Report to
DG Environment

The impact of REACH on the environment and human health

ENV.C.3/SER/2004/0042r

Revised final report
September 2005

The impact of REACH on the environment and human health

ENV.C.3/SER/2004/0042r

Agern Allé 5
DK-2970 Hørsholm
Denmark

Tel: +45 4516 9200
Fax: +45 4516 9292
e-mail: fip@dhi.dk
Web: www.dhi.dk

Client	Client's representative
DG Environment	Fabio Leone

Project	Project No.
The impact of REACH on the environment and human health	52856

Authors

Finn Pedersen
Lise Samsøe-Petersen
Kim Gustavson
Lena Höglund (DTC)
Phoebe Koundouri (University of Reading)
David Pearce (University College London)

Date: 2005.09

Approved by: Torben Madsen

02	Revised final report	KIG	LSP	TMA	2005.09
01	Final report	FIP	LSP	TMA	2005.08
Revision	Description	By	Checked	Approved	Date

Key words

Classification

☐ Open

☐ Internal

☒ Proprietary

Distribution	No. of copies
DG Environment	11
DHI: FIP/LSP/KIG/ERA	5

CONTENTS

APPENDICES

EXECUTIVE SUMMARY

A proposal for a new EU chemicals regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) was presented by the European Commission in October 2003. REACH will require that manufacturers and importers of chemicals register their chemicals, that registrations are evaluated by authorities, that certain substances of very high concern are authorised and that restrictions are imposed in cases where risks cannot be adequately controlled by other means. REACH will replace and consolidate into one single regulation large parts of the current chemicals legislation.

The introduction of the new legislation will have an impact on human health and the environment and on society and business. Numerous studies have been conducted by the Commission, by national authorities and various stakeholders on the possible impact of REACH. Most of these studies have focused on the economic costs to industry, while only a few have dealt with the potential benefits. Therefore, the Commission has initiated and commissioned the current study on the impact of REACH on the environment and human health.

The possibilities for estimating the potential benefits of REACH on the environment and on humans exposed via the environment suffer both from a lack of a sufficiently developed methodology and from a lack of data. In the present study, we have tried to circumvent these knowledge gaps by using three different methodologies for assessing potential benefits and to use a number of data at a screening level. Of course, this influences the reliability of the conclusions that can be drawn on the basis of the study.

Three possible approaches have been identified that may be suitable for assessing the potential impact and benefits of REACH on the environment and humans exposed via the environment. These are:

- Willingness to pay (WTP) among the broad population for avoiding impacts of chemicals
- Damage function approach based on past mistakes where an empirical relationship between damage and cost might be established
- Avoided or saved costs approach where costs of mitigating current pollution is estimated as the upper limit for the possible benefit of REACH

The WTP approach is seen as the economically ‘correct’ way of estimating benefits. However, only two studies are available. One study from the UK elicits the population’s willingness to pay for clean drinking water, while another study reviews the willingness to pay for avoiding health effects of chemicals pollution, in particular cancer.

The information from the first study was used to estimate the potential benefits of REACH to €1,730 mill in year 2017 if only benefits to drinking water quality are considered. The study is not sufficient for extrapolating to the benefits of REACH on the environment in the whole of EU-25. It might be assumed that the population’s WTP for environmental benefits is lower than for direct health benefits, while the WTP for avoiding serious health effects of chemicals pollution is much higher. Due to the very limited amount of input data, the results obtained are judged to be uncertain.

The damage function approach based on past mistakes was tried out using four well-known substances[1] as the basis and extrapolating to all other substances that may be affected by REACH. A system was established, which was intended to rank all substances based on their environmental and health properties in combination with tonnage; e.g. persistent toxic substances that are produced in large amounts are ranked very high. The ranking system was based on the EURAM method with input data obtained from the European Commission's IUCLID database and from the Danish EPA QSAR[2] database. The information from the IUCLID database is restricted to substances manufactured or imported in quantities above 10 tonnes/year and information on properties and amounts was provided for 8,031 substances. QSAR calculations were available for 45,452 discrete, organic substances among which 4,368 were recorded in IUCLID with information on quantities. All of the input data are uncertain and can only be used with caution.

However, although the four substances selected as case substances are among those that are now restricted, the ranking showed that many other substances seem to be of similar or higher concern. Such a large number of substances cannot be assessed on a substance-by-substance approach, as any benefit resulting from reducing the release of one substance may be shadowed by impact from other substances. Instead, a conservative 10% reduction of costs due to REACH has been calculated. Due to the large uncertainty of the input data and the huge extrapolation, this approach is judged to be the weakest of the three approaches tried out in the current study.

The avoided or saved costs approach was used to assess the current costs of mitigating the chemical pollution for a number of cases[3]. The cost estimates for some of the cases are relatively robust, as it has been possible to obtain relatively detailed and precise information. This is in particular the case for purification of drinking water, disposal of dredged sediment and incineration of sewage sludge instead of disposing it on farmlands. Costs of building larger sewage treatment plants in order to obtain room for excess nitrification capacity due to toxic effects of chemicals in sewage water and costs of cleaning of fish products are considered weaker cases. From the cases, it is estimated that today the costs of measures already implemented for mitigating the impact of releases of chemicals are huge - in total up to €7 billion per year in 2005 for only those cases included in the study. Even assuming that the potential benefit of REACH would be only at 10%, the benefit is estimated to €150-500 mill in year 2017, which over the next 25 years adds up to €2,800-9,000 mill.

An overview of the results is given in Tables A-C below. Most of the estimates are based on an assumed efficiency of REACH in reducing general environmental contamination levels by 10%.

---

[1] 1,2,4-trichlorobenzene, nonylphenol, tetrachloroethylene and PCBs

[2] Quantitative Structure-Activity Relationship (QSAR). QSAR are methods for estimating the toxicity and other properties of a chemical from its molecular structure.

[3] Sewage treatment, drinking water purification, disposal of dredged sediment, sewage sludge incineration/disposal and cleaning of fish meal

Table A Overview of potential benefits of REACH (values in mill €) determined as potentially saved costs (most robust approach)

Case	2017	2017-2041
Building of sewage treatment plants	7.1-24	131-440
Drinking water purification	49-302	896-5,564
Disposal of dredged sediment	13.1-78 (78-470)*	241-1,450 (1,444-8.660)*
Sewage sludge	83	1,520
Cleaning of fish meal	0.9	16
Total potential benefits for cases	153-488	2,804-8,990

*) Based on 60% reduction of contaminated sediment.

Table B Overview of potential benefits of REACH (values in mill €) determined as the population's willingness to pay (weaker approach)

Case	2017	2017-2041
WTP for clean drinking water	1,730	34,000

Table C Overview of potential benefits of REACH (values in mill €) determined by extrapolation from case substances (weakest approach)

Case	2017	2017-2041
Avoidance of severe health effects	210-2,500	4,000-50,000
Improved reuse of sewage sludge	16-133	300-2,600
Total potential benefits for cases	226-2,633	4,300-52,600

It appears from the overview tables that the most robust approach results in the lowest estimate of benefits, while the weakest approach results in the largest estimate of benefits. However, the three different approaches estimate different costs and benefits, with the most robust approach estimating costs and benefits in relation to cleaning or handling of polluted matrices (water, sludge, sediment, fish products) and the weakest approach mainly estimating saved health costs. To obtain the best reflection of the different methodologies used and the level of uncertainty linked to the estimated impacts (i.e. indicative values), we preferred to keep them clearly separate.

Thus, in conclusion, the potential benefit of REACH on the environment and humans exposed via the environment is estimated by use of a robust approach to as a minimum €150-500 mill in year 2017 with a potential long-term benefit over the succeeding 25 years of €2,800-9,000 mill. These estimates are based on well-documented cases of costs in combination with assumptions on the potential benefits of REACH.

Using much weaker approaches, the benefit arising from saved health costs is estimated to €200-2,500 mill in year 2017, which aggregated over 25 years corresponds to €4,000-50,000 mill. Once again, these values can only be seen as indicative values for the potential benefits of REACH on the environment and humans exposed via the environment. ***The values are based on a very weak data set***; however, the best available. A more precise estimate would require generation of new data and a key role of REACH is to generate such data.

We are particularly grateful for the input and comments received from two groups of experts, which were established for the purpose of reviewing this report. Their particular expertise in the domain of public health and environment, risk assessment, QSAR and environmental evaluation has been crucial to the successful completion of this study.

1 INTRODUCTION

The proposal for the REACH Regulation presented by the European Commission is currently being discussed in the Council of Ministers and in the European Parliament. It is the intention that REACH shall replace large parts of the current chemicals legislation. REACH will require that manufacturers and importers of chemicals register the chemicals, that registrations are evaluated by authorities, that certain substances of very high concern are authorised and that restrictions are imposed in cases where risks cannot be adequately controlled by other means. It is assumed that the REACH Regulation at the earliest will be adopted and enter into force during the year 2006 or more likely during 2007. Furthermore, an implementation period of 11 years is scheduled, which means that the full benefits of REACH will only be evident from the year 2017 at the earliest.

2 BACKGROUND OF THE STUDY

2.1 Impact of the proposed REACH regulation

The Commission has prepared an assessment of the impact of REACH including a broad assessment of both the costs and the benefits (CEC 2003). This assessment was based on a number of analyses carried out by the Commission, by various contractors for the Commission and by various stakeholders including industry and NGOs. Most attention has been paid to the potential costs of implementing the REACH Regulation, while only a few studies have dealt with the potential benefits (cf. an overview of cost-benefit analyses in Appendix A).

Three studies on the benefits of REACH preceded the present study (RPA 2003, Postle *et al.* 2003, Pearce & Koundouri 2003). None of the studies evaluated environmental benefits, only benefits to health from either an economic or a risk management point of view.

In summary, the assessments of the potential benefits of REACH are still uncertain and further work is needed in order to provide a more precise estimate of the benefits. This is in particular the case for benefits to the environment.

2.2 Objectives of the study

The objectives of the study are:

- To assess the impact on the environment and humans exposed via the environment (i.e. excluding direct consumer exposure and occupational exposure) as a result of releases of chemicals; and
- To assess the possible long-term benefits of REACH in reducing such chemical threats.

In the study appropriate methodologies were developed, available data were collected, and a number of case studies were conducted in order to create sufficient basic knowledge allowing the assessment of potential benefits of REACH.

2.3 Anticipated functioning of REACH

It is a prerequisite for assessing the possible benefits of REACH that a sufficiently precise understanding of the functioning of REACH is established. For this particular study, the potential reduction of the releases of chemicals to the environment and the subsequent reduced exposure and effects on the environment and humans exposed via the environment are the focus.

REACH may result in reduced releases to the environment through different instruments:

- Industry introduces additional Risk Management Measures (RMM) as a consequence of either having re-classified substances as a result of additional information on substance properties leading to additional S-phrases, or having identified risks by preparing a Chemical Safety Assessment (CSA) in relation to **Registration** of their chemicals.
- Use conditions are imposed as a result of an **Authorisation** obtained for certain uses of prioritised substances of very high concern.
- Restrictions on manufacturing, marketing or use as a result of the **Restriction** procedure.

Of these instruments, the restriction procedure is essentially a continuation of the current restrictions directive (76/769/EEC). The influence of REACH on this work would relate to the speed of introducing new restrictions, but this is impossible to predict. Thus, the assumption is that REACH will have no or only minor influence on releases to the environment through this instrument.

The authorisation procedure is new under REACH. Substances of very high concern will be prioritised for authorisation and specific conditions for granting an authorisation may be imposed. However, the identification of these substances is already well underway under the current legislation and the potential benefit of REACH would therefore pertain merely to additional substances that may be identified as a result of generation of new information. A general requirement for granting an authorisation is that risks are adequately controlled. In granting an authorisation, authorities will confirm that this is the case based on documentation submitted by the applicant. This means that, although the same requirement on adequate control of risks pertains to all other substances that are registered, a stricter control may apply to authorised substances than to other substances. On the other hand, for some substances where the socio-economic benefits exceed the risks, more lenient requirements may be allowed, and this can hardly be considered a benefit to the environment. Furthermore, it is anticipated that a maximum of 20-30 substances can be handled through this instrument per year; in particular in the start-up phase. Thus, all in all it is difficult to assess whether the authorisation procedure will result in major benefits to the environment and, consequently, this is not included in the current study.

Thus, the main impact of REACH on human health and the environment would probably arise as a result of the chemical safety assessment (CSA) conducted by manufacturers and importers prior to registration of their chemicals, and the subsequent implementation of necessary risk management measures by themselves and downstream users. A CSA is required as part of the registration dossier for substances manufactured or imported in a quantity of more than 10 tonnes per year per registrant. However, only for substances fulfilling the criteria for classification as dangerous or the PBT/vPvB[4] criteria, exposure assessment and risk characterisation will be part of the CSA. The exposure assessment and risk characterisation part of the CSA is the main vehicle for identifying a need for introducing additional risk management measures eventually leading to reduced releases.

The chemicals registered under REACH are any new substances that have not previously been manufactured or imported in EU as well as the so-called "phase-in substances" (essentially what currently are named "existing substances"). The requirements for new substances are, if anything, more lenient than today's requirements, which means that there will be no benefit of REACH for these substances.

Thus, *the main benefits of REACH can be assumed to be related to phase-in (existing) substances manufactured or imported in a quantity of more than 10 tonnes per year and meeting the criteria for classification as dangerous or the PBT/vPvB criteria.*

A number of substances within the scope of REACH are already covered by other legislation under which safe manufacture and use is or will be ensured:

- The existing substances review programme comprising 141 prioritised High Production Volume Chemicals eventually followed by development and implementation of a risk reduction strategy for substances for which risks are not sufficiently controlled
- PBT and vPvB substances identified among the existing HPVCs
- New notified substances
- Persistent Organic Pollutants (POP) (included in the Stockholm Convention)
- Ozone depleting substances included in the European list (EEC 2000b) and/or in the Montreal protocol (UNEP 2000) and sufficiently restricted
- Greenhouse gasses, including halocarbons (CFCs, HCFCsr, HFCs, PFCs and SF6) and sufficiently restricted

Those substances or those uses of substances that are already comprised by current programmes are therefore excluded from the study. This includes the 141 substances and groups of substances covered by the current existing substances review programme, the PBT and vPvB substances identified among the HPVCs and currently undergoing evaluation, and substances the manufacturing, marketing and/or use of which are already restricted.

However, it might also be anticipated that even without the introduction of REACH, a continued inclusion of more and more substances into the current review programme and eventual restrictions in the long run would result in the same level of environmental and human health protection as will be accelerated by REACH. Thus, the potential

[4] PBT: Persistent, Bioaccumulative and Toxic; vPvB: very Persistent, very Bioaccumulative.

benefit of REACH should be seen in relation to the level of protection that would have been reached within a certain time period. This can be illustrated as in Figure 2.1 below.

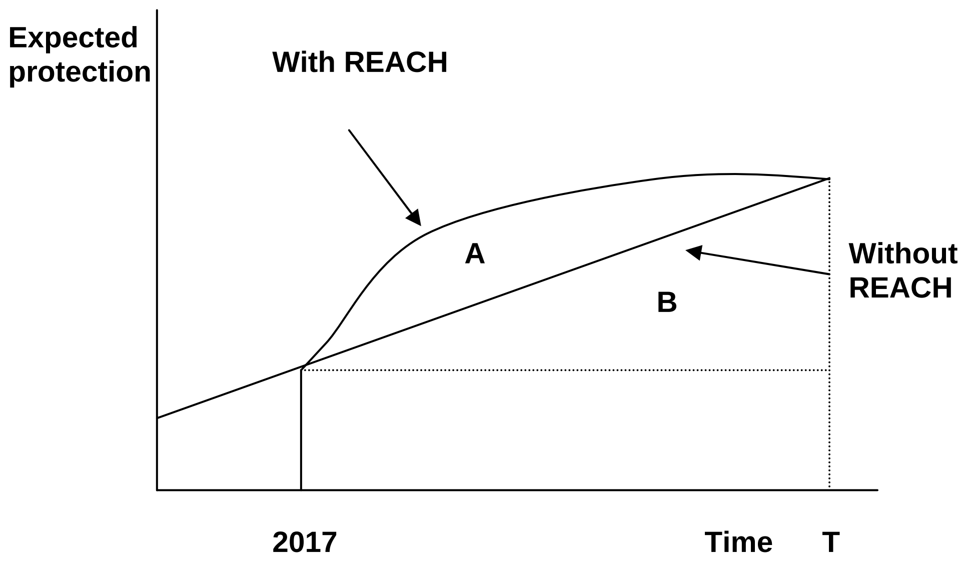

Figure 2.1 The potential benefit of REACH relative to expected protection without REACH

The methodologies used in this report effectively measure area A + B in Figure 2.1. But the true benefits of REACH are given by area A only, i.e. the difference in risk and environmental quality with REACH as opposed to without REACH. Hence the methodologies could overstate the benefits of REACH. However, while a reasonable assumption for the year at which REACH has its full impact is 2017, there is no guidance at all on the year at which non-REACH legislation will achieve the convergent level of risk reduction at time T in the diagram. Moreover, the slope of the 'non-REACH' line could be fairly flat taking the progress of the current existing substances programme into account, making the extent of overestimation small. The problem is that information simply does not exist on which to base any quantitative estimate. Finally, if there is over-estimation of benefits, it will be offset by under-estimation due to the fact that the full range of health and ecosystem impacts are not captured by any of the methodologies considered.

2.4 Effect of REACH on releases of chemicals

A number of routes of releases of chemicals to the environment from manufacture and use can be identified:

- Direct discharge of wastewater
- Discharge of wastewater via municipal sewage systems
- Ventilation outlet to atmosphere
- Evaporation to atmosphere
- Deposit of waste on unprotected soil
- Deposit of waste in municipal landfills
- Collection and treatment of hazardous waste

Most of the release pathways are regulated more or less thoroughly already under today's legislation.

Direct discharge of wastewater from larger industries is regulated by the Integrated Pollution Prevention and Control (IPPC) Directive 96/61/EC via discharge limits at EU level and/or at national level. However, this regulation deals mainly with the already known prioritised toxicants.

Discharge from industries to municipal sewage treatment systems may be regulated at national level. No direct regulation of discharges from consumers is in place, although chemicals in consumer products are regulated by, e.g., Directive 76/769/EEC on restrictions of hazardous substances. Discharges from sewage treatment plants are often regulated at national level although seldom the releases of individual substances.

Atmospheric releases of priority substances from larger industries are regulated by the IPPC Directive.

The direct deposit of chemical waste on unprotected soil, which previously has caused large soil and groundwater pollution problems, has been reduced considerably in recent years by legislation and waste collection systems (e.g. 91/689/EEC on hazardous waste). Disposal of waste products, including sewage sludge, on farmlands is regulated with concentration limits for a few prioritised substances (e.g. 86/278/EEC on sewage sludge).

The collection, handling, treatment and deposit of wastes are regulated at EU and national level by a number of EU Directives (e.g. 75/442/EEC on waste; 99/31/EC on deposit of waste (Landfill Directive); 2000/53/EC on End-of-Life Vehicles; and 2002/96/EC on Waste Electrical and Electronic Equipment).

Based on the considerations above, the starting assumption is that the potential benefit of REACH on the environment will mainly be a result of reduced releases of chemicals to water and to air.

3 IMPACT OF CHEMICALS ON ENVIRONMENT AND HUMAN HEALTH

The release of chemicals to the environment may result in environmental effects on species in the environment and in health effects on humans exposed via the environment. The magnitude of such impacts is a function of the intrinsic hazards of the chemicals and the level of exposure of the environment and humans. The exposure levels are a result of the releases, which again are caused by the manufacture and use of the chemicals.

This implies that there is a causal relationship between intrinsic hazards and manufacture and use of chemicals and the resulting impact of those chemicals. The resulting impact may be described in qualitative, quantitative and monetary terms. The cause-impact chain is illustrated in Figure 3.1.

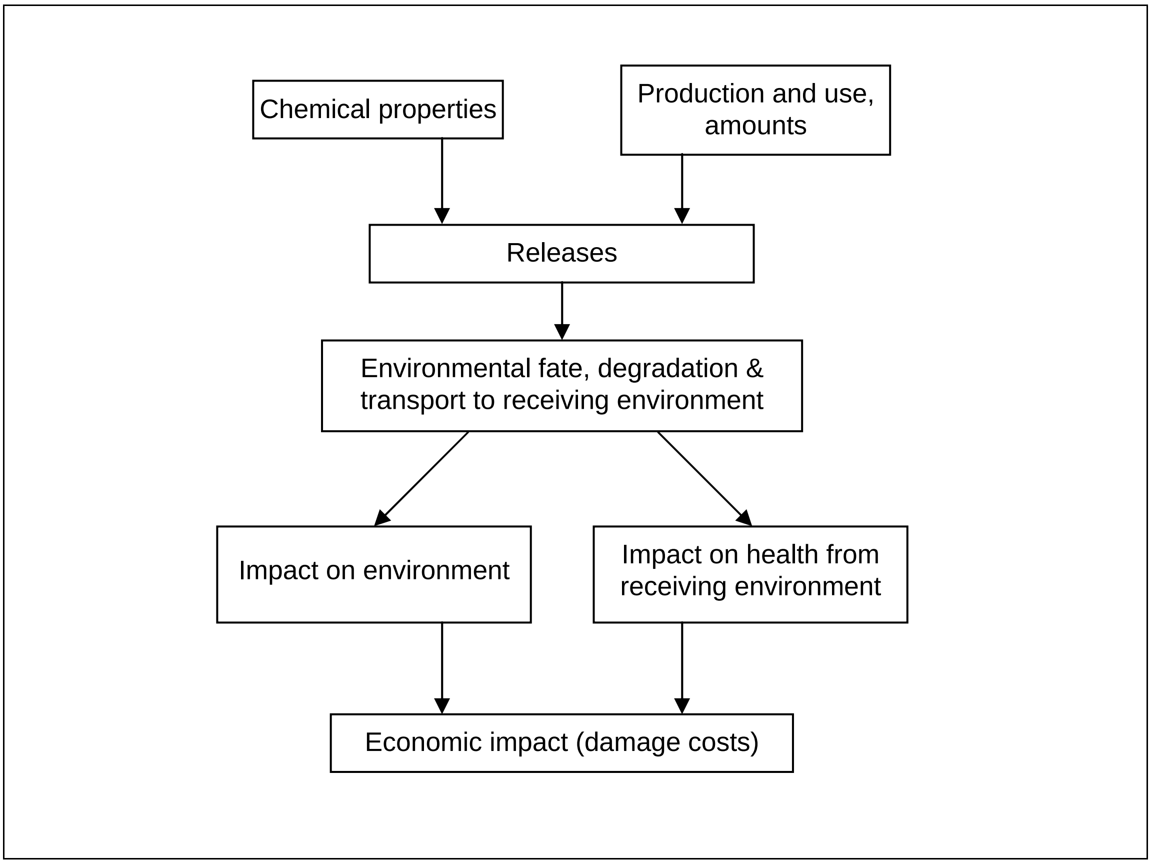

Figure 3.1 The cause-impact chain

The impact of chemicals on the environment and human health via the environment is typically identified by use of approaches either based on case studies (which are by nature retrospective) or on risk characterisations where exposure is evaluated against no-effect-levels (developed to be predictive). Such approaches are described and discussed below, while approaches for monetising such impacts are described in the next chapter.

3.1 Retrospective analyses

Most pollution effects of chemicals have been identified retrospectively on a case by case basis. Examples of cases of ecological impacts are numerous, e.g., contamination of groundwater and soil, decline in populations of birds of prey, reduced reproductive success of some species, and accumulated concentrations of pollutants in biota. There is also a large number of cases of effects on humans as a result of pollution, e.g. reduced fertility among the population in a specific area, increased incidence of foetal abnormalities and allergy incidents, as well as specific types of cancer. Some of these cases have been studied thoroughly and the causes are now well-known, while for others the cause-impact chain is still not fully understood.

Examples of pollution cases where the causes of intoxications have been identified, and the cause-effect chain has been fully described, are plentiful and include the well-known effect of organochlorines on reproduction of top predators and the effects of mercury on the population in Minamata, Japan. Also the effects of CFC gases on the ozone layer are well known today. Common to these cases is that the investigation of the causes of these effects was initiated only when the effects became alarming due to their severity or extension. However, also common is the large time span between the identification of the effect and the full understanding of the causes. Similar examples are given in the EEA report on “Late lessons learnt from early warnings” (Harremöes *et al.* 2001).

Even today new cases are found where it is not clear whether a cause-effect relationship exists resulting from manufacture and use of certain chemicals. For example, an increasing number of allergy cases appear among the European population, but the causes still remain to be identified. It is speculated that widely used chemicals may be at least part of the explanation. Another example is the relatively high concentrations of decabromodiphenyl ether that have recently been measured in samples of tissue and eggs of birds of prey from the UK, where neither the sources and environmental pathways nor the possible impact of the measured concentrations are currently known (Environment Agency 2004).

A lesson learnt from such cases is that only when it is too late and pronounced effects become evident does the quest for the causes get initiated. And only when the cause-effect chain has been identified and documented are preventive measures identified and implemented (Harremöes *et al.* 2001). Thus, considering the long time span between the first releases and the implementation of corrective measures, a predictive approach has been introduced in the chemicals legislation.

In conclusion, retrospective approaches are useful for elucidating the causal relationships between manufacture and use of chemicals and possible effects on the environment and humans. However, they require that the effects are so pronounced that they are identified as effects of chemical pollution and subsequently that the causes are identified by back-tracking. Luckily, corrective action has been taken for many of the pollution cases already under current legislation.

3.2 Predictive approaches

The purpose of employing predictive approaches in the regulation of chemicals is to prevent the use of chemicals that leads to deleterious effects on the environment and human health. The main focus of these approaches has been to define at which exposure levels no unacceptable effects occur to the environment or human health and, based on that, to make sure that manufacture and use of chemicals do not lead to releases resulting in exceedance of these exposure levels.

Thus, under the current chemicals legislation, the typical predictive approach for risk screening and assessment is based on the comparison of estimated exposure levels (concentrations, doses) with estimated no-effect-levels (e.g., Predicted No Effect Concentrations (PNEC) for environmental compartments, No Observed Adverse Effect Levels (NOAEL) for human populations). The Technical Guidance Document (TGD) on risk assessment (EC 2003) describes the elements of this approach in detail.

The basic principles of this approach may be used at various levels of detail:

- **Screening level.** Approaches for screening of chemicals have been used for priority setting for regulatory purposes (e.g., the priority list of 141 substances for risk assessment under the Existing Substances Regulation (ESR) review programme) or for product assessment (e.g., which substances contribute significantly to the potential impact of a product in a lifecycle perspective).

- **Generic risk assessment.** Under the ESR programme, generic risk assessments are conducted at local and regional levels considering the manufacture, formulation, use (industrial/professional, private) and disposal stages of the lifecycle of chemicals.
- **Site-specific risk assessment.** Risk assessments of emissions from specific sites are conducted both under the ESR programme and at the local level in connection with issuing of production permits to industries, e.g. in accordance with the IPPC directive (Dir. 96/61/EC).

