related to the enforcement will be extracted in the study analysis.

2. Background and description of expected benefits

2.1. Objectives of the Regulation

The Commission proposal of October 2003 highlights seven objectives connected to the chemicals policy reform. These objectives are used as reference to structure and define the benefits that REACH may create. Not all of the objectives can be directly translated into measurable benefits since they are more a means to generate benefits rather than a benefit in itself.

2.1.1. Protection of human health and the environment

If REACH is successful, the incidence of adverse effects caused by chemicals should decrease. However, many of the observed adverse effects suspected to be connected to exposure to chemicals have multi-dimensional cause effect links. Therefore, information to characterise the baseline situation in an analytically sound way is scarce, and it is also unlikely that measured trends can be used to verify or disprove the benefits expected from REACH.

A more measurable benefit indicator is the risk to human health and the environment, which is however difficult to quantify in monetary terms. A potential indicator would be characterised by the type of substances, their properties and their use patterns. It is expected that the use patterns of substances may change due to REACH, however also here, statistical information on the baseline situation is hardly available.

2.1.2. Competitiveness of the European Chemical Industry

This objective can be interpreted as mitigating or reducing risk assessment and risk management costs of industry as well as creating an environment that motivates innovation and protects industry against business risks due to negative public campaigning on chemicals, regulatory interventions and liability claims. Currently trust in chemicals is limited in the European public and hence the “home-base” of the EU chemical industry appears vulnerable. On top of this, REACH is designed to motivate co-operation among substance producers in sharing information on substance properties.

2.1.3. Increased transparency

This is possibly not a benefit in itself but is the anticipated key outcome of REACH. More transparency on substance properties, on types of uses and conditions of use and appropriate risk management measures will be the basis for informed decisions, shared responsibility in the chain and documentation of process and product safety. All this may contribute to objective 1 and 2.

2.1.4. Prevention of fragmentation of the internal market

Regulatory risk management practice related to chemical substances is neither harmonised among the member states nor does the current EU system of community risk assessment and marketing and use restrictions work sufficiently effective. REACH is expected to create a methodological, procedural, institutional and regulatory framework that leads to a harmonised practice in risk management and product safety across the EU market. Reaching this objective is again not a benefit in itself but will contribute to objective 1 and 2.

2.1.5. Promotion of the development and use of non-animal tests

Animal welfare is one of the policy objectives in the EU. Hence promotion of non-animal testing to satisfy the information needs related to chemical safety would be a clear benefit. REACH may lead to a set of agreed rules which information may substitute testing under which conditions. Also, the duty of companies to document substance properties may create a market for innovative non-animal testing methods. In the initial phase of REACH, animal testing may increase due to the new information requirements under REACH.

2.1.6. Integration with international efforts

This objective is again not a benefit in itself but a means to achieve globally harmonised, high standards in risk management, contributing to the benefits under objective 1 and 2.

2.1.7. Conformity with EU international obligations under the WTO

Under the WTO rules it is forbidden to discriminate against non-European companies exporting into the EU market compared to European manufacturers. In addition, it is forbidden to set up unnecessary or disproportional barriers to trade. At the same time, import of dangerous substances via preparations or articles often undermines the efforts taken by EU companies and authorities to better control chemical risks. Hence, clear, non-discriminating and proportional obligations for importers of substances as such, in preparations or in articles are needed. Again the objective is not a benefit in itself but contributes to objectives 1 and 2.

2.1.8. Conclusions on structuring the benefits

The considerations outlined above lead to the following structure in setting up descriptions of benefits:

- Business benefits at company level relating to objective 2
- Human health and environmental benefits relating to objective 1
- Animal welfare relating to objective 5
- Improved effectiveness of the regulatory framework as such (substance markets with documented safety and elimination of unacceptable risks, versus resource input) is also seen as a benefit although not reflected in the objectives. It is listed in this paper but will not be considered in analysing benefit studies.

In the following tables, the types of benefits, the assumptions of the baseline situation and the related REACH mechanisms are compiled. It should be noted that the mechanisms are described in “abbreviated” form and exceptions or specific provisions are not given. For example it is not always mentioned that CSA is needed only if the production/import volume exceeds 10 t/a. An illustration of the mechanisms and the outputs which form the link between the REACH mechanism and the actual benefit are given in Section 1.