Environment. A common feature of the approach is that it is based on an estimate of Predicted Environmental Concentrations (PEC) of chemicals. This is typically derived from information on produced or imported quantity and specific or generic information (as available) on use and release patterns and environmental fate and distribution. Often generic exposure models are used for estimating the PEC, but also more precise site-specific models or even chemical measurements may be employed. The environmental concentrations are compared to a PNEC for the environmental compartment, which is a largely theoretical value defined as the concentration below which an unacceptable effect will most likely not occur (EC 2003). If the PEC/PNEC ratio (the risk quotient) is < 1, the risk of environmental effects is considered to be at an acceptable low level.

However, although the PNEC is a limit above which unacceptable effects may occur, the PNEC does not give any indications of what types of ecological effects that may occur when this concentration is exceeded. Nor does it give information about the shape of the possible dose-response function for the ecosystem, i.e. how severe the effects may be in cases where PEC exceeds PNEC.

No direct assessment of effects in air or the atmosphere is included in the current risk assessment approach. However, deposition of air pollutants to soil and water is considered, as well as the subsequent contribution to risks to these environments.

Humans exposed via the environment. An indirect exposure of humans to contamination/pollution via environmental compartments may occur by inhalation of air, consumption of food (fish, meat, crops, (drinking) water), or dermal contact to soil or to polluted water during bathing or swimming. The common approach to perform exposure estimations is by estimating the total daily intake for humans. Normally, this is based on measurements or estimations of the PEC (for (surface) water, ground water, soil and air), the bioconcentration factor (measure for the bioaccumulation potential of a substance) and the biotransfer factor (chemical uptake by plants or animals) from the intake media, entailing the calculation of total daily intake (EC 2003).

The calculated (daily) intake is then compared to a measure of effects, e.g. the No Observed Adverse Effects Level (NOAEL) or the Lowest Observed Adverse Effect Level (LOAEL). Critical effects for humans - acute and chronic - and their critical doses are identified or estimated, the critical effects being the adverse effects occurring at the lowest dose and the critical dose being the NOAEL. The NOAEL values may be established either directly from available experimental data or by applying one or more benchmark dose models.

Methodological shortcomings
Both screening level and generic risk assessment approaches comprise a number of assessment steps starting with produced amounts of chemicals to calculation of a (generic) risk quotient. As mentioned, the current methodological relationships between some of the steps in the cause-effect chain are relatively well established, while methodological approaches for other steps are lacking or, at best, only tentatively developed.

The most important of these problems is that, very often, no relationship between exposure concentration and ecological or health effects (impact) has been established. As long as the exposure concentration is below the PNEC, it is assumed that the risk of ecotoxic effects is at an acceptable low level. In cases where the PEC exceeds the PNEC, a possibility of ecotoxic effects exists. However, the general problem with the PNEC approach is that PNEC is a no-effect-concentration at ecosystem level. Therefore, if the PNEC is exceeded there is no indication of what types of ecological effects that may occur (as illustrated in Figure 3.2). No information is conveyed about which species or functions of the ecosystem that may be affected or about the likelihood, possible magnitude or geographic scale of the occurrence of such effects. Ongoing developments within this field focus on concentration-effect relationships for individual key species in the ecosystem and the ecological impact of effects on populations of key species (e.g. Bradbury *et al.* 2004). Some knowledge is currently available, but not in a form that facilitates an ecological impact assessment exceeding individual case studies.

Thus, the problems, which must be overcome in order to assess the environmental impact, include:

- The available information on production volume and use does not allow a localisation of estimated environmental concentrations and resulting effects.
- Our current risk assessment approach (i.e. the ratio between exposure concentration and no-effect-concentration) does not give any guidance on what type of environmental effects that may occur in case the exposure concentration exceeds the no-effect-concentration.

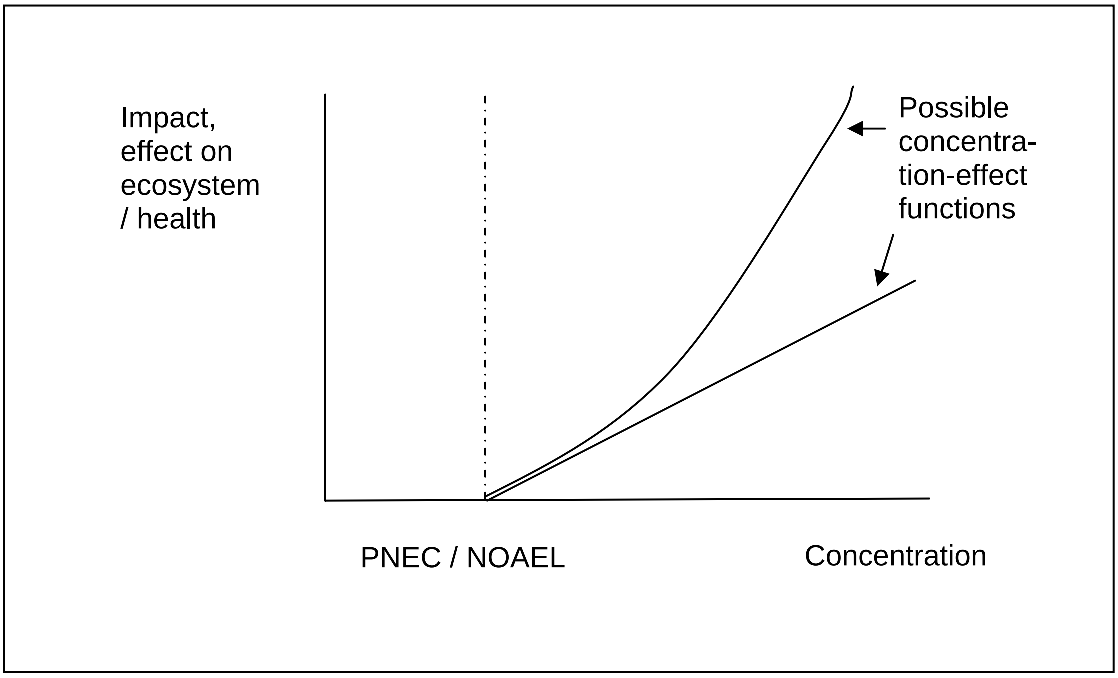

Figure 3.2 Illustration of the PNEC and types of dose-response functions, which are lacking for most chemicals

With respect to health, a similar problem exists. In many cases we can define the equivalent to the PNEC (the NOAEL) but a dose-response relationship has not been defined to show how types of morbidity and premature mortality respond to the exceedance of the no-effect level.

The problems which must be overcome in order to assess the human health impact include:

- Health damage will depend on localised exposure rather than general exposure.
- The numbers of people exposed at specific locations will generally not be known.

However, assuming that an averaging approach can be used, average exposure levels could be estimated. These could then be compared with knowledge on probable effects at these exposure levels and the societal costs of identified effects. Of course human suffering cannot be determined individually but methods for quantifying societal costs have been developed.

Nevertheless, in some cases, some relationship between measured concentrations and effects can be established from a hindsight perspective although the ecological or the human health impact may not have been predictable. Such examples can be used as a measure of the potential impact of chemicals with similar properties and emission, although the procedure is obviously subject to error. However, even if we could determine the types of effects that would occur and in which locations or environments, it may not be possible to monetise these impacts.

4 METHODOLOGIES FOR EVALUATING ECONOMIC BENEFITS OF REACH

4.1 A gallery of methodologies

Various methodologies for calculating economic costs of impact on environment and human health resulting from current manufacture and use of chemicals as well as methodologies for calculating economic benefits of REACH are outlined and discussed below.

4.1.1 An ideal approach

The ideal measurement of economic impacts involves four 'end points':

(a) health effects from exposure to ambient environmental concentrations
(b) health effects from chemicals accumulated in food and water
(c) health effects from exposure to chemicals in the workplace
(d) loss of ecosystem functioning

This could be termed the **"dose-response approach"**. For the present purpose, step (c) (workplace exposure) will not be considered.

The practical implementation of the ideal approach requires that a number of essential procedures are used as follows:

- Estimate the chemical concentrations in each environmental compartment

For assessing health effects

- Estimate dose-response relationships between those concentrations and human health – premature mortality and morbidity
- Estimate the effects of REACH in terms of the likely reductions in environmental concentrations
- Estimate the change in the health effects arising
- Value those health effects using 'values of statistical life' (VOSL), or value of life year (VOLY) and morbidity values

For assessing environmental effects

- Estimate the change in concentrations as above
- Elicit people's willingness to pay for the improved environmental conditions as a result of implementing REACH

For embodied health risks

- For risks embodied in ingested chemicals the procedures could be the same as above

Difficulties in establishing relationships between ecological or health effects and economic costs

The difficulties in securing economic damage measures are formidable, some of which were described above. Mainly they are:

- For the vast majority of the chemicals in question, no health dose-response information exists for the estimation of health effects. One approach is to take those relationships that are known and estimate the linkages for a few chemicals.
- Ecosystem effects are similarly not known with any precision.
- The effects of REACH on environmental concentrations are not known with any precision.
- Original willingness to pay (WTP) studies would ideally be required to secure valuations of ecosystem effects. However, the current study has neither the time nor the resources to conduct original WTP studies. Thus, it will be necessary to see 'standard' values taken from other studies. This is unavoidably risky and the reliability of 'borrowing' values ('benefits transfer') has been seriously questioned in the economics literature (see, for example, Brouwer, 2000).

The main problems lie not so much in the economic values themselves (the valuation of health effects is very well researched, ecosystem effects less so), but in the intermediary steps between estimating volume and toxicity of releases and the environmental and human health responses.

Thus, in conclusion, current methodological approaches are not developed to a level where ecological or health effects of chemicals can be predicted. Neither are possibilities for monetising such impact sufficiently developed. However, a number of possible approaches exist or may be developed or adapted allowing a tentative assessment of economic impact and benefit of REACH.

4.1.2 Willingness to pay and willingness to accept compensation

In all cases the theoretically correct economic value is either the population‘s willingness to pay (WTP) to avoid deleterious effects of chemicals, or the willingness to accept (WTA) compensation for tolerating the effects. The former applies when the population at large does not have the property rights to the future, improved state of the environment. The latter applies when the population does have the property right and hence compensation is required.

The difference between WTP and WTA used not to be thought to be significant, but recent literature suggests that WTA may be several times (4-20 times) larger than WTP (Knetsch 1990, Hanemann 1991). This might be entirely rational in that, from a given starting point, consumers value losses more than gains. Moreover, consumers have poor understanding of the concept of WTA as they use it infrequently in their everyday life, whereas all consumers many times per day use the WTP concept when they purchase goods and services. For this reason it is considered safer (in terms of the accuracy of the results of a valuation study) to use WTP measures.

Nevertheless, the property rights situation for chemicals is ambiguous. Directives such as the Water Framework Directive (Dir. 2000/60/EC) clearly give property rights (with caveats) to the population in respect of the future state of the environment (Pearce 2005). However, most economic analyses proceed with WTP rather than WTA because of the general presumption that individuals do not have property rights to a future, improved state of the environment. Usually, it is argued that property rights pertain to the existing level of environment: hence WTA would apply only if there are threats to make the existing environment worse through policy measures. Such situations are not uncommon - e.g. construction of a road or airport tends to infringe the rights to, say, the existing level of noise. However, in the REACH context, property rights are not so clear. It is possible to argue that the very existence of REACH implies a right to an environment with less chemical exposure. But in the absence of any clear guidance, and the fact that WTA estimates are harder to find than WTP estimates, we focus on WTP.

4.1.3 Damage function approach based on past mistakes

The approach outlined here is close to the procedures used in some of the health economics, air pollution and risk analysis literature (Desvousges *et al.* 1998; Dolan *et al.* 2004) in which a damage function is established from the relationship between damage and the costs incurred by the damage. This approach has been used recently for monetising crime victims' suffering, since harm done has been rated using quality-adjusted life years (QALYs, similar to DALYs), and the QALY-rated harm is then anchored on a form of harm where there are reasonably well established economic values (e.g. life lost) (Dolan *et al.* 2004). Similar approaches have been used for health impacts from other sources, again using QALYs or quality of wellbeing (QWB) scores (Desvousges *et al.* 1998).

Employing the same approach for chemicals means that if the damage to the environment or human health caused by releases of one (or a few) chemicals as well as the economic costs of this damage is known, it might be possible to extrapolate to all other chemicals. This would require that a sufficiently solid relationship can be established between the damage and the costs.

Assume that the damage described by an impact (*Impact*) on the environment or human health is established for a reasonably well-known chemical, for which some kind of economic analysis has either been done or could be done. Let the economic cost (*Cost*) from this 'reference' chemical be €X per unit of the chemical. Call this $Cost_R$. Let the *Cost* for any chemical *i* be $Cost_i$ but for all chemicals bar the reference chemical we do not know the economic damages. So long as *Impact* is not an ordinal but a cardinal index[5] then we can compute the economic damage from any chemical as:

$$\text{Cost}_i = \frac{\text{Impact}_i}{\text{Impact}_R} \cdot \text{Cost}_R$$

We then need some idea of the change in *Impact* arising from REACH. Call this *ΔImpact*. Then the benefit of REACH for any chemical is:

$$\Delta\text{Cost}_i = \frac{\Delta\text{Impact}_i}{\text{Impact}_R} \cdot \text{Cost}_R$$

The obvious problems are:

(a) We have no more information than the studies in the existing literature about the value for Δ*Impact*. But we may have to accept that this is going to an 'expert judgement' value.

[5] An ordinal ranking simply says A is better than B which is better than C. A cardinal ranking tells how much better A is than B and how much B is better than C

(b) If the economic valuation study for the reference chemical is not robust, all the chain-linked values will also be suspect. One way of addressing this problem is to see if we have another chemical with a reasonable valuation study, predict the damage cost of that chemical using the chain-linked approach, and then compare the predicted value with the actual value.
(c) Problems caused by individual chemicals and the solution of such problems are not independent. This means that when a problem arising from one chemical is solved, at least part of similar problems caused by other chemicals may have been solved for the same cost. E.g., the cleaning of drinking water for one identified pollutant by use of active carbon will not only remove one chemical, but many different pollutants. Thus, there is a great risk in double-counting the benefits of REACH.
(d) It is not clear that *Impact* will be a cardinal rather than an ordinal index.
(e) We have no idea about the relationship between the *Impact* and the *Cost* other than *Cost = f{Impact}*. The impact in itself is a function of manufacture, release, fate and effects, but whether a direct relationship between *Impact* and *Cost* can be established requires further research.

4.1.4 Avoided or saved costs approach

Another approach to economic valuation is to use the costs of measures that have been introduced with the purpose of preventing, avoiding, repairing or mitigating damage caused by chemicals pollution. The starting point is that excess levels of chemicals in a specific environmental compartment may restrict the possibilities of using it, thereby implying a loss of potential future income or value and/or a cost for treatment or cleaning. Thus, if the soil in a garden is contaminated so that it cannot be used for playing by children or for growing vegetables, the value of the property decreases. This is a good way of measuring some of the damages - e.g. if REACH reduces the costs that water companies face in treating water, then their reduced costs are a legitimate way of measuring benefit of REACH.

Contamination (caused by several chemicals) of specific environmental compartments or media, which reduces their usefulness for human purposes due to increased risks of unwanted effects, e.g. contamination of drinking water, may be reduced as a result of REACH. However, REACH may not affect all sources of contamination in these cases (e.g. nitrate or pesticides in drinking water), so the total costs of the problems will exceed the potential benefit of REACH. This approach could be termed the “avoided or saved costs approach”, as it describes the possible reduction in society’s costs for mitigating chemicals pollution.

However, it is important to differentiate this from the costs of restoring an ecosystem to some pre-damage state. This should not be regarded as the damage cost of the chemicals in question, because use of this procedure is not consistent with the principles of using WTP (WTA). In effect, we do not know if society is willing to incur the clean-up costs in question. Moreover, use of clean-up costs tends to make the benefit of clean-up identical with the cost of clean-up.

This type of case includes contaminated surface and ground water, sewage sludge and contaminated soil. Examples of substances, which are contaminating environments but are regulated by other legislation than REACH, are pesticides and biocides as well as nitrates.

For this type of cases, it may be possible to estimate the total (annual) costs of preventing or mitigating pollution caused by release of all chemicals in a specific area, e.g. the EU. However, because the overall impact of REACH cannot be estimated, the assessment must be based on a guess about the extent to which the problem will be reduced due to REACH. The approach would imply an estimate of the total damage from *all* chemicals followed by an assumption (a guess) regarding the extent to which REACH will reduce this damage (e.g. 10% of the costs as used by RPA & BRE Environment (Postle *et al.* 2003)).

4.2 Past studies

A number of studies have attempted to measure aspects of the benefits of REACH and several have also compared the estimated benefits with the costs. An overview of the existing studies of the costs and benefits of REACH is presented in Appendix A. There are in fact no comprehensive studies and some that claim to be cost-benefit studies do not in fact estimate benefits. This underlines the problems faced in trying to estimate the benefits of REACH.

Several observations can be made about these studies:

- No study estimates environmental impacts in terms of willingness to pay for environmental benefits, which is usually regarded as the correct economic procedure.
- All the studies focusing on occupational health benefits fail to discuss whether these are 'real' benefits in the economic sense. Some occupational risks may already be internalised in wages, i.e. wage rates may already be adjusted by the forces of supply and demand for labour if those forces recognise that extra risks in the workplace require compensation through higher wages.
- Methodologies for estimating health benefits vary widely, e.g. treatments costs, values of statistical life etc.

4.3 Conclusions on current approaches

Past studies have made some progress in measuring the benefits of REACH. However, there are several weaknesses in the studies. The weaknesses tend to pervade any approach since the relevant information is simply not available. The notable missing pieces of information are:

- Absence of epidemiological dose-response functions.
- Lack of a parameter reflecting the extent to which REACH reduces the release of chemicals to any one receiving environmental medium.
- Lack of knowledge of geographical variability in the dose-response relationships.
- Lack of knowledge of any time-lags between exposure to chemicals and onset of health or environmental effects.

Previous benefit estimates have also failed to address the environmental impacts entirely. Again information problems explain much of the omission:

- Lack of knowledge of ecosystem exposure to chemicals, geographical variability and time lags.

- Lack of knowledge of any damage functions relating ecosystem damage to exposure.
- Very limited information on the economic value of ecosystem damages from chemicals, i.e. ecosystem benefits from chemical control.

5 SELECTED METHODOLOGIES

Based on the above discussions on possibilities for predicting ecological and human health impact of chemicals and possibilities for monetising such impact, methodologies for estimating benefits of REACH have been set up. These are described below.

5.1 The WTP approach

Assuming human health and ecosystem effects could be measured in ‘physical’ units – e.g. premature mortality, morbidity, ecosystem losses – then the correct economic approach to valuing those effects in money terms is the use of either willingness to pay (WTP) or willingness to accept compensation (WTA). WTP would measure the WTP to secure the benefit or avoid the damage. WTA would measure the WTA compensation to forego the improvement (benefit) or to tolerate the damage.

WTP tends to assume that individuals have no ‘right’ to the improved state of risk that would ensure from the implementation of REACH – in the technical jargon, those at risk have no property right to the future state of affairs. WTA, on the other hand, assumes that this right does exist, and hence individuals have to be compensated for foregoing that right. In practice it is far from clear on many occasions which ‘right’ exists. Most economists argue that when the rights do not exist, or are uncertain, WTP is the procedure to use. If WTP and WTA do not differ much, then the choice between them is of little consequence. But it is known that in practice WTA can be several times and sometimes an order of magnitude larger than WTA. Why this observation occurs is debated in the economics literature. Some argue it is an artefact of the methodologies used to measure WTP and WTA, others that it reflects low substitution between the environmental assets that enter into the studies in question, and yet others that there is an ‘endowment’ effect – people attach far more importance to losses than to gains. In what follows we opt for the WTP approach whilst noting that there is an argument for the adoption of WTA. Unfortunately, even if WTA was accepted as the right procedure, there are no studies that would help with the estimation of WTA.

5.2 The damage function approach based on past mistakes

The use of a damage function approach based on past mistakes for estimating the potential benefit of REACH requires that:

- Cases are available in which a relationship can be established between a measure of environmental and/or health impact of a chemical and the economic costs
- A relative environmental and/or health impact score can be established for other chemicals that are likely to be affected by REACH
- These scores can be used for estimating or indicating the potential economic damage; however avoiding double-counting

- The effect of REACH on reducing the impact (i.e. the benefit of REACH) can be derived

Previously, assessment of environmental or health impact of chemicals was not connected to an assessment of the economic damage and neither were the possible economic benefits of mitigating the environmental or health impact estimated. However, increasingly such analyses are conducted as part of assessment of chemicals. For example, the EU existing substances risk assessment programme also includes the development of a risk reduction strategy when risks that need mitigation have been identified in the risk assessment. Another example is the recent assessment of the economic costs of the PCB pollution, where a cost of at least €15 billion has been estimated for EU-25 for the years 1971 to 2018 (von Bahr & Janson 2004). Thus, a number of case substances have been identified from which both the environmental or health impact and the corresponding economic damage can be derived. The data for this were sought in reports on the substances, in which the information has been compiled, e.g. EU Risk Assessment Reports prepared under the existing substances programme or compilations like the report of RPA & BRE Environment (Postle *et al.* 2003).

Various options for developing a relative environmental and/or health impact score exist. The impact of a chemical will always be a function of a number of parameters:

- Manufactured and imported quantity
- Fraction of release to the environment
- Distribution and fate in the environment
- Ecotoxicity and/or human health toxicity potential

REACH can only be assumed to have an impact on the first two of these parameters (as the last two parameters reflect the intrinsic properties of the substances), and if we could estimate the impact on these, this would be the most appropriate way of doing it. However, this is not possible in isolation as REACH, as mentioned previously, is anticipated to function by the identification of necessary risk management measures as a result of the chemical safety assessment. The CSA utilises all of the mentioned parameters for assessing the risks of chemicals and the assessment of the impact of REACH therefore needs to be based on all of the parameters.

Of course, it is not possible to conduct separate risk assessments for all substances that will be considered under REACH within the current study. One way to circumvent this is to use a screening approach. In selecting an approach, also the possibility for obtaining suitable data is decisive. Various screening approaches are described in Appendix C and, based on an evaluation of the suitability of different possible approaches, it has been decided to base the screening on the European Union Risk Ranking Method (EURAM), which was developed for prioritising EU high production volume chemicals for risk assessment (Hansen *et al.* 1999).

The EURAM approach was further developed with additional scores using the same basic principles. The scores which were estimated are (cf. Appendix C) measures of environmental exposure (EEX-values), of environmental effects (EEF-values) or measures combining exposure and toxic properties of the chemicals (environmental scores, ES-values). For the aquatic compartment (water), a further score (aquatic score, AS), including the bioaccumulative properties of the chemicals is used and the general measure of effects via food-chains is expressed in a biotic score (BS). The scores used include:

- EEX_{water}: Environmental EXposure score for the aquatic compartment
- $EEX_{sediment}$: Environmental EXposure score for the sediment compartment
- EEX_{soil}: Environmental EXposure score for the soil compartment
- EEF_{water}: Environmental EFfect score for the aquatic compartment
- $EEF_{sediment}$: Environmental EFfect for the sediment compartment
- EEF_{soil}: Environmental EFfect for the soil compartment
- ES_{water}: Environmental Score for the aquatic compartment
- $ES_{sediment}$: Environmental Score for the sediment compartment
- ES_{soil}: Environmental Score for the soil compartment
- AS: Aquatic Score taking account of the bioaccumulation potential
- BS: Biota Score based on distribution to biota

The environmental scores do not include health effects, e.g. such as are caused by carcinogenic or mutagenic properties of the chemicals. Therefore, they are not directly suitable for ranking substances with such effects.

The most relevant score was selected for each of the case substances based on their environmental properties and their likely release and fate in the environment. As the main problem identified for some of the case substances pertains to human health impact, the environmental scores are not directly suitable as a way of ranking the chemicals. Instead, scores for exposure of the relevant environmental compartments were used in combination with information on potential human health effects.

Information on the chemicals on which REACH will have the largest effect (cf. Section 2.3) has been obtained from a variety of sources. As this amounts to a large number of individual substances (approx. 10,000 substances manufactured or imported in quantities > 10 tonnes per year), weight has been put on the possibility for a computerised handling of the information, when data sources have been selected. Based on a scrutiny of available data sources, it was decided to base the ranking on data from the European Commission's IUCLID (International Uniform ChemicaL Information Database) database and the Danish EPA QSAR (Quantitative Structure-Activity Relationship) database, as these comprise information on a large number of substances.

Thus, information on manufacture, import and use of approx. 10,000 existing chemicals was provided by the European Chemicals Bureau as extracts of the IUCLID database (IUCLID 2004). The following data were obtained:

- CAS numbers (several entries per CAS)
- DSN number coding for the registrant (one or more registrants per CAS)
- Quantities manufactured or imported per year (per entry)
- Main Categories of use (per entry)
- Hazard classification

QSAR estimates of physicochemical and environmental properties were obtained from the Danish Institute for Food and Veterinary Research (which is now hosting the QSAR group previously at the Danish EPA). The models are described in the "Report on the advisory list for selfclassification of dangerous substances" (Danish EPA 2001). Further information is given in Appendix B. Estimates for the following intrinsic properties were obtained:

- Water solubility
- Boiling point
- Vapour pressure
- Henry's law constant
- Octanol-water coefficient (log Kow)
- Bioconcentration factor (BCF)
- Biodegradation
- Short-term toxicity to fish
- Short-term toxicity to daphnids
- Short-term toxicity to algae

It is clear that uncertainty is associated with all of the data obtained:

- The bulk of information in IUCLID submitted by industry on quantity of chemicals manufactured or imported concerns the years 1991-1995 although some entries have been updated since then.
- Information on main categories of use is on the one hand based on information available to the registrant and is on the other hand specified by a number of main categories of uses, which are a weak basis for estimating releases.
- The QSAR models used for estimating biodegradation and aquatic toxicity have not been subject to an external validation and peer review (although a comprehensive internal validation has taken place).

Due to these uncertainties, the scores calculated should only be used with caution for extrapolation from the case substances. Based on the scores, other substances or at least the number of other substances having the same or worse combinations of releases and properties as reflected in the score value can be identified. Depending on the result of the scoring, an indication of the potential benefit of REACH may be obtained.

However, it must be borne in mind that it is difficult to identify a specific cut-off value for the various scores above which risk reduction could be expected under REACH and below which the use could be considered safe. Moreover, the introduction of risk management measures with the purpose of reducing the release of one chemical may often have a similar effect on other chemicals, which would impose a risk of double counting the possible effect of REACH.

Thus, based on the results of the scoring the most appropriate approach is used for estimating benefits of REACH from the individual case studies. The approach may be quantitative or qualitative. In conclusion, the way forward was:

- A few, well elucidated case substances were selected
- For the individual chemical, the environmental and/or health impacts were determined
- The (monetisable) costs of these impacts were estimated
- A qualitative extrapolation to other chemicals that have a similar or greater ranking value was conducted resulting in a very rough estimate of costs of current use of chemicals

- The potential benefits of REACH were indicated by assuming that REACH will function by reducing the release and impact to a certain level.

5.3 The avoided or saved costs approach

The avoided or saved costs approach is essentially a two-step procedure starting with an assessment of the economic costs of mitigating the impact of releases of chemicals to the environment followed by a mainly qualitative evaluation of the potential benefit of REACH on reducing these costs.

5.3.1 Sewage treatment plants

For all chemicals in waste water, sewage treatment plants (STP) may be the first step on the path from the technosphere to the environment. During the passage of the water through the STP, part of the chemicals is degraded while those, which are not degraded or evaporated, are either carried to surface water or left in the sewage sludge, the latter typically being deposited on agricultural soil or incinerated. Thus, the environmental exposure depends on the physico-chemical and biological properties of the chemical, on the processes in the STP and on the amount of chemical reaching the STP.

Direct impacts on the STP will arise from toxic effects on the micro-organisms of the biological treatment plant. Other concerns with respect to STPs are the exposure of surface water (via the outlet) and soil (via disposal of sewage sludge) with the subsequent impacts on environment and health caused by the exposure of these compartments.

The effects of chemicals on the micro-organisms in STP may be caused by a general load of chemicals in the waste water or by pulses of high concentrations of chemicals due to accidental spills into the sewage system. REACH is expected to affect the general load by reducing it, while accidental spills are not directly affected by REACH. The route of exposure of STP is via discharges from production of chemicals and industrial, professional and consumer uses of chemicals.

As a case for STP, the malfunctioning due to toxic chemicals has been selected. The malfunctioning will be evaluated based on information on increased efficiency of STPs during periods of closed industry (summer holidays) and pilot investigations of the inhibition properties of waste water is used.

5.3.2 Drinking water purification

Drinking water is abstracted from both surface water and groundwater. In particular surface water, but increasingly also groundwater, contains contaminants exceeding drinking water limit values and consequently, the water needs to be cleaned before it can be used for drinking water purposes.

The contamination of water sources that requires purification is caused by not only chemicals that will be regulated under REACH, but also other types of contamination as caused by nutrients (nitrate, phosphate) and pesticides. Thus, the impact of REACH chemicals on the purification costs needs to be discriminated from the impact of other chemicals and from other types of pollution (e.g. bacterial).

5.3.3 Disposal of dredged sediment

The exposure of sediment takes place mainly via sorption of chemicals from the water phase and via run-off of contaminated soil particles during heavy rain or subsequent to flooding. Cases of dumping of contaminated soil and/or dredged sediment are expected to be prevented by the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, 1972 (London Convention).

For the exposure via the water phase, harbour sediment calls for immediate attention, because this is known to be heavily contaminated due to emissions from ships of oil products, combustion products and residues of paints. However, oil and combustion products will not be covered by REACH and the constituents of paint are not known to contribute considerably to the contamination of sediment – except for antifouling biocides, which are not covered by REACH, but by Directive 98/8/EC.

However, river sediment is constantly being transported and most contamination of river sediment will be from chemicals, which were emitted to the river recently. Therefore, dredged sediment of riverine origin will be used as a case for calculating costs caused by chemicals. For this, sediment dredged from rivers or sediment dredged from ports located in rivers or in estuaries where (large) rivers flow into the sea, may be used for the cases.

5.3.4 Disposal of sewage sludge on farmlands

The main economic problem pertaining to contaminated soil is contamination of city soil – former dump sites or industrial sites being used for gardens due to expansion of cities. The knowledge that a site is contaminated reduces the value of the property considerably. The reasons for such soil pollution lie with the past use of the site, e.g. dump sites, gasoline stations, metallic or dry-cleaning enterprises. In all of these sites, chemicals were simply left in or on the soil during the former use of the sites. Because other legislation has long ago forbidden such handling of chemicals, REACH is not expected to have a major impact on the occurrence of such contaminated sites.

Therefore, a main route for exposure of soil to chemical contamination is expected to be via disposal of sewage sludge. This implies that the release paths would be via waste water and STP. The chemicals, which are expected to end up in sewage sludge, are either persistent, sorptive chemicals – irrespective of the release rate - or other chemicals (even readily biodegradable) in case they are discharged at rates exceeding the capacity of the SPT and/or are not degradable in anaerobic digesters, which are frequently used in STP.

The major concerns regarding chemicals in sewage sludge for agricultural use are the risks of build-up in soil (especially of metals) and risks of ingestion of soil by livestock. Concerns regarding uptake in plants have been investigated but with respect to organic substances, there is no strong evidence of bioaccumulation in crops.

The economic costs incurred by pollution of sewage sludge by chemicals will be estimated as well as the potential impact of REACH on reducing such costs.

5.3.5 Cleaning of fish meal

Accumulation of chemicals in biota may lead to toxic effects in the food chains and on humans eating contaminated food. Accumulation in biota is mainly recognised to be a problem in the aquatic environments, where fish and shellfish are in focus. However, although the contamination is recognised, the problems are often considered in the short term by giving dietary advice and only in the long term by reducing releases to the environment of problematic chemicals.

However, recently it has been discovered that commercial fish feed produced from industrial fish caught from the North Atlantic area has elevated levels of contaminants compared to products of fish caught in the South Pacific Ocean (Hites *et al.* 2004), and some initiatives have now been taken to clean such fish products with the purpose of avoiding subsequent contamination of farmed fish. The costs of cleaning of fish meal will be estimated.

5.3.6 Estimating benefits of REACH

In general, many of the costs incurred on society for mitigating chemical pollutions result from the manufacture, use and release to the environment of hundreds of different chemicals. For some of the cases, the identity of many of the chemicals causing the problems is not known or only partly known. Furthermore, many of the chemicals identified are not covered by REACH and for some of the cases the main causes have been dealt with or are being dealt with. All in all, this means that a precise estimate of the potential benefits of REACH is at best very difficult to make.

This has also been recognised in other benefit studies in which an assumed efficiency of REACH in reducing the burden of chemicals at a level of at least 10% has been argued (RPA 2003). The same efficiency is used in the current study for the cases on retrospective errors when no other information is available.

5.4 General considerations

The information available is very variable with respect to the size of the region on which it is based, i.e. individual countries, EU-15[6], EU-25, EU-27[7], EU-28 or even "Europe32", including the EFTA countries Iceland, Liechtenstein, Norway and Switzerland on top of EU-28 (EEA 2003). For the current study, the estimates of economic costs or benefits are carried out for the current EU, i.e. EU-25. According to the EU homepage (www.europa.eu.int), the population in EU-25 is approx. 454 mill people (as of January 2003).

However, extrapolation from information obtained from any country or any sub-set of countries in the EU to EU-25 is not simple. This pertains to both physical differences and to economic differences. For example, although the chemicals legislation is the same within the EU-25 countries, the practical management and enforcement may differ. Also the degree of environmental protection and the coverage and efficiency of mitigating measures like STPs and cleaning of contaminated drinking water differ considerably within the EU.

Various approaches for transferring economic values or benefits exist and an overview of these is given in Appendix B. Market exchange rates are the exchange rates people are familiar with when changing foreign currency. 'Purchasing Power Parity' conversion factors (PPP), on the other hand, compare the values of a given bundle of goods across countries allowing for the ratios of the actual prices of each component of the bundle. The 'purchasing power equivalent' for any one good is the ratio of the price of that good in country A divided by the price of that good in country B. These price ratios

---

6 EU-15: Belgium, Denmark, Germany, Greece, Spain, France, Ireland, Italy, Luxembourg, Netherlands, Austria, Portugal, Finland, Sweden, United Kingdom
EU-25 also: Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia
EU-27-28 also Bulgaria, Romania and, eventually, Turkey

are applied to average quantities of the selected goods to build up a picture for the purchasing power equivalent for the whole bundle of goods which usually amounts to extending it to Gross Domestic Product (GDP) as a whole. Extending the analysis to many countries is far more complex. The most widely used procedure is to compute world prices so that each country's prices are expressed relative to these world prices. Even this procedure can involve error. As far as EU-15 is concerned, the use of market exchange rates (MER) rather than PPP, which is widely regarded as the proper way to compare income levels, involves little error. This is because the two rates are very close. For example, the ratio of PPP to MER for Germany in 2002 is 0.9 and for the UK it is 1.0. However, for some countries in EU-25 there are some variations. For Poland in 2002, the ratio is 0.5 and for Latvia it is 0.4 (see World Bank, *World Development Indicators*). Because of ease of data access, no attempt has been made in this report to adjust the EU-25 estimates for PPP.

Therefore, for transferring of economic values an approach based on income adjustment using real GDP per capita is used. This reflects the fact that willingness to pay (WTP) is constrained by income. Thus, if WTP is 10 units in country A with an average per capita income of €20,000, it cannot be assumed that WTP in country B with an average income of €30,000 would be the same. A rough adjustment involved 'income adjustment' such that:

$$WTP_B = WTP_A \cdot \frac{Y_B}{Y_A}$$

where Y is per capita income. In the hypothetical example given, if WTP in A is known but not in B, an estimate for WTP in B would be (30,000/20,000 × WTP in A) = 1.5 × WTP in A.

However, irrespective of the time and currency presented in the information available, the final cost assessments are updated to 2005 prices and recalculated to €. In general, a rate of inflation of 2.5% per annum has been used to convert base year prices to 2005 prices. Capital costs are annuitised at 3% for 25 years.

Furthermore, REACH is not in effect yet. The time when the full benefits of REACH will come through varies depending on the cases and it is a matter of discussion which time should be used for the calculations. In order to ensure a consistent and conservative approach in the calculations, the full benefits of REACH are not expected to occur before 2017 onwards. Therefore, discounting at 3% (as typically done in REACH impact studies), the benefits in 2017 are estimated to be 70% of the estimates obtained in € at 2005 prices (i.e. $1/1.03^{12} = 0.7$).

The benefits are further summed up over the subsequent 25 years from 2017 to 2041 again using a yearly discount rate of 3%. In practice, this corresponds to multiplying the 2017 costs or benefit by a factor of 19.

5.5 Default benefit of REACH

Some assumption needs to be made about the effect of REACH on exposure to chemicals. This is complex. Some chemicals will go out of production because of REACH. RPA & Statistics Sweden (2002) make some estimates of these effects. However, there appears to be no detailed attempt to estimate how chemical producers and users will react beyond this. For example, users may well switch into other chemicals if one is withdrawn. What matters for benefit estimation is the change in exposure rather than the change in the number of chemicals on the market. In the absence of data on behavioural response, we assume exposure change is proportional to the level of registrations. On the assumption that the regulation achieves high compliance, a low level of registrations of chemicals generally means that there are high levels of withdrawals. Conversely, high levels of registration mean low levels of withdrawal. The resulting scenarios from RPA & Statistics Sweden are shown in Table 5.1.

Table 5.1 RPA implied estimates of change in 'exposure' due to REACH

Scenarios	Full registrations (including intermediates and unintended uses)	Change in exposure relative to low withdrawals
Low registration = high withdrawals	57,285	-54%
Mid range registration	85,059	-32%
High level registration = low withdrawals	125,735	0

Source: RPA-Statistics Sweden (2002), Table 1. Note: the proportions are similar if intermediates and unintended uses are omitted, at -27% and 48% respectively.

On the basis of these estimates we could take as a 'maximum effect' scenario, a range of say 30-50% reduction in exposure due to REACH. Our judgement is that this is extremely high because it fails to account for absolute levels of chemical production and usage, simply being the change in the number of registrations. As other (registered) chemicals are substituted for withdrawn chemicals, exposure would be affected only to a limited extent. Accordingly, take a much lower value of 10 per cent. The 10% assumption can obviously be changed if it is judged that REACH will have less/greater effects.

5.6 Overview of methodologies

An overview of the methodologies used in the current study is shown in Figure 5.1.

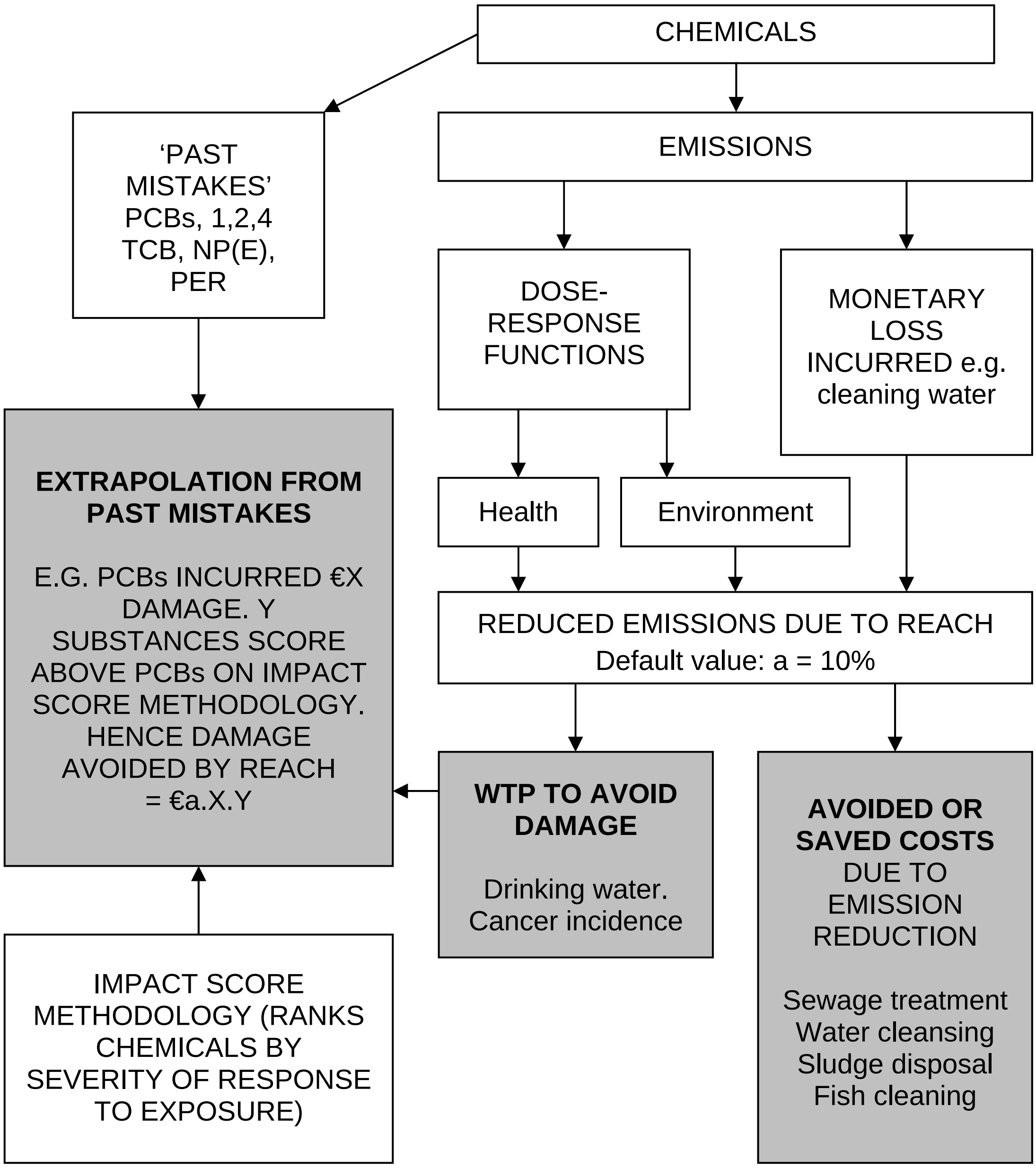

Figure 5.1 Guide to the methodologies used in the current study

Of the three methodologies, shown as shaded boxes, the extrapolation from past mistakes is ranked the weakest methodology but it indicates a way forward in contexts where, like REACH, dose-response information is very limited, i.e. this methodology is capable of further development. The WTP methodology is second best because of the problems associated with 'benefits transfer'. The strongest methodology is that based on reduced monetary costs that society incurs because of the presence of chemicals in water. Note that these understate cost savings because they are only based on releases to water and only considering some cases of mitigating impact. Nor are other health or ecosystem effects considered. But they may overstate cost savings due to the fact that REACH accelerates a baseline of improving environmental quality due to the possible evolution of non-REACH legislation.

6 RESULTS

The individual case studies are described in detail in Appendices D and E, while an overview is given below.

6.1 Willingness to pay

Two sets of studies are available on WTP for benefits that can be related to the topics of the current study.

6.1.1 WTP for clean drinking water

The first is a study by WRc (1999) on WTP for clean drinking water. It was estimated that in the UK (England and Wales), the per person annual WTP to reduce the health impacts of adverse water quality was £36. Updating this value to 2005 prices would give just over £40 per person per year. The population of England and Wales is 59 mill, so the aggregate WTP for 'clean water' is £2.37 billion corresponding to €3.2 billion.

Table 6.1 Willingness to pay for clean water

Region	Compartment	Substance	Problem	Cause of cost	WTP (2005 prices) (£/year/person)	WTP (2005 prices (€/year)
UK 59 mill people	Surface and ground water	All chemicals	Contamination of drinking water	WTP	40	3,220 mill
EU-15 380 mill people	Surface and ground water	All chemicals	Contamination of drinking water	WTP	40	20,600 mill
EU-25 454 mill people	Surface and ground water	All chemicals	Contamination of drinking water	WTP	40	24,700 mill

The willingness to pay for clean drinking water was extrapolated from WTP in the UK to EU-25, based on population sizes and income adjustment to be €24,700 mill/year in year 2005. The applicability of the UK derived WTP at £40 per person to the whole of the EU and not least the new member states, has not been evaluated due to the absence of economic studies. Discounting to 2017 gives a total WTP for EU-25 at €17,300 mill for the year 2017.

We have no information on how WTP varies with quality levels and it is very possible that the improvements generated by REACH for water quality will be small. A 10% improvement in quality might therefore be associated with a 10% reduction in this damage, i.e. €1,730 mill in 2017.

6.1.2 WTP for avoiding morbidity and mortality

A review on the literature on valuation of health effects and benefits is available (Eftec 2004) in which people's WTP to avoid morbidity and mortality caused by pollution is discussed. Eftec (2004) found some evidence of a 'cancer premium' for deaths by cancer as well as evidence for the value of non-fatal cancers (NFCs). Fatal cancers were valued at €1 mill and non-fatal ones at €400,000. These WTP estimates are used for the various case studies in the current study.

6.2 Damage function approach based on past mistakes

Detailed assessments of impacts on the environment and on humans exposed via the environment as well as the economic costs associated with these impacts have been conducted for four case substances:

- 1,2,4-TCB in drinking water
- NPE in sewage sludge
- TCE in ground water
- PCB in fish

A summary of the findings is given below.

6.2.1 1,2,4-trichlorobenzene in drinking water

An EU Community risk assessment has been conducted for 1,2,4-trichlorobenzene (1,2,4-TCB) and in particular the contamination of drinking water was considered.

It is estimated that 1.3 mill people are exposed to concentrations in drinking water exceeding the WHO-limit of 20 µg/L, which is estimated to result in 582 cancer incidents per year in EU-25. The WTP to avoid a cancer case is €400,000 per non-fatal case and €1 mill per fatal case. It is not known whether the incidents caused by 1,2,4-TCB would be fatal or non-fatal, which means that the incidents correspond to a cost in the range €233-582 mill per year. Moreover, the cost of cleaning the drinking water is estimated to €14-89 mill per year.

1,2,4-TCB is not targeted by REACH (it is handled by the existing legislation) but the relationship between the impact on health and the costs may be used for extrapolating to costs of chemicals that may be affected by REACH and the potential benefits of introduction of REACH.

The most relevant of the environmental scores estimated for 1,2,4-TCB is probably the Environmental Score for water (ES-water combining exposure and effects on aquatic organisms), as the impact considered here is contamination in drinking water abstracted from surface water and groundwater. 1,2,4-TCB obtained a ranking number of 2324, which means that 2323 substances are at a potential higher risk to the aquatic environment.

However, the main problem identified with 1,2,4-TCB is the cancer risk to humans when drinking water limit values are exceeded and not environmental impact. Therefore, the effects on aquatic organisms are not relevant but the environmental exposure score for water (EEX_{water}) gives a measure of the exposure of drinking water. Using the EEX_{water}, 1,2,4-TCB obtains a ranking value as number 3023 out of the 4368 substances. An assessment of potential serious health effects can be based on the hazard classification as reported by industry in their submissions to IUCLID. But although the impact of 1,2,4-TCB is associated with carcinogenic effects, the substance is classified only with R22 (harmful if swallowed), R38 (irritating to skin) and R50/53 (very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment)

(ECB ESIS 2005). Numerous substances have more severe classifications, e.g. 367 substances on the IUCLID extract covering 10,299 substances (i.e. 3.6%) are classified with either R45 (may cause cancer), R46 (may cause heritable genetic damage) or R60 (may impair fertility).

Among the 3022 substances with a higher ranking regarding exposure of the aquatic environment, 89 substances are classified with either R-45, R-46 or R-60. This corresponds to 2% of these substances, which is in the same range as the almost 4% of all IUCLID substances reported above and an estimate conducted by the Danish EPA based on QSAR estimates that 3% of the substances not included in Annex I to Directive 67/548/EEC are potentially carcinogenic (Danish EPA 2001). Assuming that new data generated under REACH will reveal that not only the 2% already classified for the severe hazards, but up to 3-4% should be classified, this would result in extra 1-2% of the 3022 substances having a higher score than 1,2,4-TCB being identified as carcinogenic, mutagenic or toxic to reproduction (i.e. 30-60 substances). Assuming that the toxic potential of these substances relative to the exposure concentration in average is the same as for 1,2,4-TCB, a total cost in the range €3,000 mill to €35,000 mill is estimated. As the benefit of REACH is not known with any certainty, it is assumed that REACH as a minimum will result in a 10% reduction in the health costs of these substances. Thus, the benefit of REACH would be approx. €210-2,500 mill per year in 2017 and aggregated over the following 25 years approx. €4,000-50,000 mill in saved health costs.

6.2.2 *Nonylphenol in sewage sludge*

Nonylphenol may be accumulated in sewage sludge in concentrations higher than the limit value, which is set for protection of the soil environment at farmlands. It is estimated that between 1.1 and 9.1 mill tonnes (dry weight) of sewage sludge contains nonylphenol in concentrations exceeding the limit causing it unsuitable for use as fertiliser at farmlands. There, the sludge is often incinerated and, in addition, other fertiliser has to be supplied to farmlands. The total cost of that is estimated to €229-1,829 mill per year.

Nonylphenols are not targeted by REACH but it is assumed that results may be extrapolated to other chemicals that would be affected by REACH.

The case evaluated here is the accumulation of NP(E)s in sewage sludge in concentrations exceeding the limit values set for protecting the soil environment when disposing sewage sludge on farmlands. Thus, the most relevant score would be the environmental score for soil. Here, NP(E)s are ranked as only number 2622 meaning that 2621 other substances may constitute a potential higher risk to the soil environment than NP(E)s. This means that suitable limit values might also be relevant for many other substances. It may be assumed that accumulation in sewage sludge and subsequent risks to the soil compartment may be identified for at least some of these substances as a result of the Chemical Safety Assessments conducted under REACH and that risk management measures will be implemented reducing the releases. However, reducing releases of one substance does not influence the concentration of other substances in sewage sludge. Nevertheless, some reduction in the amount of sewage sludge that cannot be disposed at farmlands may be anticipated. Thus, if it is assumed that REACH will result in a reduction of contaminated sludge of 10%, this corresponds to a benefit at €16-133 mill in 2017, which aggregated over 25 years becomes approx. €300-2,600 mill.

It is also worthwhile noting that the ranking values for the remaining four scoring systems are much different and in the range of 86-130. Only 9-13 substances of those with lower ranking values are already included in the current EU risk assessment programme.

6.2.3 Tetrachloroethylene in ground water

Tetrachloroethylene (PER) is classified as carcinogenic category 3 and intake of drinking water with a concentration of 1 µg/L causes an extra lifetime cancer risk of 1.5 in 1 million. It is estimated that 0.8% of drinking water is contaminated in concentrations exceeding 10 µg/L, but it is not known how big a percentage that exceeds 1 µg/L. However, assuming a linear dose-response relationship, it is estimated that 3.6 mill people in EU-25 would be exposed to PER in concentrations exceeding 10 µg/L, which in average results in 0.8 extra cancer incidents per year. The cost is estimated to €0.3-0.8 mill per year for non-fatal (€400,000) and fatal (€1 mill) incidents, respectively.

PER is not targeted by REACH (it is handled by the existing legislation) but the relationship between the impact on health and the costs may be used for extrapolating to costs of chemicals that may be affected by REACH and the potential benefits of introduction of REACH.

Similar to 1,2,4-TCB, the most relevant environmental scoring for PER is the environmental score for water. PER obtained a ranking as number 944 meaning that in principle 943 other substances would have a larger risk to the aquatic environment. However, as for 1,2,4-TCB the main problem with PER is the risk of cancer, which is not included in this scoring. PER is classified as carcinogenic, category 3 with the R-phrase R40 (limited evidence of carcinogenic effect) (ECB ESIS 2005).

Instead, using only the environmental exposure score for water (EEX_{water}), PER obtains a ranking value as number 386 out of the 4368 substances. An assessment of potential serious health effects can be based on the hazard classification as reported by industry in their submissions to IUCLID. Numerous substances have more severe classifications, e.g. 367 substances on the IUCLID extract covering 10,299 substances (i.e. 3.6%) are classified with either R45 (may cause cancer), R46 (may cause heritable genetic damage) or R60 (may impair fertility).

Among the 385 substances with a higher ranking regarding exposure of the aquatic environment, 28 substances are classified with either R-45, R-46 or R-60. This corresponds to 7% of these substances, which is higher than the almost 4% of all IUCLID substances reported above and an estimate conducted by the Danish EPA based on QSAR estimates that 3% of the substances not included in Annex I to Directive 67/548/EEC are potentially carcinogenic (Danish EPA 2001). It might then be assumed that new data generated under REACH will not reveal many more substances that should be classified as carcinogenic, mutagenic or toxic to reproduction. Moreover, considerations similar to the ones for 1,2,4-TCB pertains to PER and as such, they are included in the 1,2,4-TCB case.

Finally, the ranking values for PER are in the range 404-1356 with the lowest ranking number obtained with the environmental score for sediment. Thus, the sediment compartment is the environmental compartment where the highest risk may be identified, but still many other substances are causing a potentially higher risk.

6.2.4 *Polychlorinated biphenyls in fish*

PCB levels are still elevated in the environment and in particular in biota despite the ban on manufacture more than 20 years ago. The concentrations in fish are so high that the number of cancer incidents is estimated to be 194-583 per year in EU-25. As no information is available on whether these cancer cases would be fatal or non-fatal, the cost is given as a range at €78-583 mill per year.

PCBs are severely restricted in the EU and manufacture and import have ceased. Therefore, no information on PCBs is available in IUCLID. However, it is still a problem due to its long-term persistency and bioaccumulation potential. Thus, other information sources were sought for obtaining information on PCBs.

According to Breivik *et al.* (2002), the historical production of PCBs amount to more than 1.3 mill tonnes mainly in the years 1930-1993 with the biggest production in the period from 1960 to 1980. The consumption in EU countries can be estimated to approx. 20% of the total consumption based on information in Breivik *et al.* (2002). Due to the persistency, it is considered appropriate to average the consumption over the 60-years time period resulting in an annual consumption in EU of 4,300 tonnes of PCB. This was then used as input to the scoring, which was conducted using physico-chemical properties of hexachloro biphenyl.