2.2. Business benefits

Type of benefit	Assumption on baseline situation	REACH mechanism ⁶³
Prevention of business risks related to...		
... liability claims and public campaigns (M/I/DU)	Companies could face costs from liability claims or product recalls related to substances they use in their products although they have insufficient knowledge on the risks connected with the use at their direct customers' or the customers of the customers. A business environment where substances can be brought to public attention and companies do not have their safety documentation (based on EU wide accepted methodology) readily available may end a product cycle earlier than expected and create relevant sink costs. The image of a company and especially their brand names suffer from being associated with substance-related scandals, resulting in losses of turnover/profits	In the registration dossier and chemical safety assessment where needed, M/I has to assess contaminants of substances, potential risks in different applications and make recommendations as to how the substance can be used under adequate control of risk.
Prevention of re-design ...		
... of formulations (Formulators)	Formulators face significant re-formulation costs for their products due to new information on substance properties and/or regulatory interventions. Formulators cannot be sure that a potential substitute is less dangerous than the substance to be substituted, due to the fact that only insufficient hazard assessment is available from the suppliers. Reformulation needs due to regulatory interventions or new classifications of substances are often not well foreseeable.	After registration, a standard information set will be available for all substances making them comparable → informed and long-lasting (sustainable) choices. After the phase-in, new classifications will be more seldom, because a lot of information on substance properties is then generated.
... of articles (Article producers)	Article producers have significant costs for re-designing their products due to new classification and/or regulatory interventions either directly or due to changes in raw materials implemented by their suppliers (formulators)	Criteria for substances potentially falling under the authorisation regime are communicated very early, the candidate list for authorisation will add to that information and make long-term planning is possible.
Reduced costs related to damage of human health and environment		
... workers health (M/I/DU)	There is substance-related damage to workers health, because of 'unsafe handling' due to insufficient knowledge on substance properties and/or because the CAD is insufficiently implemented in SMEs and competence or resources for risk assessments at work places is lacking. Employers have to pay compensation and loose experienced workforce due to days of illness.	Information on dangerous properties of substances is generated in registration and forwarded with SDS Improved SDSs and exposure scenarios provide a better information basis for (SM) enterprises to improve risk management at workplaces.

⁶³ For reasons of simplification, the REACH mechanisms are described in 'abbreviated form', leaving out e.g. specific conditions (e.g. registration only if production volume exceeds 1 t/a). Details on the mechanisms are given in Chapter 1.

Type of benefit	Assumption on baseline situation	REACH mechanism ⁶⁴
Better environment for improved chemicals risk management at enterprises		
More efficient and effective chemicals risk management at company level (site, work place and product related) (M/I/DU)	Risk management at enterprises currently is a patchwork of mechanisms and routines, which have evolved from the need to comply with different pieces of legislation. Assessment of risks and design of risk management is done by all companies 'separately'. As there are little instruments to communicate and cooperate on comparable exposure situations, extensive duplication of work takes place. On top of that, there is no risk based assessment approach yet standardised in Europe. Hence usually for companies there is large uncertainty around the question whether it is on the "safe side" or not and which information is needed to reduce the uncertainty.	Safety assessment over the life-cycle detects substance risks and allows developing a comprehensive control strategy. Information exchange and allocated responsibilities for data compilation and assessment in the supply chain reduces costs for single enterprises (one-for-all). Enterprises will have to change their attitude and behaviour towards communication and cooperation during the REACH phase-in.
Introduction of standard procedures to facilitate communication on chemicals safety up and down the chain. (M/I/DU)	M/I is currently not obliged to make himself aware on the conditions of use of his products in the market. DU is currently not required to inform his supplier on his conditions of use. Safety assessment is only required for workplace. The safety data sheet is the only communication instrument on dangerous substances at the moment. It does not provide enough information and understanding of chemical risks along the supply chain to enable efficient innovation efforts in supply chains.	In the (pre-)registration phase and when receiving feedback from downstream users, M/I will make himself aware of substance uses. Standardised communication as required in the ES will create information benefits for all and will make the information 'IT-compatible'.
Platform for limiting testing costs through co-operation (M/I)	According to the general products directive but also as responsible manufacturer or formulator, enterprises already now want to test the safety of their products but don't do so because they cannot afford it (e.g. low volume of substance, SME enterprise etc.)	For each substance a base set of information is to be generated for its registration. For non-phase-in substances, potential registrants shall (vertebrate animal tests) or may (other information) request access to (robust) study summaries from the previous registrants. An agreement on cost sharing is to be reached.
Limited testing costs due to broadly accepted rules on using non-test data or other information in hazard assessment (M/I)	Non-test and historical data are hardly used in hazard assessment, because (enterprises assume) they are not accepted. Available information on substances is not used because they are not published/known or the owners are reluctant to share it.	Annex XI gives rules (which will be further explained in RIP guidance) on which data can be applied how. Data sharing of vertebrate tests is obligatory.
Reduced penalties related to environmental emissions	Enterprises have to pay fees, penalties for exceeding emission limit values or for discharging toxic waste waters to municipal wastewater treatment plants. These costs could be avoided if better information on used substances was available.	Information on dangerous properties will be generated in registration and forwarded with SDS. A PBT assessment has to be made for higher volume substances. Improved SDSs and exposure scenarios assist enterprises in improving risk management for the environment / complying with environmental legislation