The most relevant score in relation to the case considered is the biota score. PCBs were ranked as number 5 meaning that only 4 other substances are potentially more problematic for biota. 2 of these 4 substances are already included in the EU priority list and the risk assessment programme. The other 2 substances are derivatives of the pesticide 2,4-D and might therefore be considered under the Plant Protection Products Directive 91/414/EEC. Other substances are phthalates, which are already in focus both as potential PBT substances and due to their endocrine disruption potential and, although not all of them are on the priority list, they are considered to be covered by the current legislation. Thus, REACH might not have a significant benefit on these substances.

The four other ranking values are in the range 64-3540 with the lowest for the aquatic score considering also bioaccumulation and the highest ranking number for soil.

6.2.5 *Summary of benefits - damage function approach*

An overview of the costs incurred by the four case substances in 2005 is given in Table 6.2.

Table 6.2 Costs estimated for four case substances

	1,2,4-TCB	NP(E)	PER	PCB
Costs (mill €/year)	98-582	229-1829	0.3-0.8	78-583

An overview of the ranking numbers estimated for the four case substances is given in Table 6.3 with the percentage of substances having a higher ranking given in brackets.

Table 6.3 Environmental exposure and impact ranking numbers estimated for the four case substances

Scoring[1]	**1,2,4-TCB**	**NP(E)**	**PER**	**PCB**
EEX_{water}	3023 (69%)	436 (10%)	386 (9%)	1527 (35%)
ES_{water}	2324 (53%)	130 (3%)	944 (22%)	206 (5%)
$ES_{sediment}$	1582 (36%)	95 (2%)	404 (9%)	1178 (27%)
ES_{soil}	1650 (38%)	2622 (60%)	1094 (25%)	3540 (81%)
AS_{water}	2056 (47%)	86 (2%)	1009 (23%)	64 (1%)
BS_{biota}	1170 (27%)	107 (2%)	1356 (31%)	5 (0%)

1: EEX: measure of exposure, ES: measure combining toxicity and exposure, AS and BS measures combining exposure, toxicity and bioaccumulative potential.

Only one of the substances is very high on at least one of the ranking lists, namely PCB that is identified as very problematic for accumulation and effects in biota. This corresponds well with the measured concentrations and effects in the environment, which has resulted in the severe restrictions in manufacture ad use of PCBs.

NP(E) is also relatively high on most of the ranking lists except for the soil compartment. This substance has already been restricted due to its effects in the aquatic environment, which corresponds well with the ranking. However, the concentration in sewage sludge is also regulated in some countries due to potential risks to the terrestrial environment, but the ranking is not reflecting this concern.

For the remaining two substances evaluated, many other substances seem to be of similar or higher concern. Such a large number of substances cannot be assessed on a substance-by-substance approach, as any benefit resulting from reducing the release of one substance may be shadowed by impact from other substances. Instead, an assumed benefit at 10% of the costs has been calculated. This resulted in a potential benefit due to a reduced number of cases of cancer, mutagenicity or reproductive effects due to contaminated drinking water at €210-2,500 mill in 2017 corresponding to €4,000-50,000 mill aggregated over 25 years. A similar potential benefit due to cleaner sewage sludge has been estimated to €16-133 mill in 2017 and aggregated over 25 years to €300-2,600 mill.

6.3 Avoided or saved costs approach

Five separate cases have been elaborated where current releases of chemicals result in damages where society interferes and implement corrective actions at a cost. These cases are:

- Sewage treatment plants
- Drinking water purification
- Disposal of dredged sediment
- Sewage sludge incineration/disposal
- Cleaning of fish meal

The details of the specific methodology used for each of the cases as well as the results are presented in Appendix E. An overview of the results is given below.

6.3.1 Sewage treatment plants

Various studies have shown that the nitrification capacity of sewage treatment plants is decreased with 15-20% as a result of discharges of wastewater from industries and consequently larger STPs with a prolonged wastewater retention time are needed. Taking the lower of these estimates, this leads to the conclusion that the need for STP capacity in the EU in principle could be reduced by at least 15% if chemicals in industrial waste water did not inhibit nitrification.

The cost of upgrading a STP to nutrient removal is estimated to €29-98 per Person Equivalent (PE) in 2005 prices. With an anticipated lifetime of a STP of 30 years, this investment cost becomes €1.5-5.0/PE/year in 2005 prices. If there was no chemical stress on STPs, this need for increased nutrient removal capacity would be reduced by at least 15%. Thereby, the costs for the continuous necessary increased nutrient removal capacity are reduced by the costs for establishment of STPs equivalent to 68 mill PE/year (15% of 454 mill PE) corresponding to €102-340 mill/year for EU-25.

The calculation underestimates the potential costs, because the coverage with STP is lower in the 10 new member countries than in the old EU-15 (cf. the current large investments in infrastructure) and because chemicals management (in particular risk management and enforcement) at present is not as effective there as in EU-15 (IPTS 2005). Therefore, during construction of STP, larger margins for reduced capacity due to malfunction are used than in EU-15. Thereby, the potential reduction in treatment costs due to a more efficient chemicals policy will be higher in the 10 new member countries than in the old EU-15. Moreover, the prolonged retention time of wastewater in the STP, which is the basis for the cost estimate, is a result of conveyance of industrial wastewater only. Moreover, wastewater from consumers will add to the retention time and, thus, the cost estimate is a minimum estimate.

Assuming potential benefits of REACH at 10% level as well as the anticipated delay of the full benefit of REACH until 2017 resulting in a reduction to 70% due to a 3% annual discount, the potential benefit of REACH in 2017 is estimated to €7.1-24 mill/year, respectively. The potential 25-year benefit in the period 2017-2041 can then be estimated to be €131-440 mill.

6.3.2 Drinking water purification

Total water abstraction in Europe (EU-32, including the EFTA countries Iceland, Liechtenstein, Norway and Switzerland) is about 353 km^3/year of which 33% is used for agriculture, 16% for urban use, 11% for industry (excluding cooling) and 40% for energy production (EEA 2003). Water supplied for urban use is used in households, institutions and smaller industries and, consequently, must live up to drinking water standards. Thus, these standards pertain to 45.3 km^3/year (EU-25).

There is no information available for the whole of EU regarding either the amounts abstracted from surface water or the amounts purified before use. However, information from the UK and Denmark is available, which could be extrapolated to the EU level. Water may be contaminated not only by chemicals relevant for REACH, but also by nutrients, pesticides, bacteria, etc. It is not known how much of the treatment costs that can be related to REACH relevant chemicals, but tentatively 5% is attributed to that. Based on this, the cost of cleaning water to drinking water quality is estimated to

€0.05/m^3 in the UK and €0.02-0.10/m^3 in Denmark. For EU-25 this amounts to €695-4,317 mill/year.

For this example, there is no information available regarding the effect of the chemicals policy on the need for purification of drinking water. Thus, assuming potential benefits of REACH at 10% level as well as the anticipated delay of the full benefit of REACH until 2017 resulting in a reduction to 70% due to a 3% annual discount, the potential benefit of REACH in 2017 is estimated to €49-302 mill/year. The potential 25-year benefit in the period 2017-2041 can then be estimated to be €896-5,564 mill.

6.3.3 Disposal of dredged sediment

Sediments are dredged mainly due to navigational reasons. If dredged sediment is contaminated, different disposal possibilities exist from simple relocation to upland deposit in a Confined Disposal Facility. The costs of the different disposal types vary from €4/m^3 to about €24/m^3 in adjusted EU-25 prices at 2005 level. Possibilities for cleaning of contaminated sediment exist, but are not considered here.

Information on volumes of dredged sediment from some parts of Europe exists as well as the origin of the sediment, and it is estimated that approx. 14% of 165 mill m^3 of inland origin is contaminated. However, as only parts of Europe are included in the statistics, it is assumed that twice as much is contaminated and requires special disposal. Based on these considerations, it is estimated that this costs €187-1,120 mill per year in EU-25.

The indicative “default” reductions due to REACH of 10% of the costs of disposal of contaminated sediment can be used together with the reduction to 70% of this, caused by the anticipated delay of REACH till 2017. This results in a potential benefit of REACH with regard to disposal of dredged sediment of €13.1-78 mill per year for EU-25 for 2017. By aggregation over the next 25 years, the total benefit is estimated to €241-1,450 mill.

However, practical experiences obtained during the Rhine Research Project in the Port of Rotterdam ((Mannino *et al*. 2002) demonstrate that the amount of contaminated sediment can be reduced by 60% by imposing a better control of inland discharges. This demonstrates that the benefit may be even higher than estimated above and a benefit of €78-470 mill in 2017 has been estimated, which corresponds to €1,444-8,660 mill by aggregation over 25 years.

6.3.4 Sewage sludge incineration/disposal

Contaminated sewage sludge is an example of a damage that can be measured as the amounts of sewage sludge, which cannot be used for agricultural applications but must be landfilled or incinerated because of high concentrations of chemicals. If the concentrations of chemicals in this sludge were low, all sewage sludge could be used directly for agricultural purposes. Consequently, the costs can be estimated as the saved costs for alternative handling of sewage sludge (e.g. incineration) as well as the value of the fertilisers, which could be substituted with sewage sludge. The current amount of sewage sludge incinerated is 5.8 mill tonnes dry weight sludge per year. This amount will increase in the coming years when the STP coverage in EU-25 is increased.

Various estimates of incineration costs are available, which corresponds to about €200/tonne in 2005 prices. With an amount of contaminated sewage sludge of 5.8 mill tonnes/year (EU-25), this gives €1,152 mill per year. The incinerated sludge corresponds to 119,000 tonnes of N fertiliser/year and 115,000 tonnes of P fertiliser/year. With a cost of fertiliser at €98-130/tonne, this corresponds to a value of lost fertiliser at €23-30 mill/year. The average of the fertiliser value is used to calculate a (rounded) average total cost of contaminated sewage sludge of €1,180 mill per year in EU-25.

With a potential effect of REACH of a 10% reduction of amounts of sewage sludge being incinerated and the delayed effect of REACH to 2017, the estimated benefit of REACH with regard to sewage sludge would amount to an average of €83 mill per year for 2017 for EU-25. Over the next 25 years, the total aggregated benefit is estimated to €1,520 mill.

6.3.5 Cleaning of fish meal

Cleaning of fish products (fish meal and fish oil produced from industrial fish) to be used for fish feed can be done at a price of €18/tonne. The annual catch of industrial fish from the Baltic Sea and partly from the North Sea areas is estimated by industry to be approx. 350,000 tonnes of industrial fish per year (TripleNine 2005), which means that the total costs of cleaning the fish products amount to €6.3 mill/year.

This cost is estimated from the catch in only a small part of the EU waters. It is not known how big the total catch of industrial fish is in EU-25, and neither is it known whether industrial fish from other parts of EU is contaminated, is used for the same purpose, and potentially is cleaned. A very cautious guess would be that the figure should be doubled. This is considered a conservative value, as much of the commercial fish feed produced from industrial fish caught from the North Atlantic area has elevated levels of contaminants (Hites *et al.* 2004). Thereby, the aggregate damage due to contaminated fish meal and fish oil is estimated to €12.6 mill per year for EU-25 by 2005.

Using the indicative "default" reductions due to REACH of 10% of costs of cleaning fish products together with the reduction to 70% of this caused by the anticipated delay of REACH till 2017, this results in a potential benefit of REACH with regard to contaminated fish food for fish farms of €0.9 mill per year for EU-25. Over the next 25 years this adds up to a total benefit of €16 mill.

6.3.6 Summary of benefits - avoided or saved costs approach

For the cases referred above (and presented in detail in Appendix E), the following overview of potential benefits of REACH can be established.

Table 6.2 Overview of potential benefits of REACH (values in mill €/year)

Case	2017	2017-2041
Sewage treatment plant	7.1-24	131-440
Drinking water purification	49-302	896-5,564
Disposal of dredged sediment	13.1-78 (78-470)*	241-1,450 (1,444-8.660)*
Sewage sludge	83	1,520
Cleaning of fish meal	0.9	16
Total potential benefits for cases	153-488	2,804-8,990

*) Based on 60% reduction of contaminated sediment.

7 DISCUSSION AND CONCLUSIONS

The possibilities for estimating the potential benefits of REACH on the environment and on humans exposed via the environment suffer both from a lack of a sufficiently developed methodology and from a lack of data. In the present study, we have tried to circumvent these knowledge gaps by using three different methodologies for assessing potential benefits and to use a number of data at a screening level. Of course, this influences the reliability of the conclusions that can be drawn on the basis of the study.

Three possible approaches have been identified that may be suitable for assessing the potential impact and benefits of REACH on the environment and humans exposed via the environment. These are:

- Willingness to pay (WTP) among the broad population for avoiding impacts of chemicals
- Damage function approach based on past mistakes where an empirical relationship between damage and cost might be established
- Avoided or saved costs approach where costs of mitigating current pollution is estimated as the upper limit for the possible benefit of REACH

The WTP approach is seen as the economically ‘correct’ way of estimating benefits. However, only two studies are available. One study from the UK elicits the population’s willingness to pay for clean drinking water, while another study reviews the willingness to pay for avoiding health effects of chemicals pollution, in particular cancer.

The information from the first study was used to estimate the potential benefits of REACH to €1,730 mill in year 2017 if only benefits to drinking water quality are considered. The study is not sufficient for extrapolating to the benefits of REACH on the environment in the whole of EU-25. It might be assumed that the population’s WTP for environmental benefits is lower than for direct health benefits, while the WTP for avoiding serious health effects of chemicals pollution is much higher. Due to the very limited amount of input data, the results obtained are judged to be uncertain.

The damage function approach based on past mistakes was tried out using four well-known substances as the basis and extrapolating to all other substances that may be affected by REACH. A ranking system was established based on the EURAM method with input data obtained from the European Commission’s IUCLID database and from the Danish EPA QSAR database. All of the input data are uncertain and can only be used with caution.

Only one of the substances is very high on at least one of the ranking lists, namely PCB that is identified as very problematic for accumulation and effects in biota. This corresponds well with the measured concentrations and effects in the environment, which has resulted in the severe restrictions in manufacture and use of PCBs.

Nonylphenol is also relatively high on most of the ranking lists except for the soil compartment. This substance has already been restricted due to its effects in the aquatic environment, which corresponds well with the ranking. However, the concentration in sewage sludge is also regulated in some countries due to potential risks to the terrestrial environment, but the ranking is not reflecting this concern.

For the remaining two substances evaluated, many other substances seem to be of similar or higher concern. Such a large number of substances cannot be assessed on a substance-by-substance approach, as any benefit resulting from reducing the release of one substance may be shadowed by impact from other substances. Instead, an assumed benefit at 10% of the costs has been calculated. This resulted in a potential benefit due to a reduced number of cases of cancer, mutagenicity or reproductive effects due to contaminated drinking water at €210-2,500 mill in 2017 corresponding to €4,000-50,000 mill aggregated over 25 years. A similar potential benefit due to cleaner sewage sludge has been estimated to €16-133 mill in 2017 and aggregated over 25 years to €300-2,600 mill. Due to the large uncertainty of the input data and the huge extrapolation, this approach is judged to be the weakest of the three approaches tried out in the current study.

The avoided or saved costs approach was used to assess the current costs of mitigating the chemical pollution for a number of cases. The cost estimates for some of the cases are relatively robust, as it has been possible to obtain relatively detailed and precise information. This is in particular the case for purification of drinking water, disposal of dredged sediment and incineration of sewage sludge instead of disposing it on farmlands. Costs of building excess nitrification capacity in sewage treatment plants due to toxic effects of chemicals in sewage water and costs of cleaning of fish products are considered weaker cases. From the cases, it is estimated that today the costs of measures already implemented for mitigating the impact of releases of chemicals are huge - in total up to €7 billion per year in 2005 for only those cases included in the study. Even assuming that the potential benefit of REACH would be only at 10%, the benefit is estimated to €150-500 mill in year 2017, which over the next 25 years adds up to €2,800-9,000 mill.

An overview of the results is given in Tables 7.1-7.3 below. Most of the estimates are based on an assumed efficiency of REACH in reducing general environmental contamination levels by 10%.

Table 7.1 Overview of potential benefits of REACH (values in mill €) determined as potentially saved costs (most robust approach)

Case	2017	2017-2041
Building of sewage treatment plants	7.1-24	131-440
Drinking water purification	49-302	896-5,564
Disposal of dredged sediment	13.1-78 (78-470)*	241-1,450 (1,444-8.660)*
Sewage sludge	83	1,520
Cleaning of fish meal	0.9	16
Total potential benefits for cases	153-488	2,804-8,990

*) Based on 60% reduction of contaminated sediment.

Table 7.2 Overview of potential benefits of REACH (values in mill €) determined as the population's willingness to pay (weaker approach)

Case	2017	2017-2041
WTP for clean drinking water	1,730	34,000

Table 7.3 Overview of potential benefits of REACH (values in mill €) determined by extrapolation from case substances (weakest approach)

Case	2017	2017-2041
Avoidance of severe health effects	210-2,500	4,000-50,000
Improved reuse of sewage sludge	16-133	300-2,600
Total potential benefits for cases	226-2,633	4,300-52,600

It appears from the overview tables that the most robust approach results in the lowest benefits, while the weakest approach results in the largest benefits. However, the three different approaches estimate different costs and benefits, with the most robust approach estimating costs and benefits in relation to cleaning or handling of polluted matrices (water, sludge, sediment, fish products) and the weakest approach mainly estimating saved health costs.

Thus, in conclusion, the potential benefit of REACH on the environment and humans exposed via the environment is estimated by use of a robust approach to as a minimum €150-500 mill in year 2017 with a potential long-term benefit over the succeeding 25 years of €2,800-9,000 mill. These estimates are based on well-documented cases of costs in combination with assumptions on the potential benefits of REACH.

Using much weaker approaches, the benefit arising from saved health costs is estimated to €200-2,500 mill in year 2017, which aggregated over 25 years corresponds to €4,000-50,000 mill. Once again, these values can only be seen as indicative values for the potential benefits of REACH on the environment and humans exposed via the environment. ***The values are based on a very weak data set;*** however, the best available. A more precise estimate would require generation of new data and a key role of REACH is to generate such data.

8 REFERENCES

Allanou, R., B.G. Hansen & Y. van der Bilt (1999): Public availability of data on EU High Production Volume Chemicals. EUR 18996 EN (http://ecb.jrc.it).

Andersen, A. (2001): Disposal and recycling routes for sewage sludge – Part 3 – Scientific and technical sub-component report, 23 October 2001. European Commission DG Environment – B/2.

atsdr (2000): Agency for Toxic Substances and Disease Registry.Toxicological profile for polychlorinated biphenyls (PCBs) (update. Atlanta: US Department of Health and Human Services; 2000 Apr.

Bahr, J. & J.Janson (2004): Cost of Late Action – the Case of PCB. Copenhagen: Nordic Council of Ministers.

Bradbury, S.P., T.C.J. Feijtel & C.J. van Leeuwen (2004): Meeting the scientific needs of ecological risk assessment in a regulatory context. Environmental Science & Technology, 463A-470A.

Breivik, K., A. Sweetman, J.M. Pacyna & K.C. Jones (2002): Towards a global historical emission inventory for selected PCB congeners - a mass balance approach. 1. Global production and consumption. The Science of the Total Environment 290, 181-198.

Brouwer, R (2000): Environmental value transfer: State of the art and future prospects. *Ecological Economics*, **32**(1), 137-152.

CEDA (2005): CEntral Dredging Association (CEDA), Preliminary report on the extent of disposal of dredged sediment and the associated costs.

Chemicals Evaluation and Research Institute, Japan. Databases with test data on biodegradability and bioaccumulation of chemicals (http://qsar.cerij.or.jp/cgi-bin/DEGACC/index.cgi?E)

Commission of the European Communities (2003): Extended Impact Assessment. SEC(2003) 1171/3. Brussels: Commission Staff Working Paper

Coopers Lybrand *et al*. (1996): Cost-Benefit Analysis of Different Municipal Solid Waste Management System. Report prepared fro DG XI.

Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, *Official Journal L 257 , 10/10/1996 P. 0026 – 0040.*

Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, *Official Journal L 327, 22/12/2000, P. 0001-0073.*

Danish EPA (1998): Vandrensning ved hjælp af aktiv kulfiltre [Water purification by means of active carbon filters]. Miljøprojekt nr. 391 1998. Danish EPA (in Danish), http://www.mst.dk/199904publikat/87-7909-126-1/default.htm

Danish EPA (2001): Report on the advisory list for selfclassification of dangerous substances. Danish EPA, Environmental Project No. 636.

Danish EPA (2004): Spildevandsslam fra kommunale og private renseanlæg i 2002 [Sewage sludge from municipal and private wastewater treatment plants in 2002]. Orientering fra Miljøstyrelsen Nr. 5 2004 (in Danish).

Desvousges, W., Johnson, F.R and Banzhaf, S. (1998): *Environmental Policy Analysis with Limited Information: Principles and Applications of the Transfer Method*. Cheltenham: Edward Elgar

DG Environment (2000): Working document on sludge, 3rd draft. ENV.E.3/LM. http://europa.eu.intonnes/comm/environmentonnes/sludge/sludge_en.pdf

Dolan, P., Loomes, G, Passgood, T and Tsuchiya, A. (2004): *Estimating the Intangible Victim Costs of Crime*. London : Home Office

Ebbens, Eltjo (2005): Slufter Management Team, Rotterdam. E.Ebbens@portofrotterdam.com

EC (1996): Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control. Official Journal L 257, 10/10/1996 P. 0026 - 0040.

ECB (2003): European Chemicals Bureau. 1,2,4-trichlorobenzene, Risk Assessment Report. Final report, 2003. http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/trichlorobenzenereport039.pdf

ECB (2004): ECB website: http://ecb.jrc.it/

ECB ESIS (2005): European chemical Substances Information System. Available online on: http://ecb.jrc.it/

ECETOC (1999): Tetrachloroethylene, CAS No. 127-18-4, Joint Assessment of Commodity Chemicals No. 39, p 197.

ECETOC (2004): Targeted Risk Assessment. Technical Report No. 93, ECETOC, Brussels.

EEA (2003): Europe's water: An indicator-based assessment. EEA Topic Report No.1, 2003. http://www.eea.eu.int/

EEC (1993): Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances. Official Journal L 084, 05/04/1993, 0001 - 0075.

EEC (2000b): Regulation (EC) No 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer. Official Journal L 244, 29/09/2000 0001 – 0024

Eftec (2004): The Health benefits of Pollution Control: A Review of the Literature on Mortality and Morbidity Effects. London: DEFRA. Available at: http://www.defra.gov.uk/environment/airquality/valuation/workshop.htm

Environment Agency (2004): Update of the Risk Assessment of Bis(pentabromophenyl) ether. Draft, March 2004.

ERM (2003): New European Chemicals Strategy: UK Partial Regulatory Impact Assessment. London: DEFRA.

European Commission (2000): Recommended interim values for the value of preventing a fatality in DG Environment cost benefit analysis. http://europa.eu.int/comm/environment/enveco/others/value_of_life.htm

European Commission (2003): Technical Guidance Document for risk assessment of substances under the existing chemicals, new substances and biocidal active substances legislation.

Fiskaren (2005): Fish meal and fish oil factories in Northern Europe. Fiskaren, 7 March 2005.

Hanemann, N. (1991): Willingness to pay and willingness to accept: how much can they differ? American Economic Review, 81(3): 635-647.

Hansen, B.G., A.G. van Haelst, K. van Leeuwen & P. van der Zandt (1999): Priority setting for existing chemicals: European Union risk ranking method. Env. Tox. Chem. 18, 772-779.

Harremöes, P., A. Haarbo, M. Winther-Nielsen & C. Thirsing (1998): Six years of pilot plant studies for design of treatment plants for nutrient removal. Wat. Sci. Tech. Vol. 38, 1:219-226.

Harremöes P., D. Gee, M. MacGarvin, A. Stirling, J. Keys, B. Wynne & S.G. Vaz (eds.) (2001): Late lessons from early warnings: the precautionary principle 1896-2000. European Environment Agency, Environmental Issue Report No. 22.

Hites R.A., J.A. Foran, D.O. Carpenter, M.C. Hamilton, B.A. Knuth & S.J. Schwager (2004): Global assessment of organic contaminants in farmed salmon. Science 303, 226-229.

Huijbregts, M.A.J., U. Thissen, J.B. Guinée, T. Jager, D. Kalf, D. van de Meent, A.M.J. Ragas, A. Wegener Sleeswijk & L. Reijnders (2000): Priority assessment of toxic substances in life cycle assessment. Part I: Calculation of toxicity potentials for 181 substances with the nested multi-media fate, exposure and effects model USES-LCA. Chemosphere 41, 541-573.

IPTS (2005): Implementation of REACH in the New European Member States. Summary. European Commission, Joint Research Centre, Institute for Prospective Technological Studies.

IRIS (1997): IRIS substance file on Polychlorinated biphenyls (PCBs) (CASRN 1336-36-3). Intergrated Risk Information System, US-EPA. http://www.epa.gov/iris/subst/0294.htm

IUCLID (2004): International Uniform ChemicaL Information Database. Information obtained from ECB.

Jørgensen, K. E.H. Larsen, A. Petersen, K.H. Lund, G. Hilbert, N.L. Andersen, T. Hallas-Møller & J.C. Larsen (2000): Kemiske forureninger. Overvågningssystem for levnedsmidler 1993-1997. Del 2. FødevareRapport 2000:02. Fødevaredirektoratet, Søborg, 131 pp. http://www.vfd.dk/publikationer.

Knetsch, J. (1990): Environmental policy implications of disparities between willingness to pay and compensation demanded. Journal of Environmental Economics Management, 18: 227-237.

Krüger, A/S & Karpuhin, V.F. (2001): Water and Wastewater Engineering Handbook for Russia. DANCEE, Danish Cooperation for environment in Eastern Europe in cooperation with Ministry of Natural Resources, Russian Federation. (Available through butik@mem.dk).

Larsen, E.H., N.L. Andersen, A. Møller, A. Petersen, G.K. Mortensen & J. Petersen. Fd. Add. Contamin. 2001, 19(1), 33-46.

Larsen, H.F. & M. Hauschild (2005): Selection methods in LCIA: Comparison of chemical ranking and scoring methods for use as selection methods. Submitted Int J LCA.

Mannino, I., S. Soriani & G. Zanetto (2002): Management of dredged material: an environmental-political issue. Littoral 2002, The Changing Coast. EUROCOASTONNES/EUCC, Porto, Portugal, Ed. EUROCOAST – Portugal.

Marmo, L. (2000): Sewage sludge and the Community waste strategy. In *Langenkamp, H. & L. Marmo (Eds.) (2000): Workshop on Problems around Sewage Sludge. 18-19 November 1999 (NO) Italy Proceedings. European Commission's Joint Research Centre, EUR 19657 EN, 242, p. 25-30.*

Ministry of the Environment, Japan. Aquatic toxicity data for short and long-term tests with algae, daphnia and fish. Online available: http://www.env.go.jp/chemi/sesaku/02.pdf

OSPAR Commission (2003): Overall assessment of dumping of wastes at sea from mid 1980's – 2001.