⁶⁴ For reasons of simplification, the REACH mechanisms are described in 'abbreviated form', leaving out e.g. specific conditions (e.g. registration only if production volume exceeds 1 t/a). Details on the mechanisms are given in Chapter 1.

Type of benefit	Assumption on baseline situation	REACH mechanism ⁶⁵
Prevention of unfair competition		
Imports and EU-production of substances as such or in preparations are treated equally (M/I)	European substance producers and formulators compete with imported products, which can be contaminated with dangerous substances which have not been assessed and/or classified. There are little incentives for importers yet to market 'clean' products. The same applies to EU manufacturers still marketing substances with a significant higher level of dangerous by products compared to others.	Any manufacturer and importer has to register substances as such or in preparations and thus has to determine the identity of his substance and its impurities. Based on this, C+L and safety assessment is to be carried out. The results will be communicated via the SDS and the Agency's C+L inventory. Hence the professional or industrial customer can make an informed choice and can communicate the corresponding information to his customers.
Imports of articles and production of these in the EU are treated equally (DU)	European article producers compete with imported (semi-finished) articles containing un-assessed and 'undeclared' contaminants. There are little incentives for article importers to market 'clean' products.	Importers of articles with intended release of substances have to register these and forward respective information Importers of articles have to notify information about contained SVHC to the Agency and have to inform their professional customers
M/Is will have a better position to restrict their market based on risk considerations (M/I)	Currently companies rarely stop to supply certain customers based on risk considerations. If they do, they either risk that their competitors take over the market shares or that they are accused of abusing a dominant market position	Based on the ES and the CSA concept, the M/I can provide the arguments why he considers a certain type of use not to be safe and hence will not support this use in his registration. A competitor will (under OSOR) possibly submit an ES and a CSA in which he documents the use to be safe. These mechanisms allow for transparency and hence enable response from the market and the authorities.
Better conditions for Innovation		
Development of new substances and use of existing substances in new applications are enhanced (M/I/DU)	The current requirements for notification of new substances are discouraging for the development of new substances	Lighter requirements for 'new' substances PPORD for 'new' and 'existing' substances possible 'new' and 'existing' substances are treated equally.
Risk managements is internalised in product development allowing for quality differentiation in the market (M/I/DU)	Currently, risk considerations are not yet integrated in the product development strategies of enterprises.	For registering a new substance, risk considerations are to be performed, where a market volume exceeding 10 t/a are envisaged. Formulators of new preparations receive information on risk management of the components, which can be easily taken into account in the development process.
Level playing field		
The same chemicals related legislation exists in all EU 25 (M/I/DU – formulator)	Currently, enterprises spend a significant amount of resources in assessing and implementing different regulatory requirements for marketing their products in different EU countries.	Due to REACH, chemicals legislation will be harmonised in all EU 25.

⁶⁵ For reasons of simplification, the REACH mechanisms are described in 'abbreviated form', leaving out e.g. specific conditions (e.g. registration only if production volume exceeds 1 t/a). Details on the mechanisms are given in Chapter 1.