Ostertag, K. *et al.* (2004):Analysis of the Costs and Benefits of the New EU Chemicals Policy. Berlin: Federal Environment Agency.

Pearce D.W. (2005): Environmental policy as a tool for sustainability. In: R. Ayres, D. Simpson & M. Toman (eds). *Scarcity and Growth in the New Millennium*, Resources for the Future, Washington DC.

Pearce D.W. & P. Koundouri (2003): The social cost of chemicals. The cost and benefits of future chemicals policy in the European Union. Report prepared for WWF-UK.

Pearce, D.W & P. Koundouri (2004): Regulatory assessment for chemicals: a rapid appraisal cost-benefit approach. Environmental Science and Policy. 7. 435-449.

Petersen, J. (2003): Nitrogen fertilizer replacement value of sewage sludge, composted household waste and farmyard manure. J. Agric. Sci. Vol. 140, 169-182.

Postle, M., J. Vernon, F. Anthony, T. Nwaogu, D. Brooke & M. Crooks (2003): The Impact of the new chemicals policy on health and the environment. Final Report. RPA & BRE, Prepared for the European Commission, Environment-Directorate General.

Ritter L., K.R. Solomon, J. Forget, M. Stemeroff & C. O'Leary (1996): Persistent organic pollutants. Prepared for UNEP.

RPA (2001): Regulatory Impact Assessment of the EU White Paper: Strategy for a Future Chemicals Policy. London: Department of Transport, Environment and the Regions.

RPA (2003): Assessment of the impact of the new chemicals policy on occupational health. Report prepared for the European Commission, DG ENV.

RPA & Statistics Sweden (2002): Assessment of the impact of new regulations in the chemicals sector. Report to the European Commission, DG ENTR.

Schweighofer, P, O. Nowak, K. Svardal & H. Kroiss (1996): Steps towards the upgrading of a municipal WWTP affected by nitrification inhibiting compounds - a case study. Wat. Sci. Tech. 33, 12:39-46

SedNet (2004): Contaminated Sediments in European River Basins. European Sediment Research Network, EC contract No. EVK1-CT-2001-2002. http://www.sednet.org/

Sequi P. & F. Tittarelli (2000): The role of sludge in the re-integration of soil fertility. In *Langenkamp, H. & L. Marmo (Eds.) (2000): Workshop on Problems around Sewage Sludge. 18-19 November 1999 (NO) Italy Proceedings. European Commission's Joint Research Centre, EUR 19657 EN, 242 p. 120-132*.

TripleNine (2005): 999 News No. 2 + personal communication.

Tørsløv, J., L. Samsøe-Petersen, J.O. Rasmussen & P. Kristensen (1997): Use of waste products in agriculture. Miljøprojekt No. 366, Danish EPA. Copenhagen. 211 pp http://www.mst.dk/udgiv/publications/1997/87-7810-843-8/pdf/87-7810-843-8.pdf

Tørsløv J., M. Hauschild & D. Rasmussen (2004): Ecotoxicity. In: Hauschild, M. & J. Potting (Eds.): Spatial differentiation in life cycle impact assessment - the EDIP2003 methodology. Guidelines from the Danish Environmental Protection Agency (In press).

UNEP (2000): Available at http://www.unep.org/ozone/Montreal-Protocol/Montreal-Protocol2000.shtml

US EPA (2004): ECOTOX database, http://www.epa.gov/ecotox

van Haelst A.G. & B.G. Hansen (2000): Priority setting for existing chemicals: Automated data selection routine. Env. Tox. Chem. 19, 2372-2377.

Von Bahr, J & J. Janson. (2004): Cost of Late Action – the Case of PCBs. TemaNord 2004: 556. Copenhagen: Nordic Council of Ministers.

WRc (1999): *Potential Costs and Benefits of Implementing the Proposed Water Framework Directive*, London, DETR.

A P P E N D I X   A

Cost-benefit analyses of REACH
Summary of studies

A1. COST-BENEFIT ANALYSES OF REACH

In the table below, the existing studies of the costs and benefits of REACH are summarised. There are in fact no comprehensive studies and some that claim to be cost-benefit studies do not in fact estimate benefits. This underlines the problems that everybody faces in trying to estimate the benefits of REACH.

Date	Study	Findings (all £ and € figures are present values unless otherwise stated. Discount rate shown in brackets)
May 2001	RPA *Regulatory Impact Assessment of the EU White Paper: Strategy for a Future Chemicals Policy.* London: DETR	Coverage: UK Only. Early study based on interpretation of likely development of EU White Paper. Compliance costs = £0.42.10^9= €0.68.10^9 Benefits: Occ.injuries < £64-129.10^6 ‘over 10 years’ Occ.asthma/dermatitis < 0.6 -1.2.10^9 ‘over 10 years’ But concludes ‘it is not possible to determine the incremental benefits provided by the EU White Paper proposals’ (p.47). Estimates appear to be undiscounted. PV Cost savings = £34.10^6 (at 6%)
Mar 2003	RPA. *Assessment of the Impact of the New Chemicals Policy on Occupational Health*. Brussels: CEC	Coverage EU-15 Benefits: Occ.Non-cancer illnesses = € 23-225.10^6(at 3%) Occ.Cancers = €17.6-54.2.10^9 Occ.Total = €17.6-54.4.10^9
Jun 2003	RPA and BRE. *The Impact of the New Chemicals Policy on Health and the Environment.* Brussels: CEC (Postle *et al.* 2003).	Coverage EU-15 Analyses damages avoided for selected chemicals had REACH been implemented earlier. Benefits: Nonylphenols: >0 SCCPs: >0 Tetrachloroethylene: probably >0 TBTs: >0 No monetary quantification
Oct.2003	CEC *Extended Impact Assessment:* COM(2003)644 Final	Coverage EU-15 PV compliance costs = €2.8-5.2.10^9(at 3%) Benefits: Occ.health - >0 but not known Pub.health - >0 but not known Environmental – not known Illustrative number for health benefits based on DALYs avoided = €50.10^9 (for comparison, see Pearce and Koundouri below)

Date	Study	Findings (all £ and € figures are present values unless otherwise stated. Discount rate shown in brackets)
Nov2003	ERM.*New European Chemicals Strategy: UK Partial Regulatory Impact Assessment*. London: DEFRA	**Coverage UK only for benefits, and EU-15 and UK for costs** Costs to EU-15 put at £1.2-4.3.10^9 = €1.9-6.9.10^9 but £1.1-3.7.10^9 = €1.8-5.9.10^9 with mandatory consortia. Costs to UK = £0.3-1.0.10^9 = € 0.5-1.6.$10^9$and £0.3-0.9.10^9 = €0.5-1.4.10^9 Benefits: estimates total costs to occupational health from all chemicals = £16.10^9 = €25.6.10^9 per annum. (Figure mainly driven by fatalities. Cancer deaths valued at 2x the 'official' UK figure for VOSL of £1.2.10^6). Annuitised compliance costs for UK = £45.10^6 so REACH need only reduce chemical related health cases by 0.3% each year for benefits to exceed costs.
May2004	Danish EPA. *Valuation of Chemical Related Health Impacts.* Copenhagen: Environment Ministry (in Danish)	**Coverage: Denmark only** Does not estimate benefits of REACH but calculates resource and WTP cost of chemicals-related diseases. Asthma: €270 per attack Headaches: €50 per double attack in one day Allergies: € 40.10^3 per chronic case Lung cancer: €1.3.10^6 per fatality Skin cancer: €34.10^3 per case Note: some of these impacts would not be affected by REACH
Oct.2004	K.Ostertag *et al. Analysis of the Costs and Benefits of the New EU Chemicals Policy.* Berlin: Federal Environment Agency	**Coverage Germany only** Costs: discusses but does not estimate for nation Benefits: Allergies in general public costed at € 0.5-5.2 per capita p.a. Contribution of REACH to reducing these costs not known.
2004	J.Bahr and J.Janson. *Cost of Late Action – the Case of PCB*. Copenhagen: Nordic Council of Ministers	**Coverage EU-25** Assumes REACH will prevent one 'mistake' half the scale of the damage costs of PCB (or 5 mistakes each 10% of the costs of PCB damage). Costs based on clean-up costs taken from Swedish data. And assumed to last 23 years. Benefit: €7.2.10^9 (at 4%) €27.5.10^9 (at 1.5%)
2004	D.W.Pearce and P.Koundouri. Regulatory assessment for chemicals: a rapid appraisal cost-benefit approach. *Environmental Science and Policy.* **7**. 435-449	**Coverage EU-15 and UK** Costs –adopts the higher end of the CEC cost range, i.e. €5.2.10^9 Benefits: Estimates DALYs per capita lost in EU and UK due to 'agro-industrial pollution'. Assumes REACH reduces DALYs by 10% after time lag. Values a DALY using (a) health treatment costs and (b) WTP. Results: *healthcare costs only* UK benefits = €0.4-1.6.10^9 EU-15 benefits = €4.9-20.1.10^9 Results: *WTP-based* UK benefits = €2.0-15.0.10^9 EU-15 benefits = €12.3-93.3.10^9

A2. OBSERVATIONS

- No study estimates environmental impacts in terms of willingness to pay for environmental benefits
- Studies focusing on occupational health benefits all fail to discuss whether these are 'real' benefits in the economic sense – e.g. occupational risks may already be internalised in wages
- Methodologies for estimating health benefits vary widely, e.g. treatment costs.

A P P E N D I X   B

WTP and benefits transfer

B1. WILLINGNESS TO PAY AND BENEFITS TRANSFER

Benefits transfer involves taking a unit value of a non-market good estimated in an original or primary study and using this estimate (perhaps after some adjustment) to value benefits in another context. In the current study, limited use is made of benefits transfer. The first is the use of British WTP estimates for clean water which are then extrapolated to other countries in EU-25. Here the WTP in any country, i, is assumed to be scaled by the difference in per capita incomes (Y), i.e.:

$$WTP_i = WTP_{UK}.(Y_i/Y_{UK}).$$

The second use of benefits transfer involves the WTP to avoid the health consequences of disease. For example, the values used for fatal and non-fatal cancers come from WTP studies in various European countries.

The question is, how valid is it to transfer values? An interim conclusion (interim, because so much research is emerging on this issue) is that benefits transfer can give rise to inaccuracy of varying degrees of magnitude. Benefits transfer seems to work in some contexts better than in others, for reasons that are sometimes not very clear. However, conclusions about validity (or otherwise) need to be placed in their appropriate context. Put another way, a degree of inaccuracy is almost inevitable and some benefits transfer analysts have asked whether criteria used to judge transfer validity are too demanding relative to the accuracy needed to help evidence-based policy making. As a practical matter, it may be that some degree of imprecision 'does not matter' and that more pragmatic (but clear) rules of thumb are needed about the hurdle of accuracy that any transfer must attain.

Benefits transfer takes various forms. In its simplest form, the procedure is to 'borrow' an estimate of WTP in context S (the study site) and apply it to context P (the policy site). The estimate is usually left unadjusted, i.e.:

$$WTP_S = WTP_P$$

As a general rule, there is little evidence that the conditions for accepting unadjusted value transfer hold in practice. Effectively, those conditions amount to saying that the "sites" are effectively 'identical' in all these characteristics, and this is extremely unlikely.

One level above this naïve transfer is the income-adjusted transfer outlined earlier, i.e. an adjustment is made for one factor, income, which is known to influence WTP.

A more sophisticated approach still is to transfer the benefit or value function from S and apply it to P. Thus, if it is known that WTP at the study site is a function of a range of physical features of the site and its use as well as the socio-economic (and demographic) characteristics of the population at the site, then this information itself can be used as part of the transfer. For example, $WTP_S = f(A,B,C,Y)$ where A,B,C are additional and significant factors affecting WTP (in addition to Y) at site S, then WTP_P can be estimated using the coefficients from this equation in combination with the values of A,B,C,Y at site P, i.e.:

$$WTP_S = f(A, B, C, Y)$$

$$WTP_S = a_0 + a_1A + a_2B + a_3C + a_4Y,$$

where the terms a_i refer to the coefficients which quantify the change in WTP as a result of a (marginal) change in that variable. For example, assume that WTP depends on the income, age and educational attainment of the population at the study site and that the analysts undertaking that study estimated the following relationship between WTP and these (explanatory) variables.

$$WTP_S = 3 + 0.5Y_S - 0.3\ AGE_S + 2.2\ EDUC_S$$

That is, WTP_S increases with income and educational attainment but decreases with age as described. In this transfer approach, the entire benefit function would be transferred as follows:

$$WTP_P = 3 + 0.5Y_P - 0.3\ AGE_P + 2.2\ EDUC_P$$

Finally, meta-analysis might be used. This is a statistical analysis of summary results of a (typically) large group of studies. The aim is to explain why different studies result in different mean (or median) estimates of WTP. At its simplest, a meta-analysis might take an average of existing estimates of WTP, provided the dispersion about the average is not found to be substantial, and use that average in policy site studies. Alternatively, average values might be weighted by the dispersion about the mean, the wider the dispersion the lower the weight that an estimate would receive.

The results from past studies can also be analysed in such a way that persistent variations in WTP can be explained. This should enable better transfer of values since the analyst can learn about what WTP systematically depends on. In the meta-analysis case, whole functions are transferred rather than average values, but the functions do not come from a single study, but from collections of studies. As an illustration, assume that the following function is estimated using past valuation studies of a recreational site in a particular country:

$$WTP = a_1 + a_2\ \text{TYPE OF SITE} + a_3\ \text{SIZE OF CHANGE} + a_4\ \text{VISITOR NUMBERS} + a_5\ \text{NON-USERS} + a_6\ \text{INCOME} + a_7\ \text{ELICITATION FORMAT} + a_8\ \text{YEAR}$$

This illustrative meta-analysis seeks to explain WTP with reference not only to the features of the recreational study sites (type, size of change in provision in the wetland, numbers of visitors and non-users) and socio-economic characteristics (income), but also ‘process variables’ relating to the methods used in original studies (elicitation format in stated preference studies and so on) and the year in which the study was undertaken.

While it is tempting to suppose that increasing sophistication of the transfer procedure should increase the validity of the transfer, too little is known at the moment to make this judgement. Testing validity is itself complex. One procedure is to take a set of original studies for several (say, n) sites and then see if the results of n-1 sites predict the n^{th} site. Some of these studies indicate that transfer error ranges are small while other studies indicate that these ranges are extremely large. Benefit function transfer tests appear to perform little better in terms of reducing transfer errors. However, some authors argue that, as a practical matter, relative to other sources of uncertainty in a policy analysis, the scale of error that they find is probably acceptable.

Because of the uncertainty surrounding benefits transfer, we regard the methodology in this report that utilises transferred WTP estimates as being of only moderate reliability.

A P P E N D I X   C

Ranking methods

C1. APPROACHES TO RANKING OF CHEMICALS

EURAM

The European Union Risk rAnking Method (EURAM) (Hansen *et al.* 1999) was developed by the ECB for prioritising among the existing High Production Volume Chemicals (HPVC), i.e. substances manufactured or imported in quantities above 1,000 tonnes per year per manufacturer/importer. For this, data retrieval of information on quantities and substance properties was automated (van Haelst & Hansen 2000).

EURAM is based on electronic data retrieval from the International Uniform ChemicaL Information Database (IUCLID), which contains data not only on quantities of existing chemicals in the EU-15, but also on their physicochemical and (eco)toxicological properties – at least for the HPVC. Following data retrieval, scores for exposure and for effects are calculated and combined into an overall score used for risk ranking.

The scores for exposure are calculated by use of information on main use categories and model calculations on partitioning in the environment combined with information on the biodegradability of substances. Missing information is typically replaced by default values, which are very conservative.

Quantities emitted are calculated as a fraction of the total quantity, which is placed in one of four Main Categories (MC) with increasing emission, MC I is closed systems, while MC IV is wide dispersive use.

Subsequently, the distribution in the environment is calculated based on the Mackay level I model on partitioning between air, water, sediment, soil and biota at equilibrium. The result will be a measure of the potential exposure of each environmental compartment with each chemical.

Information on the biodegradability of the substance is included as a degradation percentage.

The environmental exposure score is then calculated as the product of the three subscores, followed by scaling calculations in order to limit the value of the score to the range 0-10. This score is calculated for each of the main environmental compartments (water, soil, sewage treatment plants (STP)) and an exposure score for top-predators is calculated from BCF or log Kow data.

Scores for environmental (and human) effects are calculated by use of IUCLID data on (eco)toxicity and physico-chemical properties (for which QSARs may be applied). Furthermore, based on the quality of the experimental work, the toxicity data are ranked before calculation of the environmental effect score, which is scaled to a value in the range 0-10.

"Environmental combined effect and exposure scores" are calculated as the product of the two individual scores thus resulting in a score with a value in the range 0-100. Scores are calculated for each of the environmental compartments water, soil, STP and biota. For the prioritising, the score for the aquatic compartment is used immediately, while scores for the other compartments are used only after expert judgement. The result of this selection process among the about 2,500 HPVC was a list of substances ranked in accordance with their potential risk to human health and the environment. Among these substances, about 140 were prioritised for a systematic risk assessment under the Existing Substances Regulation programme (ECB 2004).

Ranking in Lifecycle Assessment
Methods for ranking of chemicals have also been developed in the context of Life Cycle Assessment (LCA) or Life Cycle Impact Assessment (LCIA). Like EURAM, these methods are based on information about the toxicity and other intrinsic properties of the substances but instead of estimating the total emission, the LCA assessment is based on definition of a "functional unit", for which the emission is estimated. Therefore, the ranking is confined to the (toxicological) profile of chemicals and the emission per functional unit and does not necessarily include measures of the magnitude of total emissions.

In LCA, several approaches to the ranking of substances exist, among which the main differences are mainly the level of detail.

For a review of the parameters, which could be included in LCIA, reference is made to Tørsløv *et al.* (2004) who list and discuss parameters, which are affecting the fate of chemicals and the resulting environmental and human exposure to them. These parameters include spatial or geographical scale, dissociation of substances, the temporal cause of the emission, sorption and immobilisation, degradation under aerobic and anaerobic conditions, temperature as well as background levels of chemicals.

For details of several LCIA ranking methods, reference is made to Larsen & Hauschild (2005), who review and compare the results from five ranking methods developed for LCIA and the EURAM method. All methods are described in detail and the ranking of 27 amphiphilic and dissociating substances by these methods is compared. In general there is a good agreement between all six ranking methods even though there are a few outliers to the general picture. These are analysed in detail and the conclusions point to that some differences are caused by the definition of substance properties, like the use of assessment factors for effects parameters and inclusion of dissociation in calculations for estimating bioaccumulation. However, for some substances, the difference in ranking by different methods is caused by the fact that one method (EURAM) includes Mackay partitioning calculations for predicting the environmental exposure, while another method (priofactor) considers, which environmental compartment is initially exposed. For two (lipophilic) substances, the prediction that the substance will sorb to soil (made by EURAM) leads to a very low aquatic exposure, while the priofactor methods takes its starting point in the fact that these substances are actually emitted to water.

Two of the ranking methods currently used in LCA will be described in more detail below.

USES-LCA
This method is described by Huijbregts *et al.* (2000). The calculations are based on the Uniform System for the Evaluation of Substances (USES), which is forming the basis of the electronic version of the TGD (EC 2003). A Risk Characterisation Ratio (RCR), which is the ratio of the Predicted Environmental Concentration to the Predicted No Effect Concentration (PEC/PNEC), is calculated for each of the environmental compart-

ments fresh and marine water, fresh and marine sediment, micro-organisms in sewage treatment plants and soil as well as for fish-eating predators, worm-eating predators and humans. Subsequently, the RCR-value is weighted based on the distribution between the compartments and, finally, it is compared to the weighted RCR of a reference substance, the ratio being designated the "toxicity potential" of the substance in question.

The calculation of the PEC-values is based on a daily standard emission of the chemical into one of the compartments air, fresh water, seawater, agricultural soil and industrial soil. The possible partitioning from this compartment to other compartments is calculated based on equilibrium partitioning and possible bioconcentration is calculated from information on Log Kow or BCF.

Priofactor method

The prio(ritising) factor method was developed for assessing products with many chemical exchanges (Larsen & Hauschild 2005). The aim of the ranking is to identify those substances, which are expected to contribute (most) substantially to the environmental impact of the product - before spending resources on each chemical in a detailed life cycle assessment.

Therefore, the method is aiming at a minimum of requirements for data and calculations. The parameters needed is the BioConcentration Factor (BCF), a measure of the biodegradability (the BioDegradationFactor, BDF) and the lowest concentration of the substance in water at which 50% of the effect (e.g. mortality) has been measured in short term laboratory tests (EC50). Information regarding the BCF is attained from experimental results or – if such data are not available - on QSAR calculations based on the Log Kow, while the values assigned to the BDF are in the range 0.1-1.0. Having these parameters, the formulas are simple.

The outcome of the calculations is the dilution volume needed for one unit of the substance to reach an environmental concentration, where no (unacceptable) effects are expected. This is termed the ecotox-sub(stance)priofactor. The ecotox-subpriofactor is calculated as the ratio between the product BCF × BDF and the EC50. Subsequently, this critical dilution volume can be multiplied by the quantity emitted, to reach the measure of the environmental impact of the emission; the "ecotox-priofactor". For the environmental prioritising, only the aquatic compartment is considered. This is due to the fact that the majority of available ecotoxicity data is concerning aquatic organisms.

ECETOC-TRA

The ECETOC Targeted Risk Assessment tool has been developed by ECETOC (2004) as a simple risk assessment tool. The ECETOC-TRA is a tiered tool with a simple tier 0 for initial risk screening requiring only a very limited amount of data, a more elaborate tier 1 for simple risk assessment of standard use scenarios, and a more complex tier 2 that may be used for more complex situations when required. Basically, the ECETOC-TRA is utilising the same approaches and algorithms as in the EU TGD and the EUSES model. However, in contrast to the TGD, the ECETOC-TRA is a meta-model, which uses data ranges (bands) as input parameters instead of specific values for the input parameters. The algorithms of the tool are based on results of 1,000 iterations of EUSES calculations and an indicative PEC/PNEC is estimated.

As the ECETOC-TRA tool is used for simple risk assessment and not for priority setting, and as it is using ranges of values instead of specific values as input data making the results unnecessary uncertain, it is not discussed and used further in the current study.

Comparison of ranking methods
Table C.1 gives an overview of the data demands and the calculations used for the three ranking methods.

The estimate of the emission to the environment differs between the three ranking methods.

- In EURAM the emission of chemicals are estimated from information regarding manufactured/used amounts and different use categories both available in IUCLID.
- In USES-LCA, the “standard emission” is defined as 1×106 kg/day.
- In the priofactor method, the emission to the aquatic compartment is based on information obtained during the LCA.

The estimate of scores differs between the three ranking methods. In EURAM, scores for toxicity, biodegradability and BCF are scaled to lie in the range 0-10. In the USES-LCA methods, the score for the effect is weighted. In the priofactor method, biodegradability is given a score in the range 0.1-1.0, while neither ecotoxicity nor bioaccumulation are scaled allowing both of them to have a value of several orders of magnitude (e.g. up 107-109). Thereby, in the priofactor method, biodegradation will have only a limited influence on the ranking of substances with high ecotoxicity and/or bioaccumulation scores.

Table C.1 Overview of environmental part of ranking methods. Details on "scaling," "normalising" and weighting are not included

<table>
<tr><th>Method</th><th>Input data</th><th>Exposure</th><th>Environmental effects</th><th colspan="2">Output used for ranking</th></tr>
<tr><td rowspan="8">EURAM</td><td>Tonnage</td><td rowspan="7">Product of scores for emission, distribution and degradation + scaling
⇒ $EEX_{compartment}$
(≈"$PEC_{compartment}$")

+ Exposure $score_{top\ predator}$</td><td rowspan="7"></td><td rowspan="8" colspan="2">[1]EEX · EEF = Environmental Score (ES)</td></tr>
<tr><td>Main use categories</td></tr>
<tr><td>Water solubility</td></tr>
<tr><td>Vapour pressure</td></tr>
<tr><td>Log Kow</td></tr>
<tr><td>Biodegradability</td></tr>
<tr><td>BCF</td></tr>
<tr><td>Aquatic toxicity</td><td></td><td>Effect concentration/assessment factor
⇒
Toxicity score + scaling
⇒ $EEF_{compartment}$</td></tr>
<tr><td rowspan="7">USES-LCA</td><td>Standard emission</td><td rowspan="6">Equilibrium partitioning for distribution
⇒ $PEC_{compartment}$

+ $PEC_{top\ predators}$</td><td rowspan="6"></td><td rowspan="7">PEC/PNEC = $RCR_{compartment}$ + weighting
⇒
Weighted $RCR_{compartment}$</td><td rowspan="7">[2]$RCR_{substance}/RCR_{reference\ substance}$
⇒
Toxicity $Potential_{compartment}$</td></tr>
<tr><td>Water solubility</td></tr>
<tr><td>Vapour pressure</td></tr>
<tr><td>Log Kow</td></tr>
<tr><td>Biodegradability</td></tr>
<tr><td>BCF</td></tr>
<tr><td>Aquatic toxicity</td><td></td><td>Effect concentration/assessment factor
⇒
$PNEC_{compartment}$</td></tr>
<tr><td rowspan="4">Priofactor</td><td>Emission to aquatic compartment</td><td>Amount in aquatic compartment, Q</td><td></td><td rowspan="4" colspan="2">Q * Ecotox-subpriofactor = Ecotox-priofactor</td></tr>
<tr><td>(Bio)degradability</td><td rowspan="3"></td><td rowspan="3">BDF* BCF/EC_{50} = Ecotox-subpriofactor = Critical dilution volume</td></tr>
<tr><td>Log Kow or BCF</td></tr>
<tr><td>Aquatic toxicity</td></tr>
</table>

$EEX_{compartment}$ = Environmental Exposure $Score_{compartment}$
$EEF_{compartment}$ = Environmental Effect $Score_{compartment}$
$RCR_{compartment}$ = Risk Characterisation $Ratio_{compartment}$
1: EURAM uses the environmental score (ES) for ranking chemicals. However it is suggested to improve the score by combining the environmental score (ES) with a scaled factor for BCF in an aquatic score (AS). Not shown in the table.
2: Calculated for each compartment

For the current study, EURAM is the preferred tool for ranking. This conclusion is based on considerations regarding the wide acceptability of the model, the possibility of comparing the results of the current study with the results of the EU priority setting among the HPVC and the possibility for an automated data processing.

C2. SELECTION OF RANKING METHODOLOGY DATA AVAILABILITY

Data on manufacture, import and use as well as on intrinsic properties of chemical substances are available in many handbooks and databases. However, as is well known, the information available regarding the majority of the existing chemical substances is negligible (Allanou *et al.* 1999). Furthermore, reliable data for assessment of emissions (i.e. amounts produced/imported) or environmental concentrations of the majority of chemicals (excluding some well-known priority substances) are extremely difficult to find. An overview of some of the major data sources with comprehensive data sets is given below.