2.3. Human health and environmental benefits

Type of benefit	Assumptions on baseline situation	REACH mechanism
Improvement of public health		
Less public spending to cure health damage of workers	Public spending in the health sector also covers workplace related illness where no workers insurance covers that damage.	Prevention of damage due to safety assessment and adequate control along the supply chain
Improved well-being of workers (including: less private spending to cure health damage of workers)	There is substance-related damage to workers health, because of 'unsafe handling' due to insufficient knowledge on substance properties and/or because the CAD is insufficiently implemented in SMEs and competence or resources for risk assessments at work places is lacking. However; in this row the improvement of quality of life is addressed and not the cost savings of employers (e.g. loose experienced workforce due to days of illness).	Information on dangerous properties of substances is generated in registration and forwarded with SDS Improved SDSs and exposure scenarios provide a better information basis for (SM) enterprises to improve risk management at workplaces.
Less public ill-being	Consumer health is damaged due to exposure to dangerous substances Dangerous substances posing a risk are contained in consumer preparations and articles because of insufficient knowledge	Data generation and safety assessment including the life-cycle stage 'service life' in the registration ensure that risks are adequately controlled
Less public spending in related to reduction of health damage (curative costs)	There are significant costs for maintaining public health due to damage caused by chemicals Costs of substance related damage in public health are born by the public	Prevention of damage due to safety assessment and adequate control along the supply chain Sharing of responsibility in the chain and allocation for risk assessment and management make it possible to 'internalise' costs for health damage
Reduction of risk (expressed as decreasing exposure to CMRs or EDCs)	Currently there are health risks due to exposures to CMR s and endocrine disruptors	Identification of CMRs and endocrine disruptors in registration. Restrictions of use and/or strict conditions of use imposed in the granting of authorisations reduce exposure.
Improvement of environment		
Less environmental damage	The environment is damaged due to exposure to dangerous substances, which result from unsafe uses in industrial processes or articles. Uses of dangerous substances posing a risk exist due to insufficient knowledge Due to long risk assessment procedures, risk management with regard to the environment is started with much delay after becoming aware of an environmental threat from a substance. Current environmental legislation does not cover substance risks sufficiently.	Information on dangerous properties will be generated in registration and forwarded with SDS. A PBT assessment has to be made for higher volume substances. Improved SDSs and exposure scenarios assist enterprises in improving risk management for the environment / complying with environmental legislation
Less public spending for compensation of environmental damage	There are significant costs for remedying environmental damage caused by chemicals Costs of substance related damage in public health are born by the public	Prevention of damage due to safety assessment and adequate control along the supply chain Sharing of responsibility in the chain and allocation for risk assessment and management make it possible to 'internalise' costs for health damage to responsible
Reduction of risk expressed in decreasing emissions / exposures of PBTs/vPvBs or EDCs	Currently there are environmental risks due to exposures to PBTs/vPvBs and EDC. PBTs/vPvBs and EDCs or substances of similar concern are insufficiently regulated to prevent environmental damage at present.	Identification of PBTs/vPvBs and EDCs in registration. Restrictions of use and/or strict conditions of use imposed in the granting of authorisations reduce exposure.

2.4. Other benefits

Type of benefit	Hypothesis on reality	REACH mechanism
More rational allocation of public resources for risk assessment and restriction measures		
Less efforts for risk management with the authorities	Current procedures for risk assessment (Existing substances regulation) and risk management (Dir. 76/769/EC), environmental, workers, product-, site- and waste-related legislation are inefficient	Industry assesses and manages risks Shared responsibility along the supply chain motivates to improve knowledge base (feedback, collection of use information); authorities help to make the system run but do not run the system Unsafe uses will be phased out
Community wide measures more targeted	The information base for community wide risk management measures of substances is poor. Priority setting for risk management is mainly based on hazard information.	Substance evaluation and authorisation will be based on industry information (reg. Dossiers + further info) More risk based priority setting instead of 'selection based on hazard' of substances
Standardised assessment, management, communication on chemicals risks	Resources are inefficiently used due to differences in assessment, management and communication on chemicals risks (methodology, terminology etc.)	Methods are standardised via guidance and tools, industry involvement ensures understandability ⁶⁶ .
Re-establishing trust in chemicals and ensuring a stable business environment for innovation	'Chemicals' are mistrusted limiting application areas and increasing scepticism towards chemical innovations.	REACH will lead to more transparency on which substances are on the EU market and what properties they have. Information on very hazardous substances in articles will be notified to the agency.

⁶⁶ This will have an even greater effect in practice if the REACH approach is fully integrated into all chemicals-related risk assessment regulations.

3. REACH Mechanisms

The following figures give a brief overview of the REACH mechanisms potentially generating benefits for enterprises, human health and/or the environment. The 'outputs' of REACH which link the REACH mechanisms to the benefits listed in the tables above are shown in grey boxes at the bottom of each figure.

3.1. Registration

For registering non-phase-in substances, potential registrants are to inquire from the Agency if previous registrations have been submitted. In case there hasn't, the registrant submits his registration according to Article 10. If the substance has been previously registered, the potential registrant is to request information from the previous registrants in order to avoid unnecessary testing and share costs. It is obligatory to share vertebrate animals tests information and optional to do so for non-animal information. If several manufacturers or importers of the same non-phase-in substance want to register, they are to make a joint submission of data according to Article 11. It is however possible to opt out of the joint submission under certain circumstances.

For registering phase-in substances, manufacturers and importers have to submit a pre-registration and by this become member of a SIEF. In a SIEF, M/I have the opportunity to communicate about common registrations and data sharing. For registering, they have to compile and/or generate information on substance properties as well as on their uses. They are to submit common dossiers, except where participants of a consortium opt-out due to the reasons specified in REACH.

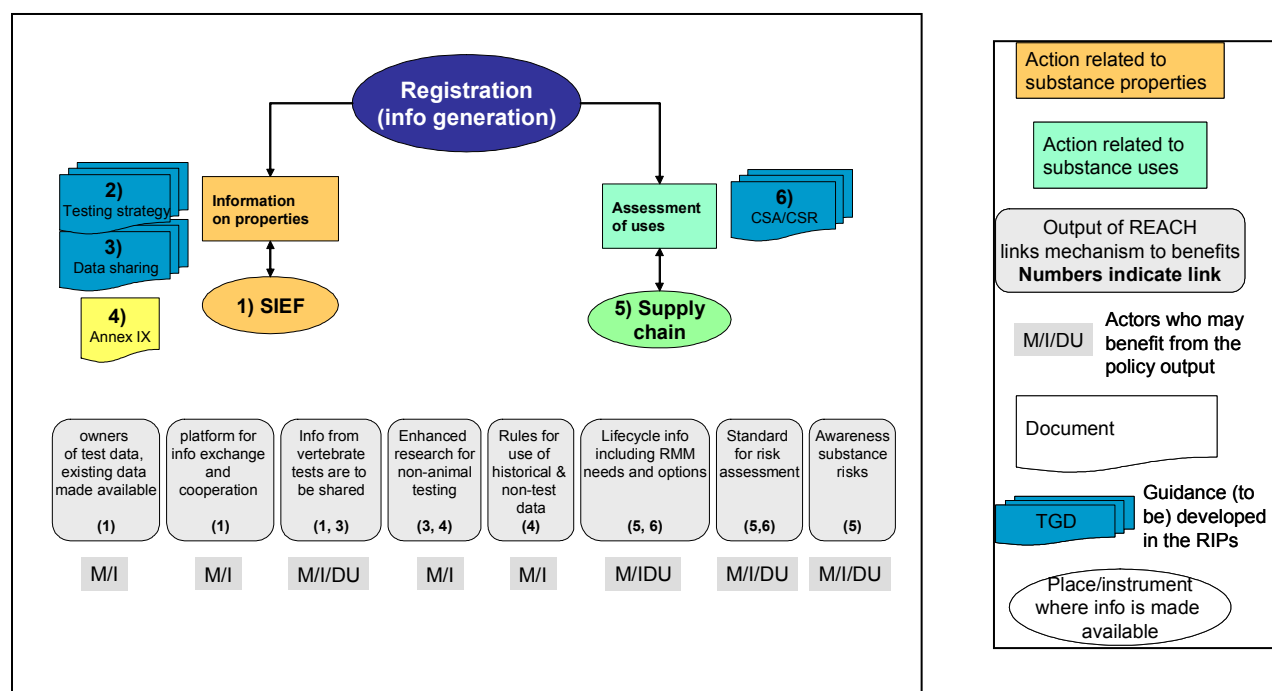


Figure 2: Outputs of info generation under REACH linking to benefits

For substances manufactured/imported in amounts above 10 t/a a chemical safety report is to be included in the registration. If the substance is dangerous according to Directive 67/548/EEC, an exposure assessment and risk characterisation of all identified uses M/I wishes to support is to be made as part of the CSA/CSR. The conditions of safe use as identified in the safety assessment are to be communicated as Annex to the SDS to the downstream users (final ES).

Registration dossiers will be checked for completeness (all), for testing proposals (where proposals are made, in general substances in volumes > 100 t/a) and for compliance (5% of all dossiers, 'random' check). Where no registration dossier is submitted, marketing of the substance will be prohibited from the date of registration of the respective tonnage band. Where testing proposals are inappropriate, the agency will require adequate data from the registrant. Where the dossier is incompliant, the registrant will either have to refine his dossier by supplying further information or lose his right to market the substance⁶⁷.