The IUCLID database

The IUCLID database contains information, which has been submitted by manufacturers and importers of existing chemicals in quantities exceeding 10 tonnes per year in at least one of the years 1991-1995. The amount of information requested for each chemical depends on the tonnage with chemicals produced or imported in a quantity of more than 1,000 tonnes per year having the largest requirements and chemicals produced or imported in 10-1,000 tonnes per year a considerably lower requirement (EEC 1993). An overview of the data requirements is given in Table C.2.

Table C.2 Overview of data requirements for existing substances

Data requirement	10-1,000 tonnes per year	>1,000 tonnes per year
Name and Einecs number	4	4
Quantity produced or imported	4	4
Classification & labelling	4	4
Reasonable foreseeable uses	4	4
Physicochemical properties		4
Environmental pathways and fate		4
Ecotoxicity		4
Acute and subacute toxicity		4
Carcinogenicity, mutagenicity or reprotoxicity		4
Other relevant information		4

Thus, for HPVC sufficient information for a priority setting is (in principle) available in IUCLID and this information was used for generating the priority lists of the existing chemicals by use of the EURAM. For lower production volume chemicals, information is available that may be used for giving a first indication of the potential release to the environment, but no information on the potential effects is required and thus for most chemicals such information is not available.

Each registration dossier from a manufacturer or importer of a chemical contains the total quantity of the chemical produced or imported per year. It also contains information on the Main Categories (MC) used to characterise the general release scenarios of the chemical as well as information on the more specific Industrial Categories (IC) describing the production and use of the chemical in more detail. One shortcoming is that the tonnage is not subdivided into which fractions that pertain to the MC or IC given in IUCLID.

Databases with test data

Several electronic databases exist, which are relatively easy to approach. Especially, the American database, ECOTOX, maintained by the US EPA (2004), is very comprehensive and contains data collected from many different sources. The current version (January 2004) contains ecotoxicity data for 10,325 substances including pesticides. However, still it must be approached on a substance by substance level and for many substances in current use, no data exist.

Several databases with test data on fewer substances are available as well. Examples are the Japanese Chemicals Evaluation and Research Institute's database with biodegradation and bioaccumulation data and the Japanese Ministry of the Environment's database on short-term and long-term toxicity tests with aquatic organisms.

QSAR databases

The most comprehensive database with QSAR estimates of physicochemical and environmental properties has been developed by the Danish Institute for Food and Veterinary Research (which is now hosting the QSAR group previously at the Danish EPA). The models are described in the "Report on the advisory list for selfclassification of dangerous substances" (Danish EPA 2001).

The Danish EPA has during the latest more than 10 years compiled and developed QSAR models for a large number of endpoints including ecotoxicity, (bio)degradability and bioaccumulation (log Kow). An internal validation of the domain and validity of the individual QSAR models have been conducted and results have been generated for about 166,000 discrete organic substances of which about 47,000 chemicals are on the Einecs list. The QSAR models for biodegradation and acute aquatic toxicity (fish, daphnids, algae) have been specifically developed by the Danish EPA by use of the commercially available MultiCase software. MultiCase is a complex 2-14 fragment artificial intelligence method that is widely used and well documented. The developer can choose to use 2 fragments as a minimum or any number up to 14. Most of the models developed by the Danish EPA use more than 2 fragments.

The domain of a model is of course depending on the diversity of the data set that has been used to develop the particular model. The domain criteria used by the Danish EPA models for indicating that a prediction is "All OK" (AOK), i.e. within the domain of the model, are stricter than those used in the US FDA cancer models. When estimating a result of a chemical, the model always gives warnings for predictions outside the domain. In fact, any warning at all is sufficient for not awarding the AOK status to a prediction. Based on this, the indication AOK is given to 60% of the biodegradation estimates, 40% of the fish toxicity estimates, 53% of the daphnia toxicity estimates and 49% of the algae toxicity estimates among estimates for 45,452 substances from the Einecs list. It is self evident that non-AOK predictions are less reliable than the AOK predictions (otherwise they would have been AOK), and predictions not within the domain are flagged.

The results of the calculations of properties by the Danish EPA QSAR models are in the process of being made publicly available through the ECB website. Furthermore, they have also been made available for the current study in a spreadsheet version, which facilitates the automated calculations.

Substances covered by the QSAR models
Not all substances can be modelled, as a precise description of the molecular structure is needed. The substances covered are described in by the Danish EPA and cited below:

"The screening was limited to cover "discrete organics", meaning that UVCBs (Unknown, Variable Composition and Biologicals) and other ill-defined structures or mixtures were excluded for practical reasons – if you don't know what it is, you can't really make a model. Exceptions were made where this seemed logical (C12 – C16 n-alcohols has been entered as C14 n-alcohol – hydrochloride salts have been entered as the parent compound, etc.).

Inorganic substances have likewise not been evaluated. These are usually better approached by simpler methods of evaluating the availability of the respective an- and cations with well known hazard profiles. "Organo-metallics" have also been excluded as being poor candidates for modelling. Finally, as a matter of resources, only such chemicals as were available with 3-D structural information were used." (Danish EPA 2001, p. 17)

Physico-chemical and bioaccumulation data
Estimated values of the following physicochemical and bioaccumulation properties were obtained:

- Water solubility
- Boiling point
- Vapour pressure
- Henry's law constant
- Octanol-water coefficient (log Kow)
- Bioconcentration factor (BCF)

The properties of all of these endpoints were estimated by use of the EPIWIN programme suite, which has been developed by the Syracuse Research Corporation and is available free of charge from the US-EPA.

Environmental data
Estimated values of the following environmental endpoints were obtained:

- Biodegradation
- Short-term toxicity to fish
- Short-term toxicity to daphnids
- Short-term toxicity to algae

The QSAR estimates of acute aquatic toxicity were based on Danish EPA M-CASE models. Estimates of aquatic toxicity are available for acute toxicity to fish (fathead minnow LC50-96h), acute toxicity to daphnia (*Daphnia magna* EC50-48h) and acute toxicity to algae (*Pseudokirchneriella subcapitata* EC50-72h). The results are given in mg/L up to an upper limit of 1000 mg/L (i.e. all estimates higher than 1000 mg/L are given as 1000 mg/L).

"M-CASE is a knowledge-based artificial intelligence system capable of learning directly from data. Models made in this program can predicts various toxic endpoints on the basis of discrete structural fragments found to be statistically relevant to a specific biological activity, either increasing or decreasing it. The program can thus provide a "chemical" explanation to observed biological properties. It assumes that the presence of fragments previously found in a number of active compounds is indicative of potential activity. This fragment-based method is assumed to be a reasonable basis to assess the activity of new molecules. On the basis of the presence of the fragments in a query molecule the program will estimate a value for its potency by using "local QSARs" for the various fragments. If so found, "global QSARs" like the relation between Log P and toxicity to aquatic organisms may also be included in the model. The program gives a warning if there are fragments in the query molecule, that are not found in the training set of the model, indicating that the query molecule is outside the domain of the model /38,43/. Estimates for substances found to be within the domain of the model and for which sound predictions could be made are referred to as AOKs ("All OK chemicals") in this paper." (Danish EPA 2001, pp. 15-16)

For the QSAR estimates based on the Danish EPA M-CASE model, an indication is given on whether the outcome is within the domain of the model and whether a sound prediction has been made. The following indications are used:

Table C.3 Indications on validity of QSAR estimates

Indication	Explanation (Jay Niemelä, personal comment)
AOK	The prediction is completely within the domain
ALL	The prediction may be used with caution (e.g. unknown fragment, statistical problems, etc.)
FRG	The prediction may be used with caution (unknown fragment combination)
OPS	Outside predicted space

The indication AOK is given to 60% of the biodegradation estimates, 40% of the fish toxicity estimates, 53% of the daphnia toxicity estimates and 49% of the algae toxicity estimates among estimates for 45,452 substances from the Einecs list.

C3. DESCRIPTION OF CALCULATIONS USED FOR RANKING

The ranking was conducted on the basis of the EU Risk Ranking Method (EURAM) (Hansen *et al.* 1999) developed for priority setting of existing chemicals under Council Regulation (EEC) 793/93. The calculation of the ranking for each chemical requires the execution of a number of consecutive steps:

IUCLID data
Information on manufacture, import and use of approx. 10,000 existing chemicals was provided by the European Chemical Bureau as extracts of the IUCLID database. The following data were obtained for each entry:

- CAS numbers (several entries per CAS)
- DSN number coding for the registrant (one or more registrants per CAS)
- Quantities manufactured or imported per year (per entry)
- Main Categories (MC) of use (per entry)
- Hazard classification

The IUCLID extract contains separate entries defined by the substance CAS number, the registrant DSN and the year for which the quantity pertains. For example, if one substance is registered by 3 registrants and each of them registers the quantity for 3 years, there will be 9 separate entries for the CAS number.

Moreover, each of the entries may contain up to 10-15 indications of Main Categories resulting from the registrants' dossier.

Estimation of releases
The estimate of releases included the following steps:

Information on Main Categories was transformed to the fraction released to the environment ($\text{Fraction}_{\text{release},i}$) according to the table below (cf. EURAM, Hansen *et al.* 1999).

Table C.4 Fraction released of substances for different Main Categories of use

Main Category		Fraction	%
I	Use in closed systems	0.01	1
II	Use resulting in inclusion into or onto matrix	0.1	10
III	Non dispersive use	0.2	20
IV	Wide dispersive use	1	100
	No information on use	1	100

For each entry with indication on n MCs, a weighted average fraction of release was calculated:

$$\text{Fraction}_{\text{release,average}} = \frac{\sum_{i=1}^{n} \text{Fraction}_{\text{release},i}}{n}$$

For each registrant, information on the tonnage manufactured or imported may be available for more than one year. However, a review of the data showed that only marginal changes in tonnages appear. Therefore, the average tonnage manufactured and imported was estimated:

$$\text{Tonnage}_{\text{average,registrant}} = \frac{\sum_{i=1}^{\text{Years}} \text{Tonnage}_i}{\text{Years}}$$

Thus, for each registrant, the average annual release was calculated:

$$\text{Release}_{\text{registrant, average}} = \text{Tonnage}_{\text{average, registrant}} \cdot \text{Fraction}_{\text{release,average}}$$

For each substance (CAS No.) the total annual average release was estimated by adding the annual average releases per registrant:

$$\text{Release}_{\text{total}} = \sum \text{Release}_{\text{registrant, average}}$$

Estimation of environmental distribution (Mackay level I model)
For substances where QSAR estimates of physicochemical properties are available, environmental distribution at equilibrium is calculated for a standard environment by use of the Mackay level I fugacity model.

The fugacity capacity (Zi in mol m^{-3} Pa^{-1}) in the compartments air, water, soil, sediment, suspended solids, and biota are:

Air, compartment 1: $Z_1 = 1/RT$

Water, compartment 2: $Z_2 = Cs/VPs$

Soil, compartment 3: $Z_3 = Z_2 \cdot \rho_3 \cdot foc_3 \cdot Koc \cdot 0.001$

Sediment, compartment 4: $Z_4 = Z_2 \cdot \rho_4 \cdot foc_4 \cdot Koc \cdot 0.001$

Suspended solids, compartment 5: $Z_5 = Z_2 \cdot \rho_5 \cdot foc_5 \cdot K_{oc} \cdot 0.001$

Biota, compartment 6: $Z_6 = Z_2 \cdot \rho_6 \cdot L \cdot Koc \cdot 0.001$

In the equations, R is the gas constant (8.314 J/mol K), T is the temperature (K), Cs is the water solubility (mol/m^3), VPs is the vapour pressure (Pa), ρ is the density of phase, f_{oc} is the mass fraction of organic carbon, and L is the lipid content in biota/fish (0.1 as default).

The organic carbon partition coefficient (K_{oc}) is derived from the n-octanol/water partitioning coefficient (K_{ow}) according to Mackay, i.e.:

$$Koc = 0.41 \cdot Kow$$

The environmental compartments in the scenario are defined as in EURAM (Hansen *et al.* 1999) and the definitions are given in the table below.

Table C.5 Definition of environmental compartments used for the Mackay level I fugacity model (after Hansen et al. 1999)

	Air (1)*	Water (2)	Soil (3)	Sediment (4)	Suspended solids (5)	Fish (biota) (6)
Volume (m^3)	10^{14}	$2 \cdot 10^{11}$	$9 \cdot 10^9$	10^8	10^6	$2 \cdot 10^5$
Depth (m)	1000	20	0.1	0.01	-	-
Area (m^2)	$10 \cdot 10^{10}$	$10 \cdot 10^9$	$90 \cdot 10^9$	$9 \cdot 10^9$	-	-
Fraction organic carbon (f_{oc})	-	-	0.02	0.04	-	-
Density (kg/m^3)	1.2	1000	2400	2400	1500	1000

*) Compartment number.

The estimated fraction of the chemical at equilibrium ($Dist_{comp,\,i}$) in compartment *i* is estimated by multiplying the fugacity (Z_i) with the volume (V_i) of the compartment:

$$Dist_{comp,i} = V_i \cdot Z_i$$

Transformation of QSAR estimates

The outcome of the QSAR estimates of biodegradability was transformed into a fraction remaining after biodegradation (Fbiodeg) according to the table below:

Table C.6 Estimated fraction remaining after QSAR result on biodegradation

QSAR outcome	Biodegradability	Fraction remaining (Fbiodeg)	Degradation
POS	Readily biodegradable	0.1	90
EQU	"Inherently" biodegradable	0.5	50
NEG	Persistent	1.0	0

The QSAR estimates of biodegradability were based on a Danish EPA M-CASE model. The programme gives three possible outcomes: POS (readily biodegradable), NEG (not readily biodegradable) and EQU (equivocal results). The latter outcome pertains to substances that may contain both structures that are readily biodegradable and structures that are not readily biodegradable. It may also be substances that contain structures that are not known by the model. For the ranking exercise, it is assumed that EQU can be translated to an inherently biodegradable substance with a fraction remaining after biodegradation (Fbiodeg) of 0.5.

The lowest of the predicted acute aquatic toxicity effect concentrations for algae, daphnia and fish ($EC50_{species}$) is selected.

$$EC50_{water} = Min\{EC50_{species}\}$$

In the absence of ecotoxicological data for soil-dwelling and sediment-dwelling organisms, the effect concentration for each of these compartments ($EC50_{comp,i}$ being $EC50_{soil}$ or $EC50_{sediment}$) was calculated by use of the equilibrium partitioning method based on the approach prescribed in the TGD (European Commission 2003). The method uses the toxicity for aquatic organisms and the relevant sediment/water or soil/water partitioning coefficient ($K_{comp-water}$) as input in the following equation:

$$EC50_{comp,i} = \frac{K_{comp-water}}{\text{Bulk density}} \cdot EC50_{water} \cdot 1000 \quad (mg/l)$$

A bulk density for soil on 1700 kg/m3 and sediment on 1300 kg/m3 was used in the calculation. $K_{comp-water}$ for soil or sediment is calculated in accordance with the TGD.

For a standard sediment (20% solids and 5% organic carbon in the sediment solids) the following equation is derived:

$$EC50_{sediment} = (0.783 + 0.0217 \cdot Koc) \cdot EC50_{water}$$

For a standard soil (60% solids, 20% water and 20% air, and with 2% organic carbon in the soil solids) the following equation is derived:

$$EC50_{soil} = (0.118 + 0.0176 \cdot Koc) \cdot EC50_{water}$$

The quality code for the QSAR prediction is maintained throughout the calculations allowing that predictions outside the domain of the QSAR model can be flagged or removed as required.

EURAM-scores
The principles of the EURAM method are described in detail by Hansen *et al.* (1999). The EURAM operates with two different scores: a score including exposure and effect elements and a score in addition also including the bioaccumulation potential of the chemicals.

EURAM - Environmental score for a compartment (ES_{comp}) is calculated by multiplying an environmental exposure score for the compartment (EEX_{comp}) with an environmental effect score for the compartment (EEF_{comp}) for each chemical emitted:

$$ES_{comp} = EEX_{comp} \cdot EEF_{comp}$$

The environmental exposure score (EEX_{comp}) is calculated from three factors:

- Release per substance ($Release_{total}$ [tonnes per year])
- Distribution into environmental compartment of concern ($Dist_{comp,i}$ where comp can be water, soil or sediment)
- The fractions of the chemical remaining after biodegradation (Fbiodeg)

The EEX is scaled to give values between 0 and 10.

$$EEX_{comp} = 1.37 \cdot \left(\log\left(Release_{total} \cdot Dist_{comp,i} \cdot Fbiodeg\right) + 1.301\right)$$

The environmental effect score for the compartment (EEF_{comp}) is calculated as a scaled value of the lowest acute toxicity data (EC50 or LC50) in combination with an assessment factor of 1000. Furthermore, the EEF is scaled to give values between 0 and 10:

$$EEF_{comp} = -2 \cdot \log\left(\frac{EC50_{comp}}{1000}\right)$$

ES_{comp} is estimated for the water, sediment and soil compartments.

EURAM - Aquatic score (AS) is a score that includes both the environmental effects (EEF) and the potential for accumulation of the chemicals. The AS is calculated by multiplying the environmental exposure score (EEX) with the aquatic effect score (AEF):

$$AS = EEX_{water} \cdot AEF_{water}$$

EEX is estimated as above. AEF is a scaled value, based on EEF and a factor for the bioaccumulation potential (AP). The AEF is scaled to give values between 0 and 10.

$$AEF_{water} = 0.7 \cdot EEF_{water} + AP$$

The factor for bioaccumulation potential is derived from the estimated bioconcentration factor (BCF) as shown in the table below.

Table C.7 Principles for determining the accumulation potential (AP)

Bioaccumulation	AP
Log(BCF) ≤ 2	0
2 < Log(BCF) ≤ 3	1
3 < Log(BCF) ≤ 4	2
4 < Log(BCF)	3

In addition, also a **Biota score (BS)** was calculated by using the distribution to biota as input parameter:

$$BS = EEX_{biota} \cdot AEF_{water}$$

Table C.8 List of parameters

Parameter	Explanation
AEF	Aquatic Effect Score in EURAM
AP	Bioaccumulation Potential in EURAM
AS	Aquatic Score in EURAM
BCF	Bioconcentration factor
BS	Biota score
$Dist_{comp,i}$	Fraction distributed to compartment *i* (air, water, sediment, soil, biota) in Mackay level I model
$EC50_{comp,i}$	Acute EC50 or LC50 for compartment *i* (water, sediment, soil)
EEF	Environmental Effect Score in EURAM
EEX	Environmental Exposure Score in EURAM
ES	Environmental Score in EURAM
$ES_{sediment}$	Environmental Score for sediment
ES_{soil}	Environmental Score for soil
F_{biodeg}	Traction remaining in the environment after biodegradation
Foc	Fraction of organic carbon
$Fraction_{release}$	Estimated fraction released to the environment
Kd	Distribution coefficient (sediment/water or soil/water)
Koc	Distribution coefficient (organic carbon/water)
$Release_{entry}$	Quantity released for each entry in IUCLID
$Release_{registrant}$	Maximum estimated release per registrant
$Release_{total}$	Total release per substance
$Residue_{comp,i}$	Accumulated amount of residues in compartment *i*
SeS	Sediment Score in EURAM
SoS	Soil Score in EURAM
$Tonnage_{entry}$	Quantity manufactured or imported per entry in IUCLID

C4. RESULTS OF RANKING

Information from the IUCLID database on 10,299 different substances identified by CAS numbers was provided by the ECB. Of these, 8,031 contained information about manufactured and imported quantities for at least one year.

QSAR calculations were available for 45,452 discrete organic substances and of these, 5,453 were included in the IUCLID database. Among these, 4,368 contained information on manufactured and imported quantities, but the tonnage of these substances corresponded to only 12% of the total tonnage of substances included in IUCLID. The main reason for this is probably that the largest tonnages pertain to high production volume non-discrete organic substances (mineral oil derivatives) and inorganic substances.

Among the 4,368 discrete organic substances for which both information on manufactured and imported quantity and results of the QSAR predictions are available, 94 substances are included in the list of 141 prioritised substances that are currently undergoing Community risk assessment and, eventually, risk reduction (the remaining substances being inorganics and structurally not precisely defined organics).

The outcome of the ranking process is individual environmental exposure scoring values for environmental compartments, individual environmental effects scoring values for the same compartments as well as the combined scoring value of each of the 5 approaches (environmental scores for water, sediment and soil, aquatic score considering bioaccumulation, biota score based on concentration in biota). Based on the scoring values for each of the 4,368 substances included, a ranking value is given to each substance. The lowest ranking value is assigned to the substance with the highest score, i.e. the substance with the potentially highest risk to the environmental compartment considered in the scoring.

The correlation between the various scoring systems was checked. In general, there is a good correlation between the environmental scores for water and sediment, the aquatic score, and the biota score, while there is no correlation between the environmental score for soil and the four other scores.

The results of the ranking are available in a spreadsheet format. The results of the case substances are presented and discussed in Appendix D.

A P P E N D I X   D

Case studies on substances

D1. 1,2,4-TRICHLOROBENZENE [120-82-1]

In the EU risk assessment programme, 1,2,4-trichlorobenzene (1,2,4-TCB) has been identified as a substance calling for risk reduction measures. In the Risk Assessment Report (RAR) from the Existing Substances Programme (ECB 2003), the drinking water scenario is ground water exclusively. It is demonstrated that the $PEC_{ground\ water}$ is higher than the taste/odour limit set by WHO, but not higher than the limit based on toxicity (Tolerable Daily Intake, TDI). However, comparing to the situation under REACH where the Chemical Safety Assessment is based on a Derived No-Effect-Level established from toxicity information (cf. REACH, Annex I), the odour/taste limit is not considered to be relevant.

Emissions
In the RAR, two use scenarios (called D3 and D4, “other uses” and “dye carrier”), which are considered to be up to date are described. In scenario D3, the annual emission to surface water is 1000 kg/year with a daily emission of 4.95 kg, resulting in a PEC_{water} of 0.038 mg/L in local surface water during emission episodes (ECB 2003, Table 3.21). This results in a total of 26 mill m^3 of contaminated water per year. Similar calculations for the dye carrier scenario (D4) result in a total of 12.5 mill m^3 of contaminated water/year with a concentration of 0.068 mg/L.

This implies that the use of 1,2,4-TCB (in EU-15) will result in a total of approx. 39 mill m^3/year of water with a concentration in the range 0.038-0.068 mg/L. In the RAR, a WHO Tolerable Daily Intake of 7.7 µg/kg body weight/day is quoted of which a 10% contribution from drinking water is allowed and based on that, a limit concentration in drinking water of approx. 20 µg/L is calculated (ECB 2003, Section 4.1.3.4 p. 160). Thus, at least 39 mill m^3/year of water exceed the WHO-based drinking water limit, or an amount equivalent to approx. 0.9‰ of the EU 25 consumption of water of drinking water standard at 45.3 km^3/year (Appendix E2).

Health impact of 1,2,4-TCB in drinking water
After repeated oral administration of 1,2,4-TCB to rats the target organs are the liver and kidneys. The absorption of 1,2,4-TCB after oral exposure is high (70-90%) (RAR Final, Section 4.1.2.5 p. 116).

Though there are weakly positive results from two inadequately performed in vivo micronucleus assays, i.e. some evidence of DNA-damage, the conclusion from the RAR is that ‘on balance 1,2,4-TCB is not considered to express systemic genotoxic effects in vivo’ (RAR Final, Section 4.1.2.6 p. 130).

WHO has proposed a tolerable daily intake (TDI) for 1,2,4-TCB to 7.7 µg/kg bw/d (RAR Final, Section 4.1.3.4 p. 159). This TDI is based on a 13-weeks feeding study with rats applying a safety factor 1000 (100 for inter- and intraspecies variability, and 10 for short duration of study). The critical effect is liver toxicity. WHO has proposed a drinking-water quality guideline for 1,2,4-TCB at 20 µg/L (RAR Final, Section 4.1.3.4 p. 160).

As 39 mill m^3 water a year are exceeding the WHO-based drinking water guideline, the human population exposed to drinking-water containing 1,2,4-TCB exceeding the guideline value can be calculated as follows:

The public water supply in England and Wales is some 5 mill m^3 per day = 1,825 mill m^3 per year or 31 m^3 per year per person (UK DEFRA, Environmental Statistics). This corresponds to a population of 1.3 mill people that may be exposed to drinking-water exceeding the WHO limit of 20 µg/L 1,2,4-TCB.

In a study from 1994, rats were exposed through the feed to 1,2,4-TCB for 104 weeks. In this case, an estimate of the dose-response relationship is possible. The incidents of liver toxicity observed in this rat study (RAR Final, Section 4.1.2.5 Table 4.14 p. 119) may be used to estimate the increase of liver toxicity in a human population exposed to drinking water containing 1,2,4-TCB above the guideline value as shown in Table D.1.

Table D.1 Values used for calculation of the regression line to be used for monetising the consequences of intake of drinking-water containing 1,2,4-TCB above the guideline value

Exposure level in food	Male rats		Female rats	
	Per cent	mg/kg bw/d	Per cent	mg/kg bw/d
	Incidence	Daily dose	Incidence	Daily dose
0+100 ppm	0	5.5	0	6.7
350 ppm	2	18.9	21	22.9
1200 ppm	20	66.7	39	79.3

Regression analysis of the values in the table results in the regression line with the equation: $y = 0.44x - 1.0$, where y is the incidents as a percentage of the exposed population and x is a measure of the exposure (substance per kg bodyweight or per litre of drinking water). It is normal in this kind of study to have 3 exposure groups (3 different concentrations) and 1 control group (not exposed). The numbers of incidents are scored for each of the 4 groups. Statistical methods are available to deal with these limited data. If more independent studies are available, a meta-analysis may be performed on the pooled data. However, this becomes more and more seldom due to animal protection reasons.

From the relationship between the WHO TDI and the WHO drinking water limit, it appears that 1 mg 1,2,4-TCB/kg bw/d corresponds to approx. 3 µg/L drinking water. From this relationship and omitting the intercept, the regression line may be converted to: $y = 0.15x$, with the slope having the unit percent per (µg/L drinking water).

For monetising purposes, the slope of the converted regression line may be used to estimate the increase in incidence of liver toxicity for a population exposed to drinking-water containing 1,2,4-TCB in excess of the WHO TDI. An excess of 1 µg 1,2,4-TCB/L drinking water would correspond to an incidence of liver toxicity of 0.15% of the potentially exposed population.

From the size of the exposed population (1.3 mill people) and the converted regression line, the number of people to achieve liver toxicity due to intake of drinking-water containing 1,2,4-TCB in amounts above the WHO TDI may be estimated.

The daily exposure to 38 µg 1,2,4-TCB/L drinking-water may be estimated to cause liver toxicity in EU-15 of ((38 - 20) µg/L × 0.15% × 1.3 mill) = 34,000 per lifetime (70 years). For EU-25 these correspond to 41,000 lifetime incidents. Recalculating to numbers of annual incidents results in *annual rates of liver cancer incidents in EU-15 at 486 incidents/year and in EU-25 at 582 incidents/year*.

Costs of liver cancer incidents
In a review of monetary value of cancers, Eftec (2004) found some evidence of a 'cancer premium' for deaths by cancer as well as evidence for the value of non-fatal cancers (NFCs). The WTP to avoid fatal cancers were valued at €1 mill and non-fatal ones at €400,000. As no information is available on whether the incidents would be fatal or non-fatal, a range of costs is estimated. Thus, the *annual undiscounted cost of all the liver cancer damage (582 incidents/year) in EU-25 in 2005 is €233 mill to €582 mill*.