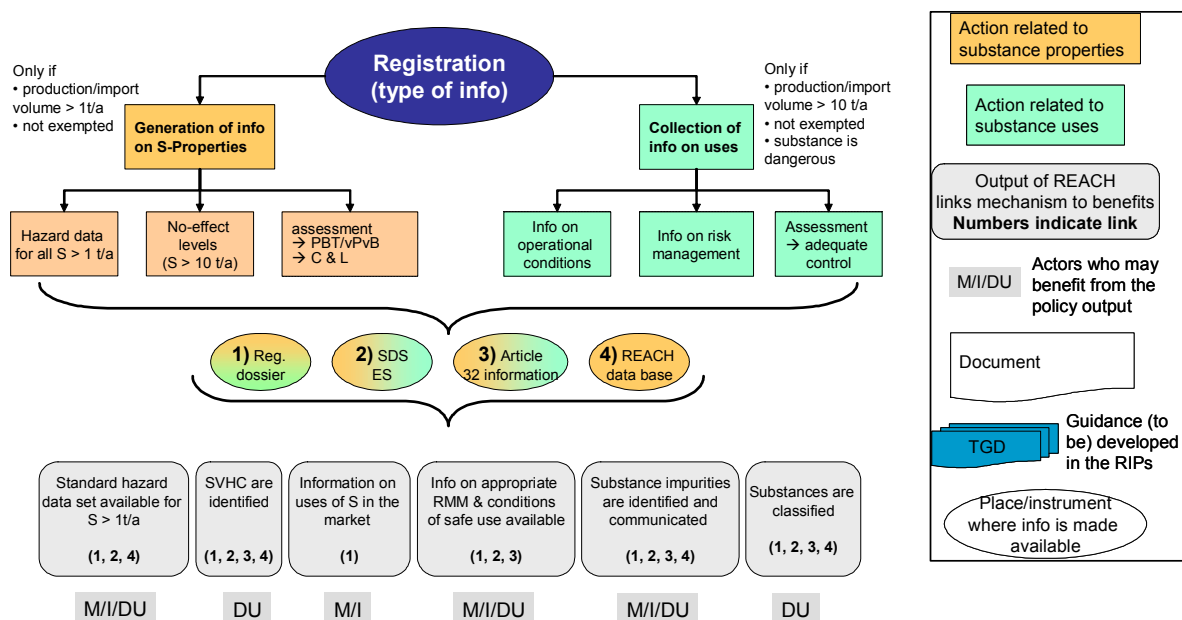


Figure 3: Impacts of registration mechanism under REACH linking to benefits

3.2. Substance evaluation

Substances where community wide risks are suspected will be prioritised for evaluation at EU-level based on the information received in registration dossiers. Member States will do the assessment work, relying on industry data and having possibilities to request further information. Depending on the result of the assessment, the substance can be introduced into the authorisation or restrictions procedure (need for risk reduction). This is largely the REACH element taken over from current ESR with however improved information basis and management procedures.

⁶⁷ Also here, enforcement is an important factor for realizing the benefits of REACH.

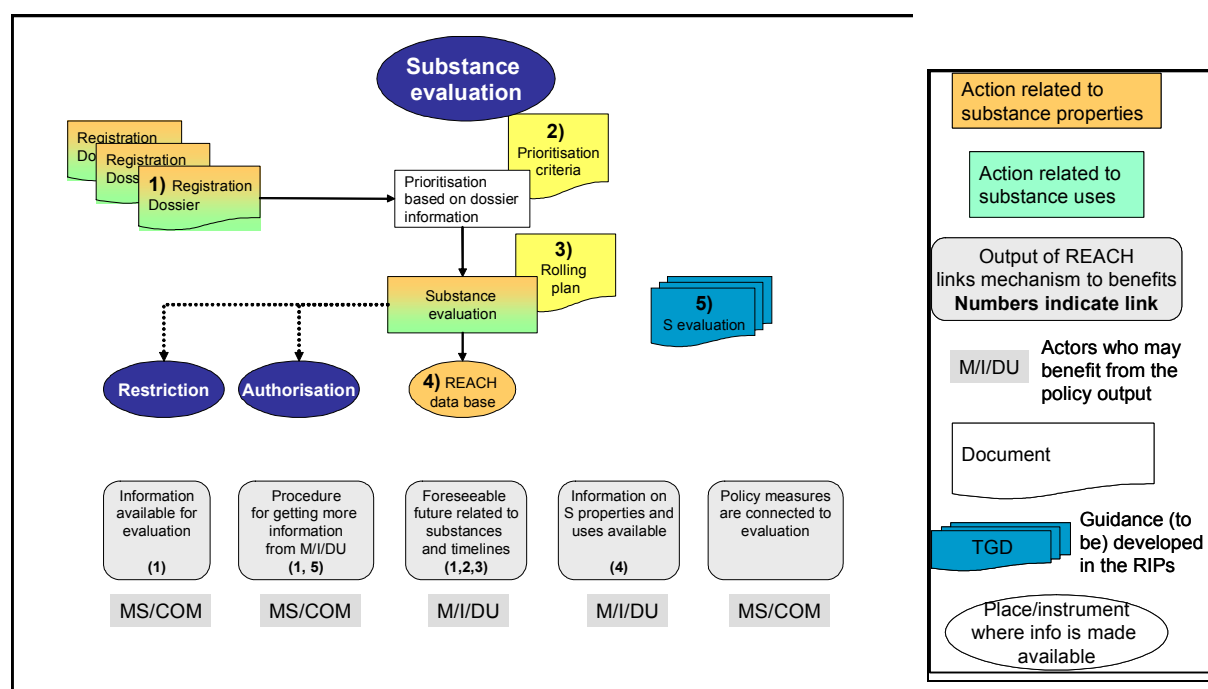


Figure 4: Impacts of the evaluation mechanism under REACH linking to benefits

3.3. Authorisation

Substances fulfilling the criteria of an SVHC will be identified and placed on the so called candidate list for authorisation. Substances meeting the priority criteria for authorisation may then be proposed for inclusion in Annex XIV. Substances included in Annex XIV of REACH will be subject to authorisation, except where exemptions are included in the Annex. Authorisations can be applied for by any actor in the supply chain and shall contain proof of adequate control via CSR and an assessment of alternatives as well as the techno-economic feasibility of a substitution. An application may contain a socio-economic analysis and/or a substitution plan.

The decision on an authorisation will be taken based on the information provided by the applicant and by other stakeholders involved in the consultation. Authorisation will be granted when adequate control can be shown, or where the societal benefits of using the substance outweigh the risks. Users of substances which have been granted an authorisation have to implement the conditions of the authorisation and notify the agency of their use. The conditions of the authorisation are to be communicated via the safety data sheet and/or the exposure scenario. Authorisations may have a fixed review date, where the decision is challenged in the view of new information or changed market / societal conditions.

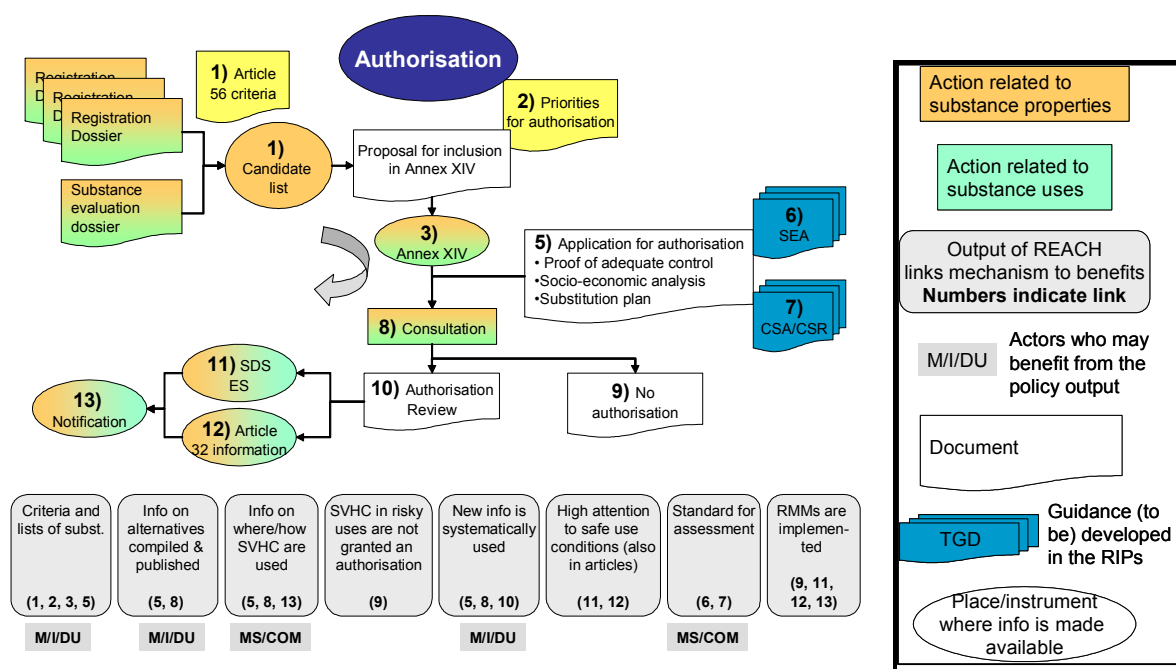


Figure 5: Impacts of the authorisation mechanism under REACH linking to benefits

3.4. Chemical safety assessment and shared responsibility along the supply chain

For substances produced/imported in amounts exceeding 10 t/a a chemical safety report has to be included in the registration dossier. For dangerous substances it documents the assessment of exposures and characterisation of risks along the entire life-cycle of the substance. Thus, at the beginning of the chain, risks are identified and, where necessary, substances are not registered for unsafe uses. M/I has to make himself aware of the life-cycle of his products and has the responsibility to communicate the safe conditions of use as final exposure scenario via the SDS. Downstream users may contribute with information to the assessment.