Costs of cleaning of drinking water
For costs the estimates of treatment costs derived in Appendix E2 are used. However, because the UK estimate was based on total costs for the production of drinking water and a % reduction assigned to chemicals, while the Danish estimates were based on chemical removal exclusively, only the Danish estimate will be used for this case. The prices in DKK are recalculated to € by current exchange rate and adjusted for differences in income per capita.

Table D.2 Costs of cleaning of 39 mill m^3 drinking water for 1,2,4-TCB (Danish cost estimate)

Compartment	Substance	Problem	Cause of cost	Amount of contaminated water (m^3/year/EU-15)	Price (2005 level) (€/m^3)	Total price (2005) (€/year/EU-15)	Total price (2005) (€/year/EU-25)
Drinking water	1,2,4-TCB	Contamination of drinking water	Purification	39 mill	0.3-1.9	12 mill 74 mill	14 mill 89 mill

Benefits of REACH
1,2,4-TCB is not targeted by REACH (it is handled by the existing legislation) but the relationship between the impact on health and the costs may be used for extrapolating to costs of chemicals that may be affected by REACH and the potential benefits of introduction of REACH.

The most relevant of the environmental scores estimated for 1,2,4-TCB is probably the Environmental Score for water (ES-water), as the impact considered here is contamination in drinking water abstracted from surface water and groundwater. 1,2,4-TCB obtained a ranking number of 2324, which means that 2323 substances are at a potential higher risk to the aquatic environment.

However, the main problem identified with 1,2,4-TCB is not environmental impact, but the cancer risk to humans when drinking water limit values are exceeded. Thus, using only the environmental exposure score for water (EEX_{water}), 1,2,4-TCB obtains a ranking value as number 3023 out of the 4368 substances. An assessment of potential serious health effects can be based on the hazard classification as reported by industry in their submissions to IUCLID. But although the impact of 1,2,4-TCB is associated with carcinogenic effects, the substance is classified only with R22 (harmful if swallowed), R38 (irritating to skin) and R50/53 (very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment) (ECB ESIS 2005). Numerous substances have more severe classifications, e.g. 367 substances on the IUCLID extract covering 10,299 substances (i.e. 3.6%) are classified with either R45 (may cause cancer), R46 (may cause heritable genetic damage) or R60 (may impair fertility).

Among the 3022 substances with a higher ranking regarding exposure of the aquatic environment, 89 substances are classified with either R45, R46 or R60. This corresponds to 2% of these substances, which is in the same range as the almost 4% of all IUCLID substances reported above and an estimate conducted by the Danish EPA based on QSAR estimates that 3% of the substances not included in Annex I to Directive 67/548/EEC are potentially carcinogenic (Danish EPA 2001). Assuming that new data generated under REACH will reveal that not only the 2% already classified for the severe hazards, but up to 3-4% should be classified, this would result in extra 1-2% of the 3022 substances having a higher score than 1,2,4-TCB being identified as carcinogenic, mutagenic or toxic to reproduction (i.e. 30-60 substances). Assuming that the toxic potential of these substances relative to the exposure concentration in average is the same as for 1,2,4-TCB, a total cost of in the range €3,000 mill to €35,000 mill is estimated. As the benefit of REACH is not known with any certainty, it is assumed that REACH as a minimum will result in a 10% reduction in the health costs of these substances. Thus, the benefit of REACH would be approx. €210-2,500 mill per year in 2017 and aggregated over the following 25 years approx. €4,000-50,000 mill in saved health costs.

D2. NONYLPHENOLS [25154-52-3] [84852-15-3]

Nonylphenolethoxylates (NP(E)s) are used in consumer products including laundry detergents. In the environment or in STPs, they are degraded to nonylphenol (NP) and NP(E)s with one or two ethoxylate groups ($NP(E)_{1-2}$). In the environment, $NP(E)_{1-2}$ is degraded to NP, which is relatively stable, bioaccumulative and toxic.

Therefore, the presence of NP and $NP(E)_{1-2}$ (hereafter referred to as NP(E)s) in sewage sludge has been considered as a matter of concern, and in the "Working Document on Sludge, 3rd Draft" (DG Environment, 2000), a limit for NP(E) in sewage sludge for agricultural use of 50 mg/kg NP(E)s dry weight is suggested (this is quoted erroneously by Postle *et al.* 2003).

NP(E)s were investigated in detail by Postle *et al.* (2003). The information obtained on nonylphenols is used for the case for assessment of costs of alternative disposal of contaminated sewage sludge – and the lost fertiliser value.

Data and calculations
Two sources of data for concentrations of NP(E)s in sludge have been consulted: Postle *et al.* (2003) and a Danish survey (Tørsløv *et al.* 1997).

On a European (EU-15) level, 82% of the values for NP(E)s in sludge are exceeding the 50 mg/kg limit (Postle *et al.* 2003). However, this is based on information from investigations dated 1984-1996 and may therefore be out of date for comparison with current production. Information regarding concentrations of NP(E)s in sewage sludge is only available for EU-15 but extrapolation to EU-25 based on population size will be made. In EU-15, the total amount of sewage sludge is 9.6 mill tonnes dry weight per year, and the corresponding value for the EU-25 population is 11.2 mill tonnes dry weight per year (cf. Appendix E4, Table E.4).

In Denmark, an investigation on samples from different STPs carried out in 1996, revealed 2 out of 20 samples of sewage sludge to contain NP(E)s in levels exceeding 50 mg/kg dry weight (Tørsløv *et al*. 1997)[8]. In Denmark around 1990, a voluntary agreement had already been made with industry not to market consumer products containing NPEs. Therefore, even if the Danish limit value for sludge was not set until 1997, it is most likely that the concentrations of NP(E) measured in Danish sewage sludge in 1995 was lower than the average European level.

For EU-25, the 82% of unsuitable sewage sludge listed by Postle *et al.* (2003) results in an amount of sewage sludge, which cannot be used for agricultural application due to the NP(E) load, of 9.1 mill tonnes. If the results of the Danish survey from 1997 are used, the amount of unsuitable sewage sludge is 1.1 mill tonnes/year.

---

8 A limit of 50 mg/kg NP(E)s in sludge dry weight has been in effect in Denmark since 1997 and has now been reduced to 10 mg/kg. Like in several other EU countries, voluntary reductions in the use of NP(E)s by Industry have resulted in a steady decrease of the concentrations of NP(E)s in Danish sewage sludge. E.g. the weighted average concentration in sludge from 174 STPs declined from 27.2 mg/kg in 1997 to 6.8 mg/kg in 2002 (NP(E)s in sludge dry weight) (Danish EPA 2004). For WP 3, the tonnage for comparison in the ranking of IUCLID substances and the equivalent amount of sewage sludge with NP(E) concentrations above the limit must be selected with care .

These two values could be used as the extremes of a range. Thereby, the amount of sludge (in EU-25), which cannot be used for agricultural application due to the NP(E) load will be in the range 1.1-9.1 mill tonnes sludge/year. However, due to the early reduction in the use of NP(E) in Denmark, it is considered to be more likely that the amount of unsuitable sewage sludge in Europe is closer to 9.1 mill tonnes/year than to 1.1 mill tonnes/year. However, for a wide estimate, the range is set to between 1.1 and 9.1 mill tonnes/year. The upper limit of this interval is far above the amount of contaminated sludge of 5.8 mill tonnes/year from the sludge statistics in Table E.4. However, as mentioned in Appendix E4, the amounts in Table E.4 are based on the current STP capacities in EU, which is not sufficient for the amounts of sewage produced.

Cost estimates
Cost estimates based on the above calculations and Appendix E4 are summarised in Table D.3.

Table D.3 Cost of contaminated sludge due to contamination by NP(E)s (EU-25)

Compartment	Case	Problem	Cause of cost	Extent of problem EU-25 (unit)	Price of cause € / t dw	Price €/year/EU-25
STP, sludge	NPEs	Limit conc.	Incineration	1.1 mill (t dw/year)	200	223 mill
STP, sludge	NPEs	Limit conc.	Incineration	9.1 mill (t dw/year)	200	1,829 mill
STP, sludge	NPEs	Limit conc.	Lost fertiliser	29,200 (t N/year) 35,600 (t P/year)	98-130	6.3-8.4 mill
STP, sludge	NPEs	Limit conc.	Lost fertiliser	240,000 (t N/year) 292,000 (t P/year)	98-130	52-69 mill

Based on the assumption regarding cost for incineration and lost fertiliser value, the costs of sewage sludge contaminated with NP(E)s can be estimated to be in the range of €223-1,829 mill/year and of €6-69 mill/year, respectively, for EU-25.

In conclusion, the *average total costs due to NP(E)s in sewage sludge are in the range of €229-1,898 mill/year for EU-25 in the year 2005.*

Benefits of REACH
Nonylphenols are not targeted by REACH but it is assumed that there are ’like chemicals’ that would be affected by REACH.

The case evaluated here is the accumulation of NP(E)s in sewage sludge in concentrations exceeding the limit values set for protecting the soil environment when disposing sewage sludge on farmlands. Thus, the most relevant score would be the environmental score for soil. Here, NP(E)s are ranked as only number 2,622 meaning that 2,621 other substances may constitute a potential higher risk to the soil environment than NP(E)s. This means that suitable limit values might also be relevant for many other substances. It may be assumed that accumulation in sewage sludge and subsequent risks to the soil compartment may be identified for at least some of these substances as a result of the Chemical Safety Assessments conducted under REACH and that risk management measures will be implemented reducing the releases. However, reducing releases of one substance does not influence the concentration of other substances in sewage sludge. Nevertheless, some reduction in the amount of sewage sludge that cannot be disposed at farmlands may be anticipated. Thus, if it is assumed that REACH will result in a reduction of contaminated sludge of 10%, this corresponds to a benefit at €16-133 mill in 2017, which aggregated over 25 years becomes €300-2,600 mill.

It is also worthwhile noting that the ranking values for the remaining four scoring systems are much different and in the range of 86-130. Only 9-13 substances of those with lower ranking values are already included in the current EU risk assessment programme.

D3. TETRACHLOROETHYLENE [127-18-4]

Data and calculations

Postle *et al.* (2003) identify tetrachloroethylene (perchloroethylene - PER) as an example of a substance giving rise to rejection of raw water for use as drinking water without prior purification. They quote a survey of the quality of drinking water in the UK showing average levels of 0.4 µg/L in municipal waters. They also quote a series of ground water samples from Anglia (1,557 samples from 127 sampling sites) of which 13 samples contained 10-100 µg/L (the EU drinking water limit is 5 µg/L). Furthermore, they give examples of the price of finding an alternative water supply (€1.5 mill per alternative) and the increased cancer risk if the water is used for drinking water.

According to ECETOC (1999), the lifetime cancer risk associated with intake of drinking water containing 1 µg tetrachloroethylene/L is 1.5 in 1 million.

Suggesting that the 13 out of 1557 samples mentioned by Postle *et al.* (2003) are representative, approx. 0.8% of the drinking water is contaminated at levels above 10 µg/L. It is not known, how big a percentage of this water contains tetrachloroethylene at concentrations ≥ 1 µg/L. Nevertheless, assuming a linear dose-response relationship, an extra lifetime cancer risk of 15 in 1 million can be proposed.

This implies that among the 454 mill Europeans (EU-25, 2003), 3.6 mill would be exposed to concentrations of tetrachloroethylene above 10 µg/L resulting in *0.8 extra cancer incidents per year*.

Cost estimates

In a review of monetary value of cancers, Eftec (2004) found some evidence of a ‘cancer premium’ for deaths by cancer as well as evidence for the value of non-fatal cancers (NFCs). The WTP to avoid fatal cancers were valued at €1 mill and non-fatal ones at €400,000. As it is not known whether the extra cancer incidents will be fatal or not, calculations of costs of both types of incidents are given in Table D.4

Table D.4 Cost of excess cancer incidents due to tetrachloroethylene (PER) in ground water. NFC is non-fatal cancers.

Compart-ment	Case	Problem	Cause of cost	Extent of problem (No. of incidents/-year/EU-25)	Price of cause (€ /NFC)	Total price (2005) (€/year/EU-25)
Ground water	PER	Cancer	NFC Fatal cancer	0.8	400,000 1,000,000	0.31 mill 0.78 mill

Thus, the annual undiscounted cost of all tetrachloroethylene health damage is *€0.3-0.8 mill per year for EU-25.*

Benefits of REACH

Tetrachloroethylene (PER) is not targeted by REACH (it is handled by the existing legislation) but the relationship between the impact on health and the costs may be used for extrapolating to costs of chemicals that may be affected by REACH and the potential benefits of introduction of REACH.

Similar to 1,2,4-TCB, the most relevant environmental scoring for PER is the environmental score for water. PER obtained a ranking as number 944 meaning that in principle 943 other substances would have a larger risk to the aquatic environment. However, as for 1,2,4-TCB the main problem with PER is the risk of cancer, which is not included in this scoring. PER is classified as carcinogenic, category 3 with the R-phrase R40 (limited evidence of carcinogenic effect) (ECB ESIS 2005).

Instead, using only the environmental exposure score for water (EEX_{water}), PER obtains a ranking value as number 386 out of the 4,368 substances. An assessment of potential serious health effects can be based on the hazard classification as reported by industry in their submissions to IUCLID. Numerous substances have more severe classifications, e.g. 367 substances on the IUCLID extract covering 10,299 substances (i.e. 3.6%) are classified with either R45 (may cause cancer), R46 (may cause heritable genetic damage) or R60 (may impair fertility).

Among the 385 substances with a higher ranking regarding exposure of the aquatic environment, 28 substances are classified with either R-45, R-46 or R-60. This corresponds to 7% of these substances, which is higher than the almost 4% of all IUCLID substances reported above and an estimate conducted by the Danish EPA based on QSAR estimates that 3% of the substances not included in Annex I to Directive 67/548/EEC are potentially carcinogenic (Danish EPA 2001). It might then be assumed that new data generated under REACH will not reveal many more substances that should be classified as carcinogenic, mutagenic or toxic to reproduction. Moreover, considerations similar to the ones for 1,2,4-TCB pertains to PER and as such, they are included in the 1,2,4-TCB case.

Finally, the ranking values for PER are in the range 404-1,356 with the lowest ranking number obtained with the environmental score for sediment. Thus, the sediment compartment is the environmental compartment where the highest risk may be identified, but still many other substances are causing a potentially higher risk.

D4. POLYCHLORINATED BIPHENYLS [1336-36-3]

In this case, PCBs are used as a ‘like’ chemical already regulated and therefore unaffected by REACH.

Fish with a high fat content from the Baltic Sea (salmon, trout and herring) contain high amounts of persistent organic contaminants, e.g. PCB.

The consequences of this contamination include two possibilities:

- The fish is caught and eaten – resulting in a health damage
- Fishing is forbidden – resulting in a loss-of-jobs/income damage

Because fishery in the Baltic Sea is allowed in most of the countries and because similar problems are expected to occur in the Mediterranean, the health damage is considered to be very relevant.

Data and calculations

A Danish study, carried out by the Danish Institute for Food and Veterinary Research (DFVF) under the Ministry of Family and Consumer Affairs, includes an estimate of intake of PCBs via food (Jørgensen *et al.* 2000), which will be used as an example of health impact assessment. The contribution from fish to this intake was considerable and is expected to dominate.

The estimate of concentrations of PCBs in fish for consumption were based on samples of 25 individual species of fish caught in Danish waters (most of which are more or less a part of the Baltic Sea). In addition, results from samples of the “fat” fish salmon (21 from the Baltic proper), mackerel (52 from different places) and herring (20 from Baltic proper and 59 from several places) were used. The average concentration of total-PCB in the “medium fat” fish was 0.035 mg/kg (fresh weight), while the weighted average for total-PCB in the “fat” fish was 0.042 mg/kg (fresh weight).

Based on this and a Danish diet composition model (Larsen *et al.* 2001) the intake of PCBs via the food by the Danes was calculated resulting in the intake estimates summarised in Table D.5.

Table D.5 Estimated intake of PCBs via food by (adult) Danes in the period 1993-1997 (Jørgensen et al. 2000)

Analysis	Average (µg/day)	0.90 fractile (µg/day)	0.95 fractile (µg/day)
PCB-sum[1]	2.2	3.2	3.6
Total-PCB[2]	4	5	6

1: Calculated as the sum of 10 PCB-congeners.
2: Measured with Aroclor 1260 as analytical standard.

Quantitative estimate of risk of cancer from dietary intake of PCBs

According to US-EPA (IRIS 1997) PCBs in general are considered a probable human carcinogen. Excerpts from the US-EPA comments:

"Some PCBs persist in the body and retain biological activity after exposure stops (Anderson *et al.* 1991a (in IRIS 1997)). Compared with the current default practice of assuming that less-than-lifetime effects are proportional to exposure duration, rats exposed to a persistent mixture (Aroclor 1260) had more tumors, while rats exposed to a less persistent mixture (Aroclor 1016) had fewer tumors (Brunner *et al*. 1996 (in IRIS 1997)). Thus there may be greater-than- proportional effects from less-than-lifetime exposure, especially for persistent mixtures and for early-life exposures. "

"Highly exposed populations include some nursing infants and consumers of game fish, game animals, or products of animals contaminated through the food chain. Highly sensitive populations include people with decreased liver function and infants (Calabrese and Sorenson 1977 (in IRIS 1997)). "

"It is crucial to recognize that commercial PCBs tested in laboratory animals were not subject to prior selective retention of persistent congeners through the food chain (that is, the rats were fed Aroclor mixtures, not environmental mixtures that had been bioaccumulated). Bioaccumulated PCBs appear to be more toxic than commercial PCBs (Aulerich *et al*. 1986; Hornshaw *et al.* 1983 (both in IRIS 1997)) and appear to be more persistent in the body (Hovinga *et al.* 1992 (in IRIS 1997)). For exposure through the food chain, risks can be higher than those estimated in this assessment. "

US-EPA has developed a so-called slope factor, which describes the risk of a typical individual, and which is useful for estimating aggregate risk across a population. Upper bound estimates provide information about the precision. EPA's central estimate of the slope factor is 1 per (mg/kg)/day, and in the case of intake of PCB's via food chain exposure, the upper bound slope factor is 2 per (mg/kg)/day, i.e. the risk of cancer could be twice as high as calculated here.

Using EPA's central estimate of the slope factor for exposure via food to PCB's of 1 per (mg/kg)/day, an exposure via food to 2.2 – 6 µg/day gives a risk of cancer for a person weighing 70 kg of 3.1-8.6 × 10^{-5} mg/kg bw/day (=slope factor × PCB intake per day / body weight). That is, out of 100,000 Danes, between 3 and 9 are expected to obtain cancer from exposure to PCB via the diet.

This could seem to be very high numbers but they should be put in perspective by comparison to general cancer statistics. The lifetime risk for females of contracting breast cancer is 10%, which is equivalent to 10,000 out of 100,000. The lifetime risk of the (Danish) population (till 75 years of age) of getting any type of cancer is more than 30% (33.8% for males, 32.9% for females), which is equivalent to more than 30,000 out of 100,000. If the incidents of specific skin cancer are subtracted, the life time risk is 28.5% for females and 29% for males (The Danish Cancer Society, 2005).

With a risk of cancer from exposure to PCBs of 3-9 in 100,000 in a lifetime (70 years) this would mean between 163 and 448 cancer incidents each year in EU-15 (assuming pop of 380 mill) and in EU-25 (454 mill), the range would be 194 to 583 cancer incidents per year resulting from intake of fish contaminated with PCBs.

Quantitative estimate of risks other than cancer

The ATSDR (2000) set a minimal risk level for oral, chronic exposure to PCBs at 0.02 µg/kg bw/day. This is based on immunological effects as critical effect. Such effects may give rise to reduced response to vaccines, increased susceptibility to infections (leukaemia virus, herpes virus) as seen in animal trials.

For 70 kg person, the minimal risk level is equal to an intake of 1.4 µg/day. This level is surpassed even by the average adult Dane (cf. Table D.5), no matter which way the PCB-content is measured. This means that at least 50% (depending on the shape of the distribution curve) of the Danes are at risk of immunological effects caused by dietary intake of PCBs.

Cost estimate human health

The previous estimates of monetary values were €1 mill for fatal cancers and €400,000 for non-fatal ones. No information is available on whether potential cancer incidents would be fatal or non-fatal. Thus, the *annual undiscounted cost of all PCB health damage is €78 mill to €583 mill* as shown in Table D.6.

Table D.6 Cost of excess cancer incidents (non-fatal cancers, NFC) PCBs in food.

Compartment	Case	Problem	Cause of cost	Extent of problem (No. of NFC/EU-25)	Cost of cause (€ /case)	Total cost (2005) (€/year/EU-25)
Food	PCB	Cancer	NFC Fatal cancer	194-583	400,000 1,000,000	78-233 mill 194-583 mill

Benefits of REACH

PCBs are not targeted by REACH but it is assumed that there are 'like chemicals' that would be affected by REACH.

PCBs are severely restricted in the EU and manufacture and import have ceased. Therefore, no information on PCBs is available in IUCLID. However, it is still a problem due to its long-term persistency and bioaccumulation potential. Thus, other information sources were sought for obtaining information on PCBs.

According to Breivik *et al*. (2002), the historical production of PCBs amount to more than 1.3 mill tonnes mainly in the years 1930-1993 with the biggest production in the period from 1960 to 1980. The consumption in EU countries can be estimated to approx. 20% of the total consumption based on information in Breivik *et al*. (2002). Due to the persistency, it is considered appropriate to average the consumption over the 60-years time period resulting in an annual consumption in EU of 4,300 tonnes of PCB. This was then used as input to the scoring, which was conducted using physico-chemical properties of hexachloro biphenyl. Information on the fate and effect properties of PCB was obtained from a UNEP assessment report (Ritter *et al*. 1996).

The most relevant score in relation to the case considered is the biota score. PCBs were ranked as number 5 meaning that only 4 other substances are potentially more problematic for biota. 2 of these 4 substances are already included in the EU priority list and the risk assessment programme. The other 2 substances are derivatives of the pesticide 2,4-D and might therefore be considered under the Plant Protection Products Directive 91/414/EEC. Other substances are phthalates, which are already in focus both as potential PBT substances and due to their endocrine disruption potential and, although not all of them are on the priority list, they are considered to be covered by the current legislation. Thus, REACH might not have a significant benefit on these substances.

The four other ranking values are in the range 64-3,540 with the lowest for the aquatic score considering also bioaccumulation and the highest ranking number for soil.

A P P E N D I X   E

Case studies on retrospective errors

E1. IMPACT ON SEWAGE TREATMENT PLANTS

For all chemicals in waste water, sewage treatment plants (STP) may be the first step on the path from the technosphere to the environment. During the passage of the water through the STP, part of the chemicals is degraded while those, which are not degraded or evaporated, are either carried to surface water or left in the sewage sludge, the latter typically being deposited on agricultural soil or incinerated. Thus, the environmental exposure depends on the physico-chemical and biological properties of the chemical, on the processes in the STP and on the amount of chemical reaching the STP.

Direct impacts on the STP will arise only from the toxic effects on the micro-organisms of the biological treatment plant. The remaining concerns with respect to STPs are the exposure of surface water (via the outlet) and soil (via sewage sludge) with the subsequent impacts on environment and health caused by the exposure of these compartments.

The effects of chemicals on the micro-organisms in STP may be caused by a general load of chemicals in the waste water or by pulses of high concentrations of chemicals due to accidental spills into the sewage system. REACH is expected to affect the general load by reducing it, while accidental spills are not affected by REACH.

Environmental impact
- Direct toxic effects on degrading micro-organisms in STP
  a) General load, to be affected by REACH
  b) Accidental spills, not affected by REACH
- Via outlet: exposure of surface water
- Via sewage sludge: exposure of soil
- Via air: exposure of soil and water

Health impact
- Working environment at STP
- Via surface water
- Via soil
- Via air

Economic impact
- Loss of efficiency of STP
- As for surface water
- As for soil

The route of exposure of STP is via discharges from production and uses of the chemical. Therefore, the release paths to be investigated are point emissions – from production – and diffuse emissions – from household waste water and storm water (i.e. run-off of rainwater, melted snow from roads and other paved or coated surfaces).

The case(s) for STP could be examples of malfunctioning of STPs due to toxic chemicals. For this, an assessment of the aggregate damage based on increased efficiency of STPs during periods of closed industry (summer holidays) and pilot investigations of the inhibition properties of waste water is used.

Case: Inhibition of nutrient removal capacity
The cleaning of waste water takes place in several steps of which the first step involving micro-organisms is the removal of organic material. This step is included in most established biological STP, while the removal of nitrate, which is driven by nitrifying bacteria, is less frequent even if it is introduced in increasing numbers of STP. Both of these processes, which are driven by micro-organisms, may be inhibited by chemicals but the nitrification process is the most sensitive. Therefore, this process is used for the calculations.

The nitrification capacity of STP determines the size of the plant, because increased nitrification capacity means that a shorter sludge retention time or aerobic sludge age in the STP is required and thereby, the dimensions can be reduced in building future STPs.

Data and calculations
Monitoring of the nitrification capacity in pilot plants of a major Danish STP and subsequent experiments have demonstrated a measurable increase in the nitrification capacity during periods without industrial activity and discharge of sewage (summer holidays) (Harremöes *et al.* 1998). The average increase in the capacity was approx. 15% in 1991. Similar investigations related to an upgrading of the municipal STP of Linz in Austria to the demand for nitrification and nutrient removal showed an inhibition of the nitrification process at the same level, i.e. approx. 20%, due to toxic substances in mainly industrial waste water (Schweighofer *et al.* 1996). Reduction of the amount of toxic substances in the waste water would reduce the inhibitory effect and then increase the nitrification capacity of the STP. Domestic waste water may also contain toxic chemicals but these are not considered here due to lack of information. Therefore, the estimate is a minimum.

Taking the lower of these estimates, this leads to the conclusion that the STP capacity in the EU in principle could be reduced by at least 15% if chemicals in industrial waste water did not inhibit nitrification.

Cost estimate
For cost estimation the total STP capacity is not relevant, because only part of the functioning will be affected by the nitrification inhibition. However, information is available on the costs of upgrading STPs for nutrient removal and this is considered here to approximate the costs of nitrification.

For this, cost estimates are based on the capacity of the STP, which is expressed in "Person Equivalents" (PE). This again can be recalculated to other units like m^3 of waste water per day (1 PE = 0.5 m^3/day). Krüger & Karpuhin (2001) estimate the investment costs (level 2001) in Western Europe of upgrading a plant to nutrient removal to lie in the range €27-92 per PE corresponding to an EU-25 cost of €26-89 per PE, which is equivalent to €29-98 per PE in 2005 prices. Operational costs of STPs are not considerably affected by the nitrification capacity, so they will not be considered. As the lifetime of a STP is assumed to be 30 years, this investment has to be written off at a 3% discount rate. Thus, the investment costs become €1.5-5.0/PE/year in 2005 prices.

If there was no chemical stress on STPs, this need for increased nutrient removal capacity would be reduced by at least 15%. Thereby, the costs for the continuous necessary increased nutrient removal capacity are reduced by the costs for establishment of STPs equivalent to 68 mill PE/year (15% of 454 mill PE).

Table E.1 Costs of 15% decreased STP nutrient removal capacity

Com-partment	Sub-stance	Problem	Cause of cost	Reduced EU-15 STP upgrading (PE/EU-15)	Price (2005 level) (€/year/PE)	Price (2005 level) (€/year/EU-25)
STP	All chemi-cals	Inhibition of nitrifica-tion	15% prolonged retention time in plant	15% of 454 mill = 68 mill	1.5–5.0	102-340 mill

The calculation underestimates the potential costs, because the coverage with STP is lower in the 10 new member countries than in the old EU-15 (cf. the current large investments in infrastructure) and because chemicals management at present is not as effective there as in EU-15. Therefore, during construction of STP, larger margins for reduced capacity due to malfunction are used than in EU-15. Thereby, the potential reduction in treatment costs due to a more efficient chemicals policy will be higher in the 10 new member countries than in the old EU-15.

Benefit of REACH
The prolonged retention time of wastewater in the STP, which is the basis for the cost estimate, is a result of conveyance of industrial wastewater only. However, wastewater from consumers will add to the retention time and, thus, the cost estimate is a minimum estimate.

Assuming potential benefits of REACH at 10% level as well as the anticipated delay of the full benefit of REACH until 2017 resulting in a reduction to 70% due to a 3% annual discount, the potential benefit of REACH in 2017 is estimated to €7.1-24 mill/year, respectively.

The potential 25-year benefit in the period 2017-2041 can then be estimated to be €131-440 mill.

E2. DRINKING WATER PURIFICATION

The surface water pollution case includes fresh water and marine environments. When considering these environments, only toxic effects are considered, because the effects of bioaccumulation are included under the environmental “compartment” biota.

Environmental impact
- Direct and indirect effects on aquatic ecosystems like abundance of organisms and/or reduced biodiversity
- Direct and indirect effects on terrestrial ecosystems via floods/irrigation water
- Leaching to ground water
- Fish farming

Health impact
- Human exposure to chemicals via drinking water abstracted from surface water or ground water
- Human exposure via contaminated bathing water

Economic impact
- Fisheries
- Value of fishing rights
- Recreative value of lakes, streams and beaches, estate value
- Agricultural yields
- Cleaning of drinking water
- Cleaning of (causes for) contaminated bathing water

The routes of exposure of surface water are via discharges from STP as well as direct releases of untreated waste water from production and uses of the chemical. Therefore, the release paths to be investigated are via STP and direct point emissions (from production) and diffuse emissions (from household waste water).

The case(s) for estimating impact of chemicals on surface water could be intoxication of fish farms and reduced biodiversity in lakes. However, the occurrence of the first impact is probably rare, while the latter is difficult to quantify especially in terms of costs (cf. discussions above). Therefore, contamination of drinking water and the costs associated with the cleaning is considered to be the most appropriate case.

Case: Cleaning of surface water to drinking water standards
Total water abstraction in Europe (EU-32, including the EFTA countries Iceland, Liechtenstein, Norway and Switzerland) is about 353 km^3/year of which 33% is used for agriculture, 16% for urban use, 11% for industry (excluding cooling) and 40% for energy production (EEA 2003). Water supplied for urban use is used in households, institutions and smaller industries and, consequently, must live up to drinking water standards. Thus, these standards pertain to 56.5 km^3/year (EU-32) or 45.3 km^3/year (EU-25).

Water abstracted for drinking water, which is contaminated with chemicals, must be purified before use.

Costs of purification of water
An estimate of the aggregate damage could be based on the total amount of drinking water abstracted from surface water in the EU and which is cleaned because of contamination with chemicals. It must be emphasised that this also includes cleaning of drinking water, which is contaminated with pesticides and nitrates due to agricultural run-off – none of which will be affected by REACH.

There is no information available for the whole of EU regarding either the amounts abstracted from surface water or the amounts purified before use. Therefore, it is not possible to estimate the aggregate damage based on EU statistics. However, information from the UK and Denmark is available, which could be extrapolated to the EU level. Because there is no information from which the ratio of surface water to ground water can be estimated, the estimates in this section will cover abstraction of water from both surface water and ground water.

UK treatment costs are given in the report of RPA (2003): Total operating expenditure of England and Wales Water Companies on water resources and treatment was £436 mill in 2002-3 and the capital maintenance charge was £1,013 mill, making £1,449 mill in all. From their data it is estimated that 14% of operational costs are due to pesticide and nitrate removal, and 8% of capital costs are due to pesticides and nitrates. RPA (2003) notes that there are no data available allowing cost to be related to other pollutants. Therefore, for the calculations, it is tentatively assumed that 5% of the costs are due to the aggregate damage of REACH-related chemicals, 5% of £1,449 = £72.5 mill p.a. or €92.3 mill p.a. including income adjustment. With a production of water in the UK of 5 mill m^3/day (1,825 mill m^3/year), the aggregate damage of chemicals becomes (2003-price) €0.05/m^3. We retain this figure for 2005 prices since the inflation adjustment for two years is negligible.

Extrapolating this cost from the 5 mill m^3/day (1,825 mill m^3/year) of the UK to the 45.3 km^3/year (45,300 mill m^3/year) of the EU-25 by simple multiplication, gives an estimated (2005 prices) aggregate damage of REACH-related chemicals in EU-25 of €2,291 mill/year.

Estimates of costs for water purification with activated carbon are available from Denmark (Danish EPA 1998). The capital cost of water purification plants depends on type of filters and capacity and varies between DKK 2.2 and 14/m^3 at 1997 prices. To this, operating costs (also 1997 prices) in the range DKK 0.2-0.9/m^3 should be added. The resulting cost (at 2005 prices) is €0.3-1.9/m^3. Assuming again that 5% of these costs can be considered as the aggregate damage of REACH-related chemicals (as above), the aggregate purification costs become (2005 prices) €0.02-0.10/m^3, which embraces the €0.05/m^3 based on information from the UK.

It must be noticed, though, that the UK and Danish estimates are not immediately comparable, because the UK estimate is based on total costs of water abstraction and treatment, while the Danish is based on treatment (chemical removal) only.

Extrapolating the costs based on the Danish estimates to the 45.3 km^3/year of the EU-25 by simple multiplication, gives an estimated range of aggregate damage due to REACH-related chemicals in EU-25 of €695-4,317 mill/year.

Table E.2 Aggregate damage, 5% of drinking water purification costs attributed to REACH-related chemicals

Source of information	Compartment	Substance	Problem	Cause of cost	5% of water purification (2003/05 level) (€/m³)	Total cost – by 2005 (€/year/EU-25)
UK	Surface and ground water	All chemicals	Contamination of drinking water	Purification of drinking water	0.05	2,291 mill
DK lower	Surface and ground water	All chemicals	Contamination of drinking water	Purification of drinking water	0.02	695 mill
DK higher	Surface and ground water	All chemicals	Contamination of drinking water	Purification of drinking water	0.10	4,317 mill

Benefits of REACH
For this example, there is no information available regarding the effect of the chemicals policy on the need for purification of drinking water. Thus, assuming as a potential benefit of REACH that 10% less purification of drinking water is needed as well as the anticipated delay of the full benefit of REACH until 2017 resulting in a reduction to 70% due to a 3% annual discount, the potential benefit of REACH in 2017 is estimated to €49-302 mill/year.

The potential 25-year benefit in the period 2017-2041 can then be estimated to be €896-5,564 mill.

E3. DISPOSAL OF DREDGED SEDIMENT

The problems pertaining to contamination of aquatic sediments are partly ascribed to the sediments themselves, partly to effects in the water column caused by escape of contaminants from the sediment.

Environmental impact
- Direct and indirect effects on organisms living in the sediment
- Exposure of pelagic organisms via partitioning of substances resulting in similar effects as for surface water
- Effects on terrestrial ecosystems via dredged sediment, disposed at land
- Leaching to ground water

Health impact
- Human exposure to chemicals via drinking water abstracted from surface water or ground water
- Human exposure via contaminated bathing water

Economic impact

- Fisheries
- Value of fishing rights
- Recreative value of lakes, streams and beaches, estate value
- Agricultural yields
- Cleaning of drinking water
- Cleaning of (causes for) contaminated bathing water
- Cleaning of dredged sediment
- Disposal of dredged sediment

The exposure of sediment mainly takes place via the water phase and run off of soil particles during heavy rain or subsequent to flooding. Cases of dumping of contaminated soil and/or dredged sediment are expected to be prevented by the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, 1972 (London Convention).

For the exposure via the water phase, harbour sediment calls for immediate attention, because this is known to be heavily contaminated due to emissions from ships of oil products, combustion products and residues of paints. However, oil and combustion products will not be covered by REACH and the constituents of paint are not known to contribute considerably to the contamination of sediment – except for antifouling biocides, which are not covered by REACH but by Directive 98/8/EC. Therefore, harbour sediments could be discarded from consideration.

River sediment is constantly being transported and most contamination of river sediment will be from chemicals, which were emitted to the river recently. Therefore, dredged sediment of riverine origin may be used as a case for calculating costs caused by chemicals. For this, sediment dredged from rivers or sediment dredged from ports located in rivers or in estuaries where (large) rivers flow into the sea, may be used for the cases.

Case: Disposal of dredged sediment

In parallel with the other cases, an assessment of the aggregate damage could be based on the total costs of disposal of dredged sediments that are contaminated with chemicals.

In general, sediments are not dredged because of contamination. However, when a dredged sediment is contaminated, it cannot be dumped without restrictions and this causes excessive costs for disposal and/or treatment of the dredged sediment.

Data and calculations

There are no statistics at the EU level on this issue. However, the independent professional society CEntral Dredging Association (CEDA), which covers Europe, Africa and the Middle East, is in the process of mapping the extent of disposal of dredged sediment and the associated costs. A preliminary report (CEDA 2005) on the results of this investigation has been made available by CEDA.

The CEDA investigation is based on questionnaires to all member countries and the preliminary report is based on answers from 11 EU member countries (Belgium/Flanders, Denmark, France, Germany, Ireland, Italy, Netherlands, Portugal, Spain, Sweden and the UK). Thereby, it is expected that the majority of the large harbours in EU-15 are covered and, furthermore, the report includes information regarding inland dredging (i.e. mainly rivers).

From these countries, the overall sum of dredged sediment amounts to approx. 200 mill m^3 per year. 168 mill m^3 is dredged from harbours located at sea, but it is estimated that 80% of this sediment is of inland origin. 30 mill m^3 is dredged from inland waters (CEDA 2005). Thus, in total 165 mill m^3 of the dredged sediment are of inland origin.

An estimate of the amounts of contaminated sediment can be based on information regarding the destination of the dredged material, which is divided into "open water" (i.e. not contaminated), "confined disposal" (i.e. contaminated) and "beneficial use", which indicates e.g. the construction of an artificial island (i.e. contaminated to some extent). However, not all countries seem to have responded to this part of the questionnaire, and this information is lacking for France and Portugal. Furthermore, it seems that Ireland, Italy and Spain do not have any contaminated sediment. Therefore, the estimate of amounts of contaminated, dredged sediment based on addition of the available amounts will be very low.

However, this estimate will be used as a minimum of the aggregate damage. The amounts of sediment reported to be disposed of in "open water" is approx. 110 mill m^3/year, while the total amount of "confined disposal" and "beneficial use" is 18 mill m^3/year (CEDA 2005). In other words, in the responding countries, approx. *14% of the dredged material is contaminated*. If this fraction is used for extrapolation from the total of 165 mill m^3/year, the amounts of *contaminated dredged sediment from the 11 countries is 23.4 mill m^3/year*.

In addition, information is available on the volumes of contaminated sediment (aggregate damage) in individual ports (e.g. Mannino *et al.* (2002) analyse the ports of Rotterdam, Marseilles and Venice) and on treatment costs for contaminated sediment, at least for Rotterdam.

From the port of Marseilles, the annual dredging amounts to 10,000-15,000 m^3 of sediment of which most is contaminated. In the port of Venice, the annual dredging amounts to 4.6 million m^3 of contaminated sediment and 2.3 mill m^3 of relatively clean sediment. Thus, in this port, two thirds of the dredged material is contaminated.

From the Port of Rotterdam, a total of 20 mill m^3 dredged sediment per year is being removed. Part of that is contaminated and must be deposited under controlled conditions. However, the amount of sediment to be deposited every year has been reduced from 10 mill m^3 to 3-4 mill m^3 per year due to the Rhine Research Project, which is aiming at identifying direct discharges to the Rhine and reducing them (Mannino *et al*. 2002). In other words, the fraction of contaminated sediment has been reduced from half of the dredged material to approximately one fifth of the dredged material, i.e. a 60% decrease.

Mannino *et al*. (2002) consider the reduction of dredged sediment for deposition from the Port of Rotterdam (from 10 to 4 mill tonnes/year) to be caused by reduced emission of chemicals to the Rhine. This indicates that the further reductions in emissions of hazardous chemicals expected by REACH will cause additional reductions in amounts of contaminated sediment both in the Rhein and probably more pronounced in other rivers.

Cost estimates

The extra costs of depositing dredged sediment instead of open water disposal at sea are estimated by the Port of Rotterdam to be approx. €4 per tonne. With a density of 1.225 tonnes/m^3 (Ebbens, pers. com.), this is equivalent to an income adjusted cost of €4.0 per m^3. Other alternatives of disposal of contaminated sediment are more expensive (Mannino *et al*. 2002), and cost of in average €24 per m^3 (income adjusted) has been reported for disposal at an upland Confined Disposal Facility (SedNet 2004). This range will be used for the further estimates.

The aggregate damage can then be estimated for 23.4 mill m^3/year at a cost of €4-24/m^3 resulting in a cost of approx. *€93-560 mill per year*.

This only covers a limited part of Europe, because only 11 countries are included in the overall amounts and for fewer, information regarding contamination is available. Tentatively, the cost of contaminated dredged sediment in EU-25 is assumed to amount to the double of this value. Thereby, the aggregate damage due to *contaminated, dredged sediment is €187-1,120 mill per year in EU-25*.

Table E.3 Aggregate damage, costs of disposal of contaminated dredged sediment. The estimate is tentative for EU-25.

Compartment	Substance	Problem	Cause of cost	Amount of contaminated sediment (m^3/year/EU-25)	Price (2005 level) (€/m^3)	Total price (2005 level) (€/year/EU-25)
Sediment	All chemicals	Contaminated sediment	Disposal of sediment	46.8 mill	4.0	187 mill
Sediment	All chemicals	Contaminated sediment	Upland CDF	46.8 mill	24	1,120 mill

Benefits of REACH

For this example, the potential benefit of REACH could be set equal to the progress made during the Rhine Research Project in the Port of Rotterdam ((Mannino *et al*. 2002), i.e. the amount of contaminated sediment is reduced by 60% of the original corresponding to a reduction from 46.8 mill m^3/year to 18.7 mill m^3/year. The potential benefit of REACH would then be 28.1 mill m^3/year less contaminated dredged material saving €112-674 mill per year for EU-25 in 2005, or – including the effect of the delay of REACH – the potential benefit of REACH with regard to disposal of dredged sediment becomes **€78-470 mill per year for EU-25 for 2017.** Aggregating for the total benefit for the next 25 years results in a benefit of €1,444-8,660 mill.

Alternatively, the indicative "default" reductions due to REACH of 10% of the costs of disposal of contaminated sediment can be used together with the reduction to 70% of this, caused by the anticipated delay of REACH till 2017. This results in a potential benefit of REACH with regard to disposal of dredged sediment of **€13.1-78 mill per year for EU-25 for 2017.** By aggregation over the next 25 years, the total benefit is estimated to €241-1,450 mill.

E4. DISPOSAL OF SEWAGE SLUDGE ON FARMLANDS

For consideration of soil contamination, only toxic effects on organisms living in the soil are considered, while possible effects of bioaccumulation are included under the "compartment" biota.

Environmental impact
- Direct and indirect effects on organisms living in the soil
- Leaching to surface water
- Leaching to ground water

Health impact
- Human exposure to chemicals via skin contact with soil
- Human exposure to chemicals via ingestion of soil and dust
- Human exposure via inhalation of vapours and dust

Economic impact
- Agricultural yields
- Animal husbandry yields
- Farmland quality, estate value
- Recreative value gardens, estate value
- Cleaning of contaminated soil
- Disposal of contaminated soil

The main economic problem pertaining to contaminated soil is contamination of city soil – former dump sites or industrial sites being used for gardens due to expansion of cities. The knowledge that a site is contaminated reduces the value of the estate considerably. However, the reasons for such soil contamination are the situation of the estate on a site, which was formerly used for other purposes, e.g. dump sites, gasoline stations, metallic or dry-cleaning enterprises. In all these sites, chemicals were simply left in or on the soil during the former use of the sites. Because other legislation has long ago forbidden such handling of chemicals, REACH is not expected to have an impact on the occurrence of such contaminated sites.

Therefore, the main route of exposure to soil is expected to be via sewage sludge. This implies that the release paths would be via waste water and STP. The chemicals, which are expected to end up in sewage sludge are either persistent, sorptive chemicals – irrespective of the release rate - or other chemicals (even readily biodegradable) in case they are discharged at rates exceeding the capacity of the SPT and/or are not degradable in anaerobic digesters, which are frequently used in STP.

The major concerns regarding chemicals in sewage sludge for agricultural use are the risks of build up in soil (especially of metals) and risks of ingestion of soil by livestock. Concerns regarding uptake in plants have been investigated but with respect to organic substances, there is no strong evidence of bioaccumulation in crops.

Case: Disposal of sewage sludge on farmlands

Sewage sludge may be utilised for agricultural soil improvement and fertilising. However, the contents of chemicals in sewage sludge often prevent this use, resulting in a need for disposal or incineration of the sludge. (Possibly, some of the sludge, which is not reused, is not contaminated but for the calculations, it is assumed to be).

The costs of the problem are partly those of disposal/incineration of the sludge, partly the lost fertiliser value.

Data and calculations

Contaminated sewage sludge is an example of aggregate damage of all chemicals and the measure of the damage is the amounts of sewage sludge, which cannot be used for agricultural applications but must be landfilled or incinerated because of high concentrations of chemicals. If the concentrations of chemicals in this sludge were low, all sewage sludge could be used directly for agricultural purposes.

Consequently, the costs can be estimated as the saved costs for alternative handling of sewage sludge (e.g. incineration) as well as the value of the fertilisers, which could be substituted with sewage sludge.

Table E.4 summarises estimates of the total production of sewage sludge and the amount being reused for agriculture in 2005 in EU-15 and in the accession countries from Andersen (2001). For EU-15, the reuse amounts to 51%, while for the accession countries, it is only 31%.

Table E.4 Production and reuse of sewage sludge in 2005 (Andersen, 2001)

Region	Total sludge Tonnes dw/year	Sludge reuse Tonnes dw/year	Sludge not reused Tonnes dw/year
EU-15	9,611,000	4,893,000	4,718,000
EU-10 (accession)	1,539,800	496,698	1,043,102
EU-25	11,150,800	5,389,698	5,761,102

In other words, the aggregate damage is represented by all the sludge, which is not reused (i.e. assumed to be contaminated) in EU-15 and EU-25, approx. 5 and 6 mill tonnes dry weight sludge per year, respectively.

These data will be used for the calculations but it must be emphasised, that they represent absolute minimum values, because the potential sewage sludge from waste water, which is not cleaned at present, is not included at all. This implies that when STP coverage in EU-25 is increased, the amounts of reused and not reused sludge will increase. The majority of this increase is expected to arise from the 10 new member states but also from EU-15, e.g. at present large cities like Brussels and Milan have no production of sewage sludge because of lack of waste water treatment.

The sources of the chemicals (organic or heavy metals) contaminating sludge are partly outside the reach of chemicals legislation, e.g. the origin of most PAHs found in sludge is combustion or wasted fuel. Therefore, the impact of REACH on this problem will be lower than the aggregate damage.

Incineration costs
According to Postle *et al.* (2003), the price of incineration of sludge instead of soil application is between 150 and 190 €/tonne. This accords very well with the incineration costs produced by Coopers Lybrand *et al*. (1996), where net economic costs of incineration were estimated at €156/tonne. In today's money this would be around €200/tonne. With an amount of contaminated sewage sludge of 5.8 mill tonnes/year (EU-25), this gives €1,150 mill per year (for total 'damage').

Fertiliser value
Furthermore, these 5.8 mill tonnes of sewage sludge per year represent a lost fertiliser value, which can be further elaborated:

1. From the Danish sludge statistics (Danish EPA, 2004), information on sludge produced in Denmark was obtained as follows:
   - Concentration of N in sludge (average of 220 STP): 44.4 g/kg dw
   - Concentration of P in sludge (average of 220 STP): 31.9 g/kg dw
   - Stabilisation under aerobic and anaerobic conditions was used for 42% and 45% of the sludge, respectively.

2. Marmo (2000) states that on an average, sewage sludge contains 35 g N and 20 g P per kg of dry matter, while Sequi *et al.* (2000) details the contents in anaerobically digested sludge (40.8 N and 9 P g/kg) and aerobically digested (23.1 N and 20.8 P g/kg).

3. From Petersen (2003 and personal communication), the fertiliser replacement value of sewage sludge was estimated. This value gives a measure of the percentage of the nutrient in the sludge, which can be utilised by the crop. They obtained the following information:

   - The fertiliser value based on total N of aerobically digested sludge is 68%
   - The fertiliser value based on total N of anaerobically digested sludge is 49%
   - The fertiliser value based on P is a long term improvement value and is 100%

There seem to be some differences between the Danish and the EU (15) information. The average contents of N and P in sewage sludge specified by Marmo (2000) (35 g N per kg dry matter and 20 g P per kg dry matter) are used for the calculations.

For the fertiliser value, the results of Petersen (2003) are used. The detailed information regarding the fertiliser value of different sludge types is simplified as follows: It is assumed that equal amounts of the two types of sludge (aerobically and anaerobically stabilised) are produced and therefore, the average nitrogen fertiliser replacement value (59%) is used.

The value of fertiliser is set to €98-130/tonne. It could be assumed that the fertiliser used will be a composite product (e.g. NPK fertiliser). Further – for simplicity - it is assumed that the fertiliser is composed of N and P in the same proportions as in the incinerated sewage sludge (which is not realistic). Therefore, the amount of fertiliser needed instead of the incinerated sewage sludge is the sum of the N and P contributions. The calculations are indicated in Table E.5.

Compiled costs from incineration and lost fertiliser
The calculations of the costs caused by incineration and the lost fertiliser value are summarised in Table E.5.

Table E.5 Cost of contaminated sludge due to incineration and lost fertiliser value based on the estimated extent of not reused sludge in EU-25

Com-partment	Case	Problem	*Cause of cost*	Extent of problem EU-25 (unit)	Price of cause € / t dw	Price €/year/EU-25
STP, sludge	All sludge	Limit conc.	*Incineration*	5.8 mill [1] (t dw/year)	200	1,152 mill
STP, sludge	All sludge	Limit conc.	*Lost fertiliser*	119,000 (t N/year) 115,000 (t P/year)	98-130	23-30 mill
STP, sludge	All sludge	Limit conc.	*Incineration +Lost fertiliser*	5.8 mill (t dw/year) 119,000 (t N/year) 115,000 (t P/year)		1,175-1,183 mill

1: Extrapolated from EU-25 production of sewage sludge in 2005 (Andersen, 2000)

The total "cost" of this problem is estimated to €1,152 mill/year for incineration costs with costs for lost fertiliser value in the range of €23-30 mill/year.

Obviously, the costs of incineration are so much higher than the lost fertiliser value that the first is determining the level of costs for this problem. The average of the fertiliser value is used to calculate a (rounded) *average total cost of contaminated sewage sludge of €1,180 mill per year in EU-25*.

Benefits of REACH
With a potential effect of REACH of a 10% reduction of amounts of sewage sludge being incinerated and the delayed effect of REACH to 2017, the estimated benefit of REACH **with regard to sewage sludge would amount to an average of €83 mill per year for 2017 for EU-25**. Over the next 25 years, the total aggregated benefit is estimated to €1,520 mill.

E5. CLEANING OF FISH MEAL

The environmental concerns arising from contamination of biota are mainly caused by reduced biodiversity at higher levels of food chains, while health problems are due to the risk of contaminated food.

Environmental impact
- Accumulation of contaminants in biota – especially at higher trophic levels
- Effects on predators, reduced biodiversity
- Fish food

Health impact
- Exposure via food

- Fish
- Game
- Crops
- Husbandry

Economic impact
- Fisheries
- Value of fishing/hunting rights
- Recreative value of lakes, streams and beaches, estate value
- Agricultural yields

The exposure of biota can take place via direct contact – especially with water – and via food (plants or prey), leading to biomagnification. Therefore, the release paths mainly include surface water and sewage sludge but atmospheric contamination with volatile substances in warm climates leading to precipitation of chemicals under colder conditions is also relevant.

The case could be contaminated food (industrial fish) for fish farms or reductions in fisheries due to contaminated fish.

Case: Cleaning of contaminated fish meal and oil
A recent example that can be mentioned is that one of the producers of fish meal and fish oil from industrial fish has decided to clean the products for dioxins and PCBs. These products originate from fish caught in the Baltic Sea and – for part of the year – the North Sea. Because several chemicals are involved, this is an example of aggregate damage.

Data and calculations
The annual catch of industrial fish from these areas is estimated by industry to be approx. 350,000 tonnes of industrial fish per year (TripleNine 2005), while the total catch and landing of industrial fish from the North Atlantic area is approx. 3.2 mill tonnes/year (Fiskaren 2005).

Cost estimate
Based on estimates from industry (TripleNine 2005), the capital cost of a plant (with a capacity of cleaning 350,000 tonnes of fish/year) is DKK 130 mill and the operating costs are DKK 20 mill/year. This results in a price for cleaning of fish products of DKK 135/tonne of fish, which is equivalent to €18/tonne for cleaning of industrial fish.

Thereby, the aggregate cost of the problem can be estimated to 350,000 tonnes/year × €18 per tonne = €6.3 mill/year.

This is the costs for cleaning caused by contamination of industrial fish in the Baltic Sea and partly in the North Sea. To include all of EU-25, catches in other waters, especially the Mediterranean, which is also known to be contaminated, should be included. Due to lack of information about the conditions in the rest of EU-25, a factor of 2 for extrapolating from the example to EU-25 is tentatively used. This is considered a conservative value, as much of the commercial fish feed produced from industrial fish caught from the North Atlantic area has elevated levels of contaminants (Hites *et al.* 2004).

Thereby, the aggregate damage due to contaminated fish meal and fish oil is estimated to *€12.6 million per year for EU-25 by 2005*.

Benefits of REACH

For this case, the indicative "default" reductions due to REACH of 10% of costs of cleaning fish products can be used together with the reduction to 70% of this, caused by the anticipated delay of REACH till 2017. This results in a potential benefit of REACH with regard to contaminated fish food for fish farms of **€0.9 mill per year for EU-25. Over the next 25 years this adds up to a total benefit of €16 mill.**