When receiving an ES, downstream users are required to apply the measures to adequately control risks as communicated to him by information from his suppliers. If they don't do so and continue to use the substance, they take over the responsibility for the assessment and safe use of the substance (DU CSA) for themselves and their customers and are to communicate the safe conditions of use via the safety data sheet. Information on the safe use of SVHC in articles when contained in concentrations > 0.1% w/w are to be communicated to recipients (industrial and professional users) of these articles.

Downstream users are to give feedback on their suppliers' SDSs, where they have differing or new information as well as where they regard the recommended risk management measures inappropriate. Through REACH, the general duty of care is made more explicit and is defined by concrete tasks as well as made more binding by defining the responsibilities of the different actors in the supply chain. As taking no action means to take responsibility for either applying the recommended conditions of use or to make an own assessment, no action becomes an action.

The following figure does not list any specific policy outputs of REACH, as these are already shown under the respective REACH mechanisms above. Nevertheless the idea of shared responsibility along the supply chain and the life-cycle approach of the CSA/CSR are illustrated here for reasons of overall understanding and reference.

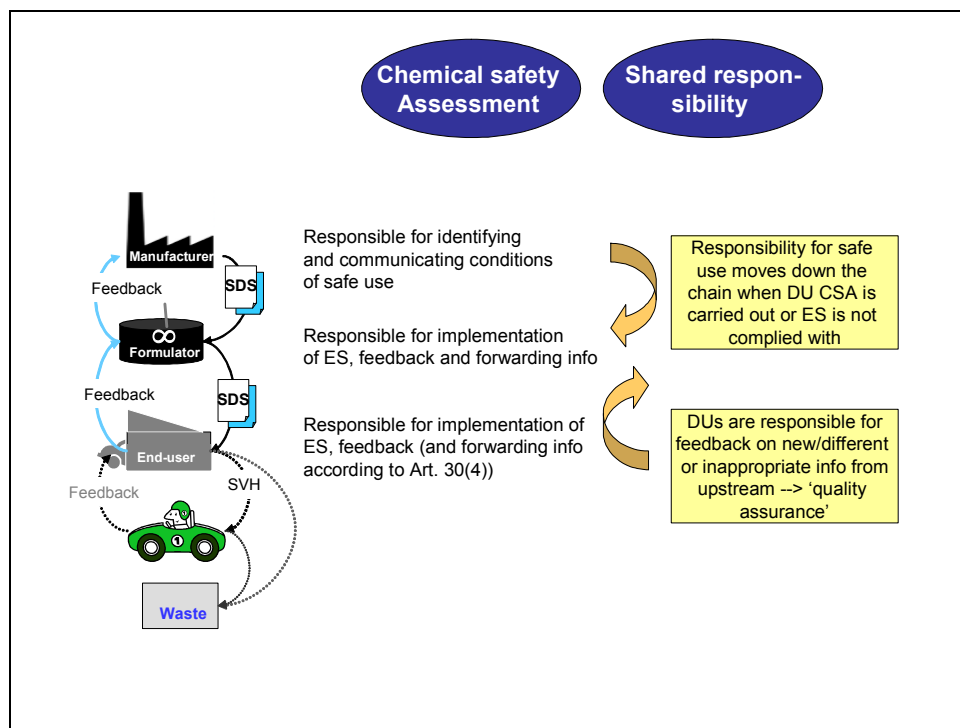


Figure 6: Impacts of the supply-chain and life-cycle approach of REACH linking to benefits

3.5. Competitiveness and level playing field

Importers of substances as such, in preparations or in articles from which they are intended to be released have to register these substances; just as EU manufactures. Thus, they will have to identify the substance including information on impurities. This will lead to an improved knowledge on substances (and impurities / contaminants) in imported products. The more level playing field also relates to competition between non-classified products based on lack of information and classified products based on good knowledge.

A more level playing field is created for EU – substance manufacturers, formulators and article producers towards importers on the one hand, but also within the EU between those actors who already now act responsibly and those who don't. The content of SVHC in articles is to be communicated to the agency and to professional users of articles where contained in concentrations exceeding 0.1% w/w.